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Author: Blanc, F.O.M.
Title: From chasing violations to managing risks : origins, challenges and evolutions in regulatory inspections
Issue Date: 2016-11-30

From Chasing Violations to Managing Risks

Origins, challenges and evolutions in regulatory inspections.

Florentin Blanc

From Chasing Violations to Managing Risks

Origins, challenges and evolutions in regulatory inspections.

PROEFSCHRIFT

ter verkrijging van

de graad van Doctor aan de Universiteit Leiden,

op gezag van Rector Magnificus prof. mr. C.J.J.M. Stolker,

volgens besluit van het College voor Promoties

te verdedigen op woensdag 30 november 2016

klokke 11.15 uur

door

Florentin Olivier Michel BLANC

geboren te Orange (Frankrijk)

in 1973

Promotor:	prof. dr. W.J.M. Voermans
Promotiecommissie:	prof. dr. M.G. Faure (Maastricht University) prof. dr. I. Helsloot (Radboud Universiteit Nijmegen) prof. dr. C. Radaelli (University of Exeter, United Kingdom) prof. dr. L.F.M. Verheij prof. dr. A.K. Yesilkagit

To my wife and children, and to my family, both the dead and the living – all those who gave my life meaning and questions, peace and restlessness, all aplenty

Acknowledgements

There would be too many people to thank here, for their contributions to this research, to my work on regulatory inspections in the past 12 years, to my involvement in development work, and for their influence on my life, interests and thinking overall. I can only name here but a few. First thanks go to Tania Lozansky at the IFC for involving me in inspections reform work, to Sanda Liepina for prodding me further in that direction, and to the fantastic teams I have had the honour to work with over these 12 years – in Tajikistan and Ukraine first, then Mongolia, Armenia, Cambodia, Kenya, Côte d'Ivoire, Kyrgyzstan, Greece and many others. Since 2010, encounters across Europe have brought me new ideas and insights, and new enthusiasm for both policy and research work – let me at least mention Jan van Tol and Ira Helsloot in the Netherlands, Donald Macrae and Graham Russell in the United Kingdom, Giedrius Kadziauskas in Lithuania, and many more from these countries and others, in particular Italy. Thoughts also go to the teams at ACTED with whom I had the chance to start development work, to my professors in the Sorbonne who taught me methods and discipline, to the many officials and businesses whom I have worked with and learned from, to my esrtwhile students whose questions kept me thinking – and in particular Giuseppa Ottimofiore who has been working with me on inspections issues for the past two years.

Special consideration goes to Laura Tilindyte, now at the European Parliament, whose PhD thesis on "Enforcing Health and Safety Regulation" was the starting point of one of this research's most important case studies.

Last but not least, thanks go to my supervisor, Prof. Wim Voermans, who was both confident and prodding, and kept his patience with me over years when things were moving at an inconstant pace. Thanks also to the members of the committee for their time and inputs, Profs. Faure, Helsloot, Radaelli, Verheij and Yesilkagit. Particular acknowledgements go to Prof. Faure for his insights and the joint work we have started together, to Prof. Helsloot for years of exchanges and collaboration, and never letting certainties unturned, and to Prof. Radaelli for his long-standing support and many productive discussions.

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List of abbreviations and acronyms

AHVLA	Animal Health and Veterinary Laboratory Agency
ASL	Aziende Sanitarie Locale (Local Public Health Establishments)
BASEEFA	British Approvals Service for Electrical Equipment in Flammable Atmospheres
BAuA	Bundesanstalt für Arbeitsschutz und Arbeitsmedizin
BCE	Before the Common Era
BEEPS	Business Environment and Enterprise Performance Subject
BIS	Business, Innovation and Skills
BLS	Bureau of Labor Statistics
BRDO	Better Regulation Delivery Office
BRE	Better Regulation Executive
BSE	Bovine Spongiform Encephalopathy
CAFO	Concentrated Animal Feeding Operation
CAP	Common Agricultural Policy
CDC	Centers for Disease Control and Prevention
CEN	Comité européen de normalisation (European Committee for Standardization)
CENELEC	Comité européen de normalisation en électronique et en électrotechnique (European Committee for Electrotechnical Standardization)
CGEIET	Conseil général de l'économie, de l'industrie, de l'énergie et des technologies
CIEH	Chartered Institute of Environmental Health
CJEU	Court of Justice of the European Union
COIN	Corporate Operational Information System
COKZ	Centraal Orgaan voor Kwaliteitsaangelegenheden in de Zuivel (Central Body for Quality Issues in Dairy)
COMAH	Control of major accident hazards
CPE	Controlebureau voor Pluimvee, Eieren en Eiproducten (Bureau of Control of Poultry, Eggs and Egg Products)
CSA	Chief Scientific Advisor
CSM	Standard Cost Model
csQCA	crisp set Qualitative Comparative Analysis
DALY	Disability Adjusted Life Years
DCFTA	Deep and Comprehensive Free Trade Area
DDT	Dichlorodiphényltrichloroéthane
DEFRA	Department for Environment, Food and Rural Affairs
DG	Directorate-General
DG SanCO	Directorate-General for Health and Food Safety (Direction générale de la santé et des consommateurs)
DGAL	Direction générale de l'alimentation
DGCCRF	Direction générale de la concurrence, de la consommation et de la répression des fraudes (Consumer Affairs, Competition and Fraud Suppression)
DGFiP	Direction Générale des Finances Publiques
DHS	Department of Health Services
E. coli	*Escherichia coli*
EA	Environment Agency
EBRD	The European Bank for Reconstruction and Development
EC	European Commission
ECDPC	European Centre for Disease Prevention and Control
ECJ	European Court of Justice
EDC	Endocrine Disrupting Chemical

EEC	European Economic Community
EFSA	European Food Safety Agency
EHO	Environmental Health Officer
EMM	Enforcement Management Model
EMU	Economic and Monetary Union
ENGO	Environmental Non-Governmental Organization
EPA	Environmental Protection Agency
ESAW	European Statistics on Accidents at Work
EU	European Union
FAO	Food and Agriculture Organization
FBOs	Food Business Operators
FDA	Food and Drug Administration
FFI	Fee For Intervention
FHIS	Food Hygiene Information Scheme
FHRS	Food Hygiene Ratings Scheme
FOD	Field Office Directorate
FSA	Food Standards Agency
FSIS	Food Safety and Inspection Service
FSM	FDA Food Safety Modernization
FSMA	FDA Food Safety Modernization Act
FSU	Former Soviet Union
FTE	Full Time Equivalent
FVO	Food and Veterinary Office
GAO	General Accounting Office
GASI	General Agency for Specialized Inspections
GATT	General Agreement on Tariffs and Trade
GB	Great Britain
GBP	Pound Sterling
GdF	Guardia di Finanza
GHP	Good Hygene Practices
GMOs	Genetically modified organisms
GPD	Gross Domestic Product
H&S	Health and Safety
HACCP	Hazard Analysis Critical Control Point
HM	Her Majesty's
HMRC	Her Majesty’s Revenue and Customs
HSC	Health and Safety Commission
HSE	Health and Safety Executive
HSW	Health and Safety at Work
ICC	Interstate Commerce Commission
IFC	International Finance Corporation
ILO	International Labour Organization
IMF	*International Monetary Fund*
INAIL	Istituto Nazionale per l’Assicurazione contro gli Infortuni sul Lavoro (National Institute for Insurance against Labour Accidents)
INPS	Istituto Nazionale Previdenza Sociale (National Institute for Social Prevention)
IPPC	Integrated Pollution Prevention and Control
IRGC	International Risk Governance Council
ISO	International Organization for Standardization
IT	Information Technology

LA	Local Authority
LBRO	Local Better Regulation Office
LFS	Labour Force Survey
LGA	Local Government Association
MMR	Measles, Mumps, and Rubella
MRLs	Maximum Residue Levels
MSHA	Mine Safety and Health Administration
NCAE	Nederlandse Controle Autoriteit Eieren (Netherlands Eggs Control Authority)
NFA	National Food Agency
NGO	Non-Governmental Organization
nvCJD	new variant Creutzfeldt–Jakob disease
NVWA	Nederlandse Voedsel- en Warenautoriteit Netherlands' (Food and Consumer Product Safety Authority)
OECD	*Organisation for Economic Co-operation and Development*
OHS	Occupational Health and Safety
OIE	World Animal Health Organisation (Office International des Epizooties)
ONR	Office for Nuclear Regulation
ONS	Office for National Statistics
OSH	Occupational Safety and Health
OSHA	Occupational Safety and Health Administration
PCB	Polychlorobiphényle
PHLS	Public Health Laboratory Service
PPP	Purchasing Power Parity
QCA	Qualitative Comparative Analysis
RAPEX	Rapid Alert System for Non-Food Products
RASFF	Rapid Alert System for Food and Feed
RGPP	Révision Générale des Politiques Publiques (General Review of Public Policies)
RIDDOR	Reporting of Injuries, Diseases and Dangerous Occurences Regulations
RoSPA	Royal Society for the Prevention of Accidents
RRAC	Risk and Regulation Advisory Council
RRR	isk Regulation Reflex
RVV	Rijksdienst voor de keuring van Vee en Vlees (State Service for Supervision of Livestock and Meat)
SAPD	Sozialistische Arbeiterpartei Deutschlands
SES	Sanitary and Epidemiological Service
SFARP	So Far As Reasonably Practicable
SFBB	Safer Food, Better Business
SLI	State Labour Inspectorate
SLIC	Senior Labour Inspectors Committee
SME	Small and Medium Enterprises
SPD	Sozialdemokratische Partei Deutschlands
SPS	Sanitary and Phytosanitary
SuGA	Sicherheit und Gesundheit bei der Arbeit
SVB	Uitvoerder van volksverzekeringen (Social Insurance Bank)
SZW	Sociale Zaken en Werkgelegenheid (Social Affairs and Employment)
TBT	Technical Barriers to Trade
TFEU	Treaty on the Functioning of the European Union
UK	United Kingdom
UN	United Nations
UNEP	United Nations Environment Programme

US	United States
USAID	United States Agency for International Development
USDA	United States Department of Agriculture
UWV	Uitvoeringsinstituut Werknemersverzekeringen (Employee Insurance Agency)
vCDJ	variant Creutzfeldt–Jakob disease
VWA	Voedsel- en Warenautoriteit (Food and Consumer Product Safety Authority)
WBG	World Bank Group
WHO	World Health Organization
WRR	Wetenschappelijke Raad voor het Regeringsbeleid
WTO	World Trade Organization
WTO	
SPS	World Trade Organization Sanitary and Phytosanitary Agreement
ZLB	Zero Lower Bound

1. Introduction

GOVERNOR. I have called you together, gentlemen, to tell you an unpleasant piece of news. An Inspector-General is coming.

AMMOS FIOD. What, an Inspector-General?

ARTEMY FIL. What, an Inspector-General?

GOVERNOR. Yes, an Inspector from St . Petersburg, incognito. And with secret instructions, too.

AMMOS. A pretty how-do-you-do!

ARTEMY. As if we hadn't enough trouble without an Inspector!

Nikolai GOGOL – The Inspector General *(1842)*

As in Gogol's quote, the arrival of a government inspector is still something that elicits instant reactions of fear and worry in a number of countries – including Russia, and most countries that used to be part of the Former Soviet Union. Most of these inspectors nowadays, by contrast with Gogol's, come to inspect and control not State institutions, but private ones, particularly businesses. "Inspectors" and "inspections" come under different names – "control", "surveillance", "supervision" – so speaking about "inspections" will not draw instant reactions in some countries, and these will only come when the notion is explained, "translated" into the appropriate words. The reality, however, in most parts of the world, is that inspections (under whichever name) are one of the most frequent and important ways in which businesses experience their relations with state authorities. While scholars and governments often look at "regulations" in a more abstract way, businesses will typically relate more to the actual experience they have of regulations, which is through procedures such as permits and licenses, and through inspections – particularly if the latter are frequent, burdensome, or otherwise problematic.

Certainly, this situation is not unique to regulations affecting business activity, and to inspections that control compliance with them. For most citizens, "laws" likewise are often distant abstractions, and the way they are experienced is primarily through concrete processes: obtaining documents, marrying or inheriting, and of course: dealing with the police. The comparison with the police is apt: to some, the police is an indispensable defense wall against crime, and a good (and strong) police one of the main elements that separate civilization from barbarism. To others, the police is a fiend, an enemy, a body that seeks to oppress them regardless of what they have done – and, as recent events in the United States once again show, such feelings are definitely not confined to actual criminals.

What this highlights is the essential ambiguity of inspections and control: absolutely necessary for some, oppressive and hostile for others. Just as many – from environmental defenders to trade unions through anti-corruption groups – will clamour for more inspections and control, others – businesses, "better regulation" bodies, libertarians – will tend to argue for less. Again, the same ideological and interest-based divisions can be seen as for law enforcement by the police – some asking for more, others pointing out its downsides, limits, unintended consequences etc. What is striking is that much of these discussions, at least in the particular case of inspections, take place with a considerable lack of investigation and understanding of what inspections

actually are, how they function in practice, and what impacts they have. Pre-conceptions abound, analysis is scarce.

There are many questions that deserve to be asked. What are inspections exactly, and are they just a form of "law enforcement", or something different? What is their place in a broader range of actions aiming at implementation of regulations? How are they organized, planned, conducted in practice? And what is their impact on compliance, public welfare, economic growth? These are all fundamental issues, and without at least some level of response on these, trying to decide the question of "more or less" inspections is meaningless.

The past decade has seen a growing interest in the question of inspections (and, more broadly, of enforcement and "regulatory delivery", i.e. all activities and tools that can be used to make regulations better complied with and implemented). Major steps in this emergence of the question were the 2005 *Hampton Review* in the United Kingdom, and the publication of the OECD's *Best Practice Principles for Regulatory Enforcement and Inspections* in 2015. Going further east, interest in the question started earlier, with various post-Soviet and post-Communist governments initiating reforms of government inspections from the late 1990s. Much of this work was (and still is) supported by the World Bank Group.

The significance of the issue stems from its relevance for economic development, for achieving public welfare goals, and for strengthening the rule of law. From an economic perspective, even though the real importance of the "burden" created by regulations and their enforcement is disputed, there is some consensus that the broad complex of "institutions" (which include rules and their enforcement) is crucial to economic development (Rodrik 2003), and that reforming (making more efficient and flexible, etc.) regulations (in particular for product markets) has important benefits for productivity and long-term growth (Bourlès *et al.* 2010, OECD 2015 a, IMF 2015 etc.). As we will discuss, regulations and inspections also have important effects on integration in international trade (see Rodrik 2003 for the interaction between "trade" and "institutions"). For public welfare, the evidence of regulatory effects is mixed, but there is generally a strong "social demand" for regulatory protection against risks, solid economic (Ogus 1994) as well as non-economic (Feintuck 2010) justifications for regulations in a number of areas, and ensuring that they reach their stated purposes more effectively, and at lower cost, is important. Finally, just as effective practices in enforcement and inspections are an important element to foster legal compliance (Kagan 1994, Ayres and Braithwaite 1992, Tyler 203), bad inspection and enforcement practices can lead to breakdowns in legitimacy, regulatory capture, corruption (Djankov *et al.* 2001). Thus, "good" inspections contribute to a range of public benefits (economic growth, protection against risks, consolidation of a sound legal order), whereas "bad" ones can endanger all these simultaneously. While the magnitude of such effects is still very difficult to assess, they are nonetheless real and make the object well worthy of investigation.

1.1. Research question – do risk-based inspections lead to better outcomes at reduced costs?

Nonetheless, answering conclusively all questions regarding nature, methods and effects of inspections would be a very tall order, far beyond the scope of this research, and maybe beyond reach in any case, at least based on the data currently available. What this research aims at achieving is somewhat more modest, and will draw on two sets of sources. The first is existing research on regulatory enforcement and compliance (spanning over 40 years of work in a variety of fields). The second is "practical experience" as constituted where possible by hard (quantitative) data, but also by the specifics (qualitatively described) of inspection structures, practices, visions and first-hand accounts of practitioners and stakeholders.

The interconnected questions this research will try to answer (or for which it will at least attempt to see if an answer *could be found given additional data*) are the following: are inspections really a specific "object", what

are some of the main aspects and variations of practices in inspections, and are there methods that can allow inspections to achieve better outcomes *both* from the public welfare and safety perspective, and from the economic growth one?[1]

The central question is clearly the last one: what are these methods that could allow for a "win-win" result, whereby the goals of inspections are better achieved (assuming, of course, some clarity on the said goals[2]) – and the entities and people subject to inspections (mainly: businesses) experience less burden from these inspections (and possibly even some support, that helps rather than hinders growth)?

The proposition we will try and put to the test in this research is the following: do risk-based approaches to inspection allow for better outcomes (in terms of safety, health, public welfare), or at least constant outcomes, while doing so at a lower cost for the state budget and/or for the economy? Or, if testing this statement conclusively should prove elusive at this stage, are there sufficient indications that this may be the case, and does it appear possible in principle to test it further, if additional data were to be collected?

In other words, this research will look at so-called "risk-based" and "smart" approaches to inspections and enforcement and try to identify what they entail, how they differ from other practices, and see whether they achieve their stated goal of reconciling improved outcomes in terms of health, safety and other public goods, and reduced economic burden or barriers.

Emerging through the research, we will also see the importance of the question of *trust* – between economic and social actors, and trust by citizens in the state, regulations and their enforcement. We will try and understand better how the need to restore or consolidate trust is a fundamental driver of the development of inspection systems – and whether (and in what ways) "risk-based inspections" can help strengthen this trust (or whether they threaten, as some claim, to undermine it).

a. Risk-based inspections and "Smart Regulation"

This question squarely puts this work in the perspective of the "smart regulation" research and policies that have developed over the past couple of decades and which, following the sub-title to Ayres and Braithwaite's 1992 *Responsive Regulation,* attempt to be "transcending the deregulation debate". Referring to "smart regulation" is, however, more a way of signalling the complexity and contentiousness of the issue. Indeed, "smart regulation" is an expression that has been given a number of definitions, and the basic tenets of which are far from being undisputed – and its current usage is quite far from the specific meaning that Neil Gunningham, who coined the term, originally gave it.

Different definitions include references to "responsiveness" and "cooperation" and to "protecting" and "enabling" – but also to the "usual" meaning of "smart" in management jargon, i.e. "specific, measurable, achievable, realistic and timely"[3]. At its core, "smart regulation" is based on the idea that regulation can be

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[1] As we shall see, there are significant limitations in terms of data in order to reach any conclusive answer to this question, both on the economic and on the effectiveness sides. As a proxy for economic impact, we will mostly consider the administrative burden created by inspections (excessive burden being generally to some extent a drag on growth), the availability of clear guidance to businesses and the coherence and predictability of inspections and enforcement (both counting as positive). In terms of effectiveness, we will focus on inspection functions where at least some key outcome data is available and reasonably reliable (e.g. occupational safety), but will not look into questions of attribution, which would go vastly beyond this research. Rather, we will limit ourselves to comparative cases.

[2] A number of inspection agencies have mandates that tend to be defined purely in terms of implementing legislation, without consideration of what public welfare interests they should aim at supporting. Assessing (and improving) their effectiveness is, without redefining their goals, very difficult (if not impossible), as we will discuss further.

[3] See definition in External Advisory Committee on Smart Regulation (Government of Canada) 2004, available at http://publications.gc.ca/collections/Collection/CP22-78-2004E.pdf - and for an alternate definition, e.g. here:

simultaneously more effective and more flexible, more efficient, more friendly to growth and innovation. Reforms to make inspections more risk-based have clearly been designed with the same aim: "more effect, less burden", as per the Dutch motto, or "prosperity and protection", as per the English one.[4]

What these mottos really mean, and how they translate into practice, is the first question. The second one is even more important: does "smart regulation" actually delivers on its promises? Many groups and authors have challenged this claim, and still do[5]. Through this research, we will try and bring our modest contribution to this debate and to the construction of knowledge on regulation and its effects, by attempting to investigate in details what the "enforcement" side of "smart regulation" really consists of, what different practices exist, and with which results.

b. Main elements of the research - hypotheses

Having defined broadly the central problem this work seeks to investigate and the question it will try to respond to, going further requires to break down further the research questions into a series of fundamental constitutive parts:

- The "inspections object": do regulatory inspections constitute a specific "object", distinct from the regulations they are aim at controlling (and enforcing) compliance with[6]? what do they entail, and how they are organised, conducted etc.? What is supposed to be the goal of these inspections and of the associated measures and activities? Is there consensus on these questions, or not – and, if there is dissent, what basis can be adopted for this research?
- "Risk-based inspections": what are the different meanings put behind these words? Is there some kind of "professional consensus" on what this entails[7]? What claims are made about these practices? How do "real" risk-based inspections look like, and how much do they differ from non risk-based ones (to the extent that such a group can be defined)? And what are the results of the introduction of risk-based methods?
- Measuring outcomes: what are the challenges involved, the limitations of existing data and methods to assess effectiveness and other aspects? To what extent can these be corrected for to make existing data more useful? To which extent do apparently conflicting results also reflect improperly formulated questions and/or incorrect understanding of what is being assessed? And what would be needed to have more significant results in the future?

In respect to these three main groups of issues, we make the following hypotheses:

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https://www.ec.gc.ca/esee-eem/default.asp?lang=En&n=1F37FC50-1&offset=2&toc=show (used by Environment Canada). For the academic definition as per Gunningham, see further in the section on "Antecedents and sources".

[4] The two mottos can be found (a) for the Dutch one, in the documents presenting the inspections reform programme (*Vernieuwing Toezicht*), e.g. here: http://www.inspectieloket.nl/english/ - (b) for the English one, in BRDO publications, e.g. here: https://www.gov.uk/government/publications/local-regulation-ensuring-prosperity-and-protection

[5] Just to give a couple of examples of stakeholders groups criticizing so-called "Smart Regulation", see: http://www.cela.ca/collections/justice/public-good-regulation-smarter-smart-regulation (in response to the Canadian report referenced above) and a recent criticism by EU Trade Unions of the European Commission's "Better Regulation" programme: http://www.euractiv.com/sections/health-consumers/european-commissions-better-regulation-has-killed-150000-says-etuc-314030

[6] While there is a significant amount of publications focusing on inspections and enforcement, this does not *ipso facto* answer the question. First, many consider more the volume than the methods. Second, there remains far more discussion of and research on "regulation" than on inspections, controls, etc. Third, there continues to be a frequent assumption that what matters most is how rules are formulated, and that this determines the subsequent inspections and enforcement measures. For these reasons, it still makes sense to ask the question of inspections as a separate research object.

[7] Again, this question is not necessarily obvious to answer, and there remain important disagreements both on the relevance of risk-based approaches, and on their meanings. See e.g. Rothstein, Borraz and Huber 2013.

- "Inspections" are a distinct object, with their own, specific range of effects, which are distinct from those of the underlying regulations they are supposed to help implement. Their goal is to promote social welfare along the lines of the regulations they cover, in particular by helping to decrease or mitigate specific risks. Under the word "inspections" are also understood a number of compliance-promoting tools. It is legitimate to organize inspection (and related) activities in ways that help achieve better results in terms of overall goals (safety, public welfare etc.), even if this has to be done at the expense of other values or legal principles (e.g. strict equality of treatment). Thus, effective inspections entail a fundamental element of discretion, and *how* to structure and limit this discretion is an important issue.
- "Risk" is a fundamental way to define what inspections are aiming at preventing or mitigating, to prioritize resources, and to select the most appropriate activities and instruments for interventions. To be effective as a criterion based on which to organize inspection activities, risk needs to be properly defined as the combination of the likelihood of a hazard actually resulting in adverse effects, and of the potential magnitude of these effects (taking into account both their scope and severity). Understandings of risk which are partial (looking only at magnitude of hazards, or at likelihood of accidents, or focusing on violations of rules rather than on actual effects) result in sub-optimal outcomes in comparison. In order to be effectively used, risk-based approaches require adequate, as-comprehensive-as-possible, up-to-date data.
- "Outcomes" of inspections should be reduced/mitigated risks, resulting in higher public welfare for the population, in a variety of ways (better health, reduced deaths and injuries from preventable accidents, protected environment, but also higher state revenue allowing for better funding of public priorities etc.). Inspections can also have negative outcomes: reduced business activity, higher prices and lower choice on the market, etc. – particularly when practices are poor. In many cases, attributing outcomes to inspections is very problematic, and thus attributing evolution in outcomes to changes in practices is similarly difficult. This is both because the phenomena observed are complex and multi-causal, and because of limitations in available data. Nonetheless existing data, in particular when looking at cross-country comparisons, allows to lend support to the central thesis of this research, i.e. that risk-based inspection approaches result, all else being equal, in better outcomes and/or lower costs. Furthermore, it is possible to conceive of ways through which better data could be produced, and hypotheses further tested in the future.

1.2. Antecedents and sources for the research

Research on inspections is not new, even though it has not necessarily always (or even frequently) been formulated as the object being studied. The earliest works considered in our research date back to the 1960s, and considerable work was done in the last four decades – thus, way before government or international programmes targeting "inspections reform" started to take hold.

The justification for this research lies therein that very little of the existing (and considerable) research has looked precisely at this combination of issues, and that none (to our knowledge) has done so in a way that seeks to overcome the limitations and difficulties in getting highly precise and reliable data by going broader, i.e. through a comparative investigation that reaches across regulatory functions and countries. The closest possibly (and a major source of inspiration we readily acknowledge) may be *Responsive Regulation* by Ayres and Braithwaite (1992), a seminal work on the topic but that looked less specifically at methods, and did not use "risk" as a central concept (focusing rather on "responsiveness" or "tit-for-tat"). Recent, important work like Malcom Sparrow's *Character of Harms* looks across functions and countries, and does consider risk (or "harm"), but with a stronger focus on operational, problem-solving questions, and not on overall goals and effectiveness of the system. Very significant work has been done on risk and regulation, including considering

the issue across jurisdictions and regulatory functions (Wiener 2003, 2006 - Bouder and Löfstedt 2014 etc.) – but this work only considers inspections and enforcement incidentally, and looks at risk more in terms of defining it and understanding its different aspects, than of using it as a guiding principle for regulatory activities. Finally, very interesting work is being done that looks specifically at how inspectorates work, how they use risk and other methods (e.g. "responsiveness", proportionality etc.) to target their actions and promote compliance, and with which results (e.g. Tilindyte 2012, Yan, van Rooij and van der Heijden 2015 etc.) – but such work has so far mostly been done on a relatively limited range of countries and issues, and from a perspective that emphasized the testing of models rather than a more "practice based", "bottoms up" approach.

a. Drawing on research findings – literature review

What we aim at doing here is to try and connect more strongly theory and practice, and to look at inspection methods, risk, and effectiveness *in combination.* Thus, while we will draw strongly on a wealth of excellent, prior research work, we hope the way the ingredients are combined will be sufficiently novel to produce new and useful results. From this perspective, several strands of research are relevant to this work on inspections, risk-based methods and effectiveness[8]:

- Drivers of compliance: a key aspect of understanding better what inspections should aim at, how they produce results, and how to make them more effective, is the investigation of what produces compliance. While the "deterrence" model formulated by Gary Becker (Becker 1968) still is used widely, there is ample evidence that it explains (at best) a limited part of compliance variations (Kirchler 2007). Later studies have sought to develop more complex and comprehensive models of compliance, looking at social, cultural, psychological as well as economic drivers. This is particularly relevant to our study, and scholars of "voluntary compliance" (e.g. Scholz 1984) and of "procedural justice" (in particular Lind and Tyler 1988, Tyler 1990) have put forward an understanding of the complexity of compliance drivers, of the potential for counter-productive effects of (perceived) "unfair" enforcement, and of the complementarity (and varying strengths and weaknesses) of different approaches that is particularly fruitful for practitioners and students of inspections and enforcement. Works that present a typology of compliance profiles, and of the effects of enforcement actions on each profile, are also very useful (e.g. Elffers and Hessing 1997, Voermans 2014). Overall, this research is greatly indebted to the typology of compliance drivers and their interaction set forth by Tyler in *Why people obey the law.*
- Studies of institutions and methods: whether conducted from a sociological, economic or regulatory studies perspective, starting from the 1980s, there have been a number of works studying how inspecting institutions are organized and conduct their work (monographies and comparative studies of a couple of inspecting institutions, as well as broader studies looking at range of institutions and their practices). Some of the most relevant for our research include in depth investigations of how specific agencies work (e.g. Grabosky and Braithwaite 1986 – Hawkins 2002 on the UK's Health and Safety Executive – HSE), comparisons of "regulatory styles" across countries (Vogel 1986 on environmental regulation in Britain and the US), but also (and most significantly) broader, thematic and problems-based reviews of practices (in particular Pressman and Wildavsky 1973, Sparrow 2008, Mertens 2011 – or with a narrower focus Robben 2010). Also important in this category are analytical

[8] Assigning works to these different categories only purports to make it easier to follow the different aspects of research that we have tried to combine. Many books and articles span across several topics, and us listing them in one category only means that from our perspective this is their dominant contribution, not that they are not relevant to other issues.

works commissioned by regulatory agencies themselves, in particular the UK's HSE, which has a long and distinguished research tradition (e.g. Centre for Corporate Accountability 2007).

- Regulations and enforcement: studies considering the interface between rules and enforcement, and how to make enforcement more effective, are is a central "pillar" of the literature used for this research. The most central reference in this category is Ayres and Braithwaite's *Responsive Regulation* (1992) which, over 20 years after publication, continues to be a significant inspiration not only for researchers but for practitioners. Along with the "procedural justice" vision of compliance drivers, "responsive regulation" clearly is one of the models that have had the most influence on our own research. Author authors have, around the same time as Ayres and Braithwaite, developed related visions of how regulatory enforcement can be conducted in ways that are more effective to promote and achieve optimal compliance levels. This includes Kagan and Scholz (both 1994), but important insights can also be found in works that focus on specific functions but attempt to draw broader lessons from case studies (Hawkins 1984). Following on the "responsive regulation" model, Gunningham (1999, 2003 – and 1998 with Grabosky) has been one of the main proponents of a broader approach to enforcement and compliance promotion that they named "smart regulation[9]". All these works have major relevance for this research and can be said to form part of its foundations..
- Risk and regulation: the growing category of "risk studies" is so large and rich that some clarification is needed as to which ones are most relevant for this research. While "fundamental" considerations of the role of risk in the society (and of understandings of and reactions to risk from a sociological and psychological perspective) are to some extent relevant, they are mostly useful for inspecting institutions themselves, in order to better understand how to communicate about risks and what reactions to expect from the public. In this first group are pioneering works like Slovic's on risk perception (1987) and Beck's on the "risk society" (1986). The most relevant for this research, because of its significance for inspecting institutions' understanding of how to work with the public, is Slovic's. Following on these early works, a number of authors have looked at how risk is managed in a public policy context, both from a normative and from a descriptive viewpoint. A number of institutions and projects (International Risk Governance Council, Duke University "Rethinking Regulation", UK Risk and Regulation Advisory Council, Dutch Risk and Responsibility Programme) are or have been involved in this field, leading to a large amount of fruitful work (e.g. Renn 2005 – Balleisen, Bennear, Krawiec and Wiener, in press – Bouder 2009 - van Tol, Helsloot and Mertens 2011, Helsloot 2012). Equally significant are authors trying to show and understand the diversity of regulatory responses to risk, and how these are influenced by a number of political, institutional, social factors (e.g. Hood, Rothstein and Baldwin 2001, Carrigan and Coglianese 2012). While all these streams of research are extremely useful to build a better understanding of what "risk" can mean, what policy (in particular regulatory) responses exist, and of what factors drive specific responses, only few of the published works fully correspond to our research focus, which is the way in which risk can be (and is) used as a tool to select instruments and approaches, and to focus resources. We will see that most work from this perspective is to be found mainly not in academic writing (though there are of course some important contributions on this, e.g. Black 2005, Black and Baldwin 2010 and 2012 etc.), but in documents developed by inspecting institutions, governmental and intergovernmental bodies.
- Studies of regulation and regulatory instruments: while it would add little to reference them at each and every step, it bears repeating the obvious, which is that such research could not have been done without the underlying "infrastructure" provided by many years of research on what regulations are

[9] Gunningham defines "smart regulation" as a "form of regulatory pluralism that embraces flexible (…) forms of social control which seek to harness not just governments but also businesses and third parties" and relies on "the use of multiple rather than single policy instruments and a broader range of regulatory actors" (Gunningham 2010, p.131). While fully compatible with the definitions used by governments or the EC, it is different in its emphasis. We will come back to this issue in the theoretical part of this research.

(and should be) used for, how rules work, what the downsides and upsides of different types of regulation are – even when such studies did not specifically focus on (or cover) inspections and enforcement issues. Particularly useful for our research have been works by Ogus (1995, 2004), Black (1997), Diver (1983) and Baldwin (1990, 1995).

- Finally, one more area of relevance is the field of legal studies on executive and administrative discretion. Unfortunately, this is an area where most research and writing tends to be country specific (focusing on each country's administrative law and legal tradition), and where the scope of this research did not allow us to fully engage. The relevance of the issue to risk-based inspections and enforcement is clear: if discretion is somehow illegitimate or severely constrained, responsive regulation, risk-based targeting and proportionate enforcement will all be impossible or highly difficult. The challenge was that considering seriously and thoroughly the literature on this topic would have required a major time investment, given that this is mostly not treated as an independent topic, but will be found as part of broader studies of administrative law, the executive branch, administrative bodies. We thus cannot in any way claim to have done a comprehensive review on this side, and have relied on more cursory research. We did nonetheless look through a variety of works on this issue, over a variety of legal systems (mostly French, British and American, for language reasons), in order to back up our analysis (e.g. Treves 1947, Williams 1994, Shapiro 1994, Solum 2002, Endicott 2011, Tifine 2012) This has been sufficient to show that a significant number of legal scholars and legal doctrines support the vision of discretion that is put forward and used in this study, but clearly a more thorough investigation of this issue would be an important area for future research. In addition, during the course of the preparation of this research, we participated in organizing an international seminar on regulatory discretion (held in December 2013 in The Hague), which allowed to discuss, enrich and validate many of the ideas put forward here on this topic[10].

b. Drawing from the practice – experiences from inspecting agencies and reformers

The review and consideration of existing research and literature is one of the key elements of its study, but its deeper foundation is in the consolidation and analysis of inspection practices across a wide range of functions and countries, as well as of the practical work undertaken to reform and improve them, including the research and guidance produced by international institutions (World Bank Group and OECD) and national ones (e.g. the United Kingdom's Better Regulation Delivery Office – BRDO) in order to support "better practices" in inspections. In order to better understand how this "practical perspective" was captured, and how we have used it, breaking it down a bit is required – considering the types of sources, the relevance of the practices, and the use we put them to.

First, there are several ways to approach the practice, different *categories of sources*:

- Reviewing documents (guidelines for inspectors, guidance for businesses, reports, etc.) produced by inspecting institutions and (to use a short name) "reform promoters"
- Analysing available data (official data produced by inspecting institutions as well as representative surveys)
- Conducting interviews, focus groups, seminars etc. directly with inspectors, inspection institutions management, businesses, reform promoters etc.

[10] See seminar agenda and contents: http://www.ial-online.org/2014/01/international-seminar-on-regulatory-discretion-summary-of-findings-and-presentations/?doing_wp_cron=1430754528.4743070602416992187500

In preparing this research, we have made extensive use of our experience leading or supporting reform work on inspections for the past 11 years in a number of countries. Through this work, we have had the chance to have frequent, in depth discussions with "inspections practitioners" in close to 30 countries. While this work also draws strongly on publicly available data and documents (including some that were prepared in connection with the reform work in which we were involved), these first-hand discussions are what brings it the strongest connection with practical experience. Annex 1 includes a summary of the countries covered, and of the types of interactions, persons interviewed and consulted, etc.

The second relevant differentiation is based on *what can be learned* from these different sources:

- Actual practices – what inspecting institutions are doing "on the ground", how inspectors conduct their work, but also how it is planned, how resources are allocated, how often different kinds of establishments are visited etc.
- Goals and visions – what inspecting institutions are expected to achieve by the governments they report to, and how they themselves conceive of their mission, but also at a deeper level of detail how they understand and conceive "risk", "compliance" and other key organizing elements of their work
- Impacts and outcomes – how effective are inspecting institutions' activities in terms of reaching their stated goals, and in terms of reducing and mitigating risks, increasing social welfare etc. – and, looking at intermediary outcomes that are sometimes easier to assess, what are the effects of their activities in terms of compliance, trust, legitimacy etc.

A third perspective is the *value (example or counter-example)* given to the cases and practices considered – i.e. the extent to which they correspond to a risk-based practice, or the opposite:

- Many countries and institutions exhibit a mix of both risk-based practices, of techniques intending to promote compliance in "smart ways", and aspects of their work which are decidedly more "traditional", which contradict or limit their intent to work in a risk-focused and risk-proportional way – looking at these limitations and contradictions can help understand the challenges involved in introducing these approaches, and also why results can at times appear unclear
- A few institutions (or at least some elements of their practices) can be seen as strong examples of what risk-based approaches purport to be – these examples will be used to show in greater detail what the actual practice of risk-based inspections is, and to look at the impacts and results to the extent that they can be measured
- Many countries and institutions will, on the contrary, provide examples of "non-risk based" practices. This can mean that there is no active effort to target resources and visits, that no difference is made between types of violations, that punishment is the main indicator rather than improving compliance, etc. Looking at these examples (and their variations) allows to understand what is the alternative to risk-based approaches (and what is the most common prevailing practice)
- In a number of cases, countries or institutions will be considered that still exhibit to a considerable extent traits of "non-risk based" practices but have started reforms in the direction of "smarter", risk-based approaches. Through these, we will try and see what can be found in terms of the conditions of possibility for such reforms, their key elements, and whether any results can be assessed (and if so, which ones).

1.3. Structure of the research

A final point to consider is *how we will structure and use* these findings from the practice. Arguably, an optimal way would have been to present clear case studies and to make direct comparisons between inspecting institutions with contrasting approaches, but otherwise similar characteristics. There are several reasons why

we in fact have *not* chosen this path. First, there are no "pure" examples of practice, one way or the other, so the findings may not, in fact, be so illuminating. Second, publicly available data is incomplete for most institutions and most countries, and gaps can only be partially bridged through more qualitative information (guidance documents, interviews etc.), and they do not offer the same level of evidence. Given that these gaps in data for the most part cannot be addressed without considerable time and resources (e.g. conducting representative surveys), most such "case studies" would have been incomplete, and not fully comparable. Third, considering the problematic character of much of the data, the difficulties in attributing changes in outcomes to specific factors (i.e. disaggregating multi-factor effects), and the fragilities of purported causality models in social sciences, we are not fully convinced that a case-study approach would have, in fact, yielded stronger results, even assuming data gaps had been mostly filled. Rather, then, that to chase an improbably chimera of certainty, we have chosen to embrace the incompleteness and uncertainty inherent to our field of research, and instead try and find whether we can find data and evidence that are rich enough to provide real insights on practices, and to support (or disprove) the *likelihood* (and not the certainty) that certain practices may have certain effects.

As a result of this, this research will not be structured around case studies, but will use different aspects and elements from different institutions and countries where relevant, i.e. where their practices and available data best allow to help understand a specific aspect of the issue. The structure we will follow goes from definitions and key theoretical underpinnings, through findings from the practice, to the evidence provided by available data, and its limitations:

- In a first part, we will first provide an overview of the historical origins of the current systems of regulatory inspections and of what the word covers in terms of variety of institutions, fields and practice. Due to the vast scope of this question, we will limit ourselves to a couple of functions, selected for their importance in modern inspection systems and because they were generally the first to be developed in the 19th century: occupational safety and health, and food safety. We will try and see to what extent this historical investigation, however limited, can help us shed some light on the relationships between inspection systems and risks (real and perceived), and trust.
- The second part will cover the theoretical perspectives relevant to our research. We will start by looking into the research on drivers of compliance, and into other key theoretical underpinnings (in particular on regulatory discretion, and on the purpose of regulation. This will be followed by a cursory review of existing research on risk and regulation, to better understand the meaning and relevance of the term.).Finally, we will consider the relevance of the issue for economic growth, as it is one of the justifications for policy reforms affecting regulatory inspections.
- The third part will then consider what the actual practice of inspecting institutions looks like, and confront the theoretical perspective with these elements of practice. First, we will discuss theoretical and actual limitations of available data, in terms of allowing us to capture the effects of inspections and of changes in methods. Then we will consider and compare examples of "non risk-based practice" (or "insufficiently risk-based") and examples of inspections that define themselves as risk-based, attempting to understand what such practices consist of, what effects they produce, how their outcomes compare. As part of this, we will attempt to better define what, exactly, risk-based inspections mean in practice, and discuss instances of what we think are misunderstandings of what "risk" means in this particular context, which lead to problems in implementation and inaccurate assessment of results.Finally, we will review a few cases of ongoing or past reforms from one system to another, so as to understand their aims, logic and results.
- In conclusion, we will consider the evidence for the contention that risk-based inspections are more effective and more efficient, i.e. produce better (or constant) public welfare outcomes (and trust) at constant (or reduced) costs. In addition, we will briefly look at what further work could be undertaken in order to produce better, more conclusive data and findings.

The selection of the cases and examples used in this research was guided by a set of criteria. First, and most importantly for scientific "robustness", cases were selected for their relevance. Regulatory domains studied (food safety, occupational safety and health) are both among the first to have seen the emergence of "modern inspectorates", among the most important from a public "risk perception" angle, among the most significant in terms of institutional size and number of inspection visits, etc. Thus, they are quite acceptable proxies for the rest of the regulatory fields, in that they form a very important part of the total. Countries selected for the historical review are some of the most important and influential economies in the periods considered, and cover the most influential legal and administrative traditions. Cases selected in the third part illustrate strongly the different approaches to inspections and enforcement – risk-focused and risk-proportional vs. "risk averse" and "zero tolerance", for instance. Since a limited number of examples had to be chosen, the effort was to take cases that would have a high significance (large economies of groups of countries, major inspection functions) and sufficiently contrasted practices.

Second, availability of data. Since the purpose of the research was to attempt a comparative study of inspections across time, countries and regulatory domains, it was inherently impossible to also undertake considerable research to "construct" data where it is not already available. Thus, the cases chosen were all instances where publications existed, quantitative data was easily available, specific surveys had been done and their findings released, etc.

Finally, familiarity. Because the study focuses largely on methods and practices, it was important that the author be as knowledgeable as possible about the practices in the cases used. To some extent, therefore, the selection of these cases was "path dependent" on the author's professional activities over the past twelve years, which allowed to get more details and depth in insights.

1.4. Limitations in scope

There are a number of important topics that, due to the need to somewhat limit the scope of this research, we will only superficially touch. Among these are the related issues of corruption and capture. While both theoretical accounts and empirical evidence suggest these are quite important in relation to inspections, and some of the reforms we consider in the second part have been launched precisely with the aim to decrease them, we will not be able to conduct a full discussion of this question. We will, however, attempt to shed some limited light on such issues, and lay down some markers for further, future research.

One of these questions that will have to remain to some extent unanswered is, however, of more significance than others – it is that of the economic impact of risk-based inspections, in comparison with other, "non-smart" practices. One of the main contentions of regulatory reform of all kinds, "better regulation", "smart regulation", is that they will allow for stronger (and/or more diversified, more sustained) growth (and more jobs), as a result of increased investor confidence, greater innovation and technology adoption, stronger competition, etc. For some countries, these growth benefits can also result from a better access to foreign markets – when such access was constrained by regulations that did not conform to WTO and/or EU approaches, for instance. Sceptics, however, point out that whatever changes to competitiveness are induced by such "micro-level" reforms are dwarfed in terms of growth and employment by the effects of "macro-level" policies (both fiscal and monetary), and of more "fundamental" growth drivers (demography, geography, capital, etc.). Seriously considering the merits of both perspectives would require an entirely different, major research undertaking – and economic skills that the author of this work clearly does not have.

What we will instead have to limit ourselves to, in this research, is a modest assumption: that, all things being otherwise equal, the advantages provided to economic activity by a "better" or "smarter" inspections regime will give economic benefits. These may be at the margin, but nonetheless real. For smaller economies, less

integrated into international markets, the benefits may be stronger. While we will not be in any position to test the validity of these assumptions from an economic perspective, we will nonetheless refer to some of the existing research that can back it up (such as Koedijk and Kremers 1996 – Djankov, McLiesh and Ramalho 2006 – Loayza, Oviedo and Servien 2005) and consider a few concrete examples and cases of changes that may, indeed, contribute to substantial economic benefits for the countries that have implemented them.

A final note is that, in this research, we have attempted to present findings for a double audience: academics and researchers on the one hand, and "practitioners" (regulators, regulatory reformers) on the other. This has meant that the volume of the work increased significantly, because we attempted to clarify issues that would be relevant for each audience, even while other points may appear relatively self-evident to one group. We hope the readers will show some indulgence and navigate this work to the sections that are of highest relevance to them.

2. Inspections, risks and circumstances – historical development, diversity of structures and practices

41. An inspector under this Act shall have power to do all or any of the following things ; namely,

(i.) To make such examination and inquiry as may be necessary to ascertain whether the provisions of this Act (…) are complied with in the case of any mine :

(ii.) To enter inspect and examine any mine, and every part thereof, at all reasonable times by day and night, but so as not to impede or obstruct the working of the mine (…)

42. (1.) If in any respect (…) any inspector finds any mine, or any part thereof, or any matter thing or practice in or connected with any such mine, to be dangerous or defective, so as in his opinion to threaten or tend to the bodily injury of any person, he may give notice in writing thereof to the owner agent or manager of the mine (…) and require the same to be remedied; and unless the same be forthwith remedied shall also report the same to a Secretary of State. (…)

(3.) If the owner agent or manager fail to comply (…) the time of making the award (as the case may be), he shall be guilty of an offence against this Act, and the notice and award shall respectively be deemed to be written notice of the offence.

United Kingdom Coal Mines Regulation Act*, 1887*[11]

Inspections are so much a part of modern economic life – and the expectation of safety regulations and their enforcement acting as a "backstop" to our daily life so anchored in assumptions of developed countries' citizens – that it is worth remembering that this is a relatively recent development. Indeed, the first inspectorates looking at *safety* were created not earlier than the second half of the 19th century. Looking briefly at the historical emergence of inspections is an essential introduction to a broader consideration of what these inspections are supposed to achieve, and more broadly of how risk, regulations and compliance are connected, and of the limits of these connections.

The history of the emergence of formal (in particular written) law has generally been given more prominence than the question of how laws were enforced and implemented (and how much they were complied with) – both for "ideological" reasons (traditional priority given to formal rules and official decisions over the more "menial" issues, one could say the "logistics" behind the laws) and for practical ones (sources on written, official laws are *relatively* abundant – finding out about enforcement and compliance is considerably more difficult).

[11] Full text available at: http://www.scottishmining.co.uk/256.html and a contemporary commentary and full text at: https://archive.org/details/coalminesregula00peacgoog

In addition, while historians have in fact covered "economic regulations" (when they were adopted), though rarely as much as other legislation (covering civil or criminal issues, say), there is no real body of historical knowledge specifically looking at the "history of regulations" – i.e. when, why and how certain economic activities or fields came to be covered by specific rules. When this has been covered in existing literature, this was mostly by economists and political philosophers, but their work has tended to look only at some examples that were relevant to the theory being developed, or were known to them. There has not really been a systematic investigation of the issue over time and space.

The reason why this is relevant to this research is that the basic premise of our work here is to question the existing enforcement structures and practices. Doing so leads us also to wonder since when they have existed, in which forms, regulating which areas – and also why they came about, what was expected from them, what they replaced. Thus, even though this can only be a short and partial overview, and there is no easy body of research to use, we have attempted this modest and partial summary.

2.1. Controlling compliance, controlling safety – the early history

a. Tracing the earliest examples of "inspections" from Egypt to Greece and Rome

To understand better what are the specificities of inspections and inspecting institutions, it is worth considering their emergence, and looking at when and how were first created structures specifically mandated with controlling and enforcing specific rules. "Regulation" of human activities, in its broadest meaning, may be at least as old as the earliest urban societies. As activities specialized in a way that we could now name "economic activities", different "regulatory" measures and instruments were introduced. Morris Kleiner (2006) thus suggests that "among the oldest evidence of rules governing occupations is the existence of the Babylonian Code of Hammurabi, dating to around 1780 B.C.E. This body of codes stipulated both the fees patients were to pay for medical services and the punishments practitioners were subject to for negligent treatment" (p. xiii). This earliest example already featured the multiple purposes of regulation: safety ("negligent treatment") but also other considerations, in particular costs, affordability etc. ("fees"). We do not have indications of the Code being enforced through "inspectors", but rather it seems to have been used in judicial rulings, though not necessarily with direct references to its text (Charpin 2010). Thus, right from the origins of regulation, we can witness the decoupling of *rules* and *enforcement.* Not every rule (far from it) has its implementation inspected and enforced by a specific institution. In fact, historically most regulations (and even today many of them) can be said to have been left entirely to "reactive" and "private" enforcement, i.e. only by judicial decisions when litigation happened[12].

Nonetheless, efforts to promote and ensure better implementation of policy directives, and compliance with rules, started early on. Ancient Egypt in the New Kingdom era (16th-11th centuries B.C.E.) already had a complex administrative system with technical staff at the lower levels that were in charge of making sure that central directives (e.g. relating to irrigation systems etc.) were properly followed (Moreno Garcia 2013). Specialized institutions or officials in charge of *control* of compliance with rules probably first came into

[12] Indeed, even though police forces often have broad jurisdiction and notionally could (and in some countries effectively do) control compliance with some (or many) regulations, this is a relatively recent development. Development of police forces itself was gradual and came relatively late compared to the establishment of urban societies, with Classical Athens (the "rod-bearers") and Augustean Rome (the vigiles) among the first reported to have had significant numbers of officers tasked with maintaining public order and fighting street crime and other hazards. Police forces were mostly small in numbers for many centuries, and clearly focused on violent crime and threats to the state authority. Even though there are some indications that there was some enforcement of weights and measures in Athens, any such activities were quite limited.

existence to supervise payments of customs duties and taxes[13] - being gradually developed in ancient Greek city-states, Hellenistic kingdoms and Rome. Officials in the ports controlled ships to ensure proper payment of trade duties. Still, these administrations underwent only limited development in staffing, professionalism and methods (at least as far as we can make out) – republican and imperial Rome relied on *publicans* (contractors) to make an advance on the product of taxes to the state treasury,[14] and then collect actual taxes – thus, tax collectors were in fact private contractors. Tax farming remained, if not the norm, at least a very common method, until the 19th century C.E. (one of the most important examples remaining France's *Ferme Générale,*[15] which was abolished by the Revolution).

Looking more closely we can, however, find some real examples of direct state control, for instance in Athens. In the *Constitution of the Athenians* attributed to Aristotle one can thus read that among the magistrates to be chosen by lots were 10 *agoranomes* (whose tasks included checking that goods on the market were not falsified), ten *metronomes* (verifying weights and measures) and ten (and later thirty-five) *sitophylakes* (checking that sales prices of wheat were in proportion of grain prices and weights, etc.) (Austin and Vidal-Naquet 1972, pp.326-327). While Athens is likely to have been "ahead of its times" in terms of how organized and specialized the city offices were, we should also remember how thoroughly incomplete and partial our knowledge of ancient times is. It may well be that such magistrates were far more frequent than the traces we have. This would thus suggest that the importance of securing the truthfulness of market transactions, but also to some extent the safety of consumers, and (more importantly considering the number of magistrates allocated) the fact that consumers were not "gouged", were very early concerns, and among the first gave rise to active state control.

A few more remarks on these early examples. First, we are not absolutely sure to which extent these controls (early "inspections") were based on clear "regulations", or enforced far more diffuse "acceptable practices" relying more on experience, customs etc. – and clearly on the question of "fair prices" at least, and of falsification, it is unlikely that rules (if they existed) were very detailed (weights and measures being one issue where, on the contrary, the rules were certainly clearer). This means that the question of inspectors *discretion* was already very relevant. Second, the Athenian magistrates were (as for most other functions) selected randomly – the idea of *professional* inspectors was one that was not yet present.

Still, while these functions undoubtedly related to enforcement, control and inspections, the structures in place did not necessarily look very similar to what we would nowadays understand as "inspections". These developed gradually, over a number of centuries – both in terms of scope, professionalism and methods. Some important steps can be sketched out as "landmarks" in this emergence of "inspecting institutions"[16] – from the Middle Ages to the 19th century.

b. The developments of the Middle-Ages and Pre-Modern times – and their relevance

The relatively simple character of fiscality – and of accounting, at least until the 14th century – in pre-modern times means that the complexity of operations needed to assess taxes and duties was limited – and inspectors were not really distinct from collectors. These collectors did not really constitute a corps of "inspectors" that would have looked in details at operations of economic agents. It is in other fields that we can trace some of

[13] See Asakura 2003, Austin and Vidal-Naquet 1972

[14] See e.g. Badian 1983

[15] See e.g. Pion 1902

[16] This outline is clearly done from a Western European perspective as, institutionally, this is where the model of modern inspecting institutions comes from. This is, of course, not to say that other regions did not develop their own approaches to problems of safety, compliance, market regulation etc. – only to focus on what is the most relevant for our present study.

the origins of modern, "professional" inspectors – and in ways that often show a very strong link between "risk" and "control".

i. Food Scares and Food Controls – unity of concerns, diversity of approaches

There were, however, other aspects to economic activities than taxes and levies, some of which were deemed very important by populations and rulers. This is the case of the "quality" of goods, works and services, in particular (the notion of "quality" is a highly problematic one, but this was the term that was most frequently used at the time). As Madeleine Ferrières has managed to sketch out (in spite of the fragmented nature of sources) in her ground-breaking book on the history of food fears (Ferrières 2002), an increasing number of control measures were brought in from the late 12th century onwards, as cities again started to grow in Western Europe, in order to alleviate "fears" about the "safety" of animals being brought into the city, slaughtered and sold. While the contents of regulations imposed, the way in which controls are implemented, were grounded in the conceptions held at the time about what was "healthy" or "unhealthy", "safe" or "unsafe", and had nothing to do with modern science (except by some chance overlaps between the two) – they still manifested a concern that is very much akin to what now drives the development of food safety regulations and inspections. The intellectual background for regulation of food was very different then from what it is now. Bacteria and other germs were unknown, as were the real mechanisms of contamination. Food, however, had a centrally important role in medieval medicine and beliefs on health. The existence of animal diseases was of course known, some parasites were, if not understood, then to some extent identified, and there were many fears, that drove the demand for regulation. Because medical conceptions were so different, and understanding of biological mechanisms was yet to be developed, many of the rules and practices imposed at the time would not make sense from our perspective[17] – but the question here is not whether rules were appropriate to control diseases (they often were not), but how they were enforced.

The number of cities regulating the sale of meat, in particular, kept increasing over the 12th-15th centuries (Ferrières 2002 pp. 43-45)[18]. Very early on, too, emerge crucial differences between what we would now call "regulatory approaches". While cities in Southern France and the Mediterranean region more broadly (Italy, Spain) relied on municipal regulations, detailed written law (these were Civil Law regions) , and officers appointed by municipal authorities to control the "safety" of meat, Northern France (and England, or the Low Countries) had a different model. There, professions such as butchers were "self-regulated" by guilds, they were "sworn trades" and swore to obey the guild's charter. Rules are less detailed in this case, the prohibition of selling "unsafe" or "unsuitable" meat is meant to be implemented by professionals who have the knowledge and "know how". Guilds themselves control compliance (*ibid.* pp. 45-46). There is no evidence of a marked difference in effectiveness between the two, but it is noteworthy that two models existed from the onset, based more on inherited legal, social and political differences between these two areas, rather than on considerations of how effective the control may be – and worth noting that this difference has, to a significant extent, endured, with a stronger reliance on self-regulation and involvement of professionals in England or Germany, and more emphasis on state control and written rules in France or Italy, say.

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[17] Even though everyday experience did yield some practices, such as thorough cooking, that do make sense from a bacteriological perspective, many other requirements would be more questionable from a "modern" view. For instance, in pre-modern Europe, rules generally mandated animals to be killed in view of all, i.e. on the markets themselves, with corresponding hygiene issues – but thus avoiding fraud on the actual state of the animals being slaughtered (see Ferrières pp. 48-51 and 348-356). It should be noted that this concern and belief that animals killed "in sight" are safer is still widely spread in developing countries around the world today, and thus probably corresponds logically to a situation where consumers have no other trusted sources of information about products than their own eyes.

[18] It is notesworthy that regulation at this time is essentially done at the municipal level. National, rather than local, regulation came in much later.

While the control of animals "imports" (into the city), slaughter, and sale of meat were the earliest food-related regulations and "inspections", successive centuries saw additional types of foods and food trades increasingly regulated – in line with epidemics and "food scares", i.e. in our modern language real and perceived risks. To these traditional forms of control was added some supervision of street vendors (*ibid.* pp. 222-223 for the example of *pâtés* and their regulation in the 16th century) and food shops in large cities by police forces (e.g. in Paris), that gradually developed and indicated an increased concern on the side of political authorities – because food scares could rapidly degenerate into unrest. This was the case with disputes about new bread baking techniques that led to royal intervention and regulation in Paris (*ibid.*, pp. 158-163). Major epizootic crises gradually contributed to a more organized and constant involvement of central state authorities (necessary to enforce quarantine), but this happened only slowly, and with a number of reversals, over the 17th-19th centuries (*ibid.,* pp. 294-311 and 392.402). Slaughterhouses, along with state-run enforcement, were introduced in France in the early 19th century, and thus live animals removed from the food markets. In 1906, sanitary inspections were made mandatory in slaughterhouses in France and the US adopted the Pure Food and Drugs Act (*ibid.,* p. 431) but it is only well into the 20th century (Ferrières. pp. 428-432 – see also Blancou 2000), long after Pasteur's work gave the scientific foundation for modern food safety control, that food safety services were systematically organized[19].

Food-related "scares" or, to use a modern term, "risks" were not, however, the only application of early efforts at regulatory control. Much as today we can still see a nuance between some types of inspections focusing strictly on safety and physical threats, and others looking at consumer protection and other "economic interests", early examples of regulation also included interventions aiming at safeguarding consumers from fraud and deceit. The food-related controls we discussed above had a dual purpose – protection against "unsafe" foods, and fight against adulteration and fraud (e.g. the purported use of cat instead of rabbit meat in pies – see Ferrières pp. 216-225). This was, however, not the only area where rules and processes existed with the aim of protecting consumers. Just as guilds were involved in the food trade, the craftsmen guilds that emerged in a number of cities from the 11th-12th centuries onwards covered most of the significant crafts and trades in Western Europe, and a major part of their functions was to control the way their members worked, and the "quality" of their wares, works and services.[20] Guilds were also found in non-European contexts and played an important role[21] in what could be called early examples of "self-regulation" or "regulated professions" or "enforced self-regulation" (depending on the specifics of each case).

In many jurisdictions and in many aspects, one could thus say that "enforced self-regulation[22]" preceded "regulation". Guilds regulated their members (often with a limited amount of details in written rules, and more emphasis on practice) – and authorities (municipal, state or otherwise) provided an "enforcement backup" for whoever would try and operate outside of the guild and its rules. In this perspective, it could be interesting to study more closely whether the liberalisation of entry into economic activities and the abolition of guilds' monopolies (e.g. in France with the *Loi Le Chapelier* adopted in 1791) had an influence (even delayed) in the gradual emergence of more direct state regulation. It would not be absurd to imagine that states that more thoroughly eliminated the old guilds system (e.g. France) would rely less on professional regulations than others (such as Germany) where changes were slower and less radical – and this could have reinforced a

[19] See e.g. overview of the United States FDA's history: http://www.fda.gov/AboutFDA/WhatWeDo/History/Origin/ucm124403.htm
[20] See e.g. Martin Saint-Léon 1922.
[21] See Lucassen *et al.* 2008
[22] We are here using in a deliberately anachronistic way an expression borrowed from Ayres and Braithwaite 1992 – see pp. 102 and 118.

difference in regulatory approaches that, as we have seen above, has some origins in the Civil Law/Common Law "divide"[23].

ii. The French Manufactures Inspection – an early example of "inspectorate"

One of the most interesting early examples of regulatory inspections, however, involved direct state intervention to ensure an adequate level of "quality" for the era's most important consumer goods – textiles. The story of textile manufacturing inspections bears striking resemblance to many of our time's inspections and enforcement logics, challenges and reform attempts. It also features England following up in France's regulatory footsteps, which does not fit with today's stereotypes on the two countries. Covering this case in some detail is worth the insights it can give us on how issues we tend to see as "contemporary" are in fact further developments of long-present trends and challenges.

One of the first "inspectorates" defined as such was created in 17th century France to supervise textile manufacturing. In August 1669, Louis XIV enacted the *Règlement Général des Manufactures et Teintures*, on the recommandation of Jean-Baptiste Colbert, *Contrôleur Général des Finances* – his chief minister. Further to this major regulatory act, in april 1670 Colbert (who was also "*Surintendant des Bâtiments, arts et manufactures de France*") issued an instruction on its implementation[24] (Lenoble 1908 pp. 1-3). The regulation included rules to ensure raw materials (wool, primarily) were not damaged, detailed mandatory prescriptions on the way weaving and dyeing should be done for different types of cloth, requirements to check the cloth for conformity and mark it with a lead seal – as well as serious sanctions for those who would violate these rules (*ibid.,* pp. 2-3). This initial regulation was followed by subsequent additions, amendments and reforms: first, aiming to strengthen and complement it and then, later, trying to make it more flexible to accommodate market demand for more diversity and lower prices, more "segmentation" as we would now say (Lenoble 1908 p. 2 and Minard 1997 p. 490). The inspection itself underwent gradual development over several decades, with inspectors appointed throughout the kingdom, then "inspector generals" created in 1727 (Lenoble 1908 pp. 3-4) – reaching a staffing level of 50-60 (Minard 1997 p. 488) – modest by modern standards, but far from insignificant for states in the 18th century, and considering the limited number of manufacturing facilities to be controlled.

Even though the inspection was to be abolished quite suddenly (Minard 1997 p. 487, Lenoble 1908 p. 9) in 1791 by the Constituent Assembly (in the same year that it also abolished all guilds and corporations, and forbade trade unions and strikes, by the *Loi Le Chapelier*), the inspection was not only well established but, to an extent, imitated elsewhere. Building further on the policies of successive Tudor monarchs who "used protectionism, subsidies, distribution of monopoly rights, government-sponsored industrial espionage and other means of government intervention to develop England's woollen manufacturing industry" (Chang 2007 pp. 40-41), in the 1720s Robert Walpole and his cabinet went further. Not only was Walpole's 1721 legislation adopted to "protect British manufacturing industries from foreign competition, subsidize them and encourage them to export" – in addition, "regulation was introduced to control the quality of manufactured products, especially textile products, so that unscrupulous manufacturers could not damage the reputation of British products in foreign markets" (*ibid.*, p. 44). While "Walpole's protectionist policies remained in place for the next century" (*ibid.*, p. 45), state-imposed quality controls were also phased out in the 19th century as part of a broader wave of free-trade reforms.

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[23] A number of regulatory features have origins as far back as the French Revolution – for instance, the way French building safety regulations are primarily enforced through a 10 year liability on builders dates back in essence to the 1804 *Code Civil* – see World Bank Group 2013 b, pp. 82-87.

[24] Full text available at: https://www-persee-fr.bibliopam-evry.univ-evry.fr/web/ouvrages/home/prescript/article/corr_0000-0002_1863_cor_2_2_928_t1_0832_0000_5 .

Cursory information suggests the system was imitated also in other countries, but since information available is limited, we will focus on the original French example in order to briefly describe some of the main goals, characteristics, challenges and lessons of the "manufacturing inspection" experience. The overall goal of the regulation of manufactures (primarily textile, but with coverage of rules and inspections also extending to other sectors) was the economic development of the country through an increase in manufacturing production (both for import substitution and exports), aiming at capturing more of what was not yet called "added value" (see Lenoble 1908 p. 1). Inspectors are supposed to help achieving this goal first by improving the consumers' confidence and trust in the products being sold to them – meaning both domestic consumers and foreign consumers, with French products supposed to gain market share, and maybe also with the idea that trust will help "grow the market" by increasing overall demand (Minart 1997 p. 489-490). In addition, inspectors also provide (or are expected to provide) advice to manufacturers (or would-be manufacturers) and to local officials such as the *intendants* on where to set up their facilities, how to source raw materials, which products are more in demand, which markets they could target, which technologies they could use etc. (Lenoble 1908 p. 6) They also collected statistics for the government.

The corps of manufactures inspectors reportedly "survived" an early "temptation" by Louis XIV who, cash-strapped after the Spanish Succession War, decided in 1704 to sell offices of inspectors and controllers of manufactures, and let them levy a duty on cloth. Petitions by manufacturers and traders led to this decision being repealed, and the corps increasingly became what Minart (*ibid.,* p. 488) calls a "laboratory" for a new type of "*Ancien Régime* Civil Servant" – with "all the elements" (or at least many) typical of the "modern civil servant": hierarchy, entrance examination[25], status, career profiles, discipline, obligation to reside in duty station, pension. The inspectors were under a clear vertical hierarchy reporting to the minister (*Contrôleur Général des Finances*) though they also coordinated to a large extent with the local *intendant* (whose role was close to the modern French *préfet*).

We do not have sufficient information (and even less data) to attempt an assessment of the inspectors' effectiveness, even more so considering that their purpose (increasing production) was one where their role would evidently be (at best) very minor compared to other factors (geography, trade, geopolitics, technology, overall institutional and political framework etc.). Nonetheless, Minart (*ibid.,* p. 489) suggests that manufacturers and traders in fact, to a large extent, supported the system because of the trade facilitation effect it created (through increased trust). The excessive complexity brought by ever-increasing detailed prescriptions, the heaviness of the limitations on innovation or lower-cost production (and the undercutting of compliant producers through cheaper, "informal" production) led to series of reforms, in particular under the ministries of Turgot (1770 – see Lenoble 1908 p. 2) and Necker (1779 – see Minart 1997 p. 490). In particular, the latter issued instructions to inspectors to "clarify and narrow down the scope of regulation", accommodate more "freedom of creation, flexibility in implementation of norms" and "quality-price oriented consumption" (*ibid.*).

In spite of this, the regulation and inspection of manufactures was increasingly seen by the French liberals as a "*carcan gothique*[26]" (*ibid.* p. 489) – and it was abolished, as mentioned, during the Revolution. What is fascinating for the student and practitioner of modern inspections, is the number of aspects where this system reminds us of contemporary product market regulations and their enforcement – and their challenges.

First, the tension between the need to enable market development through trust, and the barriers to innovation and growth imposed by excessively detailed and strict regulation. Defining precisely what certain product names should mean, and imposing specifications and certification, are still methods that are in use

[25] Though Lenoble 1908 reports famous cases of nepotism in appointments – which is not necessarily contradictory with a practice of examinations for most cases and/or at a later stage (p. 5)

[26] A "gothic straightjacket" – a qualification at least as harsh as those used by modern-day "regulatory reformers"

today – however, in the EU for instance, these are generally voluntary (i.e. to be complied with only if one wishes to sell a product using this specified controlled denomination – alternative products, named differently, are allowed) and certification is not done by state inspectors (but by accredited and authorized conformity assessment bodies)[27]. However, many countries around the world (e.g. most former Soviet countries) have systems where most products are subject to mandatory certification, alternative product types and production methods are not allowed, and certification is done directly by state bodies which also conduct inspections.

Second, the arguments used to create the institution, propose its reform and its abolition, as well as the ways in which it was reformed (and then abolished), all remind us of modern situations as well. Developing an industry and protecting consumers are oft stated goals in developed and developing countries alike when it comes to introducing regulations and creating inspection institutions. Removing barriers to innovation, reducing prices and allowing diversification are frequent reasons why reform is advocated. Introducing more flexibility compared to a more rigid initial practice is a common reform approach – just as the "radical" approach to free up markets fully from restrictions that are not necessary for safety but only aim at ensuring "quality" is another option that is just as present in contemporary reform situations.

Finally, the ways in which the inspectorate developed – an initial decision to regulate, the recognition that inspectors were needed, gradual build-up of staff without a very clear initial plan, and progressive formalization, are close to what often is seen to happen in modern times. The decision to regulate is taken quickly based on goals that seem undisputable but with a "theory of change" that is not fully thought through and excessively optimistic. The need for implementation and enforcement resources emerges quickly, but there is no initial vision of how to structure it, and it progresses in a partly "unplanned" way. Path dependence is a strong factor.

In conclusion of this small case of "pre-modern" inspection, we can say that the historical study of regulation and regulatory enforcement appears to hold much promise in order to better put our own contemporary problems in perspective, and comparisons of countries with different regulatory approaches and reform decisions could be even more enlightening. What is clear, in any case, is that our modern issues are far from being uniquely novel. There are relatively few studies of institutions that (under whichever names) could be considered as forebears of "inspectorates", but it is noteworthy that the intent to create institutions to both foster and control specific industries is not new, and neither are the tensions between these different missions, and the many questions of institutional structure, resources and methods. Further research on historical roots of inspections and enforcement regimes may yield valuable insights on today's differences between countries, as well as on the strengths and weaknesses of different institutional models.

2.2. The emergence and development of modern inspectorates

What this brief overview shows is first that control activities existed (and were seen as necessary) already in the Middle Ages in most of Western Europe (and possibly beyond), and were created at that time primarily in response to "fears" (often but not always corresponding to real hazards) related to food "quality" or "safety". Protecting a trade from competition was also an important function of guilds, but for the public, safeguarding "quality" was seen as their role. Further development of inspections in the 17th and 18th centuries were linked to "quality" again, this time of manufactured goods, with a view to strengthening trade opportunities for domestic producers.

[27] Note that, interestingly, the quickly-reversed 1704 reform that aimed at selling the offices and letting them recoup their costs through a duty on textiles would have had some features of the "private" modern system of conformity assessment.

The second notable point is that several models existed, one based on self-regulation, another on control by public authorities (municipal), and (later on) a third on inspectors appointed by the central government. The adoption of one or another model (at least between the first two) appears to have been the result not of an "effectiveness evaluation", but of institutional structures, social, legal and political dynamics. The development of more systematic control, led often (but not always) by central authorities (or at least by municipal ones), was very gradual (at least for food) – and spurred by the combination of the general growth of modern states, major food-related crises (e.g. epizootics), advances in scientific knowledge, and changes in mentalities. In contrast to this gradual process, the manufactures inspection provides the example of how a centralized institution could be created due to a deliberate government decision.

This suggests is that there is nothing self-evident in what is or is not inspected, and with which structures. Medieval cities introduced supervision of food trade, but it did not exist everywhere in the same form, and many other issues were left without a specific "inspection", even when in fact they were submitted to many rules (such as the different forms of pollution, including noise, that could arise in cities – rules were often adopted at various stages in the medieval and pre-modern times, but there was no "environmental inspection" nonetheless). It is also far from clear that these inspections were actually effective, or useful, in most cases. Ogus (1994) summarizes regulation in the "Tudor and Stuart Periods" as "often over-inclusive, incurring the hostility of those unintentionally caught by the provisions, or under-inclusive, leading to avoidance behaviour by those intended to be caught" (p. 6) and adds that "enforcement was a matter for local administration and often ineffective".

Most of the control exerted by the state (or by non-state actors with regulatory functions, such as guilds) in pre-modern times applied to the trade angle: ensuring that buyers were not defrauded, and that the quality of goods sold abroad was high enough to sustain high levels of exports against the competition. Just as weights and measures were a core prerogative of the sovereign, avoiding deceit on markets was seen as an issue worthy of rules, and enforcement. Other issues, which to us would appear as high priorities, were on the contrary mostly left without specific enforcement (if not necessarily without rules), such as safety in the workplace[28], fire and buildings safety, "environment" (even understood in a pre-modern context), etc.

Thus, while manufactures were inspected in France (and some other countries) from the 17th century at least (and most crafts in Western Europe subject to enforcement by guilds), workers safety only became an area of state control in the 19th century. Regulations and enforcement centering on health and safety appeared in connection to large-scale industry and in particular mining, and what contemporaries started to perceive as the horrifying conditions workers (and in particular children and juveniles) had to endure. Ogus suggests that the interesting and specific aspect of the new regulations appearing in the 19th century, compared to the previous period, was "the large number of measures dealing with public health and the conditions of employment" (Ogus 1994 p. 8).

As Ogus rightly points out (and as we have illustrated above), "state intervention did not result from any abrupt shift (…) but rather emerged gradually" (*ibid.,* p. 7) – and indeed regulation had been around for far longer. The new situation was "the emergence of administrative structures capable of diagnosing the problems and formulating solutions to deal with them" – as "the existence of specialist bodies served to inject an almost unstoppable momentum into the growth of regulatory law." As administrators found shortcomings while implementing existing rules, "to correct the defects, they would demand amendments to the provisions or an extension to their own rule-making powers" (*ibid.,* pp. 7-8). As we have seen above, France's Inspection of Manufactures was in many ways a prefiguration of this trend, and thus "specialist bodies" were maybe not as

[28] Lenoble (1908) specifically indicates that the manufactures inspectors did not look at safety and related issues at all – though they monitored social situations, occasionally organizing assistance for manufacture workers in times of crisis, more often warning about the dangers of strikes (p. 9).

novel as Ogus states – but the ways in which the Inspection indeed constantly prodded the further development of regulations surely validates Ogus's claim that this institutionalization was a key cause for the growth of regulatory law.

In Britain, at least, the emergence of new regulatory areas and institutions often started with "*ad hoc* commissions to investigate social conditions", which often led to the creation of "boards" and "inspectorates" to implement new legislation, but with often an unclear relationship to Parliament and state structures (*ibid.*). Eventually, criticisms led to the "decline of the independent regulatory agencies" – with, for some, powers "transferred to central or local government", for others, "more formalized arrangements regarding (…) the legislative definition of their powers and their accountability" (*ibid.*). Such trends, to an extent, can be seen in other countries, but with different degrees of speed and resilience of "independent" structures (e.g. these seem to have often survived far longer in the Netherlands[29]).

When "inspectors" were appointed or "inspections" set up, it was also often to look at the state administration itself, rather than at the private sector. This was particularly important in France, and in countries that imitated (to varying extents) the French model (or "inherited" it later through colonization). Gogol's "inspector general" was one of these. Looking at these "internal" state inspections would be the subject of a whole other research, but it is striking that Gogol's work shows issues that are still salient today: the fear of the inspector (not universal certainly, but frequent), the misconceptions about him – and the risk of corruption.

Looking at the gradual emergence of modern inspectorates in a number of countries would be a task far beyond the scope of this research, and would add little to our purpose of understanding the *problems* that inspections face, and to which extent risk-based approaches can remedy them. What is, however, helpful is trying to get a glimpse of the mechanisms that have led to the current structures and resource allocations – and, to this aim, some history "snapshots" are useful. To this aim, we will look at examples taken from the two inspection functions that were formalized in a "modern" way earliest: occupational safety and health (OSH) (in some depth), and food safety (briefly). We will describe at some length the example of OSH in the UK, a country that is often considered now among the most representative of the practice of risk-based, "smarter" inspections, with some shorter summaries of the experience of other major economies (France, the Netherlands, Germany and the United States). The consideration of food safety will be considerably shorter, for the amount of available research on the history and development of regulatory institutions in this sphere is much smaller (a point we will discuss at the beginning of that section). The idea is to look for an *illustration* (and not, at this point, for models or regularities) of how institutional structures and resources came about, and in what relation to risk, and for this purpose one case and a few "snapshots" should be sufficient – and not take up an excessive part of this research.

The cases were selected based on a combination of criteria. First, because the development of modern public administration structures largely proceeded first in a small number of major powers, which were the earliest industrial economies and wielded the most influence in the late 19th and early 20th centuries, we sought to select these in priority. This meant a long-list of Britain, France, Germany and the United States (with Britain and France having had major influence through their colonies, France and Germany having significant influence in Continental Europe and Japan, and the United States in many Latin American countries, and the Philippines). Second, we focused in particular on "prime movers", i.e. the countries that were the first to establish inspectorates in the fields selected for study (e.g. again Britain, France and Germany for OSH). To this list, for the particular case of food safety, we decided to add the Former Soviet Union, as its institutional and policy model was both relatively "advanced" for the time of its creation (1930s), taking place as it did in a

[29] Food safety supervision for dairy and eggs is still conducted in the Netherlands by private, independent bodies, which are commissioned by the central government (and can be revoked, changed etc.) – see Blanc (2012) p. 85 and websites: www.ncae.nl and www.cokz.nl

crisis context and in a situation of *tabula rasa* of earlier institutions – and as it still influences contemporary structures not only in successor states of the USSR, but in all countries that were under its influence. Third, where there are significant differences in timelines and approaches concerning the establishment of inspections and enforcement legislation and institutions, we have sought to present cases that illustrate the different paths taken (e.g. United States and European Union in food safety, or Netherlands in OSH as a "late mover" example, or Britain, France, Germany and United States as four very different models in OSH). Fourth, it was particularly important to discuss the impact of the European Union in food safety, where it has had a major impact not only on Member States but as an international model that is being imitated far and wide (even, to some extent, by the United States). Finally, there was an element of opportunity in some of the choices, as the development of inspectorates and inspections has been the object of far more studies in some countries than others, e.g. Britain and the United States. As a result, the list of countries includes Britain, France, the Netherlands, Germany and the United States for OSH. For food safety, it comprises Britain, the United States, France, the Former Soviet Union and the Netherlands.

These examples will enable us to understand better the contexts in which inspectorates have been created and have developed, the different paths taken in terms of institutional models and approaches to fulfilling their missions, the role of path dependency in explaining differences that still hold true today, and to start exploring the degree to which these historical differences may explain contrasts in practices and results today.

Finally, the reason we decided to focus specifically on OSH and food safety, and to treat them separately, is that it would be impossible in practice to try and cover the emergence and development of *all* inspection functions, and that these were both historically the first "new inspection functions" (as distinct from earlier ones such as tax or weight and measures) to emerge, and functions that were seen as so centrally important that such inspectorates ended up being created practically everywhere. They also typically represent institutions of a significant size today, with important resources and staff. Other functions (e.g. environmental protection) emerged much later (late 20th century), or are not present everywhere "as such" (e.g. fire protection), and/or have much smaller staff (e.g. environmental protection in many countries) etc. For all these reasons, we concluded that OSH and food safety could meaningfully serve as examples and as the richest and most insightful cases we could consider from a historical perspective. Studying them separately allowed to compare specific historical trajectories between different countries for a given function, which was our key purpose here. It is worth noting that these cases (countries and regulatory functions) do not fully match those selected in chapter 4 to investigate the implementation of risk-based approaches in practice. To the extent possible, we did cover some of the cases in both chapters (e.g. Britain, Germany, France and the United States in OSH, Britain and the Former Soviet Union in food safety), but we did not do so *systematically*. First, because the purpose was different – in chapter 4, we selected cases specifically to look at the results of risk-based vs. non-risk-based approaches. Second, because our selection in chapter 4 was to a large extent driven by the availability of strong "examples" (i.e. practices clearly representative of risk- or non-risk-based approaches) and – most crucially – the availability of data. Since data on inspections burden and outcomes is (as we will discuss further in chapter 4) frequently unavailable, the selection of this second set of case studies was consequently far more constrained, and could not in any case fully match those that we will now consider from a historical perspective.

a. The emergence and development of modern inspectorates - Occupational Safety and Health[30]

iii. Why did Occupational Safety and Health come first?

Perhaps surprisingly, considering that the "safety" and "quality" of food (or whatever was then understood behind these terms) had been probably the issue on which most of the early regulatory efforts were made (looking at the Middle Ages onwards), the first modern inspectorates created did not aim at improving it. Nor did they cover any of the other long-standing market issues (like weights and measures) that had been a key domain of state intervention. Rather, they targeted a problem that was "brand new" – maybe not in its substance, but in the way it was perceived: the way workers were treated in the newly developing factories and mines, and in particular the fate of women and children.

Let us pause for one instant and challenge what may seem obvious to modern readers who know well the picture of terrible abuse and horrific conditions painted by Dickens, Zola and others. While the way workers in general, women and children in particular, were treated in textile factories, coal mines and other industrial establishments was indeed horrific – it is not self-evident that this was the "greatest risk" of the time, nor is it absolutely clear that this abuse was a shocking novelty.

Looking only at the magnitude of risks, and at the impact that prevention could have had, hygiene, water and sanitation would probably come first (at least in retrospect). The time of the creation of the first labour inspectorates was also the time of the great cholera pandemic. In France, in 1832, 20,000 persons are thought to have died in Paris – and researchers estimated that mortality in affected regions doubled – and in the 1854 epidemic, mortality even quadrupled in a large swathe of Eastern France (Raulot *et al.* 1978, p. 140). In London, as late as 1866, a major cholera outbreak killed "nearly four thousand people there between the end of July and the beginning of November" (Luckin 1977 p. 32). Though the reason the epidemics did as much damage as they did was the new development of exchanges and trade, and increased mobility of people across and within countries (Raulot *et al.* 1978, p. 140-141), the direct causes of these outbreaks were (theoretically) preventable, and caused by poor hygiene.

For London in 1866 "it was the action (or, more accurately, the negligent inaction) of the East London Water Company which decisively determined the dissemination and scale of the outbreak" (Luckin 1977 p. 32). However, even in 1866, "it was only a minority within what may be loosely characterized as the *avant-garde* in the nascent profession of epidemiology which gave unqualified support to the view that the outbreak (…) was decisively carried by water" (*ibid.* p. 33). Indeed, even though the bacterium causing cholera had in fact been discovered in 1854 by Filippo Pacini[31], this discovery had been ignored, and most "experts" still clung to the old "miasma theory" of epidemics causation (which explained why the discovery was ignored). Pasteur's and Koch's[32] works were still to come. Thus, to an extent, people (including policymakers) at the time simply had too little understanding of the disease to act effectively. However, some understood the fact that clean water was important to epidemics control, even without a correct explanation for how the diseases were caused. In fact, "the [water] company had clearly contravened a clause of the Metropolitan Water Act of 1852 which outlawed uncovered reservoirs within five miles of St. Paul's" (*ibid.* p. 34). The impossibility to demonstrate the link between contaminated water (since one did not then know what contamination to look

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[30] The reader may be surprised that in the historical account below we very rarely mention the EU (only for the German case), and do not cover the International Labour Organization (ILO). The reason is that these have had at most quite a late and relatively marginal impact on the countries we are discussing, which were among the first to have an OSH inspection system, and thus took part in defining the standards to be followed rather than being "standard takers". This does not mean there was, of course, no impact at all – but that for our issue, which was understanding the different paths taken by OSH systems in these countries, the ILO convention (n. 81) on labour inspections (1947) and the EU Directive 89/391 (1989) both came quite late and, at least for the ILO, added little to the framework already existing. Where the EU additions had significant effects (i.e. at least in Germany), we shall discuss them.

[31] See http://en.wikipedia.org/wiki/Filippo_Pacini and http://www.ph.ucla.edu/epi/snow/firstdiscoveredcholera.html

[32] Whose "re-discovery" of *Vibrio Cholerae* in 1884 was, this time, fully acknowledged

for, and how) and the epidemic, however, made action impossible. “Both during and in the immediate aftermath of the virulent epidemic, the company retaliated against the accusations of the "progressives" by citing authoritative miasmatic and "sociological" theories of disease (…)The company was also able to rely on the open or tacit support of a majority of the metropolitan medical officers of health.” (*ibid.* p.35) Even though there already existed “inspectors” and “Rivers Pollution Commissioners” (*ibid.* p.38), their inability to understand cause and effect in the epidemic doomed them to ineffectiveness.

Still, in 1866, the level of understanding of epidemics mechanisms (if not of their causes) had improved enough to lead gradually to change: “it was Netten Radcliffe's persuasively commonsensical, although almost excessively non-doctrinaire advocacy of the detailed analysis of each epidemic (…) which eventually superseded its rivals. According to this approach, it was imperative to act as though unsafe water was likely to have been the primary medium during any wide-ranging outbreak of cholera or typhoid, and in the thirty years following the epidemic of 1866 it provided the ground rules for an increasingly efficient surveillance of the metropolitan water supply.” (*ibid.,* p. 42). For most of the 19th century, however, this level of knowledge and understanding had simply been missing. Addressing a major risk requires to at least understand its most basic parameters, at least some of its nature and causes. Public health, until the end of the century, was thus not a field where it was possible to create credible, effective inspecting institutions.

Returning to the origins of the first labour inspectorates, it is clear that, by contrast, poor treatment of human beings by other human beings, and malpractice in industrial installations, were problems that were both understandable, and could be addressed in practice. What remains striking is why this started to become a problem that society decided to address at this precise moment. After all, children and women had been working for centuries on farms and, in times of hardship, their lives had been in serious jeopardy. In England, in fact, the “enclosures[33]” and the rapid development of sheep breeding for wool, and of the wool industry (strongly supported by the state from the Tudors onwards) had led to a growing number of urban poor from the 16th century, and to many of them working in very unsafe conditions in “proto-factories” (including women and children). The reaction to this had not been labour inspections targeting the employers, but the “poor laws[34]” that, while organizing some scarce assistance, mostly aimed at controlling the poor – the “Overseers of the Poor” were in a way “labour inspectors in reverse”. A number of parameters, however, had changed by the first half of the 19th century.

First, one could argue, the democratisation of politics and the overall effects of the Enlightenment, suggesting slowly that poor people were also people, whose lives deserved at least a modicum of concern – and, possibly, the French Revolution had shown the risks of letting the social situation deteriorate too far. As Eves (2014) puts it: “memories of the disturbingly radical ideas of the French Revolution of 1789 were fresh in the uneasy minds of British political leaders. Amid widespread unrest, demands were being made for Parliamentary reform and fairer representation of the people.”

Second, “shocking evidence was emerging of serious physical and moral harm suffered by children and young persons in the cotton textile mills (…) as the result of an entire system for exploitation of cheap labour (the ‘Factory System’). Skilled workers employed by a ‘cotton master’ would themselves pay unskilled women and children to help them”. Beyond this, new technologies created new hazards and new harms. We could be seeing here an early illustration of what Slovic *et al.* describe as “the selective nature of attention to different sources of risk or danger” (Slovic and Weber 2002, p. 18). To the extent that modern industry and mining were, precisely, “modern”, i.e. new and radically different from the traditional activities and trade of an hitherto mostly rural society, they could have carried what Slovic calls a “dread” factor[35] - “an accident that takes many

[33] See http://en.wikipedia.org/wiki/Enclosure

[34] See http://en.wikipedia.org/wiki/English_Poor_Laws

[35] And indeed the very negative ways in which modern industry is generally described in Romantic-era literature may point to this – beyond the actual harms, industry was seen as something as “dreadful” as nuclear power or GMOs are today for many

lives may produce relatively little social disturbance (beyond that caused to the victims' families and friends) if it occurs as part of a familiar and well-understood system (…). However, a small incident in an unfamiliar system (…) may have immense social consequences if it is perceived as a harbinger of future and possibly catastrophic mishaps" (*ibid.*, p. 13).

A last point may help explain why regulating manufacturing industry and mining became a priority at that point in time. Regulation of industry by state inspectorates (e.g. HM Factories Inspectorate in the UK) intervened in a context where modern industry had developed in parallel (possibly partly thanks to) the weakening or dissolution of craftsmen's guilds hold. Modern workers were mere wage-labourers, with a very weak bargaining power, and hence without regulation extremely harsh and hazardous working conditions arose. On the contrary, in a guilds-controlled economy, freedom of establishment (and innovation, and growth) were seriously limited, but workers had a considerably higher power and state supervision was not seen as needed. There may thus be a sort of trade-off whereby less stringent conditions on establishment (partial or complete freedom) tend to lead to more supervision role for the state, and more stringent self-regulation ("sworn trades") and limits to establishment may correspond to a (real or perceived) lesser need for state supervision. Our practical experience suggests that this is a (real or imaginary) trade-off that is visible today in a number of countries, where an abundance of restrictions to entry (licensing and others) coexist with overall weak inspection and enforcement practices.

The creation of the institutions in charge of labour protection (what later became known as "occupational safety and health" in the narrow sense, as well as regulations on working hours, women and children at work etc.) was gradual. In Britain, Her Majesty's Factory Inspectorate was created in 1833, the Mining Inspectorate in 1843, the Quarry Inspectorate in 1895 – but one had to wait until 1956 for OSH provisions covering agricultural workers[36], even though all studies repeatedly show that this is a high hazard occupation[37]. For a long time, the focus was exclusively on activities that were *perceived* as high risk by the public and policymakers – as indicated above, and as suggested by Slovic *et al.*, it is likely that agriculture was deemed too "normal" to let its high level of hazard be really acknowledged. Similarly, most services (including retail warehouses and retail trade, however large etc.) were considered low risk and remained for a long time outside of the OSH net. From 1974, they have been covered by legislation, but as we will see enforcement has remained separate (under Local Authorities) as an inheritance of earlier situation and vision.

iv. OSH in Britain – from the Factory Inspectorate to the HSE

The gradual extension of the scope of control in Britain

The circumstances that led to the creation of the first inspectorate (Factory Inspectorate) were ones of broad social tensions and reform – including political (extension of suffrage and change of constituencies' boundaries): "By 1831 the Prime Minister, Earl Grey, judged the pressure for Parliamentary reform to have become irresistible and he persuaded King William IV that a Bill to widen the franchise should be introduced into Parliament. Although the Bill was passed by the Commons, it was defeated in the Lords, whereupon serious rioting broke out in several towns. (…) Another Bill was introduced by Grey in 1832. This time Parliament narrowly passed the Representation of the People Act (or 'Great Reform Act').The general election that followed and the arrival of new Members of Parliament soon led to further reforms, some the result of pressure from philanthropists such as Lord Shaftesbury, whose campaign against slavery led to its abolition in the United Kingdom in 1833. Grey also set about reforming the Poor Laws." (Eves 2014) By that same time, the need for reform of industrial conditions was also perceived as urgent, as "the 1831 census indicated that

[36] For a timeline of OSH institutions and legislation in the UK see: http://www.hse.gov.uk/aboutus/timeline/index.htm
[37] See e.g. US BLS news release for September 11, 2014 available at: http://www.bls.gov/news.release/pdf/cfoi.pdf – p. 4

among the country's population some three million people worked in manufacturing industry of various kinds, including almost a quarter of a million in cotton mills, most of which were in Lancashire. A significant percentage of these textile workers were women and children" (*ibid.*). Reform focused on conditions for children: "A Royal Commission (the 'Factory Commission') was set up (…). Its inquiries swiftly exposed the exhausting working conditions and long hours endured by children (…) [and] prompted Parliament to pass the landmark Factory Act of 1833, its full title being 'An Act to regulate the Labour of Children and Young Persons in the Mills and Factories of the United Kingdom'." In it, section 17 read: "…the Laws for the Regulation of Labour of Children in Factories have been evaded, partly in consequence of the want of the Appointment of proper Visitors or Officers whose special Duty it was to enforce their Execution" (*ibid.*).

Thus, a combination of factors was required for the inspectorate (however small at the time, with only four inspectors initially, for 3,000 textile mills) to be created: strong public concern about an issue considered as a "dread risk", favourable political conditions, and experience of implementation problems in previous reforms. A similar combination was often found in later reform steps, and successive creations of new inspectorates.

Whereas "the 1833 Act dealt principally with restrictions on the employment of children and young persons less than 18 years of age" in factories (*ibid.*), "in 1840 a Royal Commission was established to investigate working conditions in the mining industry. The Commission's findings published in 1842 made shocking reading. Accidents, brutality, lung diseases, long hours and highly dangerous and adverse working conditions were found to be the norm. Public outcry resulted and the Mines Act 1842 was brought into force. The Act allowed for the appointment of an inspector of mines and collieries and the first inspector (…) had only limited powers under the Act but undertook many prosecutions, investigated the condition of the mining community and made recommendations (…). In 1850 inspectors were allowed to enter and inspect mine premises and Tremenheere's plans for a dedicated mining inspectorate began to be realised[38]." The concern about health and safety also led to the adoption of new legislation for factories: the "landmark Factory Act of 1844 extended the law's coverage to all textile factories (except lace-making) and took a first significant step towards improvement of workers' safety. Under Section 20, children, young persons and women were prohibited from cleaning shafting and other transmission machinery while this was 'in motion for the purpose of propelling the manufacturing machinery' and from working between fixed and moving parts of machines" (Eves 2014).

Successive "Factory Acts were passed in 1861, 1864 and 1867 (…) Step by step, the scope of the law was widening. (…) The 1867 Act further extended the law's cover to some other specified trades and to 'any premises in which fifty or more persons were employed in any manufacturing process'. (…) A Royal Commission was appointed in 1875 to review the law's numerous amendments since the Act of 1802. Their report in 1876 led to major consolidation of the laws and removal of anomalies by the Factory and Workshop Act, 1878. (…)bringing almost all of manufacturing industry within scope of the law, in three clearly defined classes of Textile Factories, Non-Textile Factories and Workshops (…). Non-Textile Factories included certain specified premises such as shipyards for the first time. Greater protection was afforded to women and children: from now on children under the age of ten could not be employed anywhere and between the ages of ten and fourteen they could be employed only for half days (and must attend school). Women were allowed to work only up to 56 hours per week. The law with respect to secure fencing of dangerous parts of machinery and reporting of accidents remained much the same but children were no longer allowed to clean machinery while it was in motion and women and young persons were not allowed to clean mill gearing in motion" (*ibid.*). The 1891 Factory Act then gave power to the Secretary of State to adopt "Special Rules", which greatly accelerated the development of technical secondary legislation. Another Act in 1895 strengthened several provisions, in particular relating to health. In addition, "the Quarries Act 1894 extended the powers of the Metalliferous Mines Regulation Act 1872 to give inspectors the power to enforce provisions of notifying

[38] Quoted from: http://www.hse.gov.uk/aboutus/timeline/index.htm

accidents, undertake prosecutions and make Special Rules. This led to the establishment of the Quarry Inspectorate[39]."

During the 20th century, successive consolidations of legislation, improvements, additions (e.g. covering electricity) etc. were made. Occupational health gradually took more importance as well. Major additions came with "the Factories Act 1937, which had the effect of providing for the first time a comprehensive code for safety, health and welfare applicable to every factory, irrespective of whether it was a textile or non-textile factory and whether or not mechanical power was used (…) [and] included safety provisions for lifting machinery, floors and stairs" – and in the "Factories Act of 1948 (…) at long last, regulations were introduced for safety, health and welfare at building operations" (Eves 2014). For a couple decades, most of the focus in improving health and safety then centered on the development of the National Health Service. Still, "yet another Factories Act was passed in 1959. This improved provisions for precautions against fires, prompted in no small part by a disastrous fire in 1956 at a Keighley mill" (*ibid.*). In addition, the Offices, Shops and Railway Premises Act 1963 extended OSH protections to "a further 8 million employees[40]" – in the transportation, trade and services sectors – with enforcement left to local authorities[41].

The transformative step that was the creation of the Health and Safety Executive (HSE) in 1974 came about on a background of increasing risk overall (at least of fatal accidents), and of the emergence of new risks due to new industries and technologies: "Chief Inspectors' annual reports throughout the 1960s had frequently drawn attention to concerns over rising fatal and major injury rates" and accidents were "by no means confined to industries regulated by the Factory Inspectorate", which repeatedly "exposed a serious regulatory gap". As a result, "it was becoming increasingly obvious that the narrow, prescriptive approach of Factory Law and the limited powers of Factory Inspectors were no longer sufficient for the effective regulation of modern industry". As an additional stimulus, in 1970 "the USA passed its Occupational Safety and Health Act and created a new federal agency (OSHA) to enforce it" (Eves 2014). In 1970, the new Government "decided to invite Lord Robens, the Chairman of the National Coal Board who had experienced the tragic Aberfan tip disaster, to carry out a fundamental review. A Committee on Safety and Health at Work was formed and took evidence over the next two years, reporting in July 1972.

Their findings became known as 'the Robens Report' (…) [and] recommended that a National Authority for Safety and Health at Work should be established to replace Whitehall's existing fragmented administrative arrangements and bring together the several Inspectorates scattered between Departments." Robens "believed that a broader and more flexible framework would enable statutory inspection services to be used more constructively in advising and assisting employers and workers. At the same time, it would enable their resources to be concentrated more effectively on serious problems where tighter monitoring and control might be needed." (*ibid.*) While the 1974 Act established a Health and Safety Commission (vested with analytical functions and regulatory powers) and a Health and Safety Executive (in charge of implementation, inspections, enforcement), later reforms finally ended up with the merger of the HSC functions into the HSE (in 2008), fulfilling the original vision of the Robens Report.

The consolidation initiated in 1974 and continued in 2008 is, however, still incomplete – with a duality in enforcement between the HSE and local authorities. Löfstedt's *Reclaiming health and safety for all* report (Löfstedt 2011) lays out the problems this creates: "by allowing each enforcing authority to only consider the workplaces within their area of control" this duality generates a barrier to the most efficient targeting of enforcement activity across the board. Premises that are considered relatively low risk amongst the workplaces overseen by HSE (and which are therefore not inspected) may nevertheless be riskier than many of those under local authority control, resulting in too many inspections by local authorities of relatively low-

[39] Quoted from: http://www.hse.gov.uk/aboutus/timeline/index.htm
[40] See: http://en.wikipedia.org/wiki/Offices,_Shops_and_Railway_Premises_Act_1963
[41] See full text of the Act at: http://www.legislation.gov.uk/ukpga/1963/41/pdfs/ukpga_19630041_en.pdf

risk workplaces" (p. 5). While he does not recommend fully eliminating local enforcement of H&S rules, not to risk "losing the synergies with other local authority enforcement responsibilities" (*ibid.*), he advocates to "give HSE the authority to direct all local authority health and safety inspection and enforcement activity, in order to ensure that it is consistent and targeted towards the most risky workplaces" (*ibid.,* p. 83). Following up on this recommendations, the following changes have been introduced in the past couple of years: "HSE published a National Local Authority Enforcement Code (May 2013) that sets out the risk based approach to targeting occupational safety and health interventions that Local Authority (LA) regulators should follow. HSE has also published (…) a list of higher risk activities in specific LA-enforced sectors suitable for proactive inspection (…) [and] supplementary guidance to assist LAs (…). HSE has consulted on the implementation of the Code (ended October 2014) and has reviewed the 2013/14 LA annual returns. The conclusion was that LAs have been implementing the Code and are now more risk based in their targeting[42]." To the extent that further developments verify these claims, the "consolidation" process will have been largely completed, as well as the spread of risk-based targeting approaches for all OSH inspections. We will come back to these questions in more detail, but it is worth looking first very briefly at some markers in the development of resources, methods and powers in OSH inspections in Britain.

Evolution of resources over 180 years

While the Factory Act's enforcement was initially left to only four inspectors, "were authorised to appoint Superintendents (called Sub-Inspectors after 1844) to assist them in their duties" (Eves 2014). Numbers rose gradually, and in 1871 "the Inspectorate numbered 35 Inspectors and sub-inspectors" (*ibid.*). Nearly a century later, there were over ten times more: "By the end of 1961 the Inspectorate had 426 inspectors in post, including specialists at headquarters, with the majority working in 13 divisions spread over England, Scotland and Wales. Divisions were headed by a Superintending Inspector and generally contained six or seven small teams, each led by a District Inspector, working from 100 or more local district offices." (*ibid*.) Of course, these over 400 inspectors now had a broader remit, and a considerably larger population and economy to supervise.

The 1974 merger resulted in a much larger organization: "As well as the staff of HM Factory Inspectorate, the staff of a number of other regulatory organisations were transferred to HSE in 1975, including the Explosives Inspectorate (from the Home Office), the Employment Medical Advisory Service (with its doctors and occupational nurses returning from the Department of Employment), the Nuclear Installations Inspectorate and the Mines and Quarries Inspectorate (from the Department of Energy), the Safety in Mines Research Establishment, the British Approvals Service for Electrical Equipment in Flammable Atmospheres (BASEEFA) and the Alkali and Clean Air Inspectorate (from the Department of the Environment.)" (*ibid.*)

In 2002, the HSE and Health and Safety Laboratory had 4282 staff[43], out of which 2794 in operations (inspections and enforcement, including management and "operational policy" etc.). In 2006, the same figures were 3811 and 2497. In 2009, only 3591 and 2253 respectively. In 2014, the HSE had 3081 staff in total and (having moved to another classification method) numbered 1294 staff in "frontline roles"[44]. After the "spin-off" of the Office for Nuclear Regulation[45], these went down to 2621 and 1059 respectively – and as of 31 March 2015, 2575 and 1047 respectively (a relative stability). In 12 years, thus, HSE staff was reduced by around a quarter (comparing with the data pre-ONR spin-off, so as to have comparable scope of work).

The point here is not to try and discuss whether these numbers are "sufficient" or not, which would require to define "sufficient for what?", to have reference points, comparators etc. We will discuss later in this

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[42] See Health and Safety Executive, *A progress report on implementation of health and safety reforms – March 2015* (draft presented to HSE Board), pp. 9-10, available at: http://www.hse.gov.uk/aboutus/meetings/hseboard/2015/250315/pmarb1525b.pdf
[43] This and subsequent figures from HSE statistics and annual reports – see: http://www.hse.gov.uk/aboutus/reports/staff06.htm
[44] HSE Annual Report 2013-2014 available at: http://www.hse.gov.uk/aboutus/reports/1314/ar1314.pdf
[45] On this, see: http://en.wikipedia.org/wiki/Office_for_Nuclear_Regulation and http://www.onr.org.uk/

research the question of how well the HSE performs in terms of effectiveness. The notable fact at this stage is that staffing levels have clearly never (or at best rarely) been set based on any serious analysis of the scope of work and necessary work time, but rather based on whatever seemed "appropriate" at a given time, and increased or decreased depending on the prominence of OSH issues among public concerns, on the availability of funding, on other budget priorities (increasing spending elsewhere, or reducing the deficit) etc.

Methods and powers

Powers, methods, and approaches to planning and targeting all evolved constantly over the nearly 200 years of OSH inspections and enforcement in Britain. While, initially, inspectors were only able to bring prosecutions against violators of the applicable regulations, the 1844 Factory Act gave them power "to give written notice to a factory occupier that dangerous parts of machinery should be immediately fenced, an important addition to their ability to improve machinery safety (and a fore-runner of the powers to serve improvement and prohibition notices that were given to Inspectors 130 years later)" (Eves 2014). Formalization of how notices worked, and in which circumstances penalties could be applied, was also gradual.

There may have been some forms of targeting in the early days (as staffing levels were so low), based on whatever information was available, and probably also on material constraints. By the 1960s, "the inspection programme laid down by the Chief Inspector required every factory to be inspected on a four yearly cycle, regardless of whether risks were high or low. Larger factories were usually divided into units that could be inspected in half a day" (*ibid.*) This may have appeared appropriate in an era of concentrated, large facilities, with well-known production techniques – and when the inspectorate's mandate was still relatively narrow. This approach was to prove its relative lack of effectiveness – "the 1974 Flixborough disaster (…) prompted the swift establishment of a Major Hazards Branch, a Risk Assessment Group and a Major Industrial Hazards Advisory Committee. Meanwhile the Chief Inspector had introduced a system of priority inspections of major hazard premises, over-riding the conventional four-yearly cyclical pattern of planned inspections and encouraging Inspectors to spend as much time as was necessary to improve controls at these sites" (*ibid.*). As we will discuss more in depth in a later section, risk-based targeting has now become one of the "hallmarks" of the HSE, but this does not mean there are not important challenges remaining on this front.

Another evolution was the degree of liability and responsibility for health and safety resting on operators themselves. The question of what could or could not be prosecuted and give rise to sanctions was rather unclear in the early days of the Factory Inspectorate, as was the question of compensation (since the Act anyway had little to say about safety issues). Case law and written law both gradually evolved to strengthen the liability of employers in case of work-related injuries: "The case of *Priestley v Fowler*[46] in 1837 had been the first known civil action in which an employee successfully sued his employer. It seemed to establish the principle that an employer owed a common law duty of care to his employee which was actionable if a breach of that duty resulted in injury. Under Section 24 of the 1844 Act the Secretary of State could empower a Factory Inspector to bring an action for damages on behalf of any person who had been injured by machinery. Reports indicate that many such actions were successfully taken by Inspectors. Later in the century, (…) the Employers' Liability Act 1880 gave a worker the right to sue the employer, but the worker had to prove that the injury suffered was the employer's fault. However, under the Workmen's Compensation Act of 1897 it became necessary for a worker only to prove that the injury had occurred at work" (Eves 2014). It is, in retrospect, fascinating to see that it took over 60 years after the first Factory Act for the law to put clear liability (in a tort law perspective) on the employer – considering that this is (at least potentially) one of the strongest incentives

[46] See Stein 2003 – "*Priestly v Fowler* is the first known recorded decision of an employee having sued an employer for work-related injuries" (p. 689) but is a very confusing case and precedent is highly disputed – Stein concludes that "Priestley v. Fowler is best understood within the framework of the emerging independent tort of negligence as a failed effort to extend master/servant liability" (p. 730)

to improving occupational safety (at least if there is a reasonable likelihood that courts will award guilty verdicts and significant damages)[47].

What one could call the logical consequences of employers' liability were only drawn nearly a century after the Employers' Liability Act, with the 1972 Robens Report and the 1974 Health and Safety Act. "Believing that the primary responsibilities lay with those who created risks and those who worked with them, Lord Robens' Committee concluded that a more self-regulating system of provision for safety and health at work was needed and that the traditional approach based on ever-increasing, detailed and prescriptive statutory regulation was outdated, over-complex and inadequate. Reform should be aimed at creating the conditions for more effective self-regulation[48] by employers and workpeople jointly. (…) Much greater use should be made of agreed voluntary[49] standards and codes of practice to promote progressively better conditions." The Act "imposed general duties to ensure health and safety 'so far as is reasonably practicable' not only on employers but also on the self-employed, designers, manufacturers and suppliers of equipment and materials. For the first time, the safety of the public was to be protected when put at risk by 'the conduct of an undertaking'" (*ibid.*). As we will discuss later, this approach to defining obligations and compliance led the HSE to develop a strong "enforcement management model" in order to clarify what this requirement meant in practice, and give a transparent (and risk-based) framework to its officers' discretion.

A Medium-term perspective on methods and structures

Some of the most significant research on the HSE's work, culture and approaches has been conducted by Keith Hawkins, and it has spanned both the 1980s and 1990s (see Hawkins 1992 and 2002 in particular). Hawkins's primary focus is to understand how the HSE (and, by extension, an inspecting institution) functions in practice, what structures, frames, heuristics etc. shape decisions taken by inspectors – beyond and below the official policy documents. In so doing, he gives us important perspective on how the HSE's structures and methods evolved over the past couple of decades, since the HSE was set up following the Robens report and HSW Act 1974.

First, Hawkins shows how the culture of HSE staff, the approaches taken both officially and in practice reflect the underlying philosophy of the HSW Act. Indeed, "the Robens Committee adopted a rather benign conception of the problem of enforcing" OSH regulation "shaped by an assumption that not only the workforce but also management had an identity of interest" (Hawkins 2002, p. 144)[50]. The structure and mandate of the

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[47] See Ogus 1994 pp. 81-87 for a general (theoretical) discussion of the use of criminal justice and liability in regulatory matters. Liability (civil and criminal) is a powerful tool (see e.g. its use in the French building safety system in World Bank Group 2013 b pp. 82-87), but it has of course limitations, in particular when (a) the risks of permanent damage (incl. death) are too high given current practices and (b) potential victims are likely to be in an unfavourable position to sue (lack of resources, fear etc.) – both of which clearly applied to occupational safety and health a century and a half ago (and to an extent still do).

[48] Technically, this is not really "self-regulation" but rather a form of "enforced self-regulation" or, more correctly, of regulation with loosely defined performance requirements, the enforcement of which relies on codes of conduct and other "soft law" developed by the industry itself (both employers and employees). A similar practice can be observed in other countries and domains, e.g. in the French construction safety system the *Documents Techniques Unifiés* are developed by the different industry stakeholders, but compliance with these can be made enforceable in court as they constitute the equivalent of the 'so far as reasonably practicable' standard, i.e. the obligation of due diligence by the builders.

[49] As per previous note, "voluntary" but in fact likely to be used in enforcement when the need arises to define what is "reasonably practicable".

[50] A note is needed here on this assumption of (at least significantly) converging interests. While it is generally accepted by many practitioners (see e.g. World Bank Group 2014 a) that there is an alignment of interests between food business operators and food safety regulators (safe food is good for business, because consumers come back), it is far less often thought to be the case in OSH, which is rather commonly seen as a "trade off" field – businesses seek to save money by cutting back on OSH expenses, and gain little by complying. The Robens report took a different view, assuming that there were clear benefits of OSH for employers (less liability and court cases, better image for the company, better workers' motivation and effectiveness, less disruptions due to accidents etc.). Interestingly, while some well-publicized food scandals (see further in the US food safety case) show that the expected "alignment" is

Health and Safety Commission (since then merged with the HSE) "embodies a theory of assent in the formulation of regulation" (*ibid.,* p. 149) aiming at making compliance more likely (and easier). The HSE (and HSC) were clearly positioned from the onset not at bodies functioning in an abstract, aloof independence, but working "at the centre of an intricate web of political relationships" (*ibid.,* p. 157) - balancing different interests, priorities, needs, with negotiation as central activity (*ibid.,* p. 158). This builds a sharp contrast to France, for instance, where the Labour Inspection is seen as being (and *having to be*) fully independent (and even impervious to) any interests on the side of businesses (clearly less so on the side of trade unions), and any political pressures (whether it is so in practice is another question). While this difference is clearly linked to deep (and historically long-term) divergences in industrial relations, the role and posture of trade unions and businesses, it is likely that different approaches taken in legislation have also played a significant role in strengthening and hardening these divergences.

Second, Hawkins shows how there has been a gradual shift over more than two decades in the *focus* of the HSE, and the definition of "risk" that underpins its work, targeting, and enforcement response. Significantly, the HSW Act changes the definition of what is being supervised and enforced. Rather than pinpointing specific rules and requirements, it establishes a "duty of care" to workers, and any people who may be affected – the purpose of the Act is to "ensure that safety is a pervasive value" and it requires that operations should be "safe 'so far as reasonably practicable', specifically requiring a weighing of cost and trouble against the severity of the hazard and likely benefit" (*ibid.,* p. 145). Thus, the Act is *founded* on a risk-based and approach (addressing risks to safety is the purpose, not enforcing specific statutory points *per se*, and prioritization is not only permitted, but called for). Cost-benefit analysis, in a way, is at the core of the HSW Act. In addition, the Act "brought statute law to bear on a broader range of sites and problems" – leading to a change in the range of risks covered, and in risk prioritization (increasing attention to risks to the public, and comparatively less to risks to workers[51]) (*ibid.,* p. 147). During the 1980s there were again new trends and shifts in focus of resources and interest (*ibid.,* p. 161): "shift (…) in the balance of regulatory activities towards major hazards and the protection of the public from industrial harms, and (…) a marked increase (…) in public concern for the environmental aspects" (*ibid.,* p. 162). The EU "Seveso" Directive in 1984, for which HSE was selected as responsible body in the UK, reinforced this shift (along with further national and EU legislation).

Third, this focus on hazard control and mitigation, and this modulation of inspections and enforcement based on risk, have been officially, clearly articulated for a long time – meaning current HSE practice builds on at over 30 years of experience and gradual consolidation of this approach. Hawkins thus quotes a 1978 official HSE document stating that its goal is to "ensure that management recognises its responsibilities for the control of hazards" (*ibid.,* p. 155). In another, slightly later, official document (from 1980), the HSE explains that "the frequency with which inspections are undertaken in any premises depends on need – the standards of safety, health and welfare found (…) at the last visit, the potential inherent hazard (…) and the quality of the management" (*ibid.,* p. 167). Thus, both the risk-based targeting model, and the "enforcement management model" have long and deep roots. All the HSE inspectors' actions have to contribute to "tackle root causes rather than just the symptoms of undesirable conditions (*ibid.,* p. 166) – and this leads to an approach to enforcement that is fundamentally *instrumental* (concerned with utilitarian goals) more than *expressive* (symbolizing fundamental values).

Fourth, inspectors' decisions (and HSE actions more broadly) aim at minimizing risk and, as a means to this end, at maximizing compliance. For inspectors, "the seriousness of the event and the seriousness of the risk

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not always present in food safety, the generally good OSH situation in the UK suggests that the Robens report's assumptions may well have been correct, at least to a significant extent. This is certainly a topic worthy of further research.

[51] Hawkins does not discuss whether or not this gradual shift was "appropriate" from a data-driven risk perspective, i.e. whether risks to the public created in aggregate more harm than strictly "occupational" ones, and we did not have the opportunity to research data from this perspective.

of harm" are essential in terms of "framing the prosecution decision" (*ibid.,* p. 54). In this perspective, "decisions about legal standards and their enforcement" are made in a broader setting, within a given context, with decision 'frames' "interpretive and classificatory devices" (*ibid.,* p. 48). Whereas "prosecution can provide symbolic satisfaction to the public while doing little instrumentally to gain compliance or repair problems" (*ibid.,* p. 7) – as a result, "formal enforcement is often reserved for weightier matters", including particular seriousness, visibility, harm, persistence (*ibid.,* p. 41). This is all part of a *compliance strategy* rather than a *sanctioning* one: "sanctioning is largely concerned with rule-breaking, where compliance strategy is focused on results". Hawkins notes that such an approach is most reliably achieved when there is familiarity with the business, stability of relationships between regulator and regulated entities, which means inspectors can work on improving matters – with sanctions being far more frequent in other cases (e.g. more "transient" businesses) (*ibid.,* p. 46).

Finally, while the roots of contemporary HSE approaches go back to the 19th century ("the use of prosecution as an enforcement move of last resort goes back to Victorian times", *ibid.,* p. 17), there have been considerable efforts since 1974 to create more consistency and uniformity. At the onset, and for a couple of decades, "there were markedly different cultures and traditions of enforcement within HSE" (*ibid.,* p. 19). This was the result of HSE's "birth as the progeny of several shotgun marriages", and "throughout the 1970s and 1980s HSE remained essentially a federal structure" (*ibid.,* p. 156).In 1990, a major reorganization was made to ensure more consistency, with the creation of the Field Office Directorate (FOD), which replaced the previous "legacy" inspectorates[52] (*ibid.,* p. 163). Several other institutional changes were made with the "objective of maintaining consistency of enforcement practice" e.g. the set-up of National Interest Groups (*ibid.,* p. 154). Overall, these all show a consistent "pursuit of greater uniformity of policy and practice in the operation of HSE at all levels" (*ibid.,* p. 164).

The challenge, however, that all efforts at consistency and uniformity have encountered, is that actual enforcement work does not proceed through "implementation" of official policies – but rather, that official policies are but one of the many drivers of real-life enforcement decisions (and analysing these many drivers is what Hawkins's work is about). In practice, "inspectors have routine conceptions of 'risks', 'accidents', 'problems', and so on, which assist them in making sense of the difficulties that come to light" (*ibid.,* p. 50) – and they also have values, visions of their work, experience and uses, which all contribute to their decision-making. Reforms in HSE, in recent years, have clearly aimed at bringing consistency to a further level, and at achieving a better implementation of the *Enforcement Policy*[53]. To this aim, the approach to be used in determining whether or not to take enforcement action, and which one, has been spelled out in far greater detail, and with a number of "decision trees", in a document called the *Enforcement Management Model (EMM)*[54].

The EMM reiterates and further develops an approach that was already, as we have seen, in place in the late 1970s/early 1980s – it does so, however, with more details and precision. The fundamental idea is that the inspector should use a risk-based approach at every stage of his work – and in particular when identifying violations and assessing their relevance, and when deciding on the enforcement action (or lack thereof). We will come back to the EMM later on, but fundamentally it emphasizes the importance of "risk of personal injury" and "immediacy of risk", and to assess them, as well as the degree to which the situation deviates from clearly established standards, uses an approach called "risk gap analysis" (p. 9). When determining the enforcement action, the EMM considers the overall situation in the establishment, as well as the compliance

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[52] Keeping, however, some specialized ones for high-hazard establishments, e.g. the ones supervised under the "Seveso" directive.
[53] See *HSE Enforcement Policy Statement* available at: http://www.hse.gov.uk/pubns/hse41.pdf. See also explanatory page on the policy: http://www.hse.gov.uk/enforce/enforcepolicy.htm.
[54] See *HSE Enforcement Management Model* available at: http://www.hse.gov.uk/enforce/emm.pdf.

history (p. 25). By making the enforcement guidelines far more detailed and specific, and breaking them down in a number of steps, more uniformity and consistency is sought. Still, there remains a considerable degree of discretion in decision making, and the assessment of conditions and of the "risk gap" are done by inspectors, with all the experience, views, 'frames' etc. that they bring to the process. Hence, what Hawkins describes in his work is still essentially valid, even though it may be that the variation has been significantly reduced (recent research on the effectiveness of the EMM in this regard not being available).

The next step in improving consistency of risk-based approaches is thus to work on the inspectors themselves, on their culture and understanding of risk, on their "competencies". Considering the HSE's history outlined above, it is no surprise if the development of a new "common approach to competency" for regulators (and specifically inspectors) has been piloted to a large extent in the HSE, even though it applies to a number of other regulators (and is driven by the UK BRDO). We will come back to this in a later section, but it shows the pertinence of Hawkins's emphasis on the "personal" element in inspector decision making – regardless of how detailed and specific policy guidance is, achieving "better" risk-focus (as seen by the regulators' managers) and greater consistency involves working on what inspectors know, believe, think, how they see their work and analyse situations. In line with this, one of the "core competencies" identified in this "common approach" is "risk" (see BRDO 2015 and the Guidance for Regulators – Information Point Portal[55]).

Short conclusion

Among the most noteworthy changes over the years is the *scope* of what is now understood as OSH control. First, the way the institution and its mandate were defined: originally, it was by their *object* of control – factories, mines, quarries. The definition of a type of risk, or a regulatory area, was missing. The type of object was seen as defining the scope of work.

Second, there is the question of *what* inspectors were expected to control. The 1833 Act only looked at the question of child labour, and attempted to limit both the young age at which children could be made to work, and the types of tasks they could be made to perform. The 1844 Act went further – it introduced additional restrictions of tasks allowed to assign to children, youth and women, and it also "introduced requirements for 'secure and continuous fencing' of fly-wheels, water-wheels, wheel-races, hoists and teagles (lifting machinery) near to which children and young persons were liable to pass or be employed, and all parts of 'mill gearing' (transmission machinery)". In other words, it now clearly covered occupational safety. Under this Act, "Inspectors were authorised to appoint 'Certifying Surgeons' to whom (…) any accident preventing the injured person from returning to work by nine o'clock the following day had to be reported. The Surgeon was required to make a full investigation of the nature and cause of the accident and report to the Inspector" which allowed to seriously start monitoring, investigating, understanding occupational hazards (*ibid.*). In 1850, the Ten Hours Act was voted, "reducing the maximum length of a working day for women and young persons employed in textile factories" (*ibid.*). Successive Factory Acts and other legislation in the 19th century continued to introduce safety requirements only gradually, and to mainly regulate issues in regard to children and, to a lesser extent, women. The safety of adult workers was, for long, left unregulated.

Was it, then, that the risks were *greater* for children? Purely statistically, it is unlikely – adult, male workers were the majority, and an even greater majority of those performing hazardous tasks. What counts here is however risk *as perceived by the society as unacceptable (and requiring regulation)*. For a variety of (relatively obvious) reasons, children were seen as more vulnerable, less able to understand and manage risks themselves, more in need of protection etc. – and thus, adopting regulations to protect them (but not adult workers) was seen as appropriate. Adult males were expected to be able to assess and manage their own risks.

[55] Portal available at: http://www.regulatorsdevelopment.info – see on risk: http://www.regulatorsdevelopment.info/grip/coreskills/risk

As for women, the fact that they were awarded more protection than men (but less than children) reflects both the period's mentalities and culture (women generally seen as "minors", "weaker", "in need of protection") and sociological realities (women that had to do factory work to survive were very poor, underpaid, and often in serious jeopardy, physical and otherwise).

Perception of risks continued to shape priorities and structures for a long time. Agriculture was only covered by OSH legislation, and trade and services were included in 1963, but with enforcement left to local authorities – which resulted in the "twin peaks" problem, whereby both the HSE and local authorities build *separate and unrelated* "risk pyramids", i.e. classification of objects (establishments) on the base of risk[56]. Because the scope of competence of HSE and local authorities is different, there is the possibility (and indeed this is often the case in practice) that the "peak" of the local authority's pyramid is in fact *lower* in relative risk compared ot the "base" of the HSE's pyramid. As a result, this "local peak" will be inspected frequently, whereas the (objectively riskier) "HSE base" will be inspected rarely or not at all. As the Better Regulation Executive put it, this "limits the ability of regulators to target overall inspection resource on workplaces where the risk of injury and illness is highest" (Better Regulation Executive 2008 – quoted by Löfstedt 2011 and the main basis for his recommendation to put HSE in charge of "directing" local enforcement too).

In conclusion, the question of how risks were conceived and perceived was central to the adoption of regulations, creation of inspection institutions, development of their scope of work, powers and methods. What was required in order to have regulations adopted and an inspection institution created was not just a risk, or even a major risk, it was a combination of factors. First, the risk had to be identified and understood (or thought to be understood), and perceived as something that could possibly be mitigated through intervention – a poorly understood risk, to which science and techniques were unable to respond, would not produce the same reaction, however significant its statistical impact (as the cholera example shows). Second, it has to be seen as a risk "out of the ordinary", unacceptable, what Slovic *et al.* call a "dread risk". New techniques and industries, disruptions in what was hitherto considered normal, create "dread" – but large amounts of preventable deaths in ways and occupations that have been part of everyday life's fabric for centuries often simply do not register (e.g. agriculture). Similarly, in the 19th century at least, adult men engaged in hazardous occupations was seen as "normal" – but children exposed to the same risks appeared shocking. Third, moving from "no intervention" to "some intervention" usually takes a combination of factors including "crisis events" or broader social pressure. Finally, the way in which institutions are set up, develop and grow is generally *not* thought through at the beginning, is strongly subject to path dependence, and getting towards a somewhat more "rational" set up can take a very long time indeed (and many "lessons learned").

A few more words should be said to emphasize the complex set of changes in structures, policies and (eventually) staff training and competencies involved in making an institution more "risk-focused", and inspectors' decision-making more consistent. In all these respects, as we will see in further sections, the HSE will serve as a very important example, and help us test different hypotheses.

v. A brief look at other countries

The gradual establishment in Britain of specialized inspectorates for the enforcement of labour-related legislation was to an extent paralleled in other "advanced" economies of the time, but the timeline and specifics differed.

[56] The "pyramid" metaphor conveying the idea that, by design, there should be larger number of lower-risk businesses, and a smaller amount of high-risk ones, so that there can be real *focus* of activities – this classification is the result of prioritization, and does not mean that risk is *absolutely* low or high, but that it is *relatively* higher or lower.

France

In France, the context and timeline to some extent resembled what was seen in Britain, and so did some of the initial measures, but the two systems were to strongly diverge over time. The same social blights associated with the rise of modern industry were highlighted in France, as they were in Britain – one of the most prominent publications in this perspective being the report by Dr Villermé[57] that was commissioned by the Academy of Moral and Political Sciences and presented (for its first part) in 1839. Villermé exposes in details the living and working conditions of workers in the textile industry but, while demonstrating the hazards they create and the depth of misery, it is also very much a socially conservative account. He only criticizes "abuses" (and in particular in relation to children), otherwise puts substantial blame on the poor themselves, and calls for some remedies but clearly "no radical solutions" (Tyl 1971, Introduction). This perspective very much reflected that of the higher bourgeoisie who dominated the *July Monarchy* regime of the time – and Villermé's report led to the adoption of the 1841 law on child labour in factories, manufactures and workshops. For similar reasons to those seen in Britain, this was the issue in regard to which state intervention was seen as appropriate and urgent – safety of workers more broadly was still far from being regulated.

In the post-revolutionary context, limitation of working hours was adopted in 1848 – but further legislation had to wait for the fall of the Second Empire and the re-establishment of the Republic. In 1874, a new law further regulated child labour, as well as women employment conditions. This was also the law that effectively created a labour inspection – a full 33 years after adoption of the first law on child labour. Indeed, after some debate, the 1841 law had left the matter to the government to decide through a decree (Bouquet 1895 p. 1), and the initial decision was to have volunteer local commissions in charge of inspections. This seems to have quickly proved ineffective (*ibid.*) and, from 1847, there were repeated plans, draft laws etc. aiming to replace these by a professional inspection. All, however, failed, mostly due to far larger political events – the 1847 draft to the revolution of February 1848, a 1850 discussion was left without follow-up (in a very tense political context that led to the 1851 *coup* by then-President and future-Emperor Louis-Napoléon Bonaparte), another project in 1858 was again not followed through, and a 1870 draft was quickly side-lined by the Franco-Prussian (or Franco-German) war that started in July (*ibid.,* pp. 1-3). Even though a few local administrations (*départements*) had created their own inspections, they lacked proper powers and a clear framework and had limited effectiveness. This period seemed to demonstrate *a contrario* the usefulness of inspections, through the very limited progress in implementing the 1841 law that was observed in the absence of an inspectorate. The system created in 1874 was a kind of hybrid: it retained local discretion in hiring and appointing local inspectors (in some *départements* local authorities hired quite a few, in others none), as well as local volunteer "commissions", but added a professional, central service (with 17 inspectors) and a Central Commission[58].

In 1892[59], a new law was voted regulating employment of women (in particular minors) and children – and, crucially, this new law restructured (and strengthened) the inspection function. It got rid of local inspectors altogether, as well as of local volunteer commissions. The labour inspection now would have 11 superior inspectors, 76 departmental inspectors (in charge of a *département*) and 16 departmental female inspectors[60]. Inspectors were henceforth to be recruited via a *concours* (competitive examination) covering a range of legal

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[57] See Tyl 1971 for a modern edition and presentation

[58] With representatives from industry, politics and science, and a role that in some way could be seen as a prefiguration of the UK's Health and Safety Commission created a century later: assessing problems, proposing solutions, developing recommendations etc. The commission filled a need (as the inspectorate was not endowed with the regulatory powers given to HM Factory Inspectorate in Britain), and helped "bridge the gap" between government administration and private industry (cf. Bouquet 1895 pp. 4-5).

[59] A point of context was the 1890 International Conference on Labour Law in Berlin.

[60] In line with the prejudices of the day, there were arguments against having female inspectors at all, but they were retained due to successful local experimentation in Paris and its suburbs in the earlier period – but they were confined to all-female factories and workshops, and to workplaces with no engine-powered mechanical equipment (and their entrance examination had the same topics as male inspectors, with the exclusion of mechanical engineering issues) (Bouquet 1895 p. 8).

and regulatory, chemistry, engineering, safety and workplace organization questions (*ibid.* p. 9). The profession of inspector now opened to a real career. For mining establishments, the 1892 law left responsibility of inspections to the corps of mining engineers (a long-established state body).

Like in Britain (but in a faster succession – which is understandable given much later creation of the inspectorate), the remit and mandate of inspectors gradually expanded – starting only from rules on children and under-age girls in manufacturing. In 1883 they were given authority to enforce the 1848 legislation on work duration in manufacturing industry. The 1892 law which re-organized the inspectorate added the employment of children in "peddling and itinerant trades". It was only with the 1893 law on workers hygiene and safety in manufacturing establishments, however, that their functions really came to cover "health and safety" in a broader meaning, beyond the limited provisions until then existing for children and women (*ibid.,* p. 11). This last addition, one could argue the most critical one from a "risk prevention" perspective, was however to be the most complex to translate into practice – requiring the development and adoption of specific technical norms, and requiring a relatively complex enforcement procedure (Guérard 2000 – see below).

The fact that regulations and inspections first focused on regulating children (and later women) employment (and left adult men to fend for themselves for a long time) again reflects contemporary vision and ideology – in other words, risk perceptions are mediated by what is considered normal and acceptable, or not, rather than being purely (or even mostly) driven by objective data such as injury or fatality rates. A prominent representative of that day's legal thinking, Advocate General at the Court of Cassation Louis Sarrut, put it thus: "if one can, to an extent, argue against the legislator's setting working conditions for men having completed their physical development and with full civil capacity, it is beyond doubt that the legislator has to intervene in the interest of minors and women (…) For a well-organized State, valid citizens are needed. The limitation of women employment is indispensable to the good upkeep of the household" (Sarrut 1894, pp. 16-18, author's translation). What is being seen as a risk, here, is mostly the social risk: "the withering of the race" (*ibid.*) is what could happen if the state did not intervene (and this would have, one can read between the lines, consequences in the international rivalry and contest, particularly with Germany). Still, in Sarrut's time, the view that harm to (male, adult) workers was also a risk worth addressing had prevailed (but it had not been self-evident). As Sarrut himself puts it, commenting the introduction (under discussion at the time, adopted into law in 1898) of no-fault liability for employers in labour accidents: "modern industry (…) has become by itself hazardous for the worker. (…) Accidents proceed far more from the kind of work and tools than from worker's actions. Industrial work implies risks – and this kind of work and these tools are established by the employer" (*ibid.,* pp. 20-22). The justification of no-fault liability also relies on economic reasoning: "industrial labour is the source of the master's benefits. These benefits are the risks' compensation. The worker, on the contrary, is limited to a set salary. It is thus as rational as it is equitable to (…) impose to the employer the reparation of damages" (*ibid.*). This view of risks, once again, has part of its foundation in the "dread risk" aspect of industrial employment as distinct of, say, farm work – but it receives conscious justification and elaboration, a justification that is linked to the economic question as well. Because industrial activities (unlike farming, at least at the time, and/or at least in the mind of contemporaries) involves novel techniques, arrangements set by the employer (and not, say, by tradition), and unique perspectives of profit, regulation is justified[61], which would not be possible from a classical legal perspective. Indeed, on the question of no-fault liability, Sarrut approves of the departure from "very ancient doctrine, transmitted by Roman Law (…) that the affected party can only obtain reparation of the damage in court if it can demonstrate fault" (*ibid.*, p. 20).

[61] The 1898 law excludes agricultural activities, as well as most trade and services – it covers "workers employed in construction, factories, manufactures, public works, land and water transport, loading and unloading, public warehouses, mines, quarries and any establishment (…) where are manufactured or used explosives, or machinery activated by a force other than man or animals".

Decisions on the scope and aim of legislation were thus strongly driven by ideology and perceptions, rather than be actual data on the health and safety risks presented by different activities. The same seems to have been the case for enforcement approaches and instruments. Commenting on the implementation of the 1892 law, Sarrut wrote: "sanction can seem insufficient, for violations are brought before the Police Court [*note: Minor Offences Court*], and a fine is in principle the only penalty; but fines are cumulative in case of several violations or felonies (…) Anyway the legislator, not without reason, appears to expect full compliance with the law more from the vigilance of inspectors and commissions than from penalties" (*ibid.,* p. 16). Inspecting as frequently as possible seems to have been the approach taken in practice – commenting on the pre-1892 set-up, Bouquet wrote that inspectors "saw at a maximum a little over half [of establishments under supervision] per year. The inspection of each establishment, particularly small workshops, was thus insufficiently frequent to avoid that, in the meantime, the industrialist fell again in its old errors" (Bouquet 1895, p. 7, author's translation).

Unfortunately, little can be said about these inspections' effectiveness. Statistics of the time, and later articles, have focused mostly on the volume of enforcement activities (see e.g. Guérard 2000 p. 12), but not on whether it made factories more compliant with child labour rules, or reduced the rates of injuries and fatalities. These were in any case still very high at the beginning of the 20th century – 130 for 100,000 in construction, over 100 in metal industry (1905 data, quoted in *ibid.* p. 3), whereas similar rates at the end of the century in major industrial economies would be around 10-15 times lower for construction, even lower for industrial activities (see Feyer *et al.* 2001 and section 4.2.a.i. below).

Many other aspects and issues of early labour inspections in France were to have long-lasting effects. We will only briefly discuss one of the most important: enforcement tools and the requirement to use "improvement notices" (or their French equivalent).

On the first issue, the 1893 law on labour safety, further detailed by a 1894 decree, required inspectors, when they enforced regulations taken by the government on safety issues, to first issue a "*mise en demeure*" (improvement notice), and give a delay for putting the establishment in compliance (Guérard 2000 pp. 1 and 7 – Bouquet 1895 p. 14). This was opposed to cases where inspectors enforced direct provisions of the law, in which they could directly issue a "*procès verbal*" and bring the offender to court for swift sanctioning. The delay foreseen for the improvement notice was a minimum of one month, and could be much longer in some cases.

Such a provision is quite unusual in French law – leaving officials some discretion as to whether they should enforce a rule or not is done in some (though not all) laws, but requiring them to first give a warning and improvement period is quite a unique case. The suggested explanation is that there was a legal problem in foreseeing sanctions for violations which were still for the most part vaguely defined (or not defined at all yet). While violations of the rules on employment of minors and women (1892 law) were clear, the safety requirements (1893 law) had mostly not been laid out yet. As Guérard puts it (*ibid.,* p. 1): "so that an employer could be penalized, in accordance with the legal principles formulated by the French Revolution, all the elements of the violation have to be defined in the law or in legislation that stems from it. But in matters of safety, the law can obviously not foresee everything. It is thus necessary to rely on implementation decrees already (…) that are insufficient, in the initial state of prevention concepts and methods, to define in detail the measures to be implemented. Whence comes the use of improvement notices by labour inspectors, procedure imposed by the (…) 1893 law for all regulations issued to implement it".

The extended delays for improvement foreseen by the 1894 decree, the lack of flexibility and exceptions in the procedure (e.g. for construction sites which, unlike many other establishments, are temporary and change rapidly, improvement notices with long delays were simply inadequate – see *ibid.* p. 7), as well as the cumbersome way in which notification had to be done (see *ibid.* p. 8 and Bouquet 1895 p. 14). As a result, inspectors are constantly complaining about this requirement, and a new law in 1912 includes a number of specific safety requirements so that they can be directly enforced (Guérard 2000 p. 10). Later on, a 1931 law

will reform the system so that improvement notices become the exception rather than the norm. By contrast, in Britain, improvement notices are a major part of the HSE's activities, and inspectors are clearly satisfied with the system's effectiveness (see Tilyndite 2012 pp. 137-138 and 249-253). While the difference may reflect a number of institutional and cultural issues, the exceedingly unpractical notification procedure and long delays adopted in France in 1893-1894 probably played a role in making the system function poorly, thus lastingly "disqualifying" this instrument – and contributing to a modern system which is seen by employers as often excessively harsh. It is also interesting to see that the practice of prior notices was in a way only seen as a "stop gap" measure until more precise requirements could be developed, and not as a useful tool by itself. Finally, this initial difficulty also reflects the problems created by constant technical developments, which meant that regulations were always outdated compared to the latest innovations (Guérard 2000 p. 5) – a problem that was only gradually solved over the following decades, with the growing reliance on performance or target standards, rather than specification standards (see Ogus 1994 pp. 151-152 and Baldwin 1995 pp. 175-185)[62]. Even in the way such performance-based rules are used, however, French labour inspectors exhibit to date a considerable reluctance to give specific guidance[63], in strong contrast to the HSE's practice[64].

A couple more remarks on the long-lasting effects of initial choices. First, the initial choice to have "departmental" inspectors, and to keep one inspector per *département* even once they became state inspectors, has been preserved in a structure where the fundamental organizational unit is local (in spite of inspectors being state civil servants), and staffing levels are only poorly proportional to the level of activity (the "one inspector per department" was evidently inbalanced froms this perspective). Second, merging the different inspectorates respectively in charge of "general" labour inspections, labour inspections in agriculture, and labour inspections in transports, had to wait until 2009[65]. Finally, France's decision to build a medical insurance system based on a "Bismarckian approach" in 1945 (i.e. based on a network of industry-specific statutory health insurance funds) rather than a "Beveridgian approach" (a national, tax-funded health service) resulted in a duality of inspections, whereby the health insurance funds conduct occupational health visits with no connection to the labour inspection[66], a problem that is not without connection with what can be observed with the occupational accidents statutory insurance funds in Germany (see Tilyndite 2012 pp. 162-164).

A very brief look at a few other countries[67] confirms both some level of similarity in timelines, and some important differences that relate to different "country trajectories" in terms of overall political and institutional context, social issues etc.

Netherlands

In the Netherlands, labour legislation was introduced relatively late compared to Britain and (to some extent) to France. In 1874, child labour was banned in factories (van Houten legislation), then in 1919 the Labour Law comprehensively prohibited child labour and mandated rest periods and maximum working hours. It was only in 1934 that the Safety Act introduced mandatory norms on labour safety. The Labour Inspection was created

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[62] For more explanation and discussion of the different types of standards, see below pp. 107-112

[63] Author's interviews with French government officials and businesses.

[64] See illustrations of it at: http://www.hse.gov.uk/guidance/

[65] See France's report to the ILO for 2009, available at: http://travail-emploi.gouv.fr/IMG/pdf/Rapport_au_BIT_intranetW_28022011.pdf. Note that labour inspections in mining, electricity and gaz industries remain separate.

[66] Author's interviews with French government officials and businesses.

[67] The following cases were selected for their relevance (major economies, among the early industrial powers, particularly for the US, Germany and France) and because they exemplify very different approaches (Germany and France for instance), and diverging timelines (earlier actions in Germany and France, later in the Netherlands and the US). As such, they allow to present an overview of the diverse paths taken in setting up OSH inspections, their similarities and differences, and the significance of historical path-dependency for today's inspections practices.

in 1890, which is also considerably later than in Britain (and a bit later than in France). It would be interesting to look more closely in future research as to why there was this delay (given comparable stages of industrial development), and whether this resulted in any difference in how injuries and fatalities rates evolved (declined) over time (i.e. whether this decline was slower in the Netherlands, which could be because of later introduction of regulation and inspections, or whether there is no observable difference, and the main drivers appear to be technology, culture, economic structure etc.).

An interesting feature of the Dutch system was the creation, in 2012, of the Inspection for Social Affairs and Employment ("Inspectorate SZW" in English or "*Inspectie SZW*" in Dutch, with SZW standing for "*Sociale Zaken en Werkgelegenheid*"). This institution regroups "the organisations and activities of the former Labour Inspectorate, the Work and Income Inspectorate and the Social and Intelligence Investigation Service of the Ministry of Social Affairs and Employment[68]". It thus gathers a number of functions, *some* of which are frequently found combined elsewhere, but rarely all. It supervises compliance with "regulations in the area of working conditions and the prevention of major hazards" (like the HSE – but unlike the French Labour Inspectorate, which does not oversee major hazards[69]), regulations concerning illegal employment and minimum wages (*to some extent* like the French Labour Inspectorate[70] but unlike the HSE, which deals only with health and safety[71]), and it is also involved in "detection of fraud, exploitation and organised crime within the chain of work and income (…) under the direction of the Public Prosecution Service (some of which, but only a small part, falls within the purview of the French Labour Inspectorate[72] – and none of which is done by the HSE) as well as "studying the implementation of social security acts by the Employee Insurance Agency (UWV), the Social Insurance Bank (SVB) and municipalities[73]" (a function that is typically done, if at all, by completely distinct bodies from OSH/labour inspectorates).

There is no easily accessible, open information on the reasons why the Dutch government decided to go for this precise merger, rather than envisioning potentially different mergers, with different synergies, e.g. merging all functions related to social security fraud with the Tax Service[74] – it is not even clear that other merger options (or full transfer of some functions to other institutions) were considered at all. The only official information we were able to access (internal documentation of the Ministry of Social Affairs and Employment from 2012, gathering working documents from 2009) treats the merger as a *fait accomplis* and does not discuss the reasons this precise merger was decided – it only advocates its benefits, and lays out how to make it happen. What we can piece together[75] is that, at some stage probably in the first half of the 2000s, the Netherlands government decided to consolidate national inspectorates (excluding the Tax Service) and to more than halve their number (from 25 to 10), as a way of reducing staffing levels (down close to 30% over 15 years) – consolidation being seen primarily as a way to make this staff reduction possible while keeping roughly similar levels of effectiveness.

It is too early to discuss the results of this merger, and it may turn out to be a very good decision in terms of overall effectiveness, but what is interesting from our perspective is that (at least based on the information

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[68] Official English-language brochure "What does the Inspectorate SZW do?" – available at: http://www.inspectieszw.nl/Images/What-does-the-Inspectorate-SZW-do_tcm335-330702.pdf

[69] In France, this is done by the *Inspection des Installations Classées* see: http://www.installationsclassees.developpement-durable.gouv.fr/

[70] Which does not look at social contributions, handled by the bodies in charge of the social security system.

[71] In the UK, illegal employment of foreigners is tackled by the UK Border Agency and the Gangmasters Licensing Authority (see: http://www.gla.gov.uk/) which "regulates businesses who provide workers to the fresh produce supply chain and horticulture industry, to make sure they meet the employment standards required by law". Compliance with wage and working hours regulations is not enforced by public inspection institutions, but by litigation, wherein workers are supported by Trade Unions. Payment of social contributions is handled as part of the tax inspections by HM Revenue and Customs.

[72] Social security fraud is handled by social security institutions themselves. Organized crime is tackled by special units in the police.

[73] And some additional analytical functions, risk assessment in the field of social affairs etc.

[74] Whereas collection of social contributions has been done for a long time already by the Tax Service – see Bakirtzi 2011 pp. 67-71

[75] Author's discussions with current and former Netherlands government officials involved in inspections issues.

we could obtain) there does not seem to have been a real conceptual review of what inspectorates were doing, what (if anything) from this set of duties could possibly abandoned, what could be done better through mergers or transfers of functions (and which ones). Rather, it was decided to conduct mergers to save costs, and these were done by grouping together the functions that looked most similar or, simply, were under the same ministry (in this case SZW). This illustrates once again how rarely "evidence-based" decisions are taken regarding inspection structures, staffing levels etc.

Germany

The occupational safety and health regulatory and enforcement system in Germany, as in the other countries we have reviewed, has features reflecting its history – but maybe even more so than others.

The German OSH system is characterized by a system that is both "federal and dual" (Tilyndite 2012 p. 161[76]) – there is a federal labour law but inspections are done by the *Länder* (federated states), and in parallel there is a set of "non-governmental" (but government-backed) regulations and inspections handled by the "statutory insurance bodies" (*"Berufsgenossenschaften"*). We will try and briefly cover the origins of such a rather unusual structure (and we will discuss in a later section how the system appears to perform compared to the British one).

The early origins of the OSH system are not very different from what they were in Britain and France, and contemporary as well – but, due to the political fragmentation of Germany at the time, they took place in one state at a time. The most significant developments were in Prussia, which was to become the "unifying" state over the 1860s (and with full unification of Germany achieved in 1871). Like in other countries, the first concern was about children working in factories, and the emergence of the concern took place in the 1830s. A particular twist of the German situation was that the driving worry that led to call attention to the plight of children in modern industry was military – that, because of stunted development, the army was unable to find sufficient numbers of able recruits[77] (report of Lieutenant-General von Horn to King Friedrich Wilhelm III). This, and other similar reports, led to the adoption in 1839 of the "Prussian Regulation" (*"Preussisches Regulativ"*) that, similarly to the 1833 UK Act and the 1841 French Law, limited employment of children (in terms of minimum age, maximum duration, schooling requirements). Like in France, and unlike in Britain, no specific inspectors were appointed – enforcement was left to local police, school authorities and (from 1847) voluntary local commissions. Due to their limited effectiveness, in 1853 state inspectors were appointed (and, at the same time, rest on Sunday and public holidays made mandatory). In 1869, a regulation (first applicable to the Northern German Confederation, then from 1871 to the whole German Empire) gave a stronger basis to the activities of labour inspectors, and further reinforced existing requirements on working conditions, age, hours etc.

The developments from the 1870s again to some extent paralleled those observed in France and Britain, with a legal amendment adopted in 1878 that allowed inspectors to conduct at any time a "revision" of the workplace, and order safety improvements, but implementation was still problematic. From 1874, the

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[76] This short account of the German system and its origins is based on Tilyndite 2012 for the present, and on publicly available information, in particular websites such as the *Helmut Schmidt Universität*'s http://www.hsu-hh.de/arbeitsschutz as well as the *Arbeitsschutzverwaltung im Freistaat Sachsen*'s http://www.arbeitsschutz.sachsen.de/ as well as a section on "40 years of labour law" on the *TÜV Rheinland* website http://www.tuv.com/de/deutschland/aktuelles/40_jahre_arbeitsschutzgesetz/40_jahre_asig.html. Given the fact that we just aimed to present some of the key characteristics of the system, and how it differs from France and Britain, such publicly available facts were sufficient and we did not do a further literature review.

[77] Note that this concern, though not necessarily articulated in the same way, was clearly present elsewhere, at least in France – see Sarrut 1894 and his concerns about consequences for "the race", which mirror von Horn's. This again shows that what was perceived as "risk" was not necessarily what we would imagine from our modern standpoint (harm to people), but more a "social harm" or "social risk".

increasingly significant scores obtained in elections by "workers'" and "socialist" parties[78] were creating a growing incentive for the Government to try and "undercut" these parties by making significant reforms that would secure the support of industrial workers for the regime. Accident and health insurances for workers were announced in an Imperial statement in 1881, and turned into law in 1883 (health insurance) and 1884 (accident insurance) (cf. Tilyndite 2012 p. 167). The latter, crucially, replaced the 1871 regime of compensation for work accidents (where workers had to prove the responsibility of the employer, which seldom was possible) by a "no-fault" compensation regime. Finally, in 1891, the "Law on Worker Protection" (*"Arbeiterschutzgesetz"*) was adopted. This gave a stronger foundation to state labour inspections, and extended them to all industrial activities regardless of size and sector. As a result of these reforms in the 1880s and early 1890s emerged a dual system of state supervision and supervision through the mandatory insurance bodies institutions (since the "no fault" system meant there was otherwise a risk of "free riding", where employers with poor safety practices would just be subsidized through other employers' contributions, the *Berufsgenossenschaften* had from the start a supervisory role). The new system saw a strong decrease in work-related injuries and fatalities until the First World War – though, as we will see in other sections too, how much of this can be attributed to the specifics of the inspection system is debatable.

The "state supervision" side was from the start exercised by the federated states – and this was further reinforced by the 1949 Constitution, which reserved a number of powers to the *Länder.* Further developments of labour law included the 1973 Labour Safety Law ("*Arbeitssicherheitsgesetz"*), which required for each business to have an assigned medical doctor for occupational health, and one (or several) staff members assigned for safety (mirroring developments in Britain and France, and institutionalizing gradual developments in Germany since the 1920s). In 1996, a new Labour Protection Law (*"Arbeitsschutzgesetz"*) incorporated the EU OSH directives and principles, in particular risk assessment.

What is particularly noteworthy is how specific early decisions, and features of the legal and institutional structure, have had a defining effect on the OSH inspection system. First, *Länder* inspectorates, even though they implement the same law, are organized in very different ways (see Tilyndite 2012 pp. 166-167), and with varying staffing levels (*ibid.*, p. 176). In addition, in some of the federated states, "state inspectors perform not only OSH tasks but have functions in the areas of, for example, consumer or environmental protection" (*ibid*., p. 175). While a similar variety can to some extent be seen between different Local Authorities in Britain, the HSE provides unity in methods, and of course directly supervises "higher risk" sectors. Second, a complete parallel system of inspections by the mandatory insurers exists, with its own legal foundation (*"Sozialgesetzbuch VII"* – Seventh Volume of the Social Code, adopted in 1996, is the current framework), and a considerably higher number of inspectors than state inspectorates (see Tilyndite 2012 p. 175). Indeed, even though their purposes are defined differently (with a strong emphasis on prevention for the insurers) and stem from different laws[79], both state and mandatory insurers inspectors "have similar enforcement mandates but different tasks, organizational structures and enforcement approaches[80]" (*ibid.* p. 195). We will see in a later section that this appears to result in far higher frequencies of inspection visits, and difficulties in coordination.

United States

[78] Until 1887, these got up to around 10% of the votes in each *Reichstag* election. From 1890, the SAPD and then SPD got 20% and more. See: http://de.wikipedia.org/wiki/Reichstagswahl_1884

[79] In addition, the mandatory insurers enforce their own statutory requirements (binding accident prevention regulations), resulting in a certain level of complexity and even confusion (cf. Tilyndite 2012 p. 170).

[80] When the system was created, in the late 19th century, state inspectors were more clearly focused on rules concerning employment of children and women, and working hours and rest days, whereas mandatory insurers looked more at the technical safety issues – but this allocation of responsibilities, if it ever was clear, has long ceased to be straightforward, as state labour law has increasingly regulated technical safety issues.

By contrast with the different European cases seen above, which share a number of common characteristics at least in terms of initial timeline, the development of OSH regulations and inspections in the United States has a number of specific features – the late emergence of state intervention in the OSH sphere, the prominent role of industry actors for several decades, the choice of a radical reform path in 1970, and of a legal framework that very starkly constrains inspector discretion.

As Aldrich (2001) puts it "Before the late nineteenth century we know little about the safety of American workplaces because contemporaries cared little about it. As a result, only fragmentary information exists prior to the 1880s" – which means that the recognition of the relevance of labour conditions came significantly later than in Western Europe. For a variety of reasons, including "legal and regulatory climate that diminished employer's interest in safety" (*ibid.*) as well as economic and natural conditions, and the practice of piece rates payment, which incentivized workers to producer more, even at the expense of safety[81]. As a result, injuries and fatalities appear to have been substantially higher than in Britain, for instance (Aldrich 1997 calculates that in coal mining, fatality rates were approximately 2.5 times higher than in Britain between 1890 and 1904. Similarly, fatality rates in railroad work were approximately twice higher).

In many matters, the United States are often said to have a more "litigation-based" than "regulation-based" approach – while the general validity of such a claim can be disputed, it certainly seems to have been the case for OSH in the 19th century. Unfortunately, as Aldrich (2001) puts it: "workers injured on the job or their heirs might sue employers for damages, [but] winning proved difficult. Where employers could show that the worker had assumed the risk, or had been injured by the actions of a fellow employee[82], or had himself been partly at fault, courts would usually deny liability. A number of surveys taken about 1900 showed that only about half of all workers fatally injured recovered anything". This meant that the economic incentive was too limited for most firms to do real efforts (and investments) in worker safety.

The first responses came in form of insurance coverage against accidents, which developed in the late 19th century, some purchased individually, some provided by unions, and some by the (larger) employers themselves. The first state-led efforts were some commissions to improve the situation in railways and mines, which developed from the 1840s and 1860s respectively, but with little powers and even less results. The first noticeable improvements "began on the railroads in the 1880s as (…) railroad regulators, workers, and managers began to campaign for the development of better brakes and couplers for freight cars" (*ibid.*). The technological solutions turned out to mean "not only better safety, but also higher productivity and after 1888 [railway companies] began to deploy it". State intervention then further accelerated the process. First, through information "in 1889-1890 (…) the newly-formed Interstate Commerce Commission (ICC) published its first accident statistics. They demonstrated conclusively the extraordinary risks to trainmen from coupling and riding freight (…). In 1893 Congress responded, passing the Safety Appliance Act, which mandated use of such equipment" (*ibid.*). This led to the rapid diffusion of the new equipment, and major improvement in injuries and fatality rates for trainmen.

The next steps of state intervention in OSH took place in the "Progressive Era" between 1900 and 1914, which also saw the adoption of the Pure Food and Drug Act (1906) and of the Federal Reserve Act (1913). In 1910, the Bureau of Mines was established, but it "was to be a scientific, not a regulatory body and it was intended

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[81] E.g. the differences in types of deposits and methods of exploitation between British and US coal mining – "In Britain, coal seams were deep and coal expensive. As a result, British mines used mining methods that recovered nearly all of the coal because they used waste rock to hold up the roof. British methods also concentrated the working, making supervision easy, and required little blasting. American coal deposits by contrast, were both vast and near the surface; they could be tapped cheaply using (…) coal pillars and timber to hold up the roof, because timber and coal were cheap. (…) labor supervision was difficult and much blasting was required to bring down the coal. Miners themselves were by no means blameless; most were paid by the ton, and when safety interfered with production, safety often took a back seat. For such reasons, American methods yielded more coal per worker (…) but were far more dangerous" (Aldrich 2001).

[82] See also Stein (2003) on the difficulties of the "emerging tort of negligence", employers' and co-workers' responsibilities.

to discover and disseminate new knowledge on ways to improve mine safety" (*ibid.*). The most important step for OSH was the passing in 1908 of a "federal employers' liability law that applied to railroad workers in interstate commerce and sharply limited defences an employer could claim", and sharply increased compensation. Following up, "in 1910, New York became the first state to pass a workmen's compensation law", modelled on "no fault" compensation already in place in much of Western Europe. It "appealed to businesses because it made costs more predictable and reduced labor strife [and] to reformers and unions it promised greater and more certain benefits. (…) Between 1911 and 1921 forty-four states passed compensation laws" (*ibid.*).

As per Aldrich (2001), "the sharp rise in accident costs that resulted from compensation laws and tighter employers' liability initiated the modern concern with work safety and (…) the long-term decline in work accidents and injuries. Large firms (…) suddenly became interested in safety. (…) Managers began to look for hidden dangers at work, and to require that workers wear hard hats and safety glasses. They also set up safety departments run by engineers and safety committees that included both workers and managers. In 1913 companies founded the National Safety Council to pool information" (*ibid.*), Government agencies and universities participated in the effort. As a result, after 1910, fatality rates in railroads, steel making, and a number of other major industries (e.g. chemical) declined. There were also social and technological changes, such as a "decline in labor turnover [that] meant fewer new employees who were relatively likely to get hurt, while the spread of factory electrification not only improved lighting but reduced the dangers from power transmission". Overall, "manufacturing injury rates [went down] about 38 percent between 1926 and 1939" (*ibid.*). Improvements, however, remained uneven, particularly in smaller firms – and, in spite of progress, hazards in mining remained significant, which led to the 1941 Federal Mine Inspection Act. Other inspections, where they existed, were organized by the states. While not insignificant in many instances, they had a "relatively conciliary stance" and "saw themselves less as adversaries of industry than as technical advisers to it" (Vogel 1986 p. 232, quoted in Clark 1999 p. 97).

Against this background and early history, the adoption of the 1970 Occupational Safety and Health Act comes as a major turning point, a radical change of course. The view of backers of this new legislation was that it had been made strictly necessary by the situation with workers' health and safety, which they saw as having gotten worse. A few years after the Act's entry into force, for instance, Stender (1974) wrote: "The increasing growth and complexity of modern industry, with its sophisticated work processes and cascade of new materials, were resulting in the deaths of more than 14,000 workers and disabling injuries to more than two million others in the years immediately preceding passage of the Act. (…) In addition to the needless human suffering involved, this workplace toll constituted a significant drain on the resources of the country. Lost wages exceeded $1.5 billion a year and the total workmen's compensation cost to employers was $4.82 billion in 1970 alone. By the middle of the last decade it was apparent that the efforts of those concerned with this problem-state legislatures, industry and its safety specialists, and labor unions-had not decreased the workplace toll" (p. 641). Now, we have seen that this particular claim (that the "workplace toll" had not decreased) is false when seen in longer perspective. It is unfortunately difficult to access statistics from the decades immediately preceding 1970, so we have not been able to verify how true it was *from a shorter historical perspective*, i.e. for the decades immediately after WWII. Aldrich (2001) puts it thus: "in the 1960s however economic expansion again led to rising injury rates[83] and the resulting political pressures led Congress to establish the Occupational Safety and Health Administration (OSHA) and the Mine Safety and Health Administration in

[83] As evidenced by Smith (1972), injuries usually rise when unemployment falls because work intensity increases and many inexperienced workers are hired.

1970". It seems that there may indeed have been a plateau in the decline in injury and fatality rates in the 1950s and 1960s, at least in some sectors[84].

There was also an emergence of the "health" concerns in OSH – while injuries and fatal accidents were readily observable, the long-term health effects of many substances were poorly understood, or had been hidden on purpose, for a long period, leading to serious health effects on workers. Stender (1974) thus mentions several chemicals-related concerns: "occupational health was often misunderstood or ignored completely. Even where effective state regulation was attempted, it was necessarily limited by state boundaries. When Pennsylvania banned the manufacture, use, and storage of the chemical betanaphthylamine, an extremely hazardous substance linked with cancer of the bladder, the manufacturer moved its plant to Georgia, which did not then regulate the chemical. Industry's response was similarly ineffectual. Many large manufacturers had developed programs designed to create employee awareness of safe work habits (…) [but] few of these programs even considered the deleterious effects of toxic substances, partly because of the long studies necessary to prove a correlation between a substance and its effect on those exposed to it" (p. 642). Stender goes on to show that this concern with long-term health effects of chemicals was one of the points highlighted by the bill's sponsors, e.g. Senator Williams: "the competitive disadvantage of the more conscientious employer is especially evident where there is a long period between exposure to a hazard and manifestation of an illness. In such instances, a particular employer has no economic incentive to invest in current precautions, not even in the reductions of workmen's compensation costs, because he will seldom have to pay for the consequences of his own neglect" (quoted in *ibid.*). The reform's advocates were thus well aware of how the previous setup had achieved considerable improvements by relying on workers' compensation and economic incentives, but they considered that the system was not anymore adequate to current conditions, in particular because (i) those that invested the most in safety ended up at a competitive disadvantage (since insurance covered all workplaces and rates were set regardless of their record) and (ii) the health effects of many technologies and products were too long-term to be properly addressed through this system anyway, as the effects could happen far beyond the time horizon businesses were planning for.

This leads us to several extremely important points. First, we can see that in this case there seems to have been a combination of actual risks possibly increasing (and/or at least stopping a secular decrease), and new risks that scored strongly on the "dread" and also on the "unknown" dimensions (see Slovic and Weber 2002, p. 11) – and were also for many of them *objectively* under-addressed by current regulations and practices[85]. Second, when the United States had established worker compensation insurance as the cornerstone of its OSH efforts in the early 20th century, it had only partially copied the German system – in that it took "no fault" compensation, but not the inspection and enforcement powers of the "statutory insurers". Thus, there was a real problem of "free riding" by the least conscientious businesses, since there also was generally little (if any) link between insurance premiums and the track record of a business in terms of safety[86]. This illustrates well that, for any system intending to promote compliance and safety practices, it is essential to understand how all pieces of the system fit together. Third, context played again an important role – as these trends did not take place in a vacuum but on the contrary concerns with health and safety, and in particular with toxic chemicals, were growing outside of the workplace as well, and environmental and consumer activism were on the rise. As Clark (1999) puts it, the 1960s and 1970s "marked a major transformation of US politics, with the

[84] See CDC (1999), p. 466, for a graph of mining fatality rates, which shows precisely such a plateau between 1950 and 1970, but the time periods are too broad to identify precisely the turning points.

[85] On the policy mistakes in the field of chemical safety caused by over-optimism about long-term effects, see e.g. Blanc, Macrae and Ottimofiore 2015, pp. 61-62.

[86] This contrasts e.g. with the French system for mandatory insurance of construction contractors – where premiums are based on the risk of the project *and* on the risk profile of the company being insured (research by F. Blanc and G. Ottimofiore for a forthcoming World Bank Group publication).

emergence of new social movements pressing for change in fundamental social values in the areas of civil, welfare and consumer rights (…) and environmentalism" (p. 98).

These elements led to a reform coalition where "US advocates for occupational health and safety reform had ties to the contemporaneous environmental and consumer movements" but where, on the contrary, labour unions had limited influence – which helps explain "why a statutory approach to the occupational health and safety 'problem' was pursued" despite US unions' "wariness" towards "legislative solution for 'industrial' issues" (*ibid.,* p. 99). The reform design adopted was aimed at preventing by all means "regulatory capture" and reformists, considering that "political influence of industry" had made previous efforts ineffective, were "resistant to any regulatory solutions that institutionalised collaboration between regulatory officials and industry representatives" (p. 99). In this new system, "conflict was deliberately designed [in] (…) and discretion (…) was deliberately designed out" (Vogel 1986 p. 255 quoted in Clark 1999 p. 98). A small example can illustrate this approach – on advance notification. While the 1947 ILO convention (of which the United States are *not* a signatory, but which we use here simply as reference point) requires that signatories give the *right* to inspectors to enter premises at any time, unannounced, the 1970 OSH Act goes a step further. Indeed, not only did the Act authorize "OSHA compliance officers (inspectors) to make unannounced inspections of virtually any establishment" but "anyone giving advance notice of an inspection without authority from OSHA will, if convicted, be fined up to $1,000, imprisoned for up to six months, or both" (Stender 1974 p. 645). The rationale for this, of course, is that "if employers received advance notice of an inspection, they would tend to make cosmetic corrections of hazardous conditions, which result in no more than momentary protection for employees" (*ibid.*). Now, in reality, OSHA standards usually require considerable investments for compliance, and short-term "cosmetic corrections" would be very unlikely to bring an establishment from massive violations to complete compliance, but this illustrates well the spirit of the Act. It is also worth noting that, precisely because "discretion was designed out", OSHA inspectors are far more restricted to looking at "objective" and "material" aspects than inspectors in, say, the HSE, who can look more at practices, how workers and supervisors understand their roles, how risk-assessment is conducted etc. – and thus could on this basis see beyond any "cosmetic" improvements anyway[87].

Short conclusion

Overall, all the OSH cases reviewed above show how much the scope and type of regulatory intervention, structure, powers, methods and resources of inspection agencies all depend on a number of factors – perception of risks as mediated by the culture of the times, institutional and political context etc. As the effects of initial decisions can still be seen many decades later, many aspects of the structures and practices of inspection institutions end up having far more to do with contingent historical trajectories than with a science-based risk assessment.

b. The emergence and development of modern inspectorates - Food Safety

As we have seen above, some of the earliest regulations and reported cases of "inspections" applied to food – aiming at preventing fraud, adulteration, ensuring that consumers are not abused, but also not poisoned. Thus, controls of food safety and food labelling have deep roots in the past. In spite of that, and in sharp contrast with the OSH field, there are few research works looking at the origins and developments of food regulations and food control functions. Most of the research work is not "about" food safety but "in" food safety – microbiological, chemical, epidemiological work, looking at pathogens, contaminants, prevention

[87] Authors' interviews with officials in HSE and UK Better Regulation Delivery Office. See also HSE Enforcement Management Model (discussed in later section), available at: http://www.hse.gov.uk/enforce/emm.pdf.

measures etc. The issue appears to be simultaneously far less contentious than OSH (where debates between advocate of more or less regulation have fuelled a considerable amount of writing), and more technical (at least in comparison with the "safety" part of OSH, not with the "health" side), thus possibly "scaring away" lawyers, social scientists and economists. It may also be that the topic is simply too little known to attract much interest – whereas "hotter" food safety issues, particularly when it comes to whether certain practices, additives etc. are "safe" or present "unacceptable risk", have ignited major disputes (and significant research efforts). What historical research on food regulation and its enforcement is mostly focused on the United States Food and Drugs Administration, its origins and development – which makes our aim to compare different cases difficult to reach.

Because of this scarcity of sources, we will limit ourselves to a relatively cursory overview of some of the most relevant aspects of the historical development of food inspectorates, in particular inasmuch as they help to understand lasting differences in practices, and challenges in the implementation of the most modern approaches – with more details on the United States case, by virtue of the larger volume of accessible research (and of its strong relevance to our central questions). This overview will rely to the extent possible on some of the most significant publications, e.g. Wagstaff 1986, Young 1989 and 1992, Coppin and High 1999, Koolmees 2000, Theves 2000 and 2002, Ferrières 2002, Shears 2008, Lásztity *et al.* 2009, Hardy 2010, Manion 2012 *et al.* – but these cover more heavily the United States than other countries, and rarely cover the control and inspection questions in depth. Thus, we have supplemented them with a combination of public information (websites of the relevant agencies and institutions), and on authors' repeated interviews and discussions with regulatory officials involved in food safety in all the countries covered here.

We will first briefly present the timelines and most salient features of several food safety inspection systems (the United States and Britain in greater details, France with less details on the timeline, the Netherlands more cursorily – and we will also add a short discussion of post-Soviet systems), as well as the influence of international organizations (the *Office International des Epizooties,* OIE – as well as UN FAO and UN WHO) and of the European Union (which, in this area, has had a major impact), then briefly consider the factors involved in the emergence and development of different structures and approaches (and the way these factors, including "crises", present similarities between past centuries and the most recent period). From this, we will consider three transversal themes: the interaction between food regulatory inspections and science (in particular the limitations of science at the time of regulation, and the difficulty to fit new science into old structures), the difficulty to settle disputes as to the effectiveness and relevance (or lack thereof) of these inspections, and the question of how risk is and has been understood, assessed and prioritized.

i. Emergence and development of food safety inspections – introduction

At different points in the 19th and early 20th century, most of what then counted as the world's "developed" economies established systems of food control that featured a stronger emphasis on safety as had been the case until then, a new vocabulary, and new methods. The extent to which these new controls were in fact really "scientific" increased gradually – the first decades had maybe a scientific *ambition* but not really a scientific content (or the science was simply too weakly developed to be of use), this changed from the 1900s at the latest, but considerable gaps in understanding remained. Successive decades, in particular post-WWII, brought major improvements in our understanding of food-borne diseases[88]. These led to significant changes in the regulatory and institutional frameworks – but also revealed weaknesses and tensions in the structures

[88] Which, we would argue, should make us *modest* about our assessment of our current level of understanding – it is likely that much will be discovered in future, leading to re-assessments of risks.

inherited from earlier steps, not all of which have been solved to date (far from it), showing once again the significance of path dependence.

ii. Food Safety in Britain

Early developments – Britain as a "precursor"

As in the field of OSH, Britain was in some ways a precursor in food control regulation and inspections (but, as we shall see, this "early mover" status also included significant shortcomings). In response to growing reports and concerns about food "adulteration", and complaints and worries about "nuisances" (e.g. from slaughter), a series of Acts of Parliament were adopted, some of them accompanied by the creation of new types of inspectors. "Nuisances" came first, driven by the growth of "hygienist" conceptions: "Edwin Chadwick, a Poor Law Commissioner, conducted an inquiry into the causes of poverty which concluded that people often became poor because of ill health due to a bad environment. He believed that improving sanitation was the key to breaking this vicious circle. Chadwick led a vigorous campaign for change (…) resulting in the Public Health Act 1848. The Act provided for the appointment of Inspectors of Nuisances (…) in areas of need[89]". However, the scientific basis for "nuisance inspections" was tenuous, hiring of inspectors at the discretion of local authorities, and their effectiveness mixed at best[90]. More clearly focused on food (but also on drugs) was the "first Food Adulteration Act (…) passed" – but several key points were missing, "most importantly perhaps the compulsory appointment of food inspectors" (Shears 2008 p. 126). The real creation of food safety[91] inspections in Britain came in 1872 with the "Adulteration of Food and Drugs Act strengthening enforcement powers by requiring the appointment of a public analyst and empowering local enforcement officers to take samples and bring prosecutions" (*ibid.*). This was followed by the 1875 Sale of Food and Drugs Act which "created two basic adulteration offences: the mixing of injurious ingredients; and selling to the prejudice of the purchaser a food not of the nature, substance or quality demanded. (…) The Public Health Act 1875 gave local enforcement officers powers to inspect and seize." (*ibid.*) The entire food safety inspection system in Britain was to remain based on local authorities' inspectors, first called "Public Sanitary Inspectors" and later "Environmental Health Officers", organized in an Association in 1883 (since 1984 the Chartered Institute of Environmental Health), and with gradually increasing qualification requirements (a certificate was required for London in 1891, then this became the norm gradually throughout the country, and the level of qualifications increased throughout the 20th century)[92].

While, as elsewhere, the initial remit of these inspections included food fraud even when no adverse effect on safety was expected, their focus was clearly on health, and issues of consumer fraud not involving safety were to become over time the purview of Trading Standards Officers (also working for Local Authorities). One of the most marked specificities of the model was that, in England and Wales at least (though not so in Scotland), veterinarians were mostly excluded from the build-up of the inspection services and practices. Indeed, "Britain's public health administration" as first between 1850 and 1875 "was dominated by medical men and medical models of human disease (…) [that] medicine viewed the opinions of veterinarians with suspicion" (Hardy 2010 p. 371). This early feature was driven both by the relative weakness of the veterinary profession in comparison with other countries in Western Europe (e.g. the stronger prominence of veterinary medicine in France where the first royal veterinary schools had been founded in the 1760s), and by what was to be a lasting feature: "the popular perception that animal disease constituted a very small risk to human health in

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[89] Chartered Institute of Environmental Health (CIEH) website – "history" section, accessed at: http://www.cieh.org/about_us/history.html

[90] See above on their lack of effectiveness in the context of the 1866 Cholera epidemic in London.

[91] In terms of their purpose, and regardless of their scientific basis and effectiveness, or lack thereof, at the time.

[92] See CIEH website at http://www.cieh.org/about_us/history.html

Britain" (*ibid.*). This situation also contrasts with the US's where, as we will see in the next section, veterinary inspections were set up at the federal level even before the Food and Drug Administration's creation[93].

Attempting to understand the weak role of veterinary control in Britain

This difference is important in understanding the contrasts between the UK and "continental Europe" systems, in both its relative strengths and weaknesses – and thus, understanding its roots is relevant to our research. The origins of this dominance of "medical men" and of the veterinarians' weakness appear to lay in a combination of specific aspects of the British market, both cultural and economic, combined with path dependence.

First, the British market, until World War II, was wealthier than the rest of Europe, with higher meat consumption, and more of it coming from imports. At the same time, eating habits contributed to relatively safer conditions: "the country felt wealthy enough to dispense with [meat hygiene controls], priding itself on the production and import of quality meat, and (…) was comparatively free from meat-derived human disease owing to the British preference for well cooked meat, and to livestock more or less free from such conditions as trichinosis and beef measles (…). In other words, tuberculosis apart, animal infections had not constituted any serious threat to human public health in Britain in the period before World War II" (Hardy 2010, p. 374). In addition, the country's relative wealth meant that there was a far greater importance of imports, and as a result more emphasis on import than on domestic controls: "meat consumption in Britain was[94] amongst the highest in Europe (…) The market share of imported meat rose from less than 30% in 1880 to a peak of around 50% by 1923 (…). Precisely during this period, major meat exporting countries around the globe, as well as most European states, were implementing meat inspection systems under veterinary supervision (…). By 1930, Britain's imports came from countries whose exports were certified by qualified veterinary inspectors, and verified by meat inspectors at the port of entry. (…) Meat coming into Britain was examined and passed as fit for human consumption according to the rules of 'meat hygiene', a more rigorous system than that imposed on home-killed meat[95]" (*ibid.,* p. 377).

A second aspect that seems to have driven this weak role of veterinary control is trust. Whereas there is a general assumption that confidence in the effectiveness of control is an important factor in securing trust in the market, it can be observed (e.g. in the US's case, see next section) that the "demand" for inspections only arises when pre-existing trust is on the decline because of changes in the structure of the market. In Britain's case, it seems that trust in the market remained relatively strong as far as meat is concerned, for a variety of cultural factors, and thus the push for more regulation remained rather weak for a long time. This is at least what research on consumer trust in Britain can suggest: underlying trust in the mechanisms of food control may provide the key to this apparent British indifference to germs in meat and milk. One recent study, which argues that trust in food is dependent on the way in which a given country or government deals with food issues, found high levels of trust in food among modern Britons, despite the food crises of the years 1985-2000 (Kjaernes, Harvey and Warde, 2007, 1, 60-1). The British consumer, this study noted, trusted her local butcher, and advice given on food labels (…) In the nineteenth century, Keir Waddington has argued, food consumption was shaped by material concerns, standards of living and domestic technology rather than by medical or press reports and the fears they engendered around food and disease (Waddington, 2010, pp. 51-

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[93] Even though Hardy (2010) lists also the US as having a weaker veterinary involvement than most European countries in food safety, this involvement has clearly been far earlier, and stronger, than in the UK.

[94] Again, before World War II.

[95] Exactly how and at which stage these controls happened changed over time, of course: "Domestic supplies were augmented initially with live animal imports, and veterinary surgeons became involved with state efforts to limit the associated import of animal diseases following the major outbreak of cattle plague in 1865 (…). By the end of the century, animals were being slaughtered on arrival at the ports; and, by this time, developments in transport had led to a significant shift to the import of chilled and frozen meat" (Hardy 2010, p. 376)

71). This seems to have been especially the case in respect of culturally prized staples like meat, where actual food poisoning was only rarely associated with the meat itself rather than with manipulated foods (pies, sausages), and where episodes of more or less minor gastric disturbance were a commonplace experience" (*ibid.,* p. 375). None of this appears entirely conclusive, but we can assume that cultural and social factors played a role in making meat safety concerns relatively less prominent in Britain.

Finally, once the original set up of the system started being in place, path dependence ensured it remained mostly in place going forward, i.e. that veterinary control remained secondary for in-country meat trade: "medical men were the managers of Britain's public health administration, and their loyalties lay with their staffs of trained sanitary and meat inspectors, who vigorously resisted the claims of the veterinarians" (*ibid.,* p. 372).

Limitations in effectiveness – pressure for change

Overall, not only were veterinarians "marginalized"[96], but the overall level of supervision of the meat supply was, for a long time, markedly more relaxed than elsewhere in Europe – where national veterinary supervision and systematic inspection in slaughterhouses were introduced in many countries from the late 19th century. Whereas "Belgium and Norway passed meat inspection acts in 1891, and their example was followed by Luxembourg (1892), Germany (1903), France[97] and Spain (1905), Austria-Hungary (1908), Switzerland (1909) and Denmark (1911)", England focused on regulating imported meat "with Merchandise Marks Acts between 1887 and 1953, and for the inspection of imported meat with the Public Health (Foreign Meat) Regulations of 1908, but placed that responsibility in the hands of customs official and medical men" (Hardy 2010 p. 377). It was assumed that domestic supply was safe – which was, in fact, a somewhat heroic assumption.

Indeed, "in general, slaughtering in England and Wales was conducted in small, local slaughterhouses, of which there were said to be some 15,000 on the eve of World War II. (Bywater, 1948, p. 219). Many of these were in rural areas which were very difficult to regulate systematically. At any point when slaughtering became concentrated in a particular locality, either on grounds of economy of effort during the Great War, or through the very gradual movement towards the establishment of municipal abattoirs, startling increases in the number of carcases being condemned were noted" (*ibid.,* p. 378), which strongly suggests that problems existed, but control was too infrequent and unequal to consistently detect them[98]. This also raised, as Eleni Michalopoulou has noted, serious questions of market distortion between producers and traders in more strictly controlled areas, and others operating in loosely supervised ones. This was only addressed at the end of the 20th century with the development of a national meat hygiene service, and then the creation of the Food Standards Agency.

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[96] "In Scotland, the veterinary supervision of meat supplies was introduced in 1897, and local authorities in England and Wales, slowly and in piecemeal fashion, began to do likewise; by 1937, local authorities were employing some 220 full-time and 700 part time veterinary inspectors" (a trend that was to be reversed after the establishment of a national veterinary service in 1938, which led to a decrease in the number of local authorities' veterinarians) – but "medical men were the managers of Britain's public health administration, and their loyalties lay with their staffs of trained sanitary and meat inspectors" (Hardy 2010, p. 372).

[97] Cf. also Koolmees 2000 – passing laws did not always mean creating serious inspection services – while Belgium did create a real veterinary inspection, in France it was only present in major cities – see below.

[98] Indeed, "when, during the war, the Home Counties kill was concentrated in the London borough of Islington, and the private slaughter houses closed, the amount of meat condemned rose from some 2-300 tons per annum to the 'appalling figures' of between 1,600 and 2,000 tons (…). A similar situation arose when the city of Sheffield opened a new public abattoir in the late 1920s: the amount of diseased meat detected shot up by 80%. As the abattoir's designer noted, the only possible inference was that this was the amount previously eaten, mostly by the poorest classes" (Hardy 2010, p. 378). Similarly, worrying issues are noted in an unpublished presentation by Eleni Michalopoulou, University of Liverpool, School of Veterinary Science, e.g. the very poor conditions even in centralized slaughterhouses (e.g. Manchester in early 20th century), and unequal levels of inspection, unequal stringency in seizures etc. See: http://www.northwest-zoonoses.info/writedir/963aRegulation%20of%20food%20controls_Eleni%20Michalopoulou.ppt

Increasing international "benchmarking" and harmonization were the forces that started to generate changes, as they showed not only the specificity, but the overall laxity of the system: "by the mid-1950s, when a survey of meat hygiene practices in Europe was conducted under the auspices of the World Health Organisation, Britain was the only country (…) which did not normally carry out ante-mortem inspection by qualified veterinary surgeons, and (…) [Scotland excepted] where the post-mortem examination of animals slaughtered for commercial purposes was not obligatory by law" (*ibid.*). Only during WWII was 100% inspection achieved in slaughterhouses, and this was quickly reversed by the reopening of a vast number of private premises once rationing ended.

Growing evidence of contaminations and outbreaks (in particular caused by *salmonella*) in the 1950s led to the Slaughterhouses Act 1958 and several sets of successive regulations and legal amendments (including to empower local authorities to "close private slaughterhouses under certain conditions"). In particular, "the establishment of the Public Health Laboratory Service (PHLS), initially as an emergency war-time measure, now led to more systematic and rigorous scientific investigation of many of these outbreaks" (*ibid.,* p. 381) – which, in turn, built up knowledge and evidence, and led to increased action. This shows an important link between better detection ability and increased demand for control, that we will also observe in other cases (e.g. the US food safety case in the next section). The new evidence meant that a "chain of infection" had been "demonstrated from the farm to the consumer, and abattoirs (…) shown to act as a focal point for the transmission of infection among animals awaiting slaughter" (*ibid.,* p. 383), which led to increased attention paid to the problem. In addition, effectiveness was hampered by the lack of continuity in food chain supervision: "it was pointed out that veterinary surgeons were greatly handicapped in their work with animal disease by the unavailability of slaughterhouse evidence that could be correlated with live animal statistics" (*ibid.*)[99].

While the number of slaughterhouses was reduced, and the physical premises much improved, practices remained problematic, and the lack of a link between veterinary surveillance and pre-slaughter inspections also created a gap in surveillance[100]. Additional regulations in the 1960s only brought about limited change (*ibid.* pp. 384-385). Even Britain's joining the EEC did not bring major changes initially, as European regulations in the 1970s only covered exports. This changed radically with the European Single Market, and the unfolding of the Bovine Spongiform Encephalopathy (BSE) crisis[101]: the Fresh Meat (Hygiene and Inspection) Regulations 1992 (adopted in view of the Single Market start date in 1993) led to 300 local authorities establishing full meat hygiene services (*ibid.* p. 387). The worsening of the BSE and nvCJD scare then led to "the establishment of the Meat Hygiene Service in April 1995, in which veterinary surgeons played a central role, local authority veterinarians being transferred into the new service" (*ibid.*).

The BSE crisis, the creation of the Food Standards Agency, and the modern food safety system in Britain

The considerable loss of credibility caused to the system by the BSE crisis (and other scandals) then led to another radical reform: the creation of the Food Standards Agency (FSA) in 2001. The Government vision was of "an Agency with a clear focus on protecting the public and a powerful statutory remit across the whole food chain, at arm's length from Government and independent of sectoral interests, governed by a Chairperson

[99] An early example of the importance of "Farm to Fork" control, that we will discuss in the EU section later on.

[100] Hardy 2010 p. 383: "it was pointed out that veterinary surgeons were greatly handicapped in their work with animal disease by the unavailability of slaughterhouse evidence that could be correlated with live animal statistics" – as we will discuss further, all models of effective food safety inspections emphasize the importance of achieving unified surveillance over the food chain.

[101] The BSE scare *alone*, as previous food scandals too, had not been enough to profoundly change the system – it led to limited changes only: "Authorised Officers (Meat Inspection) Regulations 1987 included veterinary surgeons among the personnel permitted to undertake such duties, along with Environmental Health Officers and qualified meat inspectors. Responsibility for meat inspection remained in the hands of the local authorities" (Hardy 2010 p. 387).

and Commission appointed openly on the basis of their personal standing and expertise, operating under guiding principles which put the interest of the public unequivocally as the first priority, able to make public its views on any issues related to food and public health, taking a strategic view of food safety and standards issues across the whole food chain, with wide-ranging powers to commission research and surveillance, propose legislation, monitor food law enforcement and take action to remedy problems, with a clear responsibility to provide the public with information and advice[102]". The FSA took over the Meat Hygiene Service as one of its divisions, and assumed a role of guidance and supervision on the inspection and enforcement work of local authorities (which supervise the food chain "downstream" from primary production), of coordination and sharing of information, as well as of scientific risk assessment.

This historical process has resulted in a structure where nowadays control responsibilities are divided between local authorities on the one hand ("lower tier" authorities, e.g. district councils, are responsible for food safety and hygiene - there are 406 of these - and "upper tier" authorities, e.g. county councils oversee food labelling), and central structures on the other[103]. Local authorities in fact handle most of what would have been the province of the "hygienists" or "sanitarians" in earlier times[104] - and are responsible for the food chain "downstream" from primary production (processing, transport, handling and storage, sale, catering etc.). Primary production is controlled by the Meat Hygiene Service (part of the FSA), animal health and welfare are supervised by several agencies under the Department for Environment, Food and Rural Affairs (DEFRA), and other parts of DEFRA supervise plant protection and phytosanitary issues generally, but specifically safety of phytosanitary chemicals is overseen by the Health and Safety Executive (HSE)[105]. In spite of the creation of the FSA, and of some consolidation efforts within DEFRA, the set-up has remained to a large extent as "inherited" from earlier times. Thus, efforts to make regulatory supervision and enforcement better coordinated, more consistent, built on a stronger risk analysis have proceeded without affecting the structure, using different mechanisms (guidance, evaluation, Primary Authority scheme etc.) that we shall describe further in this research.

The creation of the FSA appears to have been, overall, successful. Anecdotal evidence can be taken from the fact that the reaction to successive food-related "scandals" or "scares" (e.g. the 2013 horsemeat scandal) have not given rise to the same loss of confidence as in the 1990s – but also from the fact that these scares were simply far less significant in terms of danger to human health. The FSA also was found to enjoy strong public support, and rumors that it may be abolished in 2010[106] did not come true (though the Government did take away some of its responsibilities relating to nutrition – which in turn led Scotland to create its own "Food

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[102] *The Food Standards Agency, A Force for Change*. Command Paper presented to Parliament by the Minister of Agriculture, Fisheries and Food, January 1998 – available at https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/265718/fsa.pdf

[103] For details on the basic FSA/Local Authorities split see the FSA website: https://www.food.gov.uk/enforcement

[104] As we have noted above, this is a feature of the British system that is relatively unusual in the EU, and among developed countries – but a number of other countries around the world have food inspection systems with a strong prominence of sanitary inspectors with a medical background – e.g. most of the former Soviet Union (where, by contrast with Britain, inspectors are typically MDs, and not environmental health officers).

[105] We have to clarify that this presentation is an over-simplification, based on public information and on many clarifications given directly by staff of the UK Better Regulation Delivery Office. Exposing full details would take much space and time, and add little to the essence. One point of importance, however, is that the exact set up differs in each constituent part of the United Kingdom, and is evolving. The latest change is that Scotland now has its own Food Safety Scotland agency, instead of the FSA, with the same remit as the *original* FSA remit (the UK Government having in 2010 taken the decision to transfer responsibility for nutrition and food labelling and standards in England from the FSA to the Department of Health and the Department for Environment, Food and Rural Affairs – a decision that was widely seen as following industry complains about the FSA being "too aggressive" – led to the Scottish Government deciding to create a new agency for Scotland, with the full original mandate) – see https://www.food.gov.uk/about-us/new-scotland and also http://www.foodstandards.gov.scot/about-us.

[106] The discussion was well covered by the media at the time – see e.g. in the *Guardian*: https://www.theguardian.com/politics/2010/jul/11/food-standards-agency-abolished-health-secretary and *Reuters*: http://uk.reuters.com/article/uk-britain-food-idUKTRE66A1AI20100711. The Chair of the FSA reacted through an open letter to the Health Secretary: http://www.food.gov.uk/sites/default/files/multimedia/pdfs/board/letter140710.pdf

Safety Scotland" agency, with nutrition included in its mandate[107]). Rumors of the FSA being abolished after the Conservative Party's 2015 electoral victory also met with negative reactions[108], and were not followed up in fact. Existing evaluations also conclude broadly to the FSA's success in improving food safety governance, enforcement effectiveness and consistency (see Flynn *et al.* 2004), and to its ability to do so with innovative approaches, and a more "growth-friendly" approach (see BRE, BERR and NOA 2008). We can thus conclude that the FSA's set up and activities appear to have been successful, as have been reform efforts in the local authorities' practice in the last decade, and there is reason to consider the "new" British system as a very interesting example of risk-based and risk-proportionate inspections and enforcement, and of "responsive regulation"[109]. It remains, however, that the system has many features that result clearly from historical accident and not from rational design, and have long hindered its effectiveness and development, and that only strong external pressure and major crises were able to bring about deep changes. On the positive side, however, one can argue that the reliance on local authorities "environmental health officers" (as they have been known for the last few decades) has considerable advantages: more flexibility and ability to experiment and innovate in methods (compared to a centralized system), more information and resource sharing between different, related inspection fields (food safety and OSH, which environmental health officers both supervise, but also trading standards, which are controlled by other specialists, but as part of the same enforcement services of local authorities). Thus, one should not look at idiosyncrasies in structures only as a negative – but clearly as evidence that the shapes and functions of inspection bodies how much to history, culture, institutions, and little to rational planning.

iii. Food Safety in the United States

While discussions of adulteration and the risks it created to health were intense, and roughly contemporary with the same concerns in the UK, the development of regulation and inspections took a very different route – and, overall, was significantly slower and difficult. The specific features taken by the regulatory framework and the inspections system in the US can, it seems, be traced back to a significant extent to their historical development – starting from a background of purely municipal/local regulations (as in much of Europe at the time), but with a somewhat slower and more conflicted development of "national-level" intervention (with the tension of whether this should mean "state" or "federal"), and successive major turning points in the 20th century.

Early History: controlling export quality to build trust

The first rules and controls applying to food appear to have been aimed at ensuring exports were of adequate quality, and thus the exporting city or region (colony, state) did not lose export markets. The risk that was being addressed was that of losing market share, and thus precious income. As Young (1989) puts it, in the 17th century, "officials were far more concerned with the city's commercial reputation than with what the citizens ingested" – for instance, Massachusetts "began to inspect exports of fish, beef and pork routinely (…) in 1641" (p. 35). Even though Young also writes that "legislatures in British American colonies imitated statues earlier enacted in the mother country seeking to protect the purses and safeguard the health of their citizens"

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[107] See an archived FSA web page on this creation: http://webarchive.nationalarchives.gov.uk/20150624093026/http://www.food.gov.uk/about-us/new-scotland

[108] See article in *Environmental Health News*, the magazine of the Chartered Institute for Environmental Health: http://www.ehn-online.com/news/article.aspx?id=14246

[109] One point to note is that the FSA's creation and demonstrated independence, and the overall perceived success of the reforms, have managed to re-establish public trust in food safety regulation, which had been dented by the BSE and other crises. The high level of trust is noted in Kjaernes, Harvey and Warde 2007. The interpretation of this being because of the FSA's role and overall changes in the system is not necessarily proven, but is one widely shared by current and former Government officials we interviewed.

(p. 3), the main focus in terms of controls appears to have been on exports. This shows the intimate relationship between the establishment of inspections and the need for establishing trust. Local commerce and food supply clearly were perceived as inherently more "trustworthy", better known, less risky. Imports from distant locations were where trust could break down – and where inspections could help safeguard or restore it.

Drug regulation as a precursor of food regulation – the "adulteration" issue

The first half of the 19th century seems to have seen rather a loosening up of regulations than their strengthening, with a combination of democratic and *laissez faire* trends resulting in the United States being most probably one of the most lightly regulated countries in the North Atlantic space. An example of this is the trend in health care and drugs regulation (which, in the United States, has its history tightly linked to food regulation). Whereas, in the early years after the Revolution, the "patrician elite" of doctors educated in the first medical school "used their prestige and power to strengthen (…) a licensing system to control admission to their profession", these restrictions came under strong criticism. As a result "opponents of orthodoxy swept licensing laws from the statute books" (*ibid.,* p. 22).

What brought back regulations and control efforts was the fear of *adulteration* (very much like what was observed in the United Kingdom). Scientific and technical progress was one of the driving forces for this - "American scientists adopted the ever-improving European techniques of analytical chemistry (…) which advanced the art of detecting adulterants beyond the centuries-old organoleptic tests" (*ibid.,* p. 8). Tools were now available, which enabled scientists to ascertain (to some extent) whether a product was indeed what it was advertised to be. The first efforts to fight adulteration focused on drugs – and relied on a treatise published in 1846 by Dr Lewis Beck that purported to show the extent of adulteration (particularly of imports), as well as the means to detect it (*ibid.,* pp. 9-12). There does not appear to have been actual reports of *adverse effects* of this adulteration, at least nothing that could pass as even rudimentary statistics showing effects on life and health. Indeed, while science had made progress in chemistry, it had made significantly less in medicine, and the adulterated medicines were judged a danger from the perspective of medical theories which were mostly to be proven wrong later on. Dr Oliver Wendell Holmes Sr. (the father of the later Supreme Court Justice) famously wrote: "I firmly believe that if the whole *materia medica*, as now used, could be sunk to the bottom of the sea, it would be all the better for mankind – and all the worse for the fishes[110]" (quoted in *ibid.,* p. 19). It is likely that much adulteration was indeed dangerous (*ibid.,* p. 12) – but it is noteworthy that the fight for regulation was based more on the availability of detection tools, than on an observed public health crisis.

The first attempt at regulating drug imports was a 1848 law establishing border controls, but its enforcement was difficult and haphazard, and unscrupulous traders could always go to another port "at which the examiner was more lenient" (*ibid.,* p. 15). Then, "when poor enforcement kept that [1848] law from being effective, organized pharmacy launched a new attack on drug adulteration by reviving state laws (…) Enforcement, however, was feeble" (*ibid.,* p. 31). Then, during the Civil War (in a time when the effectiveness and safety of drugs was of course a major concern), Congress enacted "a law aimed at banning adulterated drugs offered for import" (*ibid.,* p. 3). All these laws were limited in their effectiveness by the weakness of enforcement means – one also is brought to wonder to what extent these issues appeared to be a serious concern to the public at large, as opposed to the medical professionals that were pushing for their adoption – indeed, regulating the trade and sale of drugs was linked to a large extent to chemists, doctors and pharmacists trying to strengthen their social and economic status (Swanson 2011, p. 339).

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[110] He made exception for opium (clearly and effective medication, but which we owed to nature), and for wine ("which is a food", he added, and for which doctors could thus claim no credit). He led an ongoing fight against "massive bleeding and purging" (*ibid.*, p.21), but was very much in the minority at the time.

Key drivers of early efforts at food regulation

While the first efforts at strengthened regulation focused on drugs, foods were not very long to follow – indeed "throughout much of the nineteenth century, the boundary between food and drugs was porous" (*ibid.,* p. 341)[111]. Again, the successive efforts at promoting stricter regulation, and the regulations effectively adopted, were largely linked to the development of control methods, to commercial interests, and to conceptions of disease and health that were later often disproved. Infectious diseases were of course widespread (and among them a large amount of food-borne diseases), but there is little evidence of a link between outbreaks and regulation. We will look briefly at each of these drivers of regulation.

The emergence of modern methods for chemical analysis clearly was a critical factor in the push for more food regulation: "microscopes and lactometers offered enhancements to traditional ways of seeing based on the intuitive knowledge of the dairyman or housewife. But chemistry, that is, laboratory analysis of compounds, offered an entirely new understanding of both food and drugs. In the laboratory, any food or drug could be analysed for its constituents" (*ibid.,* p. 345). Indeed, not only did the new chemistry offer tools to identify adulteration, it also "created a new ontology of food and drugs" by allowing to define them based on a "cellular and molecular understanding" (*ibid.*). Selling consumers anything else could be presented as abuse – not necessarily endangering their health (though this was often argued), but definitely defrauding them financially.

Commercial interests did contribute powerfully to the development of food regulation and control –not necessarily always the consumers' best interests, but rather that of groups of producers and traders. In practice, "although most of the rhetoric of regulation addressed itself to issues of nutrition and health, most of the actual regulation addressed itself to competition" (Coppin and High 1999, p. 18). One of the earliest focal issues for food regulation was the "dreaded" oleomargarine (a French invention, followed by successive similar products developed by American industrialists) – dreaded not because of its health effects, but for its effect on sales of butter. Thus, the margarine regulation fight pitted dairy producers (supported by a number of scientists and officials, whose views and/or interests coincided with theirs) against oil-seeds farmers and margarine processors. Arguments were that margarine was not natural – but "Wiley [who was to be the lead inspirator of the 1906 Pure Food and Drugs Act] used the term natural not as a scientific term, but as an emotional term that commended products of which he approved" (*ibid.,* p. 32). The words of a deputy food commissioner for Connecticut, working on the enforcement of a new law regulating margarine, are telling: "we are trying to make everybody believe we are doing them a favor by enforcing the oleomargarine law" (*ibid.,* p. 26). Low-income consumers clearly were ready to buy the cheaper product (margarine)[112], and dairy production was losing considerable market share. In the end, the fight between two lobbies resulted in a 1886 Act of Congress "placing a tax of two cents per pound on margarine and requiring license fees (…) Although burdensome, the legislation did give margarine official recognition as a food product" (*ibid.,* p. 32). Overall, the "consumer information" or "consumer protection" driver of regulation was (and has remained) ambiguous from the onset. On the one hand, "consumer advocates would increasingly identify knowing foods as a problem, eventually calling for federal regulations setting standards for a multitude of foods, particularly those sold in packaged and/or processed forms. A pickle, it turned out, could be defined and known scientifically[113]"

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[111] This connection between food and drugs has a long history – cf. Ferrières 2002 pp. 38-42, 105-113, 364-369 etc.

[112] Indeed, the very persistence of massive adulteration on the market strongly hints to demand for these products: "given the large percentage of income that they spent on food, workers often chose the cheaper cut of meat (…) even goods that were classified as adulterated found a market if the price was low enough" (Coppin and High 1999, p. 26). Note that once again "adulterated" was far from meaning *ipso facto* more hazardous than other foods (which were themselves often unsafe given problems with hygiene, preservation etc.). On demand for cheaper (even adulterated) foods see also Alsberg 1921 p. 213.

[113] Margarine was one of the first foods thus regulated. The FDA was to adopt many standards defining what given food names were to cover starting from the 1930s (see Swanson 2011 p. 365). Many other countries, and the EU, were to follow the same approach.

(Swanson 2011, p. 346). On the other hand, in these early times of food regulation development, "although most of the rhetoric of regulation addressed itself to issues of nutrition and health, most of the actual regulation addressed itself to competition" (Coppin and High, p. 18) – and the strongest forces seem to have been those of commercial self-interest.

Another important area of early food regulation, milk, would appear at first glance to have been more driven by safety concerns (and thus more in line with our modern understanding of food safety regulation, and with the official pronouncements of proponents of regulation) – but a closer look makes this seem less of a clear case. Milk has long held a particular place in North-Western European and North American food culture[114] - and in the 19th century fresh milk was the only substitute to breastfeeding for infants. Because of its inherently high epidemiological risk (a warm, nutrient-rich liquid is just about the most conducive medium for bacteria growth), milk was certainly a major factor in food-borne disease outbreaks (and consecutive deaths) in the 19th century – in fact, even before the science to explain it (Pasteur's and Koch's discoveries in particular) emerged, observation of epidemics origins and spread led to the conclusion that milk was involved in a number of them – "the first typhoid fever outbreak traced to milk was in the year 1857, in Penrith, England" (North 1921, p. 247). In this context, it is not surprising that some early efforts to impose new rules and controls focused on milk. In New York City in the 1830s, a "crusader against impure milk", Robert M. Hartley, launched a campaign against "swill milk" – milk produced by cows held in stables adjacent to alcohol distilleries in the city, and few "swill", the remnants of fermented grain and malt used for distillation. He saw "distillery milk as the primary cause of death among slum children" (Young 1989, p. 36) his arguments combined religious piety, "common sense public health" and compassion. A 1848 report by "a committee of the New York Academy of Medicine (…) blamed swill milk for the high infant death rate in the city" (*ibid.*). Then in 1858, Frank Leslie's Illustrated Newspaper launched a "major continuing campaign" against swill milk – with pictures that attempted to "depict the filth of the stables" (*ibid.,* p. 37). While conditions depicted by Leslie's reporters were indeed quite gruesome, they went further and "quoted physicians reiterating the earlier charge that distillery milk was the leading cause of infant death" (*ibid.,* p. 38). The City Aldermen, however, essentially did nothing – some very friendly investigation, leading to them declaring distillery milk fully fine. Young sees this as a clear proof of corruption resulting in Aldermen protecting the industry – which, knowing the 19th century "Tammany Hall politics" is indeed quite likely. What is interesting, however, is that modern science does *not* support Leslie's (and others') insistence that "swill milk" was particularly bad. In fact, distillery residues are highly nutritious feed, and are among the animal feed types routinely used in modern farming[115]. That "swill milk" was held to be uniquely evil was most probably due to the religious and moral vision of its opponents, and the link with anti-alcoholism views. Probably, distillery stables had indeed very poor hygiene and practices, and their milk was unsafe – but so was the milk from pretty much every stable at the time, regardless of how "natural" and "rural" it was. Eventually, "swill milk crusaders" were successful - in 1862 the State adopted a law making it "a misdemeanor to sell of exchange 'impure, adulterated, or unwholesome milk" (…) [and] keeping cows in "crowded or unhealthy conditions' and feeding them food that made their milk impure" (*ibid.,* p. 39) and an amendment two years later clarified that distillery milk was "automatically impure". But this is vanishingly unlikely to have had any significant effect on public health, in particular on infectious diseases. What was to change matters on that front was the understanding of microbial contamination, and how to prevent it.

What has increasingly emerged as modern "good practice" food regulation, however, is that such "labeling" rules are mandatory only to the extent that one wants to use a certain name that is protected by legislation – but producers are free to put other goods on the market, as long as they are safe. In many countries, however, food standards are fully mandatory, i.e. it is forbidden to produce and sell goods that are not included in the list of food standards, and/or not made in accordance with them (this is the case in many post-Soviet countries).

[114] See Ferrières 2002 pp. 99-104 and 387-389 or, for a more recent example (and from the United States), North 1921.

[115] See e.g. the absolutely neutral, dispassionate and factual account in the Feedipedia portal (a joint project of INRA, CIRAD, AFZ and FAO): http://www.feedipedia.org/node/4266.

The run-up to the 1906 Pure Food and Drugs Act – progress without regulation, and a jarring scandal

In 1906, after several decades of discussions about the topic, Congress adopted the first real federal regulation of food and drugs – the Pure Food and Drugs Act. The "classical narrative" is one of a breakthrough against industry abuse, and of the forces of progress finally overcoming corrupt opposition. The impetus for the Act's adoption was given by Upton Sinclair's *The Jungle* – a book whereby he in fact purported to advocate for socialism against the havoc wrecked by capitalism upon the poor's lives, but whose descriptions of astonishing malpractice in Chicago's "meat packing" industry led to a public outcry against slaughterhouses and factories seen as poisonous and deceitful. The direct cause-and-effect relationship is taken as granted by most authors: "public outcry over unsanitary meat products in the early 20th century resulted in the passage of the Pure Food and Drug Act of 1906" (Manion 2012, p. 539).

Several elements are in fact somewhat puzzling for a modern analyst of food safety regulations and inspections. First, food safety is commonly seen as being one of the areas where incentives for producers/sellers are to a large extent aligned with regulatory objectives: indeed, poisoning one's customers is rarely good business, and unlikely to lead in increased or sustained market share – thus, deliberate flouting of hygiene and other food safety rules (as opposed to involuntary mistakes) is expected to be rarely seen outside of "fly-by-night", deliberately criminal operators, who aim at a quick profit before disappearing. How to understand, then, that the Chicago "meat packers" exhibited such massive, total, lasting disregard for all the most basic, "common sense" precautions? Second, a substantial part of the food industry was in fact actively working on improving safety – for well-understood commercial reasons (and, possibly, for philanthropic reasons too in some cases). The first federal meat inspections themselves were "made available at the request of meat packers whose products needed Government endorsement before they would be accepted for import into certain foreign countries" (Wagstaff 1986, p. 630)[116]. It had long been understood that higher, more reliable safety could be a commercial argument – in the mid-19th century, the inventor of condensed milk, Borden, "had to overcome any suspicion that his milk was contaminated. He developed a strict set of sanitary rules for the farmers (…) and even sent inspectors around" (Coppin and High 1999, p. 20)[117]. In fact, some of the most significant changes in production and processing practices in terms of reducing morbidity and mortality were introduced voluntarily by the industry, using processes recently developed by scientists and inventors, with very little or no regulatory pressure, at least at first – this is particularly the case for milk. As North (1921) retraces, medical and scientific developments in the years 1880-1890 led to better understand the "necessity for heating milk for the artificial feeding of infants" (p. 238, see also pp. 265 and 269-277). Improvements in sanitation of dairy in the early 1900s were an important step (*ibid.*, pp. 265-266), but what brought a "decided drop in the number of epidemics (…) and also a great reduction in the infant mortality" (*ibid.*, p. 242) was the spread of milk pasteurization in 1907-1910. This, however, had nothing to do with the Pure Food and Drugs Act (or the Meat Inspections Act) of 1906, neither of which mandated pasteurization. Rather, it was primarily driven by the industry itself (eager to secure market share with a demonstrably safer product), gradually supported by a number of municipal regulations (*ibid.*, pp. 275-277).

Considering this, while it would not be surprising at all (in the context of a still very partial understanding of microbiology and other food safety issues) that the *Jungle*'s "meat packers" would have *some* important lapses in hygiene or cross-contamination control, Upton Sinclair's description of pure horror remains puzzling. It

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[116] But early meat inspections had limitations: "A meat inspection law was passed in 1891, but this law was not very effective and meat inspection did not become so until 1906, when the present meat inspection law was passed and machinery in the Bureau of Animal Industry provided for its enforcement" (Alsberg 1921, p. 216)

[117] This helped him gain a very strong standing in the regional market around New York – the Civil War then proceeded to make his product a major success nationally, as a fundamental army supply.

would be tempting to partly dismiss it as literary hyperbole, but all accounts report that President Theodore Roosevelt's envoys on site generally confirmed all or most of the book's descriptions (see e.g. Young 1985). Now, it may of course be that these envoys were also complicit in a conspiracy aimed at tarnishing the meat industry and helping the adoption of new legislation, but this kind of conspiracy theory makes for bad history. Far more likely is that conditions in Chicago's slaughterhouses and the attached processing plants were indeed really dismal – but the modern reader then is bound to think "how was there no outbreak of fatalities prompting action, why was a novelist's work necessary?". Several hypotheses come to mind. First, there might indeed have been an increase in morbidity and mortality, but little noticed among a generally high prevalence of infectious diseases and overall far higher mortality compared to today's rates. Second, meat was at that time generally thoroughly cooked – this would have strongly limited the potential for infections – remained possible chemical contaminations, but even all the dirt described by Sinclair as making its way into sausages would not generally have killed people in any sudden way. Any spikes in morbidity would likely have taken years to be visible, and only if there had been serious statistical research (which was not yet the case). It thus seems that, in an age of higher mortality, weaker statistics and safer cooking habits, the "meat packers" could maybe genuinely think they could get away with such practices without losing their customers. Once exposed, however, the damage was severe, particularly for exports - "in response to these types of writings, American meat purchases, both domestic and foreign, fell by one-half. As a result, Congress passed the Pure Food and Drug Act and the Meat Inspection Act in 1906" (Manion 2012, p. 539).

Still, from the above it is obvious that what could be called the "*Jungle* meat packing scandal" was only one part of the story – the last drop, rather than the main driving force. As we have outlined above, there was a coalition of interests and beliefs at play, as well as scientific theories – which all seem to have pre-existed any actual scandal or outbreak. Coppin and High (1999) see the 1906 Acts[118] as linked to a combination of "conflict between local and national food companies" (with "federal regulation [conferring] competitive advantage on national firms") (p. 6) and "bureaucratic entrepreneurship" on the side of the Bureau of Chemistry and Wiley, his head (p. 5). In support of this perspective, it is noted that the new regulations and control power did relatively little (at least in the short term) to effectively promote safety (in spite of their claims to this effect) – in fact, "the 1906 [Act] was built on the idea that false claims must be prosecuted, rather than addressing the real issues of whether food put on the market [was] safe" (Manion 2012, p. 542). The Act did deem food to be adulterated "if it contain[ed] any added poisonous or other added deleterious ingredient which may render such article injurious to health" (*ibid.*, p. 539) but it made no difference between this and other (relatively harmless) forms of adulteration, and had no provisions for preventive control at the production or processing stage.

Most research seems to concur on the question of *trust* having been the most fundamental and powerful driver for the new regulation – both in terms of long-term, deep trends, and in the way the "meat packing" scandal unfolded and was addressed. At its core, the increasing demand for food regulation came from "the transformation of the United States from an agrarian to an industrial society changed the way in which people ate. Food became something to be purchased rather than something to be home-grown" (Coppin and High 1999, p. 18). "Through urbanization, consumers and producers became strangers to each other, separated by distance, and through industrialization, dairy products also became strange to consumers, created by mechanisms of production that were no longer part of the general knowledge of an agrarian population" (Swanson 2011, p. 339). With food obtained more by trade than self-production, and trade increasingly

[118] Note that the Pure Food and Drugs Act is mentioned far more often than the Meat Inspection Act, even though one could argue that the latter was far more important to advance actual food safety at least for the first decades (until the Food and Drugs Administration – FDA – was created and its powers increased) – just as nowadays the FDA is far better known than the US Department of Agriculture's Food Safety and Inspection Service (FSIS), even though the latter plays a major role in ensuring safe food (in charge of all the meat supply chain). Whether this is due to the more striking name (including "food" prominently), the different institutional status, or other causes, it somewhat distorts the public perception of the US food safety system.

involving large distances and very unequal actors (individual consumers vs. large corporations[119]), trust increasingly became problematic. Regulation and regulatory control (inspections) came to be increasingly seen as a response to this breakdown of trust – as an instrument that would make it possible to move from "trust from familiarity" (which was not possible anyway) to "trust in rules and control" (which was to be established).

Very interestingly (and this is one of the reasons why we thought it worthwhile to present this historical account in some details), the situation has many similarities with what is observed in contemporary regulatory issues, and with a phenomenon that has been coined the "Risk Regulation Reflex"[120]. In both cases, a real issue of lack of trust on the side of customers and citizens is used by active interest groups to promote specific regulations that correspond to their (financial, professional or ideological) interests – the resulting regulation may have some benefits for safety, but its costs may be higher than its benefits, and/or its impact on safety may be far smaller than its effects on competition, markets etc. Coppin and High (1999) thus write that "on the consumer side, the change from growing food on the farm to buying it in the market created doubts about purity and healthfulness. These doubts were the origin of demand for food experts" (p. 33). They also insist on the importance of "bureaucratic entrepreneurs" in promoting new regulation, on the need for such "entrepreneurs" to "influence voters or elected officials" (p. 13) – reminding that "voter preferences (…) can be manipulated and created through the information and misinformation provided" (p. 14). Such an account is very close to what Helsloot and Schmidt (2012) write about the role of "experts" in pushing for new regulation in a "Risk Regulation Reflex" situation: "The single minded risk professional is (…) only interested in the best possible defence against his own pet risk, his advice is difficult to ignore for administrators when they have no other means of mobilising expertise to balance that advice" (p. 312). They also expose the way in which "risk experts" effectively work to *shape* public opinion in favour of regulation "no matter the costs", whereas an informed and nuanced public debate could end up with public opinion striking a very different balance (pp. 308-310).

The early days of food regulation in the 20th century

The twin Acts of 1906 (Pure Food and Drugs and Meat Inspection) foresaw significantly different provisions and mechanisms, and led to different evolutions. The Food and Drugs Act[121], as we briefly indicated, mostly went after "adulteration" and "deception" – it was more about ensuring that label were not deceiving consumers than controlling production, and constitutional limitations also meant that it had to be combined with state legislation in any case (which was also true of the Meat Inspection Act): "because of the limitations of Commerce Clause jurisprudence, it outlawed [only] the interstate shipment of "adulterated" or "misbranded" food or drugs and their manufacture [solely] within the District of Columbia and the territories" (Swanson 2011, p. 363).

The focus for meat inspections was relatively clear from the onset – led by the Bureau of Animal Industry, they took place at slaughter/processing stage, they concentrated largely on "controlling Trichina and other types of parasitic infestations of meat" (Wagstaff 1986, p. 628). Over time, these infestations (and their health

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[119] Quoting Coppin and High: "mass distribution in the form of chain stores" as well as "large firms that integrated mass production with distribution had begun to appear in the 1880s and 1890s" (p. 18).

[120] See on the "Risk Regulation Reflex" (RRR) e.g.: Tol 2012, Tol 2014, Helsloot & Schmidt 2012 (a), and Blanc, Macrae and Ottimofiore 2015.

[121] It is worth pointing out that the way the Act was drafted was not a foregone conclusion – it ended up conforming mostly to Wiley's vision, but many others had pushed for alternative approaches: ""Wiley's version of a pure food law was vigorously opposed by many respectable persons who simply wanted a different law". Many (but not all) state food officials "favored national legislation, but could not agree on the administrative mechanisms of a national law (…) Some advocated (…) a new agency headed by a national food commissioner (…) Others saw little need for a regulatory agency at the national level; they believed that a law allowing states to regulate all foods entering a particular state would be sufficient" (Coppin and High 1999, pp. 5-6). On this last point, modern experience and science strongly suggest this belief was mistaken – and indeed "with even fresh milk crossing state lines from producer to consumer, the best efforts at the state level were unsatisfactory" (Swanson 2011, p. 349).

effects) indeed went down "there were 13 deaths reported for Trichina in 1913 compared with none in 1978" (*ibid.*). By contrast, the Bureau of Chemistry that was tasked with implementing the Food and Drugs Act controlled mostly at the market stage, with a far broader scope, and with less clear-cut rules. The Act prohibited "adulterated", "misbranded", "poisonous" etc. foods, but with no clear guidelines on how to assess this – and "judicial decisions narrowed the capacity of the Bureau of Chemistry to enforce the statute by requiring high standards for proof of fraudulent intent" (Manion 2012, p. 541). In addition, enforcement powers were burdensome to use: "it required that the government take each offender to court and prove that each particular food was adulterated or mislabelled, and by what standard it was making that judgment." (*ibid.,* p. 542). This means that, even though inspectors apparently very easily found a number of violations (Young 1992, p. 120), it is unclear how much of an impact they could have on the *overall level of safety* of the food supply.

In terms of approach and methods, the Bureau under Wiley was very prone on controversy, with the support of "some branches of business" hoping to use this "as a weapon against competitors" (*ibid.,* p119). The "impetuousness" of Wiley led his superiors to start to "distrust his science" (*ibid.*) and he was eventually replaced by Alsberg (*ibid.*). In these early days, methods were still to be developed, and planning was essentially non-existent: "the inspectors, hired to collect samples of foods and drugs entering interstate commerce, were given minimal training and no structured plan of action was initially devised" (*ibid.,* p. 120). Interestingly, after the initial "conflict-oriented" phase, a far more "cooperative" approach emerged: inspectors found that "shortcomings seldom resulted from "wilful intent" but rather from "law or faulty control" systems" – and this cooperative approach allowed the Bureau to overcome (to some extent) the Act's limitations: "the law did not give the Bureau direct authority over sanitation in processing plants, but inspectors (…) realized how poor sanitation could lead to illegal products" and passed on this lesson to manufacturers" (*ibid.*, p.120). Manufacturers, in turn, often agreed to follow these recommendations to keep good relations with Bureau officials.

Gradually, "the Bureau's somewhat haphazard method of sample collection [was replaced] with a project system (…) [which] set priorities of effort for each year" (*ibid.,* p. 121). Investigation of outbreaks (as the botulism poisoning case with olives in 1920) led to new knowledge and new processing standards. The "*entente cordiale"* between "regulators and major segments of the regulated industries" allowed officials to proclaim victory over "adulteration and misbranding". It is interesting to note the sharp contrast with OSH: whereby OSH inspections in the United States are (as we have seen above) characterized by a high emphasis on deterrence, and very limited discretion, food safety inspections from early on were far more "cooperation-based", and far less rigid. It is likely, in fact, that this experience, and the claims (justified or not) of "regulatory capture" that it led to, was an important factor in the way the OSH Act was drafted.

Weaknesses and reform – from the 1938 Food, Drug and Cosmetic Act to the 2011 Food Safety Modernization Act

In 1927 already the Bureau of Chemistry had become the Food, Drug and Insecticide Administration – but changes in name were not sufficient. The crisis that triggered legal reform was drugs-related, but affected food regulation and inspections too. The "Elixir Sulfanilamide" scandal resulted in 107 deaths in 1937 (Manion 2012, p. 542) – and it showed that the focus on "adulteration" was clearly insufficient. In fact, the "Elixir" was mostly compliant with existing rules, and the FDA could have done little against it *before* people died – the ingredients used were legal, and the label compliant with rules. However, one of the ingredients had not been tested for safety, and proved mortal. The new Act brought completely new powers to the FDA: it "authorized administrative establishment" of definitions of "standards of food identity" (*ibid.*) and also established "remedy of court injunctions" and "authorized factory inspections". On its basis, the FDA "established food standards and lists of [authorized] ingredients" (*ibid.,* p. 542-543).

Problems in the US food safety regulatory system – reality or perception?

While US food safety regulations and controls continued to develop in the subsequent decades, many criticisms have been made of insufficient modernization, inadequate methods, lacking resources, weak enforcement - "at the turn of the twenty-first century, Americans are inundated with news stories suggesting that their food and drugs are not safe. (…) Often, critics suggest that the FDA is inadequately funded to perform this inspection role well (…). Other critics identify overregulation by the same agency" (Swanson 2011, p. 332). International comparisons have their pitfalls, but in the past couple of decades at least EU food regulations have increasingly appeared stricter, and better enforced, than US ones, at least to a number of observers[122] – even though this is a highly debated issue, with data pointing in opposite directions[123] (and presenting many reliability issues anyway), and there are many more differences that may influence the results (for instance the significantly higher income level of the US, with the EU incorporating countries with very different GDP/capita levels, histories, regulatory systems etc. – all of which means that *even* if its regulatory enforcement system were indeed more effective[124], the EU could well have overall worse outcomes on food poisoning than the US). At this stage, it is enough to note that there was growing agreement that the US system *needed improvement* – in methods, powers, and practice[125].

From an anecdotal perspective, a number of high-profile cases in recent years have pointed to apparent weaknesses in the US's food safety inspection and enforcement system. In 2015, an outbreak of Listeria

[122] For arguments and data suggesting higher effectiveness of the EU food safety regulatory system over the US one, see e.g. the following articles in ThinkProgress (website of the Centre for American Progress): http://thinkprogress.org/health/2014/09/30/3573680/trade-deal-europe-food-safety/ and http://thinkprogress.org/health/2013/02/20/1601231/meat-industry-horsemeat/ (but both compare two sets of data that are not directly comparable, resulting in incredibly low disease prevalence in the EU – the source for their EU data is here: http://www.foodsafetynews.com/2010/01/food-ills-sicken-45000-kill-32-in-eu/#.VX2d49LS383). For a contrary view that the US system performs better, see e.g.: http://achesongroup.com/2014/03/foodborne-illness-us-eu-compare/. In fact, none of the data sets are fully reliable (too much depends on self-reporting, detection rates etc.).

[123] Many arguments centre on the relatively low life expectancy in the US given its high income level, and the fact that it used to have higher life expectancy than all EU members – and now lags many of them – see e.g. for a ranking of countries https://en.wikipedia.org/wiki/List_of_countries_by_life_expectancy. Any internet search of "life expectancy US Europe" will return a number of articles drawing conflicting conclusions. While causality is clearly complex, broadly-defined "lifestyle" and "environmental health" are likely to play a role (along with health care) – and food safety could be a part of the explanation (but most likely very minor). Other food issues (nutrition) are likely to be far more important, and are also handled differently by regulators on both sides of the Atlantic.

[124] In spite of *perceptions* on both sides that one or other system may be "stricter" or "more risk-averse", research suggests caution in conclusions. Wiener *et.al.* 2011 showed that the level of precaution is higher in the EU for some areas, higher in the US for some others. For a specific application to food safety, see a summary presentation of findings by Wiener at: https://ssri.duke.edu/sites/ssri.duke.edu/files/Wiener_Duke_Food_Working_Group.pdf - which again suggests the importance of different risk perceptions leading to different intensity of responses to different risks, with variations between the EU and US – rather than a uniform trend of one or the other being more "risk averse". A 2005 presentation by G. Kushner on the US Farm Foundation website provides a convenient comparison of some aspects of the two systems: http://www.farmfoundation.org/news/articlefiles/971-gkushner.pdf - but, as several other documents written in the US, it focuses in our view too much on the European Food Safety Agency (EFSA), which is not at all analogous to the US FDA, but rather is only in charge of scientific risk assessment. The operational coordination is ensured by the EC Food and Veterinary Office (see below), a very important entity (and often insufficiently perceived as such).

[125] For more detaild insights see e.g. Fagotto 2015

monocytogenes in *Blue Bell Creameries* products comes at the latest[126], and shows that "upmarket", highly regarded brands are not immune to problems[127].

This comes on top of several significant scandals in the past. In 2009, a major *Salmonella* outbreak[128] was traced to *Peanut Corporation of America* products – and investigations revealed that violations at this firm's plants had been particularly blatant, and repeated over the years[129]. Eventually, this became one of the rare cases in the US where a guilty verdict was delivered on criminal felony charges – highlighting the particularly reckless behaviour of the management, and the way in which the contamination resulted from intentional and major safety violations aimed at increasing (or maintaining) profits[130]. Major outbreaks have repeatedly been linked to the fast food chain *Taco Bell*: a 2006 *E.coli* outbreak that sickened dozens and killed at least 3[131], and *Salmonella* outbreaks in 2010 and 2011[132]. One of the early cases that led to developments in food safety practices and in regulatory discussions was the 1992-1993 *Jack in the Box* fast-food chain *Salmonella* outbreak[133].

Of course, an anecdotal collection of outbreaks does not substitute statistically significant data, and there are conflicting arguments as to whether the recent *Listeria* ice cream contamination cases reflect systemic issues with the US food safety system, or just the difficulty to control this bacterium (suggesting that the EU should not feel that is immune to such problems)[134] . Different outbreaks point to different issues. While the 1993 outbreak arguably opened a "new era" of heightened attention to microbiological contamination[135], and while the company (*Jack in the Box*), after dramatically botching its initial response, changed tack and ultimately became by some accounts a "leader" in food safety practices[136], the successive outbreaks and controversies at and around *Taco Bell* show how some other firms are far slower at improving – and seem to tend to fight

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[126] As of late Spring 2015, the outbreak caused 3 fatalities. Details are avaialable on the CDC website: http://www.fda.gov/Food/RecallsOutbreaksEmergencies/Outbreaks/ucm438104.htm and the final CDC update on this outbreak here: http://www.cdc.gov/listeria/outbreaks/ice-cream-03-15/ as well as additional information on the Wikipedia page for *Blue Bell*: https://en.wikipedia.org/wiki/Blue_Bell_Creameries#2015_recalls.

[127] *Jeni's Ice Creams*, another (smaller) upmarket brand, has also had to conduct a *Listeria*-caused recall at the same time, though so far no human cases have been reported because of it – see: http://www.foodsafetynews.com/2015/05/a-tale-of-two-recalls-blue-bell-and-jenis-ice-cream/#.VYPKcNLS381. This article also points out the difficulty and complexity of *Listeria* management.

[128] See detailed description of the outbreak on the CDC website: http://www.cdc.gov/salmonella/typhimurium/update.html.

[129] See Wikipedia page for *Peanut Corp. of America*: https://en.wikipedia.org/wiki/Peanut_Corporation_of_America#Inspection_findings.

[130] See a CNN news report on the case and verdict: http://edition.cnn.com/2014/09/19/us/peanut-butter-salmonella-trial/.

[131] Details on the outbreak from the CDC: http://www.cdc.gov/ecoli/2006/taco-bell-12-2006.html and overview from Wikipedia here: https://en.wikipedia.org/wiki/2006_North_American_E._coli_O157:H7_outbreaks.

[132] The CDC description of the 2010 oubreak is here: http://www.cdc.gov/salmonella/baildon-hartford/index.html and that for the 2011 outbreak is here: http://www.cdc.gov/salmonella/restaurant-enteriditis/011912/ but in both cases the CDC refused to specifically name *Taco Bell* – see on this point several articles (quoting several state food safety authorities among other sources): on the 2010 outbreak http://www.foodsafetynews.com/2010/08/taco-bell-sued-over-salmonella/#.VYVyrtLS380 - and on the 2011 onea number of articles: http://www.foodsafetynews.com/2012/02/analysis-restaurant-a-revealed-to-be-taco-bell/#.VYVyndLS380, http://www.theatlantic.com/health/archive/2012/02/restaurant-a-how-bill-marler-tied-taco-bell-to-salmonella-outbreaks/252778/ and http://www.cbsnews.com/news/taco-bell-tied-to-2011-salmonella-outbreak-that-sickened-68-report/.

[133] See CDC summary here: http://www.cdc.gov/mmwr/preview/mmwrhtml/00020219.htm and the Wikpiedia page on the outbreak, which outlines the follow up and consequences: https://en.wikipedia.org/wiki/1993_Jack_in_the_Box_E._coli_outbreak.

[134] Arguing that the outbreaks reflect systemic US issues is e.g. this article (but it is by an author writing mostly about environmental issues): http://www.salon.com/2015/04/24/americas_frightening_food_safety_gaps_how_our_massive_complex_system_undermines_public_health/ - on the other side, this article in a professional food industry website suggests the problem could just as well affect Europe: http://www.foodmanufacture.co.uk/Food-Safety/Listeria-in-ice-cream-could-also-be-a-UK-problem. The EC regulations on *Listeria* emphasize HACCP-based control (which is only now becoming mandatory in the US, see below) – but they also allow for residual levels of the bacterium that are higher than the levels found in some US outbreaks – see EC guidance here: http://ec.europa.eu/food/food/biosafety/salmonella/docs/guidoc_listeria_monocytogenes_en.pdf and UK FSA guidance here: http://www.foodlaw.rdg.ac.uk/pdf/uk-06001-micro-criteria.pdf.

[135] See on how it opened a "new era" in food safety practices and regulations here: http://www.foodsafetynews.com/2013/01/food-safety-since-jack-in-the-box-progress-made-and-progress-still-needed/#.VYWJ0dLS380.

[136] See for instance: http://www.ou.edu/deptcomm/dodjcc/groups/02C2/Jack%20in%20the%20Box.htm.

back against criticism more than they actually solve problems. The recent *listeria* outbreaks may point to specific weaknesses in the US regulatory requirements and controls[137] – but they may also indicate how difficult the bacterium is to control, something that may come to create challenges for other food safety regulatory systems.

A note of context is required to assess better the degree to which these large food outbreaks reflect (or not) on the underlying robustness of the food safety regulatory regime, and of regulatory enforcement and inspections in particular. The United States has a very different enterprise structure from the EU: large enterprises (more than 500 employees) make up a substantially larger share of total number of firms and (even more strongly so) of total employment – and this holds true in manufacturing and services (in particular food service)[138]. This means that, considering a unified supply chain for many large food firms, outbreaks may mechanically end up being larger and more "visible", even assuming identical prevalence rates for a given disease. There may also be a specific vulnerability linked to size and methods of animal feeding commonly used in the US: concentrated animal feeding operations (CAFOs) a.k.a. "feed lots" present strong potential for spreading of bacteria strains to a vast number of animals[139]. A tendency to have generally much smaller food service operations in the EU may have led so far to more fragmentation and more isolated, undetected cases. Supply chain integration, conversely, brings the potential for larger, observable outbreaks, such as the infamous 2011 *E.coli* outbreak originating in Germany and caused by fenugreek seeds used for sprouts[140].

Overall, in spite of claims made on both sides, and of the obvious elements of imitation of some aspects of EU regulations in the 2011 FDA Food Safety Modernization Act (see next section), it is not possible on the basis of available data and research on whether the US food safety regulatory system performs worse, better, or on the same level as the EU one. Some US-specific features, such as the greater reliance on litigation as a compliance driver, may relate to characteristics of the entire regulatory enforcement regime, and not only to food safety. Indeed, in the US, class action suits are an important force driving regulatory compliance[141] - and this is true across all regulatory fields. By contrast, in spite of developments in the past few years, class action possibilities and practice in EU countries are still narrow and limited in scope, as well as in the amount of damages (and thus deterrence strength)[142]. In this perspective, one could argue that the salience of civil lawsuits in food safety scandals in the US is as much a reflection of a strength (the power of this avenue of

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[137] In particular the lack of systematic testing for *listeria* (which was not legally mandated), and the delays between the first test results showing *listeria* and the broader recalls – see this set of articles on these inter-related issues: http://dfw.cbslocal.com/2015/05/22/fda-documents-show-early-problems-at-blue-bell-plants/ - http://www.dallasnews.com/business/headlines/20150605-blue-bell-ice-cream-made-in-alabama-was-tainted-with-listeria-private-lab-says.ece - http://bizbeatblog.dallasnews.com/2015/05/blue-bell-explains-why-it-didnt-test-its-ice-cream-after-first-discovering-listeria.html/.

[138] See OECD 2005 (b) pp. 18-20 and OECD 2014 (b) pp. 26-33.

[139] For the argument that the apparently somewhat larger number of major outbreaks in the US reflects the size of operations, and thus makes it possible to observe outbreaks (as opposed to a number of isolated, apparently unrelated, and often unresearched cases), see this article by Bill Marler (one of the leading attorneys involved in the 1993 *Jack in the Box* litigation, on the victims' side): http://www.foodsafetynews.com/2013/03/publishers-platform-mcdonalds-and-e-coli-30-years-later/#.VYWJ3NLS380.

[140] This case clearly showed the vulnerability of at least some EU Member States' systems (in particular Germany) – see e.g. Wikipedia's article on the outbreak: https://en.wikipedia.org/wiki/2011_Germany_E._coli_O104:H4_outbreak and see how it compares to other food outbreaks here: https://en.wikipedia.org/wiki/List_of_foodborne_illness_outbreaks_by_death_toll (which again anecdotically suggests a higher number of *large* outbreaks "making the news" in the US compared to the EU).

[141] Even though there is an old usage of "private prosecutions" in the Common Law tradition, most class actions are strictly *civil* cases, not penal, and thus usually do not involve the award of criminal (or other) sanctions that would stem from the regulations directly – in this narrow sense, they are thus not an "enforcement" action. However, because the damages awarded are potentially extremely high, US class action lawsuits often have a stronger "enforcement" effect (in the broader sense), and definitely a very strong power of deterrence.

[142] For comparisons of US and EU practices in class actions, see: short overview but with a number of useful links and references http://www.cpradr.org/About/NewsandArticles/tabid/265/ID/593/International-Practice-OverviewComparison-of-US-EU-Judicial-Class-Action-Structures-Web.aspx - a far more detailed summary of practices in different EU Member States can be found here: http://www.libralex.com/fr/publications/class-actions-in-europe-and-the-us - an EU FAQ on "collective redress", including comments on the European Commission's concerns about the US system leading to "excessive litigation" can be found here: http://europa.eu/rapid/press-release_MEMO-13-530_fr.htm.

redress as a driver for regulatory compliance and safety improvements[143]) as of potential weakness (of the federal and state regulatory enforcement system). The few cases of major food scandals briefly outlined above, however, do suggest that some of the concerns with the US food safety enforcement system may indeed be founded: one company (*Taco Bell*) not only was repeatedly involved in several outbreaks (suggesting limited, if any, improvements in handling practices and internal control systems), but was shielded from negative publicity by the CDC and FDA (and thus one of the most important compliance drivers was left unused). In the *Blue Bell* outbreak, delays in identifying the problem point to weaknesses in internal control (HACCP-type) implementation, lateness in recalls indicate insufficiently strict legal requirements in terms of food business operator responsibilities, and so does the fact that *listeria* problems appear to have been "endemic" at *Blue Bell* facilities for a while. All this anecdotal evidence does not allow to adjudicate conflicting claims of effectiveness between the EU or US (nor is this necessary for this study), but do suggest that there are some aspects of concern in the US system – and we will see in the next section what efforts are currently made to address them.

Addressing the problems? The Food Safety Modernization Act, and implementation difficulties

The 2011 FDA Food Safety Modernization Act came as the result of several years of pressure for reforms (with a first Food Safety Enhancement Bill having passed the House in 2009 already), and negotiations in Congress. It focuses on the FDA, and to a large extent bridges an important gap in powers and approaches between the FDA and the USDA FSIS, in charge of meat inspections. In the approaches it mandates, the requirements it puts on food business operators, and the new powers it gives to the FDA[144], the Act is clearly strongly inspired by current EU food safety legislation (namely the 2004 "Hygiene Package" and in particular EC Regulation 882/2004 on Official Food and Feed Controls[145]).

The Act grants "greater systematic oversight of all food production facilities" (Manion 2012, p. 537). It specifically gives increased inspection powers – including "comprehensive preventive controls for most facilities" (*ibid.,* p. 546), rights of access to records, as well as a mandated (minimum) inspection frequency for high risk establishments[146] (*ibid.,* p. 548). Specifically, "the frequency of food facility inspections will be based on the level of risk associated with the facility, and an increased risk level will result in immediate increase in inspection frequency. All high-risk domestic facilities must be inspected within five years of the date of enactment and no less than every three years after that." (*ibid.,* p. 549)

It also introduces new requirements for food business operators, e.g. mandatory testing in accredited laboratories for specific food products and contaminants (p. 548). The Act emphasizes the "scientific" basis of new regulation: it "mandates that the FDA 'establish science-based minimum standards' to conduct hazard analysis and employ preventative controls" (*ibid.*, p. 538). In the Act, "science based" specifically means approaches similar to Hazard Analysis and Critical Control Point (HACCP) methodology, data collection and

[143] See OECD (2014) principle 2 suggesting the usefulness and relevance of class-action as a regulatory compliance driver. See also Bentata and Faure (2015) for an example of how collective litigation can powerfully drive changes in regulatory compliance and regulations.

[144] See explanation, contents, guidance on the FDA website at: http://www.fda.gov/Food/GuidanceRegulation/FSMA/.

[145] See summary and full text of the 882/2004 regulation on the EC website at: http://europa.eu/legislation_summaries/food_safety/veterinary_checks_and_food_hygiene/f84005_en.htm.

[146] The fact that the Act sets a *minimum* frequency, that is mandatory for the FDA to achieve, speaks to the *ex ante* situation as being one of (at least perceived) under-inspection. In a number of countries, as we will see in subsequent chapters, risk-based planning serves to *reduce* the frequency of inspections – in the US food safety context, it is being used as basis for an increase. Indeed, as we will discuss in the last chapter and conclusion, there probably is a lower threshold under which risk-based inspections are not effective anymore because overall inspections are too rare – in this perspective, this provision of the FSM Act can indeed make sense.

management to monitor and assess epidemiological risks, and is also to be understood in line with the World Trade Organization Sanitary and Phytosanitary Agreement (WTO SPS)[147] (*ibid.,* p. 539).

In a US context where introducing new regulation tends to be very difficult because of concerns about administrative burden, the Act specifically "includes language to alleviate undue burdens on small food producing facilities" (*ibid.,* p. 549) – but its adoption did meet a lot of resistance by wholesalers, farm organizations, small and organic farm advocates[148] etc. (*ibid.,* p. 545).

As we have mentioned, rather than breaking entirely new ground, the Act (to a large extent at least) is rather bridging the gap between meat inspections and other food inspections in the US – and between FSIS and FDA powers and methods. The FSIS work has long been strongly "science based" as the Act now mandates the FDA to be[149] (*ibid.*, p. 557) – and HACCP has been a cornerstone of FSIS work and requirements for some time as well. FSIS can serve as a model of "risk-based" inspectorate for the FDA, as it relies heavily on data collection to detect and respond to food contamination hazards. FSIS methodology involves a data analytics technique called the Public Health Information System, a web-based application establishing an automated data-driven inspection system. This system allows "analysts to identify trends that will automatically adjust domestic and import inspections and sampling" (*ibid.,* p. 558).

Adoption of the FSM Act does not, however, solve all challenges with food safety regulations in the US. First, there are significant implementation problems with the Act itself. Second, even though FSIS has in many aspects stronger methods (and has had stronger enforcement powers for longer), there are resource limitations and areas where its methods are questioned. Third, the duality between federal and state-level enforcement not only creates complexity, but also is likely to lead to important variations in effectiveness. Finally, the question of the overall institutional structure remains to be addressed (but is starting to be asked).

Implementing the FSM Act has proven difficult – both in terms of rule-making and of actual controls. The FDA's implementation timeline for the Act shows many draft regulations having been published, but none yet adopted so far (though first approvals are forecast to happen by end 2015)[150]. Possibly even more significant is a major funding shortfall that means the required retraining of staff, additional resources for intensified in-country and border controls are currently not possible to implement. In order to raise the needed resources, "the F.D.A. proposed user fees that would cover the bulk of the cost of carrying out the food safety law. Last year, for example, it asked for $263 million for the law, with about $229 million coming from fees on food companies. But lawmakers soundly rejected those proposals after lobbying by the food industry[151]". As a result, the FDA has asked for budget funding to compensate for the shortfall, but the requested amount is around 50% lower than the projected user fee would have been – and it is unlikely that Congress will even

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[147] There clearly is an increased attention to the international aspect of food safety in the FSM Act, not only by the adoption of language that is comparable to EU or WTO rules, but also by the emphasis on border controls – it "emphasize prevention, inspection and compliance, response, regulations on foreign imports, and enhanced partnerships with other government agencies" (Manion 2012 p. 547).

[148] Two observations are in order here. First, that there has been insufficient assessment of the business and economic impact of the EU 2004 "Hygiene Package" (see below on this point). Second, that there are real tensions between environmental sustainability goals and food safety regulations (particularly the latest "generation" of ever more demanding ones) – which makes the opposition of organic farm advocates relatively unsurprising. This tension between different regulatory objectives (environmental protection, food safety) is one that can be expected to be felt increasingly sharply in Europe as well, even though it is still not really widely perceived.

[149] "The term "science-based" also surfaces often in reference to the Food Safety and Inspection Service (FSIS). The FSIS is a public health agency of the USDA responsible for overseeing the safe production of meat, poultry, and eggs. (…) FSIS assures processes are scientifically validated. Teams of expert auditors conduct periodic in-depth food safety assessments which can take days or weeks to complete and may involve extensive microbiological sampling of the plant's environment and finished products. Annually, FSIS conducts more than 8,000 microbiological tests to verify the production processes are under control" (Manion 2012 p. 557)

[150] See the FDA website here: http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm257986.htm and a recent New York Times article: http://www.nytimes.com/2015/09/11/science/food-industry-gets-new-safety-rules-to-prevent-illness.html?_r=0

[151] See New York Times article here: http://www.nytimes.com/2015/04/08/us/food-safety-laws-funding-is-far-below-estimated-requirement.html?ref=topics

approve it (given the current Republican majority's opposition to both government spending and regulation)[152].

On the FSIS side, there are also significant challenges, once again related to funding. Presumably for relatively similar reasons (industry opposition prevailing), FSIS slaughterhouse inspections are not user-funded[153], contrary to what is the case in the EU[154]. Partly as a result of this, and partly because of active policy choices leading to a reform of poultry inspections in 1997, FSIS does not conduct 100% inspection of every slaughtered animal (unlike what is the rule in the EU). To accommodate higher production speeds, and to cope with lower inspection requirements, FSIS allows treatment of chicken carcasses with chlorine or other antimicrobials[155] – which is frequently and sharply criticized, even within the US but most strongly in the EU[156], which has imposed a ban on some imports, resulting in a WTO dispute[157]. Critics of the new FSIS approach (less-than-100% inspections, but a more systemic, HACCP-based control approach – and authorization of the use of antimicrobial products) say that the antimicrobials are toxic for workers, potentially toxic for consumers (though there is no proof of this at present), and that they provide illusory safety only (surface decontamination changes nothing to potential internal meat contamination). The HACCP-based approach has also been strongly criticized as being too industry-friendly[158] – in fact, looking more closely, it appears there is a case of confused goals and designs, resulting in problematic implementation. The changes, introduced following a series of pilots in the late 1990s and early 2000s, apply to all meat inspections – purporting to increase effectiveness, and to put more responsibility on the industry, but doing so in a way that raises concerns about other pressures (cost cutting, industry demands). In 2001, the General Accounting Office conducted an audit of the pilots and of the proposed reforms, and was highly critical: "notwithstanding the project's design problems[159], which we believe make the results unreliable, we found that, so far, the data themselves do not conclusively demonstrate that modified inspections are at least equal to traditional inspections" (GAO 2001, p. 4). The GAO made a series of recommendations[160], which the USDA and FSIS implemented (or at least reported to have followed).

What is remarkable in the case of FSIS reforms and the negative reactions they provoked, is that many food safety experts would agree that the general idea of the reforms is valid: 100% regulatory inspections of carcasses are inefficient and (because they mostly rely on visual checks) not always effective[161], putting more

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[152] See *ibid.*

[153] See on the USDA FSIS website the Federal Meat Inspection Act: http://www.fsis.usda.gov/wps/portal/fsis/topics/rulemaking/federal-meat-inspection-act as well as summary information on slaughter inspections: http://www.fsis.usda.gov/wps/portal/fsis/topics/food-safety-education/get-answers/food-safety-fact-sheets/production-and-inspection/slaughter-inspection-101/slaughter-inspection-101.

[154] For an overview of EU practices see e.g. the UK FSA website – summary here: https://www.food.gov.uk/enforcement/monitoring/meat and the guide to different applicable charges here: http://www.food.gov.uk/sites/default/files/multimedia/pdfs/chargesguide0311.pdf

[155] See applicable regulation and its annexes here: http://www.fsis.usda.gov/wps/portal/fsis/topics/regulations/directives/7000-series/safe-suitable-ingredients-related-document

[156] See e.g. the following article in *Bloomberg Businessweek*: http://www.bloomberg.com/bw/articles/2014-08-08/why-chlorine-chicken-from-america-inspires-dread-in-europe and this article in *Salon* for a critical view from within the US: http://www.salon.com/2014/05/26/chlorine_in_your_chicken_why_poultry_is_more_dangerous_than_ever_partner/

[157] See US background paper on this dispute: https://www.fas.org/sgp/crs/misc/R40199.pdf

[158] See an example of such criticisms – *Washington Post* 2013 article: http://www.washingtonpost.com/politics/usda-pilot-program-fails-to-stop-contaminated-meat/2013/09/08/60f8bb94-0f58-11e3-85b6-d27422650fd5_story.html - there is considerable media coverage on this topic, nearly uniformly negative. Also a related article on reductions in the number of inspections in exporting countries: http://www.foodsafetynews.com/2012/11/usda-quietly-eliminated-60-percent-of-foreign-meat-inspections/#.VYfOxtLS381.

[159] The GAO highlights in particular the lack of a control group, and the non-random selection of the plants for the study.

[160] See summary results of the study, and recommendations, here: http://www.gao.gov/products/GAO-02-59

[161] The GAO reports the FSIS inspectors' views that the new system would be more effective (GAO 2001, p.5). This is also the opinion of a number of UK food safety and regulatory enforcement specialists (author's interviews), suggesting that many practitioners have doubts about the old "100% visual inspection" method and suggest it is costly without being really effective.

emphasis on responsibility (and liability) of operators is considered a foundation of modern food safety regulation[162], and HACCP is likewise seen as an approach that is essential to delivering reliable, consistent safety throughout the food chain[163]. The reform, however, reveals some level of confusion between the introduction of HACCP as a requirement and a change in inspection methods (which should logically be two distinct, though related issues), and tensions which seem related to pressure to reform primarily with a cost-cutting and burden-reducing perspective, with effectiveness being more of a window-dressing claim than a real concern. The enforcement weaknesses seen above when dealing with major outbreaks (even though the examples mostly related to the FDA and not to FSIS) may also explain why many (the GAO, food safety advocates etc.) are concerned that FSIS may not sufficiently follow through on the "deterrence" aspect in order to give credibility to this new, more "focused" scheme. In addition, the GAO highlighted problems in the legal basis for FSIS work in terms of enabling discretion and more "focused" inspection activities: "this report reiterates our previous recommendation for legislative revisions aimed at reducing the potential for further legal challenges by providing USDA with clear authority to modify its inspection system" (*ibid.,* p.5).

Overall, even though there is no certainty (at this stage) in terms of health outcomes, there is some evidence that indeed US food inspections are cost-constrained in comparison with what is the case in the EU at least in some respects[164]. A final challenge faced in improving their effectiveness is due to the fragmented structure of food safety control in the US – the duality between FDA and FSIS at the federal level, and the complex articulation of federal and state regulation (with state controls themselves coexisting with local inspections conducted by counties, cities etc.). The boundaries of different agencies' competence are dictated by the history we have tried to outline, and by US constitutional arrangements – but end up being seriously problematic from a "comprehensive food chain safety" perspective (a.k.a. "from farm to fork" or "from stable to table"). While the FSIS controls animals and meat at the slaughter and processing stage, it is neither responsible for milk and dairy, nor for control of animal health prior to slaughter. Whereas the FDA supervises supermarkets, state (or local) authorities are in charge of restaurants. Dairy production is supervised by state authorities, dairy products can be supervised by the FDA if they are destined to interstate commerce, but only by state authorities if they do not cross state borders. The FDA also does not control conditions in farming – the use of pesticides is regulated by the US Environmental Protection Agency (EPA), and state authorities supervise compliance with state laws.

While such complexity and involvement of different agencies and levels is not unusual in practice, it is not easily reconciled with aims of achieving optimal effectiveness and efficiency. International organizations tend to recommend "unified agencies" dealing with most food safety matters, or at least a very clear split of

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[162] See for instance: (a) World Bank Group (2014) – module 2, page 8 (pillar 3) "In a food safety system, primary responsibility (and liability) for the safety of food rests on food business operators" – (b) in the EU context see EU Standing Committee on the Food Chain and Animal Health (2010) p. 14 as well as the text of Regulation 178/2002. In addition, "Directive 85/374 lays down the principle of strict liability of the producer, which means that a producer may be held responsible for a damage caused by a defective product s/he has put on the market even in the absence of fault" (van der Meulen 2013, p. 88).

[163] See the *Codex Alimentarius Recommended International Code of Practice General Principles of Food Hygiene* (links: http://www.fao.org/docrep/005/y1579e/y1579e02.htm and http://www.codexalimentarius.org/download/standards/23/CXP_001e.pdf) – as well as World Bank Group (2014) – module 6, pp. 6-7 (which also mentions the high costs that an excessively "rule bound" application of HACCP in small businesses can entail).

[164] Though the difference exists, it is not as "massive" as critics of recent trends would have it – a comparison of the USDA FSIS audits of foreign countries for meat exports (see here: http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/importing-products/eligible-countries-products-foreign-establishments/foreign-audit-reports) and of the EU FVO work programme for third countries (see here: http://ec.europa.eu/food/food_veterinary_office/audit_programmes/docs/fvo_inspect_prog_audit_en_2015.pdf) shows indeed overall more EU FVO audits (and with a somewhat more systemic approach to food safety), but the difference in numbers is not very large (10 for FSIS in 2014, 16 for FVO planned in 2015 counting only FSIS-supervised issues, but with different approaches and FSIS has a somewhat narrower remit, making it difficult to fully compare numbers – this does show, in any case, that FSIS has not become "inactive").

responsibilities with effective data-sharing mechanisms, and coordination of work[165]. Though a memorandum of understanding between FDA and FSIS on data sharing is in place (since 2012 only)[166], it is a long way from automated sharing or integrated information management. While the FDA has undertaken efforts to make state regulations and enforcement more homogeneous[167], this is far from being fully accomplished, and concerns exist about the effectiveness of its audit programme to ensure state inspections are all roughly equivalent[168]. In a number of states, the FDA contracts to a large extent its own oversight to state inspection agencies[169]. The overall result is a system where uniformity of means and methods is far from guaranteed, and where swift communication of information[170], while desired, is not always ensured. In response to this situation, and in addition to the efforts to improve coordination and consistency through the (difficult) implementation of the FSM Act[171], there have been growing calls for the creation of a unified food safety agency. In Congress, a proposal has been made to create a new, centralized "Food Safety Administration", and President Obama has expressed support for the initiative and included a variation of it (consolidating all existing agencies under the Department of Health and Human Services) in his 2016 Budget proposal[172]. While the current political situation (in particular the Republican majority in Congress) mean this is unlikely to happen any time soon, the proposals show that policymakers' views on the topic are evolving towards more "radical" solutions.

Conclusion – path dependence and the challenges of introducing "risk-based inspections" in a difficult context

The notion of *path dependence* originates in economics, where it is used to explain primarily the entrenchment of particular standards, but also the lasting attractiveness of large metropolitan areas due to network effects[173] and – particularly relevant for us – the development of specific institutions. In the perspective of historical institutionalism[174], which is the one most relevant for our research, the notion means that the development

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[165] See e.g. World Bank Group (2014) module 4 pp. 7-9, OECD (2014) principle 6 ('coordination and consolidation'), FAO guidance on food safety systems here: http://www.fao.org/docrep/006/y8705e/y8705e05.htm. The EU has also been pushing all candidate countries to consolidate their food safety systems as much as possible, something which was done e.g. in Croatia, Estonia, Latvia, Lithuania etc. Fragmentation, on the other hand, has been seen by some as a factor in the seriousness of some food contamination outbreaks, e.g. the *E.coli* 2011 crisis in Germany (see: http://www.bloomberg.com/news/articles/2011-06-09/scattered-health-model-draws-fire-for-germany-s-response-to-e-coli-threat) or the 2008 *Listeria* outbreak in Canada, which led to some institutional changes (see: http://www.phac-aspc.gc.ca/about_apropos/evaluation/reports-rapports/2011-2012/feipdra-pdimeoa/app-ann-b-eng.php).

[166] See : http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/ucm294512.htm

[167] See e.g. guidance on milk processing http://www.fda.gov/ICECI/Inspections/InspectionGuides/ucm074974.htm - even though FDA does not have jurisdiction (except when products are shipped in interstate commerce), it attempts to promote some uniformity of approach.

[168] See Gibbs Brown 2000 (Inspector General of the Department of Health and Human Services' report). Unfortunately the report is not recent, but it points out shortcomings in terms of audit frequency and overall resources available to ensure consistency (pp. 2-5).

[169] See http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm315486.htm#coordination_local_state and Gibbs Brown 2000

[170] Which also involves the Centers for Disease Control for outbreaks detection, monitoring, investigation.

[171] See FDA summary on these efforts here: http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm436155.htm

[172] See a summary of the proposals in *RegBlog*: http://www.regblog.org/2015/02/17/knofczynski_food_safety_admin/ - and some media reports about it: *New York Times* http://www.nytimes.com/2015/02/21/us/obama-proposes-single-overseer-for-food-safety.html?_r=0 – *USA Today* http://www.usatoday.com/story/news/2015/02/02/obama-proposes-consolidating-food-safety-oversight/22764529/. Unsurprisingly, officials in existing structures are unenthusiastic about a merger: http://www.foodsafetynews.com/2015/05/top-food-safety-officials-value-collaboration-between-agencies-over-combination-into-one/ (but their concerns and remarks also point out to the real challenges involved in making a merger successful, and achieving better collaboration is often a more realistic goal indeed).

[173] For a good definition, examples and bibliography, see: Puffert, D. (2008) "Path Dependence". EH.Net Encyclopedia, edited by Robert Whaples. February 10, 2008. URL http://eh.net/encyclopedia/path-dependence/

[174] See Thelen (1999) and Steinmo (2008). A quote from Steinmo about Theda Skocpol's work perfectly illustrates the gist of historical institutionalism: "Most famously, Theda Skocpol wanted to explain the sources and patterns of the great revolutions (Skocpol 1979). But rather than assume that class structure or elite power would explain different patterns, she did the hard work of examining actual revolutions and placing them in their comparative and historical contexts. Eventually, Skocpol realized that the structure of state

of specific systems and practices is neither only determined by the different forces at play (economic, social, political) and the interests of different parties, nor by rational calculations and/or ideological models, but also (and in a very important way) by the specific choices made at an early stage (possibly under completely different conditions, with different forces at play, different ideological models etc.). In a *path dependence* perspective, the fact that specific institutions have been created, laws adopted, officials hired, practices put in place, means that it will be far likely that future developments will take place *on this basis* rather than *ex nihilo*. As Steinmo (2008) puts it: "political choices made at time A have important consequences for time B", and the different variables and factors in historical evolution are not independent. This means in our case that the current differences in institutions, legal systems and practices that are found, for the same field of inspections, between countries such as Britain, the US or Germany cannot be solely (or even primarily) explained by reference to today's situations (differences in political and social contexts, for instance), but to a significant extent arose because of the accumulated differences resulting from initial diverging choices made when designing the first regulatory responses to specific issues.

This overview of the history of food safety regulatory inspections and enforcement in the US has taken us far and wide, and abundant sources have allowed us to understand better the roots and successive transformations than was possible in other countries and regulatory spheres. If we decided to use this opportunity and make this a considerably longer chapter than others in this section is that it allowed us to investigate some key issues of relevance for the entire research, and for inspections issues everywhere.

First, the importance of *trust* (or its breakdown) and of demands for reassurance in driving inspections development. Rather than addressing statistically-assessed risks, regulations and institutions often seem to have been created and grown in response to shortfalls in consumer or citizen trust.

Second, the difficulty of objectively and reliably estimating regulatory inspections' contribution (or lack thereof) to safety improvements, when other forces (e.g. scientific and technological change) are at play in the same period, and when data (in particular epidemiological) are subject to caution (at least in terms of doing reliable international comparisons). We know that food safety improved over the past century, and we know that it is now at a high level (notwithstanding some issues, outbreaks etc.) in both the EU and US – but we cannot tell how much of it was caused or even made faster by regulatory interventions, and we cannot really tell whether the EU or US perform better (at least not with currently readily available data – in principle, an epidemiological survey, or maybe an in-depth review of existing sources, may yield robust results).

Third, introducing new, more "risk-based" and "risk-focused" approaches is particularly difficult when the context features acute political disputes about regulation where its very necessity and legitimacy are disputed[175], and success is made less likely when reforms that ostensibly aim at improving effectiveness and efficiency are made in a context of (and/or as cover for) budget restrictions. There is a serious possibility, in such context and circumstances, that public trust will further decrease, and that this will undermine the whole regulatory system, and the reform effort.

iv. Snapshots of developments in food safety inspections

Going into the same depth for a number of cases would go far beyond the scope of this research, but considering briefly a few country cases, as well as the influence of international organizations and the EU, will help us build a sketch of how (and to some extent why) food safety inspections have developed. We will first look at a couple of country snapshots, in particular at the Netherlands, but also at some of the "new" EU

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institutions in the pre-revolutionary period had enormous consequences for revolutionary outcomes". What we are attempting here is, in a very modest way, somewhat similar in looking at the development of inspection institutions and practices.

[175] Which, on the other hand, is one of the reasons why the US case has far more abundant literature available. Conversely, situations (e.g. in France) where regulation is seen in a large part of the population as an absolute good that cannot be discussed or relaxed, however slightly, also create a very difficult context for any reform effort.

Member States. Then, we will briefly consider, some broad international trends, the role of international organizations such as FAO and WHO, the effect of the WTO on food safety regulations, and the transformations brought about by the EU. We will then try and summarize a few short and tentative conclusions.

A few country snapshots

What we have seen above for the UK and the US can, to a large extent, be seen in other countries too: first, "food safety" as such was for a long time not perceived as a unified field, but rather different aspects of it were addressed separately, often combined with other policy issues, creating a fragmented regulatory field. Second, institutional building was gradual, often slow, and generally came significantly later than the adoption of regulations.

France

In France, for instance, municipal veterinary inspections existed since 1898, but really effective only in Paris and, to a lesser extent, other major cities. Regulations ensuring somewhat uniform control were not adopted before 1933, and a national food hygiene service (with a veterinary focus) only created in 1965 (Theves 2002, p. 56). As for the 1905 *Loi sur la répression des fraudes* (Law on fraud and adulteration) its focus was initially, much like what we have seen in the US, more on protecting commercial interests than on protecting consumers from hazards (Canu and Cochoy 2004, p. 6). A service is set up in April 1907[176] to implement it, but though it looks after consumer interests, it is (at least in the first decades) mostly in terms of prices, labelling and adulteration – controlling safety only comes incidentally (*ibid.,* pp. 12-16). The parallel development of veterinary legislation and inspections, and of consumer protection legislation and services, has led to a dual structure which persists to this day, with two national *Directions Générales* (General Directorates): one in charge of *Alimentation* (Food), the other of *Consommation, Concurrence et Répression des Fraudes* (Consumer Affairs, Competition and Fraud Suppression). The term of "food safety" as such is absent, and the mandates of both directorates are broader, with safety only one of several issues. The Food DG looks at production and supply as well as safety, at all that is "upstream" (primary production, processing, storage and handling etc.) but also au trade and catering). The Consumer DG looks at consumer complaints, competition, intellectual property, labelling, and safety only at the consumer stage (catering, retail). The division of responsibilities is not "obvious" in that both DGAL and DGCCRF look at the consumer stage - the former from a sanitary safety perspective, the latter from a consumer protection and fraud prevention one. In practice, however, though inspectors report to the national DGs in terms of professional competence, career, guidelines, their operational management is at the local (*département*) level. Thus, actual inspections and control measures are conducted by inspectors that report to local directorates at the administrative level of the *département* and thus report to a local director and to the *Préfet,* who heads all state services in each *département.*

Since January 2010, as a result of the *Révision Générale des Politiques Publiques (RGPP* – General Review of Public Policies[177]), both groups of inspectors have been part of the same joint local directorates, called *Directions Départementales de la Protection des Populations*[178]*.* They continue, however, to have different

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[176] Initially under the Ministry of Agriculture, the *Répression des Fraudes* was later merged with services in charge of price controls (later price monitoring), competition, consumer protection. After having been part of the Ministry of Consumer Affairs, the service has been assigned to the Ministry of Finance since 1983. See: *Historique des Directions et des Services du Ministère de l'Économie, des Finances et de l'Industrie - CAEF - Août 2004* available at: http://cadastre.pagesperso-orange.fr/Fichiers/historique_direction.pdf

[177] See 2012 report on the RGPP (assessing results, outcomes, lessons) by the General Inspectorate of Public Administration – available at: http://www.ladocumentationfrancaise.fr/rapports-publics/124000520/index.shtml

[178] In some (less populated) *départements*, these have been merged with social assistance services too and are called *Directions départementales de la Cohésion Sociale et de la Protection des Populations.* See: http://www.economie.gouv.fr/dgccrf/coordonnees-des-DDPP-et-DDCSPP and https://fr.wikipedia.org/wiki/Direction_d%C3%A9partementale_de_la_protection_des_populations

cultures, qualifications, guidance from the centre, keeping a "technical" reporting line to their respective DG and using different information systems depending on which DG their work relates to. The unusual experiment to conduct mergers at the local level while leaving central structures separate[179] needs to be evaluated further, but actually overcoming the cultural differences between different *corps* is likely to take a long time and be rather difficult, and it is less than clear that this challenge is really being addressed. A vision of food safety controls, and a corresponding effort on developing guidelines and training, are both lacking[180].

Former Soviet Union

Such a division between several services, each looking at food safety from a different perspective (and, often, along with other issues), is quite frequent – as the idea of "food safety" as a unified problem appeared relatively late, and with institutional structures already well established. In the Former Soviet Union (FSU)[181], for instance, supervision of food safety issues has for decades been divided between the Sanitary and Epidemiological Service (SES), the Veterinary Service, and inspectors controlling conformity with Standards (some elements of which relate to food safety). The SES embodied a "holistic" conception of health, not unlike the UK's "Environmental Health" approach (but even broader in some ways) – the SES institution, and its inspectors (normally all medical doctors, most often epidemiologists), would be responsible for environmental issues, epidemiological control, and food safety. While in principle the Veterinary Service should be responsible for all food of animal origin, there is, in such a system, a vast area of overlap between Veterinary and SES – as soon as meat, dairy or eggs leave the farm and enter the processing and trade chain, SES claims responsibility, but Veterinarians do not relinquish it. On top of this, Standards inspectors control nearly every food product for conformity with their mandatory standards. In addition to problems of overlap and conflicting responsibilities, such systems also feature strong "cultural" rivalries between veterinarians and medical doctors (not unlike, again, what has been seen in the early development of food safety control in the UK, but with veterinarians having achieved a somewhat stronger position in the Soviet/post-Soviet systems).

While this dual system of SES and Veterinary control (or in fact triple control, including Standards) has to a large extent remained the norm in most Former Soviet republics (e.g. Russia[182], Kazakhstan, Kyrgyzstan[183], Uzbekistan, Tajikistan, Azerbaijan, Belarus), some have initiated reforms that are at varying stages of

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[179] See short overview in Blanc (2012) pp. 29 et 66

[180] Interviews with senior officials in the President's Office and both DGs, 2012-2013.

[181] All this section is based on the author's direct experience working on this topic in these countries since 2004, and numerous interviews with senior officials in all relevant institutiona (SES, Veterinary, Standards, line ministries, ministries in charge of economic development and administrative reforms). In addition, the reader can refer to the following published sources: Gotsadze et al. (2010) provides a comprehensive overview of reforms in the FSU and Central and Eastern Europe (CEE), but with a health (not a food safety) focus – IFC (2009 b) describes in some detail the Ukrainian system, and how it contrasts with accepted practice in the EU (see e.g. pp. 23-25 and 44-47) – World Bank Group (2014), module 8, has four relevant case studies: Armenia (pp. 5-6), Lithuania (pp. 17-18), Moldova (pp. 19-22) and Ukraine (pp. 27-29) - Josephson, Dronin and Cherp (2013) provides information on the early history of the SES that is relevant for food safety, even though the book focuses on environmental issues.

[182] Some consolidation has taken place in Russia, but a fundamental duality remains: *Rosselkhnadzor* on the one hand (Russian Federal Service for Agricultural Surveillance, in charge of veterinary and phytosanitary safety) and *Rospotrebnadzor* (Russian Federal Service for Consumer Rights and Human Wellbeing Surveillance, which merged the SES functions with consumer protection and standards supervision). See the respective websites for overview of functions: http://www.fsvps.ru/fsvps/main.html?_language=en (*Rosselkhnadzor)* and http://www.rospotrebnadzor.ru/en/deyatelnost/san_epid.php (*Rospotrebnadzor*)

[183] Consolidation of the SES and Veterinary Service was attempted in 2012 by the Government (see IFC 2012, pp. 32-33), but rolled back after a few months and fierce lobbying of the former SES (author's interviews with officials, 2012-2015)

implementation (e.g. Ukraine[184], Armenia[185]), and some have completed complete transformations including the creation of unified food safety agencies, as part of their entry into the EU (Estonia, Latvia, Lithuania).

In September 1922, in order to fight what they considered a dramatic epidemiological situation[186], Soviet authorities created the first sanitary and epidemiological centre – and in 1931-32, the Government set up what became a nationwide network of SES[187]. The system was successful in eradicating epidemic typhus and cholera[188]. While in 1933 the inspection function was separated from the Sanitary and Epidemiological Centres, they were merged again at the beginning of the 1950s, and the structure remained essentially unchanged until the end of the Soviet Union and, to a large extent and for the majority of post-Soviet states, until today. Interestingly, the Soviet SES developed a kind of early and rough "risk-based classification" of establishments[189], with some being designated as "of acute epidemiological risk". However, this classification remained set in the conditions which presided to the SES's creation – thus, alongside hospitals, hairdressers and beauty parlours are considered "high risk" all over the Former Soviet Union[190].

This early approach to risk-based prioritization, however, has not resulted in a real "risk based approach". Rather, contemporary SES (or successor institutions) and (to a lesser extent due to generally lower staffing levels) Veterinary Services are characterized in most FSU countries by complete "risk aversion", and efforts to achieve "total control" of every establishment and product on the market. We will come back to what this means in terms of inspections' depth, and effectiveness. It is worth noting that it reflects both an ideological vision (that each and every risk should be prevented by the state), and vested interests (considering the extent of corruption in inspections)[191]. This has led, in several countries, to deep and comprehensive reforms. While the Baltic States have all set up unified Food Safety inspections (following very strict EU guidance during the accession process), Georgia in 2003-2004 took a different, radical approach.

Reforms in both the Baltic States and Georgia were a response to somewhat similar problems (though they were certainly even more acute in Georgia): ineffective controls, high administrative burden, significant levels of corruption[192]. In Estonia, Latvia and Lithuania, new institutions were set up, with mandates covering all food safety inspections – and sometimes an even broader food safety responsibility[193]. Old institutions were shut down, merged or split, staff was profoundly retrained (and partly renewed), and methods entirely transformed. This resulted in a new institutional framework that proved considerably more effective, and far less corrupt (it is always difficult to assert that corruption does not exist at all, hence our cautious wording).

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[184] As in Russia, the Veterinary and Phytosanitary Services were merged in an Agriculture Inspection. In Summer 2014, the new Government of Arseniy Yatsenyuk took a decision of principle to create a wholly new, consolidated inspectorate, that would include all of food safety, as well as non-food products market surveillance, but this institution is not yet operational (author's own interviews with officials, 2015).

[185] In Armenia, a unified Food Safety Service exists, but there remain some "grey areas" of overlap on hygiene issues with the Public Health Inspections, and methods and approaches have not really been reformed.

[186] Typhus, spread by body lice, was a particularly deadly disease towards the end of WWI and in the Revolutionary War period. Lenin is quoted as saying "either the lice conquers socialism, or socialism conquers the lice" (quoted by Josephson *et al.* 2013, p. 90) – see also this page at the University of Kansas Medical Center: http://www.kumc.edu/wwi/index-of-essays/typhus-on-the-eastern-front.html

[187] See Josephson *et al.* 2013, p. 90 and http://www.rospotrebnadzor.ru/en/region/history.php

[188] *Ibid.*

[189] Which was not necessarily unusual for the Soviet Union – the Fire Safety Service had a similar classification, which emphasized a combination of inherent fire risk, potential for life loss and potential for economic loss (in which it differed strongly from contemporary "western" approaches, which emphasize only life loss potential – but the Soviet State was an economic operator as much as a State) (author's interviews working with Fire Safety Services in Former Soviet Republics since 2004).

[190] Though typhus is spread by body lice and not hair lice, all hygiene-related establishments were critical to epidemiological progress in the 1930s. The situation, however, has changed considerably over 80 years – but not the classification and targeting.

[191] On all this see Blanc 2011 b and 2012 b.

[192] On Georgia, see World Bank Group (2012).

[193] E.g. in Lithuania where the State Food and Veterinary Service covers all food safety inspections, as well as the network of food laboratories, a rule-making function for veterinary issues, and the scientific risk assessment function (author's interviews and discussions from 2011 to 2015 – see also SFVS website at: http://vmvt.lt/en/about.sfvs/)

The new setup played a strong role in transforming the food processing sector, with a number of establishments closing as the costs of putting their operations in conformity was prohibitive[194]. The new system was found to satisfy EU requirements and thus fulfil one of the conditions for EU accession. In fact, the Baltic states provide examples of full implementation of the EU Food and Veterinary Office (FVO) recommendation for unified food safety inspectorates, something which in practice has remained the exception (due to the historical path dependence we have been researching here, in no small part). In Georgia, by contrast, the reform essentially shut down the previous inspecting bodies, drastically reduced their staff and activities, and in effect was a major deregulation effort. Only from 2006, with the process of negotiation (and, after signature, the implementation) of a Deep and Comprehensive Free Trade Agreement (and thus with both EU pressure and EU assistance) was a new National Food Agency (NFA) set up. This Agency barely conducted any inspections, however, for the first years of its operations. The NFA only started ramping up its staffing and inspections significantly after 2012, with a new government in charge[195]. We will come back to this example and its impact in further sections, for it provides a very interesting experiment of essentially shutting down food safety inspections for several years – and, this much we can say already here, it did not result in the disaster that critics predicted.

Netherlands

In the late 19th and early 20th centuries, the Netherlands was relatively slow to introduce food safety legislation, and controls, compared to a number of other countries in Western Europe. According to Koolmes (2000) this is because of the prevalence of "liberal doctrines of free trade and the restriction of state interference" (p. 58)[196]. As he shows, there was very little control in practice, including regarding meat slaughter, processing and sale, which exposed the population to contamination hazards (*ibid.,* pp. 55-56). While legislation was adopted in 1908 to control meat exports, it was not before 1919 that it was extended to cover the internal meat market (Theves 2002, p. 56).

The development of regulations and inspections in food led, however, to a similarly fragmented structure, as we have seen in other countries. First, because of a duality between consumer products inspections, and veterinary inspections. Second, because of a Dutch specificity, the delegation of regulatory conformity inspections in some areas of food safety to institutions of a private nature (COKZ, NCAE[197]). Simplification and closure of several private sector "product boards" (*product- en bedrijfschappen*) which were in charge of supervision in different agricultural areas has been going on in recent years, but this delegation of powers remains a specificity of the Dutch system[198]. In addition, some inspections (of hygiene in catering, in particular) are done by the local authorities, independently of national food safety bodies. While there are efforts to introduce coordination and information sharing, and these have been going on for several years, the duplication remains[199].

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[194] We will come back to this question of costs in the last part of this research.

[195] Interviews with government officials conducted in 2014.

[196] As we have seen above, there was a similar delay in adopting OSH regulations and controls, possibly due to similar reasons.

[197] COKZ (*Centraal Orgaan voor Kwaliteitsaangelegenheden in de Zuivel,* Central Body for Quality Issues in Dairy) is tasked with conducting regulatory food safety inspections (based on national and EU legislation) in dairy production/processing. NCAE (*Nederlandse Controle Autoriteit Eieren*, Netherlands Eggs Control Authority) is tasked with the same for egg production/processing. NCAE is a subsidiary of COKZ, and took over egg inspections from CPE (*Controlebureau voor Pluimvee, Eieren en Eiproducten*, Bureau of Control of Poultry, Eggs and Egg Products) in 2012. They work on the basis of an official delegation of powers and competences (and funding allocation) by the state. For details, see websites: http://www.cokz.nl/SitePages/over-COKZ.aspx http://www.ncae.nl/pages/over-ncae.aspx.

[198] The model appears to enjoy strong legitimacy since, when CPE functions were taken back, they were not given to the state inspectorate, but to another private sector entity (NCAE).

[199] See e.g. *Werkprogramma samenwerkende rijksinspecties 2014* (Work Programme for State Inspections Cooperation 2014), avaialble at: http://www.inspectieloket.nl/organisatie/publicaties/Werkprogramma_samenwerkende_rijksinspecties_2014.aspx.

National (state) food safety inspections in the Netherlands have been considerably consolidated in the past 10-15 years (starting ca. 2000[200]), resulting in a novel institutional structure. The *Nederlandse Voedsel- en Warenautoriteit* (NVWA - Netherlands' Food and Consumer Product Safety Authority), under the Ministry of Economy (and an additional reporting line to the Ministry of Health), was established in two steps in 2002 and 2006. In 2002, services controlling meat and livestock (*Rijksdienst voor de keuring van Vee en Vlees*, RVV - State Service for Supervision of Livestock and Meat) and those supervising consumer products (*Keuringsdienst van Waren*, Consumer Products Supervision Service) were both put under the VWA as "umbrella organisation". Then, in 2006, they were fully merged, and what was now the NVWA underwent an internal reorganisation so that its internal structure matches better the modern approach to food and consumer safety.

This followed previous efforts at consolidation and mergers, over more than two decades. In 1980, the RVV was formed merging local meat inspection services and the veterinary services from the Ministry of Agriculture. In 1988, provincial and municipal products inspection services were merged into a State Inspection, that itself was consolidated in 1995 with other services in charge of food, alcohol legislation supervision etc. In the late 1990s and early 2000s, the "consumer products" and "veterinary and meat" sides were themselves gradually merged. At the same time, there remain specific inspection functions that are *outside* of the NVWA's mandate - eggs, milk and milk products, the control of which is delegated to institutions of a private nature (COKZ, NCAE). Simplification and closure of several private sector "boards" (*schappen*) which were in charge of supervision in different agricultural areas has been going on in recent years, but this delegation of powers remains a specificity of the Dutch system.

Thus, not unlike in the UK, the original situation involved control mostly implemented by local authorities, a gradual emergence of the food products control function, and a separation between control of products and of production (in particular animal health). Consolidation was a process that was slow and complex. A feature of particular interest (and again underlining how much variation there can be, and how little of these structures is "obvious") is that in the Netherlands the NVWA groups inspection and control of both food *and non-food* products, which is quite unusual (though not unheard of[201]) internationally.

The role of international institutions and international integration

In sharp contrast with OSH, food safety is an area where international institutions and structures (of a variety of nature and scope) have a very important influence – not only on the formulation of norms but, at least in some cases, on the ways in which inspections are organized, and the manner in which they are conducted. This, of course, is linked to inherent characteristics of food safety issues. First, food is a tradable good – and not only tradable, but in practice largely traded across borders. Second, some food-related pests, parasites and diseases can spread rapidly – regardless of whether they affect humans, plants or animals. Third, the development of food safety regulations and regulatory practices has been strongly underpinned by the development of science regarding food-borne human pathogens, as well as plant and animal diseases, providing a common basis for rules and enforcement across the globe. As a result, while there remains considerable differences in both contents of rules and practices, there has been several growing and concurring trends: harmonization of regulatory requirements, adoption of generally applicable principles,

[200] While the author has had the opportunity to see internal Government documents laying out the consolidation process starting in 2000, it is not entirely clear when the initial decisions were taken, and the documents are not published.

[201] A couple countries, such as Bosnia and Herzegovina (2004) and Mongolia (2003) created "unified inspectorates" covering most inspection functions (Croatia was one of the first, but with a narrower scope). Ukraine (2014) decided to create a body similar to NVWA. But these remain exceptions. (Sources: World Bank Group (2010), author's interviews and experience in Mongolia 2008-2015, Bosnia 2010). In France, there is a partial combination in the functions of the DGCCRF, but it has only narrow food safety competence, and mostly looks at consumer products. In the UK, non-food products safety is controlled by the Trading Standards inspectors (which are part of local authorities' services) – they also control labeling, including for food, but no substantial food safety issues..

endorsement of "best practices" – and, at least in the EU context, increasing harmonization of practices. There are a number of institutions involved in this process – in particular a group of UN agencies (Food and Agriculture Organization – FAO – and World Health Organization – WHO), the World Trade Organization (WTO), two structures with a specific status but related to the UN and WTO (the World Animal Health Organisation, OIE, which is recognized as competent organization by the WTO – and the International Plant Protection Convention, a convention ratified under the auspices of FAO) – and the European Union (EU). We will limit ourselves to considering WHO and FAO, WTO and EU – as regulations and inspections relating to animal health (epizootic diseases) and plant health (phytosanitary issues) are, though important, further from our core focus in this research (and would entail detailed considerations of border control and quarantine regimes).

FAO, WHO and the Codex Alimentarius

While FAO is primarily concerned with food security[202], in the sense of ensuring a continuous and sufficient supply of food to populations around the globe[203], it has some activities related to food safety, i.e. ensuring that food for human consumption is safe to eat. Limited funding resources means that operational projects implemented by FAO to support the development of food safety in developing countries are relatively rare and small in size. Likewise, while FAO has developed a number of important guidance documents on food-related legislation and inspections[204], these do not have as much influence as, for instance, the EU's (even when considering non-EU members). As for WHO, it is "the directing and coordinating authority on international health within the United Nations' system[205]" and, as such, responsible for a very wide range of issues – in particular, coordinating responses to major epidemics and pandemics, e.g. the recent Ebola outbreak. Considering limited means and the vast number of issues WHO is responsible for, its activities in food safety are limited, even though it runs a few projects on this topic in some developing countries[206]. In fact, the main way in which FAO and WHO are active, and significant, in food safety regulation is through the *Codex Alimentarius.*[207]

The *Codex Alimentarius*[208] (or, shortly, *Codex*) is primarily "a collection of standards, codes of practice, guidelines and other recommendations. (…) Some deal with detailed requirements related to a food or group of foods; others deal with the operation and management of production processes or the operation of government regulatory systems" (FAO – WHO 2006, p. 10). The *Codex* is developed by the *Codex Alimentarius Commission*, which was created in 1961 by the 11th FAO Conference, and met for the first time in 1963[209]. The main aims of the *Codex* are to be a reference guide to define (a) what particular food names actually mean (contents, definition of foods), (b) what are acceptable (safe for human health) residue levels of specific contaminants, (c) how to conduct sampling and testing procedures, (d) what are safe methods for the

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[202] It defines its mandate thus: "Our three main goals are: the eradication of hunger, food insecurity and malnutrition; the elimination of poverty and the driving forward of economic and social progress for all; and, the sustainable management and utilization of natural resources" - http://www.fao.org/about/en/

[203] But FAO is not responsible for emergency food relief, which is the mandate of the UN World Food Programme (WFP).

[204] See in particular for legislation http://www.fao.org/food/food-safety-quality/capacity-development/food-regulations/en/ and for inspections http://www.fao.org/food/food-safety-quality/capacity-development/inspection/en/. Main publications include the *New Model Food Law* (FAO 2005 – see: http://www.fao.org/3/a-a0274e.pdf) and the *Risk Based Food Inspection Manual* (FAO 2008 – see: http://www.fao.org/3/a-i0096e.pdf).

[205] See: http://www.who.int/about/what-we-do/en/

[206] Direct author experience and observations in several dozen countries since 2001.

[207] For details on the *Codex Alimentarius* work and its effects e.g. in EU law, see for instance Everson and Vos 2008, Matthee 2009.

[208] Interestingly, the name was taken from a much earlier codification exercise regarding food, the Codex Alimentarius Austriacus (see: https://en.wikipedia.org/wiki/Codex_Alimentarius_Austriacus), which was developed in the last decades of the Austro-Hungarian Empire. Much like the modern *Codex* standards, its norms were not directly enforceable, but could be referenced in case of litigation.

[209] See: http://www.codexalimentarius.org/about-codex/codex-timeline/en/

preparation and handling of specific foods and (e) how to organize and conduct controls of food safety (both internal controls and regulatory inspections)[210].

While *Codex* "standards[211]" are not mandatory for the countries that participate in the Commission (186 in total, plus the European Union as such), they provide an importance reference point, in several ways. First, they provide a basis for standards, regulations and practices that can be adopted by member countries – and, in fact, they frequently form the basis of modern food safety regulations. Second, they are recognized by the WTO (in the SPS agreement, see below), and thus they are used to adjudicate trade disputes. In particular, having stricter requirements than those foreseen in *Codex* would have to be justified in case of a dispute.

Nonetheless, while generally OECD and EU members have regulations that are mostly aligned with *Codex,* this is far from the case everywhere – be it because *Codex* standards would be too complex, too costly to comply with, set the bar too high – or because there are vested interests which benefit from using older standards (e.g. Soviet or post-Soviet ones), or simple path dependence and refusal to change[212]. The development and increasing influence of *Codex* standards is important for our topic because it has driven, or at least supported, a growing approximation not only of *rules* being enforced, but also of *methods*, in particular of what gets checked during inspections, and how. In particular, the *Codex General Principles of Food Hygiene* (introducing the HACCP approach) and the standards for inspection and certification practices are significant in this respect. While *Codex* standards are not necessarily driving the development of new practices (but rather codifying them), they constitute an important factor of diffusion of risk-based inspection approaches, at least in terms of targeting of controls, and of focus of attention during controls (but not as strongly when it comes to risk-proportionality in determining regulatory instruments, and enforcement actions).

The WTO Sanitary and Phytosanitary (SPS) Agreement

In 1995, the General Agreement on Tariffs and Trade (GATT), which had been in effect since 1948, gave birth to (and was replaced by) the World Trade Organization (WTO). Thus, from a multilateral agreement, world trade regulation moved to an international organization, i.e. a stronger structure, with more robust regulation and litigation mechanisms[213]. During the Uruguay Round of the GATT, along with the main treaty creating the WTO, were negotiated two key agreements on product market regulations and their effects on trade: the Agreement on Technical Barriers to Trade (TBT), and the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS)[214], both of which entered into force in January 1995. These two agreements marked a major turning point[215] in the way states regulate their product markets (both food and non-food) because, for the first time, international agreements applicable to the vast majority of the world's nations (161 countries as of April 2015) lay out what are the acceptable practices in terms of restricting free market access, what level of protection and methods are acceptable – and do so in a way that is backed by the possibility of litigation. While the conflicts that reach the main headlines (such as the UE-US conflict on poultry that we briefly discussed above) are mostly between the most developed economies, and point to areas of acute

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[210] For more details on what *Codex* covers see FAO – WHO (2006) pp. 11-12.

[211] We put the word in quotation marks because, even though they are officially called thus, they differ strongly from the definition of "standard" used e.g. by the International Standardization Organization and the WTO Technical Barriers to Trade (TBT) agreement.

[212] Broadly speaking, there are two cases of non-adoption of *Codex* standards: low-income, low-capacity countries, which lack resources to translate and, even more, implement them (and, in some cases, non-adoption is wise, as the standards may just be impossible to implement in practice) – and countries, where existing rules are in fact costly and complex, and less adequate than *Codex* ones (either because they are less effective, or because they harm trade), but where regulators and/or incumbent businesses benefit from them (a case that is observed in many post-Soviet countries – see e.g. IFC 2009 b).

[213] See WTO website: https://www.wto.org/english/thewto_e/thewto_e.htm.

[214] For more in depth considerations of the balance between risk prevention and trade in the SPS agreement, see Prevost 2009.

[215] GATT rules with a similar purpose existed earlier, but weaker and less specific. In addition, the WTO has considerably expanded compared to the GATT membership. See WTO (2010) p. 14.

disagreement but rarely to deep and far-reaching differences in how regulatory systems are organized, the more substantial effects of the TBT and SPS agreements are often felt in developing countries and transition economies, during or just after the accession process, where they can result in very important transformations of the regulatory framework.

From our perspective attempting a review of food safety inspections experience, the SPS Agreement is the relevant one[216]. The WTO defines the problem to which the Agreement intends to respond thus: "How do you ensure that your country's consumers are supplied with food that is safe to eat — "safe" at the level you consider appropriate? And at the same time, how can you ensure that unnecessary health and safety regulations are not used as an excuse to protect domestic producers from foreign competition?" (WTO 2010, p. 9). This means that, from the onset, the WTO SPS perspective is one of *balancing* the expected benefits of regulation (safe food, in this case) against its costs (in this case, barriers to trade protecting domestic companies from competition[217]). What is important and interesting from our perspective is *how* the SPS Agreement seeks to regulate this: by emphasizing the notion of *risk,* and using it as the foundation to determine the legitimacy of SPS "measures"[218].

In the SPS Agreement, international standards form a "baseline", which allows to avoid a complex cost-benefit assessment model: implementing the international standards (as adopted by *Codex,* OIE and IPPC) is accepted as the baseline option, doing *less* (i.e. being having a higher tolerance of risk) is accepted in the sense that it restricts trade less (and thus does not harm the WTO's purpose), however doing *more* needs to be justified – using "risk" as the fundamental criterion. As the WTO puts it, "WTO member countries are encouraged to use the standards developed by the relevant international bodies whenever they exist. However, members may use measures which result in higher levels of health protection, so long as their measures are based on an appropriate assessment of risks and the approach is consistent, not arbitrary" (WTO 2010, p. 9). The Agreement clearly articulates that risk assessment must be the foundation for adoption of "measures", that science must be the basis for risk assessment, and that in any case the "measures" must be non-discriminatory (treat domestic and foreign producers equally) and their necessity must be demonstrated: "regulations must be based on scientific findings and should be applied only to the extent that they are necessary to protect human, animal or plant life or health; they should not unjustifiably discriminate between countries where similar conditions exist" (*ibid.*). The Agreement goes further than just a general requirement to base "measures" on risk, however, it also "clarifies which factors should be taken into account when risks are assessed" (*ibid.,* p. 10). First, "measures" should be based on an assessment of "the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations". Then, "Members shall take into account available scientific evidence" as well as "relevant economic factors" such as "the potential damage" and "the relative cost-effectiveness of alternative approaches to limiting risks" (SPS Agreement Article 5, quoted in WTO 2010, p. 30).

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[216] The TBT Agreement is very important for other types of inspections, those concerned with non-food products safety, as well as with labeling (all together commonly called "Market Surveillance"). The labeling component has some implications for food, of course, but from a food safety perspective the fundamental agreement is the SPS one. What we write here of the SPS Agreement's effects is largely, *mutatis mutandis*, applicable to the TBT Agreement and non-food products regulations and inspections, with ISO and other international standards playing a somewhat comparable role to the *Codex,* OIE and IPPC standards under SPS, and the same overall approach of minimal level of trade restriction and risk-based approach to regulatory intervention (there are also important differences, e.g. the TBT's reliance on the notion of "technical regulation", which is not applicable to the SPS field). See WTO (2010) pp. 16-17 for the scope of the two agreements.

[217] Many have argued against considering free trade as an unalloyed benefit, and thus necessarily seeing barriers to trade as costs (see e.g. Chang 2007), but *from the WTO perspective*, in any case, limiting competition is a negative (and a majority of economists would generally support this view).

[218] The Agreement does not refer to "regulations" in order to avoid any peculiarities in various legal systems, but the neutral "measures", which covers any form of SPS-related restrictions to trade.

Interestingly, what the SPS Agreement emphasizes is the risk-based *approach*, but not the specific level of risk that should be acceptable. This, as befits an international agreement, is left to the states that are party to it to decide upon: "the SPS Agreement allows countries to give food safety, animal and plant health priority over trade, provided they can demonstrate that their food safety and health requirements are based on science. Each country has the right to assess the risks and determine what it considers to be an appropriate level of food safety and animal and plant health". Once this level is set, "there are often a number of alternative measures which may be used to achieve this protection (such as treatment, quarantine or increased inspection)" (WTO 2010, p. 20). The SPS Agreement thus aims at ensuring that WTO member states select the least burdensome, most efficient, most trade-friendly way to achieve the goals they have set themselves, i.e. the level of risk-mitigation they deem appropriate.

Risk assessment must also be demonstrated and justified in case of challenge or litigation: "Countries' SPS measures must be based on an appropriate assessment of the actual risks involved. If asked, they must make known what factors they took into consideration, the assessment procedures they used and the level of risk they determined to be acceptable" (*ibid.,* p. 11). The Agreement emphasizes that countries do not have to accept international standards "as a floor or ceiling" (*ibid.,* p. 19) – but they have to justify variations (particularly if their requirements are more stringent, more restrictive).

The SPS Agreement has relatively little details on the question of *inspections* specifically – in any case it covers only the measures imposed to imports (i.e. primarily border controls). It states in its Annex C that "any requirements for control, inspection and approval of individual specimens of a product are limited to what is reasonable and necessary" and that "any fees imposed for the procedures on imported products" have to be "equitable in relation to any fees charged on like domestic products or products originating in any other Member and should be no higher than the actual cost of the service" (*ibid.,* pp. 43-44). Thus, it prescribes general principles of "reasonableness" (proportionality), and non-discrimination. Nonetheless, the Agreement is fundamental in that it sets binding limits on the way in which SPS regulations can be imposed, and mandates that they be based on a risk-based approach. Such a requirement means that aspiring members often need to revise their applicable regulations and, in so doing, end up changing the basis on which inspections are conducted, and pushing their inspection bodies towards a new way of doing things.

Of course, compliance with the SPS Agreement is far from universal. Disputes are relatively numerous (43 disputes stating the SPS Agreement as basis, as of July 1, 2015[219]), but mostly involve major countries (the US, China, India, Canada, South Korean) and the European Union. The way in which the SPS Agreement influences changes in regulations and practices, however, is often less visible, and has to do with the WTO accession process. When applying, and until accession is ratified, countries (particularly those with a relatively weak bargaining position) often have to make considerable changes – or, if these changes have not been made, they sometimes happen post-accession, reacting to the *threat* of litigation[220]. In this way, gradually, the SPS Agreement pushes a growing number of countries to adopt food safety regulations that are based on risk assessment and risk proportionality[221].

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[219] See: https://www.wto.org/english/tratop_e/dispu_e/dispu_agreements_index_e.htm?id=A19.

[220] No detailed account exists of the process, but this is what happened in relation with mandatory state certification of food products in Ukraine (which was not in conformity with the SPS Agreement requirements). Though it remained in place in spite of ratification of the WTO accession treaty (which foresaw its cancellation), in 2008, the threat of litigation was used as one of the drivers to push for the elimination of this mandatory certification, which eventually happened in 2009 (on paper – and in practice in 2011-2012) (see World Bank Group 2014 a, module 8, pp. 27-29 – also based on author's direct experience of involvement in the negotiations regarding elimination of this requirement).

[221] A last point worth noting is that the SPS Agreement, by using internationally accepted standards as "baseline", avoids the need for complex cost-benefity analysis, which is often a major hurdle in implementing "better regulation" or "smart regultion" programmes. With these standards as baseline, any additional cost or hurdle has to be justified, based on a clear benefit in terms of risk mitigation.

The EU: towards the Single Market, the "Hygiene Package" and the role of the EC's Food and Veterinary Office (FVO)

Of all the international institutions we have reviewed, the European Union (and its predecessor, the European Economic Community) have (and have had) the strongest impact on how food safety inspections are structured and conducted (as well as what they aim at). Arguably, the EU may in fact currently be *the* most important institution worldwide when it comes to food safety regulation[222] – more important than its member states, and possibly (through the influence of its model) more influential than any other state as well. The primary reason for this influence is the sheer size of the EU market: over 500 million of "high income[223]" consumers, and the largest exporter and importer of food (raw and processed) worldwide[224]. Being the largest food market (by value), the EU's regulation mechanically carry the most weight. Their influence is further increased by two factors: the large number of countries having entered (or aiming at entering) agreements with the EU and/or joining it[225], and the level of development of the EU's food safety policy (including its inspections and enforcement component), which has led it to be in some ways considered as the "model" to follow by others – a fact that comes from its having had to solve a number of issues in order to build a "single market", as we will see below.

To understand better how this came about, and what the EU "model" exactly consists of, we will consider successively its early history, the turning points that allowed to move from limited mutual recognition and narrow areas of Community action to full harmonization, and the main elements of today's EU food safety regulations and inspections.

The early history: the EEC's gradual intervention in food safety issues

When the 1957 Rome Treaty created the European Economic Community (EEC), with six members at the time, its primary objective was the establishment of a customs union between its members, but its overall goals and scope went beyond. In its Article 3, it foresaw as activities of the Community "the elimination(…) of customs duties and of quantitative restrictions on the import and export of goods, *and of all other measures having equivalent effect*" (emphasis ours), as well as "the abolition (…) of obstacles to freedom of movement for persons, services and capital" and "the approximation of the laws of Member States to the extent required

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While this does not quantify (or attempt to quantify) costs and benefits, it forces to consider them, and prevents the imposition of additional burden with no clear benefit.

[222] Emphasizing the *arguably* – in the author's experience, this is probably the case, and a vast number of countries are taking the EU's food safety system at least as reference point (though not always as model) – we would certainly not endeavour to *prove* that it is indeed the most influential. It is in any case *one of the most* influential.

[223] In the sense of international income classifications used e.g. by the World Bank, OECD etc. It does not of course mean that *everyone* has a high income inside the EU.

[224] EU 2007, p. 28.

[225] As of July 2015, 5 official candidate countries (which have to approximate entirely the EU *acquis*, including all the food safety legislation and enforcement systems), 2 potential candidate (which are trying to approximate as much as possible to be able to apply officially in the future), 3 European Free Trade Area members (Iceland and Norway, members of the European Economic Area, and Switzerland, which has bilateral agreements – all three of which have approximated their regulations to a very large extent), and a large number of Association Agreements and Free Trade Agreements in force (which include various levels of approximation – 17 countries, counting only those with an Association Agreement or "extended/deep" Free Trade Agreement – plus Georgia, where the Deep and Comprehensive Free Trade Agreement has provisionally entered into force), and ma number of countries targeted by the EU Neighbourhood Policy, which includes a large approximation component. See http://ec.europa.eu/enlargement/countries/check-current-status/index_en.htm - http://ec.europa.eu/trade/policy/countries-and-regions/agreements/ - http://eeas.europa.eu/enp/about-us/index_en.htm.

for the proper functioning of the common market[226]". The Treaty had other elements, e.g. foreseeing a Common Agricultural Policy (CAP), a common transport policy, competition regulations, coordination of economic policies etc. – but its core was what became known simply as "the Common Market", which was for decades the EEC's nickname.

If the EEC had been only a customs union (and not an endeavour towards "ever closer union", as per the Rome Treaty's Preamble), there would have been no need or impetus for harmonization of technical rules – a customs union is not a single market, it just means there are no duties to be imposed, and no quantitative restrictions. What made the EEC different was that it also targeted "other measures having equivalent effect" to quantitative restrictions, in order to ensure the common market was not distorted by what would now be called "technical barriers to trade" in the WTO's vocabulary[227]. Going further, the Treaty established four fundamental freedoms of movement – of goods, people, services and capital – which were to be the foundation for much of the developments to come. – and it created a litigation mechanism, and a European Court of Justice (ECJ) which had the power to make jurisprudence.

In the first decade and more of the EEC's existence, there was relatively little done on food safety regulations. The focus was increasing food *production,* something the CAP (which entered into force in 1962) aimed at doing[228]. Unsurprisingly, given the important and visible cross-border impact of animal health issues, regulations started from animals and meat. The first significant pieces of regulation date from 1964: "Council Directive 64/432 on animal health problems affecting intra-Community trade in bovine animals and swine, and Council Directive 64/433 on health conditions for the production and marketing of fresh meat. The new rules harmonised regulations across Member States, such as laws on testing for tuberculosis. Intra-Community trade" (EU 2007, p. 15). It was not before 1971 that "the EU established harmonised hygiene requirements for the treatment of poultry meat in slaughterhouses, storage and transportation" (*ibid.,* p .20), followed in 1972 by a Fresh Meat Trade Directive[229]. Then, "the EU also laid down health rules for imports of cattle, swine and fresh meat, and made the inspection of meat for *Trichinella spiralis* mandatory" (*ibid.*), but that only came about in 1977. In parallel to these directives in the sphere of competence of the Agriculture Directorate General (DG) of the Commission, environmental regulations led to the adoption in 1976 of the first Maximum Residue Levels (MRLs) for pesticides in food (*ibid.,* p. 22).

Limited awareness and perception of risks explains to some extent (as for national regulations) this relatively slow development. Changes in the food supply and to the perception of risks were one of the drivers in regulatory changes, as we have seen in other contexts: "At domestic level, a rise in home refrigeration and an increase in consumer purchasing power saw a change in shopping and eating habits in the EU. In order to meet the rising demand for easy-to-prepare, processed food, large-scale manufacturing grew and the chain of production expanded. While this enabled the needs of the mass market to be met, it also meant that there were more instances in which food safety problems could arise" (*ibid.,* p. 16). The regulations, however, remained sector-specific, "vertical" in nature, not looking at food safety in a comprehensive way. Consumer issues were handled by a separate DG from agriculture. When regulations were adopted, they tended to be highly prescriptive, mandating the exact characteristics a product had to comply with.

Turning points: "Cassis de Dijon", the "New Approach", crises and the construction of the "Single Market"

[226] See full treaty text at: http://ec.europa.eu/archives/emu_history/documents/treaties/rometreaty2.pdf.
[227] And clearly the TBT and SPS Agreements owe much to the development of EEC law and jurisprudence over several decades.
[228] Notwithstanding the many issues raised by the CAP, particularly in the last 30 years, it clearly contributed to the major increase in food production in Europe in the past decades.
[229] See the Food Law webpage of Dr. David Jukes, University of Reading, for a chronology: http://www.foodlaw.rdg.ac.uk/hygiene.htm

Several important regulatory, institutional and judicial decisions in the 1970s started paving the way for deeper and broader changes: in particular the 1974 *Dassonville* ECJ case, the adoption of a directive on food labels in 1979, and the creation of the Rapid Alert System for Food and Feed (RASFF) in the same year. With *Dassonville,* the ECJ drew radical conclusions from the Rome Treaty and, in particular, the clause about "measures with equivalent effect" to quantitative restrictions – and severely curtailed the power of Member States to adopt measures restraining free trade across internal EEC borders, stating that "all trading rules enacted by Member States which are capable of hindering, directly or indirectly, actually or potentially, intra-Community trade are to be considered as measures having an effect equivalent to quantitative restrictions[230]". With the food labels directive, the EEC started using new measures to facilitate cross-border trades: information regulations rather than standardization of contents and processes. By setting up the RASFF[231], the Commission implicitly acknowledged the limit of regulations, and the need to be able to identify and respond to problems rapidly and effectively.

The *Cassis de Dijon* case

Even though changes were evidently gradual and parts of long-term trends, some important "turning points" can be identified – the first being the ECJ's *Rewe-Zentral AG v Bundesmonopolverwaltung für Branntwein* (120/78) case[232], better known as "*Cassis de Dijon*", after the product that was at issue in the dispute. With *Cassis de Dijon*, the ECJ significantly changed its own *Dassonville* jurisprudence, in a way that simultaneously enabled regulation, but put requirements on its contents and effects that significantly shaped further European regulatory efforts in food (and in product markets more generally).

Since *Dassonville* meant that "nearly any national measure which qualifies as a "trading rule" could be scrutinized by the ECJ", while it "formed an "effective tool to cull the dead wood of centuries of accumulated legislation" it also threatened rules that "often served a social purpose" and "interfered deeply into the sovereignty of Member States, maybe a little too much for what the Member States could handle", thus threatening a backlash (Purnhagen 2014, p. 7). In *Cassis de Dijon*, while the ECJ found for the plaintiff and struck down the regulation[233] (which prevented fruit liquors of less than 25% alcohol content to be marketed in Germany), it put forth a reasoning that clarified the parameters that would define *legitimate* regulation. It first determined that, if they are "necessary in order to satisfy mandatory requirements", "obstacles to the movement within the community resulting from disparities between the national laws relating to the marketing of the products in question must be accepted." The Court then listed some of these "mandatory requirements": "the effectiveness of fiscal supervision, the protection of public health, the fairness of commercial transactions and the defence of the consumer.". This meant that the Court accepted in particular

[230] From *Procureur du Roi v Benoît and Gustave Dassonville*, ECJ case 8/74.

[231] "The RASFF network has been in place since 1979 and was enhanced by the General Food Law in 2002. Members of the network are the Member States, the European Commission, the European Food Safety Agency, Iceland, Liechtenstein and Norway. RASFF enables the rapid exchange of information between national competent authorities on all foodstuffs and animal feed, specifically when a national authority has identified a risk to human health and taken measures, such as withholding, recalling, seizure or rejection of the products concerned. Thanks to the system, Member States can identify if they are also affected and respond appropriately, ensuring coherent and simultaneous actions across the EU and protecting the safety of consumers. To keep the public fully informed, the EU publishes weekly and annual reports containing information on all notifications on its website." (EC 2007, p. 20)

[232] Which was decided in 1979, making this is a crucial year for European food safety regulations history.

[233] Quoting the decision: "The concept of measures having an effect equivalent to quantitative restrictions on imports (…) is to be understood to mean that the fixing of a minimum alcohol content for alcoholic beverages intended for human consumption by the legislation of a member state also falls within the prohibition laid down in that provision where the importation of alcoholic beverages lawfully produced and marketed in another member state is concerned".

the "defence of the consumer" and the "protection of public health[234]" as justifying restrictions to trade (Purnhagen 2014, p. 9).

The decision sought to avoid both total and careless de-regulation, as well as endless possibilities to regulate and break down the common market (*ibid.,* p.10). It performs a balancing act between "removing obstacles to trade in Member State law in order to ensure the benefits gained from comparative cost advantage" and recognizing and addressing "negative externalities resulting from de-regulation" (*ibid.,* p. 11). To this aim, the decision formulated two key principles that then went on to form the basis for further development of European regulation and of the common market (and then "single market"):

- The "information paradigm", i.e. whenever a market failure has been identified, "preference should be given to an information-related rule wherever that seems sufficient to cure the problem" (*ibid.,* p. 12)
- The "principle of mutual recognition" (or "principle of equivalence) which grants "any producer the right to circulate a product, once lawfully marketed in one Member State, freely in any Member State (…) Disparate regulations may hence generally not hinder the free circulation of such a good, even if they have not yet been harmonized" (*ibid.,* p. 14).

The exception to the second principle is when regulatory measures are needed for one of the "mandatory requirements" (fiscal fairness, public health, fair trading and consumer protection) – but even then, the first principle applies and, whenever possible, an information requirement should be used instead of a stricter standardization, "content related" one – so, in any case, proportionality applies (*ibid.*, p. 14). In addition, underpinning the emphasis on information rather than content regulations, is a view that has been called the "confident consumer", one that refuses to "take the ignorant consumer as a yardstick since such an approach would ultimately require the prescription of uniform products" (*ibid.,* p. 29-30).

Cassis de Dijon is a decision that is well known and has been abundantly studied by scholars of EU law. What interests us here is that its principles have far-reaching implications, not only for regulatory issues, but for their enforcement – and that these principles help define some of the most fundamental differences between the EU regulatory approach and others, in a way that makes the EU *less risk averse*, i.e. more "risk proportional". In addition, these principles can be seen at work also in the WTO Agreements we discussed above.

By mandating mutual recognition except when a real risk to some essential issues can be demonstrated, the decision opens the way to a more selective, risk-focused regulatory approach. By emphasizing the use of information provisions whenever possible, rather than prescriptive content-focused regulations, it leads into risk-proportional regulation, where instruments are differentiated based on the level and type of risk at issue. Finally, by relying on a vision of the "confident consumer"[235], it embraces a certain level of "risk acceptance",

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[234] Neither were relevant in the case, since mandating a *higher* alcohol content clearly was not beneficial for public health, and since the alcohol content was clearly displayed, nor was consumer protection affected. On this last point, the decision strikes down the over-reliance on mandatory standards when there is no overwhelming public benefit: "standardization of products placed on the market and of their designations (…) in the interests of a greater transparency of commercial transactions and offers for sale to the public (…) cannot be taken so far as to regard the mandatory fixing of minimum alcohol contents as being an essential guarantee of the fairness of commercial transactions, since it is a simple matter to ensure that suitable information is conveyed to the purchaser by requiring the display of an indication of origin and of the alcohol content on the packaging of products."

[235] This is a vision which can be taken both in a normative and positive sense. Purnhagen (2014, p. 26) writes: "the early protagonists of an information paradigm for internal market (…) were certainly not naïve as to the realities of consumers', investors' or other market players' individual capacity to process information and to reach rational decisions on that basis. Steindorff, for instance, made it clear that his concept had to be understood as a normative one when he wrote that the internal market "demanded" a circumspect consumer". At the same time, EC/EU and Member States' institutions have made considerable efforts to significantly increase, over time, the information level (and information processing ability) of consumers – thus taking the "informed consumer" as a positive goal, not just a normative view.

and at the same time *ipso facto* makes consumer education and empowerment important activities, including for regulators[236].

The ECJ decision did not come in isolation, but rather had its effects coalesce with the results of ongoing trends affecting European regulations. In particular, what later came to be called the "Old Approach" to product market regulation, which relied on "vertical", product-specific, detailed and content-oriented rules and standards. As Purnhagen (2014) puts it: "this purely centralized regulator model was subject to heavy criticism on several accounts. For some, this traditional harmonization approach was ill-suited to achieving the objective of market integration, as these Directives regularly covered only one of a wide range of aspects in the respective product sectors. For others, the "Europeanisation"-approach resulted in the use of this command-and-control-regulation to an extent which had never been exercised before even in national law. In their view, "it produced 'Europroducts', which alienated the consumer." Either way, there was widespread agreement that the classical standard setting approach envisaged by Art. 100 EEC (now Art. 114 TFEU) was not suitable for the achievement of the goals set by the respective Directives (p. 8). One can just add that this is a very moderate account of the extent of the backlash that EEC attempts at product standardization started to receive in the late 1970s and in the 1980s, particularly in food. All over Europe, complaints of Brussels bureaucrats wanting to standardize sausages, vegetable and the like abounded[237]. There was a double pressure to change the approach: making it more effective (both in terms of trade, and of safety), and more acceptable (to consumers, producers, opinion-makers etc.).

The "New Approach"

In 1985 was adopted Council Resolution 85/C 136/01 "on a new approach to technical harmonization and standards". This term of "New Approach" came to designate the way in which the EEC (and later the EU) has developed its product market regulations since then – a term normally used for non-food products regulations, but an approach which also permeates the food safety sphere.

The first change was breadth: developing "general rules which are applicable to sectors or families of products[238] as well as types of hazard[239]". The second was the affirmation that mutual recognition would apply to "the results of tests", and the decision to "establish harmonised rules on the operation of certification bodies" – thus clarifying the practicalities of mutual recognition, and moving towards harmonization of control and certification[240].

The Resolution established a set of fundamental principles, most importantly that "legislative harmonisation is limited to essential safety requirements (or other requirements in the general interest) with which products put on the market must conform". Standards are to be developed by "organisations competent in industrial standardisation". The standards' "technical specifications are not mandatory and maintain their status of voluntary standards" – while the authorities must "recognise that products manufactured in conformity with

[236] This reliance on the "confident consumer" is a very stark difference between the EU food safety regulatory system, and what can be found in post-Soviet countries (and more broadly former Communist countries), and this difference has made approximation of systems difficult. The (broadly speaking) "post Communist" regulatory approach is one that firmly assumes the consumer to be helpless and constantly under threat, and sees as the only solution a full standardization of products. Even when regulations have been approximated to the EU's, this has continued to create challenges in transforming practices.

[237] In this respect, the "Old Approach" in food was far closer to the post-Soviet model, where standardizing everything, including sausages and yoghurt, is the norm, and consumer choice as well as producer diversity are severely restricted.

[238] Cf. Purnhagen (2014), p. 34: "the 'new approach' was the first systematic regulation to be applied to several product groups".

[239] This quote and subsequent ones are all from Council Resolution 85/C 136/01 accessible at: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=URISERV:l21001a.

[240] The Resolution also asserted what one could call an early "better regulation" goal: "keep a constant check on the technical regulations which are applied so as to withdraw those which are deemed obsolete or superfluous" (a kind of "sunset clause" aim, which has been inconsistently applied).

harmonised standards are presumed to conform to the essential requirements established by the Directive", a producer can opt to produce goods without adhering to these standards, in which case "he has an obligation to prove that his products conform to the essential requirements". Crucially for implementation, and for our research, the Resolution was also concerned with the means of realization of its aims, and building trust in the system – it stated: "the public authorities must ensure the protection of safety (or other requirements envisaged) on their territory. This is a necessary condition to establish mutual trust between Member States."

Moving from the "Old Approach" to the "New Approach" did not only require a change of concepts and principles – it required a constitutional, legal basis. The combination of market pressure (by consumers and producers alike) and change of legal paradigm after *Cassis de Dijon* enabled this transformation. Whereas early European regulations "stipulated classical command-and-control mechanisms, which regulated the product's lifecycle (…) by the setting of detailed, obligatory substantial and procedural standards", the "change in approach of the ECJ (…) provided the basis for the introduction of more conceptual and systematic EU product safety regulation" (Purnhagen 2014, pp. 33-35). The default assumption was from then on that goods could be freely traded and sold across all the EEC as long as they did not "form a hazard to the health and safety of consumers" (*ibid.,* p. 34) – and, through its preference for information rather than content rules, the ECJ pushed for "lighter" regulation.

As indicated, the "New Approach" is significant also by the emphasis it puts on the effectiveness of post-market control. Growth in market volumes and complexity, even before 1985, led to "an increasing realization that only pre-market measures (…) would not suffice and could not ensure European product safety" (*ibid.,* p. 34). There was a fear that "if it was left to the Member States to establish post-market measures, the result would be a divergence of the marketing of hazardous products. Such divergence would be contrary to the goal of the single-market integration, which enabled the free movement of goods only to the extent that they did not impose a hazard to consumers" (*ibid.*).

To address this problem, the EEC took a dual track, which is highly relevant for the study of inspections and enforcement: while it undertook to make "market surveillance" more uniform (to the extent possible) and effective[241], in line with the "New Approach" Resolution, it also decided to considerably strengthen the liability of economic operators. Thus, it attempted to draw on two compliance and safety drivers at once: more effective direct controls by the state, and stronger economic incentives through liability. As a result, in 1985 was also adopted the "Product Liability Directive" 85/374/EEC – "within this Directive, the Council understood post-market control in a wide sense, covering not only classical post-market administrative supervision, but also, and in line with the 'regulation through litigation' - approach, rules on product liability" (*ibid.,* p. 36).

While the "New Approach" *stricto sensu* applies only to non-food products, the same evolution and thinking also came to be applied to food safety regulations. Several important "horizontal" directives were adopted (under the auspices of the Industry DG) in the 1980s and early 1990s: "Methods of Sampling and Analysis" in 1985, "Official Control" in 1989, "Hygiene of Foodstuffs" in 1993 – while, at the same time, DG Agriculture continued to develop a number of "vertical" directives covering milk, eggs, fishery products, game etc. The logic of the *Cassis* decision applied as much to food as to non-food products. Some additional factors came in to push for a more complete transformation of the food safety sphere, which we will now consider.

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[241] "The General Product Safety Directive also introduced classic regulations on administrative market surveillance. Besides some action towards pre-market regulation, the Directive obliges Member States to supervise the safety of products and empowers them to take specific measures. Inter alia, these measures include the issuance of warnings and the withdrawal of products. It also introduced a notification system to the Commission and a Union-wide system of withdrawal of products in case of urgency, which has been affirmed by the ECJ. The European institutions' political agenda to widen the "new approach" also to enforcement came fully to light when the Commission issued a 1994 Communication to ensure the uniform enforcement of Union legislation across all Member States." (Purnhagen 2014, p. 37)

Food safety crises and the construction of the "Single Market"

Over the 1980s and 1990s, a series of food safety crises and "scares" contributed to a growing awareness of food safety issues and an increase in the demand of regulatory protection by consumers, at the same time as the European construction moved from the "Common Market" to the "Single Market". This, combined with the new foundation for regulation provided by the *Cassis* ruling and the perspectives opened by the "New Approach", led to a completely transformed European food safety framework.

First, food safety crises and public "scares". The beef hormone case unfolded from 1980 until 1985, resulting in a complete ban (EU 2007, p. 26). Outbreaks of botulism, salmonella and *E. coli* were recorded over the decade, and made a significant impression on the public (*ibid.*). Clearly, however, the most significant in terms of its regulatory impact was the Bovine Spongiform Encephalopathy (BSE) crisis, and the cases of variant Creutzfeldt-Jakob Disease (vCDJ) it caused in humans[242]. This crisis cast doubts simultaneously on the science used as basis for regulations and inspections, on the credibility of the authorities and the reassurances they issued, on the regulatory requirements, on the controls conducted to ensure safety – and led to border closings and embargoes, a significant breakdown of the market integration process which ran contrary to the whole European project.

As these successive crises unfolded, the development of the European project entered a new phase with the ratification of the 1986 Single European Act. This first major revision of the Treaty of Rome had as main objective the creation of a "Single Market", to be fully operational by 1 January 1993[243]. The move from the "Common Market" to the "Single Market" was not just semantics, but substantial. In the "Common Market" setting, free trade was the objective, but national markets still functioned separately. Physical border posts (including customs) were still operational. Goods were still exported from one country to another. In the food safety perspective, this had very important consequences. Whereas food markets were to a significant extent segmented until December 1992, they made one from January 1993. This meant that no additional requirement whatsoever could be imposed (except in emergency circumstances, such as came to be the case during the BSE crisis) on food shipments from one European Community Member State to another. Until 1992, for instance, veterinary controls in England were applied specifically to meat destined for exports, while (as we have seen above) controls for the internal market were significantly looser. From 1993, there was no longer an "internal" and an "external" market for England, only a single, unified European market – and thus new procedures (and bodies) had to be introduced for England to guarantee the same level of inspections as other Member States.

Establishing a single market meant that the European Community (and in particular its operational branch, the European Commission) had to guarantee consumers that the same level of safety would be ensured (or even, preferably, a *higher* level of safety, given the weaknesses in existing systems laid bare by the successive crises). This does not mean that an identical level of safety was *objectively* reached – nor that the choices made were, with certainty, the most effective – though both may be the case[244]. It means, however, that citizens, traders

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[242] We write here "caused" even though there have been some doubts and questions remaining on the transmission mechanism. We also indicate the crisis as being most significant for its regulatory impact. This is not to say the impact on public health was minor, but it was considerably smaller than feared at some point. Worldwide, the total number of vCJD cases (and fatalities) is 229 as of April 2015 – see the following website for background and data: http://www.cjd.ed.ac.uk. See also Blanc *et al.* (2015) p. 30.

[243] There were other important elements e.g. in relation to political cooperation, but these are not relevant for this research.

[244] In order to assess such claims, one would need to have very detailed and reliable data, allowing to correct for a number of external factors, so as to evaluate the impact of the changes introduced. As we have discussed above (in the section on the United States), the performance of the EU food safety system overall appears high. In addition, it includes (as we will discuss below) a significant component of monitoring aiming at ensuring that the performance of all Member States is adequate and comparable (if not identical, which is a difficult goal to achieve) *in practice*.

and customers had to be *confident* that this level of safety was ensured, in order to provide appropriate *trust* for the market to function.

With hindsight, it is likely that either the full consequences of the changes required by the "Single Market" were not perceived, or that political agreement for the institutional changes required could not be secured at the time. Indeed, while efforts were made at harmonization in the run-up to January 1993, no permanent structure existed to ensure that practices remained both adequate and roughly equivalent, except for veterinary control (and even then, its resources were limited). While the European market was now as integrated as the US market[245], and while European food safety legislation was to a large extent harmonized (possibly more than in the US)[246], there was no equivalent to the FDA and FSIS. We have briefly referred to the discussions, which took place in the US in the years leading to 1906, on which institutional model would be appropriate for food controls, including the view that controls at state borders by state regulators would be sufficient – and, eventually, the creation of federal agencies with a mandate over interstate commerce. The EC/EU situation was and is different – the single market does not make differences between interstate and other commerce (more integration), but the principle of subsidiarity[247] means implementation should as much as possible be done at the Member State level or lower (less integration).

The BSE crisis[248] led to the creation of a new institutional framework[249]. First "in 1997, the Food and Veterinary Office (FVO) was established as a successor of the former "veterinary inspection unit" to carry out inspections to "ensure compliance with EU food safety and animal health rules" (EU 2007 p. 33). Then, in 1999, "within the European Commission, the previously dispersed food units merged to form a part of the Directorate-General for Health and Consumer Protection. This enabled a separation of tasks between those responsible for ensuring food safety, animal health and welfare and plant health, and those in charge of agriculture and food markets" (*ibid.*). With the Food and Veterinary Office reporting to this new DG (called in short "SanCo"), the EU (which superseded the EC with the Maastricht Treaty) now had a new, and original, institutional setup. One "quasi-regulatory" institution with a mandate covering all the food chain, all food products, everywhere in the EU – and an implementation body, not conducting inspections of food businesses and premises directly, but rather inspecting and auditing the way Member States' "competent authorities" do so. Finally, in 2002, was adopted Regulation (EC) 178/2002 called "General Food Law" which "introduced the "farm to fork" approach, i.e. the application of good food safety practices and controls at each and every point in the food chain and the necessity for food to be traceable right back to its original source" and also "provided for the creation of the European Food Safety Authority" and overhauled the Rapid Alert System for Food and Feed (EU 2007, p. 38). The European Food Safety Authority (EFSA) was the last piece in the institutional puzzle, in charge of scientific risk assessment (and thus evaluation of "novel foods" and the like), and the strengthening of RASFF improved the inter-operation of national food safety systems.

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[245] Not necessarily in volumes and percentage of trade, but in freedom of movement for goods, animals etc.

[246] While Member States have retained (at least in some cases) some additional requirements (which, as per ECJ jurisprudence, end up in many cases applying only to their own businesses), EU food safety law covers *all aspects of food safety*, and *all types of products* – which is a significantly higher level of integration than the US case.

[247] As well as strong objective factors such as the difficulty of creating control bodies that would have to function in all EU languages, and of achieving acceptance by the public for controls performed directly by "Brussels". Both obstacles are daunting enough, even were subsidiarity to be weakened.

[248] Additional crises and scandals took place over the 1990s, which also contributed to the changes, e.g. the discovery of dioxin in chicken feed produced in Belgium in 1999 (and subsequent food chain contamination)– see http://www.ncbi.nlm.nih.gov/pubmed/11896663

[249] And, eventually, to the the strict liability regime being "widened to apply to agricultural and fishery products" (Purnhagen 2014, p. 37)

As a result, the EU has an institutional structure for food safety which has some similarities with the UK's[250], in the way it is "two tiered": a top-tier agency (FVO) ensuring some level of consistency and uniformity in practices, and bottom-tier agencies actually performing controls with, for some Member States, a middle-tier of national "Competent Authorities" who co-ordinate and supervise controls that are performed by local authorities (as in the UK).

Key characteristics of the EU food safety regulatory system – and consequences on inspections

The contemporary EU food safety regulatory system, beyond the 2002 General Food Law, relies essentially on a set of regulations adopted in 2004, which are known collectively as the "Hygiene Package", and have been regularly updated since then. The "Hygiene Package" generally replaces and supersedes previous "vertical" legislation, and embodies the principles affirmed in the 2002 Food Law. The four regulations are: 852/2004/EU on General Food Hygiene, 853/2004/EU on Specific Hygiene Rules for Food of Animal Origin, 854/2004/EU on Official Control of Food of Animal Origin Intended for Human Consumption, and 882/2004/EU on Official Food and Feed Control[251]. The "Hygiene Package" is complemented by a number of "horizontal" directives and regulations that have remained in force (or been added/revised after its adoption), e.g. 1996/23/EC (monitoring of residues in live animals and animal products). The new regulations did not only supersede "vertical" legislation, but also earlier attempts at "horizontal" regulation, which we briefly discussed above – and, in so doing, brought a greater level of integration in controlling the entire food chain. For instance, in contrast to directive 1993/43/EEC, which was the previous attempt at regulating general food hygiene, regulation 852/2004/EU covers also primary production, "from farm to fork" (a.k.a. "from stable to table"), in a way that the previously existing division between the Agriculture and Consumer DGs did not allow.

It is not relevant for our work to enter here in the details of these regulations, but important to highlight their most important elements. First, the regulations embody the "farm to fork" principle by requiring from all operators to ensure traceability of their products "one step up and one step down" (at least to the immediate supplier and customer) They apply to the entire food chain – they also apply across all sectors and sub-sectors, and to all kinds of operators (producers, processors, traders, transporters, food service). Second, they rely on the full liability of "Food Business Operators" (FBOs), as they designate all establishments and entities dealing with food – and this liability is seen as a fundamental tool to ensure compliance with the regulations (by raising the potential costs of non-compliance, since FBOs are responsible for any harm caused) - as well as secure the legitimacy of the system (since victims are compensated). Third, the regulations internalize the impossibility of "zero risk" – they foresee the conditions in which a recall is mandated, and the ways in which it should be performed, in adequate detail. They do so in a way that provides real incentives for FBOs to proactively initiate a recall if they detect a problem – since their liability is engaged in case they do not perform the recall, but can be at least to some extent mitigated if they do so in a timely manner. Fourth, they require of FBOs not only to comply with hygienic requirements or Maximum Residue Levels (MRLs), but also to put in place and effectively implement permanent self-control systems, in order to ensure that food is constantly and consistently safe at every stage – a requirement that is based on the Hazard Analysis and Critical Control Points (HACCP) approach[252]. Fifth, they openly and clearly formulate *risk* as an organizing principle – on the basis of which

[250] Which one could see as ironic. It should be noted that the FVO was set up before the UK FSA. The similarity is partial, since the split of responsibilities is different: the FSA does some controls directly (Meat Hygiene) and includes scientific risk assessment, whereas the FVO relies entirely on Member States for controls of Food Business Operators (FBOs), and scientific risk assessment is done by EFSA.
[251] In the narrow sense, the "Hygiene Package" designates only regulations 852, 853 and 854, but regulation 882 is very closely linked, and generally considered as part of the "package" by many professionals. It was adopted in the same year, and with the same approach.
[252] A few remarks are needed on this "HACCP requirement". First, flexibility is foreseen for small operations, in particular if no clear "Critical Control Points" can be identified, and "Good Hygiene Practices" (which otherwise are a pre-requisite for HACCP) can be

regulatory instruments have to be chosen, regulatory resources allocated, enforcement responses decided upon. Sixth, they apply this risk-based approach not only to inspections of already operating businesses, but to the pre-operation stage – under the "Hygiene Package", only FBOs producing/processing food of animal origin are subject to mandatory approval before start of operation, all others can start operating after a simple registration (notification). Seventh, and crucially for us, they regulate also *official controls*.

Regulation 882/2004/EU on official controls[253] is of particular importance for us, in more ways than one. In its approach, because it squarely defines *risk* as the fundamental criterion on which food safety controls should be organized. In its reach, because it is a regulation that governs how national inspection bodies should work – and seeks to do so in a way that provides *confidence* that official controls are essentially *equivalent* all over the EU's territory. In its details, finally, because it demonstrates a level of attention to the fineries of inspections and enforcement, to the questions of risk assessment, planning, quality control, staffing levels and training, funding level and sources, methods and tools. This makes it a rather unique document, in that it is vanishingly rare to see national legislation on inspections being this detailed and comprehensive[254].

Risk – the foundation of official controls' planning and implementation

Point 13 of the Regulation's preamble prescribes that "the frequency of official controls should be regular and proportionate to the risk, taking into account the results of the checks carried out by feed and food business operators under HACCP based control programmes or Quality Assurance Programmes, where such programmes are designed to meet requirements of feed and food law, animal health and animal welfare rules". The Regulation mandates the use of *risk-based planning*, specifically through "multi-annual national control plans in accordance with broad guidelines drawn up at Community level. These guidelines should promote coherent national strategies, and identify risk-based priorities and the most effective control procedures[255]" (Preamble, point 34). In its Article 1, the Regulation then goes on to state that the aims of official controls are "preventing, eliminating or reducing to acceptable levels risks to humans and animals, either directly or through the environment" and "guaranteeing fair practices in feed and food trade and protecting consumer interests" – thus, it keeps the old duality of purpose (safety, and market rules) that we

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accepted as sufficient. The level of flexibility shown *in practice* varies considerably between countries [author's own observations discussing with senior food safety officials in 6 different EU countries: UK, France, Italy, Latvia, Lithuania, Poland], and European Commission guidance on this topic is often not known, and in any case not mandatory as it is only a guidance document (i.e. "for information purposes only" – available at: http://ec.europa.eu/food/food/biosafety/hygienelegislation/guidance_doc_haccp_en.pdf). Second, in primary production, the application of all principles of HACCP is not mandatory but the introduction of GHP is compulsory and the elaboration of related hygiene guidelines are suggested. Finally, what the regulation requires is application of HACCP *principles,* not the obtention of a HACCP certificate from a conformity assessment provider.
In primary production, the application of all principles of HACCP is not mandatory but compulsory the introduction of GHP and the elaboration of related hygiene guidelines are suggested.

[253] "Official controls", in the context of this Regulation, include: "audit" (systemic check of whether activities comply with planned arrangements in particular internal quality/safety controls), "inspection" (thorough verification of compliance of operations/products with legal requirements), "monitoring" (planned sequence of measurements/observations to obtain a representative view of the compliance level). While the first two target individual FBOs, the third one is aimed at producing statistical information to assess the regulatory system's effectiveness.

[254] The OECD *Best Practice Principles* of 2014 cover most of these issues (though in limited details, due to the nature of the document), but in all national-level legislation studied by the author (covering well over 20 countries), nearly no law was covered that would cover all these aspects (some draft laws being developed with World Bank Group support, e.g. in Mongolia, would do so, but have not yet been adopted). Though it is practically impossible to *prove* an absence, we can safely say that Regulation 882 is one of the very few examples of legislation covering all these aspects (and doing so in significant detail). The European Commission is now trying to somewhat replicate this approach in the field of non-food products safety with the new "Product Safety and Market Surveillance Package" (still under consideration) - http://ec.europa.eu/consumers/consumers_safety/product_safety_legislation/product_safety_and_market_surveillance_package/index_en.htm.

[255] Which means not only should planning be risk-based, but the choice of instruments be linked to risk as well.

have observed elsewhere, but clearly puts risk prevention or mitigation first. Then, in its Article 3, the Regulation goes on to define more specifically the risk factors that should be taken into account: "identified risks associated" with specifics of the product or operation (inherent risk), "operators' past record as regards compliance", the "reliability" of internal controls and external information "that might indicate non-compliance"[256]. Article 54 further directs that "when deciding which action to take [in case of non-compliance], the competent authority shall take account of the nature of the non-compliance and that operator's past record with regard to non-compliance", which outlines a risk-proportionate enforcement approach not unlike the UK HSE's – and Article 55 also prescribes that sanctions should be "proportionate". In short, risk, risk assessment, risk proportionality are the foundations of the entire Regulation.

Regulating official controls and ensuring coherence and equivalence across all the EU

This is, of course, the very purpose of the Regulation: ensuring as much uniformity of food safety controls all over the EU. While mitigating risks is the main aim, and risk is the foundation for organization and implementation, uniformity is the direct operational objective. The Regulation attempts to achieve it through a number of prescriptions on methods, capacity and means. First, procedures: "official controls should take place on the basis of documented procedures so as to ensure that these controls are carried out uniformly and are of a consistently high quality" (Preamble, point 14). Second, coordination at all levels: "competent authorities should ensure that where different control units are involved in carrying out official controls, appropriate coordination procedures are in place and effectively implemented" (Preamble, point 15). The same is mandated between "central level" and "regional or local level" in countries where it is relevant (point 16), between different competent authorities including those in charge of "environmental and health protection" (article 4), across Member States (Preamble point 22) etc. Third, the Regulation requires competent authorities to have adequate human capacity (numbers and competence), equipment and access to laboratories (with a number of additional prescriptions specifically for laboratories), and legal powers. Adequate resources are required by point 32 of the Preamble, as well as Article 26. Staff numbers and competence are covered repeatedly, e.g. in Preamble points 11 and 12 and Article 4. Equipment and laboratories access are in Preamble point 11, Article 4, Article 16 etc. The requirements on laboratories are covered in details in Article 12 and in Title III (Reference Laboratories) of the Regulation. Legal powers are in Article 4, and Title VII (Enforcement Measures).

In order to ensure that these different aspects are all being adequately complied with, and with a particular focus on the *planning* and *implementation* of controls, the Regulation foresees a whole system of "control of the controllers". In this two-tier system[257], the Commission controls Member States' Competent Authorities, in particular their implementation of the "multi-annual national control plans" – which should "enable the Commission inspection services to verify whether the official controls in the Member States are organised in accordance with the criteria laid down in this Regulation" (Preamble, point 36). Member States should also submit annual reports to the Commission (Preamble, point 37).Title VI, Chapter I covers "Community Controls". The "Commission experts shall carry out general and specific audits in Member States" (Article 45), it shall "establish an annual control programme" (*ibid.*).

[256] And Article 16 mandates an essentially similar approach for checks of imports. Article 46 prescribes that the frequency of third-countries controls should also be risk-based.

[257] Or three-tier, when national Competent Authorities themselves supervise local authorities which conduct the actual controls.

A comprehensive understanding of inspections issues

As we have briefly indicated, the Regulation attempts to cover all of the issues relevant to inspections' effectiveness. We have already mentioned the sections dealing with resources, staffing, laboratories, powers. The Regulation also covers the question of *fees*, to be used as one of the sources of funding for official controls – and, in so doing, it builds on previous EC/EU legislation starting from 1985, which enabled to raise fees for veterinary controls[258]. The Regulation also emphasizes the importance of training, and it empowers the Commission to organize EU-wide training to ensure effectiveness and consistency (cf. Article 32 for reference laboratories, Article 51 for control staff)[259]. Thus, the Regulation covers every aspect of inspections: goals, legal powers, risk assessment, planning, tools and methods, resources (incl. staff and equipment), sampling and testing, decision making, reporting, training, coordination, exchange of information – as well as crisis contingency planning, emergency response, recalls etc.

Tentative conclusion

The EU has tried to not only transform the methods of its food safety regulatory system (with a strong emphasis on *risk*), but to put a lot of focus on improving inspections and making them more coherent and consistent. This has led to a rise in the FVO's importance, including through its audits[260] of Member States[261], and its work on assessing candidate countries' readiness (and advising them on reforms to get ready). To the extent that evidence is available, this appears to have been a real success, in the sense that the overall performance of the system is high (in spite of the limitations in assessing how high, and how well it compares, that we discussed above) – and that it has allowed a far greater integration of the EU market, and accommodated an increase in trade volumes and complexity. Success on consumer trust and confidence is not perfect, but real, particularly considering how difficult the situation was in the 1990s. New Member States have been "brought up" from (in some cases) very problematic situations up to levels of food safety that are generally in line with the older EU Members – as evidenced by FVO audits and EFSA monitoring.

There are, however, important limitations that prevent us from drawing strong conclusions on the effectiveness of the different systems. First, there is insufficient epidemiological data to assess if the system performs indeed better now than in the past, or (as some claim) than the US's (and, if so, to what extent) – and in any case, there are very serious attribution issues. It is unclear how strong is the link between food safety data, and improved (or assumed to be improved) controls. Second, while the inspection regime foreseen by EU Regulation 882/2004 is strongly *risk based* in terms of what aspects of operations should be regulated*, risk focused* in terms of inspections planning, and (to a large extent) *risk proportional*, it fails to incorporate a really comprehensive approach to *compliance.* This means that food safety controls based on the implementation of this regulation, while risk-based, are not necessarily "smart" in terms of incorporating several complementary instruments, or a responsive enforcement approach.

Indeed, throughout the directive, when compliance is mentioned it is primarily from a *deterrence* angle (requirements to have dissuasive sanctions: Preamble point 41, article 55). The FVO harmonization efforts are

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[258] Veterinary inspection fees are important because they play a strong role in the EU's capacity to have far more systematic slaughter inspections than the US (see above on this) – the fees are foreseen in Preamble point 32, and covered in details in Article 27, which distinguishes between areas where fees are mandatory (detailed in Annexes IV and V, essentially: veterinary control of slaughter, and imports) – and other areas, where Member States *may* impose fees. The Regulation also sets a minimum level for mandatory fees, and guidelines for fee-setting overall (including proportionality to complexity/size, possibility to reduce fees when risk is low etc.).

[259] In practice, this has resulted in the *Better Training for Safer Food* programme – see EU 2007, pp. 17 and 38.

[260] See audit programme here: http://ec.europa.eu/food/food_veterinary_office/audit_programmes/index_en.htm and audit reports here: http://ec.europa.eu/food/fvo/audit_reports/index.cfm

[261] EFSA is playing the main role in monitoring – see: http://www.efsa.europa.eu/en/panels.htm, http://www.efsa.europa.eu/en/topics/topic/salmonella.htm etc. But the FVO is also active in some areas, see e.g. http://ec.europa.eu/food/fvo/specialreports/pesticides_index_en.htm on pesticides.

conducted from this perspective as well: ensuring inspections are well targeted, and technically competent – but not that there are serious efforts made to support understanding of requirements and actual compliance levels. To the extent that compliance promotion efforts can make a real difference in economic, social and safety outcomes (something which, as we will discuss further in this research, there are serious grounds to consider), this is a major shortcoming.

2.3. Conclusions and relevance for our research

This historical overview has served to show the sheer diversity and path dependence of institutional structures. Even in a field as "science based" as food safety, where official guidelines from the EU (and recommendations from agencies such as UN FAO) push towards an institutional model (single agency or at least greater integration), there is very significant diversity, and often fragmentation[262]. There are also all kind of "national peculiarities" (delegated functions to private sector bodies in the Netherlands, importance of local authorities in the UK, etc.). This means that efforts to make inspections more risk-focused, "smarter" etc. take place in an institutional context that is rarely "optimal", and that in any case was generally not really "designed", and emerged as a result of many historical accidents. When real consolidation takes place, it is often either in the context of dramatic external and internal pressure ("transition crisis" and EU pressure for Baltic states), or over several decades (Netherlands). This both creates an apparent challenge to reform and efficient improvement efforts, as well as an opportunity to examine whether different institutional set ups have a major incidence on results, or whether it is possible to improve the way inspections are organised and conducted regardless of these.

At the same time, though, we have observed a number of trends, from which we can try and extract some lessons – which, though they do not have the strength of statistical observations or demonstrations, can nonetheless shed some lights on the origins and development of inspection functions, and their relationship to the question of risk.

A first common aspect across countries and regulatory areas include the fact that inspection mandates and agencies emerged not so much in relation to quantified, scientifically determined risk – but far more in reaction to risk *perceptions*, breakdowns in trust, emergence of new hazards that generated strong reactions

[262] Modern food safety approaches, as advocated for instance by UN FAO and mandated by the EU legislation on the topic, emphasise the importance of "farm to fork" traceability, and thus of a control system that ensures integration of information and findings along the entire food chain. Considering that distinct agencies under separate ministries typically have difficulties effectively sharing information and coordinating their actions, the European Commission (and in particular the Food and Veterinary Office, part of DG SanCo) has been pushing candidate countries very strongly to create "unified" food safety agencies or inspectorates. As is wont to happen, this pressure has been more or less strong and effective depending on the relative size and/or negotiating positions of candidate countries - and countries have reacted to it in different ways (resisting or embracing it) depending on their own contexts. Thus, Poland entered the EU with fragmented food safety control (trade inspection, hygiene, veterinary service), as well as Slovenia (health and veterinary service - in the meantime, a new unified Food Safety Inspection has recently been created), whereas Lithuania and Estonia created very strongly integrated institutions (Lithuania gathering all control functions related to food safety and animal health, adding a large swathe of the regulatory powers, the laboratory network etc.). Absent strong external pressure, it is far more rare to see countries radically transforming their own administrative structures, given the organisational inertia and status quo bias, and lobbying power of large regulatory enforcement agencies. Thus, in many countries of the Former Soviet Union, there still are at least three agencies (not counting those in charge of plant protection) looking at food safety: the sanitary and hygiene, veterinary and standards services (as most of these countries still make widespread use of mandatory standards in the food sphere). Some countries (e.g. Armenia) have gone towards establishing a single food safety agency, but this has usually been in the context of international negotiations (as Armenia was at the time negotiating a free-trade agreement with the EU), which gave additional strength to an internal reform initiative.

of "dread" (in line with the findings in Slovic 1987) , and also as a result of active "lobbying" by what we could call, following Helsloot and Schmidt (2012), "risk experts".

A second element we have found consistently is path dependence. Creating fully new institutions, revising mandates or resources radically, are all very rare. Even when reforms, mergers etc. do occur, they usually do so on the basis of whichever structures, legal framework and practices existed. Path dependence applies not only to structures, mandates and resources, but to regulatory approaches, and in particular to inspection and enforcement methods and objectives. We will come back to this question in more depth because of its importance in our research perspective.

The third tentative finding from our historical review would be a gradual, incomplete but real tendency to some convergence in structures and methods, at least in some areas, e.g. food safety, where international integration (and competition) is stronger. This convergence appears to incorporate a growing emphasis on *risk* as a fundamental criterion for determining the appropriate enforcement response, focusing inspection resources – and, to some extent, even the adequate level of regulation. This qualified (and far from universal) finding, however, appears to run contrary to some recent research on risk and regulation, and requires further discussion.

a. Understanding path dependence, and its limits

The importance of path dependence has been well perceived by many authors. In trying to understand different "risk regulation regimes", Hood, Rothstein and Baldwin (2001) consider several explanatory factors, which they group under the notion of "context". They thus look at the extent to which the actual features of different regulatory regimes[263] can be explained through three key elements: "market failure"[264], opinion-responsive regulation, and the interplay of the different interests, lobbies and experts. They find, overall, that even though these different context elements appear to explain *some* features in *some* cases, there are important variations and discrepancies that appear difficult to explain within the chosen models. They then turn their attention to "inherent" aspects of these different regimes, and path dependence[265]. The authors find that the "historical points of departure" influence successive developments, and how "context" elements (e.g. "interest-group activity") play out (p. 140). The difficulty of "introducing radically new legislation or standards" means that "incremental adjustment and patching" is frequent (p. 140-141).

There are several ways in which such path dependence functions. One is, as indicated, the fact that radical changes to laws, standards, rules and institutions are difficult, and correspondingly rare. Another is that the "regulatory community" has in a way an "inner life", and definitely develops over time a certain culture and view of what is appropriate or not (*ibid.*, p. 141-142) – something which our examples above clearly also validate. More broadly, the entire "context" explanation is, in a way, a form of "path dependence" vision to an extent, because many "context" elements have themselves been shaped by historical evolution, in particular how responsive (and with which types of response) the government is to public risk perceptions, and also how interest groups, lobbies and experts view their interests, play them out and influence policy.

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[263] Though the authors call them "risk regulatory regimes" we would suggest that they would be more accurately termed "hazard regulatory regimes", in keeping with the difference between "hazard" and "risk" exposed e.g. by BRDO (2012).

[264] We will not discuss here the question of whether it was pertinent in the first place to adopt this list of "context" elements, but clearly 'market failure' is primarily a *justification* for regulatory intervention (from a purely economically rational standpoint), and not an explanatory factor for the *actual features* of regulation.

[265] Defined here as the idea "that policy and administrative routines tend to be heavily influenced by their historical point of origin, with inertia leading to persistence of original form, patterns of development that are path-dependent and often characterized by sudden abrupt changes rather than smooth adaptation to changing context" (Hood, Rothstein and Baldwin 2001, p. 69).

There are, however, powerful elements that come to (at least partly) counterbalance path dependence. The first is the occasional discontinuity occasioned by sudden high-profile accidents – even though the strength of this factor is unequal[266]. The evolution of science and techniques is a second, sometimes very powerful driver, e.g. by making hazards visible or understood, and/or by giving the tools necessary to detect and control them – as we have seen for instance in the food safety case, at repeated points. Supra-national factors also clearly play a significant role (though exactly *how significant* is not easy to determine), at least in some areas – as we have seen in the food safety sphere, where the EU has pushed quite profound transformations in institutions and methods, and the WTO also introduced new requirements (and litigation mechanisms to try and enforce them). Clearly, these unifying forces are not able to overcome all specificities and historical inheritances – otherwise we would see far more unified food safety inspectorates, for instance. But the creation of the FSA in the UK, the FSMA in the US (and new discussions on potentially merging several agencies), both testify to the reality of such forces. Likewise, the creation and successive development of the HSE demonstrates that evolutions in the society, economy and techniques can lead to quite significant changes – but the ways in which these changes are different and happen at different paces in varying countries shows the importance of historical and context factors.

Assessing the significance of path dependency in terms of effectiveness and efficiency of inspections and enforcement is complex. In some instances, it may relate to issues which end up not being binding constraints in terms of methods, practices etc. – such as the exact split of institutional mandates between several agencies, or whether central or local government is in charge. While these aspects clearly *influence* the choice of methods and approaches, they do not generally prevent change e.g. the adoption of a more risk-based or compliance-promoting model. Where path dependency is more significant is when

b. Is there (and can there be) a convergence towards risk-based approaches?

In the above case studies and 'snapshots', as well as in the conclusion, we have suggested that there was to some degree a trend towards a 'convergence' of sorts, at least in some regulatory areas – and that this convergence appeared to be in the direction of more "risk-based" inspections. We saw that the prescriptions about risk that can be found in the EU "Hygiene Package", the US FSM Act, or the WTO SPS agreement, were generally consistent with each other – and also corresponded to the definition of risk that is most commonly used in regulatory inspections: the combination of the likelihood of hazard, and its potential severity and magnitude[267]. We did not, however, look closely as to whether (and to which extent) references to 'risk' e.g. in WTO and EU documents were in fact matched by reality of practice. Thus, while there is undeniably a *claim* of increasingly risk-based practices (at least in food safety), it does not follow that this claim is fully backed up by practice, and even less that it is applicable to other regulatory areas.

Some authors have, in fact, radically challenged claims of 'convergence' and questioned whether they are, in fact, "universally applicable foundations for improving the quality, efficiency, and rationality of governance across policy domains", as some of their proponents have claimed (Rothstein, Borraz and Huber 2013). They point out that, as of 2013, "no comparative research has sought to explore whether the emergence of risk-based approaches to governance in the UK has been mirrored in other member state contexts, nor for that matter, at the level of the EC" (*ibid.,* p. 218) – an important gap, which that article and subsequent work aimed at contributing to filling, and which this present research also intends to help address. In their short overview

[266] What has been "termed 'tombstone-ability' – the capacity of a risk to produce deaths or suffering victims through dramatic catastrophes (…) seems likely to augment the force of public opinion in shaping regime content" but "only one of the observed elements of regime content that was way out of line with the opnion-responsive hypothesis involved a 'tombstone-able' risk" (*ibid.*, p. 140).

[267] See BRDO 2012 and World Bank Group 2013 a.

of the cases of France and Germany, in counterpoint with the UK, the authors find (somewhat unsurprisingly, one could add) that "the emergence of risk as an organizing concept of governance varies across countries" (p. 231). More importantly, they find considerable barriers to the adoption of risk-based approaches in France and Germany. In both countries, a combination of cultural and legal factors appear to make such approaches really problematic, and to result in risk-based regulation remaining very limited in scope and depth.

In France, they find that the idea of risk-based regulation[268] runs contrary to several key organizing principles of public policy: "the culturally established commitment or "promise" by the French state to provide security for its population", "the priority given to maintaining "public order;" a principle that is defined in administrative law, has been interpreted by the courts, and (…) underpins a core role of state officials in preventing any event that could create disorder and undermine the authority of the Republic", the "principle of equal treatment for all (…) [which] can conflict with risk-based approaches to setting priorities and allocating scarce resources" and "the concept of the "general interest", which civil servants are expected to represent and defend, under the supervision of the *Conseil d'Etat*" – a role which risk-based approaches, because they result in "more open and deliberative styles of decision making", could threaten (*ibid.,* pp. 222-223). In Germany, they find that barriers to the use of risk-based approaches come from both "the juridified character of German policymaking" and "the fragmented federal system that distributes competences – depending on policy domain – across at least three levels" (*ibid.,* pp. 225-226). On the courts' side, the problem is the difficulty they have found to balance "the state's "duty of protection" from dangers (*Schutzpflicht*)" with the need to accept "some degree of "residual risk" (…) [and their] great difficulty in using "probability-x-impact" frameworks to define the boundary between unacceptable "dangers" and acceptable "risks."" The federal system, in turn, results in the "presence of multiple decision makers with varying philosophical approaches to governing risks and often contradictory interests in the distribution of risks, costs, and benefits" (*ibid.*).

The authors go on to show examples of how these resistances have limited their introduction "even where risk-based approaches have been internationally mandated" – for instance, "in the case of EU-mandated risk-based food safety inspection". In France, "local state services complement the assessment of food safety risks posed by businesses with an additional "fudge" risk factor that takes into account the "sensibilities" of the *département* (…). Such factors can undermine the value of risk-based approaches in protecting public health if the field-services or the *préfet* decides that inspection resources should be directed towards maintaining public order or protecting their own reputation" (*ibid.,* p. 224). Generally, French state authorities "in situations of uncertainty or under pressure from social movements (…) prefer to be risk averse or invoke the precautionary principle, even if it means facing later criticism for over-reaction" (*ibid.*). In Germany likewise, "even internationally mandated risk-based approaches to governance can fall foul of constitutional arrangements for their implementation. One example was resistance by *Länder* to EU rules on risk-based food safety inspection on the grounds that they contravened constitutional expectations" (*ibid.,* p. 226).

There are several reasons why we do not think that these views seriously rebut our perspective on risk-based approaches. First, we are focusing on inspections and enforcement, not on policy- and rule-making – and this is clearly the area where (in spite of shortcomings) there has been the strongest "push" for more risk-based approaches (at least in food safety) at the EU level. Second, we would take a somewhat different view of the same situations that Rothstein, Borraz and Huber describe – namely, that of the "half-full bottle". If one compares the practices in France and Germany to an *ideal* of risk-based approaches, or even to the practice in the UK (which is not "ideal", but clearly far more strongly risk-based), then clearly the assessment will be that France and Germany are "resisting risk-based approaches". If one, however, compares the *current*

[268] Defined by the authors as premised on the "idea that governance cannot, and indeed, should not, aim to eliminate all potential harms or more generally, "adverse outcomes" (…).Rather, in an adaption of Paracelsus' maxim – the likely dose makes the poison – "risk based" approaches pay attention to both the probability and impact of potential adverse outcomes" (*ibid.,* pp. 215-216).

practices in France and Germany with that of a couple of decades *earlier* in the same countries, there is some evidence of *changes* in the direction of gradually *more* use of risk-based approaches, at least in some areas. Thus, taking again the example of food safety, even though inspections in France and Germany are in some areas probably not in full conformity with EU regulations and guidelines (and we would certainly agree, as we will discuss in later sections, that they are *less* risk-based than in the UK), such partial non-conformities are a normal part of "real regulatory enforcement". Considering how much power and clout the EC FVO wields, and of how frequently it audits national systems, it is unlikely (to say the least) that France and Germany could get away with completely avoiding implementation of EU Regulation 882 – rather, there are problems "at the margin", and indeed the margin can be somewhat too wide.

This brings us, in conclusion, to two points: the effectiveness question, and the challenge of overcoming "national cultural and institutional resistances". On the first, an earlier paper (focusing on environmental regulations and their enforcement) by Rothstein, Irving , Walden and Yearsley (2006) concluded that "case studies suggest that they have the potential to improve regulatory understanding and efficiency and overall outcomes. (p. 1063). Subsequent sections of this research will consider other evidence, but we have already seen some pointers suggesting that "risk-averse" systems are not immune to problems, e.g. the *E. coli* outbreak originated in Germany, whereas Rothstein *et al.* (2013) have found resistance from local authorities in Germany to implementing EU-directed risk-based approaches – in all likelihood in the belief that their own system would be more effective, a belief that we now have strong evidence to find mistaken. If indeed there are significant differences in effectiveness between risk-based approaches and others, then the question of how to foster the adoption of these approaches becomes a very important one. From such a perspective, the findings from the 2013 paper suggesting that France and Germany present strong inherent factors making the adoption of risk-based approaches very difficult can cause concern. Without discussing this question in depth here, it is worth pointing to the *limitations* of these barriers. Indeed, clearly, introducing risk-based approaches may be more or less difficult in different countries, and face in some cases very strong resistances – and possibly fail. But there are many examples of reforms in a more risk-based direction taking place in countries where cultural and institutional resistances were considerable, e.g. in Lithuania, one of the cases we will consider in later sections. There are also examples in the very countries taken as examples of "risk resistance" that show that there are limitations to these cultural and institutional factors, and more complexity than first meets the eye. On building safety regulation, for instance, France has a system that is far more risk-based, and far less reliant on state inspections, than the UK – and this system is very much uncontroversial, showing that the demand for more state protection is neither constant nor universal. This system, however, draws on very deep roots, going back all the way to the 1804 Civil Code, and again showing the importance of long-term perspectives[269]. Going into the details of this example is beyond our scope here – it is enough, however, to suggest that what is claimed by actors to be insuperable obstacles to new approaches is sometimes little more than a smoke-screen to shield existing practices from review. If France can have far less state inspections and far more acceptance of risk in one sector than the UK, it means there is nothing absolutely and permanently "determined" in the relative acceptance of risk-based approaches in different countries. Clearly, national political and regulatory cultures are important, as illustrated e.g. in the case of the US by Scholz (1994). But cultures are transient, evolve and change.

[269] A full explanation of the system can be found in World Bank Group 2013 (b) pp. 82-87 and Helsloot & Schmidt 2012 (b) pp. 57-60 and 115-130. In short, state inspections of compliance with building safety norms are close to non-existent in France. Rather, there is a 10-year liability for all operators involved in construction, backed by mandatory insurance for builders and developers. In addition, the stringency of third-party controls required (and of state approvals) is linked to the risk level of the building (or part of the building), and insurance premia are also risk-proportional.

c. Conflicting directions – steps "forward" and "backward"

A last remark is needed: just as inspections are not an unalloyed good (or bad), evolution of institutions and practices does not follow a uniform path. Bardach and Kagan (1982) show how the powers of the inspectors, if left unchecked, are in some ways even more prone to abuse than policemen's, because of the lower limits on "searches and seizures" (p. 32-33). Inspections can thus tend to abuses of power, but they can also be threatened by ineffectiveness and capture by influential regulated entities (*ibid.*, pp. 42-44).

In the US, what was perceived as capture by "criminal" businesses led to a very strong backlash in the late 1960s and early 1970s – a consumer advocacy report championed by Ralph Nader compared the consultations and cooperative meetings of the FDA with businesses to a situation where the Justice Department would hold regular meetings with the mafia (p. 44). The "reform agenda" in response involved "new regulators, preferably at the federal level", "more comprehensive and explicit regulations", sharply curtailing "administrative discretion and leniency" and enhancing "deterrence by increasing the severity, speed, and consistency of sanctions" (p. 45). The "new-style protective regulation", worried about capture, prescribed an "explicitly legalistic enforcement style" (p. 72), and resulted in blurring the difference between inspectors and police, with a "young regional FDA enforcement official" being quoted as saying: "We're a law enforcement agency, not a service agency" (p. 73). This whole evolution was to lead, in turn, to what Bardach and Kagan called "regulatory unreasonableness", and a considerable backlash *against* regulation and inspectors[270].

The development we are trying to investigate in this research is precisely the next phase of this "back and forth" – the attempt to develop approaches that would strike an appropriate balance between the twin pitfalls of excessive discretion and legalism, of ineffectiveness and unreasonableness. Risk-based approaches are promoted as being the way to reconcile apparently contradictory concerns, but we can see that they are not the product of a seamless evolution, and that conflicting views and perspectives exist, and carry regulation and inspections in different directions, depending on the relative strength of different actors and factors over time.

Having now completed this historical introduction, we will turn our attention to the theoretical underpinnings of risk-based inspection approaches, before moving to consideration of data in order to assess comparative effectiveness.

[270] See also p. 123 for a more positive take by the same authors on the contributions made by the "stricter" approach of the 1970s.

3. Theoretical underpinnings: costs and effectiveness, compliance drivers, discretion issues, risk and regulation

> *The starting point of most discussions of the law is compliance, since the purpose of creating laws and empowering legal authorities is to establish and maintain social order by regulating public behavior. (…)*
>
> *At the time that* Why People Obey the Law *was written, the conception of the relationship between community residents and legal authorities was a reactive one, with obedience to legal rules viewed as the key behavior that legal authorites wanted from those in the community. Since that time it has been recognized that authorities need the more active cooperation of those in the community.*

Tom R. TYLER– Afterword *to* Why People Obey the Law *(2006 edition)*

> *Good policy analysis is not about choosing between the free market and government regulation. Nor is it simply deciding what the law should proscribe. (…)*
>
> *Participants on both sides frame the deregulation debate as a kind of "Live Free or Die" policy choice. Even lovers of liberty might reasonably ask whether third alternatives do not exist.*

Ian AYRES and John BRAITHWAITE – Responsive Regulation (*1992)*

After having sketched out the historical emergence and evolution of the regulatory inspection function (or at least of *some* regulatory inspection functions), and before we consider current examples of purported "risk-based inspections" (and compare them to other practices), it is necessary to summarize and discuss the theoretical underpinnings and research findings that can shed light on both "regulatory inspections" and "risk".

We will consider prior research mostly from three perspectives. First, an introductory section where we will summarize perspectives on the uses and appropriateness of regulation, and on the question of its costs and effectiveness[271], since risk-based inspections are touted as a way to improve both. Before we look at what data can indicate of practical results, it is thus needed to look at the context against which risk-based inspection reforms are implemented – how relevant regulation is both to economic issues, and to its purported social welfare goals. Second, we will look at theories seeking to account for regulatory compliance, and how

[271] Considering here not only "regulation" as a whole, but also to some extent specific *regulatory instruments* – the distinction being here that "regulation" is a set of rules, to which economic operators are subject, and "regulatory instruments" are specific procedures and processes through which these rules are administered, implemented, enforced etc.

well they seem to fare in experimental research. Indeed, given that the primary justification given for the existence of inspections is generally the aim to increase compliance, understanding better what drives compliance is vital to attempting to better assess inspections' effectiveness, and the ways in which it might be improved. Discussing compliance visions will also enable us to briefly touch on the question of regulatory discretion, which is a fundamental element of risk-based approaches (and one that is, at times, hotly debated). Third, and finally, we will attempt to summarize at least some of the considerable amount of research that has developed on the interaction of risk and regulation. While we may not purport to be exhaustive on this count, these insights will be crucial to put risk-based inspections in perspective, and help clarify the meaning of risk and challenges associated with risk-based approaches.

3.1. Regulation: uses, costs and effects – a brief overview

a. The uses and abuses of regulation – introduction

The very word "regulation" has a wealth of meanings, and is far from uncontroversial. It can be (both in English and its different translations) understood to mean in a legal sense any sort of secondary legislation (decrees or other norms issued by the executive), or at the other extreme a complex system ensuring a cybernetic equilibrium, be it is in economics or social science. Over the past couple of decades, the word has acquired also a specific use in relation with economic activities, but even this field sees several competing meanings – with "regulation" either used for the oversight and control of prices and services imposed on monopoly or quasi-monopoly privatized (or quasi-privatized) utilities (and providers of fundamental consumer services), or for the entire set of rules (technical, fiscal, related to starting or closing an activity, etc.) applicable to economic operators.

It is this latter sense, which is sometimes called "non-economic regulation" (to distinguish it from regulation of utilities etc.) that is relevant to our research. Within this field, we in fact focus mostly on a specific subset of regulations that relate to safety and health in the broadest sense, including environmental protection, and the protection of other public interests – including product market regulations, as well as regulations relating to the construction and operation of business premises[272]. While the use of "regulation" in a specific sense (or rather, at least two specific senses) in the economic sphere has gained international acceptance[273], it is not necessarily uncontroversial. Why, some ask, should laws, decrees and other norms that apply to businesses (or to private citizens acting in an economic capacity, e.g. as "sole traders") be treated differently from other laws, suggesting in some ways that they are "less legitimate" or "less mandatory" than other rules[274]?

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[272] Unfortunately, no satisfactory single term currently exists to cover this sub-set of business regulations – "technical regulations" has a specific WTO TBT meaning, "health and safety" is often understood to mean only/mostly "occupational safety and health", etc. Moreover, some of these regulations do not directly relate to *safety*, but to other public interests, e.g. consumer information etc.

[273] See e.g. different OECD publications, where "regulation" and "regulators" are understood in subtly different ways: in the *OECD Best Practice Principles for the Governance of Regulators* (2014, available at: http://www.oecd.org/gov/regulatory-policy/governance-regulators.htm) and the *OECD Best Practice Principles for Regulatory Enforcement and Inspections* (2014, available at: http://www.oecd.org/gov/regulatory-policy/enforcement-inspections.htm). Interestingly, the OECD treats the use of "regulation" in the specific economic sense as fully obvious, but very rarely attempts to define it. One such attempt is in an early document in the OECD's "Regulatory Policy" workstream, the 1995 *Recommendation of the Council on Improving the Quality of Government Regulation*, which refers to the "framework of responsibilities and constraints established by government regulation" – in this (very broad) meaning, "regulation" covers all the rules (creating obligations or prohibitions) that apply to economic operators.

[274] See e.g. the views of Carson as summarized by Hawkins (2002): "prosecution as a last resort in Victorian times can be seen as evidence of a process of 'convetionalization' of occupational safety and health offences. Hist contention is that such offences were suffused with a sense of ambiguity which led to matters formally enacted as criminal becoming regarded as merely quasi-criminal and

Engaging in depth with this debate would take us far beyond the scope of this research, but some level of clarification is nonetheless needed to give our work a sound basis. First, we will try and articulate very briefly why it can be held as legitimate to handle "regulation" distinctly from other legislation. Second, we will summarize some of the prevailing views on why and how regulation should be used. Finally, we will attempt to sketch out why, in our view, the attempt to oppose "smarter regulation" because it would show undue leniency towards businesses is misguided, but rather the principles and tools of "smarter regulation" should also be used in matters that do not pertain to businesses but to citizens' private lives, as they are sound ways to make public policy in general more proportionate and effective.

i. Questions around the legitimacy of treating "regulation" specifically

Historical introduction – economic freedom and regulation

When considering the legitimacy and appropriateness of treating "regulation" as a distinct field, the historical perspective cannot be avoided. The significant restrictive rules that affected economic activity in pre-modern times, including various duties, tolls and levies, monopolies, restriction on entry, product-related rules etc., all corresponded to a situation where economic activity[275] was regarded as part of a broader social order, a collective undertaking where each member of society had to carry tasks according to its assigned place. In the medieval tri-partite vision, alongside those in charge of prayer and of fighting, were the many assigned to labour – and, among them, each had his or her role. Movement was very much discouraged, as a form of challenge against the God-assigned order, and the established powers, both spiritual and secular. In such a world, rules restricting certain trades to guild members, setting down exactly how products should be manufactured, limiting trade etc. were but manifestations of the social order, as necessary and as little disputed as the rules of monastic orders. They cemented the cohesion of the community, and the various duties and levies both ensured the funding of the praying and fighting orders, and protected local producers against competition, again fully in line with the broader social vision[276]. The gradual changes in world view, social order and economic structures that took place over the 15th to 18th centuries brought about a complete reversal[277], with the notion of *freedom*, specifically of *individual freedom* – and, alongside the political one, of *economic freedom*. In the new social order, such as it emerged in France and Britain after the French Revolution and the more than two decades of wars that ensued, political freedom was far from always ensured, but economic one was secured to a large extent. "*Laisser faire, laisser passer*" became, if not always the norm in practice, at least the position that best reflected dominant ideology.

In such a context, regulation of economic activities can of course exist as a "left-over" of the previous social order (e.g. the persistence of regulations on certain professions such as notaries in France, even after the Revolution), or can arise as the result of conflicting values (e.g. the demand for more social justice, or concerns about keeping "order"), but it can also be developed in a way that is internally coherent with the primacy of individual (economic) freedom. Indeed, as the 1789 *Déclaration des Droits de l'Homme et du Citoyen* puts it, "freedom consists in being able to do everything that does not harm others: thus, the exercise of each man's natural rights has no other bounds than those that ensure that other Members of Society can enjoy these same rights" (article 4). This means, in an economic perspective, that regulation that limits economic freedom

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not as 'real crime' at all" – a situation "revealed, for example, in the fact that offenders were not dealt with as part of the usual criminal justice system, but by regulatory bodies" (p. 19).

[275] Which, of course, was not considered under this name at all. The words "economy" and "economics" in their modern meaning only started being used in the late 18th century.

[276] See Duby (1978), which remains the fundamental work on this topic. Many other works have covered this topic since then, e.g. Arnoux (2012) – but Duby's work remains valid.

[277] See in particular Gauchet (1985), but also Mercier (1960), Muchembled (1988) *et al.*

can be legitimate when the effects of economic activity would harm the freedom of other people, including by endangering their health, or affecting their property (as, in the view of the *Déclaration'*s authors, there can be no freedom without safety of body and property). Within this framework, considering "regulations" as *distinct* from other fields of legislation is logical – because it limits specific (economic) freedoms. Such specificity, however, is not different in nature from that which should apply to other areas of legislation that limit other fundamental freedoms (e.g. press and media law). Thus, the internal coherence of an individualistic and liberal world view (and legal order) makes it legitimate to consider economic operations' regulation specifically, but not more so than a number of other legal domains, which also impinge on freedoms.

Clearly, that "regulation" has come to be named and handled in a specific way, different from other "freedom infringing" areas of legislation, is due to the centrality of the issues it impacts on for modern societies: wealth, distribution of income, labour relations, economic and political power, growth and employment etc. This manifests itself both in terms of regulatory capture due to the power of influence wielded by economic operators, but also in terms of regulations developed with a specific "anti-business" intent, supported by political and social forces critical of the existing economic order. Regulation is, thus, a particularly *contentious* area of legislation.

In line with its contentious nature, regulation has been (and still is) criticized from a variety of corners, with the different perspectives reflecting to some extent ideological preconceptions, but also to a large extent the diversity of regulatory questions, and the complexity of regulatory interactions. Hawkins (2002) provides a very condensed summary of what he calls "the debate about command and control regulation" (pp. 13-15). Because this summary is both clear and comprehensive, we will just refer readers back to it for details, and present only the key elements here. First, while "command and control regulation is generally justified in instrumental terms" (Baldwin 1995 *et al.*), its effectiveness is often far from optimal, and many authors have linked this to the "capture" of the regulators (Bernstein 1955 *et al.*), to a regulatory life-cycle where the "energy of the regulatory body is sapped" (*ibid.*), or to the interplay of "interest groups" (Posner 1974). Others have suggested that the problem may be in the nature of command and control itself, that tend to lead to costly, inefficient, short-term solutions (Sinclair 1998), to complexity, rigidity, costs and delays (Bardach and Kagan 1982). Designing "perfect" or "optimal" rules seems impossible, and rules tend to fail on both sides, creating high costs with limited effectiveness (Baldwin 1995). As for the practice, negotiation is often the rule in enforcement (Hawkins 2002, Hutter 1997), with some authors lamenting the lack of more vigorous enforcement (Tombs and Whyte 2008, Pearce and Tombs 2009). Others suggest that more "responsive" or "smarter" enforcement can lead to regulation that is more efficient and more effective (Ayres and Braithwaite 1992, Gunningham and Grabosky 1998).

What is of great interest here, in our view, is that in fact these challenges (and potential solutions) are in no way exclusive to regulation of economic operators (or of "businesses"). They are, in fact, to varying extents, applicable to any set of rules that have an *instrumental* purpose[278] - i.e., they tend to be far less effective than their proponents envisioned, create important costs and side-effects, be difficult to enforce – and it may be that "smarter" enforcement methods allow to improve their effectiveness. The specificity of regulation may well reside primarily in the fact that, because of the centrality of economic issues in our societies and of the strength of the different interest groups involved, a real discussion has arisen around them, including on the question of their implementation and enforcement, which may well hold lessons for other areas of legislation.

Distinguishing between different categories of norms, and different uses of legislation

[278] See Hawkins (2002) pp. 3-13 for a discussion of "instrumental" vs. other (in particular "symbolic") uses of the law.

The question of whether it may be acceptable to differentiate enforcement approaches (inspections frequency, enforcement decisions etc.) based on the level of risk (and other factors) is tied to the nature and status of the legal norms being enforced. This, in turn, relates to the possible distinction between different types of laws and norms – and between different uses of legislation.

Types of norms and levels of obligation

One way to attempt and make sense of the distinction between regulation of economic activities and other parts of legislation is to consider the difference between several types of laws or norms – in the perspective of the old question of a "natural law", and to the possibility (or lack thereof) to distinguish between norms that would correspond to an "overlap" between natural and positive law, and other norms that would only belong to positive law, but not carry greater weight, i.e. obligate but not "in the fullest sense" (Finnis 1980 quoted in Hemma 2015).

The idea of a "natural law" is as problematic as it is old, and long-debated. It can be understood to have a huge variety of meanings, and is tightly linked to a series of religious, philosophical or ideological perspectives (Goyard-Fabre 2002, pp. 7-8). Recent controversies and judicial decisions in the United States around homosexual marriage, which featured references to "natural law" among opponents, and reference to "fundamental human rights" among supporters, show the difficulties and ambiguities that abound in this notion. Nonetheless, just as the philosophical discussion around the idea of a natural law should not be avoided and can yield real fruits (*ibid.,* pp. 14-15), the distinctions it enables to introduce can shed some light to our topic.

Rather than going back all the way to Aquinas and different interpretations of classical natural law theory, we will draw on a few modern authors, whose ideas bear clear relevance to this research. First, as indicated above, Finnis distinguishes between "obligation" and "full obligation": the "essential function of law is to provide a justification for state coercion (…). Accordingly, an unjust law can be legally valid, but it cannot provide an adequate justification for use of the state coercive power and is hence not obligatory in the fullest sense" (Hemma 2015). This view does not really *conflict* with legal positivism (Finnis does not challenge the validity of positive laws), but introduces a nuance into the strength of the obligation they impose. Laws that correspond to an overlap between fundamental moral norms and positive law have, in this view, a power of obligation "in the fullest sense".

Second, Dworkin considers "that there are some legal standards the authority of which cannot be explained in terms of social facts. In deciding hard cases, for example, judges often invoke moral principles that (…) do not derive their legal authority from the social criteria of legality contained in a rule of recognition" (Dworkin 1977, p. 40, quoted in Hemma 2015). Dworkin uses as an example the famous *Riggs v. Palmer* 1889 decision by the Court of Appeals of New York, wherein the Court decided that a murderer could not benefit from his victim's will, even though there was no positive law to back their decision – drawing on "a requirement of fundamental fairness that figures into the best moral justification for a society's legal practices considered as a whole" (*ibid.*). Further to this, and in the same perspective, Dworkin introduces a fundamental distinction between "two kinds of legal argument. Arguments of policy "justify a political decision by showing that the decision advances or protects some collective goal of the community as a whole" (Dworkin 1977, 82). In contrast, arguments of principle "justify a political decision by showing that the decision respects or secures some individual or group right" (Dworkin 1977, 82). On Dworkin's view, while the legislature may legitimately enact laws that are justified by arguments of policy, courts may not pursue such arguments in deciding cases. For a consequentialist argument of policy can never provide an adequate justification for deciding in favor of one party's claim of right and against another party's claim of right. An appeal to a pre-existing right, according to Dworkin, can ultimately be justified only by an argument of principle" (Hemma 2015). This distinction is of great importance for us, in that a large part of the norms subsumed under the "regulation" moniker are clearly expressions of *policy choices*, but not of fundamental *rights and principles*.

Third, Fuller's vision of "procedural morality" in law posits that "law's essential function is to "achiev[e] [social] order through subjecting people's conduct to the guidance of general rules by which they may themselves orient their behavior" (Fuller 1965, 657)" and this "implies that nothing can count as law unless it is capable of performing law's essential function of guiding behavior" (Hemma 2015). In order to perform this function, "a system of rules must satisfy the following principles: (P1) the rules must be expressed in general terms; (P2) the rules must be publicly promulgated; (P3) the rules must be prospective in effect; (P4) the rules must be expressed in understandable terms; (P5) the rules must be consistent with one another; (P6) the rules must not require conduct beyond the powers of the affected parties; (P7) the rules must not be changed so frequently that the subject cannot rely on them; and (P8) the rules must be administered in a manner consistent with their wording. On Fuller's view, no system of rules that fails minimally to satisfy these principles of legality can achieve law's essential purpose of achieving social order through the use of rules that guide behavior." (*ibid.*).

Connecting these views to our field of research is easy, and enlightening. First, most matters covered by regulation simply do not relate to fundamental issues of morality (whichever way, and on whichever basis one construes them), and thus fail in Finnis's perspective to "fully obligate" (they do obligate, but in a "lesser" way). Second, most norms pertaining to regulation are adopted in order to advance policy choices, and do not relate to fundamental rights and principles – and thus fail to carry the same weight, even though they are legally binding. Third, the principles identified by Fuller as necessary for the law to achieve its purpose form the foundation of many "better regulation" or "smart regulation" principles, showing the link from these newer approaches to longer-standing visions of good legal practice. These (and in particular the first two points) form important theoretical justifications for practices that we will consider further in this research, and which involve a level of discretion in the enforcement of regulation[279].

Nor are these purely theoretical, but rather jurisprudential practice shows the relevance of these distinctions. In international law, for instance, the notion of *Jus Cogens* (peremptory norm) refers to norms for which no exception or variation is admitted, for their moral strength (viewed as applying to all humanity, throughout moral systems) gives them particular weight[280]. By contrast, other norms arise through convention, and do not carry the same peremptory strength. The whole tradition and practice of Common Law is likewise built on the idea that some fundamental practices can be identified, and built upon, even in the absence of a positive norm. Such idea is not absent from Civil Law countries either: in France, the "*principes généraux du droit*" (general principles of law), which apply primarily (but not only) to administrative law, can lead to courts ruling against administrative norms and decisions based on principles rather than positive law[281].

From this perspective, as a result, it appears legitimate to challenge the view, which we have seen held in many countries, that risk-focus and risk-proportionality would be somehow illegitimate because they would conflict with the absolute obligation created by law, and the absolute duty for the executive to enforce it.

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[279] The inspiration for this section was provided by a presentation by Donald Macrae at the International Seminar on Regulatory Discretion held in The Hague in December 2013 – in which he presented a vision of a "hierarchy of norms" – the most fundamental ones expressing *values* (and carrying the most weight, being the most "peremptory"), a second category being the foundation of *order* (e.g. driving rules), and thus having to be strictly complied with in spite of them being purely conventional – and a third category corresponding to the bulk of regulation, and expressing *policy.* We have tried here to provide a theoretical underpinning for this distinction which, in our experience, is extremely valid in practice. The presentation can be accessed at: http://www.ial-online.org/uploads/2014/01/The-Hague-131205-session-2-presentation-1-Macrae1.pdf.

[280] For illustrations, and discussions of the effects of what the author sees as "excessive" application of the criminal law to regulatory issues, cf. Malcolm (2014 a) – "Unlike *malum in se* offenses, most criminal regulations do not prohibit morally indefensible conduct. Regulations allow conduct, but they circumscribe—often in ways that are very hard for the non-expert to understand—when, where, how, how often, and by whom certain conduct can be done" (p. 1).

[281] These principles are "identified" drawing on "ideological conceptions of the national consciousness" and a "mass" of national, international and other texts (Frier and Petit, quoted in Tifine 2010, 2nd part, chapter 1, section IV).

Rather, as these authors suggest, there are meaningful distinctions to be made between different types of norms, which carry different levels of obligation.

Legislation and regulation – the different uses of law

Another important distinction is between the different purposes of *legislation* and *regulation*, which are essentially distinct in spite of their important overlaps – and between the different uses of law. As Voermans (forthcoming) puts it, "with 'legislation' we mean the authoritative, and constitutionally controlled form in which law is cast and the procedure leading up to the enactment of it (the decision). With regulation we mean a public intervention in a market or in society. (…) Legislation and regulation coincide in a lot of instances. A lot of regulation is cast in the form of legislation. (…) But not all regulation needs to be cast in the form of legislation (…), and not all legislation is regulation". While the distinction is essential, and shows that there is no full overlap between the two notions, what matters even more to us here is that the two have a different *focus* and *purpose*. To quote Voermans again, "the focus of and underlying notion of regulation (…) is on government intervention in markets, i.e. on acts private actors cannot perform with private capital, on interventions beyond regular market mechanisms (…) Legislation on the other hand focuses not primarily on markets but – to use a big word – on the human psyche, especially morale and social relations: the oughts of our existence."

The scope of legislation is thus much broader than that of regulation – which, to the extent that it is cast in the form of legislation, can be seen as a specific subset of the broader field of all legislation. Beyond their different focus, the two also have different goals. Regulation "predominantly functions as a market intervention aiming for a correction" (Voermans, forthcoming), and this holds true regardless of whether one considers *normative* or *positive* theories of regulation. Normative ones will consider the instances in which regulation could be seen as appropriate from an economic perspective, in particular to address market failures and inefficiencies, but also issues of distribution, fairness etc. in some instances (Veljanovski 2010, pp. 22-24). Positive ones will look at how regulation is produced in practice – interest groups at play, effects on wealth transfers between different groups, etc. (*ibid*., pp. 23-26). In all cases, the focus is market relationships and economic issues. By contrast, legislation "serves other and broader functions": it "provides both the basis and the framework for government action", "works as a safeguard against government action by enshrining rights and obligations" and provides "legal certainty". It also can "serve as an instrument to further government policies (instrumental function)", "offers the basic framework for the operation of a bureaucracy" and "communicates and reaffirms public morals, values and public goods (symbolic function)" (Voermans, forthcoming).

In spite of the apparently clear differences, there exists a tension because legislation increasingly has been used over the past century and a half to make "continual improvements in the life of the community by means of explicit legal innovations" rather than (as was hitherto its most common function) being predominantly a "benign instrument of codification through which hitherto scattered and inaccessible common law could be systematized and made accessible for everyone" (*ibid.*). To the extent that legislation is an instrument for polciy objectives, and that some of these policy objectives affect economic issues, there is a significant overlap with regulation. While regulation primarily focuses on affecting economic activities to achieve specific goals, legislation more broadly seen has a number of other fundamental roles – expressing moral values, and ensuring the functioning of the constitutional order. As Voermans (*ibid*.) puts it, "from a constitutional point of view (and the symbolic function which is closely related to it) the only right measure for the quality of legislation is its ability to express law" and "the extent to which the criteria, emanating from constitutional principles, are met" – whereas regulation treats legislation as a means to other ends, and assessing its quality thus requires to take an *instrumental* perspective.

To the extent that a significant part of regulation is enacted by legislation, and that the purposes and criteria are fundamentally different, there can thus be cases where different perspectives will result in conflicting views on enforcement. Reducing legislation to an instrumental perspective is inherently problematic – Voermans (*ibid*.), referring to Tamanaha (2006), reminds that "instrumentalism may in the end undermine important social and symbolic functions pertaining to legislation". In an interesting twist, there are strong reasons to believe that the more "social and symbolic functions" of legislation themselves have important economic value – for instance, "European legislation also creates trust, security, legal protection and all kinds of other, more or less imponderable, benefits for the internal market" meaning that the "pricing" of costs and benefits may be "extremely difficult" (Voermans, forthcoming).

There is thus no easy solution to our issue – from an instrumental perspective (befitting "regulation"), it may make sense for enforcement to be responsive and risk-proportionate, but this may conflict with other values expressed by legislation. Voermans (*ibid.*) reminds rightly about the relevance of a political perspective: because "Better regulation" and "Better lawmaking" policies are "essentially political programmes resting on political perceptions as to the overriding values of legislation and regulation", their effect and success has to be "weighed politically". In other words, there can be no politically neutral consensus on the right approach, but rather one can look at the adequacy of a given approach (or programme) to a clearly stated political objective.

A last point of note is that importance of *trust* – Voermans (*ibid.*) repeatedly emphasizes how essential the function of *building trust* is for legislation. Not only was this the key role of legislation in enabling markets before regulation with specific "transformative" goals came about – but it is a role that has remained crucial. In fact, enabling trust is one of the fundamental functions of modern regulation, as we have seen above e.g. with respect to food safety legislation. A criterion that may therefore be common to both a "regulatory" and a "legislative" perspective is whether enforcement practices actually are effective at reinforcing trust between market actors, or not.

ii. Justifications of regulation – why, when and how to regulate

If regulation is indeed primarily the expression of *policy preferences*, and not of fundamental principles or rights (though it is the latter in *some* cases), some guiding principles are needed in order to define why, when and how to regulate. In such a perspective, regulation is a *policy tool* – as any tool, it is not all-purpose or "one size fits all", and can produce damage as well as positive results. Thus, such principles are essential. It is fair to say that, at least for authors who place themselves within the framework of a broadly "liberal" market economy, the most broadly accepted foundation for regulation is what is called *market failure*. Even considering authors that advance a different view of society and the economy, the following principles may remain applicable insofar as they also relate to the best choice of instruments, and not only to the goals being pursued (even in a radically redistributive perspective, for instance, regulation may not be the best option, as compared to taxation and spending, for instance).

Anthony Ogus, in *Regulation. Legal Form and Economic Theory* (1994), did far more than give a specific account of how regulation had evolved and acquired more prominence as a public policy instrument in the 1980s – he attempted to give a comprehensive account of regulation's foundations, purposes and forms from a *normative* perspective. This perspective can be complemented, in particular for a concise summary of the *positive* perspective on regulation, with Veljanosvki (2010).

Understanding the role and limitations of regulation in a market economy is crucial in order to the consideration of inspections and enforcement – because they cannot be considered fully separately from the

rules they are meant to enforce. Inspectorates define priorities, give guidance and instructions to their officials, and in many cases adopt and publish guidance documents for the public, or even secondary legislation. We have observed in many cases how these were often based on a vision of regulation as an all-purpose instrument, that could be used in any circumstance, for any type of problem, and was expected to be effective in all of them (and, consequently, inspections and enforcement would likewise be appropriate to solve this problem). By contrast, a more precise and limited vision of what regulation can really achieve, and of when it is appropriate, is fundamental to define priorities and methods in a more targeted, focused and differentiated way, which is what risk-based and compliance-focused approaches generally seek to achieve. In this perspective, we will thus briefly summarize some of the key normative perspectives on the proper role and instruments of regulation.

Why and when to regulate

In a market-based context, regulation comes as an *exception* to free economic activity. In an "ideal" market, parties should be left fully free to contract – but the need for regulation arises primarily from "imperfections" in the market, what is broadly termed "market failures", which mostly arise when "negative externalities" (negative effects of economic activities, beside and beyond their main purpose, affecting third-parties) are significant (and not addressed), or when "transaction costs" (costs needed for information gathering, negotiation, transaction) are too high (Ogus 1994 pp. 17-19[282]). In theory, and again in an ideal (and clearly unreal) market setting, negative externalities could be dealt with through private contracting[283] - in practice, however, this is often impossible, either because transaction costs are too high, because some externalities are not "priced" (some goods are entirely free and there are major problems involved in "privatizing" them to allow for contracting to resolve externalities – e.g. this is the case of air), because the benefits are highly concentrated and the harm diffuse (making collective action unlikely and costly), to name just the main problems (Ogus 1994 pp. 19-22).

Situations where negative externalities of economic activities are significant, and where private contracting cannot provide an adequate response, are at the root of most of the regulations for which we consider inspections and enforcement in this work. In some cases, it is possible to avoid using "command-and-control" regulations by relying on tort law (Ogus pp. 20-21) and private law more generally, but "the courts have jurisdiction to enforce rights only *ex post*", meaning "after the damage has been inflicted" – and in some cases the infringer may "avoid the sanction by insolvency" (*ibid.,* p. 28). In any case, in many cases relying on private law will be inadequate because potential plaintiffs "will only seek to enforce rights where the expected benefits exceed the expected costs" and "thus externalities which affect large numbers but which impose only a small loss on each (…) will not be 'internalized' by private law instruments and serious misallocations will remain uncorrected" (*ibid.,* p. 27). This is not mentioning the serious problems arising when the right-holders are in a situation where they are ill-equipped to avail themselves of the judiciary (poverty, lack of legal literacy, etc.) – and assuming an unbiased judiciary, of course. In short, there are situations where "market failure" is

[282] See also *ibid.* pp. 41-42 on "coordination problems" i.e. issues where in principle negotiated agreement would be possible, but the number of actors and interactions makes it absurd, e.g. the driving code. While the driving code rules to a large extent are purely conventional (e.g. whether to drive on the left or right side of the road), having each pair of drivers negotiate them is simply impossible (and even absurd). A regulatory intervention is far more "optimal", and in fact clearly necessary (and this corresponds to what we described above as essential conventions allowing the proper functioning of society).

[283] And this is what radical (right-wing) libertarians like Nozick (or, earlier, Hayek) would advocate: no regulation, only private contracts. We will not discuss here the many problems that plague such views, but essentially the problem of transaction costs is the first that, even in a purely market-oriented worldview, makes the full reliance on private law inadequate. Akerlof (1970) provides a perfect example of why information asymmetries make it in practice impossible for many markets to function properly absent any regulatory intervention.

accompanied by "private law failure", which builds "on public interest grounds a prima facie case for regulatory intervention" (*ibid.*, p. 28).

In practice, there frequently are problems caused by unaddressed negative externalities and high transaction costs – because the assumptions for perfect functioning of the market are rarely met – these include fully rational, "utility maximizing behaviour" by all market actors, sufficient information for all actors "to make utility-maximizing choices"[284], absence (or full correction by private law mechanisms) of negative externalities, and fully "competitive markets" (*ibid.,* p. 24). In practice, these conditions are generally only partially and imperfectly met, at best. Thus, regulation can be needed, and can aim at addressing any or all of these problems and imperfections – prohibiting or constraining operations that create significant negative externalities, reducing transaction costs by establishing uniform requirements for products[285]. Regulation can also focus on specific market imperfections, e.g. mandate the disclosure of specific information in a standardized way, "nudge" people towards more utility-maximizing behaviour[286], or intervene to limit the power of dominant market actors[287].

Thus, overall, regulation can be justified in a such a system when, absent regulatory intervention, there would be a problem of inefficient allocation of resources – for which, following Ogus, we would adopt the Kaldor-Hicks criterion rather than the Pareto one[288]. Addressing market failures and private law failures, "inefficiencies" in economic terms, "infringements of rights" (including the right to life, in some cases), all require regulation, at least in some cases. But it does not follow that regulation always works as intended, or that the form and tools of regulation are indifferent. Ogus of course discusses the different ways in which regulation can fail its objectives, be driven by private interests from the onset, or "captured" during implementation (see in particular *ibid.* pp. 55-58 on "regulatory failure"). We have already discussed this question above, and will now focus on how to select appropriate instruments for regulation.

How to regulate

The types of regulation that are most commonly controlled through inspections are mandatory technical norms (that Ogus calls "standards", a name which we avoid here because of its polysemy[289]), as well as

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[284] See Ogus (1994) pp. 38-41 on the problems of information often being limited, imperfect, costly or impossible to process.

[285] Of any kind: these can be uniform requirements for physical products (e.g. food),but also for financial ones (loans or insurance contracts), rental agreements etc.

[286] See Sunstein and Thaler 2008. While it is frequently understood that the "nudge" approach is an *alternative to regulation,* it is in fact often better understood as an alternative to "command and control" regulation. Behavioural economics insights are used to design regulatory requirements that require specific ways to disclose or present information, mandate some default options, etc. For more on the use of behavioural economics in regulatory policy see Lunn (2014) report to the OECD, and Alemanno and Sibony (2015). In particular, see Lunn pp. 39-41 on the application of behavioural economics insights to "regulatory delivery" (including inspections and enforcement).

[287] Be it in positions of monopoly/oligopoly, or monopsony/oligopsony – in practice, most regulation focuses on (quasi-)monopolies linked to natural resources, utilities etc.

[288] See Ogus 1994 pp. 24-25 – whereas a Pareto distribution is efficient if it is impossible to make any change without making at least one person worse off, and thus prohibits improvements that would benefit the vast majority if even the smallest minority stands to lose from them, the Kaldor-Hicks test allows for *compensation.* In this meaning, a policy is efficient if the overall gains it produces are sufficient to *potentially* allow to fully compensate all the losers and *still* produce an aggregate benefit. It is easy to understand that these two definitions of "efficiency" lead to radically different policy perspectives (and tend to correspond to radically different political sides, as well).

[289] The word *standards* can have at least three major meanings. In its *technical sense* (used in the WTO TBT agreement for instance), it is a document that provides requirements, specifications, guidelines or characteristics that can be used consistently to ensure that materials, products, processes and services are fit for their purpose . Standards are *voluntary* in nature, and developed by institutions (national, regional – CEN, CENELEC etc. – or international – ISO) that are normally acting on behalf of stakeholders (particularly businesses) and not of public authorities (which, however, often provide some funding to standardization bodies). On the other hand, in countries where many standards are mandatory, the standardization body is often a state agency. In its *vernacular meaning,* a "standard" is a norm, convention or requirement of any kind – but also can mean (as when one writes "the highest standards") the

information obligations[290]. Information obligations can cover a variety of issues and fields, and include e.g. mandatory price disclosure (Ogus 1994 pp. 126-128), weights and measures[291] and requirements on display of quantity (*ibid.,* pp. 130-132), and rules on "identity and quality disclosure", i.e name, description and composition of products[292] (*ibid.,* pp. 132-138) and warnings and instructions about use of the product being sold (*ibid.,* pp. 141-144).

Information requirements are not cost-free, and there can be a tendency on the side of regulators to impose too many of them, because they are *mutatis mutandis* significantly less restrictive than mandatory technical norms. Information requirements still allow economic operators to produce and market goods pretty much as they decide to, provided that they comply with rules in terms of labelling and other information. Nonetheless, the way they are worded and controlled can result in higher or lower constraints and costs for economic operators (and, in turn, in different economic effects).

In spite of the importance of information obligations, and of their pervasiveness, they have been the subject of relatively less study (and debates) than mandatory technical norms, possibly because of the latter's more "reassuring" character (what may be hazardous is forbidden, rather than just carrying warnings) and of the greater economic distortion they can impose (direct restriction on the possibility to bring products to market).

Mandatory technical norms are one of a gradient of regulatory interventions, ranging from the least to the most restrictive. Ogus ranks such intervention types (*ibid.*, p. 151) with information requirements as the least restrictive, prior approval as the most restrictive[293], and "standards" (mandatory technical norms) in between. Ogus further differentiates between "target", "performance" and "specification" standards (mandatory technical norms), and this is a distinction that is very important for inspection practices. We will not summarize here the detailed discussion of cost-benefit aspects of different types of interventions, and of cost-benefit analysis models (*ibid.*, pp. 155-165), on which there is considerable literature[294]. The distinction between "target", "performance" and "specification" norms is, however, central for inspection work (*ibid.,* pp. 166-171).

While "target" norms "render unlawful the causing of certain harms" (p. 166), they do not specify how an economic operator should conduct its activities, nor do they deal with "intermediary outcomes", which may arise between the activities and the harms that the norms aim at preventing. Thus, while they allow the greatest flexibility in economic operations, and thus could theoretically be the ones that impose the least

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way in which something is done or executed, regardless of whether this is codified or not. There is often the assumption that when "standards" are spoken of, then "high standards" are expected, and that more or less automtically "standards" are "a good things" (hence: more standards are better). This has implications in policy discussions, where there is often an automatic bias for "more standards". Finally, *regulatory standards* (the meaning Ogus uses) refer to mandatory technical norms (applying to anything from hygiene to occupational health, fire safety to environment). Given the potential for confusion, we prefer not to use the word at all here, and refer to mandatory technical norms.

[290] Other forms of regulation covered by Ogus, e.g. prior approval (licensing, permits etc.) and economic instruments (incentives etc.) also frequently involve different forms of inspections – they are nonetheless less "central" in the work of inspecting institutions.

[291] Which, as we have seen above, belong to the oldest areas of government regulation, as well as inspections.

[292] Such requirements can *mandate* that specific information be given, and/or regulate *when and how* the use of certain names, descriptions or claims can be allowed.

[293] In fact, information requirements could be further disaggregated between different types: disclosure rules vs. restrictions on the use of certain names and descriptions, for instance. Likewise, "prior approval" can cover a number of situations with varying degrees of restrictions, requirements, short or long procedures, need to obtain other "prior prior approvals" etc. And, of course, these requirements can be *combined*: the same business operator and product can be subject to prior approval, and then mandatory technical norms, and information requirements in addition (in fact, this is generally the case that "stronger" requirements come *on top* of "weaker" ones).

[294] See e.g. Radaelli and Dunlop (in press), and of course a number of previous publications e.g. by OECD. The question of cost and benefits is of course connected to the question of inspections and enforcement, in that the potential costs and effectiveness of inspections and enforcement should be considered when conducting RIA (or any other form of impact assessment). In practice, they often are not, or insufficiently, taken into account.

burden on the economy (and least distort allocation of resources), they often create difficulties. Depending on the level of discretion and authority granted to the regulatory agency in charge of enforcing these norms, the difficulties may be more on the side of economic operators, or of regulators. Where regulators have limited discretion and their authority is subject to strict judicial review, it may be difficult for them to enforce such norms, because of the difficulty to prove a causal relationship between specific economic activities and the harms covered by the norms, and/or the time lag may be too long for effective prevention. At the same time, such norms can also be very problematic for economic operators, because of high uncertainty ("the information costs to the firm on determining what quality of performance will ensure compliance" may be high because of uncertain causalities, third party activities also having an effect, etc.). Thus, while such standards are attractive at first glance from an economic efficiency perspective, and can be particularly conducive to innovation and technological flexibility, they carry potentially important costs and operational difficulties.

"Performance" norms are somewhat less "uncertain", while leaving a significant room for flexibility. They impose prescriptions (e.g. maximum level of certain emissions) on the direct outcomes of economic activities, while leaving the specifics of the operations open. Such norms have the advantage of providing regulators with more directly verifiable (and enforceable) indicators, and of burdening economic operators with less uncertainty. They also leave a fair amount of room for technological innovation (though less than "target" norms). However, because they focus on intermediate outcomes and not the final harms that the regulation aims at reducing, they can fail (partly or fully) in preventing or reducing such harms, if the causality between regulated outcomes and harms is less strong than anticipated, and/or any unexpected effects take place (involving third parties, side effects etc.).

Finally, "specification" norms directly impose how certain economic activities should take place, which materials, products, processes, methods are allowed, which ones forbidden, etc. The relationship between "specification" norms and the harms they are supposed to prevent is indirect, and it can often happen that the norms cover a number of issues but fail to address the harm because some critical issues were left out (because of limited knowledge, or poor design, etc.). To address one given issue, "it is often necessary to lay down a series of specification standards" (*ibid.*, p. 167), resulting in a large number of norms, but with compliance requirements being clearer (and enforcement simpler) than with "target" or "performance" norms. While "specification" norms thus bring greater certainty and predictability (and may make deterrence easier and stronger), they have "significant disadvantages", in particular inducing high "technological rigidity" and making it more difficult to introduce new techniques, methods, processes (even when these would actually improve performance in terms of harm reduction). They also often, as indicated, fail at preventing harm because they do not address it comprehensively, but rather target only some of the precursors of harm, and may miss some critical ones. Such highly detailed and prescriptive norms are also, in most cases, the oldest type of norms[295], and the most widespread[296].

From an inspector's perspective, "specification" norms hold much appeal: they are clear and unequivocal, lend themselves to relatively easy enforcement decisions, make control work easier and faster, and both deterrence and advice are also easier (there is higher certainty of detection and sanction – and clearer

[295] Norms on manufacturing in pre-modern times were, for instance, "specification" norms. Such were also the earliest occupational safety norms, even though we may find that some of the specifications were relatively vague compared to more modern standards.

[296] Pre-1970s, most countries were essentially using detailed specifications. Since then, a number of jurisdictions and regulatory agencies have introduced "target" or "performance" norms (e.g. the US EPA, UK HSE, EU "New Approach" directives etc.). Nonetheless, around the world, the bulk of technical norms tend to remain "specification" ones, e.g. in the post-Soviet space, or in some post-colonial countries (though in this latter category the most frequent problem is the *lack* of technical norms, resulting in excessive enforcement discretion). Many of these specification norms end up being outdated, and/or exhibit contradictions between different regulatory areas or regulators.

recommendations to make). They also offer benefits to firms, particularly smaller ones, which have less resources (both human and financial) to investigate how to be in compliance with "target" or "performance" ones – specific norms can offer certainty and predictability[297]. They tend, however, to create major problems too. First, because of what Baldwin (1995) calls "errors of inclusiveness" – "because they discourage desirable activity (through over-inclusiveness) or they fail to rule out undesirable activity (through under-inclusiveness)" (p. 177). Such situations can arise because of initial rule-design mistakes, but even more frequently occur because rules have not kept up with technical and scientific changes – something which the vast number of rules needed in a "specification" approach makes it likely to happen. This can result in situations where rules directly impose using an inferior technology, not only from a business perspective but from a public welfare perspective – this is the case of a number of Soviet standards that are still in force in many post-Soviet countries, e.g. in hygiene and fire safety, and specifically mandate the use of certain materials, techniques, processes, that were "state of the art" in the 1960s (when the standards were adopted), but have long ceased being so (see International Finance Corporation 2008 on technical regulations in Ukraine, for instance).

Baldwin (*ibid.*) extensively discusses the question of rule-design, and questions the possibility to find an "optimal" degree of rule precision (pp. 176-181). What he also emphasizes is the importance of considering, along with the rule's design and contents, questions of "form, force and type of sanction" as well as "how such problems [of inclusiveness] may be dealt with during the compliance-seeking process" (p. 181). Rightly, Baldwin considers not "rules" in isolation, but rules *along with their enforcement process.* Having discussed the different explanations for over-inclusiveness[298], and the problems involved in addressing them at the rule-making stage, Baldwin suggests that "an alternative response is to write rules that devolve discretion down to enforcers so that issues of inclusiveness are dealt with by selective enforcement", e.g. the famous example of UK health and safety rules based on the notion of "so far as is reasonably practicable" (p. 184). This, however, relies on "high levels of enforcer discretion", raising the twin risks of capture or abuse. It is also far from certain that enforcers will, indeed, be selective, and this "depends on regulatory styles and traditions" (*ibid.*). In addition, it is also essential to consider *which enforcement tools and methods* will be used: "compliance-seekers have at their disposal a number of alternatives to prosecution (e.g. persuading, advising, and promoting) and it cannot be taken for granted that the kind of precise rule that complements a prosecution strategy will be the best kind of rule to use in association with other techniques (p. 178).

Other authors, from different perspectives, fundamentally concur with Ogus (1994) and Baldwin (1995). As Morgan and Yeung (2007) put it: "rules are not self-executing, and scholars have devoted considerable energy to understanding the challenges associated with the use of rules as a mechanism for guiding behaviour" (p. 153). To a large extent, they add, rules are "indeterminate", i.e. their application depends on subjective and contingent factors (*ibid.*). Black (1997), in particular, has written on the ways in which the inherent generalization and abstraction necessary to develop rules results in problems when applying them. Indeed,

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[297] At least when enforcement is fair and transparent, and there is not a maze of partly contradictory norms. In many post-Soviet countries, for instance, conflicting requirements between e.g. hygiene, occupational safety, construction safety etc. result in situations where economic operators *cannot* be in compliance with all. We observed such situations directly e.g. in Ukraine (conflicting requirements on materials to be used, and on location of garbage disposal, between sanitary and fire inspectors) and in Lithuania (labour inspector demanding that an escape door be locked shut to prevent undue entry, whereas fire safety regulations would mandate that it be free to open in case of evacuation need).

[298] Baldwin lists several possible causes for over-inclusiveness (pp. 182-183, building in particular on Bardach and Kagan 1982): first, "the informational costs of designing rules of optimal inclusiveness are considerable" leading to the tendency to "externalize costs on those who are regulated or on to enforcement officers". Second, a tendency to "risk-regulation reflex" behaviour (see further in this work) that leads to "opt for an across the board solution" in response to "mischief at a particular location". Third, pressure from interest groups. Fourth, the tendency to build on public outrage to a disaster and thus get rules adopted as soon as possible (again, a variation of the "risk-regulation reflex" problem). Fifth, a "regulatory ratchet", through which new rules get added, but old ones are not removed .We would add to these problems of limits of scientific and technical knowledge, regulatory culture (risk aversion), and (as indicated above) the simple effect of time (rules getting outdated).

"the generalization which is the operative basis of the rule inevitably suppresses properties that may subsequently be relevant or includes properties that may in some cases be irrelevant" – and in addition "the causal relationship between the event and the harm/goal is likely to be only an approximate one". Black adopts a squarely instrumental view: "legal rules, and particularly regulatory rules, perform social management and instrumental functions (…) and their success is measured in terms of the extent to which they ensure that the substance of policy is achieved. (…) Under-inclusion can represent 'missed targets'; over-inclusion, excessive intrusion" (pp. 5-15). Overall, there is always an "imperfect correlation between proxy requirements and actual hazards" (Bardach and Kagan 1982, p. 71).

The observation of inspections and enforcement practices suggests that the theoretical impossibility of designing "optimal" rules (that Baldwin 1995 appears to demonstrate[299]) is validated by experience. In fact, the impossibility may be even stronger than suggested in reality, because even very specific and precise norms end up not working uniformly in practice because of differences in enforcement methods. While some agencies and officers will register a violation and impose a sanction even for the slightest variations from the norm[300], regardless of whether it corresponds to a real risk to the public welfare, and of the consequences of the sanctions[301], others will apply a "risk proportionate" enforcement approach.

Thus, there seems to be no escape from enforcement discretion if one is to avoid the twin pitfalls of under- and over-inclusiveness[302]. Ogus (*op. cit.,* pp. 170-171) attempts to find ways to make standard-setting more "optimal", but they all end with relying on regulators and their staff to administer wisely rules written in a more flexible language[303]. Trying to curtail discretion can lead to difficulties in fighting "creative compliance", i.e. formal compliance with specific requirements that "covers" effective undermining of the regulation's objectives (see Baldwin 1995, pp. 185-189). A recent report by the Scientific Council to the Netherlands' Government (*Wetenschappelijke Raad voor het Regeringsbeleid* – WRR) underlined the same risk of "creative compliance" as a major concern, and called in response for *increased* regulatory discretion and less specific norms (WRR 2013).

If only highly damaging (both for the economy and the regulation's own objectives) rigidity can minimize discretion, and if even in such cases discretion can never really be fully avoided, then trying to understand better *how to organize* this discretion is indispensable. This is particularly true considering the very real and considerable pitfalls of unfettered, uncontrolled discretion – regulatory capture on the one hand, abuse and rent-seeking on the other (and corruption and ineffectiveness in both cases)[304].

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[299] *Ibid.* pp. 179-181, building on Diver (1983).

[300] A case frequently observed directly by the author in post-Soviet countries (see International Finance Corporation reports, various years) – but also often reported by businesses in other countries, e.g. in France with labour inspectors (direct interview with the authors of a recent government review of regulatory inspections – see also Chapelle and Clément 2015).

[301] Taking the above examples: in Ukraine or Tajikistan, many inspectors impose sanctions for the slightest variation from the norms imposing a precise height from the floor for items such as electric sockets or fire extinguishers, even if the variation is less than 1 cm, and has absolutely no risk impact. In France were reported examples of labour inspectors filing a violation and imposing sanctions for every minor discrepancy from the legal work time, regardless of circumstances, significance etc. (and of the impact, which in one case was the withdrawal of a foreign investor from a locally significant business).

[302] As our examples above suggest, there may be no escaping discretion in any case. Even in systems (e.g .US OSHA) which try and minimize regulatory discretion (with a number of side-effects), discretion remains – if not in the hand of regulators, then in the hand of judges called upon to decide conflicts between regulators and businesses.

[303] Ogus (*ibid.*) suggests e.g. the reference to a "general principle" that "may be accompanied by guidelines", or to "confer power on an agency to create formal differentiated standards for invidiual firms or groups of firms" – or to leave differentiation "to the enforcement stage". All of these "solutions" are in fact different ways of establishing and framing discretion (and of assigning it to different organizational levels and operational stages). It remains that it means basically that regulatory discretion is unavoidable if one wants to have at least a "decent" combination of effectiveness and efficiency of rules.

[304] Ogus (*ibid.*) also discusses several of the issues arising around the enforcement approaches and practices. He shows that, in many cases, inspection officials will tend "in exercising their discretion" to "find it difficult to resist arguments for leniency based on grounds" such as financial difficulties, local unemployment etc., even when these are clearly *not* foreseen as factors in the regulation (pp.

A short *coda* is in order to this discussion of why, when and how to regulate: the question of *who* should do it. The importance we have found of regulatory discretion speaks strongly in favour of adequate *professionalism* of inspection and enforcement staff, and maybe also of officials in charge of improving regulatory implementation methods *across the board.* We will discuss the question of inspectors' professionalism in the third part of this research, looking at practical examples. As for the idea of having officials who understand regulatory issues, and are tasked with coordinating and improving them, it can be found e.g. in Breyer (1992). Having shown the importance of expertise and professionalism issues in regulation (see e.g. pp. 49-50) Breyer, looking for solutions towards more effective and efficient "risk regulation", proposes creating a "new career path" of civil servants with expertise in all major regulatory fields, and a "small, centralized administrative group charged with a rationalizing mission" (pp. 59-60). This would, in Breyer's view, help build a more rational, "reformed", "risk-based" mission for regulators (pp. 64-65). We will see in the third part that there have been experiments in this direction, for instance the creation of the UK's Better Regulatory Delivery Office, and that they bear a close relation to attempts to use "risk-based approaches" more systematically.

iii. Conclusion – the importance of implementation – learning from the regulatory field

From the above, we can conclude several points of relevance for the rest of the research. First, regulation has costs as well as benefits, and it has limitations – and this applies also to various types of regulation or regulatory instruments. Within this framework, "optimizing" regulation's effectiveness and efficiency appears to require leaving a significant space for discretion in enforcement – thus *how to structure* this discretion is an important question. This is what we will focus on in the rest of this research.

Second, regulation can legitimately be treated as a *specific* field, and there are sound reasons to apply strict scrutiny to limitations of economic freedom and their potential adverse effects, but not more so than would be true for a number of other legislative fields. Rather, the specificity of regulation has emerged to a large extent as a result of the interplay of conflicting actors, and the salience of economic and social issues it relates too. There may thus not be real legitimacy to treat regulatory issues *differently* than we would other fields of legislation that impinge on fundamental rights or freedoms – but maybe there are ideas and lessons that have been developed in the study of regulation that have emerged there more strongly (precisely because of conflicting interests, salience of issues etc.), and that could be applicable to other fields. We will see when discussing compliance theories that much can be learned from non-regulatory fields (e.g. interactions between citizens and the police). It may well be that much could in turn be learned from "better regulation", "smarter regulation" and "risk-based inspections" that could be applicable to interactions between the state and citizens, civil society organizations, the media or other stakeholders, in a variety of fields. This could be the case of the requirement to analyse costs and benefits, demand extended consultations and discussions before

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211.212 – note that the 2014 UK Regulators Code now explicitly *mandates* that all regulators should have regard to economic impacts when taking their decisions – see: https://www.gov.uk/government/publications/regulators-code). We have seen, on the other hand, many countries where regulatory officials did not pay *any* attention to such issues in most cases (see above Ukraine, France etc. examples). Ogus also mentions how command and control regimes correspond to "power, prestige and job satisfaction" for regulators (p. 256), something which is even more true in countries where corruption issues are significant. Again, these different (somewhat conflicting) pitfalls all make it only more important to study more closely how regulatory discretion can be better understood, "framed" and managed.

issuing new rules, focusing on key risks and leaving more room for voluntary compliance when risks are low, modulating enforcement responses based on risks etc.

As Voermans (2015) has shown, the lack of consideration of issues such as compliance drivers and methods to assess, understand and improve compliance levels is one of the roots of implementation problems for European legislation (see pp. 357-359 in particular). This is an interesting case where considering the best practices in regulation and regulatory enforcement could greatly benefit a broader field of legislation, and a "higher" institutional level (since EU legislation applies primarily to Member States, and not only or firstly to individuals). Thus, the lessons learned in studying regulatory practices, and in particular regulatory enforcement and inspections, could be found to have broader relevance – to other legislative and policy fields, and to a variety of actors and institutional levels.

Finally, a short point is in order to clarify the exact place of *inspections and enforcement* within the context of justifications for regulation. There are several ways in which inspections and enforcement are relevant when considering the need for and legitimacy of regulation, and in deciding on the most appropriate method. First, when the potential costs of a given regulation are assessed (both for the state, the duty holders, and the economy at large), it is essential to consider the specific costs of the "enforcement" stage, and for this to decide between different inspections and enforcement approaches (including the "none" option)[305]. Second, when the expected effectiveness of a given regulation is envisioned, the inspections and enforcement stage is equally important (and, again, there are several options with different expected results). Third, inspections and enforcement can also be considered *independently*, when a regulatory framework already is in place and there is no discussion of its being revised. In such circumstances, different inspections and enforcement choices (in terms of institutions, resources, approaches, "on the ground" methods etc.) will present very different costs, expected outcomes, and also levels of restrictiveness and intrusiveness, and thus can be subject to the same kind of analysis as would be done of regulations themselves in terms of both legitimacy and adequacy.

b. Costs and effectiveness of regulation and enforcement – theory and evidence

In a number of ways, costs and effectiveness questions are central to regulatory discussions, and regulatory inspections and enforcement issues are no exception. We have exposed in the first section the ways in which regulatory inspections were explicitly set up in order to *address perceived problems,* meaning that, given this utilitarian purpose, *effectiveness* is a central consideration. Furthermore, as we will highlight in the third section (covering experiences of risk-based inspections and reforms), claims to *reduce costs* (to private businesses, citizens, the economy at large etc.) of inspections (and, by extension, of regulation) are central to the drive for more risk-based inspections. At the same time, *effectiveness* problems are also important to the risk-based inspections discussion, and have given the impetus to many changes in rules and practices. There are only few research undertakings that have focused specifically on assessing *inspections' effectiveness*, and even fewer that have looked seriously at costs (a topic on which, on the other hand, there is a certain amount of publications from governmental and inter-governmental institutions). We will consider these in the third section, but for now we will briefly review the broader accounts of *regulation*, under which inspections and enforcement are generally subsumed, to see what they can tell us about these issues.

In fact, assessing effects (positive or negative) of regulation is easier said than done. Even though regulations have been given far more prominence in public discussions and research over the past couple of decades,

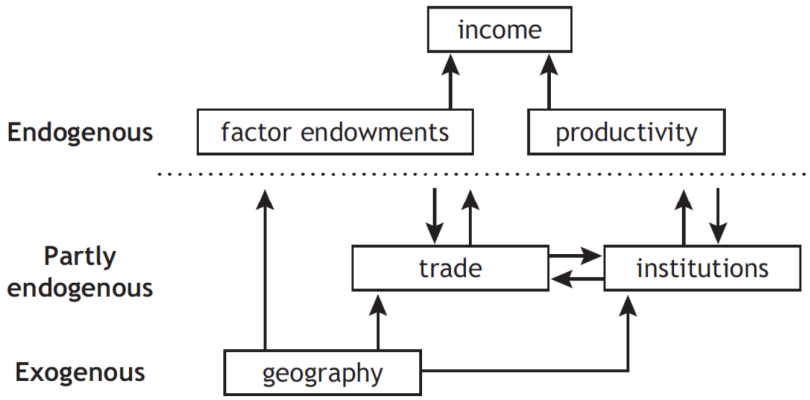
[305] See OECD 2014 (b), in particular the principles on "evidence-based enforcement" and "selectivity"

there is little solid proof or undisputed evidence that they make a considerable difference – be it to economic growth, or to the public welfare they aim at supporting. While this may sound provocative or even contrarian, and the parallel progress of regulation and welfare over the past couple centuries may seem to be proof enough, there are in fact a number of studies that cast doubt on causal relationships around regulation. If regulations themselves are of limited relevance, then one may argue enforcement and inspections are also matters of secondary importance. We cannot pretend to make a comprehensive review of the literature on these topics, but will try and cover them briefly to show some of the main findings and problems, and look at reasons the issue may matter regardless of the "inconclusiveness" of economic studies.

Regulatory reform and growth – context and specific and content of reforms matter

First, the impact of regulations on economic growth, competitiveness or jobs, is indeed disputed. On the one hand, Djankov, McLiesh and Ramalho (2006) write that "our results indicate that government regulation of business is an important determinant of growth" and that "relationship between more business-friendly regulations and higher growth rates is consistently significant in various specifications of standard growth models, and more consistently so than other determinants commonly used in the growth literature". They conclude that "Our results also have significant implications for policy [and] suggest that countries should put priority on reforming their business regulations when designing growth policies". Many other economists, however, beg to differ – both with the findings about the significance of regulatory issues, and about the policy prescriptions pushed by Djankov *et al.* (which all link to the *Doing Business* report, a project which Djankov long headed).

From a general perspective, there is consensus that "institutions" (part of which are regulations, and regulatory inspections and enforcement) are *one of the components* of growth. There obviously are many other components, including geography, demography, social and cultural factors, technology – but institutions have an important role, and interact with many other factors. Rodrik (2003) shows the ways in which good institutions supports growth in several ways (by directly impacting productivity, and through its effects on trade) in the following chart (*Introduction,* p. 5 – figure 1.3).



Rodrik, looking at the case studies gathered across the world, writes further that "institutions that provide dependable property rights, manage conflict, maintain law and order, and align economic incentives with social costs and benefits are the foundation of long-term growth. This is the clearest message that comes across from the individual cases" (*ibid.*, p. 10). However, there is far less of a "standard prescription" of what exactly these "institutions" should entail than there is in Djankov *et.al.* Indeed, as Rodrik indicates further, "good institutions can be acquired, but doing so often requires experimentation, willingness to depart from orthodoxy, and attention to local conditions (…) Perhaps nowhere has this been clearer than in China. Qian's

discussion of China focuses on what he calls "transitional institutions"—institutions that can differ greatly from off-the-shelf, "best practice" institutions (…) [and] can have the virtue of being more suited to the realities on the ground on both economic efficiency and political feasibility grounds. Qian shows that the Chinese leadership experimented and purposefully crafted imperfect, but feasible institutional arrangements (…) [which] succeeded because of their high ratio of economic benefits to political costs" (*ibid.,* p. 13).

A particular area of focus for reform is that of product-market regulations, and this is an important one for our research, as many inspections relate to product-market rules (e.g. food safety, non-food products market surveillance etc.). The findings are generally quite consistent that improvements in this area have a strong positive impact on productivity. These productivity-boosting effects of making product-market regulations more flexible are visible not only in the sectors directly affected, but "downstream", i.e. liberalizing production/intermediary goods has effects on the productivity of all the sectors that use these outputs: "Regulations that bridle access to otherwise competitive markets and unnecessarily constrain business operation can be a drag on productivity growth. While most analyses of this issue have focused on the effects of these regulations on the productivity of the firms or sectors directly concerned, the main point of this paper is that such regulations can also have powerful indirect depressing effects on the productivity of other sectors through input-output linkages" (Bourlès, Cette, Lopez, Mairesse, Nicoletti 2010, p. 28).

In short, regulatory issues (and particularly product-market regulations, which have a strong link with inspections) are relevant to long-term growth prospects, among a number of other drivers – but exactly in what way, and what improvements are most important, is likely to depend significantly on the broader country context. What, then, of the importance of such issues to *developed* countries, and to economic recovery in the current crisis (one dare not yet say "post-crisis") context? While the European Commission (EC) (EC 2014) and the OECD (OECD 2015 a) frequently emphasize the importance of "structural reforms" (which include employment law, tax administration, product-market regulations etc. – and which as a result cover reforms in a number of inspections), the prominence of discussions of these structural reforms in a "crisis recovery" context is somewhat misleading. Even the EC and OECD take pains to remind readers that these reforms are not "quick fixes": "Structural reforms to labour and product markets help to improve economic growth prospects and the ability of economies to adjust to shocks by expanding flexibility and improving the efficiency of how and where productive factors are used. The recent financial and economic crisis prompted EU countries to under-take considerable reforms, which are now starting to show tentative results. Their full benefits, however, may take years to materialise, which means that governments must avoid the temptation to give up on them now that the economic situation is somewhat more comfortable" (EC 2014, p. 1). The OECD states that: "overall, structural reforms implemented since the early 2000s have contributed to raising the level of potential gross domestic product (GDP) per capita by around 5%, with most of the gains coming from higher productivity" and that "further reform (…) could further raise potential GDP per capita by up to 10% on average across OECD countries" (OECD 2015 a, p. 106).

The IMF take is somewhat similar, but more precise and grounded in more economic analysis. In its latest take on the issue (IMF 2015), it indicates: "The analysis illustrates that structural reforms in the euro area can increase its real GDP markedly, though it may take time for their full potential to be achieved. Structural reforms are critical to improving the long-term capacity of economies to grow through both more intensive use of resources and higher productivity". Within these reforms, the "largest gains for euro area countries could come from product market reforms" (where inspections are an important aspect). However, the IMF cautions that "Weak demand conditions may dampen the already small short-term impact" (IMF 2015, Ch. 7, p. 22). Some independent analysts[306] are far more critical of the idea that structural reforms are what is

[306] As EC, OECD and IMF have all been advocating structural reforms, there is an incentive for their publications to be moderate in their skepticism of such reforms' impacts.

urgently needed in a time of recession. They note that "a broad consensus has emerged: Peripheral euro-area countries need to urgently adopt structural reforms that increase competition in product and labor markets" (Eggertsson, Ferrero and Raffo 2013, p. 2). Their conclusions, however, show that, while "structural reforms can greatly reduce the competitiveness gap between the EMU core and periphery and boost income prospects in the region", "the timing of such reforms is crucial. If undertaken during a crisis that takes monetary policy rates to the ZLB[307], structural reforms can deepen the recession by worsening deflation and increasing real rates" (*ibid.,* p. 32). In summary, "in a crisis that pushes the nominal interest rate to its lower bound, these reforms do not support economic activity in the short run, and may well be contractionary" (*ibid.,* p. 1). While the authors consider all kinds of structural reforms (product markets and employment) together, and there may well be differences between the effect of these two types (with most of the demand depressing effects coming from employment reform), caution remains in order.

Thus, to summarize these overall findings about the positive impact of regulatory reform on growth: it is likely to be significant (possibly major) in the long term, however its impact on the short term is more limited (and particular caution is needed in times of recession due to a shortfall in demand), and the exact contents of the regulatory reforms that will be effective is highly context- and country-specific.

Regulations impact on competitiveness, growth and jobs – more complex than it may seem

A related contention to the one that regulatory reform is "good for growth" is that "regulations" (or at least their abuse) would be "bad for competitiveness". While this appears to be grounded in simple logic (if you add more hurdles and demands on businesses, their costs of operating should be higher, and this in turn should make them less competitive globally), findings again show that this is not as clear-cut as it may seem.

A first problem is that, while regulations impose costs, it is not clear how high they are. Even the Australian *Taskforce on Reducing Regulatory Burdens on Business*, which had a clear interest in showing the relevance of its own task, had to acknowledge that "while a number of studies have sought to estimate the economic costs of regulation in Australia, the limitations of such studies mean that the estimates should be treated with caution" (Banks 2006, p. 12). This same report, however, suggested that "the economic cost of complying with regulations is a key determinant of national competitiveness and the investment environment for businesses. These costs can be direct, such as capital and operating costs. They can also be indirect, that is, opportunity costs, where the principal(s) of the businesses are taken away from their strategic roles of driving innovation, securing investment and increasing productivity" (*ibid.,* p. 11). Thus, the importance of improving regulations is predicated on their (negative) impact on innovation, investment and productivity – and, through these, competitiveness.

It is, then, worth considering the literature on one of the most prominent areas of regulation, environmental rules, and their impact on competitiveness. A quick review of findings gives a picture that contrast sharply with the above emphasis on regulations as a serious problem: environmental regulations appear to have very limited, if any, negative impact – and some studies even suggest a positive long-term impact. We summarize a few interesting studies, not in the aim of reaching strong conclusions, but in order to show the complexity of the topic, and the many factors that may influence findings. From our perspective, these apparent contradictions are interesting because they may point to the importance of (too often neglected) *implementation* questions in order to understand the impact of regulations.

The finding that environmental regulations have (at worst) little negative impact on competitiveness is relatively constant through repeated studies over a decade. One of the earliest studies (Jaffe, Peterson,

[307] Zero Lower Bound

Portney and Stavins 1995) concluded that "there is relatively little evidence to support the hypothesis that environmental regulations had had a large adverse effect on competitiveness, however that elusive term is defined" (p. 157). The conclusion is not entirely one-sided, though, and they add that "long-run social costs (…) may be significant, including adverse effects on productivity" – but studies looking at "exports, overall trade flows and plant-location decisions" show impacts that are "either small, statistically insignificant, or not robust to tests of model specification" (*ibid.,* p. 158). The authors, however, have interesting insights on *why* this may be so – i.e. why indeed these impacts may be small in reality, and why there may be measurement issues. We will come back to these a bit later.

More recent reviews report roughly similar findings. A review prepared for the United Kingdom's ministry in charge of the Environment (Department for the Environment, Food and Rural Affairs – DEFRA) in 2006 provides with nuanced, interesting points (SQW Limited 2006). On trade, it writes that "the evidence seems consistently to be that the costs imposed by tighter pollution regulation are not a major determinant of trade patterns even for those sectors most likely to be affected by such regulation. However, there is some evidence that regulatory stringency may exercise an influence once account has been taken of the factor intensity of the different industries and the relative factor abundance of countries. Thus, for a country in which a specific production factor is relatively scarce and an industry intensively uses this factor, then even a modestly stringent environmental regulation will induce a decline in exports" (p. iii). At the firm-specific level, the report finds that "there is a modest productivity penalty in the short term associated with increased stringency of regulation. But, they also provide evidence of a countervailing innovation push over the longer term – especially in larger firms with a track record of innovation" (*ibid.,* p. iii). In macro-economic terms, the conclusion is that "regulations are unlikely to increase competitiveness (…) and may adversely affect it" but "the adverse effect can, to varying degrees, be offset" – through tax incentives, multilateral agreements with "competing nations and regions" or (more interestingly for our research) by ensuring that "businesses are made aware of the regulations" and prompting "them (through advisory and grant support) to invest in improved operating practices" (*ibid.* p. ii).

A more recent research paper supports further the same views (Dechezleprêtre and Sato, 2014). The paper states that "environmental regulations can reduce employment and productivity by small amounts, in particular in pollution- and energy-intensive sectors, at least during the transitory period when the economy moves away from polluting activities and towards cleaner production processes. Job effects are more likely to occur within countries, where relocation barriers are low, than across borders" and that "over the longer run, when macroeconomic adjustments, geographical and sectoral reallocation are factored in, job effects are even smaller than in the short run" (p. 3). The authors add that " There is little evidence to suggest that strengthening environmental regulations deteriorates international competitiveness. The effect of current environmental regulations on where trade and investment take place has been shown to be negligible compared to other factors such as market conditions and the quality of the local workforce. However, the impact could increase in the future if efforts to control pollution diverge significantly across countries" (*ibid.*). The authors go on to add that "benefits of environmental regulations often vastly outweigh the costs".

A last research paper is worth quoting on the economic impact of environmental rules. In this paper (Bivens 2012), the author argues that "when significant economic slack persists even when the interest rates controlled by the Federal Reserve are held at zero, the overall effect of cost-raising regulatory changes is almost surely expansionary" (p. 2). In other words this suggests that (at least from a macro-economic modelling perspective), when the economy is in recession (producing below its output potential), i.e. suffering from a lack of demand, raising regulatory demands can act as a kind of "stimulus", because the need to invest in order to comply with the new rules would generate a form of additional demand. Since the economy is not capacity-constrained in such a setting, but demand-constrained, the new rules can have a positive economic impact (rather than a slight negative). As a result, "the effects of some specific regulatory changes (…) are

surely positive for job creation". This is in line with what has been called the "Porter hypothesis", formulated by Michael Porter and co-authors in a number of important papers (see e.g. Porter and van der Linde 1995, Esty and Porter 2005). Quoting Esty and Porter (2005, p. 425), "our findings suggest that the environment need not be sacrificed on the road to economic progress. Quite to the contrary, the countries that have the most aggressive environmental policy regimes also seem to be the most competitive and economically successful. Moreover, we find preliminary evidence that countries that adopt a stringent environmental regime relative to their income may speed up economic growth rather than retard it."

Making sense of apparent contradictions

This short "review of reviews" leaves us with what can be a counter-intuitive result for many: regulations (in this case, environmental, but there is reason to think that the same mechanisms may apply to many other types of regulation) seem to have at worst a very limited impact on competitiveness, trade and macro-economic results – and may even have in some circumstances (persistent economic slump) a positive impact on jobs and for some firms (and with the right type of context, support etc.) a positive impact on adoption of latest technologies and thus competitiveness. It may seem somewhat conflicting with the previous findings, which suggested that regulatory reform (product-market regulations mostly) would have a positive impact on growth and competitiveness.

The solutions to this apparent puzzle may lie in at least three directions: differences in the nature of industries affected, flaws in studies and data and a difference between the "level of regulation" overall (i.e. the substantive requirements embodied in the rules) and the specifics of regulation i.e. how it is worded, which instruments are used to implement it, and how control and enforcement are handled (and support provided, or not). The second and third point, in particular, are highly significant for our research.

First, for some industries, the cost of compliance may be far higher than for others – and/or international competitive pressures may be higher. As Jaffe, Peterson, Portney and Stavins (1995) put it "for all but the most heavily regulated industries, the cost of complying with federal environmental regulation is a relatively small fraction of total cost of production" (p. 158) – but this means that for *some* industries the effects may be far stronger. The same authors add that "although U.S. environmental laws and regulations are generally the most stringent in the world[308], the difference between U.S. requirements and those in other western industrial democracies is not great" – and that "even where there are substantial differences" in environmental requirements, U.S. and multinational firms "are reluctant to build less-than-state-of-the-art plants in foreign countries", at least after the Bhopal disaster. They further contend that "even in developing countries where environmental standards (and certainly enforcement capabilities) are relatively weak, plants built by indigenous firms typically embody more pollution control (…) than is required" (*ibid.*). These last points raise several concerns, since it is far from clear that these different points are all true across the globe now, if they ever were. Certainly, the major changes in the global economy in the past couple decades, and in particular the relocation of a substantial part of manufacturing activities to China and other countries combined with persistant reports of "less-than-optimal" compliance with a number of safety and environmental standards in these countries, suggest that the findings of some studies may not hold true anymore. Given that many reviews of evidence incorporate studies that are years or sometimes decades old, this may weaken their findings.

Second, data limitations are significant, and may explain the variations in findings (and in other words mean that many "findings" are no such things, but rather illusions caused by inadequate data). Quoting once more from Jaffe *et al.* (1995): "in many of the studies, differences in environmental regulation were measured by

[308] This may not always be the case anymore as in a number of cases EU regulations for instance are more stringent.

environmental control costs as a percentage of value-added, or some other measure that depends critically on accurate measurement of environmental spending. Even for the United States (…) compliance expenditure data are notoriously unreliable. The problem is even more pronounced in other OECD countries (…) Thus, we may have found little relationship between environmental regulations and competitiveness simply because the data are of poor quality" (p. 158). As we have purported to show on the section on practical data limitations, the quality of much of the data on regulatory issues, compliance burdens etc. is of very poor quality, be it due to the difficulty or unwillingness of respondents to answer correctly, or because of lack of quality control etc. In any case, it seems that we may face another case of the tendency of many studies to draw major conclusions from calculations based on faulty data. Looking at the broader picture of both quantitative and qualitative findings, and at longer time periods, international comparisons of "growth trajectories" etc. may thus be the best we can do at this stage to compensate for these data problems.

Finally, and this is the most significant for this research, the (apparent) contradictions in findings may be to a significant extent due to the lack of attention of most studies to the major distinction between the underlying technical requirements (what businesses are supposed to achieve, substantially) and the procedures, processes and regulatory instruments associated with these requirements (what permits and licenses have to be obtained, through which processes, how controls are conducted, what avenues exist for redress etc.). Quoting Jaffe *et al.* (1995) one last time: "only two of the studies we reviewed controlled for differences in "regulatory climate" between jurisdictions. If the delays and litigation surrounding regulation are the greatest impediments (…) these effects will not be picked up by studies that look exclusively at (…) standards or (…) spending" (p. 158). The DEFRA study (SQW Limited 2006) likewise noted "that there is not a great deal by way of empirical work on the different forms that regulation can take and the effects of their form of implementation on firm behaviour" (p. 41). Further, it adds that "Regulation design, stringency and efficiency can influence the relationship between environmental regulation and competitiveness. Stringency may well be less important than the design of regulation itself" (p. 46-47). The same study also suggests that "awareness" of regulations may play a role in mitigating possible adverse effects (p. 37), but does not go in any further details.

What these points all suggest is that existing studies may have focused far too much on either the underlying requirements themselves ("standards"), regardless of their enforcement context, or on the estimated costs (with the associated problems in data quality). It may thus well be that researchers have been ignoring one major direction of inquiry: how regulations are "delivered", and what effects this has – and in particular, what role inspection methods play in this. We will see in the next section that such attention to regulatory instruments appears to be very fruitful in the case of licensing.

The specific effects of regulatory instruments – the example of licensing

Looking at the effects of "regulation" *in general* is, in our view, inherently problematic, since it assumes that the ways in which regulations are implemented are largely indifferent (and it also assumes, more or less, that regulation *is indeed implemented* – which can be a heroic assumption indeed). Rather, there is evidence that *specific regulatory instruments* can have different effects, both positive and negative – but there is still only limited research on this, and on the comparative costs and benefits of different instruments.

From an economic perspective, the most significant research has been conducted on licensing, mainly by Morris Kleiner[309] and under his direction – and this research has recently gained a higher public profile, and

[309] See in particular Kleiner and Kudrle 2000, Kleiner 2006, Kleiner and Krueger 2010, Bryson and Kleiner 2010, Kleiner and Krueger 2013.

been taken up and summarized in a report of the US Council of Economic Advisers[310]. This research is primarily done from an economic perspective, and considers what the costs of licensing are in terms of employment effects, and its effects in terms of increased health, safety etc. Kleiner *et al.* look at what is called in the US "occupational licensing", i.e. the licensing of professional occupations (generally licenses given to individuals), and not to the entire range of license types – of buildings, economic operators[311] etc. Kleiner *et al.* do not question the scope of licensing by looking at the actual level of risks (even though this is one possible approach), but rather use economic models to capture the comparative effects of licensing and other, "milder" regulatory instruments, such as certification of practitioners (which is similar to licensing, but voluntary – i.e. consumers can choose between certified and non-certified practitioners), or registration (which is a significantly weaker instrument, only resulting in a catalogue of practitioners, but not necessarily indicating competence).

To compare these, Kleiner *et al.* look at (a) comparable types of activities, some of which are licensed, and the others not, in the same jurisdiction – (b) identical activities in different jurisdictions, some of which require a license, and others not – (c) identical activities in the same jurisdictions before and after a change in legislation which altered the licensing regime. The studies then compare different outcomes that can be linked to licensing (or its alternatives): effectiveness in terms of achieving social welfare goals on the one hand, and employment and income effects. If licensing is seen to produce significantly better outcomes, e.g. better dental health where dentists are licensed (or where licensing requirements are more strict), it may balance the costs that it imposes. Conversely, if the economic effects (reduced employment, higher "rent" for licensed professions) are very significant, and the benefits marginal, this may lead to questioning the appropriateness of licensing.

The potential (and purported) positive effects of licensing stem both from its direct "screening" effect (expected to improve quality, health and safety) and from its market information effects (increasing consumer trust and thus potentially increasing consumer demand for specific goods and services where it may otherwise remain low because of information asymmetry)[312]. The two aspects are complementary. The former (safety) that is generally put forward as the main justification for introducing (or tightening) licensing requirements.

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[310] See Department of Treasury, Council of Economic Advisers and Department of Labor (2015), available at: https://www.whitehouse.gov/sites/default/files/docs/licensing_report_final_nonembargo.pdf.

[311] "Licenses" or "permits" (two terms which come from different latin words both meaning that something is allowed) are regulatory instruments that are used for a number of issues, in many different ways and for a variety of purposes. One can at least distinguish licenses applying to buildings, premises and equipment (construction permits, licenses/permits for specific machinery, facilities etc.), licenses applying to operators (banking, tourism, television, mobile phone operators etc.), and licenses applying to individuals (doctors, hairdressers, taxis etc.). Licenses may be open-ended or time-limited, they may be issued in unlimited numbers or submitted to a *numerus clausus*, they may or may not require a number of documents, qualifications, fees etc. Their goals may combine safety and protection against risks with economic objectives (managing scarce resources), etc. Finally, some forms of entry regulation can be understood by some (e.g. Kleiner) as equivalent to licensing, even though no actual license is issued. This is the case of what many EU countries call "regulated professions", whereby the exercise of some professions does *not* require a specific license to be issued *but* requires some qualifications including e.g. a state-sanctioned diploma, a certain number of years of exercise etc. For clarity, we would advocate to distinguish such regulated professions from licensed occupations – both are restrictive regulatory instruments, but somewhat different. The same goes for self-regulated professions, e.g. doctors or lawyers in a number of EU countries, which are not officially called "licensed", even though the effect is similar.

[312] Kleiner 2006: "existence of licenses may minimize consumer uncertainty over the quality of the licensed service and increase the overall demand for the service" (p. 1). Department of Treasury, Council of Economic Advisers and Department of Labor 2015: "Even when health and safety are not an issue, increasing consumer information through regulation can be beneficial. If consumers are unable to distinguish between high- and low-quality providers before purchasing a good or receiving a service, low-quality providers can remain in the market without being recognized as such, reducing the average quality in the market and reducing the incentives for other providers to invest in quality improvements.12 Furthermore, if consumers are sufficiently concerned about getting a low-quality provider, then informational uncertainty may depress demand for goods and services. Consumers who would otherwise purchase a product if they knew it were high-quality might forgo their purchase if the quality were uncertain. Licensing is one possible way to address these problems through forcing providers to meet certain quality benchmarks, and creating greater incentives to invest in increased training and skill development" (p. 11).

Arguments in favour of licensing invariably put forward risks and safety justifications – licenses being supposedly necessary to avoid a number of catastrophes (see Kleiner 2006 p. 1). In the original emergence and spread of the licensing system in the US, consumer demand for information on the quality (safety) of service for critical professions appears to have played an important role (*ibid.*, pp. 22-23). However, the resulting "licensing map" does not necessarily suggest a strong match between licensing requirements and hazards: to take a typical example, a taxi driver needs one, but not the manager of a chemical plant, even though the latter most likely has a stronger potential "risk level". Consumer information and addressing information asymmetries may appear to be a better match with actual licensing practices (a company has time and means to screen applicants when hiring a manager, not so with someone hailing a cab on the street, or with a patient urgently looking for a doctor). Remains to be seen whether the beneficial effects of licensing are actually observed *in practice.*

Kleiner, in 2006, used one example of licensed occupation that, with hindsight, shows perfectly the limitations of licensing's effectiveness as a regulatory instrument. Quoting work by Wheelan on occupational licensing in Illinois, Kleiner pointed out, as a good example of "capture" of licensing, the parallel rise in the secondary mortgage market and increasing level of regulation on mortgage brokers (*ibid.*, pp. 46-47). Given what we have seen in the meantime, it is clear (with hindsight) that mortgage brokers licensing did essentially nothing to ensure the adherence to strict standards of practices. A more systematic look at the evidence likewise suggests that regulatory capture is a stronger predictor of actual licensing patterns than public interest.

Quoting the Department of Treasury, Council of Economic Advisers and Department of Labor's report, "with the caveats that the literature focuses on specific examples and that quality is difficult to measure, most research does not find that licensing improves quality or public health and safety" (Department of Treasury, Council of Economic Advisers and Department of Labor 2015 p. 13). Similarly, Kleiner (2006) had already found that "the analysis of studies of licensed occupations finds that the impact of regulation on the quality of service received by consumers is murky, with most of the studies showing no effects on average consumer well-being relative to little or no regulation" (Kleiner 2006 p. 63). Crucially, in spite of being (as acknowledged by the Department of Treasury, Council of Economic Advisers and Department of Labor's report) fragmentary and partial, studies have focused in a number of cases on examples where strong public safety and health effects were claimed (e.g. dentistry), and found them to be at most very limited, and often wholly lacking. Economic impacts, however, tend to be strong – and to support a "capture" view of licensing, with economic welfare for the whole of the population (or country) decreased, but rents for the licensed professionals increased. Indeed, "there is compelling evidence that licensing raises prices for consumers" (Department of Treasury, Council of Economic Advisers and Department of Labor 2015, p. 14) – and "monopoly power [of licensed occupations] may reallocate income from lower-income customers to higher-income practitioners" (Kleiner 2006 p. 59), meaning that licensing has in many cases a negative distributional impact (increasing inequality). In addition to price and income distribution effects, "licensing affects who takes what job. If licensing places too many restrictions on this allocation of workers, it can reduce the overall efficiency of the labor market. When workers cannot enter jobs that make the best use of their skills, this hampers growth and may even lessen innovation" (Department of Treasury, Council of Economic Advisers and Department of Labor 2015, p. 12). Considering the evidence on employment effects, Kleiner (2006) finds that "within an occupation, the employment growth rate is approximately 20 percent higher in states that do not require licensing, but impacts differ widely based on the methods and occupations" (p. 149). On balance, there appears to be a substantial redistribution effect from the general population to the licensed occupations (estimated by Kleiner at $116-139 billion – *ibid.*) and significant lost output due to misallocation of resources (estimated at $34.8-41.7 billion – *ibid.*).

Thus, while licensing appears to have at best limited positive impacts on public safety and market trust, it has clearly demonstrated negative impacts on income distribution and on resource allocation. What is important

is that these are not effects of what is too often, and indiscriminately, called "regulation" – but of *a specific type of regulatory instrument*. The choice of regulatory instruments, and of their characteristics, is thus important, independently of the content of substantive regulations that economic operators have to abide by in terms of practices, safety etc. Interestingly, the Department of Treasury, Council of Economic Advisers and Department of Labor 2015 report contrasts licensing with inspections – noting that licensing board tend to conduct only limited oversight of the license holders after issuance, but that inspections can constitute an effective (and possibly less burdensome and economically harmful) regulatory instrument in place of licensing (pp. 43-44). This is an argument that, as a reform practitioner, we have seen discussed in a large number of countries, e.g. in Greece and Ukraine in recent years[313]. While having merit at first glance (periodic inspections are more likely to help in verifying and supporting sustained compliance than a licensing check administered before start up, and with permanent validity), this leaves aside the question of whether inspections are really effective, and how to make them more so. This shows once again the importance of conducting more research on the specifics of regulatory instruments, and not only on "regulation" considered as an indistinct block.

Regulations, inspections and corruption

In developing countries and emerging markets in particular, but also in high-income economies, regulations can, in a number of instances, be associated with corruption. Inspections, being one of the main points of contact between regulators and regulated businesses, are often associated with corruption in regulatory dealings. While we cannot do justice do this important topic within this research, of which it is not the focus, we will attempt to indicate a few of the ways in which the link with corruption makes the improvement of inspection practices particularly relevant. First, however, let us give a somewhat more precise meaning to the highly loaded and polysemic term of "corruption".

In its broadest sense, corruption can be understood as any way in which the regulatory, legal or administrative process is made to serve a purpose that is fully different from its stated aims, and to function in a way that is in contradiction with its official rules. In a somewhat narrower meaning, which is the one of interest here (and the most commonly accepted one), corruption is when a process or rule is subverted in order to serve specific private interests, for private gain (financial mostly, but possibly political etc.). Money does not always need to change hands, and corruption in inspections certainly does not always mean that bribes are given during the inspection visit. Corrupt behaviours can involve gifts, employment, expectations of future "tit for tat", or any variety of favours, from the business side. From the regulator's side, they can involve turning a blind eye on violation, interpreting rules leniently, harassing competitors, or simply doing one's job normally (in cases where regulators abuse their powers systematically against those that refuse to "pay up" or "play the game")[314].

Regulations and regulatory processes are not the only *locus* of corruption, of course, and poorly structured rules and institutions are definitely not the only (or the main) cause of corrupt behaviours. They are, however, one of the most important areas of corruption (along with police interactions), because both of the large number of rules and regulatory instruments, and because they affect economic activity, and thus present strong opportunities for rent-seeking behaviours (both for regulators and regulated entities). Corruption in inspections generally presents important differences with, for instance, corruption in rule-making. The latter

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[313] There is a lot of evidence that the problem of the right use and design of licensing, and more broadly of regulatory instruments, is essential to developing countries and emerging markets. There is rather little academic literature on this topic, and not always recent (see e.g. Ogus and Zhang 2005, Zhang 2009). Practical reform work done by the World Bank Group has highlighted repeatedly the importance of the topic, but literature produced is mostly focused on "how to reform" rather than on an analysis of the *pro* and *contra*. See nonetheless World Bank Group 2006 and

[314] See Ogus (2004), *Introduction* and section *Definition and Typology of Corruption*, for a discussion of the different meanings and types of "corruption".

usually involves high-level capture by major firms, aimed at keeping competition out and/or building captive markets, and (at least in middle- and high-income countries) is likely to involve more "revolving door" offers for officials than outright bribes. Inspections, by contrast, offer opportunities for "decentralized" corruption, involving front-line inspectors, small and medium firms, a variety of "gifts" and favours. In some countries, corruption is essentially the default setting: inspectors go from firm to firm, bribes or gifts are expected, and in their absence enforcement will be ruthless, if needed "making up" violations where there are none.

Unfortunately, the topic is notoriously difficult to investigate, since reliable data on corruption is, nearly by definition, hard to come by. Survey data, for instance, can be very misleading in countries where businesses have reasons to believe that being open about corrupt behaviours could end up creating problems for them (which means the majority of countries). That said, some evidence exists, as gathered for instance in successive surveys by the International Finance Corporation in post-Soviet countries[315]. Even though inspections-related corruption, much as petty corruption more generally, is primarily a problem for developing countries, some high-profile scandals should warn against complacency in high-income, developed countries – for instance the crane inspections scandal in New York City[316]. It is also worth remembering that corruption can manifest itself in misuse of administrative power not for private gain, but for the "profit" of the institutions themselves, as has been abundantly demonstrated in recent years in the United States by the accumulation of fines intended not to deter crime but to fill municipal coffers, and by the abuse of the "civil forfeiture" programs to the "quasi private" benefit of local police departments[317].

Clearly, corruption is linked to a multiplicity of factors: prevailing cultural norms, income levels and distribution patterns, strength or weakness of institutions, social structures etc. It remains nonetheless that rules and regulations, as well as regulatory practices, also have their importance in creating or sustaining corrupt behaviours. Simply put, if rules are impossible to comply with because they are obsolete, excessively demanding considering available resources, overly complex and prescriptive, or any combination thereof, corruption will be the way through which the economy manages to somehow function *in spite* of the rules (much as smuggling is the "natural" consequences of duties that exceed an "economically optimal" level, and smuggling thus rises when duties go over a certain point). Similarly, procedures that are excessively long, opaque, burdensome, and leave too much unchecked, arbitrary power to regulatory officials will tend to lead to abuses of power and corruption, with regulators tempted by rent-seeking, and businesses seeing it as the easier (or the only) way out[318].

Little research exists at this stage on corruption specifically in the context of inspections and enforcement, and as we pointed out already data is often unreliable and makes this a difficult topic to investigate with precision. There is, nonetheless, a body of work on regulation and corruption, that shows the relevance of the issue. Djankov *et al.* (2001) have shown, in particular, how excessive business entry regulation, disconnected from a clear purpose in terms of social welfare, can result in increased corruption and serious economic harm. They write that "in principle, the collection of bribes in exchange for release from regulation can be efficient [from

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[315] See successive surveys from 2003 onwards in Tajikistan, Ukraine, Kyrgyzstan in particular.

[316] See the official account of this scandal by the City of New York's Department of Investigation available at http://www.nyc.gov/html/doi/html/about/cases_bribery.shtml - and newspaper articles e.g. in the New York Times: http://www.nytimes.com/2008/06/07/nyregion/07crane.html?pagewanted=all&_r=0 and a recent article covering a broader scandal in construction-related inspections http://www.nytimes.com/aponline/2015/02/10/us/ap-us-bribery-investigation.html.

[317] See e.g. the following posts and articles: http://marginalrevolution.com/marginalrevolution/2014/08/ferguson-and-the-debtors-prison.html on the excessive use of fines as a budget funding mechanism – as well as the following: http://www.latimes.com/business/hiltzik/la-fi-mh-the-ferguson-crisis-20140821-column.html https://www.themarshallproject.org/2015/04/29/david-simon-on-baltimore-s-anguish http://www.governing.com/topics/public-justice-safety/gov-ferguson-missouri-court-fines-budget.html and on "civil asset forfeiture" and its abuse: http://www.vox.com/2014/10/14/6969335/civil-asset-forfeiture-what-is-how-work-equitable-sharing-police-seizure.

[318] See Ogus (2004), section *The Benefits of Corruption* for a discussion of some of the ways in which corruption enables inadequately (in particular: excessively) regulated economies to function nonetheless.

an economic perspective]" but "in practice, however, the creation of rents for the bureaucrats and politicians through regulation is often inefficient, in part because the regulators are disorganized, and in part because the policies they pursue to increase the rents from corruption are distortionary" (p. 3). Indeed, looking at a "cross-section of countries" they "do not find that stricter regulation of entry is associated with higher quality products, better pollution records or health outcomes, or keener competition. But stricter regulation of entry is associated with sharply higher levels of corruption, and a greater relative size of the unofficial economy" (p. 4). Overall, the research data shows that "better governments regulate entry less" and that "entry is regulated because doing so benefits the regulators" (p. 5). Djankov *et al.* further conclude that "the regulation of entry produces the double benefit of corruption revenues and reduced competition for the incumbent businesses already affiliated with the politicians" (p. 20) and that "entry is regulated more heavily by less democratic governments, and such regulation does not yield visible social benefits. The principal beneficiaries appear to be the politicians and bureaucrats themselves" (p. 27). In addition, in another paper (2006), Djankov *et al.* find that "results indicate that government regulation of business is an important determinant of growth and a promising area for future research. The relationship between more business-friendly regulations and higher growth rates is consistently significant in various specifications of standard growth models" (p. 4). Thus, abuse of business entry regulations appears to result in increased corruption, no visible social benefits, and reduced growth[319].

Even though business entry regulations are clearly not the focus of our research, these results can serve as a useful proxy for the relevance of investigations of how regulatory inspections are organized and conducted. Indeed, entry regulations, much like inspections, are primarily *procedures*, more than substantive regulations. What Djankov *et al.* have shown is that regulatory instruments, when excessively burdensome and indiscriminate, can have serious negative consequences on both the rule of law and economic growth. Similarly, abusive inspections can be expected to also lead to important negative results. In fact, investigating regulatory practices, and inspections and enforcement in particular, *in more details* can be expected to be particularly beneficial in terms of improving growth strategies. As Rodrik (2003) puts it (summarizing research by Kaufmann, Mastruzzi and Zavaleta), high-level reforms are often not enough, as shown in the case of Bolivia, where "the authors identify petty corruption, uncertain property rights, and inadequate courts as the source of problems". He emphasizes the need to "unpack "institutional quality" and show how aggregate indices or country averages can be misleading" (p. 14).

Preliminary conclusion

Concluding on the relevance of regulations, regulatory reform, and specifically of the improvement of regulatory instruments such as inspections to the complex issues of economic growth, social welfare and the rule of law is, to say the least, difficult. On the one hand, clearly, regulation and regulatory instruments are only one factor among many, and their short- and medium-term effects, at least, often pale in comparison with more immediate drivers (e.g. macro-economic policy). On the other hand, however, there is a converging body of research and evidence that points to their significance for long-term growth prospects, and to the harmful effects of "bad" (excessive, non-targeted, prone to arbitrary etc.) regulation. The limitations of data, as well as the complexity of the phenomena considered, means that absolute conclusions may be out of reach – but there seems to be enough ground to consider that making inspections work more effectively, efficiently and transparently is a worthwhile undertaking.

Supporting this view is one more angle that we have only alluded to so far, which is the relevance of inspection issues to trade. As we have shown above in the case of the US and the EU in particular, access to major markets

[319] On regulations having negative effects in terms of "barriers to entry", see also the pioneering work of Stigler (1971).

for important products such as food is increasingly subject to an exporting country's inspection systems being audited and found to be adequate (see also World Bank Group 2014 a). In other fields, countries have found themselves under pressure of potential boycotts, loss of trade preferences etc. because of glaring shortcomings in their occupational safety and labour law inspections (e.g. Bangladesh after the Rana Plaza disaster, or Jordan after labour abuses were revealed in the mid-2000s). Increasingly, a well-functioning inspection system is a pre-condition (or an important factor) for a country to avail itself of its trade opportunities. In all these areas, risk-based approaches are touted as an important way forward, making their study of real relevance to public policy

The point is not to come up with a "ready-made", "cookie cutter" approach, but to understand better the details of how inspections work, and with which results. As Rodrik (2003) writes, it is crucial to "go beyond simply asserting that "institutions matter" (…) [and] provide a richer account of where good institutions come from, the shape they take, and how they need to evolve to support long-term growth" (p. 12). Such work can support what has been called (Rodrik quoting Qian) "transitional institutions" (and, we would add, "transitional practices") that can be "more suited to the realities on the ground on both economic efficiency and political feasibility grounds" (*ibid*., p. 13).

The challenge, however, is to move from this recognition that "institutions matter" and that what matters are the details of how these institutions function, and with which effects. In this research, and particularly in the section covering practical cases, we will be attempting to look into the details of practices – but assessing the impact of these different practices is more difficult. As the brief selection of cases presented above shows, assessing the full economic impact of specific sets of regulations is a very difficult undertaking (assuming that it is even possible), and would require essentially an *ad hoc* study for each case, which would go far beyond the scope of this research. As a result, the only viable option for us was to select some *proxy indicators* for the economic impact of specific inspections and enforcement systems and practices.

As we have outlined above, the economic impact of regulation includes, crucially, *trust* (cf. Voermans, forthcoming, and the discussion e.g. of the history of food inspections). Unfortunately, quantifying the level of trust and its evolution would require specific surveys of market actors, that are not generally available. In order to look at the evolution of trust levels, a follow-up research would be required, looking for existing surveys and other data to try and construct indicators that can be compared over time and across jurisdictions. We were not able to attempt this within this research, but rather limited ourselves to anecdotal evidence suggesting higher or lower degrees of trust between jurisdictions, which we will consider in the overall conclusion. While this will obviously be inadequate to draw any strong conclusions, this may enable us to point towards directions for further research, and also have some preliminary indications of whether risk-based approaches appear adequate to provide the required level of trust.

Another side of the economic impact of regulation is (Djankov 2001, Kleiner 2006 etc.) more negative: barriers that limit market entry and reduce competition, procedures that give rise to corruption in various forms, costs that reduce profitability and productive investment etc. Many of these effects are, once again, difficult to measure – even though they may be the most significant. This is the case for instance of effects on competition, market entry, jobs etc. that were researched e.g. by Kleiner (2006). Direct administrative costs, by contrast, are relatively easy to capture. They are a key part of all Regulatory Impact Assessment (RIA) models that have been introduced since the late 1970s and have gained increasing acceptance since the late 1990s (cf. Blanc *et al.* 2015 pp. 48-49, OECD 1997, Radaelli 2007). One of the most widespread methods to measure direct administrative burden from specific regulatory procedures is what is called the "Standard Cost Model" (SCM), which is used in a number of countries (in the OECD and EU, but also developing countries), by

the EU itself, as well as by international organizations such as the OECD or the World Bank Group[320]. The SCM approach has been applied to inspections in various ways – either by relying on very detailed time measurements but a limited set of respondents (e.g. the "domain-focused" inspections burden measurement conducted in the Netherlands in 2007-2010)[321], or covering a larger (representative) sample of respondents but with far less detailed measurements (e.g. the calculations based on business surveys conducted by the World Bank Group e.g. in Kyrgyzstan, Tajikistan, Ukraine, Mongolia in the past decade)[322].

Unfortunately, administrative burden measurements are not an optimal measure. In many cases, they may count as a "burden" an inspection visit which, if conducted in a way that is transparent and focuses on compliance support, may in fact be experienced as a net positive by the business. In other cases, it may be that inspections appear to create relatively low burden in terms of what the SCM measures (primarily lost work time), but in fact create major barriers to business development through uncertainty, corruption etc. Administrative burden measurements, even though very frequently conducted, are clearly not measuring what matters most – and governments touting their success at decreasing burden sometimes miss the issues that most limit business developments. They are, however, far easier to conduct than other measurements, and are relatively frequently available.

In conducting this research, we have chosen to settle on an indicator that is simpler than aggregate administrative burden (as estimated through SCM calculations), but that in our experience is more reliable than an SCM based on a small sample[323], and can be an acceptable proxy for many other aspects of inspections: the overall number of inspections per business (combining both coverage – the percentage of businesses inspected in a given year – and frequency – the number of visits per inspected business). First, a high number of inspections is a very strong component of administrative burdens. It is very rare to have a country where very frequent inspections do *not* result in high burden – it would require extremely short inspection visits and, even in such cases, the aggregate burden remains significant[324]. Second, a high number of inspections is often indicative of an approach that relies primarily or exclusively on deterrence, and not on compliance promotion, and thus of inspection visits that are indeed perceived generally as a burden by businesses. Clearly, this indicator is not sufficient to indicate proof of negative economic impact, but there is sufficient evidence to suggest that it is generally an acceptable proxy for it[325]. We hope that, based on the preliminary findings of this research, there will be sufficient indications of the relevance of further research to support additional work, that would consider more closely the question of economic impact – being mindful of the fact that,

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[320] See International working group on Administrative Burdens (2004) and Lundkvist (2010) as well as SCM Network (undated).

[321] These studies were not compiled in one general report, nor is there a general page presenting them. There were both baseline measurements and post-reform measurements. Some of the reports can be found at the following links: https://www.ilent.nl/Images/Eindrapportage%20Nulmeting%20toezichtlast%20vervoer%20over%20water_tcm334-318315.pdf https://www.nvwa.nl/onderwerpen/inspectieresultaten/bestand/26422/ https://www.ilent.nl/Images/0000%20Eindrapport%200-meting%20toezichtlasten%20domein%20overige%20chemie_tcm334-320054.pdf https://www.rijksoverheid.nl/binaries/rijksoverheid/documenten/rapporten/2010/04/22/eindrapportage-regeldruk-bedrijven-april-2010/voortgangsrapportage-april2010.pdf . All reports include the methodology.

[322] See section 4.1.b for a presentation of these surveys. Reports see e.g. World Bank Group 2009 (Mongolia), World Bank Group 2012 (Kyrgyzstan). Both reports include methodology and calculations.

[323] As inspections are not a universal procedure that every business has to go through, but rather can affect some businesses and not others. See e.g. Blanc (2009) on the limitations of SCM exercises for inspections when relying on a very small sample, and see 4.1.c for an illustration of how inspections can be concentrated on a limited sub-set of enterprises, meaning that having an unrepresentative sample could bias the results very strongly (example of Italy).

[324] This was the case e.g. in Kenya, where a 2010 survey conducted by the World Bank Group that around 90% of businesses were inspected each year, on average more than 5 times a year. The visits were mostly very short, so a strict SCM-type burden measurement would have given relatively low figures (though not *very* low) – but the burden was quite high in fact, because many visits were associated with corruption or harassment (report unpublished).

[325] See also LBRO (2010) for business perspectives showing both that inspection visits, when done in a supportive way, can be seen as more positive than burdensome, but also that very frequent visits are seen as a problem, and indicative of a poor business climate.

given the complexity of the phenomena observed and the interactions, full certainty of effects may not be achievable.

3.2. Promoting compliance: models, drivers, methods and issues

a. Models of compliance – deterrence, cooperation, responsive regulation – and beyond

i. A brief overview of compliance models

Introduction – the limits of compliance

Attempting to improve the effectiveness of regulation in achieving its intended effects, understanding the role of inspections and enforcement in this perspective, as well as the relative merits of different inspection approaches, all require to understand the links between rules and compliance, and the drivers that push people to comply. Of course, understanding and analysing compliance is not the same as explaining how outcomes in terms of public welfare are achieved, for there is not necessarily a direct link from compliance to public welfare (and there are in fact many situations where even perfect compliance will be insufficient to achieve the regulation's stated goals). We have discussed briefly above the question of the optimal precision of rules, which appears to be an impossible quest: only "target" technical norms would seem to give the "certainty" that what is required from the business corresponds to the intent of the regulation, and compliance *ipso facto* is equivalent to the desired result – but these norms leave business in complete uncertainty as to *how to* reach the desired result, and usually put inspectors in a difficult situation too, because of time-lags, third party effects etc. Given that *in practice* the vast majority of technical norms are "performance" or "specification", or a combination thereof, there is generally an imperfect match between compliance and intended regulatory outcomes. This mismatch is highest when regulation was inadequately drafted (because of haste or incomplete knowledge), and tends to increase as technological changes accelerate, or when third party effects increase (for whichever reason). This partial disconnect between compliance and outcomes (safety, public welfare etc.) is consequential for inspections, and one of the reasons some advocate for risk-based inspectors' discretion to be able to respond with more flexibility to the situation as it develops[326] – which, in turn, raises concerns from a rule-of-law perspective.

In fact, it has been demonstrated that even "target" rules are not immune to being "gamed", and emptied of their meaning – because it is impossible for rules to "target" everything that would be meaningful (not to mention the problems inherent in data collection). Bevan and Hood (2006) have thus shown how the "governance by targets and measured performance indicators" introduced by Tony Blair's "New Labour" government in Britain in the 2000s did not necessarily produce the expected results. Reported performance data appeared to show "notable improvements in reported performance by the English NHS" (National Health Service). In practice, however, there is substantial evidence that the system was gamed and that improvements were often "offset (…) [by] reductions in performance that was not captured by targets". While the authors rightly point out that none of the alternatives to this target system is "problems-free", their work

[326] See e.g. WRR 2013 (*op.cit.*)

clearly shows that we cannot expect that achieving targets automatically equates achieving the regulatory goals[327].

No form of rules appears to be immune to some form of gaming or evasion, e.g. through "creative compliance" that "uses formalism to avoid legal control" (McBarnet and Whelan, 1991). Indeed, "the combination of specific rules and an emphasis on legal form and literalism can be used artificially, in a manipulative way to circumvent or undermine the purpose of the regulation". We would add that, in our experience, such formalism that defeats the true intent of the regulation can just as easily be wielded by abusive officials (be they motivated by corrupt rent-seeking, or "simply" the enjoyment of arbitrary power) as by evading businesses. The proportion of creative compliance versus enforcement power abuse will depend on the characteristics of the country and of the regulatory interactions, but both are inherently possible in a system of rules, and quite difficult to fully avoid.

Going "beyond compliance" thus seems to be necessary in order to really achieve the full purpose of public policies, the full intended effects in terms of public welfare. Gunningham, Kagan and Thornton (2003) have devoted a large part of their research on the different degrees of "greening" of polluting industries to precisely this question of what could drive businesses to *exceed* regulatory requirements and engage on more significant and comprehensive pollution-abatement. At the same time, the authors point out why, in spite of its obvious limitations, so many still look to regulation (and enforcement) as the foundation for improvements (in the environmental field and elsewhere): "until the past decade or so, politicians, environmentalists, and scholars, observing the ongoing degradation of the environment in industrial societies, understandably assumed that the opportunities for such "win-win" investments were few and far between (…) and hence it has been assumed that legal coercion is necessary" (p. 21).

Indeed, even though rules cannot be designed "perfectly", and thus compliance with rules cannot fully ensure that regulatory goals are reached, rules and compliance still appear as a necessary foundation – necessary, though not sufficient. There remains a significant degree of causality between compliance and safety or other public welfare goals (as long as regulations are at least somewhat competently drafted and up-to-date), and in practice the shortcomings of the different types of rules will be somewhat alleviated by combining them ("specification", "performance", "targets" – as well as systems-based "to ensure genuine and long-term (…) improvements" – Tilindyte 2012 p. 17). This all matters to us because the primary purpose of regulatory inspections is, precisely, to *increase compliance*[328]. Of course, for inspections to be effective at this task, the drafting of the rules definitely matters[329] – but so do a number of other factors that we will now discuss.

Models of compliance - foundations

[327] Of course, the targets-based management of public health service provides that the authors study, while it is in some ways a form of "regulation", is quite distinct from the types of regulation we focus on in this research. What is relevant from our perspectives is that this shows that even targets-based rules cannot be automatically assumed to deliver the intended substantial outcomes.

[328] Or at least *one of the primary purposes*. There is also, in a different perspective, an "expressive interest of justice" (Hawkins 2002 p. 7), which demands as much as possible detection and punishment of rules violations – and detection requires inspections. The instrumental view of inspections and regulations corresponds to utilitarian values. Different sets of values (e.g. putting fairness and the rule of law first) will put a greater emphasis on the need to *enforce regulations* regardless of whether this is effective at achieving these particular regulations' purposes (cf. Morgan and Yeung 2007 p. 200, Ashworth 2000, Yeung 2004). We will return later to this question of values.

[329] Diver (1983) has proposed a set of "subcategories of potential costs and benefits" of different types of rules: *rate of compliance* (precise rules perform best), *over- and under-inclusiveness*, *costs of rulemaking* and *cost of applying a rule* (again precise rules tend to work better). The details of these criteria show how much depends on implementation, i.e. inspections. Thus, regardless of the type of rules chosen, and as long as they are more or less "fit for purpose", effectiveness will largely depend on the enforcement stage.

Many of the views held on public policy issues are based on assumptions, foundations, that are rarely even perceived, let alone questioned. Academics are not exempt from such "blind spots", with fundamental assumptions often remaining unchallenged for long periods of time. A common view underpinning (consciously or not) public demands for "more inspections", "more checks", "more enforcement" in relation to perceived risks (after an incident or in view of an "emerging risk") is that people comply with rules only if they are under supervision and there is a realistic threat of punishment for violations. This view is held even more widely and strongly in regard to businesses, which are seen by many as purely profit-driven – "amoral calculators". Business operators and owners are thus commonly held to be likely to comply if the costs of non-compliance are high, and punishment close to certain. The specific mistrust of businesses is often associated in the political field with radical left or anti-capitalist views, but the overall belief that people comply only under pressure and supervision is quite frequent in more conservative perspectives, so overall this view of people as reluctant to comply, and of regulation as requiring very strong enforcement to function, is held very widely and across the political spectrum (with different points of emphasis – but a shared foundation). Interestingly, such a perspective is also that of the compliance model proposed in 1968 by Gary Becker –which happens to be the first of the modern compliance models to have been formalized and still remains very influential[330].

This view, anchored in a pessimistic view of human nature (and understandably given credibility by the fact that crime and violations seem to be always recurring, and by human proclivity to estimate probabilities from negative experience and not from statistics – see e.g. Bennear in Balleisen, Bennaer, Krawiec & Wiener, in press), has been further reinforced by successive works attempting to model compliance based on neoclassical economics[331]. In these models, compliance is strictly based on maximisation of expected utility. The costs of compliance are weighed against the potential gains of non-compliance, minus the costs of possible sanctions multiplied by the probability of detection[332]. This model offers a convenient formalisation of the commonly held "pessimistic" view described above. The question is whether this model in fact describes observed behaviour accurately.

Defining this first compliance model is relatively easy – but there are several possible typologies of the other models. Scholz (1994) proposes a tripartition of what he calls "enforcement techniques and strategies" (that each correspond to a vision of what produces compliance): "deterrence strategy", "educational strategy" and "persuasive or cooperative strategy" (p. 425). He notes that the first is the "most familiar and best understood", "based on the assumption that regulated entities are amoral, and will not obey regulations unless given an incentive to do so". On the second, he writes that it "assumes that at least some noncompliance stems from the difficulty certain firms have with understanding regulations and implementing effective internal controls to prevent noncompliance" – an "educational strategy" does not "shy away from coercion" but rather uses it "to focus attention rather than to punish noncompliers", and it acknowledges potential negative side-effects of sanctions ("distracting" from some "recurrent problems", fostering resistance etc.). Finally, the third approach "assumes that firms perceive enforcement agencies as one of several important actors that the firm must deal with over the long haul" and that "firms develop principles to govern their relationships with all actors" (*ibid.*). Thus, while the first approach is squarely grounded in a deterrence model, the second corresponds to a model that introduces (and holds as fundamental) the issues of *understanding of rules* and of *capacity to comply.* The third approach is one that seeks to go beyond

[330] In our view, the influence of Becker's model (in spite of its limitations, which we will discuss below) can be traced both to its congruence with the commonly held "pessimistic" view of compliance, and its alignment with fundamental neo-classical economic assumptions (full rationality of market actors), and thus its being the most frequently taught compliance model in economics faculties.
[331] For instance, in the field of tax compliance, the works of Becker (1968), Allingham and Sandmo (1972) and Srinivasan (1973).
[332] This means that a maximal sanction of 1,000 EUR combined with a detection probability of 10% will result in an expected cost of 100 EUR – if the benefit from non-compliance is higher than 100 EUR, the person or business will choose not to comply.

compliance considerations – it should reduce the "inherent economic inefficiency of the regulations being enforced and the costs of monitoring and prosecution" (p. 441), and most importantly "maximize goal achievement rather than compliance" (p. 442). But the persuasive strategy also corresponds to a compliance model that sees firms as far more complex than the deterrence vision: "the persuasive strategy assumes that desired behavioral changes will only occur if they reflect the self-interest of the firm, just as the deterrence strategy does [but] the primary difference between the two (…) is that persuasive techniques appeal to a broader range of motivations (…), particularly the firm's concerns over its long-term relationships with the agency and other organizations such as unions, suppliers, purchasers, and the general public" (*ibid.*). Through his comments (pp. 425-448), Scholz suggests that all enforcement strategies have strengths and weaknesses, and that combining them has clear advantages but is far from easy because of contradictions between at least some of them (deterrence vs. education). Overall, he appears to be closest to a compliance model corresponding to the "persuasion" strategy – firms as rational actors with relatively complex calculations of costs and benefits, with deterrence being applicable to some situations and education to others, and a well-designed set of complementary strategies being optimal (thus suggesting that both "ignorance and lack of capacity" and "amoral calculations" drivers are relevant, either in the same firms or in different ones).

Another perspective is that put forward by Kagan (1994) of "legal enforcement style" – combining two perspectives, "the way officials assess compliance or noncompliance with regulatory standards" and "what officials do once they have decided that the regulated enterprise's actions constitute violations" (p. 387). Kagan then summarizes the different "styles" in a chart where the "enforcement style" can range from "inactive/unresponsive" to "active/responsive" and from "retreatists" to "legalistic" through "conciliatory" and "flexible" (p. 388). Kagan then attempts to connect these "enforcement styles" to "regulatory outcomes", which themselves can range from "excessively lenient" (ineffective) to "excessively stringent" (effective but with considerable negative side-effects, inefficiencies)[333], through an optimal "welfare-maximizing" range (pp. 388-389). These classifications are primarily based on a vision of intra-agency dynamics (attempting to understand why enforcement styles differ based on a combination of "legal design", "task environment", "political environment" and "agency culture" – pp. 390-391) – and on an economic perspective (looking for economically efficient outcomes, while acknowledging that "it usually is very difficult to determine whether agency enforcement decisions produce" them – p. 389). The underlying model for compliance is one which is based on rational calculations – a somewhat sophisticated vision of deterrence, including economic considerations for the viability of the approach (p. 398), and incorporating the "tit-for-tat", "responsive" approach to deterrence formulated first by Scholz (1984). The foundation remains one where enterprises are to be motivated for compliance through rational calculations, and the reason to not select a "strong" deterrence approach is only overall *public welfare* maximization, not the idea that that strong deterrence could be less-than-fully-effective at maximizing *compliance*.

In their influential work *Responsive Regulation* (1992), Ayres and Braithwaite[334] put forward a preferred model of enforcement as well as a vision of why businesses comply that is significantly different from the "deterrence model" and its variations. The authors formulate the fundamental debate as being "between those who think that corporations will comply with the law only when confronted with tough sanctions and those who believe that gentle persuasion works in securing business compliance" – with "most, although by no means all, regulators (…) in the compliance camp" and "most regulation scholars (…) in the deterrence camp" (p. 20). They add that many academics (of whichever ideological persuasion) "interpret this state of affairs as evidence of how captured the regulators are" (*ibid.*). Instead, they suggest that one can "strike some sort of

[333] The emphasis on deterrence has effects on inspectors' practice that lead to consequences in how they inspect, seeing the inspection more as a "case to be won" than as "problems to be solved", which tends to lead to poor cooperation, and can make actual detection and solving of real hazards less likely – see Bardach and Kagan 1982, pp. 80-81.

[334] Itself building on Scholz (1984), Braithwaite (1985), Braithwaite and Grabosky (1986) etc.

sophisticated balance between the two models", the question becoming "when" to use which approach (p. 21). The motivations for mixing or balancing the two approaches comes, however, from a somewhat different perspective than Scholz's (*cf. supra*) – indeed, while Ayres and Braithwaite also use the game theory perspective as a foundation for "tit-for-tat" enforcement (p. 21 and pp. 60-81), they combine it with a greater attention paid to the "mixed motives" for compliance[335]. Based on empirical work, they propose "alternative motivational accounts" to the vision of "the firm (…) [as] a unitary actor concerned only with maximizing profit" (p. 22). First, corporate executives value "a good reputation" and care "deeply about the adverse publicity", viewing "their personal reputation in the community and their corporate reputation as priceless assets" (*ibid.*)[336]. Second, "corporate actors are not just value maximizers – of profits or of reputation", but also act according to values (ethics, social responsibility etc.). In practice, "there is evidence of economically irrational compliance with the law" (pp. 22-23). The authors are realistic about the strength of values-based motives, and recognize that they will often not be stronger than profit-based motives, but insist on the need to recognized that, in a significant proportion of cases, they are (pp. 23-24). Third, another key aspect that Ayres and Braithwaite emphasize is that "firms are not monolithic" and that "not all of the relevant actors have the same interest in profit maximization as those at the top may have" – there can be, in any organization, "law-abiding constituencies" (p. 33). Overall, they propose a model of compliance that emphasizes *complexity* and *multiplicity*: several drivers, several groups, several motives inside a same person or company. Depending on the business being considered, and on the situation, various combinations may arise, and the resultant profile may be more or less profit-maximizing, more or less ethical – and Ayres and Braithwaite see it as "responsive" enforcement's purpose to reinforce the compliance-maximizing forces and weaken the others, meaning that theirs is also a view of *dynamic* compliance drivers. Crucially, this includes the possibility that some enforcement actions that would make sense from a deterrence perspective would be counter-productive by decreasing intrinsic (values-based) compliance forces[337]

The emphasis on the complexity of factors leading to compliance, and the view of corporations as multiple rather than unitary, are further developed in the work of Gunningham, Kagan and Thornton (2003)[338]. They emphasize the importance of "endogenous" factors within corporations: "more generally, "new institutionalism" theories of organizational behavior reflect findings, as summarized by Mark Suchman and Lauren Edelman, that: 'institutional factors often lead organizations to conform to societal norms even when formal enforcement mechanisms are highly flawed. Frequently cited institutional influences include historical legacies, cultural mores, cognitive scripts, and structural linkages to the professions and to the state'" (pp. 22-23)[339]. More fundamentally, they propose a new, broader concept, instead of a narrow and unilateral causality

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[335] Which, in turn, is also reflected in Scholz's later work (1994), where he includes the complexity of motivations in grounds for the "persuasive strategy".

[336] Though Ayres and Braithwaite do not directly qualify this claim, they also do not suggest that it is universally true. We would add that it clearly is not, the financial crisis that started in 2008 having revealed the depth of inadequate corporate behaviours in the financial sector, and the apparent weakness of the "adverse publicity" driver for many of its executives (though on the other hand the many *op eds* written by banking executives, e.g. in the US, seems to show that adverse publicity is still something that they strongly resent – it may just not be enough to overcome other drivers).

[337] A point also noted by Scholz (1994) when noting that deterrence strategies can contradict education ones.

[338] Itself building on earlier work such as Gunningham and Grabosky 1998, Gunnigham and Johnstone 1999.

[339] A note here is needed: in this book, the authors specifically look not only at what makes firms comply with regulations, but also what makes them go *beyond*, i.e. improve environmental performance above and beyond regulations. That said, many of the factors at play are essentially similar when it comes to complying with or when it comes to *exceeding* mandatory norms. They build a typology of reasons for firms to go *beyond* compliance (p. 24) – it includes "win-win measures" ("sometimes the firm [invests in nonrequired methods] because [they] are more cost-efficient than those required by the rules, and sometimes because they feel it is "good business" to develop co-operative and mutually trusting relationships with regulatory officials" - p. 21), "margin of safety measures" (ensuring that compliance is always guaranteed even when there are variations in production conditions), "anticipatory compliance measures" (avoiding costly upgrades/retrofits when regulations change by building equipment "one or two steps ahead") and "good citizenship measures" (which improve the image of the company e.g. with consumers). To some extent, all these different cases correspond to a broad vision of "profit maximization", based on a far larger consideration that the narrow cost of compliance vs.

of "drivers": "in the course of our field research, we came to regard the concept of "drivers" as somewhat impoverished. It implies the existence of independent, unidirectional, and unambiguous pressures, whether from regulation, communities, or markets, which impact upon corporations with sufficient force that they react to them. Yet we found that these external factors, rather than being independent, often gain their force through mutual interaction; that far from being unambiguous, the responses they demand are often unclear; and hence that they do not operate unidirectionally" (p. 35). By contrast to the over-simplifying notion of "drivers", "the concept of a license to operate (…) captures the complexity of the relationship between the regulated enterprise and key stakeholders in a way that the concept of "drivers" does not" – it "encapsulates the extent to which various stakeholders can bestow or withdraw privileges from a company" and "that business is dependent upon" these stakeholders' relations – it also means that the relationship "is an interactive one" – it includes "the regulatory license, the economic license, and the social license" (p. 36)[340]. Among the different forces at play, the authors find a combination of different dimensions, which correspond to their vision of three different "licenses": "the external pressures that push enterprises toward improved environmental performance can be divided into three broad categories: economic, legal and social" (p. 35). This tri-dimensional vision already represents a considerably higher level of complexity than the narrowly economic one, and a model that appears better suited to a diverse reality.

Other authors have researched and underlined the importance of a fourth category of "driver" or "pressures": psychological factors. As Hodges (2015) puts it: "the science of cognitive and behavioural psychology has undergone revolutionary development in the past few decades" – but, he adds, "the findings have not been noticed by many legal theorists" (p. 2). In fact, both among legal scholars and economists, there is a significant group of authors who have built research and models on the basis of these advances in psychology – but it remains true indeed that the majority of scholars tend to ignore them and to rely on far cruder models and visions of human motivations. By contrast, "psychology posits decision-making that is based on multiple factors other than costs and benefits" (regardless of whether one speaks of monetary benefits, or "immaterial" ones such as reputation etc.) (*ibid.*). One of the most important compliance models based on psychological insights is commonly called *procedural justice*, and has been developed and exposed in particular by Tyler (1988, 1990, 2003 *et al.*)[341]. Importantly, this approach does not negate other insights on economic or social drivers of legal compliance, but rather subsumes them in a more comprehensive vision – while suggesting that "psychological" and "social" factors (ethics, legitimacy, procedural justice) may be stronger than "economic" (deterrence) ones[342].

The compliance model developed by Tyler views legal compliance as driven by a combination of motives: rational calculation (deterrence) being one, along with moral values, social norms, legitimacy and procedural

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probability of detection and potential sanction calculation that is at the core of the "deterrence" model, but still mostly predicated on the same "amoral" logic.

[340] The authors use of the word "license" also corresponds to their studying a population of businesses that is, in fact, subject to precisely this form of regulatory instrument (prior approval). Their study population is made of generally large companies, large facilities, with a very high environmental impact – and correspondingly strong regulatory attention. Even though this means that not all of their findings or lessons are applicable to other fields, their view of the complexity of compliance (and "beyond compliance") factors appears relevant far beyond this study population and aligns well with the findings of other research.

[341] The notion of "procedural justice" can be found already in Rawls's *Theory of Justice* (1971). The development of this notion in a legal compliance perspective is due e.g. to the work of Leventhal (*Fairness in Social Relationships*, 1976) as well as Thibaut and Walker (*Procedural Justice*, 1975). Tom Tyler has been one of the researchers leading the development of this notion specifically applied to the question of "why people obey the law". E. Allan Lind was another early proponent of this vision, which is now supported and used by a growing number of scholars – and practitioners.

[342] The distinction between "psychological" and "social" is not necessarily an easy one – just as biology and physics, the two attempt to describe and explain the same reality, but at different levels of detail or "granularity". We will qualify as "psychological" the factors that are related primarily to the internal views and thinking mechanisms of the individual, as "social" those that primarily involve group values and behaviours, and as "economic" those that (while of course anchored in psychological mechanisms and social values too) correspond to (neo-)classical economics' emphasis on "amoral calculations" and pure rationality.

justice (which, in turn, reinforces legitimacy). Procedural justice is a term that corresponds to authorities treating those subject to them in a fair manner, irrespective of the outcomes of the decision-making process[343] - and this "fair process" is defined as one that combines consistency (of treatment, criteria etc.), impartiality (or at least perceived best efforts to be impartial), ethical behaviour (including civility of persons in a position of authority) and adequate representation (i.e. giving a "voice" to the person affected by the procedure)[344]. Within this model, legitimacy (of authorities and rules) is seen as the real foundation of compliance (see Tyler 1988 pp. 19-70), and procedural justice as the instrument through which such legitimacy and compliance can most effectively be increased. The central importance of procedural justice in this model lies therein that it appears to be the factor that can be most easily strengthened, as well as individually possibly the most potent one. Indeed, deterrence appears very costly, and relatively weak. Moral values are built from childhood, and difficult to alter. Social norms (prevalent behaviour in a given group) are a complex product of various influences, and thus usually can only be altered gradually. By contrast, legitimacy of public authorities (and of the rules they impose) appears strongly influenced by procedural justice[345] – which also has its own positive compliance effect. Thus, procedural justice appears overall as the most important factor in increasing compliance. It is also *relatively* easier for authorities to influence since it depends directly on how they behave in relation with those affected by their actions (citizens, businesses etc.). These findings rely on several decades of research on criminal matters, and on interactions between citizens and authorities (police and courts in particular), as well as some more recent (and so far less extensive) research on regulatory dealings (Lind and Maguire 2003) and public services interactions (van den Bos, van der Velden, and Lind 2014). At its core, the model states that deterrence does play a role in fostering compliance (i.e. deterring crime), but that it tends to have an effect that is quite limited, except if considerable resources are expended so at to make the probability of detection really high. On the other hand, process-based factors appear to play a crucial role in determining sustained attitudes in respect with laws and regulations, and with public authorities.

Tom Tyler summarizes deterrence's impact and limitations as follows (2003): "studies of deterrence (…) point to factors that limit the likely effectiveness of deterrence models. Perhaps the key factor limiting the value of deterrence strategies is the consistent finding that deterrence effects, when found, are small in magnitude. (…) A further possible limitation of deterrence strategies is that, while deterrence effects can potentially be influenced by estimates either of the certainty of punishment or its severity, studies suggest that both factors are not equally effective. Unfortunately from a policy perspective, certainty more strongly influences people's behavior than severity, and certainty is the more difficult to change. (…)To influence people's behavior, risk estimates need to be high enough to exceed some threshold of psychological meaningfulness" (p. 302). This means that, in practice, deterrence is impossible to achieve in most cases: the resources required would be far too high (in a world of limited resources, society cannot commit enough resources to deterring violations in each and every regulatory field), and the intrusion on privacy and limitations of individual freedoms would be far too high. Tyler cites murder as a key example: on this topic, society has allocated enough resources that indeed there is a real deterrence effect – but achieving similar intensity of enforcement in all other fields is

[343] The fairness of outcomes corresponds to distributive justice – which is often difficult to assess independently or objectively, meaning that the perception of distributive justice tends to vary from one person to the next and (when there is a conflict) may tend to be zero-sum: what one perceives as a fair outcome is seen as unfair by the other. By contrast, procedural justice can be perceived by *both opposing parties* as high, since it relates to characteristics of the process, and not to the outcome.

[344] See e.g. Tyler 1988 pp. 136-139.

[345] We are simplifying here (on purpose and to make its main points clearer to the reader) the complex model developed and extensively tested by Tyler (1988). In this model, Tyler tests a number of cross-relations between different factors or drivers, and there is evidence of multiple influences on legitimacy, including not only procedural justice but also (perceived) distributive justice. This influence, however, is consistantly found to be *weaker* than that of procedural justice (a finding strongly confirmed by van den Bos, van der Velden, and Lind 2014) – and, in addition, consistantly increasing perceived distributive justice is very difficult, given the conflicting views of it that co-exist (see previous note). Thus, procedural justice appears not only as the strongest, but also the most realistically "improvable" driver of legitimacy. See Tyler 1988 (pp. 106-109 in particular) as well as Bottoms and Tankebe 2013.

impossible. In addition, deterrence approaches "are not self-sustaining and require the maintenance of institutions and authorities that can keep the probability of detection for wrongdoing at a sufficiently high level to motivate the public" (p. 304).

By contrast, process-based approaches aim at increasing the legitimacy of rules and authorities by improving the level of fairness as perceived by citizens. The focus is not primarily on "distributive justice" (i.e. having *outcomes* that are deemed fair) – although this also has been found to have a significant impact on compliance, it is significantly less strong than the process effect, and in addition it is in practice impossible to reach decisions that would satisfy everyone. Rather, the emphasis is on "procedural justice". In the words of Tyler (2003), who has been one of the key proponents of this approach for several decades: "The procedural justice model involves two stages. [First,] public behavior is rooted in evaluations of the legitimacy of the police and courts. (…) In other words, people cooperate with the police and courts in their everyday live when they view those authorities as legitimate and entitled to be obeyed. [Second,] the antecedents of legitimacy. The procedural justice argument is that process-based assessments are the key antecedent of legitimacy (…). In this analysis, four indicators – summary judgments of procedural justice, inferences of motive-based trust, judgments about the fairness of decision making, and judgments about the fairness of interpersonal treatment-are treated as indices of an overall assessment of procedural justice in the exercise of authority" (p. 306). Crucially, a considerable body of research has shown that the effect of procedural justice appears *significantly stronger* than that of deterrence[346].

The procedural justice effects are found in many fields and settings (mediation decisions Lind et al. 1993, dismissal from employment Lind et al. 2000 etc.). What also matters is that procedural justice, and the legitimacy it fosters, are long-term drivers of compliance, and largely self-sustaining (at least they do not require an *increase* in resources – but a change in behaviours and approaches)[347]. The changes involved in how authority is exercised are, however, significant compared to what is the practice in many cases. Quoting Tyler (2003) again, the key conditions needed to achieve a procedural justice effect are: "that decision making is viewed as being neutral, consistent, rule-based, and without bias; that people are treated with dignity and respect and their rights are acknowledged; and that they have an opportunity to participate in the situation by explaining their perspective and indicating their views about how problems should be resolved" (p. 300-301).

The validity (or lack thereof) of different compliance models is in no way a purely "academic" question – since it provides the foundation for different inspections and enforcement approaches. A "classic" deterrence-based approach (where increasing probability of detection or severity of sanctions are seen as equivalent) will lead to the use of punitive sanctions or damages (in tort cases), whereas a deterrence-based view that takes into account research suggesting that people react more to probability than to severity will try and increase inspections coverage and at the same time refine targeting (e.g. by doing at least some basic "risk-based" targeting, looking for higher probabilities of violations if not magnitude of potential effects). By contrast, an approach that takes a more complex, multi-factor view of enforcement will be quite different. It will consider alternative approaches to promoting compliance (in particular education, guidance, opinion-forming), it will pay attention to the importance of ethical behaviour of inspectors and "procedural justice" more broadly. It will also look at the potential adverse effects of excessively frequent, burdensome inspections, or of enforcement seen as disproportionately severe. Indeed, if their negative procedural justice effects were to be higher than their deterrence effect (something which is a distinct possibility in such a model), then the net compliance effect of more inspections and stricter enforcement may well be negative. We will come back

[346] See Tyler 1988, 2003 – Hodges 2015 *et al.*

[347] On this point, see e.g. Tyler 1988 p. 107 (procedural justice acting as a "cushion of support when authorities are delivering unfavourable outcomes", as well as Tyler 2003 p. 283 etc.

further in this research on the evidence concerning different compliance models, but we can already say that, evidence notwithstanding, these different models have very concrete "real-life" effects, as different inspectorates across the world base their operations on very different visions.

ii. Mapping the foundations of compliance – economic, psychological, social, cultural

In summary, theoretical accounts of compliance and research-tested models have gradually moved away from a narrow, deterrence-based vision to a more complex, multi-factor model – or one could also say that such a complex vision has long existed, but has gradually gained ground against a once-dominant deterrence model. Indeed, the deterrence model appears overly simplistic – applied to business regulation, "it assumes that all businesses make all decisions based solely on objective economic rationality, weighing all costs and benefits in financial terms. It is further assumed that an organisation can be treated as a single entity, and that it can control the behaviour of every person and decision that is taken" (Hodges 2015, p. 3). Rather, firms are made up of many individuals, and human decisions and behaviour are shaped by their "cognitive development and "moral understanding", their "sense of justice", as well as "exemplars of a social norm or custom" (*ibid.*, pp. 15-16). Crucially, decisions are more often taken on the basis of the "fast heuristic approach", which "involves impulsiveness and intuition", than using the "slower system that is capable of reasoning [and] is cautious" (*ibid.*)[348]. Thaler and Sunstein have shown the importance of heuristic biases (1998, pp. 19-39) in our decisions. For all these reasons, effectively promoting compliance appears to require an approach that combines a number of drivers or dimensions.

We have seen that the number and categorization of such drivers varies between authors. Hodges (2015) sees "three primary motivations for explanations of law-abidingness in humans": "fear of detection and punishment", "fear of humiliation or disgrace" and "internalized sense of duty" – the latter being in turn influenced by "internalised moral values", "processes by which the rules are made and applied" and the alignment (or lack thereof) of "the rules and culture of the group(s) to which the individual belongs (…) with the norms that are sought to be applied by society" (pp. 16-17)[349]. In addition to these, we would also underline the importance of *capacity to comply*: both the knowledge and information aspect (emphasized e.g. by Scholz 1994, *cf. supra*) and the material side of compliance (technical capacity and feasibility, and cost of compliance)[350].

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[348] Cf. Tversky, A. and Kahneman, D. (1974), "Judgment under Uncertainty: Heuristics and Biases" 185 no 4157 *Science* 1124-1131 – as well as Bennear in Balleisen *et al.* (in press), and Sunstein and Thaler (2008) pp. 19-39.

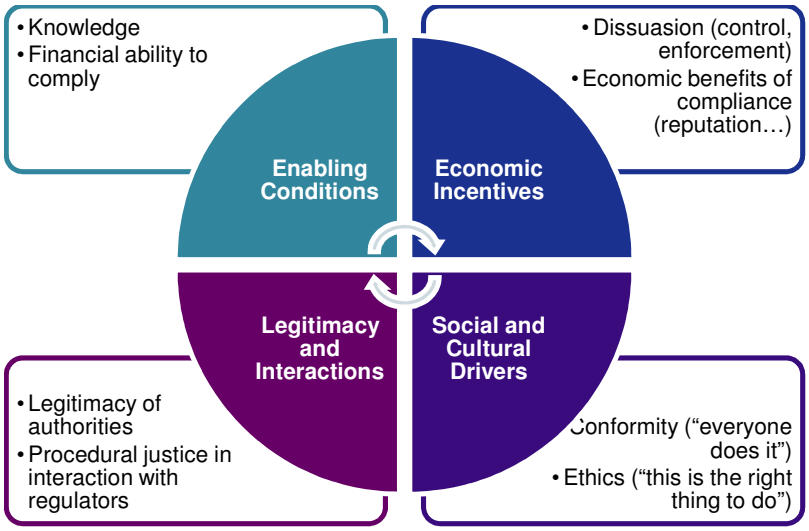
[349] See also Kagan, Gunningham and Thornton 2011 (p. 37): "Sociolegal explanations of law-abidingness among regulated business enterprises, as well as among individuals, point to three basic motivational factors: fear of detection and legal punishment; concern about the consequences of acquiring a bad reputation; and a sense of duty, that is, the desire to conform to internalized norms or beliefs about right and wrong"

[350] See e.g. Winter and May 2001. This aspect is also covered under the "economic" side of the "license to operate" concept outlined by Gunningham, Kaghan and Thornton (2003) – see also Ogus (2004) on how corruption can help an economy to function in spite of excessive, inefficient regulations. Note that Ogus takes a limited example (procedural regulations). In our experience, the effect is even stronger when substantive regulations are "impossible to comply with" given prevailing technical and financial conditions: rather than most businesses just shutting down, either implementation of the rule has to be scaled back by the regulatory authorities, or corruption will enable businesses to function nonetheless, but at a significant cost (and profit for corrupt officials) – in both cases, compliance will be non-existent (or close to it). For an example of non-implementation of an unrealistic rule, see the example of the constantly pushed-back full implementation of accessibility rules for handicapped people in France, Eliakim (2013) (chapter "Maintenant, ils regrettent…). For a similar example on lifts regulation in France, see Blanc *et al.* (2015) p. 8 and Eliakim (2013).

Drawing on these different streams of research and scholarship, and on inspections and enforcement practice, we would propose to categorize the different *foundations*[351] of compliance in four groups[352]:

- Enabling conditions: knowledge and understanding of rules, financial and technical ability to comply without putting the business viability in jeopardy
- Economic incentives: deterrence (probability of detection primarily, amount of potential sanctions as a secondary aspect – and also risk of reputation loss), potential economic benefits of compliance (increased reputation leading to improved market position, or compliance investments resulting in higher productivity, reduced losses or any other economic benefit)[353]
- Social and cultural drivers: group conformity (other members of the group and/or "models" behave in a compliant way), group ethical values (values of the cultural group the person belongs to are aligned with the values of the regulation and/or values of the cultural group posit legal compliance as an absolute good)
- Legitimacy and interactions – individual psychological drivers: legitimacy of authorities (influenced by social and cultural drivers, but also directly by personal, individual experience), procedural justice (or lack thereof) experienced in interactions with authorities, regulators.

Evidently, these categories are only useful as a device to help clarify and make sense of the complexity of compliance. "Enabling conditions" have economic aspects, "legitimacy" and "values" are both social and psychological, etc. Rather than four separate categories functioning in isolation, it is useful to see these as part of a circle of "contextual elements", all of them interacting with one another. Visually, one can represent it as in the following scheme.



An illustration of the "compliance foundations circle"

[351] A term that is broader than "drivers" in that it also includes elements that are rather "pre-requisites", "enabling" factors.

[352] Of course, many different categorizations are possible. Parker and Lehmann Nielsen (2011) for instance propose: "four main conceptual themes or sets of independent variables of interest in explaining compliance: motives, organizational capacities and characteristics, regulation and enforcement, and social and economic environments (or institutions)" (p. 5). We consider that having "regulation and enforcement" as one of the variables is too broad, for instance, and consider "institutions" in their different aspects under several headings. Each typology will have different strengths and weaknesses, and will depend on the focus of the author(s).

[353] The *complexity* (often under-estimated) of this group of "economic or material motivations that influence businesses to comply (or not) with regulatory dictates" is underlined by Simpson and Rorie (2011, p. 59): "our discussion acknowledges the importance of micro and macro distinctions and the linkages between organizational members and the company as a whole".

It is worth emphasizing that this is not a scientifically-grounded typology, where the different categories would be very tightly defined. Rather, their relative porosity reflects the inherent complexity of the behavioural processes that result in compliance, and the many interactions between all the factors at play. The intent is to have a typology that is above all practice-oriented: if indeed the factors described are found to be significant (and we will discuss below the question of their respective importance), then an effective and efficient inspection and enforcement approach has to try and address all of them comprehensively, paying attention to potential side effects, trade-offs, and attempting to find the "optimal" mix of tools[354].

In sharp contrast with some theories' pretentions to definitely "explain" human interactions, we think it behoves scholars to be modest and accept the limits of humans' ability to understand themselves[355]. Whether these limitations are inherent or temporary, we clearly are nowhere near reaching the same success in understanding *and transforming* behaviours as we have had in regard to natural, physical phenomena. Accepting and understanding to some extent the complexity of forces at play and of interactions may be a first step. In this perspective, breaking down artificial barriers between different theories is a first, useful step. In agreement with Hodges (2015), we see the combination of procedural justice studies, behavioural economics, as well as the more sophisticated analyses of "deterrence" effects as different aspects and angles of the same attempt to make sense of human behaviours. Whether one looks at "compliance", at "beyond compliance", or targets "behaviours" more broadly – the drivers, conditions, foundations are all essentially the same.

b. Challenges in understanding compliance, and promoting it

i. Determining the relative strength of compliance drivers: a difficult quest

Considering that there are several competing compliance models, and different perspectives on the relative importance of compliance drivers or factors, and that these different models and drivers suggest sharply diverging enforcement approaches, attempting to assess the relative strength of these different drivers is very important. It is also very challenging – at least if one wishes to have definitive certainty, or close to it. Many studies have attempted to test the effect of different approaches, in particular deterrence, but also (for a smaller number) procedural justice, education etc. Tyler (1988 *et al.*), in particular, has attempted to disaggregate the effects of different drivers, while testing a procedural justice model of compliance. Still, we would argue that none of the studies is fully conclusive, and that it is hence not surprising that many yield partly or fully conflicting results. All of these studies have their limitations: they cover typically one (often small) jurisdiction, and one legal or administrative field. There may be a number of reasons why the effects found differ between locations, topics, groups affected etc. There are also considerable issues with data

[354] As Parker and Lehmann Nielsen (2011) put it, "understanding and explaining 'compliance' (…) requires mapping, understanding and testing the interactions of a complex range of factors and processes" (p. 8). There are, of course, many different ways to consider and categorize existing research on and scholarly accounts of compliance. Parker and Lehmann Nielsen see the field as divided between "objectivist research aimed at building and testing theories" that look at "what 'procudes' compliance" – and "interpretive understanding of organizational responses to regulation, and of the processes by which compliance is socially constructed" (p. 3). If we had to choose, we would locate our work in the first group – but the authors quickly add a note that there is "creative dialogue" between the two, and that many scholars "use both styles" (p. 4).

[355] Tyler's *Why People Obey the Law* (1988), precisely because it attempts to capture all the different (and possibly conflicting) drivers, is a good example of such modesty and inclusiveness.

quality, reliability, representativeness in many studies – and with the meaningfulness of respondents' responses to "qualitative" questions.

We are not the first to point the limitations and difficulties of data on compliance. For instance, Kagan, Gunningham and Thornton (2011) write that "the regulatory agency databases that researchers use to measure noncompliance vary in quality, while researchers who rely on those databases often differ in what they treat as significant noncompliance" – but we think this is an understatement of the problem. Lehmann Nielsen and Parker (2011) go somewhat further in stating that: "to the extent that data are available from individuals inside firms or from records collected by regulatory agencies, the data will be filtered and biased according to what those who collected it saw as relevant and important to compliance and what they see as socially and politically desirable to share with the researcher" (p.6). Similarly, the conclusions drawn by May and Winter (1999, 2011) on different "enforcement styles", and their respective effects on compliance, while very interesting, are subject to caution given the limitations of the data they use (which they partly acknowledge). Their 1999 study relies on surveys asking respondents to rank enforcement styles on a set of criteria (which already can incorporate a significant amount of respondent bias, as with every "qualitative" questions) – and then combines this with questions where inspectors are asked to assess the effectiveness of their own actions. As the authors write, "we relied on municipal inspectors' reports of the effectiveness of their enforcement efforts" (2011, p. 234). While the authors do grant that there may be concerns with the objectivity of such a data source, they still consider it as fundamentally valid[356], and draw important conclusions from their research, in particular that "the effects of formalism [in enforcement style] were positive and somewhat stronger when awareness of rules was low. In such circumstances the use of formalism gives regulatees more certainty about what is expected from them" (p. 235). While the conclusion may well be valid, it remains a distinct possibility that more "formal" inspectors may also, for a variety of reasons, *consider* their own actions to be more successful – and thus, different perspectives may build an inherent bias in the data.

We would argue that self-reported levels of compliance, whether reported by businesses themselves or by inspectors, are highly problematic. The former may have an imperfect understanding of what full compliance would be, and a reluctance to report fraud and violations. The latter have a number of incentives to report compliance levels that may differ from reality (not necessarily better – policy priorities may also mean that reporting worse compliance than actual makes career sense), and also of course never have a full view of the level of compliance in any given business, even one that they inspected – and by definition have no information on non-visited businesses. While one may assume that the "imperfect information" issue may be relatively constant, and thus not skew evaluations of *relative* effectiveness[357] (or skew them only in a limited way), the same is not true of pressure from inspectors' management, policy makers etc. May and Winter (2011) in fact acknowledge the importance of superiors and politicians in how inspectors' enforcement style varies, for instance, even though they also find this effect to be variable and often limited (pp. 230-232) – there is no

[356] See May and Winter (1999): "Our measure of the effectiveness of enforcement actions in bringing about compliance is based on assessments made by the main municipal inspectors. Each was asked to rate on a 10-point scale the "total effect of the municipal supervision of farmers' pollution of water resources in relation to making farmers comply with regulations governing livestock." The end points for the scale ranged from "no effect" to "has caused all farmers to comply." Municipal inspectors generally report high degrees of effectiveness of their actions (…) Inspectors have some incentives to provide rosy estimates of their effectiveness; if nothing else, to look good. However, the Danish Environmental Protection Agency regularly requires the municipal inspectors to make reports about farm inspection for which inconsistent reports over time are evident. (These reports are one source of our data.) Given these considerations, we presume that the inspectors' reports of enforcement effectiveness provide reasonable measures of relative differences among municipalities. However, we recognize that they may not provide accurate assessments of absolute levels of enforcement effectiveness or of compliance" (pp. 635-636). The authors cite other studies that report inspectors' own assessment of compliance to be accurate. Clearly, it is *possible* that these are indeed accurate – but it is far from certain. Inspectors may well have understood how to "game the system" and consistently report "better than actual" outcomes (cf. Bevan and Hood 2006).

[357] Although more qualified and professional inspectors tend to be better at detecting violations, as May and Winter (2011) also note.

reason to assume that this influence does not also extend to reporting of compliance levels. In fact, extensive research in the field of crime and law enforcement has repeatedly shown major issues with the way police forces register and report crime levels (including under-registration of crimes that the police would be unlikely to be able to solve, so as to increase the rate of success – or systematic enforcement against petty crime in order to make "activity" statistics look up, thus making it appear as if there were a surge in some violations, etc.)[358]. There is no reason to believe that such problems are not also present in regulatory enforcement. Indeed, Bardach and Kagan (1982) have shown that, when inspectorate management emphasizes a "looking tough" approach and penalizes inspectors who appear to have lower activity and enforcement numbers, this mechanically produces a more legalistic, more "aggressive" enforcement practice (pp. 76-77), with considerable side-effects (what the authors call "unreasonableness"), without this reflecting on the real, underlying level of compliance and safety.

For all these reasons, we believe it makes sense, in order to assess the effectiveness of inspections and enforcement approaches and styles, to look at actual *outcomes* and not at whichever compliance levels are reported. Obviously, there are major issues also with this approach (in particular, the difficulties in attributing variations in extremely complex phenomena to different causes), and we will come back to this in the third section. In the meantime, and in spite of the limitations outlined above, considering the evidence from existing research is a crucial step in order to provide a sound foundation for inspection practices. We will attempt to do this briefly, focusing on the most significant results, and assessing whether some trends can be more or less reliably identified.

Two fields of law and regulation have been the object of most studies of compliance and its possible drivers: tax regulations, and interactions with police and courts ("law and order" issues broadly speaking, and not only criminal justice). While there is no comparable set of quantitative studies on other areas (environmental or occupational regulations compliance, for instance), there is good reason to assume that findings from these two spheres can extend to other fields too. Indeed, in neoclassical compliance models, the cost-benefit calculations are assumed to extend to any kind of regulation as well. From our perspective, taxes and "law and order" issues have the benefit of covering very different types of regulations – complex for tax and simpler for "law and order", applying only to individuals for the latter and also to businesses for the former, etc. That they have been most studied is a function both of their very strong relevance to society (very fundamental fields of state regulation), and of the relative ease with which compliance and non-compliance can be measured (quantitatively in tax, and with simple questions in terms of law and order – whereas environmental or occupational regulations, for instance, would entail many different questions and compliance could be partial, with difficulties in rating it). While neither of these fields is the core focus of this research, there is reason to think that findings in these spheres can be transposed to others[359].

Evidence from tax compliance studies

If we thus accept that we can generalize the findings from tax compliance and "law and order" studies to other fields of regulation, there is a significant amount of evidence *against* the view of people and businesses as complying only on the basis of fear and rational calculations. To quote from an important study reviewing and

[358] There is a vast amount of literature on this issue – the reader can refer e.g. to Skogan 1975, Smith 2006.

[359] Tyler (2011) himself considers the application of his findings to business regulation writing (p. 78): "deterrence mechanisms of the type being widely used are usually less effective than is generally believed, and are particularly unlikely to be optimal approaches to regulating the actions of those who work in business settings. In contrast, research findings suggest that efforts to build a value based climate of rule following are a promising approach that is likely to lead to more widespread voluntary acceptance of, and deference to, workplace rules and policies. (…)Studies find that the primary factor shaping legitimacy, morality and rule adherence is the procedural justice that employees experience in their workplace". We will come back to this question of the "ethical" workplace, which is also the focus of Hodges (2015).

summarizing several decades of research on tax compliance (Kirchler 2007) "empirical research consistently shows that the rational model is not working as neoclassical economics had intended[360]". Kirchler, in this study, goes through all the conflicting evidence put forward by a number of studies in different countries, some in a laboratory setting, some based on surveys, some others looking at actual tax data. Most show a stronger effect from audit frequency, a few from higher fines (though from a model perspective they ought to be equivalent), some show no effect or an adverse effect (more audits and/or higher fines leading to *decreased* compliance) – and in all cases the effects are small. Among the most interesting findings from our perspective are that "oppressive tax enforcement and harassment of taxpayers seem to increase tax resistance, as does discontent with the delivery of public service[361]" – and that another study[362] "yielded neither a significant audit probability effect nor significant effects of fine and tax rates, whereas trust in the legal system and direct democratic rights proved to be highly significant determinants of tax morale. These findings prove that perceived procedural justice as described above is a crucial determinant of citizens' voluntary cooperation, whereas in a system perceived as treating citizens unfairly, cooperation must be enforced by coercion".

Overall, Kirchler summarises the key findings as follows: "there are many explanations of why probability of audits and fines does not have the predicted high effect on tax compliance. First of all, the assumption that taxpayers are trying to avoid taxes if it is in their benefit must be doubted. Various studies in different countries use different methodological approaches to show that a vast majority of citizens are willing to pay taxes and do not seem to undertake economic decisions under uncertainty in order to maximise income. Most taxpayers seem to take for granted the legitimacy of the tax system and its overarching objectives". Even to the extent that audit probability and fear of punishment do play a role, their effects are mediated by the values of the taxpayers: "individuals generally make poor predictions of the probability of audit and magnitude of fines from tax evasion. Moreover, there is consistency between their sense of a moral obligation to be honest and the tendency to overestimate the chance of being caught". In short, and even though there appear to be differences linked to other elements of the context (country, tax rates etc.), it seems clear that the probability and severity of punishment are *not* the primary drivers of tax compliance – but rather, that the moral values of taxpayers, and their views on the legitimacy of the tax system and its rules, are the fundamental drivers, to which inspections and enforcement only come as an addition[363].

Evidence from research on citizens, police and courts

Several decades of research on criminal matters, and on interactions between citizens and authorities (police and courts in particular), paint a similar picture to what we have seen for tax. Of course, deterrence does play a role in fostering compliance (i.e. deterring crime), but it tends to have an effect that is limited (or even very limited), except if considerable resources are expended so at to make the probability of detection really high. On the other hand, process-based factors appear to play a crucial role in determining sustained attitudes in respect with laws and regulations, and with public authorities.

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[360] Full quote: "In 1992, Fischer, Wartick and Mark reviewed a bulk of studies directed at learning more about the relationship between probability of detection and compliance behaviour. It appears that the reviewed studies, which employed different methods, generally point in the same direction and strengthen the confidence that increasing the probability of detection will result in less non-compliant behaviour. However, the effect is, if anything, very small. Similarly, while the effect of fines is significant in many studies, their impact on tax compliance in general is small, if not negligible (Andreoni, Erard and Feinstein, 1998)"

[361] Quoted by Kirchler from Fjeldstad and Semboja (2001) - study on tax behaviour in Tanzania.

[362] On tax morale in Switzerland by Torgler (2005).

[363] Quoting one last time from Kirchler (2007): "Based on the rather small effects of variables considered in the neoclassical economic approach (i.e., audit probability, fines, marginal tax rate and income), several studies conclude that it is important to consider also citizens' acceptance of political and administrative actions and attitudinal, moral and justice issues as they are central to psychological and sociological approaches (Lind and Tyler, 1988 ; Pommerehne and Frey, 1992 ; Pommerehne and Weck-Hannemann, 1992 ; Tyler and Lind, 1992 ; Weck-Hannemann and Pommerehne, 1989)."

Tom Tyler, summarizes deterrence's impact and limitations as follows (2003): "studies of deterrence (…) point to factors that limit the likely effectiveness of deterrence models. Perhaps the key factor limiting the value of deterrence strategies is the consistent finding that deterrence effects, when found, are small in magnitude. (…) A further possible limitation of deterrence strategies is that, while deterrence effects can potentially be influenced by estimates either of the certainty of punishment or its severity, studies suggest that both factors are not equally effective. Unfortunately from a policy perspective, certainty more strongly influences people's behavior than severity, and certainty is the more difficult to change. (…)To influence people's behavior, risk estimates need to be high enough to exceed some threshold of psychological meaningfulness." This means that, in practice, deterrence is impossible to achieve in most cases: the resources required would be far too high (in a world of limited resources, society cannot commit enough resources to deterring violations in each and every regulatory field), and the intrusion on privacy and limitations of individual freedoms would be far too high. Tyler cites murder as a key example: on this topic, society has allocated enough resources that indeed there is a real deterrence effect – but achieving similar intensity of enforcement in all other fields is impossible. In addition, deterrence approaches "are not self-sustaining and require the maintenance of institutions and authorities that can keep the probability of detection for wrongdoing at a sufficiently high level to motivate the public."

By contrast, process-based approaches aim at increasing the legitimacy of rules and authorities by improving the level of fairness as perceived by citizens. The focus is not primarily on "distributive justice" (i.e. having *outcomes* that are deemed fair) – although this also has been found to have a significant impact on compliance, it is significantly less strong than the process effect, and in addition it is in practice impossible to reach decisions that would satisfy everyone. Rather, the emphasis is on "procedural justice". In the words of Tyler (2003), who has been one of the key proponents of this approach for several decades: "The procedural justice model involves two stages. [First,] public behavior is rooted in evaluations of the legitimacy of the police and courts. (…) In other words, people cooperate with the police and courts in their everyday live when they view those authorities as legitimate and entitled to be obeyed. [Second,] the antecedents of legitimacy. The procedural justice argument is that process-based assessments are the key antecedent of legitimacy (…). In this analysis, four indicators – summary judgments of procedural justice, inferences of motive-based trust, judgments about the fairness of decision making, and judgments about the fairness of interpersonal treatment-are treated as indices of an overall assessment of procedural justice in the exercise of authority." Crucially, research has shown that the effect of procedural justice is *significantly stronger* than that of deterrence.

The procedural justice effects are found in many fields and settings (mediation decisions Lind et al. 1993, dismissal from employment Lind et al. 2000 etc.). What also matters is that procedural justice, and the legitimacy it fosters, are long-term drivers of compliance, and largely self-sustaining (at least they do not require an *increase* in resources – but a change in behaviours and approaches). The changes involved in how authority is exercised are, however, significant compared to what is the practice in many cases. Quoting Tyler (2003) again, the key conditions needed to achieve a procedural justice effect are: "that decision making is viewed as being neutral, consistent, rule-based, and without bias; that people are treated with dignity and respect and their rights are acknowledged; and that they have an opportunity to participate in the situation by explaining their perspective and indicating their views about how problems should be resolved."

Refining the models: *responsive regulation, smart regulation*, and their challenges

Responsive regulation: the original vision

Confronted with the limitations and contradictions of simple models of understanding and fostering compliance, scholars (and practitioners) have been developing more complex models, attempting to *combine* several approaches in a coherent framework. The first, and arguably the most famous, is the *responsive regulation* model that was formulated in 1992 by Ayres and Braithwaite (relying on earlier work, and later further developed by Braithwaite and others, in particular Grabosky). The fundamental idea of responsive regulation is that different approaches are needed (and warranted) for different businesses, that these different approaches need to be seen as part of a *pyramid* of *escalating severity*, and that the regulators need to be *responsive*, i.e. change approaches as business behaviours change. In addition, they argue that the overall "enforcement pyramid" needs to be publicized so that regulated entities know exactly what to expect, and thus have an additional incentive to comply, so as to remain at the "bottom of the pyramid" (Cf. Ayres and Braithwaite 1992, pp. 35-41).

The foundations for this model, precisely, combine different compliance drivers, and recognize that different businesses (and different employees within them) may be at different points in the pyramid (corresponding to different drivers being strongest), and that their position may change over time (in particular in reaction to regulatory enforcement actions). The bottom of the pyramid corresponds to pure persuasion, while successive moves *up* the pyramid correspond to increasingly strong deterrence (and, ultimately, incapacitation) (p. 35). Of course, the precise list of actions will depend on the context, and in particular on the legal tools available to the agency.

The *shape* of the pyramid is meant to convey the idea that "most regulatory action occurs at the base of the pyramid where attempts are initially made to coax compliance by persuasion" (*ibid.*). The same pyramid model is suggested for *enforcement strategies* – meaning that, at a strategic level, governments and regulatory agencies should tailor (and communicate) their strategies in the same way. The specific regulatory instruments included in this pyramid can vary (the authors present an example ranging from self-regulation to "command regulation with non-discretionary enforcement" at the top, on p. 39) – but the general benefit is that "clear communication in advance of willingness by the state to escalate up the pyramid gives incentives to both the industry and regulatory agents to make regulation work at lower levels of interventionism", in the hope of avoiding the "cost of increasingly inflexible and adversarial regulation" (pp. 38-39).

In order to work effectively, responsive regulation requires that regulatory agencies have at their disposal a broad range of potential responses (including varied sanctions of increasing severity), that allow them to have an enforcement approach that can be as "finely graded" as possible. By contrast, if an enforcement agency has only very severe sanctions available, the threat to "cooperate or else" will not be credible because regulated entities will know that this (exceedingly drastic) sanction will usually *not* be used. When the different sanctions available do not fit well with the range of severity of possible offences, there will be situations where there is "no politically acceptable way of punishing these offences" (pp. 36-37)[364]. We would add, writing from experience in very different jurisdictions, that this last point is true for democratic polities, and even (within these) for polities with a strong voice for businesses. There are a number of situations where such exceedingly severe sanctions *will* be used, and where the effect will be that not only will violations be deterred, but

[364] There are ways to introduce "nuances" in practice with what appears at first to be a limited "response kit". For instance, Hawkins (2002) shows how British HSE inspectors developed rather sophisticated techniques of persuasion to address the limitations of their available range of responses – with formal enforcement including only improvement notice, prohibition notice and prosecution. Tilyndite (2012) argues in fact that their use of notices has been so effective as to make the introduction of administrative penalties rather unattractive.

legitimate investment and economic activity, with serious consequences for growth and employment. Ayres and Braithwaite also suggest the idea of what they call a "benign big gun" (pp. 40-41), where enforcement agencies have sanctions reaching *very high* (until full incapacitation), so that (using the pyramid approach) they can use the threat of this power to, in fact, push *most* regulatory interactions to the bottom end of the pyramid. The combination of responsiveness, gradation and very high "top of the pyramid" would thus function optimally.

The responsive regulation approach incorporates earlier findings and ideas on "tit-for-tat" (in particular Scholz's work – cf. pp. 20-23), but goes significantly further. Indeed, "tit-for-tat" is premised on assumptions of rational behaviour, and can be formulated through a game-theoretical analysis (cf. pp. 21, 60-81). Ayres and Braithwaite's vision, by contrast, incorporates a complex view of compliance motives (what they call "mixed motives" – cf. pp. 22-35), and thus modifies the "tit-for-tat" vision into the "compliance pyramid". The pyramid acknowledges that different motives work (to different amounts) for different people (and in different situations), and seeks to rely as much as possible on voluntary (values-based) compliance, while keeping deterrence (calculation-based) in the background. Being particularly open about the potential for very high escalation, but mostly *not* using sanctions, i.e. "speaking softly and carrying a big stick" is the core of their approach. But the vision they lay out in their 1992 book (as distinct from the many summaries produced later on by other scholars) has many other aspects. In particular, it envisions a strong reliance on "tri-partism" (cf. pp. 54-100), whereby the role of "public interest groups" (trade unions, NGOs and civil society organizations) would come into play to avoid regulatory capture, and ensure more optimal outcomes than a simple two-way relationship would (cf. pp. 86-97). They also discuss at length the potential for "enforced self-regulation", and the different ways in which it can be structured, as a potential application of the "pyramid" approach (pp. 101-132). While these are very interesting directions for reflexion, and they are *connected* to our area of research, their relevance to our concerns is at this point marginal, and we will not discuss them further[365].

From "smart regulation" to "really responsive regulation"

Already, through their vision of "tri-partism", Ayres and Braithwaite started to consider the importance of *other actors* in the question of compliance and of public welfare outcomes. Gunningham and Grabosky developed this further into an approach they called "smart regulation" (1999), a term which quickly became used in a confusing variety of ways. Their understanding of the notion was "an emerging form of regulatory pluralism that embraces flexible, imaginative and innovative forms of social control which seek to harness not just governments but also businesses and third parties" (Gunningham 2010, p. 131). Their fundamental insight is that there are many influences that shape business behaviour, far beyond regulation (and simple cost-benefit calculations related to narrowly-defined compliance), such as "international standards", "trading partners and the supply chain", "financial markets", "peer pressure", "internal (…) culture" and "civil society" (*ibid.*). This is an approach that we see as very relevant, and indeed we will try and show in our examples from the practice (in the third part) that "risk-based" inspection systems tend to also try and leverage all or at least several of these different factors. Nonetheless, we will not discuss these in depth, as our focus in this research is specifically on the regulatory enforcement aspect.

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[365] We will just note three more things about Ayres and Braithwaite's work. First, the "tri-partism" vision, while it is clearly very context-related (i.e. rooted in Australian conditions) is very interesting – and has clearly been influential in further research (see next paragraph on *smart regulation*). Second, "enforced self-regulation" can be linked to other models such as third-party conformity assessment in product-market regulations, or to the vision of "ethical regulation" by Hodges (2015) etc. It definitely warrants further research. Finally, the authors also call attention at the opening of the book to the relevance of their research not only to OECD countries but, for instance, to post-Soviet countries (p. 7). We very much agree, in spite of all the practical difficulties, as we will further develop in the third part of this research.

A number of criticisms, or remarks, have been done concerning the original responsive regulation model (and Braithwaite himself has introduced a number of additions to it). To our mind (and contrary to the way in which these remarks were sometimes done, which suggested that something was fundamentally amiss in the original design), they do not reflect any essential flaw in the design of responsive regulation, but rather point to specific points in detailed implementation, which could not possibly be all addressed in the original work, which was rather short and conceptual. One of the most important points is the difficulty to "ratchet down" enforcement, "rebuilding trust" after an escalation (Gunningham 2010, p. 127 – quoting Haines). Other points relate to the fact that, in many situations, the ideal "pyramid" model will not be (or not be fully) applicable. For instance, interactions may be too rare (or too rarely repeated), or several regulators may be involved (with different approaches) (*ibid.,* pp. 128-130). The second problem (several overlapping regulators with inconsistent approaches) is indeed a frequent problem – in our view, however, it does not suggest anything wrong with the responsive regulation model, but with the institutional setup (as there are many other reasons why overlapping, uncoordinated regulators covering the same issue are *not* an optimal setup)[366]. The first problem, however, is quite rare in fact in our experience. While indeed some very small agencies, or agencies covering very specific issues (such as fisheries inspections used as example by Baldwin and Black 2008), may have very rare interactions with regulated entities, it remains that the inspectorates which "matter" in the experience of businesses (and, generally, in the perceptions of the public) have typically rather large staffing levels, and relatively frequent interactions with businesses. In addition, if and when there are violations or problems found, re-inspections are relatively frequent, and thus the problem of "too rare repeat interactions" is not, in our experience, a very serious challenge to the responsive regulation model.

Another view, which is more relevant in practice, is that in many instances it would be sub-optimal to rely *only* on the pyramid, for a variety of reasons. The first is that interactions, while not being necessarily so rare that the pyramid is inapplicable, can be relatively infrequent (e.g. for small, low-risk businesses), and thus the pyramid is a less-optimal approach than *segmentation,* whereby regulators select "the most appropriate regulatory tool from a variety of options" for a given target group or entity (Gunningham 2010, p. 130). Likewise, there may be case where interactions' frequency is not the issue, but where "the classification of regulated enterprises into one of a variety of motivational postures" is "relatively straightforward". In such cases, a "target-analytic" approach can be more efficient than a "tit-for-tat" one (*ibid.*, p. 128). Again, we see here nothing actually *contradicting* what Ayres and Braithwaite outlined, particularly if one considers that they specifically suggested having a pyramid of *enforcement strategies* and not only one of enforcement *responses* to a given entity. Such selection of tools based on profiling can perfectly fit the perspective of an enforcement strategies pyramid.

Developing a number of these criticisms, concerns and additions, Baldwin and Black have written two papers on "really responsive regulation" and "really responsive risk-based regulation" (2008 and 2010, respectively). These are important contributions, and try and integrate a number of different strands of scholarship and practice – responsive regulation, risk-based regulation, Sparrow's "regulatory craft" approach, and close consideration of practical challenges of regulatory agencies. Here again, we would argue that the way the authors present several points as criticisms or contradictions of the original responsive regulation framework somewhat overstates the real differences – which are more about nuances, practical applications, and consideration of implementation challenges. Nonetheless, they make a number of very important points. First, they rightly point out that the pyramid needs to be combined with a risk-proportionate response: "

[366] See Blanc (2012) pp. 22-25

in some circumstances step by step escalation up the pyramid may not be appropriate. For example, where potentially catastrophic risks are being controlled it may not be feasible to enforce by escalating up the layers of the pyramid and the appropriate reaction may be immediate resort to the higher levels" (p. 6)[367]. Second, they emphasize the fact that "tit-for-tat" may be wasteful when it is clear which approach is appropriate (or not) for a group of regulatees (p. 7 - again, this is a point which the pyramid of enforcement approaches would, in principle, cover). Third, they point out the problem of regulatory regimes where inspection and enforcement activities are "spread across different regulators with respect to similar activities or regulations" (p. 8) – a point which, as we noted above, is very important in practice, but says little about the model, and more about institutional problems that require a solution (because incoherent and inconsistent enforcement would be a problem with or without responsive regulation).

Baldwin and Black go on to make a certain number of recommendations to achieve "really responsive" regulation. These are sound recommendations, that mostly relate to the attention to *implementation*. They include paying attention to "the constraints and opportunities that are presented by the institutional environments within which the relevant regulators act" (p. 19) and attention to the "logics of different regulatory strategies and tools" (which involve "different understandings of the nature of behaviour or of an institutional environment, and in turn have different preconditions for effectiveness" – p. 20). They stress the crucial importance of "responsiveness to the regime's own performance and effects", and thus of developing adequate tools for "performance evaluation *and modification*" (emphasis ours – p. 21)[368]. On this basis, they develop a set of key questions covering the five challenges of "detection, response development, enforcement, assessment and modification" (p. 26). While this is a very interesting grid to assess regulatory responses, much of it goes beyond the scope of this research, were we really focus on the enforcement phase (and, to some extent, on response development). Detection problems (cf. p. 30-31) are also very relevant for inspections issues, and we will to some extent discuss them in the third part. We would, however, suggest that they are *in many cases* somewhat less acute than Baldwin and Black suggest. First, because the example they use (fisheries regulation) is particularly extreme, and detection is far easier in many of the more "common" regulatory functions and regulated sectors. Second, because if detection issues are really so considerable for a given type of inspections that they make it essentially impossible or ineffective, then this issue should be considered at an earlier stage of regulatory design, i.e. when identifying the problem and coming up with a regulatory solution. If inspections *cannot* realistically work, then maybe they were never the right tool in the first place[369].

In conclusion, one could say that the responsive regulation model, with a number of additions and nuances, has given a solid basis for further theoretical and practical developments, by formulating a coherent framework which allows differentiated approaches based on context, target group, interaction history etc. "Smart Regulation" and successive contributions have brought more attention to multiple stakeholders and tools, and to implementation challenges. "Meta Regulation" (Cf. Gunningham 2010 pp. 135-139) has suggested to develop Ayres and Braithwaite's vision of "enforced self-regulation", looking at systems put in place by firms themselves, and verifying their effectiveness. All of these additional models and contributions

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[367] Nothing, in the original *Responsive Regulation* model, suggests that *no other factors* should be taken into account – and, to us and to many practitioners, it is clear that they should be combined (as they are in OECD 2014) with risk proportionality. This articulation is, however, missing from the original model which, as we have seen, was rather short and conceptual in most areas.

[368] While we will return several times to the question of *measuring* effectiveness, discussing the challenges of *transforming* practices and institutions on the basis of performance evalutions would go beyond the scope of this research.

[369] For radically different approaches of fisheries regulation see e.g. Eythórsson 1996 or Runolfsson 1997. Measuring the performance of different approaches, which Baldwin and Black see as a very problematic, could arguably be done through looking at fish stocks evolution rather than at compliance. It is worth considering, in cases that appear extremely problematic, whether the reliance on command-and-control regulation, enforcement and compliance is possibly not the right approach.

consolidate the view that it is most effective to rely on a combination of tools and approaches, based on the specifics of the regulated entities and the regulations being enforced, on the context, and on prior history.

The challenges raised by Baldwin and Black (2008, 2010) also remind us of the importance of *first* thinking through whether command-and-control regulation, and subsequent enforcement efforts, have any chance of success at solving the problem at hand, and are likely to be an effective and efficient response – regardless of the specific inspection approach taken. In many cases, the answer may simply be negative, and other policy interventions will be more adequate[370] (see Ogus 1994 for an overview of other regulatory tools, and all the literature on Regulatory Impact Assessment for discussions of other policy options). Using methods that come from beyond the narrow "regulatory" field may also bring major benefits from this perspective. Increasingly, the "causal pathway" methodology[371] is being used in the regulatory and enforcement area, to determine what are the mechanisms that cause the unintended effects (increased risk, decrease in public welfare) that regulation is meant to address. The models allow to consider whether regulation is really likely to be useful and, if so, which intervention mechanisms may be most helpful (see BRDO 2013 for a practical application of this methodology).

Diverging data, diverging conclusions

In spite of some meta-studies (like Kirchler 2007) seemingly indicating some more-or-less clear trends, the data on compliance effects of different approaches is, in fact, disputed. As Simpson and Rorie (2011) put it, there are "several general traditions in this regard, each with its own logic and empirical base" (p. 59), which is a way to say that different streams of research seem to come up with data that cannot fully be reconciled. For instance, while we have quoted above Tyler at length, and his findings on the strength of procedural justice effects (confirmed by a number of other scholars), some research seems (at least at first glance) to question his confidence (in the possibility to found compliance primarily on "procedural justice" ("studies find that the primary factor shaping legitimacy, morality and rule adherence is the procedural justice that employees experience in their workplace", 2011 p. 78). Similarly, it is not certain that Hodges's (2015) confident assertion that "public enforcement based on a policy of deterrence does not "in fact [have a] significant deterrent effect" (p. 26).

In the interest of presenting the evidence in a clearer way, we have of course somewhat over-simplified the different perspectives, and it behoves the topic's complexity to add some important nuances. First, a distinction is often made between "general deterrence (premised on the notion that punishment of one enterprise will discourage others from engaging in similar proscribed conduct) and specific deterrence (premised on the notion that an enterprise that has experienced previous legal sanctions will be more inclined to make efforts to avoid future penalties)" (Gunningham 2010, p. 122)[372]. In addition, evidence "shows that regulated business firms' *perceptions* of legal risk (primarily of prosecution) play a far more important role (…) than the objective likelihood of legal sanctions" in determining general deterrence's effectiveness (*ibid.*). Thus, there is maybe not a sharp distinction to be drawn between "rational" motivations (calculations) and other drivers – since even so-called "rational" deterrence estimates are based on perceptions rather than on objective data, and perceptions appear to be strongly interrelated with values-based thought processes.

[370] A point very similar to that made by Ashworth (2000) on the excessive use of criminal law for problems where it is inadequate.
[371] Which is also widely use in a number of domains (political science, ecology, epidemiology etc.) – see a theoretical summary on Cornell Evaluation Centre website: https://core.human.cornell.edu/research/systems/theory/causalpathways.cfm
[372] The "evidence of a link between past penalty and improved future performance is stronger", suggesting that *specific deterrence* is more powerful than general one – but research shows also that "action falling short of prosecution" can achieve substantial effects, i.e. that it is more the *warning effect* rather than the punishment which matters (Gunningham 2010, p. 124).

Indeed, research suggests that many respondents struggle to "disentangle normative from instrumental motivations" (*ibid.,* p. 123).

The effect of deterrence may also vary over time, or be complex rather than linear. As Gunningham writes, "it is plausible (…) that the deterrent impact of tough enforcement may be weaker today, than it was in past decades, at least in industries that have been subject to substantial regulation for a considerable period and/or are reputation sensitive" (*ibid.*). This is clearly hypothetical, and *may* be true in some cases – while there is also some evidence that, possibly in other regulatory fields and/or countries, *new* regulation that is primarily implemented through "tough" enforcement tends to fail, and more "persuasion-grounded" efforts fare better. There also is evidence of weak deterrence effects in completely different contexts from Gunningham's. This all suggests that there may be specific contexts where the effects are stronger or weaker, which cannot however just be explained by one variable, but rather by a combination of many factors.

One study, many findings, complex interpretation

In a study of Chinese farmers, the findings of which were published in a series of papers in 2015, Yan, van Rooij and van der Heijden attempted to observe directly the actual level of compliance, and to assess the strength of different drivers through interviews. They took a very comprehensive and "non-partisan" view of compliance drivers, looking at the whole range: ability to comply (physical/economic capacity, legal knowledge), deterrence, procedural justice, prevailing social norms, and internalised moral duties (2015 b pp. 2-3). Their findings, though founded on a study of only a bit over 100 farmers, are highly interesting – and require careful interpretation.

In a first paper (2015 a), the authors simply crossed the different types of behaviour (compliant/non-compliant for three different norms on pesticides) with the different drivers of compliance (ranked as positive or negative), and examined correlations. They had several conclusions: first, that deterrence was overall limited in effectiveness, not because of an absence of correlation between probability of detection and compliance, but because high probability of detection seemed to be closely correlated with a high level of other (voluntary compliance) factors. In other words, the farmers most frequently inspected (the large farmers, as the authors found) were also those that were anyway the most likely to comply even without inspections and enforcement (pp. 7-8). Second, that "apart from deterrence, operational costs and benefits, personal norms, social norms, and, less clearly, legal knowledge all play a role in compliance" (and that this role is significant) (p. 13). By contrast, the authors found no "clear relationships between the general duty to obey the law, procedural justice and compliance", leading them to add that "these variables are not crucial aspects of voluntary compliance, and thus enforcement does not have to take them into account" (p. 11).

It is worth, however, pointing out a few points from the authors' *data*, which may support different interpretations. First, across the board, compliance (and apparent responsiveness to "drivers") is strongest for the type of regulation that is the most directly understandable and, arguably, has the greatest safety effect: the prohibition of some hazardous types of pesticides. Rules on disposal and time interval before marketing are far less well respected (a point the authors note, but do not necessarily pay enough attention to). Second, procedural justice is overall quite consistently low: most respondents have a feeling of negative procedural justice. It may simply be that, in a context where interactions with authorities are nearly uniformly marked by "rough handling" and top-down commands, farmers simply fail to register the very few exceptions as being significant. This does not *ipso facto* mean that they would not respond to a sustained experience of a different approach, or that this type of authoritarian behaviour has no negative effect (e.g. possibly on the overall respect for laws etc.). Finally, the authors' conclusion that the targeting used by Chinese inspectors (who primarily inspect the larger farms, which are found to be the ones most likely to be voluntarily compliant) is wrong can also be disputed. Their view is that this results in deterrence failing to have an impact on those

most likely to be non-compliant, and write "as a matter of principle, enforcement should be targeted especially at those types of farmers and those types of rules for which voluntary compliance is less likely" (p. 13). We will come back further below to the question of defining "risk" and of what targeting makes more sense – but from a practical perspective, targeting the highest-impact farmers is far from being irrational. Furthermore, the authors have no way to be sure that (a) frequent inspections of larger farmers have not played a role in them understanding rules better, and being generally more supportive of voluntary compliance and (b) inspections and enforcement would be the most appropriate tool to target smaller farmers and increase their knowledge and voluntary compliance (in fact, it is possible that inspections would increase costs, through time lost and sanctions, and thus further decrease their financial capacity to comply – for instance).

Their second article drawn from the same data (2015 b), but with a different analytical methodology ("crisp set Qualitative Comparative Analysis" – csQCA)[373], yields conclusions that are somewhat different, and very interesting. The most striking result is the absence of equivalence between the conditions of compliance, and that of non-compliance: "our data also point to a non-symmetrical relation between the deterrent effect of sanctions and compliance. The analyses of necessary conditions pointed out that (experienced) deterrence is not a necessary condition for compliance, but that the absence of (experienced) deterrence is a necessary condition for non-compliance (…). Our data further indicate that deterrence (as part of a set of compliance conditions) does play a marginal role in affecting compliance (in one path for one compliance behaviour), the absence of deterrence does, however, play a considerable role in affecting non-compliance (in five out of six paths for both non-compliance behaviours). This finding challenges our thinking about the assumed compliance–non-compliance dichotomy in the literature—it indicates that compliance is not necessarily the inverse of non-compliance" (p. 14). This suggests that, while deterrence may indeed be of little importance for active compliance (voluntary compliance drivers being sufficient), in order to "drift" into non-compliance, the absence of a significant deterrence effect is an important "trigger". The authors interpret it thus: "deciding to comply is not the same as (also) deciding 'not to violate'—if we decide to stick to speed limits, we likely do not (also) decide to not hit the pedal to the metal (building on insights from behavioural economics, cf., Kahneman 2011). What we observe is not a reassurance and reminder function for compliant decision making from deterrence, but the lack of deterrence as a reminder and reassurance that violation goes unnoticed or unpunished (…). This reasoning is in line with Ian Ayres and John Braithwaite's (1992) responsive regulation model, which assumes that most compliance will occur without active deterrence" (p. 15). Looking more closely at the conditions for non-compliance, one finds "the absence of a deterrent effect of sanctions, a non-positive cost-benefit analysis, the absence of (experienced) descriptive social norms, and the absence of (an experience of) procedural justice" but with "relatively low coverage scores" (i.e. weaker effect) for deterrence and procedural justice. The conditions for compliance, by contrast, include (different combinations in different compliance paths) "law as a source of moral authority", "descriptive social norms to comply", "positive cost benefit analysis", "legal knowledge", "capacity to comply", and "general duty to obey" – with "law as a source of moral authority" being present in every path.

Complex processes, nuanced conclusions

What all the evidence summarized above suggests is first that interpreting results and compliance processes finely may be vital: deterrence may well be superfluous for the majority (of voluntary compliers), but would

[373] As the authors explain: "QCA differs from other methods in its focus. 'The key issue [for QCA] is not which variable is the strongest (i.e., has the biggest net effect) but how different conditions combine and whether there is only one combination or several different combinations of conditions (causal recipes) of generating the same outcome' (…). QCA is grounded in set theory, a branch of mathematical logic that allows the study, in detail, of how causal conditions contribute to a particular outcome. A particular strength of QCA is that it can be applied to arrive at evidence-based typologies" (p. 5)

be needed (and need to be targeted) for those who are "on the brink". Second, the fundamental drivers appear to be social and personal norms and ethics: accepting the law as source of moral authority, following social norms, feature as the strongest drivers. Third, capacity to comply is also crucial: financial and physical, as well as (to a lesser extent) legal knowledge – but also cost-benefit analysis. In other words, norms that are realistic given prevailing conditions, well explained and communicated, and tailored so as to be economically viable, stand the best chances of success (a relatively unsurprising finding, one may add, but still an important one). Finally, the variables that correspond most closely to traditional "enforcement" (both deterrence and procedural justice) appear, in fact, the weakest (and this second paper puts procedural justice alongside deterrence, somewhat nuancing the conclusions of the first one). What fundamentally matters is whether citizens (including those that work in businesses) adhere to norms that make them comply – not whether they are checked frequently, and how. Inspections and enforcement work at the margin. Precisely because they work at the margin, we would add, means that they should use each and every tool at their disposal (including procedural justice) to be more effective – because affecting social and individual norms is, at best, a long-term undertaking[374]. In fact, all these findings (including the importance of information) all match what many practitioners know and do, at least in what one could call "smart inspections" regimes, as we will discuss in the third section.

Thus, the overall importance of "enforcement" aspects for compliance may be relatively weak compared to deeper, longer-term factors – and in addition the respective strength of different aspects and factors is, as we have seen, not so easy to ascertain, and/or varies according to circumstances. In addition, different approaches carry some trade-offs, that are in evidence in a number of studies.

Charting a course in spite of uncertainties

There may be some ways to move forward, and try and make sense of inspections and enforcement methods, in spite of these uncertainties. This requires first to understand how *context* may cause differences in results, then to acknowledge the *limitations* in methods and findings – and finally to suggest *alternative* sources of evidence.

Context and typologies

The models of compliance we have outlined above seem to a significant extent to be contradictory, and conflicting research findings do not lead to an easy way to decide upon their validity or to reconcile them (even though some models do seem to be more strongly validate than others). This creates difficulties for our research object, since the question of compliance drivers is essential in order to provide a foundation for the choice between different enforcement approaches. A way to make sense of these contradictions, and to end up with a model that somewhat reconciles different drivers and perspectives, is to consider *context* and *typologies.* Context, because one of the reasons different models appear to be validated (or invalidated) by different studies may be that some compliance drivers are stronger (or weaker) depending on the broader circumstances where they apply. Typology, because it may also be that different drivers apply to varying

[374] Simpson *et al.* (2013) reach a somewhat similar conclusion in their assessment of crime-control strategies for corporate environmental crime: "First, both informal sanctions and command-and-control strategies lower the likelihood of corporate crime. The risk of corporate offending increases when there is not a credible legal threat or when one's duty to behave ethically is not reinforced by colleagues or through fear of informal sanctions. Second, the deterrent capacity of these control mechanisms does not negate certain corporate or individual risk factors, which remain significantly associated with noncompliance. This suggests that current policy levers do not fully mitigate offending risks and may indicate that a one-size-fits-all policy is shortsighted." (p. 267)

extents and with varying strengths to different types of people (or of groups of people). This is what we will now attempt to consider.

As Kirchler (2006) puts it, the research on tax compliance has come into its own "as a research area within economics and economic psychology", and studies have "considerably increased" over a few decades, but there is serious concern "since the results obtained in different studies are heterogeneous" (p. 1). The way he suggests to make sense of these (apparent, at least) contradictions is that "some heterogeneity in results can be reconciled by considering the relationship between the authorities and the taxpayer". In other words, the drivers of compliance may be different (or at least have different relative salience) in a "*cops and robbers* climate" and in a "*service for clients* climate" (*ibid.*). In a climate of distrust, the primary driver will be deterrence, based on rational calculations – so compliance will occur only if detection and sanctions are really credible. In a climate of trust, social representations, norms and fairness perceptions will be the main drivers (pp. 1-3). From this, Kirchler proposes a model of three-dimensional representation of compliance, whereby the dimensions are compliance, power of authorities and trust in authorities (pp. 8-9). An enforced compliance approach will tend to succeed only if it can maximize power, a voluntary compliance one if it can maximize trust – and there is a significant amount of trade-off between the two, because "sharp undifferentiated control" and "severe punishment" tend to result in a sharp reduction of taxpayers' willingness to comply voluntarily (p. 6). In other words, different findings e.g. regarding the effectiveness of deterrence activities, or of procedural justice aspects, may reflect at least in part different contexts[375], in which ongoing relationships between administration and taxpayers have shaped certain attitudes and expectations[376].

Clearly, such aggregate differences also cover different types of compliance profiles within a given society – linked both to individual and social differences, resulting e.g. in differences in perceptions of fairness (p. 16). This results in different profiles, "motivational postures" as V. and J. Braithwaite have called them – ranging from "commitment" through "capitulation", "game playing" and "disengagement" through "resistance" (p. 17). As Kirchler points out, such findings strongly support the "responsive regulation" approach, which allows to tailor the type of response to the type of regulated person or entity, and to minimize the use of deterrent enforcement (thus minimizing the negative responses which weaken voluntary compliance).

Another possible typology, proposed by Elffers and Hessing (1997) and taken up by Voermans (2014) distinguishes "conformist compliers" ("those who comply with rules only because they fear punishment"), "identifiers" ("comply with rules because they want to belong to a social group for which compliance is the norm") and "internalisers" ("who comply with rules because they have made these rules part of their own world view")[377]. These different types require different responses: sanctions are superfluous for the third group, and have an indirect effect on the second (serves to "maintain the social norm" by showing that infringements are punished). For the first group, sanctions *can* be effective but need to be "*certain*, *quick* and *severe*", which is difficult to achieve – and may be counter-productive, as we have seen that systems which deploy an excessively harsh deterrence approach tend to weaken voluntary compliance.

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[375] This perspective is very important because it also suggests that it may be difficult to move from one approach (*cops and robbers*) to the other (trust-based). This is certainly what our experience in post-Soviet states suggests. Years of outright hostility from inspectors towards businesses have yielded a situation where gaming the system is the norm, trust is non-existent, and moving to a better situation is extremely difficult. The situation in these countries also strongly validates Kirchler's concerns about how to "control the controllers" in systems based on distrust. Indeed, inspectors in such countries tend to abuse their powers routinely – and this is a risk in any system where regulated subjects are seen as suspects, and controllers vested with very strong powers (and few checks and balances).

[376] Taking also into account, as Kirchler emphasizes, that "perceptions" and "representations" (what people think about the authorities, the tax system etc.) are in practice more important than "what actually is" (p. 13) – and that what is fundamental is the overall "aggregate" of "knowledge, attitudes, norms, perceived opportunity, fairness considerations and motivational postures", i.e. "tax morale" (p. 17).

[377] Voermans (2014) p. 57.

Gunningham (2010) lends additional support to such views by indicating the complex, intertwined workings of "normative" and "instrumental motivations": many business operators "wrestled with the temptation to backslide when legally mandated improvements proved very expensive" and "many acknowledged that, in the absence of regulation, it is questionable whether their firms' current good intentions would continue indefinitely – not only because their own motivation might decline, but because they resented others 'getting away with it'" (p. 123)[378]. He also warns against the other downside risk, which may materialize when excessively harsh and "across the board" deterrence approaches are used – fostering a "culture of regulatory resistance", and "being counter-productive as regards corporate leaders who respond badly to an adversorial approach" (even as it may be "effective when applied to the recalcitrant and perhaps to reluctant compliers") (p. 124).

It is difficult, of course, to estimate how many businesses or operators may belong to each category. Bardach and Kagan (1982), suggested a rule of thumb of 20% of "bad apples" and 80% of "good apples" (p. 65), founded on several studies and testimonies. In particular, they reported that a "study of housing code enforcement in New York City found that 65 percent of recorded violations were attributed to 12 percent of all multiple-dwelling buildings" (*ibid.*). They also quoted the reflection of the WWII head of the Office of Price Administration in the US, Chester Bowles, that "20 percent of the regulated population would automatically comply (…) simply because it is the law of the land, 5 percent would attempt to evade it, and the remaining 75 percent would go along with it as long as they thought the 5 percent would be caught and punished" (pp. 65-66). The authors' conclusion is that "the absolute and relative proportion of good apples is large, almost certainly constituting a sizable majority (…) with respect to most regulatory domains". They note that "the absolute number of bad apples is also large" but that "ready recourse to coercion" and "uniform, specific regulatory prescriptions" that may be necessary for "bad apples" can, when applied to "good apples", lead to a "considerable amount of unreasonableness" and unintended adverse consequences (p. 66).

Building on these different but concurring views, it is worth adding that these typologies need not be understood as categories in which businesses, or people, can be ascribed permanently. Depending on the circumstances, the type of rule being considered[379], the administration with which one is dealing, the same person may have very different behaviours, and could be categorized in one or the other group. This is even more true when considering a complex entity such as a business, where different workers and managers may be significantly different. If this perspective is correct, then indeed different findings may simply reflect different situations, and the "optimal" enforcement strategy would be one that seeks to combine all different drivers[380], with careful attention to the risks of negative interactions between them, e.g. of deterrence weakening voluntary compliance. "Responsive" and "smart" enforcement would appear to fit best with such a perspective.

Limitations of methods

Science in general is difficult and, by definition, provisory and uncertain (radically so if we take Popper's definition of science as being characterized by "falsifiability"). Social science and psychology are made even more difficult by the complexity of their objects, and the considerable difficulties involved in measurement.

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[378] See also *ibid.* the risks when excessively "persuasion-based" enforcement strategies "degenerate into intolerable laxity" (p. 125).

[379] As we have seen above in Yan, van Rooij and van der Heijden (2015 a), compliance levels differed strongly for three different types of rules, and this could not be explained fully by differences in probability of detection. Illustrations of this point are easy to come by, and it is frequent to find that the same person will have different attitudes concerning different parts of the traffic rules, or between the tax code and the prohibition of theft and murder, for instance.

[380] A related perspective is that of Badarch and Kagan (1982), whose model is fundamentally deterrence-based, but who acknowledge the number of adverse, unintended consequences of "pure deterrence", and seek how effects could be achieved at lower costs, and with less adverse effects on compliance through deterrence-induced "resistance" (see pp. 96-97).

Kirchler (2006) points out many of these issues in relation with tax compliance: difficulty to measure evasion, different definitions of concepts, etc. He finds, in particular, significant problems with surveys, because of lack of correspondence between "respondents' self-reports of tax evasion and officially documented behaviour". He also points out the limitations of models, which inherently tend to reduce complex phenomena to a limited number of variables (p. 17-18). A recent major study looked at the "reproducibility of psychological science" and found that a large proportion of original findings could *not* be replicated (only 36% of replications resulted in a statistically significant effect that was similar to the original one – while in a number of other cases the results appeared to be somewhat similar, but not fully statistically significant etc.)[381]. As the authors emphasize, "how many of the effects have we established are true? Zero. And how many of the effects have we established are false? Zero. Is this a limitation of the project design? No. It is the reality of doing science, even if it is not appreciated in daily practice. Humans desire certainty, and science infrequently provides it. As much as we might wish it to be otherwise, a single study almost never provides definitive resolution for or against an effect and its explanation." Accepting and understanding these limitations is essential (and, we would add, not always understood, both by scholars and by those who use their results). This is a very complex field of research, and one that is only a few decades old. Studies generally have a number of limitations, including size. Thus, rather than expecting total certainty, we should draw from this wealth of findings a nuanced view, with more frequently convergent results suggesting that some effects may be stronger or more reliable than others[382].

Putting too much faith in the result of one or a few studies is one risk. Putting too much faith in explanatory theories and models is another one. As Ariel Rubinstein, one of the founding fathers of game theory, himself wrote: "there are those who believe that the goal of game theory is ultimately to provide a good prediction of behavior (…) I am not sure on what this vision is based". He adds, "then there are those who believe in the power of game theory to improve performance in real-life strategic interactions. I have never been persuaded that there is a solid foundation for this belief" (p. 634). He suggests, by contrast, that "the object of game theory is primarily to study the considerations used in decision making in interactive situations. It identifies patterns of reasoning and investigates their implications on decision making in strategic situations. According to this opinion, game theory does not have normative implications and its empirical significance is very limited. Game theory is viewed as a cousin of logic. Logic does not allow us to screen out true statements from false ones and does not help us distinguish right from wrong" (*ibid.*). This is an important reminder. Ayres and Braithwaite, in *Responsive Regulation* (1992), had an entire section (pp. 60-81) devoted to a game theory perspective of "tit-for-tat" and tri-partism. While they acknowledged the limitations of the model, Rubinstein's words should serve us to take such models *in general* with caution[383]. They can be useful as explanations of what the authors think, and of logical interactions, but putting too much confidence in their explanatory or predictive power is fraught with dangers. Once again, we are led to a posture that is one of modesty: no explanation or model is likely to have all the answers, and trying to combine different perspectives may be a safer and sounder approach.

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[381] Open Science Collaboration (2015) – full text available at: http://www.sciencemag.org/content/349/6251/aac4716.full#corresp-1. Since the authors first screened the studies for which replication would be attempted, and only took those that cleared a number of quality hurdles, the percentage from *all* studies (taken at random) would be even lower.

[382] A good example of how scope and duration may produce interesting results that may not be visible otherwise is provided in Wittberg (2006). In the experiment he relates, the Swedish tax administration undertook a long-term campaign to strengthen "tax morale" through education, and regular (large scale) surveys to measure changes. The results appeared to be strongly positive – meaning that the fundamental social norms that are one of the foundations of compliance could be gradually changed (and that this could be measured). But such experiments have so far been very rare. Having more will require a substantial amount of time.

[383] One particular obvious weakness of game theory is its reliance on rationality – examples of real-life negotiations, such as those involving Greece and the Eurozone in the first half of 2015, show by contrast that actors are driven to a very large extent by ideological considerations and a variety of values. Had rational interest been the sole mover, and actors been entirely rational, the outcome of these negotiations would most likely have been very different, and come far earlier.

Looking for evidence

Caution about the strength of studies' results makes it more difficult to develop conclusions that may serve for further development of evidence-based policy making, and of evidence-based inspections and enforcement approaches in particular. If evidence is inconclusive, then deciding between competing views is hard. As we have seen, evidence is certainly not *fully* inconclusive. There appears to be many studies finding compatible or partly similar results, and ways to reconcile many of the apparently contradictory findings. Still, for all the reasons listed above, the foundation for evidence-based inspections, if it were limited to these different studies and models, would not appear to be as solid as we would wish it to be – and making any conclusions about, for instance, the effectiveness of risk-based inspections would be difficult.

What we will undertake to do in the third section of this research (after concluding this theoretical section by looking at research on risk and regulation) is, precisely, to look for such complementary, alternative evidence basis. As Kirchler (2006) and others have pointed out[384], the past decades have seen a number of inspections agencies (in the tax field as in others) transform their approach, moving for instance from a strict deterrence approach to a more "compliance-based" or "responsive" one. Some agencies have moved strongly in the direction of more risk-based inspections. Others, in the same or in nearby jurisdictions, have not done so.

For all these reasons, we believe there is value in looking for evidence in a different way – not only through focused studies (which yield more details and better attribution, but have a number of problem, as we have seen), and rather by comparing practices and aggregate outcomes of different inspection systems. A first possibility is to consider changes over time in the same jurisdiction - and a second one is to compare across different jurisdictions. The first approach is possible when there is a clear change (or at least a strong inflexion) in practices over a well-defined period of time, and when data on practices outcomes is available for the same period. The second is feasible when two or more jurisdictions, which are otherwise sufficiently similar, present sharply contrasted inspections practices, and have data of good quality and adequate for comparisons. We will see when considering concrete cases (in the third section) that it has proven more feasible to find examples of the second case than of the first – but at this point we will limit ourselves to a few clarifications of method.

When attempting to compare practices *and outcomes* between countries, or across time, the two parts of the comparison pose radically different problems. Outcomes, on the one hand, are relatively easy to define, at least for some of the major inspection functions: for instance reducing as much as possible occupational injuries and deaths, or deaths from food-borne diseases. The (considerable) problems stem from data reliability (often problematic, because of under-detection or under-reporting)[385], and even more strongly from attribution: how much can the level of a given indicator in a jurisdiction, and its evolutions, be attributed to inspections practices, which generally have only a minor influence compared to economic, technical, social and cultural factors? Practices, on the other hand, pose far less problems of attribution – even though they may be shaped by a number of factors, our main concern here are not the causes, but the practices themselves. Measuring them is, to some extent, difficult, because data on targeting is not public in most cases, and because the "qualitative" aspects can of course vary considerably between different inspectors, localities etc. We will see that *in practice* this potential difficulty can be to an extent overcome because the differences between different jurisdictions are in certain cases so considerable that, at least in first approximation, the underlying nuances can be discounted. Remains attribution as the main problem.

Here, there is certainly no perfect solution, and moving forward requires a set of assumptions. First, that while there are many factors influencing outcomes such as occupational safety and health, if all major known factors

[384] See in particular studies in Elffers, Verboon and Huisman (2006) and in Parker and Lehmann Nielsen (2011).
[385] And also, frequently, from different data definitions, but these can often be overcome.

are relatively constant, and only inspections practices are known to be different (either across jurisdictions, or because they have changed), then one can tentatively posit that the differences in inspections practices *may* be the explanatory factor. When comparing across jurisdictions, this means taking as much as possible countries that are similar in most relevant respects (economic profile, social and political structure, technologies, even natural conditions, etc.)[386]. When comparing across time, it means making sure that none of these major factors have changed – and, because in most cases they *have* indeed changed (in particular technology, economic structure etc.), comparisons across jurisdictions are more frequently possible. An alternative, sometimes interesting approach is to take jurisdictions that are significantly different (thus making the comparison clearly imperfect), but have extremely contrasted inspections practices, and outcomes that are also different but in the opposite direction from what certain models would predict. This may yield important lessons about the need to refine or qualify such models.

There is, of course, a major limitation as to what such comparisons can yield. Even if we were to have series of data long or large enough to calculate correlations (which is not the case, and we will thus not attempt such calculations), correlation is *not* causation. We cannot be claiming to prove, in any way, causation. Rather, what we are attempting to do is to find whether there is additional evidence that either aligns with what certain models and studies propose (and thus could strengthen their findings), or on the contrary lead to question or nuance some of them. What we hope for, is that the accumulated evidence may, without yielding certainties in any way, at least suggest fruitful directions for both research and practices.

ii. Compliance promotion and discretion – legal questions

Instrumental and expressive visions of the law – can tensions be resolved?

These considerations on compliance promotion and the relative effectiveness of different approaches were made from a strictly utilitarian, instrumental perspective. Such an approach is well summarized by Hodges (2015), who writes: "the purpose of regulation is to affect behaviour and performance. The purpose of 'enforcement' should be to address issues of behaviour and performance, not simply to impose sanctions in the expectation that they will affect behaviour" (p. 26). Hodges himself acknowledges that there are other principles and issues at play when considering enforcement (and tort law). Enforcement should "censure" certain actions: "it remains important for an ethical society, which supports people having respect for the prevailing moral norms, that certain behaviour should be declared to be socially unacceptable and to 'deserve' the imposition of criminal sanctions by the state (alone)218 as retributive censure for a wrongful act, and that some sanctions should be proportionate to the seriousness of the unacceptable acts" (p. 26). And tort can have a role for "securing compensation" (p. 3) – even though Hodges concludes it is highly inefficient at this task and should be generally replaced by administrative compensation systems (p. 7).

The difficulty is first, of course, that it is not that easy to define which are the cases which are serious enough to "deserve" criminal sanctions – but there are approaches to this aim, combining risk assessment and intent of the actions, and we will discuss them in the third section. The challenge to such a viewpoint is more fundamental, and comes from those putting forth a fully different vision of the law, one which is anchored in different *values.* Hawkins (2002) refers to such approaches as reflecting an "expressive" conception of laws. Ashworth (2000) is one of their exponents, and defines it thus: "my conception of the criminal law gives

[386] An example that we use in the third section is comparing Britain and Germany. Evidently, there are major differences between the two, but there also are major differences *within them*, between different regions and localities, which in some cases may well be greater than the differences in averages between the two countries. Economic structure, social patterns, etc. are all indeed different between the two – but, as we will argue further in more detail, considerably close when comparing them to most of the rest of the world.

primary place to its censuring function (…) which should be exercised in as fair and non-discriminatory a manner as possible". Scholars which consider the *expressive* value of laws as fundamental tend to take exception to the "responsive regulation" approach (and later approaches building on its fundamental vision of a need to *differentiate* the regulatory response). Yeung (2004), for instance, writes that: "the Ayres and Braithwaite model (…) overlooks the constitutional values of proportionality and consistency, which are themselves rooted in the right to fair and equal treatment". What she identifies as the key tension between her perspective and the responsive regulation approach is that the latter adopts as "reference point the goal of effective future compliance, rather than the nature and seriousness of the defendant's violation". By contrast, Yeung (and others) consider that individual rights (to a fair treatment etc.) should take precedence over effectiveness considerations. She suggests that, in fact, the responsive regulation enforcement pyramid may conflict with "the requirements of procedural fairness" (which in addition would mean that, even from a utilitarian and instrumental perspective, the approach would have problems since it could weaken one of the compliance drivers).

How much should we be concerned about such values-based concerns? We would argue here that some of the tensions can be decreased by looking more closely at how a compliance-focused enforcement approach works – but that not *all* tensions can be removed, as some fundamental divergences will remain. Looking more closely at Ashworth's arguments, he in fact makes the case for his approach *in the realm of the criminal law* – not for all types of regulations. While in a specific context such as the UK's many regulatory offences are indeed "criminalized" by statutes (but in fact rarely prosecuted, cf. Hawkins 2002 *et al.*), in most other countries the majority of regulatory offences is covered by lesser *administrative penalties* (reflecting differences between common law and civil law countries, to a large extent – even though administrative sanctions are being gradually introduced in the UK as well, cf. Tilyndite 2012 *et al.*). Ashworth states that he does not "suggest that the prevention of harm is irrelevant to criminal law: it remains significant as a fundamental justification for having a criminal law with sanctions attached". He further suggests that the problem may be the over-reliance on criminal law, whereas there are "a range of initiatives in social, criminal and environmental policy" that could be used for the "prevention of harm". His recommendation is that "the aim should be to produce a set of criminal laws that penalise substantial wrongdoing and only substantial wrongdoing, enforcing those fairly and dealing with them proportionately".

These statements by Ashworth are not necessarily in contradiction with Voermans's assertion that "rules and regulations that are not systematically observed are – in the end – pointless and futile. The overarching aim of all regulation is to have an effect on (social, economic, or institutional) behaviour" (2014, p. 42). The main difference may be that legal scholars who consider consistency and proportionality to be too fundamental to suffer "modulations" as part of a responsive approach would contend that inadequate criminal laws should be repealed, rather than enforced in a "flexible" manner. Proponents of an instrumental approach, by contrast, may contend that perfectly designed laws and regulations will never exist (even assuming that best efforts are made to improve them, the impossibility to achieve an "optimal precision" of rules has, as we have seen, been rather convincingly demonstrated). In such a universe of imperfect rules, where discretion is unavoidable, we should seek to *structure* discretion in a way that is as *effective* as possible. Effectiveness is indeed doubly important: first because *effects* are precisely what the rules are adopted to achieve, and second because if they are ineffective "the authority of the legal rules themselves may be compromised" (Voermans, *ibid.*). There is thus a values-based, rule of law case to be made *for* inspections and enforcement approaches that target improved compliance – because ineffective laws undermine the very idea of the rule of law[387].

[387] And, we would add, there are many examples of criminal legislation which have consistently and fully failed at their stated goals, and indeed produced major side effects that go counter to these goals, such as drugs criminalization – and remain nonetheless on the

Looking more closely, the is partly one of whether, and how, to apply discretion. If we accept that there is no "optimal precision of rules", then discretion is unavoidable as rules will always require some interpretation, except if they are so narrow as to become essentially useless, and even counter-productive in many instances (cf. Diver 1983, Baldwin 1995). Even if one were to attempt and remove as much discretion from inspectors' and other officials' hands, judicial discretion would remain in considering cases. The question then becomes how to structure this discretion, how to "frame" it. As Bardach and Kagan (1982) put it, "while there are powerful (…) reasons for regulators to treat all regulated entities more or less "alike" (…) under certain conditions it may be possible to justify *dissimilar* regulatory treatment" to achieve "more reasonable regulation" (p. 92).

There are, of course, scholars (and policymakers, judges etc.) who would contend that decisions can be made essentially "without interpretation" of the rules' meaning, at least in most cases. A particularly famous proponent of this view is Justice Scalia of the US Supreme Court, who wrote in *The Rule of Law as a Law of Rules* that it is essential to avoid "uncertainty regarding what the law may mean" (Scalia 1989, p. 1179). While cautious to admit that there will always be cases where "legal determinations that do not reflect a general rule" cannot be avoided (pp. 1186-87), he nonetheless advocates for making decisions as much as possible that "adhere closely to the plain meaning of a text" (p. 1184). In spite of reading very pleasantly, and of some of its caution, we think Scalia's "originalist" or "textualist" vision does not stand close scrutiny. Following Black (1997), there is good reason to think that rules are essentially "indeterminate" because of the limitations and nature of language, even before considering the questions of their anticipating situations while being unable to predict all future events, and of the social context through which their misleadingly "obvious" text has to be understood. Other scholars, commenting specifically on Scalia's thesis, have shown its weaknesses. Strauss (2008) for instance writes that "he choice between rules and discretionary standards confronts legislators and regulators routinely. It also confronts judges, or at least Supreme Court justices. The *Rule of Law as a Law of Rules* is an elegant and appropriately cautious defence of the position that rules are, as a general matter, superior" but adds that "rules in constitutional law, like many other things in the world, are most often the product—the ongoing, unfinished product— of evolution" (p. 1013) – meaning that they cannot be derived from the "plain meaning" of the legal text. Solum (2002) takes a more radically critical view[388] and writes: "The rule of law does not require a law of rules; nor does a law of rules guarantee the rule of law. The problem of judicial constraint is not that simple, and the strategies that are adequate to advance the predictability and uniformity of the law defy easy summary. The rule of law requires sound practical judgment by judges of integrity" (p. 23).

Let us conclude this short discussion by acknowledging that tensions between conflicting views of the law, and of its enforcement, can certainly not all be reconciled. There will remain a side of the debate where the preference is for consistency and predictability, and which holds the discretion can be minimized, if not abolished. This does not mean that the instrumentalist vision of regulation advocates unbridled discretion, quite the contrary – but that it holds discretion for unavoidable, and thus considers that it is best addressed by embracing it, and trying to give it a transparent and predictable framework (to the extent possible). We would also argue that such a framework should also try and give some guidance on how to determine the facts themselves, for facts are often no more "obvious" than the meaning of legal texts[389].

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books. Thus, laws that are designed with a purely expressive approach, and without consideration for an instrumental perspective, tend to be deeply problematic.

[388] But definitely not because the author would be instrumentalist – he in fact writes about the "vice of instrumentalism" in judicial decisions (p. 23).

[389] The determination of facts is a problem more frequently addressed in a judicial perspective, but is in fact often a serious issue in regulatory matters. From our original training as a historian, we have learned that "facts" in human matters are highly problematic –

Framing discretion

Administrative discretion – theoretical overview

In spite of the many real differences between different legal traditions and systems, we would argue here that *to a first approximation* all major jurisprudences allow for a degree of administrative discretion, and it is more a matter of how it is defined and bound, than of *whether* it exists. As Bardach and Kagan (1982) showed, even when an administrative agency purports to be enforcing very detailed rules strictly "by the book", it is often impossible in practice, and "the needed flexibility, in such agencies, traditionally is attained by not enforcing the rules literally" (p. 37)[390]. Certainly, there are cases where officials and judges *refer* to fundamental legal norms that are country- or system-specific to justify or explain the refusal or reluctance to use certain forms of discretion (cf. Rothstein, Borraz and Huber 2013 for the specific example of France and Germany in relation to risk-based discretion). Similarly, we have heard from government lawyers in countries as distant as Mongolia and Ukraine that it was "impossible" to give discretion to inspectors to enforce certain norms and not others. The question of what discretion covers, and of what is allowed within it, is thus a relevant one. Unbound discretion leads to serious problems of lack of consistency (cf. Bardach and Kagan 1982, pp. 86-87), which are to be balanced against the benefits of flexibility. While we certainly cannot treat the issue here in its full depth and complexity, we will nonetheless attempt to set down a few markers.

As Voermans (2014) writes, "the duty to implement and enforce laws is generally perceived as something required by the rule of law" but "although public authorities in the rule of law-based jurisdictions are under the obligation to implement law, and enforce it if necessary, they do not have total discretion in doing so. Implementation and enforcement activities generally need to have a basis in law as well, and the law itself sets conditions for implementation" (p. 46). In other words, the first limitation on discretion is one on *how much* the state authorities can do, *how much* power they can wield. This includes fundamental principles such as *nulla poena sine lege priori* (non-retroactivity of laws), *lex certa* (clear definition of what is prohibited) and proportionality (*ibid.*). While there are many countries where these principles (while they may exist on the books) are not respected in practice, there is no disagreement among scholars as to the *legitimacy and appropriateness* of these limits on discretion – what we could call "ceilings" on what state officials can do. Rather, what is cause for disagreement are the limits on *how little* the authorities may do without violating their duties, of what would be the "floor" on discretion.

If one looks at practices, it is clear that there is essentially no case of absolute, full enforcement of any law – simply because means for enforcement are inherently limited. Even in the case of murder, for which Tyler (2013) points out that this is where deterrence can (at least in many countries) work most effectively (in principle) because elucidation rates are high (because society has agreed to allocate massive resources for each case), elucidations are clearly not 100%, and police resources *are* limited. This is even truer for other violent crime, and considerably more true for non-violent crime, and many regulatory issues. Thus, *de facto* the state exercises "downwards discretion" in not inspecting and enforcing "everything, all of the time" – because it would be impossible. One can also frequently observe that governments delay preparation and adoption of secondary legislation, in countries where it is absolutely needed for laws to function, in many

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the naïve confidence of the "positivist" school having long been set aside (see e.g. Delfau 1978 on the evolution of historical thought, through positivism and away from it).

[390] Quoting a 1972 article by P. Schuck: "The inspector is not expected to enforce strictly every rule, *but rather to decide which rules are worth enforcing at all*. In this process, USDA offers no official guidance, for it feels obliged, like all public agencies, to maintain the myth that all rules are rigidly enforced" (in Bardach and Kagan 1982, p. 37). If such a picture has more general validity (which our experience suggests), then discretion is unavoidable, and trying to negate and repress it only makes it more arbitrary – acknowledging it openly allows, by contrast, to give it a clear, transparent, consistent foundation, for instance risk proportionality.

cases presumably because of lack of resources (both for drafting and for enforcement)[391]. If, in practice, "less-than-complete" implementation of laws is commonplace, remains the question of whether it is *legitimate.* This, in turn, can be examined both through legal doctrine, and through the possibility (or lack thereof) to *sue* the government (or any agency reporting to the executive) for inadequate enforcement of a statute.

At its root, the question is a constitutional one – and the very existence of an *executive branch* supposes that it has some power that is *independent* or at least *distinct* from the legislative one. In this sense, discretion is consubstantial to the existence of an executive power. Moving to specifics, however, the question appears far less clear-cut. It would reach far beyond the scope of this research to consider it seriously in a number of different constitutional and legal settings. What we will attempt to do is just give brief illustrations of why there is reasonable basis to consider that, in most contexts, there will be sufficient room for discretion in existing legal norms and principles to accommodate the enforcement practices that pertain to "risk-based inspections" and "smart inspections and enforcement". Investigating in more depth to what extent, and through which legal means, this can effectively be done in each given jurisdiction will be a task for further research.

In France, the question of administrative discretion corresponds to the "*pouvoir d'appréciation*" – which is foreseen by some laws, and not by others (or can be made necessary because several different principles are in conflict[392]). Administrative courts have the power to review administrative decisions (including, possibly, decisions "not to act") – and the administrative jurisprudence of the *Conseil d'Etat* has established principles that define and limit (in some cases) the ways in which the executive branch and administrative bodies can exercise discretion. When the applicable law or other norm has vested the public administration with a "bound competence" (*"compétence liée*") then there is no discretion – and the administrative courts will invalidate any administrative decision that did not strictly implement what the norm required. By contrast, when applicable law gives "discretionary power" (*"pouvoir discrétionnaire*"), the control by administrative courts will be more limited[393]. While in earlier times judges used to refuse to exercise strict review for decisions pertaining to an area of discretionary power, case law has moved towards a control of whether the public administration did not commit a "manifest error of judgement" ("*erreur manifeste d'appréciation*"), in other words a control that is not only of legality, but of opportunity[394]. Typically, administrative judges will defer to administrative decisions in cases that are highly technical. In some cases, judges apply a strict scrutiny, looking at whether the decision taken is overall proportional to the *costs and benefits* of the situation. In such situations (which, overall, are quite rare), judges in practice replace the administration's discretion with their own[395]. In some instances, the *Conseil d'Etat* has done so in order to substitute a *stricter* or *harsher* decision to the administration's relatively more flexible one[396]. From this short summary we can conclude that: (a) in a number of cases, administrative discretion indeed is present (basically, every time it is not excluded by the wording of the law) – (b) administrative case law takes into account cost-benefit and proportionality

[391] This is relevant e.g. in France, where many laws simply cannot be enforced without the additional level of precision given by Cabinet decrees (and this duality is foreseen by the Constitution). Since most laws adopted by Parliament are the reflect of a strongly executive-led majority, the frequently observed delays are not typically the reflection of political splits between Cabinet and Parliament, but of sheer overload (driven also by excessive legislative "production").

[392] There is for instance a directly applicable constitutional principle of "reconciling the protection and valorization of the environment, economic development and social progress" (Tifine 2014, Second Part, Chapter 1, Section I – accessed on 30/8/2015 at http://www.revuegeneraledudroit.eu/blog/2013/08/21/droit-administratif-francais-deuxieme-partie-chapitre-1-section-i/#.VeLnYtLS2zk)

[393] Cf. Tifine 2014, Second Part, Chapter 2, Section II, par. I – accessed on 30/8/2015 at http://www.revuegeneraledudroit.eu/blog/2013/08/17/droit-administratif-francais-deuxieme-partie-chapitre-2/#.VeLn4tLS2zk. In this latter case, in fact, a first type of error ("erreur de droit") would be for the public administration to disregard the fact that it had, in fact, discretion.

[394] Cf. Tifine 2014, Second Part, Chapter 2, Section II, Par. II A

[395] Cf. Tifine 2014, Second Part, Chapter 2, Section II, Par. II B

[396] See e.g. Tifine 2014, *ibid.*, sub-point (b) – and Eliakim (2013) (chapter *Pour quelques centimètres de trop*)

considerations, at least in a number of cases and (c) in some instances, administrative judges will overrule the public administration with their *own* discretion. Moreover, if we consider not administrative but *criminal* law instead (in the cases when regulations foresee criminal liability for some violations, which is decidedly less common in France than in the UK, for instance), the discretion *not to prosecute* is even clearer, and is a fundamental principle ("*principe d'opportunité des poursuites*"). When the public prosecutor is informed of facts that "constitute a violation", the prosecutor decides "whether it is opportune" to either "initiate prosecution" or "initiate an alternative procedure", or "to close the case" (Art. 40-1 of the Code of Penal Procedure)[397]. While there can be an appeal of this decision (to a higher ranking prosecutor), and while civil action is not excluded, this prosecutorial discretion is not limited – not initiating a prosecution is purely a matter of judgement.

The oft-stated difference between "Continental" or "Civil Law" systems and "Anglo-Saxon" or "Common Law" systems, which in any event is generally a woeful over-simplification[398], appears of little relevance to the matter of discretion, at least as far as the *principles* are concerned (the mechanisms of action and litigation being, evidently, country-specific). First, administrative discretion is grounded in the principles of *comity* and *deference.* The first "is the respect that a public authority ought to show for the work of another public authority", and is in a way nothing else than "respect for the separation of powers" (Endicott 2015, p. 20). The second derives from comity will posit that "it takes some special reason for the court to interfere with [a given] decision maker's answer to" the initial question at hand (*ibid.*, p. 234). Deference requires to pay attention to the "legal allocation of power", "expertise", "political responsibility" and "processes", four reasons for which the initial decision-maker may be in a better position to decide than the court (*ibid.,* p. 234-235)[399]. In spite of this, however, there *are* situations when the "presumption of non-interference by courts" (*ibid.*) can be over-ruled. This involves situation which are not defined as *discretion* but as *arbitrary*, *abuse of power* or *unlawful exercise of power*. Different criteria can be applied, which include: "fraud and corruption", "bad faith or malice", "use of a power for a purpose that is contrary to the statute" and taking into account considerations that are "irrelevant" to the purpose of the statute being enforced (*ibid.,* p. 230). An alternative "check-list" includes: "error of law", "irrelevance" (of matters considered in the decision), "absurd" decisions and "bad faith" (*ibid.*, p. 239). The criteria are not unlike those used in France, including the "absurd decision" criterion which is similar to the "*erreur manifeste d'appréciation"*: "if the judges are able to say that no one *in the position of the public authority* could present the action in good faith as a genuine exercise of their discretion, then the judges can interfere (…) with no breach of comity" (*ibid.,* p. 237). Deference applies to judicial review of decisions that are political in essence (e.g. budget decisions), which are either excluded ("non-justiciable", e.g. an Act of Parliament[400]) or deserve "massive deference" – but it also applies to "administrative" decisions in the narrower sense, as long as the authority making them is vested with some discretion. The latter can arise from a number of situations: "express discretion" and "implied discretion" arise from the wording of a law that gives specific powers to a decision maker (either *expressly* giving discretion, or leaving the power to act or not open, i.e. giving it *implicitly*), while "inherent discretion" relates to a power that "is essential if the body is to carry out its role" and "resultant discretion" arises when the wording of a statute is sufficiently vague to require a substantial degree of interpretation (*ibid.,* pp. 243-245). From a regulatory perspective, it is worth noting that courts "defer massively" to administrative authorities e.g. in matters of planning (*ibid.*, p.

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[397] Accessed on 30/8/2015 at http://legifrance.gouv.fr/affichCodeArticle.do?cidTexte=LEGITEXT000006071154&idArticle=LEGIARTI000006574935&dateTexte=20150830

[398] Of course, one should note that French Administrative Law is in fact very similar to Common Law in its approach: it is nearly entirely based on Case Law, and relies on sets of fundamental principles, rather than on written law.

[399] For an illustration of practical decision-making by courts on this basis, cf. Endicott 2015 p. 233.

[400] See on non-justiciability Endicott 2015 pp. 251-260

262) as well as towards prosecutors when it comes to the decision to prosecute or not (*ibid.,* p. 266[401]). Hence, "typical" regulatory decisions (planning decisions by local inspectors, decisions to prosecute by HSE inspectors) are mostly covered by strong deference to the officials' discretion.

A concrete example of "discretion in dispute"

We have seen that, in countries apparently as different as the UK and France, there are in fact quite similar principles at play when it comes to administrative discretion and possibilities of judicial review thereof. Deference is the norm, but there are exceptions to it, and principles for screening and reviewing are relatively close. This leaves us with apparently quite a solid basis for discretion, including the discretion *not to act*. Let us consider a final example, a more contentious one, to see if it can strengthen our findings. Recently[402], President Obama decided to in a way sidestep Congress on immigration policy, due to the impossibility to forge a bipartisan compromise, and to act in this matter entirely on the basis of executive discretion. Not, however, the *individual,* prosecutorial "bottom-up" discretion of officials in charge of making case decisions, but *structured,* "top-down" discretion, through instructions from the Secretary of the Department of Homeland Security). The President (through his Secretary) did not, of course, instruct immigration agents to stop all actions against illegal immigrants – but he established "expansions of deferred action, with guidelines for when someone should be protected; and the new "clear guidance" enforcement memo, which lays out much clearer, and more restrictive, guidelines for when someone should be deported"[403]. This elicited of course sharp reactions from Republicans, and scholars on the conservative side of the ideological divide. This is, in several ways, an "extreme" case: first, because it corresponds to a very hotly debated issue, rife with ideology and electoral interests, and thus one where it can be expected that scholars on all sides will "push" their argument as far as they can. Second, because it relates to a "discretion-framing policy" that is particularly sweeping in its scope and strict in its guidance – and particularly in its guidance *not to act*. .

Considering this, it is striking that, if we look at the arguments made *against* the policy, they are quite moderate and limited *in substance* (if not in tone). The *Heritage Foundation*'s John Malcolm (2014) thus starts by writing that the President has a "constitutional duty to enforce the law" that derives from the Constitution's stating that "the laws be faithfully executed" (Art. II, sec. 3) – and that the Supreme Court "Court determined that the President must carry out all of the objectives and the full scope of programs for which budget authority is provided by Congress" (p. 2). He fully acknowledges prosecutorial discretion, but argues that this, "with respect to an executive's enforcement duties is based on equitable considerations in an individual case or a small set of cases" – and "is designed to help achieve statutory objectives— which in this case would include promoting the integrity of the U.S. legal immigration system and deterring violations of our immigration laws—not to frustrate statutory objectives or to effectuate a change in policy" (p. 3). Thus, he argues, since prosecutorial discretion should be the exception (and aligned with the aim of the statute), the announcement that it will be used in a sweeping, systematic way (and in a manner that the authors sees as contradicting the statute's finality) contradicts the law, and the Constitution. He goes on to acknowledge, however, the following: "this rationale may end up squeaking by in a court of law, assuming it is challenged by a plaintiff who is able to establish the legal requirements of standing" (p. 4). He adds in note the following explanation: "the Supreme Court held that the presumption against the reviewability of discretionary enforcement decisions can be overcome "where the substantive statute has provided guidelines for the agency to follow in exercising its enforcement powers" and that an agency might be subjected to a more

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[401] Endicott does point out that there were some variations in jurisprudence on the question of reviewing decisions to prosecute (or not), but the latest, prevailing jurisprudence is basically full deference.

[402] Starting from November 2014

[403] Dara Lind, *The government can't enforce every law. Who gets to decide which ones it does?* Online article accessible at: http://www.vox.com/2015/3/31/8306311/prosecutorial-discretion

exacting standard of review if it "consciously and expressly adopted a general policy that is so extreme as to amount to an abdication of its statutory responsibilities." Nonetheless, no court has ever invalidated as a violation of the Take Care Clause a non-enforcement policy premised on prosecutorial discretion" (*ibid.*). In other words, while *in theory* the Supreme Court considers that discretionary enforcement decisions *could be* reviewed, it would only be possible in an exceptional case (and would require that the plaintiff demonstrates standing, i.e. that they are being harmed by the discretionary action, which may not be easy). In short, even in the United States (where the Constitution as well as jurisprudence tend to limit the executive's discretion in internal affairs), it appears that policies "framing" regulatory discretion would pass legal and constitutional muster, except in the most extreme of cases.

Even Malcolm's critiques, however little consequence they have in the end considering the case law he himself quotes, are not undisputed. Shoba Sivaprasad Wadhia, a scholar of immigration law and prosecutorial discretion issues, advances strong arguments against all of Malcolm's views. She first describes in far more details the actual *contents* of the policy in debate, and notes that in fact the guidance specifically grapples with "the more complicated cases" and thus "permits the agency to go beyond a "one-size-fits-all" approach when applying its policy on prosecutorial discretion" (p. 106). She then emphasizes the economic impossibility of full enforcement: "the government has resources to deport approximately 400,000 individuals annually—less than four percent of the deportable population" (p. 107) – which means that *in fact* full enforcement of the law is impossible, and that the practical choice is only between *structured (and consistent)* discretion and between *individual (and inconsistent)* discretion. She also demonstrates that the humanitarian basis for the new discretion policy has a long history, and that "One of the earliest documents used by the immigration agency (then called Immigration and Naturalization Service) was an Operations Instruction that allowed for "deferred action" (then called "non-priority status") for noncitizens who could show one or more of the following factors: advanced or tender age; presence in the United States for many years; need for treatment in the United States for a physical or mental condition; and adverse effect on family members in the United States as a result of deportation" (p. 109) – i.e. criteria very close to today's. Finally, she gives a very different summary of the case law, quoting the Supreme Court's earlier recognition that ""[a] principal feature of the removal system is the broad discretion exercised by immigration officials. (…) Federal officials, as an initial matter, must decide whether it makes sense to pursue removal at all" (p. 112). She adds that the "Take Care Clause" in fact has been repeatedly understood by the Supreme Court to include "broad discretion" in enforcement (*ibid.*) – and that in fact the Immigration and Nationality Act specifically "prohibits judicial review for three specific prosecutorial discretion decisions (commencement of proceedings, adjudication of cases, and execution of removal orders), only reaffirming the delegation of prosecutorial discretion powers to DHS" (p. 113). It thus appears that, even in this most hotly contested field that is immigration law, prosecutorial (administrative) discretion is as essential as it is, essentially, enshrined in Constitutional law (and case law in particular).

The legitimacy of discretion

We have clearly not *proven* (if such a thing is even possible) that discretion in regulatory decisions, and particularly the discretion *not to act*, is possible and legitimate always and everywhere. There are evidently exceptions, limits, and ways in which this discretion is organized – and this will vary from one country to the next, with significant divergences between different legal traditions. What we think can be said with some confidence, however, is that regulatory enforcement policies (adopted by the executive branch) that organize how discretion will be exercised, including in providing guidance to individual officers on what violations can be "treated lightly", are certainly not shocking innovations, or *generally* contrary to sound constitutional and legal principles (though they can be problematic in *certain* constitutional systems).

Accepting discretion as a necessary element of risk-based inspections and enforcement also does not need to mean that accountability is reduced. As things stand, in most countries, the majority of inspections and enforcement structures are usually accountable to the executive, and only through the executive to the legislative branch[404]. This is not changed by risk-based approaches, but rather they introduce an element of clarification regarding which criteria will be used to exert accountability. By publicizing a clear methodology to guide inspections focus, and to take enforcement decisions based on risk (such as the UK HSE's *Enforcement Management Model*), an inspections agency clearly defines within which parameters it will exercise discretion, and how, rather than having the default situation of "atomized" discretion at the individual inspector level (which can, in practice, never be ruled out – an inspector can always decide s/he has *not seen* something, even if rules say it should be subject to a penalty every time, for instance). Moreoever, if inspection agencies define their goals and objectives in terms of public goods to be increased and/or risks to be reduced, they allow for far more meaningful accountability, since the executive (and, in turn, the legislative) can scrutinize whether the methods used have indeed allowed for maintained or improved outcomes, or not.

It will be a task for future research to investigate how such policies can be designed, adopted and implemented in different jurisdictions – but we believe to have established sufficiently that they are *possible and legitimate.*

In addition, there is sufficient evidence that minimizing discretion results in situations where efforts end up diverted to low-priority tasks, and/or in "minimal compliance" (Bardach and Kagan 1982, pp. 102-109). As they demonstrate, "going by the book" and treating every regulatory violation, no matter how small or inconsequential, exactly with the same attention, produces results that are not only "sub-optimal", but can be downright negative, and undermine the very objectives of regulation. As they conclude, "such diversion leads managers and compliance specialists to denigrate the inspectors, to characterize them as ignorant and legalistic nitpickers, and to resist rather than cooperate with them" (p. 104). On this basis, we can now turn to consider the contents and practice of risk-based approaches that aim at making such discretion better framed – more consistent, more transparent, and more effective. Indeed, this last point is important – unbound, unmanaged discretion also has its pitfalls. As Bardach and Kagan show, the reliance on "traditional legal structure" and prosecutorial (and judicial) discretion largely resulted, in the years before the 1970s "tightening" of regulations and enforcement in the US, in a situation of "underenforcement" (p. 40). While discretion is important to "distinguish between serious and nonserious violations, between the basically well-intentioned regulated enterprise (…) and the recalcitrant firm" (p. 39), there is also a serious downside risk of capture or simply excessively lenient approach (pp. 39-42). A well designed risk-based approach, we will argue, can offer a framework that allows the positive sides of discretion to operate, while avoiding or limiting its downsides.

Finally, it is important to point out that the degree to which executive discretion (e.g. prosecutorial discretion, but also by extension prosecutorial discretion) is generally construed as legitimate depends on the legal tradition. Whereas both in the British and American tradition, and in the French and Roman one, there is deference to the opportunity principle (the executive and prosecutors may elect *not to prosecute* or otherwise enforce if it would not be opportune, i.e. would not support overall goals of public welfare etc.), the German legal tradition (and that of all countries that build on it) does not include this principle. There, by contrast, the principle of legality (*Legalitätsgrundsatz*) would suppose that every violation is equally prosecuted. While this does not really happen *in practice*, and thus the difference between legal traditions is not that stark in fact as it is in theory, it remains that the legitimacy of regulatory discretion will not be as easily established in countries where the legality principle is the norm as in others which embrace the opportunity principle.

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[404] Financial sector regulators, or other high-profile "independent regulators", can be exceptions to this rule, but they are not the focus of this research.

c. Conclusion

It is clearly difficult to conclude on a topic which presents such conflicting views and apparently contradictory findings. The large number of very valuable studies also makes it hard to do justice to the field. We will nonetheless attempt to do so, in order to provide an adequate basis for the consideration of evidence from the practice. First, we will return on the need to accept the complexity of compliance, and to look beyond simple models. Second, we will return to the "big picture", and the consideration of *outcomes*. Finally, we will see that a "modest" vision of complementary, complex compliance factors is sufficient as a foundation for risk-based inspections, and that risk can in fact be a tool that allows to move beyond some of the apparent contradictions and challenges.

i. A second look at "deterrence" studies

Let us first look back at a couple of studies specifically considering "deterrence-based" compliance. Faure and Garoupa (2005) consider the limitations on deterrence in cases where fines may fail to be commensurate to the illicit gain for a variety of reasons, and where forfeiture (of illicit gain, or of wealth deemed to come from an "illegal source", etc.) is introduced as a complement. Importantly, the authors underline that such "measures" also respond to the idea that "crime should not pay", and not only to a deterrence logic (p. 280). They also see forfeiture of illegal gain as substituting itself to compensation payments in the case of "victimless crimes" (*ibid.*), and put in the perspective of "corrective justice" (pp. 289-290). They consider the legal frameworks for such practices, including the use of *civil forfeiture* in the US[405], but considerations of effectiveness are based on *models* and *assumptions* followed by *logical deductions* – without any guarantee that they correspond to practice. The authors refer to "criminal lawyers" considering the deterrence model as particularly appropriate (p. 282), and to both economics and the principle of proportionality as requiring *marginal deterrence*, for which forfeiture of illegal gain can be a useful instrument, when combined with fines (the fines can be modulated based on the seriousness of the offence, while forfeiture provides a "baseline" bringing back offenders to the *statu quo ante* – p. 288). In fact, the authors themselves acknowledge that many criminals are (evidently) not being deterred (p. 283), but they do not really question the model. While many of their arguments of *principle* are convincing (e.g. regarding proportionality, ensuring crime does not pay etc.), these are values-based arguments. The *effectiveness* case for the deterrence side is unproven.

In a 2015 paper, Bentata and Faure consider the evidence on the activity of Environmental NGOs (ENGOs) in France, through environmental cases litigation brought before the *Cour de Cassation*. They suggest that, in a context of limited inspections and enforcement resources (p. 5), ENGOs take up important cases (in terms of environmental damage) that would otherwise be left out – because the regulator is focusing on the higher-risk, larger-size entities, and individual damage is too small to lead to private litigation. They further show (pp. 6-7) that ENGOs focus on cases with a high impact on the environment rather than on "personal nuisances"

[405] The civil forfeiture practice in the US has come under increasing criticism in recent times for the manyfold abuses it has led to, with weak rules of evidence and perverse incentives leading to police departments routinely abusing their powers. There is a growing, and increasingly bipartisan consensus that the practice should be ended – see e.g. concurring conclusions from the American Civil Liberties Union (https://www.aclu.org/issues/criminal-law-reform/reforming-police-practices/asset-forfeiture-abuse), the Cato Institute (http://www.cato.org/events/policing-profit-abuse-civil-asset-forfeiture), libertarian writers such as Radley Balko (https://www.washingtonpost.com/news/the-watch/wp/2014/05/19/new-media-investigations-show-that-the-asset-forfeiture-racket-is-still-humming/) etc.

issues (ENGOs focus more on water issues, private cases on noise and soil, relatively speaking). ENGOs and enforcement through court cases thus appear as meaningful complement to state regulatory inspections (p. 11), but again the question of *effectiveness* is not fully investigated. The authors show that, over time, defendants' overall compliance rate with safety measures (as evidenced by court proceedings) has increased, following an increase in ENGO litigation, but this is at best correlation between two trends – and the fact that there is litigation suggests that this compliance was insufficient to ensure environmental protection. Thus, the ENGOs' role appears potentially meaningful, but within a broader concept of deterrence which remains unproven, at least within the paper.

Rousseau, in a 2007, considered closely a dataset on environmental inspections and enforcement in Flanders, which gives the possibility to look at correlations between compliance and inspections/enforcement more closely, particularly given the relatively long time-series, and the repeated inspections of each establishment[406]. The model used to investigate enforcement effects is squarely rooted in the "deterrence" vision (p. 2)[407]. Rousseau summarizes her findings as confirming the deterrence effect of increased inspections, but not that of sanctions. She discusses the fact that the agency uses sanctions relatively rarely, and that the level of fines remains far lower than what the legislation authorizes, i.e. the fully "enforcement pyramid" is not really being used (but the *threat* of the pyramid's "top" is likely to be used – cf. pp. 8-11). On the *interpretation* of results, we feel like there are important points that could be seen differently from the author. First, she outlines factors increasing likelihood of inspection on p. 17 which, in fact, squarely show that the agency is using a risk-based targeting approach - meaning that, if targeting is done well, one would precisely expect (i) a relatively high percentage of violations (which indeed is found) and (ii) some effect of inspection and enforcement visits (which, again, seems to take place). Thus, the findings may not really reflect the effect of inspections *overall* but of a *targeted risk-based project*. Second, and most importantly, the fact that the increased inspections programme seems to have an effect, but sanctions do not seem to have one, may suggest that the effect is *not* (or not entirely) linked to *deterrence*. It could very well be that the repeated, extended (longer duration of visits) interactions have allowed to increase the inspected businesses' knowledge, and to build a trust relationship where persuasion has played a significant role. Finally, and relatedly, the fact that inspectors and courts do not use the full scale of sanctions available, and impose (when they do) sanctions that tend to be far lower than marginal abatement costs for major violations, again challenges the "deterrence" approach – this time in a "feasibility" perspective. One can assume that both inspectors and judges are not ignorant of the problem – but imposing massive financial sanctions on businesses, while it *may* increase the general deterrence effect (which may or may not a really important driver of compliance), would surely pose serious financial hardship to the sanctioned enterprises. This could in some cases put them out of business, or at least threaten their viability, and in the meantime make it *even more difficult* for them to invest in the required pollution abatement equipment. Thus, overall, while the finding that this specific inspections project was successful at increasing compliance appears robust, the *reasons* why it was so are probably more complex than suggested.

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[406] Two remarks are required. First, the group under consideration is a high-risk group, specifically targeted by the environmental inspectorate as part of a "project" – which translated into more than 3 inspection visits per entity and per year, on average (see p. 7), which is a very high number, and thus makes it difficult to assume that findings can be easily generalized. Second, the findings incidentally show the problems with the notion of "compliance", because so many of the non-compliances are administrative rather than substantial (*ibid*.), i.e. are non-compliances without a direct environmental impact (and, for some, without even an increased *risk* of harm).

[407] The introduction includes a short literature summary. It includes a point on Nadeau's 1997 findings that inspections and enforcement actions reduce *the length of time spent in non-compliance*, and that enforcement has a stronger effect. This is an extremely unsurprising finding, we would say, and very different from a conclusion on relations between enforcement actions and compliance *overall.* There is little doubt that, if you are inspected (maybe repeatedly) and sanctioned (again, possibly repeatedly), this is likely to push you to start putting yourself in compliance. The question is whether controls and enforcement actions are the most effective approach to increase compliance *across the board* among all regulated entities.

ii. Taking a more modest and nuanced approach

While we have collected examples suggesting that the deterrence model is generally unproven, it is not to single out so much this factor, as because it has been the model used the most uncritically across many studies. Scholars investigating psychological drivers such as Tyler *include* deterrence, while suggesting that it may be weaker than e.g. legitimacy – but many deterrence-based studies barely acknowledge (and then proceed to ignore) other drivers. This conclusion by Parker and Lehmann Nielsen (2011) seems to us highly appropriate: "the range of factors that are hypothesized to influence compliance are so complex and interrelated that it is very difficult to holistically test them all, or even to clearly hypothesize how they interact and in what direction causation flows" (p. 6). Likewise, in their summary of contributions on "Effective enforcement of consumer law in Europe", van Boom and Loos (2007) conclude to the importance of a multiplicity of complementary approaches. They challenge the idea that litigation against an infringing firm (even successful) necessarily leads to a change of behaviour (p. 6), and cover several examples of effective interventions based on information, informal pressure etc., rather than formal enforcement (p. 4). They also see merit, however, in systems which enable *group action* (with important nuances compared to US *class actions* – cf. pp. 5-10). Their concluding view is that self-regulation (with or without a state regulatory "backstop") and public supervision and enforcement are complementary and not contradictory, and that group action can be a useful supplement to both (pp. 10-11), a view that would fit well with a view of complex (and evolving) compliance factors.

In a 2007 paper, Voermans talked about the "aspirin-like effect of sanctions", suggesting that (just like for aspirin or, say, homeopathy) many people will assert that "it helps", without being able to explain why or how (and without, it goes without saying, scientific evidence thereof – cf. p. 59). He considers the problem of laws that "do what they are meant to", of rules "that are functional", as central (p. 57), but the question of what mechanisms lead from rules to behaviours as very much still unsolved. Indeed, while voluntary compliance is preferred, we know it does not always happen – conversely, while no one really doubts that enforcement has *some kind of effect* on compliance with rules, how, and how much, are other questions (p. 58). The *assumption* that more control and more enforcement will lead to better results has led to what he sees in the late 1990s and 2000s as a considerable increase in inspections and enforcement efforts, in particular on the part of local authorities – involving more professionalism, but also a number of new (previously unheard of) enforcement directions – all without much basis in evidence (p. 56-60). Rather than looking at the *logic of motives* behind compliance, these measures have followed an *administrative logic* – the more is done, the more it is expected to be effective. Voermans considers both large-scale, high-level data, and findings from psycho-social studies. Data first: quoting van Velthoven, he shows that the chances of being caught, and the potential fine, are so vanishingly small that it is impossible to plausibly explain widespread legal compliance based on deterrence (pp. 61-62) – even though, of course, in specific cases, targeted and focused deterrence may be effective on specific persons. Findings second: studies find that most people appear *not* to be motivated by the fear of sanctions (but by values), but that on the other hand they think *others* are motivated by calculation and fear (deterrence). One reading could be that we want laws and sanctions (and make them, if "we" sit in Parliament) for "others" – based on very much unproven conceptions of what drives behaviour. Another (not incompatible) reading is that compliance is complex, and that "we" may be in both positions, successively or at the same time: of complying because of values, or because of fear. Just as much as we cannot dismiss the fact that enforcement surely has *some* effect, it is clear that most compliance *cannot* be explained through deterrence. A vision of complementary compliance drivers, of varying importance according to contexts and groups affected, is the best we have.

In addition, there are good arguments to be made that compliance should not be the *only* objective of enforcement activities and mechanisms, and that there are legitimate value-expression issues that should be

considered. We have seen how this is relevant in the case of illegal gain, for instance. Yeung (2013) stresses the importance of balancing the effectiveness considerations of "better regulation" approaches with "constitutional values, including transparency, accountability, due process and participation" (p. 3). She also cautions that many of the more "efficient" or "responsive" sanctioning and enforcement approaches proposed may conflict with key principles of criminal law ("censuring the wrongdoer", sanctions entailing "serious consequences" and "moral stigma" – but also "procedural safeguards"). We have also noted above Yeung's concerns about the tensions between proportionality and responsive regulation. All these are important, and valid – reminding that effectiveness cannot be the sole consideration. In fact, from a procedural justice perspective, we would argue that not properly considering these values would in the end probably *harm* effectiveness. This further reinforces the case for a complex and balanced vision.

iii. Using "risk" to overcome (some) problems and tensions in models and theories

As a transition to the next section, we would like to point out the way "risk" can be a powerful tool to overcome some of the tensions and problems in compliance theories and compliance-promotion models. As we have indicated above, risk-based targeting is quite possibly the reason why the environmental inspection project that Rousseau (2007) studied yielded rather convincing results. More generally, modulating inspections and enforcement approaches in relation to risk is an "ideal" complement to the responsive regulation approach, as Baldwin and Blanc (2007, 2010) have already noted. We see the relevance of "risk" as coming from two perspectives: a legal one, and an effectiveness one.

On the legal side, risk can be an instrument on which to base the application of the key principle of *proportionality*, that Yeung for instance is worried can be harmed by a purely responsive approach to enforcement. In a risk-based approach, enforcement measures should always be proportional to the risk caused by the violation(s) found. The behaviour of the business operator, which is key in the responsive regulation approach, can be integrated as one of the *risk dimensions*, alongside the inherent hazardousness of the activity, and the severity of the violation. Thus, responsiveness remains, but on a foundation of risk proportionality.

On the effectiveness side, whatever the combination of compliance factors and drivers, risk-based *targeting* can be a way to optimize the intervention. It should help minimize the intrusiveness of inspections and enforcement where they are little needed (thus rating well from a procedural justice perspective, and minimizing resistance to voluntary compliance), while intensifying contacts where they are most needed – not only from a deterrence perspective, but also from a "quality of the regulatory relationship" one (more time and attention on cases which need it, meaning also more advice and time to create trust where possible). At the same time, if the balance between different risk dimensions is properly done (i.e. targeting incorporates both probability of a violation, and potential severity of its effects), risk-based targeting can maximize the effectiveness of deterrence effects (by focusing this deterrence on where it will yield most results). Before considering practical cases, and how much these optimistic expectations hold up, we will now consider the existing literature on risk and regulation and what it can bring to our understanding of risk-based inspections.

3.3. Risk and regulation – definitions, debates and issues

a. Defining and measuring risk

If, as we have suggested above, risk may be a potentially useful instrument to overcome internal tensions and contradictions in compliance strategies, and to help give discretion a sounder foundation, we first need to have as much as possible a clear understanding of how to define, and measure, risk. Evidently, considering how polysemic the word is, and how widespread its use is in common language, narrowing down its meaning is not easy. Scholars who speak about "risk" in writings focusing on regulation and enforcement sometimes do it in a way that is very much open, not to say vague, and without a clear definition. Others, who research "risk" as their core subject, investigate its different meanings and perceptions among different groups, and the effects of these differences – and, in order to do so, they precisely need to leave the definition open (is "risk" what people perceive as such). By contrast, practitioners of regulatory enforcement have been working on building a definition that commands some consensus, in order to create a foundation for their work.

Both of these aspects of risk are, of course, of interest for this research. The "open ended", multi-faceted approach allows us to understand how extremely contrasted visions of what is "risky" or "dangerous" can coexist, and how they shape the emergence of regulations and regulatory bodies. Once we move to our assigned task of trying to assess risk-based inspections practices, however, we need to have a meaningful definition of what this means, one that is not "all-encompassing". We will thus examine what it is that is called "risk" in the context of risk-based inspections. Because one of the important challenges is also how this risk should be measured and assessed, we will also briefly consider this question.

i. Risk, hazard, compliance – from "risk as likelihood of violations" to the "two dimensions" of risk

When considering research on regulatory enforcement, some of it appears to have a very narrow understanding of what "risk-based targeting" could be, equating it with targeting entities that are the most likely to commit violations. May and Winter (2012), for instance, write that "the enforcement literature is consistent in arguing that effectiveness is increased by going after the types of cases that historically have higher rates of violations" (p. 224). Though they add that there are also "other ways of identifying higher risk entities", they do not list any. Equating "risk" with "likelihood to commit violations" is of course exceedingly simplistic, and assumes that all violations are equivalent in potential consequences – or that "risk" has no other meaning than "risk of violation". Generally, looking at enforcement essentially from a "deterrence" perspective tends to lend itself to equating "risk" with "probability of non-compliance" (see e.g. Scholz 1994, pp. 426-427 for an example).

Some other studies take the opposite tack, and suggest that "risk-based approaches" consider only the potential consequences of the damage, without really looking at probabilities of violations. This is how the following remark by van der Heijden *et al.* (2015 a) could be interpreted. Looking for an explanation of why Chinese inspectors seem to target precisely those that have the strongest voluntary compliance level: "another explanation may be that agents use a risk-oriented approach to enforcement, and prioritize those farmers and types of violations that could create the largest damage. Whilst such risk-oriented approaches make theoretical sense, there is a risk of an overly technocratic implementation and too strong a reliance on the heuristics underlying these approaches" (p. 13).

By contrast Baldwin and Black (2010), who have closely studied how regulatory agencies define risk-based approaches, rightly start by clarifying that such approaches "walk on two legs": "The key components of such [risk] assessments are evaluations of the risks of noncompliance and calculations regarding the impact that the noncompliance will have on the regulatory body's ability to achieve its objectives" (p. 181). They also underline that risk-based approaches are a clear departure from regulatory visions based exclusively on compliance with rules: "the frameworks vary considerably in their complexity. All, however, have a common

starting point, which is a focus on risks not rules. Risk-based frameworks require regulators to begin by identifying *the risks they are seeking to manage, not the rules they have to enforce*" (p. 184 – emphasis ours).

The summary offered by Baldwin and Black indeed matches the practice as we have also been able to observe it in many countries. A good example and summary is offered by BRDO's 2012 *Common approach to risk assessment,* which distinguishes *hazard* from *risk.* Hazard (pp. 8-9) is the adverse effect that could arise from public welfare from given activities that are within to the regulatory body's competence – and the severity and magnitude of this hazard need to be assessed as *one dimension* of the risk. The second dimension is the "likelihood of compliance" (pp. 9-10). The *combination* of these two dimensions allows to assign a level of risk to a given activity, establishment etc. Definitions used by the World Bank Group (2013 a) and the OECD (2014) make do without the reference to compliance entirely, and rather focus wholly on the notion of "adverse event": "Risk should be understood here as the combination of the likelihood of an adverse event (hazard, harm) occurring, and of the potential magnitude of the damage caused (itself combining number of people affected, and severity of the damage for each)" (OECD 2014, p. 27).

In other words, while It is relatively uncontroversial to point out that inspecting roughly every type or size of business establishment equally is unlikely to yield optimal resource allocation (cf. Kagan 1994, pp. 409-410), it is not as easy to agree on which criteria should be used to measure risk, as this first requires to agree on a definition of risk. Our own experience working with inspectorates in former Soviet countries shows this to be one of the most difficult and essential questions – getting agreement on the fact that risk-based targeting "in general" would be better than no targeting is relatively easy, but disagreements arise when trying to define what risk-based targeting means.

ii. Several visions of risk – strengths, weaknesses and challenges

As pointed out, the notion that "risk" is the combination of the likelihood and potential magnitude of damage caused by an adverse event is not self-evident, nor is it universally accepted, even though it corresponds to what inspectorates and regulators claiming to have a "risk-based approach" generally understand under this term. There are at least three ways to conceive risk from a practical perspective, in terms of business establishments or objects of inspections:

- Probability of non-compliance with applicable regulations
- Relevance of the type of establishment to a specific "risk type" that is seen as an important priority by the government or administration
- Combination of likelihood and potential magnitude of hazards that can be caused by the specific type of establishment, be they measured through statistical work or through more "qualitative" experience and practical insights.

These three ways of defining (and thus of assessing) risk all have their own legitimacy, but are unlikely to yield similar results. They tend to be dominant in different countries or institutions, and/or to be supported by different groups, linked not only to different worldviews but to different interests. Rothstein, Borraz and Huber (2013) showed how "risk-based approaches" (in the sense of "proportionality of regulatory response to the likelihood and potential magnitude of hazard") have had difficulty to emerge in France. A different way of phrasing the same would be to say that, in France, "risk" conceptions tend to correspond to the second type: priority areas determined (based on a variety of factors) by the government and/or public administration. We will shortly discuss here some of the most salient issues pertaining to each of these visions of "risk".

Risk as "likelihood of non-compliance with regulations"

Focusing on the *risk of non-compliance with regulations* is the approach that may seem most correct from the perspective of an *expressive* use of the law, and supported by many regulators and scholars[408]. Laws are to be complied with, the executive branch (and its regulatory agencies) are there to implement these laws, and thus inspections should aim at identifying, punishing and deterring non-compliances of all kinds. "Risk" is thus nothing else than the risk of someone not complying with norms. It is worth nothing that this tends to be the prevalent understanding of "risk" in former Soviet countries, and when inspectorates there are required to adopt a "risk-based approach", and if there is no further implementation follow-up to ensure they consider *harm* rather than *violations,* this is the one they generally follow.

Such an approach, however, has practical results, if it is followed by an inspectorate. In the former Soviet examples we have observed, for instance, when developing criteria to classify establishments in different risk categories (and subsequently plan inspections prioritizing "higher risk" ones), inspectorates start by defining "high risk" as "more likely to infringe rules". This is generally done without consideration to the importance or relevance of these rules, or to the magnitude of the potential negative impact of infringements. Since non-compliance is seen as a risk *per se*, it does not matter what type of rule is infringed, or.to what degree. This results in considering smaller businesses as systematically higher risk (non-compliances, though often minor, are most frequent there, because of lower resources and expertise), and in a focus on high-volume activities such as trade, catering etc. – where, again, non-compliance tends to be frequent but usually minor in terms of effects on public welfare[409].

In theory, one could develop a more sophisticated risk-based planning approach from a "legal compliance" perspective, using the type of sanctions that can be incurred as a proxy for the seriousness of the offences. However, this would be complex to implement *seriously* (classifying all infractions recorded, analysing where the most severe are found, etc.). More importantly, one cannot assume that the legislator had a full technical understanding of the field being regulated, and insight into what activities would potentially create the highest threats. Thus, the classification would likely remain sub-optimal in terms of achieving useful social outcomes[410]. Finally, simply because there is a vast number of regulations and potential infractions, it is not unlikely that most businesses would end up being "high risk", because many (however minor) violations can be found in most establishments[411]. Since the purpose of a risk-based classification is *targeting*, this would defeat its purpose, as the "target" would be too broad.

Experience in the FSU shows that this is indeed what happens when risk criteria are developed in this spirit (and this is made even more obvious because the regulations there lack focus and are over-detailed and over-prescriptive). In Ukraine or Kazakhstan, for instance, risk criteria for inspections developed by the Standardization agency ended up classifying the vast majority of wares as "high risk", regardless of whether any injuries or deaths were ever recorded as a result of their use.

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[408] See May and Winter 2012, Scholz 1994 for instance – an approach that puts compliance with legal norms as the key objective is congruent with the centrality of equal treatment before the law expressed e.g. by Yeung (2004, 2013).

[409] Though Baldwin and Black (2010) rightly point out that, in some cases, there can be a "huge cumulative effect of particular types of compliance failures across firms" that the harm-based vision of risk may underestimate (p. 203). In the cases we have observed, however, the disproportion between the means employed and the pettiness of problems addressed was generally striking.

[410] On the limitations of rules see e.g. Baldwin 1995, Black 1997.

[411] This is a contentious and clearly unproven assumption but there are some pointers suggesting it may be correct. Even in the UK, where efforts are clearly being made to (a) reduce the overall "regulatory burden" (whatever one may think of whether this expression is appropriate) and (b) inform businesses about rules, regulatory agencies generally target bringing most businesses to be "broadly compliant" rather than "fully compliant", an objective they consider to be as impossible as it would be relatively useless (again, considering the vast number of rules and the fact that many of them are of little significance). In former Soviet republics, we have repeatedly heard from both businesses and inspectors that, if an inspector wants to find violations, s/he will find them, considering the myriad of confusing norms. Hawkins (2002) as well as other scholars having studied in details "enforcement styles" all concur that, in general, inspectors avoid enforcing *everything* because there is *always* some norm or other that is not being complied with.

"Politically prioritized" risk

Relying on *risks as prioritized by political programmes* (or by political, elected office-holders in general) can also claim to have a legitimacy, i.e. the political one (clearly a stronger claim in democratic regimes than in authoritarian ones). In this perspective, the executive branch is legitimate to prioritize hazards that it sees as more important. This is articulated in some EU countries (e.g. by some in France) to justify having inspecting agencies directly subordinated to ministers, and receiving direct instructions from them that "interfere" with their usual planning. The justification is that ministers (owing their positions to elections) are more responsive to citizens' concerns, and that this responsiveness is essential[412].

In the former Soviet context, such "responsiveness to citizens' concerns" is not absent, even where elections are not free – since even in authoritarian regimes, keeping the majority "not overly dissatisfied" is important for stability. Ministers or presidents frequently interfere with planning by inspection agencies – sometimes for reasons that correspond to real public concerns, but often for other reasons than safety (e.g. to increase government revenue, or target businesses associated with rival politicians, etc.). We saw, for instance, the President of Tajikistan ordering different agencies to inspect all gas stations, because (supposedly[413]) of some concerns (supposedly) with fraud, and with price increases.

The problem is that very often, instead of responding to a "real" issue[414], these are sequences whereby politicians "spin" some incident reported by the media, focus on it and proclaim a "strong" regulatory response as a solution – without the problem having been analysed, and without knowing whether inspections can in any way improve it. There is neither analysis of the real risk level , nor of the response's adequacy. In this perspective, politically-driven inspections have been conducted in Tajikistan to "respond" to increases in fuel prices (gas stations inspected), in Mongolia during discussions about foreign investment in mineral extraction (mines inspected), etc. None of these, of course, made any difference to the real issue. In theory, of course, such "politically-identified" risk approach could be genuinely responsive to the "perceived risk" (as defined by Slovic *et al.*[415]) of the majority of the voters – but it appears that, in both democratic and authoritarian countries, it is more often used as a way to divert attentions from problems the government is failing to solve, and give the illusion of action. Generally, the evidence available strongly supports the case to make regulatory delivery agencies more independent from direct political supervision – and the definition of "risk" independent from political intervention.

Risk defined, and assessed, in relation to probability and degree of harm

In contrast to the first two approaches, defining risk as *the combination of the probability and the possible magnitude of adverse outcomes* is more of a "technical" (or "technocratic") view. It is based (as much as possible) on science, but in the end assessments, classifications and prioritization are done by "technical specialists" rather than scientists – and risk-based approaches have to make assumptions where there is scientific uncertainty[416]. Risk is defined as what can create harm (to life, health, the environment, etc.[417]) –

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[412] This "responsiveness" is precisely what is seen by advocates of "risk acceptance" as a problem. What one side calls "responsiveness to citizens' concerns", the other calls "risk regulation reflex" (see next section on discussions of risk and regulation).
[413] While fraud in gas stations was certainly a concern, few believed that the inspection campaign would decrease it, but rather it was seen as a fig-leaf for more rent-seeking for inspectors and their supervisors.
[414] I.e. one that would be confirmed as really significant by examination of data.
[415] See Slovic *et al.* 1981, 2002.
[416] See next section for a discussion of the issue of uncertainty in relation to risk and regulation.
[417] "Harm" is not limited to physical issues – it can be financial/economic (loss in state revenue, market distortion, etc.).

and the risk level is proportional to how likely such harm is to occur, how severe it may be and how many people it would affect (or what would be its scope in environmental or financial terms etc.).

In this perspective, inspections should be targeted at the establishments where the combined likelihood and potential harm is greatest, which means not just greater frequency of inspections, but also "deeper" inspections, with more time spent on site, more qualified staff involved etc. In the third part of this research, we will be examining the available empirical evidence of the effectiveness (or lack thereof) of such approaches. Thus, we will for the moment set aside the first challenge to such approaches, whereby opponents of "risk-based inspections" suggest that it amounts to "regulatory surrender", and results in excessively weak enforcement[418].

If we set aside this question of effectiveness, there remain two major challenges in implementing such a system based on "actually measured/assessed risk to public welfare": a technical one (how to get relevant data and how to plan in practice) and a legal one (is it legally acceptable to thus focus and "willingly neglect" what is considered as "lower risk"). Both challenges have been raised both by scholars and in practice.

The legal principles argument against risk-focus and risk-proportionality is related to the challenges made against "responsive" approaches, and rests on the idea that risk-based approaches may break equality before the law, which is a fundamental principle (see e.g. Yeung 1984 pp. 82-83, 87). While we have discussed this argument already in the context of compliance models and discretion, it is worth restating here that, to us, this is not really a tenable position when considering actual practices rather than theoretical models, at least in the vast majority of cases. Indeed, "non-risk based" inspection approaches do not show less disparity in inspection frequencies, criteria used by inspectors, enforcement decisions etc. in most cases (see Blanc 2012 pp. 21-27 for some examples – interviews with both businesses and officials in France suggest disparity of inspectors' approaches and decisions, and disparities in targeting, are very significant issues)[419]. Thus, risk-based approaches should not, in our view, be appraised against an "ideal type" of entirely unbiased inspections, but against a reality of inconsistent and sometimes incoherent practices. Rather than introducing bias, risk-based approaches can thus be seen as introducing an *organizational principle* in practices where "equal treatment" does not exist anyway[420]. .

As for the technical implementation challenge, it has two key elements:

- What parameters should the risk classification be based upon, how to measure them, and how to then "rate" establishments according to these?
- How to turn these criteria and rating systems into a functioning planning tool, in particular how to get the relevant data on establishments and manage it?

There is a trend to base risk analysis, criteria development, ratings etc. on sophisticated "data mining" techniques, using statistical tools to determine "objectively" (though the selection of the parameters being analysed is never purely objective) the most relevant parameters and thresholds. This approach is most often proposed for tax inspections planning (see e.g. chapter by Vellutini in Khwaja, Awasthi and Loeprick 2011) – and is most applicable in their case, as tax and accounting data are suited to processing through such tools.

In practice, deploying such approaches is often simply impossible, or extremely difficult. As Baldwin and Black (2010) point out, regulators may be "dealing with low frequency events from which reliable probabilistic

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[418] See e.g. Tombs and Whyte 2010 with precisely this title.

[419] See also Badarch and Kagan 1982 pp. 67-69, *contra* Yeung, on the many unintended and negative consequences of an excessively rigid adherence to "equal treatment", "impartiality" and "objectivity" if they are not balanced by other principles.

[420] The same remarks could be made about the problems of consistency and transparency noted by Baldwin and Black (2010) in some examples of implementation of risk-based approaches (p. 204) – while their points are perfectly valid, we would still argue that risk-based approaches should be compared to "actually existing alternatives" rather than to "perfect models".

calculations cannot easily be drawn or with conditions of uncertainty in which the risk is inherently insusceptible to probabilistic assessment" (pp. 184-185). Even when the issues regulators deal with (say, food safety) could *in principle* lend themselves to data-driven approaches (because contaminations, outbreaks etc. are frequent), the quality of data makes it frequently impossible *in practice* (because detection of contaminations depends on reporting by and testing of patients, which rarely happens, and leads to considerable under-detection and bias). In addition, even when it comes to the data that inspectorates themselves could hold, the relevant data on establishments and inspections results is either unavailable in consolidated and computerized form, or incomplete and inconsistent. This is not just the case in the poorest countries of our sample (such as Tajikistan, where no data is yet computerized, except for tax data of the largest taxpayers and the main cities), but in middle-income countries such as Ukraine or Kazakhstan (where some data is available, but incomplete, often inconsistent etc.) – and for many inspectorates in the EU, even among its richest members (data might exist but not consolidated, or may be in numerous incompatible systems, etc.). Thus, in practice, such statistical analysis as the "pure" foundation of risk-based planning is not a feasible option.

In practice, there exists a workable alternative way to develop such rating systems, far less statistically rigorous, and thus introducing more bias and discretion. The essential parameters of risk for a given "sphere" of regulation and control (e.g. "food safety" or "building safety") can be determined by a group of experts (scientists and practitioners) based on (a) the existing state of science, (b) practice and experience around the world and (c) experience in-country (even if summarized more in a "qualitative" than strictly "quantitative" way) as well as (d) available data on the issues being supervised (whatever its limitations). If done properly, in our experience, the main parameters will often be agreed upon relatively easily, be rather consistent across countries, and effectively correspond to actual risks "on the ground". For instance, in the food safety sphere, key parameters to classify establishments according to risk tend to be: (i) type of products processed, (ii) types of processes used, (iii) volumes, (iv) specifics of population served, (v) prior history and track record. This corresponds to the combination of "*inherent risks* arising from the nature of the business's activities and, in environmental regulation, its location" and "*management and control risks*, including compliance record" (Baldwin and Black 2010, p. 184)[421].

In the absence of "data mining", rating and ranking based on these parameters is subject to improvement and refinement through a "trial and error" process. The group of experts developing the rating instrument will affect scores to different parameters (corresponding to different types of processes, different sizes of establishment etc.), then define overall score thresholds for classification as (e.g.) "high", "medium" or "low" risk[422] –based on practical experience and outside examples. The thresholds' levels have to ensure that establishments with only minor risk factors end up as "low", those with several critical risk factors end up as "high" etc. It is then crucial to *test* and *adjust* these scores and thresholds: the risk criteria are tested against real-life cases of establishments. If obvious aberrations occur, the scores and/or thresholds are modified. Once the system is in use, adjustments may occur if too many, or too few, businesses end up in "high risk" and "medium risk" categories. These categories are to be used to selectively allocate limited inspection resources, so the risk classification should look like a pyramid, with more in "low", less in "medium" and even less in "high"[423].

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[421] A variation of this is to consider "inherent risks" as linked to the type of activity and its size, "vulnerability factors" that can increase inherent risk (e.g. location, populations affected), and "track record".

[422] Three categories of risk being the minimum, and in our experience usually a sub-optimal number. Baldwin and Black (2010) rightly remark that the number of risk categories varies greatly. See BRDO (2012) for one example of "more than three but not too many".

[423] A key "reality check" is to compare the risk categories thus created to relevant statistics on hazards affecting the country, when possible), otherwise absurdity can ensue. E.g. in Kyrgyzstan hairdressers were classified uniformly as "high risk" due to old Soviet-time

Implementing these criteria for actual planning is often another challenge, because it requires consolidated data on establishments and software to use it. Research has shown that not only are consolidated databases with adequate information rare in developing countries and transition economies, but also in many agencies of OECD countries (cf. Blanc 2012). Some of the challenges involved in setting up such systems are:

- Collecting the information initially to create a database;
- Setting up a mechanism to update this data constantly;
- "Pooling" data across inspectorates to improve efficiency and effectiveness.

The overall take-away from the experience in designing risk-based rating and planning systems is that this is feasible if one moves away from a "statistics-based" approach and adopts a more flexible one, which incorporates generally available scientific finding, aggregate data, lessons from the practice etc.. The difficulty is then mainly in the implementation, which requires data and information management. While such approaches may appear excessively "unscientific", the point is again to question to what practices they should be compared. When put against a complete absence of targeting except by the whim or hunch of individual inspectors or managers, or very crude approaches based only on individual experience of seasoned inspectors, such imperfect risk-based approaches are considerably more evidence-based and consistent.

An "alternate account"? "controlling harms" through "projects"

At least one author has somewhat challenged the terminology of "risk" altogether, and proposed an alternate account of what "control" work is about, and how to improve it. Sparrow (2008[424]) deliberately avoids the word "risk" and prefers "the word "harm" for its freshness and for its generality, and for the fact that scholars have not so far prescribed narrow ways to interpret it. I'd like to find a way that covers the broadest set of bad things.[425]" In practice, the use of "risk" is probably far more flexible than Sparrow suggests, and for all intents and purposes his use of "harm" is not very different from what we have named above "adverse effect". In fact, many of the definitions of "risk" in a regulatory inspections context in fact use the word "harm" (risk being equivalent to the combined likelihood and potential magnitude of harm). This being clarified, let us consider what Sparrow has to say about both *harms* and *risks.*

His primary concern is that broad terms such as "risk" cover a number of different "operational challenges", and that these are insufficiently investigated. First, there are both probabilistic risks, as well as current or past problems[426] – and, in most cases, regulators have to deal with both types, but they involve different "operational challenges". In addition, there can be many *levels* at which "risks" or "problems" manifest themselves and, in Sparrow's view", the "literature seems to have gravitated to the highest levels and to the lowest levels of aggregation, with less attention (so far) paid to the messy, complex and textured layers in between[427]". This is the core of Sparrow's argument – that the actual *operational* level has been mostly forgotten. He sees risk perceptions research (e.g. Tversky and Kahneman 1974, 1979) as helping us to understand reactions, decisions and behaviours at the individual level – and "at the opposite extreme – the highest levels of aggregation – risk analysis helps us navigate the complexities of macro-level resource allocations for risk-control, and helps us evaluate the costs and benefits of various macro-level interventions[428]". Let us consider his views and recommendations for the intermediate, operational level.

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rules (and rent-seeking considerations), even though no health statistics backed this up (note: see chapter 1 on the roots of this classification in the Stalin era).

[424] See also Sparrow 2000.

[425] Location 285, Kindle edition.

[426] *Ibid.*

[427] Location 307, Kindle edition.

[428] Location 331, Kindle edition.

In Sparrow's perspective, "it is practitioners, not theorists, who need to know how to navigate the textured substructure of any general risk. It is they who have to know at what level of aggregation (…) to define a new project, and how many knots (harm-reduction projects) to take on at any one time. It is they who have to construct the data gathering practices and analytic lenses that enable them to spot the knots (risk concentration).[429]" His approach is one that squarely focuses on operational practice.

Some of the key *challenges* he identifies on the way to *harm-reduction* are linked to the *nature* and *characteristics* of specific harms: some "have a brain behind them" (involving authorities in a "game of intelligence and counter-intelligence"), some are "essentially invisible, with low rates of reporting or detection"), some correspond to powerful performance incentives, others are rare but potentially catastrophic[430]. These different challenges, to be properly addressed, require a set of methods and approaches that Sparrow covers in the second part of the book.

Another critical question is that of measurement – which, as we have seen above, is highly problematic. He points out the inherent tension between regulatory enforcement work that is mostly organized around "functions", "programs" or "processes" – and the need to give a "compelling account of *harm controlled*"[431]. Moving from reporting on *outputs* to reporting on *outcomes* can be mandated from above, but achieving it is far more difficult. It involves solving the questions of *causality* and *attribution,* as well as whether "it is possible to measure prevention", "accidents that didn't happen"[432]. Sparrow's contention is that it is in most cases practically impossible to prove causality, but that changing the way work is organized and performance is reported can allow to make a convincing case based on "the contributing micro-level outcomes: *the stories of the projects*[433]". While such a method will definitely not be "scientific" and will not "prove" causation, by building accumulated convincing micro-success stories, and as long as they "constitute significant progress towards important strategic objectives"[434], it will make it far easier for the organization to make a strong case for its effectiveness.

Without doubt, Sparrow's work is important, and it is influential among practitioners, because it focuses on a level of "operational challenges" that has generally been under-researched. His central recommendation in operational terms is to focus on "unpacking" aggregate harms and identify "knots", causalities, patterns, and structure interventions on this basis, i.e. by "projects" rather than through fixed functional structures. From our perspective, his emphasis on practice, and his suggestion that convincing patterns of effects may be more realistic than absolutely scientific attribution are clearly relevant. On the whole, however, we would not say that Sparrow's vision really is an "alternate account" of risk-based planning and risk proportionality in inspections and enforcement. Rather, it gives inspection officials very useful directions on how to make sense of problematic patterns, how to design more "creative" interventions.

Not only is our research focus at a somewhat more "aggregate" level, but we also believe that Sparrow's insights are best applicable within organizations that have *already* moved to a risk-based approach. His recommendations will then improve effectiveness, review organizational structures, put the question of risk (or "harm reduction") at the centre of operational decisions in practice and not just in theory. Thus, while we consider these insights as sufficiently important to cover them in some details here, we will make limited references to his work elsewhere in this research, as it mostly relates to the question of operational implementation within the context of an already "risk-focused" agency.

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[429] Locations 366-375, Kindle edition.
[430] Locations 385-395, Kindle edition.
[431] Locations 2365-2372, Kindle edition.
[432] Locations 2422-2432, Kindle edition.
[433] Location 2516, Kindle edition.
[434] Location 2575, Kindle edition.

b. Dealing with risk: precaution, risk aversion, risk proportionality

i. Risk aversion and crisis-driven "panic" reactions

Introduction and definitions

In many areas of life, consciously or not, citizens rely on rules and regulations protecting them, and on these regulations being effectively complied with and enforced. Such expectation of protection underpins the trust in the food we eat, the products we buy, and the air we breathe. In practice, however, if designed inadequately or with unrealistic expectations, regulations can fail to work. In other cases, market incentives and contractual obligations may be sufficient, without the need for regulation to intervene. Often, implementation is the problem: insufficient guidance and support, or lack of resources for control and enforcement, or wrong methods, can all lead to disappointing levels of compliance. But there clearly remain "market failure" situations where regulations are indispensable to ensure safety and protect the public interest and where, if well designed and implemented, they can be very effective. Likewise, for some of these regulations, inspections and enforcement by state authorities are indispensable to promote compliance and, if done with the right methods, can ensure that regulatory goals are reached.

Over the past two decades, tools and methods of "better regulation" have been developed and put in practice, aimed at ensuring that existing and new regulations are of the efficient and effective kind. Somewhat more recently (but since at least 10 years), these improvement efforts have also extended to the whole "regulatory delivery" sphere, all the actions and tools that aim at turning regulation into practice, in particular regulatory inspections and enforcement. In spite of these tools and efforts, however, complaints abound that many new laws and regulations continue to be adopted that fail to pass muster in terms of necessity, cost-benefit and other key criteria, and political decisions on delivery tools and methods (licenses, permits, inspections, enforcement approaches) also frequently appear at odds with evidence and best practice, disproportionate, inefficient, or frankly counter-productive.

In some cases, this seems to happen because regulations, decisions, priorities are pushed through in response to sudden accidents, crisis situations, in a kind of panic reaction that has been called the "risk regulation reflex", a term coined by Margo Trappenburg in an essay she prepared for the "Day of Risk" conference, organized in May 2010 by the Dutch Risk and Responsibility programme[435]. The term "risk regulation reflex" is meant to refer to a mechanism leading to disproportionate government interventions surrounding a risk or following an incident. A corollary of the risk regulation reflex is that preventing, avoiding or compensating for risks is often seen as a government responsibility by default – in other words, the "risk regulation reflex" would be in some ways the *opposite* of "risk-based regulation"[436]. The "risk regulation reflex" concept can apply to both "short term" incident responses, and to the broader, "long term" trend towards ever more safety. It can designate "a trend towards ever more far-reaching safety measures which carry the chance of imbalance between the gain in safety and the costs and side effects of the measure, and the pitfall of public demand for a swift response following an incident leading to disproportionate measures" (van Tol 2012). From our

[435] Over 2008-2009, originally as part of the Netherlands' Inspection Reform Programme, increasing focus was put on exploring "overreaction to risk" and how to address it, building on the UK RRAC's work (van Tol 2012). This led in November 2009 to the creation of what came to be called the "Risk and Responsibility" programme (van Tol 2012, 2013) – in Dutch "Risico's en Verantwoordelijkheden".

[436] See Rothstein, Borraz and Huber 2013 on how the "duty of protection" (*"Schutzpflicht"*) embedded in German legal principles makes it difficult to implement risk-based regulation.

perspective, both aspects are essentially linked: disproportionate responses to incidents are made possible by a context of "risk aversion" and, in turn, successive incident responses end up building a trend. Both can lead to changes in inspections and enforcement practices that go opposite what "risk-based inspections" seek to achieve.

Is risk aversion on the rise? A disputed issue

Unfortunately, solid statistics on regulations, and in particular on how many may have been adopted as a result of such "reflex" situations, are hard to come by – meaning that it is impossible to prove beyond doubt that the phenomenon is real. Anecdotal evidence, as well as important studies[437], suggest however that risk aversion (e.g. in the form of the "risk regulation reflex") is a significant cause of inadequate policy responses – either directly (new rules developed in the immediate aftermath of the event), or by making their way into the election platform of a party, and being introduced after an election victory. In all cases, what happens is that political priorities trump analysis and evidence, and that these political priorities are defined based on risk avoidance and "absolute" statements ("this risk is unacceptable" and "this should never happen again").

In 2005 already, Tony Blair, then Prime Minister of the United Kingdom, issued the following warning: "In my view, we are in danger of having a wholly disproportionate attitude to the risks we should expect to see as a normal part of life. This is putting pressure on policy making [and] regulatory bodies (…) to act to eliminate risk in a way that is out of all proportion to the potential damage. The result is a plethora of rules, guidelines, responses to 'scandals' of one nature or another that ends up having utterly perverse consequences[438]." This same speech was quoted in *Rethinking Regulation,* a report published in January 2006 in Australia and summarizing the work of the "Taskforce on Reducing Regulatory Burdens on Business" (Banks 2006). This report opened with remarks on the growth of regulation, which covered Australia but could have been about many other countries: "Australia has experienced a dramatic rise in the volume and reach of regulation, in response to a variety of social, environmental and economic issues". It then moved on to discuss the possible causes of this regulatory inflation: "It is important to recognise the forces behind the growth in regulation if sustainable solutions are to be found. Perhaps the most fundamental of these is the changing needs and expectations of society itself. Some of this is a natural and desirable consequence of rising affluence and increased scientific knowledge. However, in the Taskforce's view, a more problematic influence has been increasing 'risk aversion' in many spheres of life. Regulation has come to be seen as a panacea for many of society's ills and as a means of protecting people from inherent risks of daily life. Any adverse event (…) is laid at government's door for a regulatory fix. The pressure on government to 'do something' is heightened by intense, if short-lived, media attention."

Both Tony Blair and the Banks report thus give a "classical" summary of the "risk regulation reflex": excessive reaction to adverse events, excessive demands for absolute safety and protection, resulting in regulations that go far beyond the needed and the reasonable. While the Banks report focused on regulations affecting businesses (and particularly small businesses, reminding that "regulatory burdens fall disproportionately on the economy's many small (including 'micro') businesses, which lack the resources to deal with them"), Tony Blair expounded also on the impact of such risk-averse regulations on "daily life": "something is seriously awry when teachers feel unable to take children on school trips, for fear of being sued" – and further in the same speech: "for example, one piece of research into a supposed link between autism and the MMR single jab, starts a scare that, despite the vast weight of evidence to the contrary, makes people believe a method of

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[437] See e.g. Productivity Commission 2012 – page 316. All this work owes a lot to the work of the UK's Risk and Regulation Advisory Council – see RRAC 2009 (series of publications) in bibliography section.

[438] 'Common Sense Culture, Not Compensation Culture', Speech to the Institute of Public Policy Research, London, May 2005 - http://www.theguardian.com/politics/2005/may/26/speeches.media

vaccination used the world over is unsafe. The result is an increase in risk to our children's health under the very guise of limiting that risk". Indeed, the MMR vaccination scare is a perfect example of "scare" leading to adverse health effects. Problems with what used to be routine school activities (school trips, or bringing home-baked cakes) have also been reported (and felt sorely) in many European countries – though they do not always originate in new regulations, but sometimes in increased litigation and enforcement of liability originating from quite "old" regulations.

Critics have pointed out (Carroll 2006) that the Banks report was making important claims, but did not always have data to back them up. Showing that the volume of laws and regulations has increased may only reflect the calls for higher quality of rules and increased quality, and the estimates of administrative burden are (by the Banks report own admission) difficult to make and highly variable. Furthermore, again as per the Banks report itself: "While a number of studies have sought to estimate the economic costs of regulation in Australia, the limitations of such studies mean that the estimates should be treated with caution (…). Further, none of the studies measure the extent to which the compliance costs exceed what is necessary to achieve the policy goals underlying the regulations, which is the focus of this review. Quantifying this unnecessary element is even more difficult, and clearly". Indeed, it is difficult to convincingly prove (or disprove) that the regulatory burden has increased, and/or that regulation is ever more intrusive and covering areas of life that used to be freer, *and* doing so in ways that add little or no discernible safety or other benefit. It could conceivably be done by thorough analysis of changes in regulations, benchmarking across countries etc. – but it would require a significant research undertaking, and resources.

In short, there is some discussion as to whether such "risk adverse" responses are overall on the rise or not, whether the volume (and consequences) of poorly-designed policy responses they produce is increasing or not – and overall it is very difficult to quantify how large the effect of such policies is (see Helsloot, Schmidt 2012 and UK National Audit Office 2011). Available evidence however suggests that "risk aversion" and the "risk regulation reflex" are not insignificant problems – not only in economic terms, but also because excessive regulation undermines the legitimacy of public action, both because it hinders legitimate private activity, and because it fosters the illusion that the government can achieve "perfect safety", which is bound to be disappointed ("it can hinder society's self-reliance and resilience, restrict the freedom of citizens and businesses, diminish the government's authority as a result of promising too much" – van Tol 2012). In addition, a negative impact on the economy in turn will have significant negative impact on safety and health – as pointed out by Helsloot and Schmidt (2012): "life expectancy is strongly related to a person's income (…). Life expectancy actually increases up to seven years for people with a higher income compared to people which are poor, and the difference in the number of years the two groups experience a good health is as much as 16 to 19 years. A safer society, at least if we define safety in terms of average life expectancy, can consequently be reached by boosting prosperity in lower income groups" (see also Mackenbach, Kunst, Cavelaars 1997).

Thus in our view the limitations in evidence are not a major obstacle in terms of establishing the importance of risk-based approaches as a way to balance "risk aversion" trends. First, because "anecdotal" evidence of "regulatory creep" and "risk aversion" in regard with "daily life" activities is quite substantial, and the growing discontent it generates in a number of countries sufficient cause to think about how to alleviate it. Second, because there is also considerable evidence, through benchmarking in specific regulatory areas, that some countries within the EU, i.e. with many of the same fundamental parameters and many harmonized regulations, impose far more burdensome regulations and regulatory procedures (licensing, permitting, inspections etc.) than others – without additional safety to show for it in many cases[439] - and it is precisely this

[439] An important clarification is in order here: in *some* cases, countries impose higher regulatory requirements than is the case elsewhere in the EU *and* have a clear difference in results to show for it (e.g. several nordic countries in environmental matters). In

evidence that we intend to consider more closely in the third chapter. Finally, because in any case, regardless of overall trends in risk aversion or regulation, ensuring that the best possible policy decisions are taken in terms of effectiveness and efficiency is of public benefit.

In this perspective, rather than focusing the discussion on whether there is convincing proof of an increase in regulatory burden (which is debatable, particularly if we are talking about net burden, i.e. "burden less benefits"), or an increase in risk aversion in the society (with some clear examples in some areas, but also important counter-examples), the focus should be on what situations, contexts and systems produce bad decisions – and which ones can, on the contrary, foster good ones. To quote the authors of The Government of Risk: "macroscopic and world-historical perspectives on risk and its management may have their uses. But most of them do not explain, or even describe, variety within the putative 'regulatory state', 'risk society' or 'audit society'. Yet casual observation, academic inquiry, and official surveys alike indicate substantial variety in the way risks and hazards are handled by the state" (Hood, Rothstein, Baldwin 2001).

Understanding "risk regulation reflex" processes

One may wonder why reacting to a disaster would necessarily lead to the wrong response. Since the Middle Ages at least, if not earlier, regulations (and institutions) have come into existence in response to risks, real or perceived, and often in the immediate aftermath of disasters of some kind (be it a sudden event or a prolonged situation). This has been particularly true of the growing system of regulations and regulatory implementation structures that has developed over the past two centuries – covering occupational safety and health and labour rights, environmental protection, food safety etc. We have outlined some of this early history in our first chapter. While we attempted to show how much of the adoption of new rules and creation of new institutions was linked to risk *perceptions* (mediated by a number of social, political and economic factors), it is nonetheless clear that some important regulatory steps responded to very real risks. Just as clear is the fact that, in spite of the difficulties in causality and attribution, and the evidence that some improvements predated regulation, at least *some* of the improvements in safety and public welfare were driven by these regulatory changes.

Taking a couple of examples will help illustrate the point. In the UK, the 1833 Factories Act led to the creation of HM Factory Inspectorate in the same year, and the 1842 Mines Act to the creation of the Mines Inspectorate in 1843 (with increased powers from 1850). In both cases, this came in reaction to public opinion being shocked about working conditions in factories and mines (particularly for children and women). In the United States and much of Europe, as in the UK, mining accidents led to safety regulations being adopted, and often inspecting institutions set up, in the 19th century. The same goes for instance for the US Food and Drugs Administration, created in 1906 following scandals about adulterated or otherwise hazardous foods and drugs[440]. Tragedies caused by drugs touted as "safe" (e.g. Thalidomide) led to increasingly stringent prior approval regimes for medicines in the 20th century (and further scandals, such as the *Mediator* one in France, have led to further changes in these systems). Mid-20th century "killer fogs" in London led to pollution controls. The Seveso disaster gave its name to an EU directive (and its successive iterations), and other chemical disasters such as Bhopal in India, Love Canal in the US etc. all led to strengthened regulations and oversight[441].

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such case, it becomes a question of cost-benefit analysis and of prioritization in values and objectives whether to opt for such stronger regulations or not. In other cases, countries impose considerable burden often through numerous permits, approvals etc., or additional regulatory norms (like the lift safety example we used above), with very little or no positive impact at all. This latter case is the one we are referring to here.

[440] http://www.fda.gov/AboutFDA/WhatWeDo/History/CentennialofFDA/default.htmUK

[441] See e.g. Balleisen, Bennear, Krawiec and Wiener (in press) as well as IRGC Conference presentations by the same authors

Even though critics of government regulations would argue that current occupational safety or food regulations impose too much burden on economic initiative, the part of these regulations that dates back to a century or more ago is widely accepted as having delivered considerable benefits at what appears to have been a very limited cost to economic growth, innovation etc. What, then, has changed so that nowadays dramatic events are said to lead far too often to regulatory responses whose costs outweigh the benefits they may bring (or even sometimes bring only negatives)? What is it that would explain a "risk regulation reflex" with overwhelmingly negative outcomes? The first change is probably the increasing marginal cost of adverting accidents and other hazards: the higher the existing safety level, the higher the cost of additional improvements in safety. As Helsloot and Schmidt (2012) put it: "every improvement curve flattens out at a certain point. Consequently, anyone who wants to achieve anything in the 'tail' of the curve needs to be very cautious about making substantial investments, as [their costs] can easily be disproportionate [to their benefits]".

This "flattening of the improvement curve" is a feature that is very difficult or impossible to affect through public policy – and thus there is an inherent character, to some extent, in the fact that further improvements in safety and health will, more or less inevitably, have greater costs than the ones that came from earlier "low hanging fruits". There are, however, a number of other factors that can lead to an excessively costly and poorly thought-through "risk averse" way of regulating, and they are often understood to be:

- Lower risk-tolerance, meaning that we tend to address issues that in earlier times would have been accepted as the normal state of things
- Difficulty for scientific evidence to overcome ideological preconceptions, pseudo-science, and fundamental psychological patterns with regard to risk
- "Positioning" of political and other actors (media, interest groups) in a world where information flows extremely quickly and where what used to be small, local news items swiftly become national or global. This leads to over-reaction, and to decisions being taken too quickly and without proper analysis, insufficient attention to regulatory design etc.

We would argue that all three points are important, and indeed there are factors pertaining to risk-tolerance and risk-aversion (and their psychological underpinnings), to the trust or lack thereof in scientific advice and in policymakers statements, and to policy actors – but the characterisation above leads to many misunderstandings of how unavoidable risk-aversion is (or is not).

Psychological aspects of the risk response

Indeed, psychological aspects are important, and indeed human heuristics are poorly suited to dealing with uncertainty and statistical aspects of risk (see Tversky and Kahneman 1974, 1979)[442] – but research and experience also show that, when engaging properly with the public, it is possible to discuss risk in a rational way and to ensure that risk perception does not necessarily degenerate into risk aversion, but rather that risk acceptance can be fostered. Indeed, while risk perception is essential in determining each member of the public's initial response to a risk or incident (see e.g. Slovic, Fischhoff, Lichtenstein 1982, Slovic 2000), what matters in the end is whether the initial perception is "frozen" or not.

Repeated research (see Helsloot, Schmidt 2012) has shown that, while simple questions asked without any background or any additional information tend to produce responses where people manifest strong risk aversion, this can change when additional information and context are provided. Indeed, people do not

[442] See p. 187 below for more discussion of human heuristics. For a specific discussion of availability heuristics and their effects on risk regulation, see Kuran and Sunstein 1999.

respond to risk only from a "more" or "less" risk perspective – but integrate a number of other values (fairness, equality, liberty, self-reliance etc.) (see Eeten, Bouder 2012[443]). Research suggests that "people seem to be able to make a difference between their own risk perception and what risks should be accepted reasoning from an administrator's point of view" – when given sufficient information on costs and benefits, they will balance the advantages of addressing a specific risk with its downsides and with other alternative uses of resources, whereas if only asked whether a given risk is important and worth addressing, they will usually answer "yes"[444].

The conclusion here would seem to be that the public may well be far smarter than usually given credit for – engaging members of the public takes time and resources, but can yield a far more balanced and rational approach to risk than relying on rushed "yes/no" questions with no context and information[445]. Balancing these findings and optimistic views on the possibility of a rational debate on risk comes other evidence that public discussions of risk are very difficult because of the problem of risk perception. We have already presented the findings by Slovic and others on how perceptions of risk are often very distant from what statistical estimates would suggest. In addition, other psychological factors mean that a discussion of a statistical risk may see the very salient and understandable risk ('death') be perceived far more strongly than the statistical probability ('one in a large number', which is very difficult to conceive). A more nuanced conclusion would thus be that attempting to have public discussions of risk is possible, but requires to set a discussion framework that starts in small settings and builds understanding of the issue (and of the data) among stakeholders (including the media). When risk discussions suddenly break out in public discourse without such an effort at building a joint understanding, the results tend to veer much more towards risk aversion and "panic" reactions.

Science, transparency, trust

Likewise, the public's relationship with science is also more complex than many experts would suggest, who mostly see the public as insufficiently listening to science and not able to properly distinguish "real" from "pseudo" science. Most of these conclusions lead their authors to recommend that efforts be made to ensure that the public defers more to scientific advice, but in ways that seem more like "communication" and "propaganda" than real engagement.

There is certainly a share of the public who will not accept scientific findings and rather adhere to other views – be they based on religion, ideology, conspiracy theories or any other worldview. When a significant share of the population holds such views, it is important to acknowledge them in the public discussion, including indicating that the policy decision will *not* be based on them, but on scientific findings and utility maximization[446]. What matters more to us here is that, for those members of the public (typically, the majority) that do *not* hold deeply views that are fundamentally at odds with a scientific perspective, trust in scientific advice (and in policies that claim to be based on it) can be built up – and can be destroyed as well.

Dissimulation or manipulation of evidence, claims of full harmlessness for things that later are proven to have been extremely hazardous (or the opposite: claims that something is very dangerous whereas further evidence

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[443] For an excellent overview of the different values that can underpin radically different approaches to risk and trade-offs in the criminal justice field see Buruma 2004.

[444] In one of the experiments presented by Helsloot and Schmidt (2012), 35% of respondents essentially change their mind within the course of one single interview, when moving from simple dual questions to a more considered discussion and asked to put themselves "in the shoe" of a policy maker.

[445] Supporting this view, see Posner 1998 and Esptein 2008.

[446] Discarding them without even a proper mention, by contrast, decreases legitimacy by making the process "unfair" from a procedural justice perspective, as dissenting views are not even given a "voice" (regardless of the final policy outcome).

demonstrates it to be less so), can severely damage the public's trust in science – or at least in official claims for policies to be based on "science". We will discuss these issues in more details further in this research.

Policy actors – the risk aversion cycle, and the problem of "risk experts"

Finally, the question of policy actors is important, and has at least two aspects – one being the way all actors in the "risk regulation reflex" are linked through a kind of cycle, the other being the activities and impact of "policy entrepreneurs".

The circular aspect is the way, in a "risk regulation reflex" process, all actors in a way attribute responsibility for decisions and actions to someone else: the media claims that the public is outraged and demands action, politicians say they have to act because the issue is all over the media – and civil servants claim they are compelled to act by politicians and the media. As for the public, it faces a barrage of media coverage, and politicians all promising that "it should never happen again", and feels reinforced in all feelings of risk aversion. This relationship has been called "Februari's Circle" (van Tol 2014) after Maxim Februari, who exposed it as part of the work done for the Risk and Responsibility programme (van Eeten *et al.* 2011). The crucial element of this circle is that no one is taking responsibility – and everyone claims to be doing their job. The media say they have a responsibility to voice public concerns (and an interest in "crisis", which sells well). Politicians say they have to respond to their constituents' demands (and an interest in winning, not losing, elections). Civil servants say they have a duty to follow priorities laid out by elected politicians (and an interest in keeping their jobs). In all this, interest is more evident than duty – and the attitude of members of the public is typical of the "Not In My Backyard" (NIMBY) pattern (Helsloot, Schmidt 2012).

As we have indicated above, this circle is not a fatality: breaking may be possible, by providing the public with more information and context, and initiating a real public conversation about the risk at hand. This requires, however, initiative from at least one group of actors. This is not easy – as Carrigan and Coglianese (2012) put it: "Intense reactions by the public (…) drive an intense desire by politicians to take action. Under such circumstances, taking any action targeted at the regulatory process, regardless of how well or poorly crafted, will be better politically than taking no action at all. Political incentives point in the direction of quick legislative action that responds to calamities. Voters focus much less on considerations of how a law will be implemented than on the enactment of a new law itself (Mayhew 1974; Mazmanian and Sabatier 1983). Legislators can reap rewards from passing legislation regardless of whether doing so turns out to be realistic or effectual". However, we have seen that research also shows that engagement with the public can yield real changes – thus, if the "circle" can be interrupted, the pressure to act regardless of effectiveness will stop. This report aims at presenting ways in which space for such a "rational conversation" can be created.

In addition to actors in the "circle" seeking to push responsibility on others, there are some specific actors who *actively* seek to strengthen risk aversion, who have an active interest in reinforcing the reflex, in making the particular risk appear as particularly serious so as to maximize the response. What many authors call "policy entrepreneurs" can be of many kinds, and have been studied from a variety of angles (see e.g. Roberts, King 1991 – Mintrom, Norman 2009 – Cohen 2011). The importance of "policy entrepreneurs" as one of the elements shaping response to risk has been pointed out by Hood, Rothstein and Baldwin (2001)[447], and the presence and activity of these "entrepreneurs" is for them one of the elements that can lead to different "risk regulation regimes". From the perspective of the RRR, which represents a specific case of "risk regulation regime" (one with particularly strong response compared to what could be expected from a rational analysis of the "market failure" – see again Hood, Rothstein, Baldwin 2001 for a broader typology), a feature seems to

[447] And we have seen that this role is not new, as it also had its importance in the creation of the US FDA in the early 20th century.

be that there are "policy entrepreneurs" particularly successful at pushing for such a response. These "policy entrepreneurs" were generally already pushing for their favourite policy, and the incident gives them an opening: "Crises provide opportunities for policy entrepreneurs to place at center stage those solutions they have already been seeking to see adopted (Kingdon 1984:91). Even if those solutions were not developed to address the particular problem at hand, politicians often feel compelled to consider them— to "do something" (Carrigan, Coglianese 2012).

They can belong to different categories – private businesses in some cases (e.g. suppliers of equipment or services to address the particular risk considered, e.g. lifts retrofitting as in the French example presented above), NGOs in others (e.g. those focusing on environmental protection, or some trade unions etc.), but also "experts" (independent or affiliated with consulting firms, research institutions, NGOs, businesses etc.) – and they are also quite often *inside* public administration (and in such cases, pushing for more regulation in their sphere of competence is a way of entrenching their importance, and their budgets – see Helsloot, Schmidt 2012).

Not all such "policy activism" is motivated by self-interest, far from it – "risk experts tend to really believe, and policy makers are made to believe, that an incident is proof that regulation should be tightened" (Helsloot, Schmidt 2012). The difficulty for civil servants and elected officials alike (and for journalists) is to decide whether these "risk experts" are right – to screen their proposals, or to review existing rules adopted in a previous "RRR moment". Indeed, "knowledge is required in order to determine what rules are disproportionate and can therefore be repealed. This knowledge is usually only available to the risk professionals of policy departments and their external advisors" (*ibid.*).

Thus, again, an essential step in order to avoid risk-averse, "reflex-driven" decisions is to provide time and space for careful consideration of arguments and evidence, rather than relying immediately on whichever "solutions" are advocated by "experts" which, even in the absence of material interests, will have a personal investment in their own field of study and expertise.

Modelling the policy decisions in a risk context

Another, more detailed way to look at these factors of "reflex" reactions and their consequences is the model proposed by, Balleisen, Bennear, Krawiec and Wiener (in press). In this model, crisis events can lead to small or large changes in risk perceptions, and the latter again to major or minor shifts in policy agenda. The magnitude of changes depends to a large extent on how the crisis fits or contrasts with baseline risk assumptions, and how the perception of the crisis is mediated by ideologies, heuristic models, narratives ("master-stories") etc. The interplay of interest groups' agendas, resources available, trust or distrust in specific institutions or actors, etc. then again influences whether the changes are substantial or mostly "cosmetic". Weber (in Balleisen *et al.,* in press) adds a psychological dimension to the analysis (based in particular on Tversky and Kahneman): for instance, humans tend to under-estimate the actual risk of events that are common and that they perceive as "normal", and to over-estimate the risk of events that have a very low probability but that they have previously experienced. There are many psychological mechanisms which mean that perception of risks by non-experts (be they politicians, journalists, citizens) can differ widely from what data shows the actual risk level to be. This is of course one of the primary reasons why over- (or under-) reaction to accidents and crises can occur.

In terms of sequence of events and reactions, this model sees events as being first mediated through baseline risk assumptions, and then modulated by a series of filters (ideologies, "master-stories", heuristics, media) in order to produce a "causal narrative" of the crisis. Depending on the different aspects of the context, this may result in blaming culprits or scapegoats, looking at structural issues, "policy regret" or bias confirmation. The

causal narrative may be agreed upon, or disputed. Then, the causal narrative or narratives themselves get complemented by expert analysis (or analyses) and the whole agenda or "policy menu" gets itself filtered by interests at play, resources available, institutional structures and the level of trust (or distrust) in institutions), to result in policy decisions. Depending again on the whole set of events and context, these may be "cosmetic" or "substantial" changes.

In a more formalized way, this model emphasizes the same factors as the "risk regulatory regime" approach of Hood, Rothstein and Baldwin (2001) or the key elements of the RRR evidenced by van Tol (2012) and Helsloot and Schmidt (2012): the importance of a context where values and visions of the public and the different actors shape how they perceive and react to risk, the impact of the intervention of experts and other actors to shape events into a "causal narrative" and a policy agenda, etc. It adds to this the importance of institutional capacity (or lack thereof) in steering the final policy decisions – Helsloot and Schmidt (2012) present, however, several examples of how the RRR can lead to policy decisions in favour of new regulations even in the absence of capacity to implement them (in several of these cases, the new regulations later end up being abolished, because they have not been seriously implemented).

All these analyses and models concur in highlighting the importance of *perceptions* and *shaping* of the issues, and also of what interests are at play, and what context the crisis occurs in. The key about the "reflex" mechanisms is the tendency to react *too fast* to the event – without giving sufficient time for inquiry and analysis. Against this, Bennear (in Balleisen *et al.,* in press) suggests that the answer should be "deflect" (take visible but inconsequential actions showing political attention but not locking-in potentially harmful decisions – thus giving time for further consideration) or "reflect". The key seems to be to create a shared understanding of this need to defer meaningful action until the situation has been more fully understood, to create the "conditions of possibility" for this time and "breathing space".

Relevance to the inspections and enforcement issue

The trends, research and discussions we have attempted to summarize relate to "regulation" in general, and not only or specifically to inspections and enforcement. They are, however, fully *applicable* to the inspections and enforcement "stage" of regulation. As mentioned above, the Netherlands' Risk and Responsibility programme, which led to the definition of the "Risk Regulation Reflex" concept, itself originated from the Netherlands' Inspection Reform programme. This inherent link between reaction to risks and regulatory control and supervision is an important angle for our study, and one of the areas where addressing risk aversion is most important.

Indeed, when incidents happen, inspectors and inspection services are often among the first to be blamed – and stricter, more frequent inspections very often top the list of "risk regulation reflex"-driven requests. When new technologies or practices emerge, inspectors may be the first to notice them – and possibility in some cases to prohibit them. Inspectors are on the "frontlines" of regulation, the main interface between rules and those who have to abide by them (mostly businesses, but also citizens).

Most of the difficulties related to inspections and enforcement in a perspective of rational risk management and risk mitigation come from a number of fundamental misconceptions on inspections themselves (their role and methods), and on compliance and safety (and their drivers) – misconceptions that are not only held by many members of the public (as well as "experts", interest groups etc.) but also by a number of inspectors and inspectorates managers.

These misconceptions revolve around the assumption that more inspections and stricter inspections (or more and stricter control, police checks etc.) will mechanically drive higher compliance, and that this will in turn automatically result in higher safety. This assumption in turn stems from a vision of compliance with rules is

primarily or exclusively driven by deterrence, fear and rational calculations. It also implies a belief that inspections, checks etc. do not have significant adverse and unintended effects. In turn, this excessive and unfounded assumption that deterrence is the major driver of compliance (and safety) and that inspections and checks are thus the primary tool to be used (and used as much as possible) fosters excessive expectations from inspections – i.e. that they should manage to ensure perfect safety, complete protection from risks in a given field.

Thus, the consequences of risk aversion on inspections and enforcement questions are serious. Understanding better the mechanisms of the "risk regulation reflex", and the ways to achieve a more balanced approach to risk, are essential to provide a foundation for "risk proportional" inspections.

ii. Uncertainty, trade-offs and transparency

Conflicting goals – and the pitfalls of excessive certainty

Individuals, societies, governments, international or "supra-national" organizations, all have sets of goals and objectives that coexist but may in some cases (or even frequently) come in conflict. Many would argue that the quest for more material well-being (observed both at individual and social level, and backed up by policies supporting economic development and the private sector) can conflict with another objective of both individuals, societies and public bodies, the protection of health and more broadly the environment. Certainly, it is not always the case that these goals conflict, as for instance the whole "green growth" idea (and realities) show. But there definitely are instances when objectives (and the values underpinning them) conflict. This conflict is clearly visible about risk – with risk-averse, "precautionary" demands on one side, and the push for a more risk-proportional, freedom-enhancing approach on the other.

A very good example of such conflict in goals, and of its possible consequences in terms of regulation, is presented by Ragnar Löfstedt in his article on the 'Swing of the Regulator Pendulum' (Löfstedt 2004): "the issue of both improving and implementing regulations are closely linked to the three main drivers of EU regulatory concerns: competitiveness, good governance and sustainable development. For example, if regulations are not improved, not only will European competitiveness be adversely affected, but also the criteria for good governance will not be met. Similarly, if environmental and health regulations are not properly implemented how can the EU state that it is taking sustainable development seriously?" He goes on to indicate that "the three drivers (competitiveness, sustainable development and governance) are, according to the Commission, closely interrelated and compatible. The Commission has long held the view that there is no actual conflict between environmental protection and competitiveness. It stated in the 1993 5th Environmental Action programme that: *The perceived conflict between environmental protection and economic competitiveness stems from a narrow view of the sources of prosperity and static view of competition*." While not commenting on this optimistic view held by the Commission, Löfstedt further exposes the tensions between the "precautionary" and "impact assessment" philosophies, and suggests that, in attempting to build credibility by showing "fairness" through "tough" decisions against business interests, the EU regulatory bodies have probably overshot their target and that the pendulum is likely to start swinging back towards "risk assessment" rather than "harm prevention".

This example suggests implicitly that there are, indeed, trade-offs – at least, in the author's perspective, between legitimacy of public authorities and economic growth. But we would argue that the cases presented in the article actually show that there is a tension between environmental and health protection and, if not economic growth overall (on which it is more difficult to comment because of the complexity of the effects involved), at least the availability of cheap products on the market, and possibly short-term job creation. One

of the examples used by Löfstedt is the ban on virginiamycin in animal feed, and the use of the precautionary principle by the European Court of First Instance in its 2002 ruling against Pfizer. Since the article states that "there was no reputable scientific evidence that there was a transfer of antibiotic resistance to humans as a result of the use of the antibiotic in animal feed" and further suggests that the decision was excessive (and an example of steps that may in the end trigger a "swing of the pendulum" in the other direction), it is worth looking (of course with the benefit of hindsight) at how well this decision has stood the test of time in terms of science and risk assessment. In its latest guidance for industry on the subject of use of antibiotics in animal feed[448], the United States Food and Drugs Administration (FDA) emphasizes the need "to help phase out the use of medically important antimicrobials in food animals for production purposes[449]". In 2013, the US Center for Disease Control (CDC) stated in its *Antibiotic Resistance Threats in the United States* report: "Antibiotics are widely used in food-producing animals (…) This use contributes to the emergence of antibiotic-resistant bacteria in food-producing animals [which] are of particular concern because these animals serve as carriers. Resistant bacteria can contaminate the foods that come from those animals, and people who consume these foods can develop antibiotic-resistant infections. (…) Scientists around the world have provided strong evidence that antibiotic use in food-producing animals can harm public health (…) Because of the link between antibiotic use in food-producing animals and the occurrence of antibiotic-resistant infections in humans, antibiotics should be used in food-producing animals only under veterinary oversight and only to manage and treat infectious diseases, not to promote growth."

We have quoted on purpose from US rather than EU agencies, because many authors (see e.g. Löfstedt 2004, Wiener 2003) would agree that they have been (at least in recent decades) rather *less* precautionary, and because (partly as a consequence of this regulatory stance and partly as a result of different economic structures) antibiotic use in animal feed is considerably more widespread in the US than in the EU. The fact that the FDA guidance documents are voluntary (a clear result of the need to balance safety issues and economic interests, and of the difficulty to overcome industry resistance) cannot obscured the fact that both the FDA and CDC are highly concerned and are trying hard to eliminate the routine use of antibiotics in animal feed, particularly when there is no disease being controlled and antibiotics just function as growth aid. In April 2014, the FDA released a list of "voluntary withdrawal" including 16 Antimicrobials for use in food-producing animals[450] – it included virginiamycin, the drug at issue in the *Pfizer* 2002 case. It seems that the Court's "precaution" was not so mistaken and groundless after all.

This shows the importance of caution when considering risks where significant uncertainty exists and knowledge is still under development. While designing adequately proportionate decisions in cases of well-known and understood risks is in general possible, there is a strong case to be made for a combination of "precaution" and "proportionality" when dealing with uncertainty. This may occasionally result in decisions that hindsight shows to have been excessive, but also in a number of other cases may result in avoiding very significant damage or disasters (see European Environment Agency 2001 for numerous examples). This is true not only for strictly-speaking "regulatory" decisions (adoption of new rules) but also for inspections and enforcement decisions. Inspectorates are often expected by public opinion to immediately address any risk, even when that risk is not certain, through control visits, withdrawal of products, sanctions etc. In cases where the "uncertain risk" is covered by the agency's mandate (i.e. it has authority to act), but also in other cases

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[448] Guidances #209 issued April 13, 2012 - #213 issued December 2013 – both referencing guidance #152 issued October 23, 2003 – see http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM299624.pdf and http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM216936.pdf

[449] "FDA's Strategy on Antimicrobial Resistance - Questions and Answers" http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/ucm216939.htm - see also http://www.fda.gov/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/JudiciousUseofAntimicrobials/default.htm

[450] http://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm392461.htm

(because the agency could be at least lobbying to have its mandate extended), it is crucial for them to have a transparent approach to how they seek to balance risk management and precaution.

This applies for instance to authorizations and supervision of the use of medical drugs and devices, chemicals (food additives, pesticides etc.), or any other new technology. When considering the long-run, such a careful balancing act is important, and adopting a 'risk-based approach' should not be understood to automatically mean discounting risks that have not been proven significant simply because data is still lacking (as opposed to well-known risks where the data clearly points to their being of low importance). Indeed, a track record of discounting risks when uncertainty is significant, and of subsequent damages where it had been claimed that there was none to be feared, results in undermining the credibility and legitimacy of public authorities and their scientific advisors – and thus in undermining support for risk-proportionality. It is not just a question of costs and benefits in terms of life and health, and economic and social impact, but of the "snowball" effect that credibility loss will have.

Understanding and accepting trade-offs

A far better path towards understanding the "risk regulation reflex" problem and laying out potential solutions seems to us to be sketched out in the contribution of Cary Coglianese and Christopher Carrigan to the collective volume *Regulatory Breakdown*. Quoting them: "Is it possible that the ultimate failure of the U.S. regulatory system is that the American public, through its elected representatives, asks regulators to oversee activities that are at once desired but also deadly?" (Carrigan, Coglianese 2012). In other words, there *are* trade-offs: to a certain extent, different goals may be compatible, but at some point, they may conflict with each other, and choices (conscious or unconscious, open or hidden) will have to take place.

This is important in terms of managing expectations from inspections and enforcement agencies specifically, and not only expectations from government regulation generally – and thus in achieving support for risk-based approaches that are *explicitly* founded on the premise that preventing every risk is impossible, and that there are some risks where the costs of attempting prevention would be higher than the potential benefits. Thus, the very idea of trade-off is central to risk-based inspections, and the refusal of trade-offs is a key driver of risk-averse approaches, and of attempts to inspect every establishment, and to practise "zero-tolerance" enforcement.

As Carrigan and Coglianese point out, denying these trade-offs may well be one of the key reasons behind the RRR – as "insufficient" or "failing" regulation becomes an ideal scapegoat when something goes wrong. Quoting them (*ibid.*): "Calamities, we suggest, bring with them strong tendencies for faulty assessments of both underlying causes and necessary reforms. These tendencies are due to a host of factors, including both psychological biases as well as nuances in the policy process itself. The pressure politicians feel to adopt change even without solid policy analysis (…) means that solutions can end up being adopted that are either unrelated to the true cause of disasters or that actually work at cross-purposes to improving conditions. In addition, sometimes the underlying problem may not have to do with the (…) operations of the regulator or the regulated industry but may instead reflect inherent societal choices about trade-offs."

Disasters easily lend themselves to faulty assessments, based on heuristics that humans have developed to survive in their natural environment hundreds of thousands years ago, but are increasingly inappropriate to understanding situations in a technologically advanced environment and highly complex societies (Bennear 2014 and Carrigan, Coglianese 2012). Again quoting from the latter: "psychological and behavioral economics research (…) support the notion that people tend to focus more on worst-case outcomes and to believe that vivid events are more common than they really are (Tversky and Kahneman 1973). Moreover, researchers studying these phenomena— known as the "availability heuristic," along with other cognitive biases— also

report that they can be exacerbated by the media, which for obvious reasons tend to focus on especially dramatic events (Shrum 2002)." In such situations, regulators and regulations provide ideal points of fixation for negative emotions. The "culprits" in the narrow sense may be the business operators or individuals who were directly involved in the disaster, but regulators often end up receiving nearly as much blame. They form ideal "scapegoats" to blame for something that went wrong – regardless of whether this was in fact at all possible to predict, whether there were any structural elements or not.

If indeed the issue is fundamentally linked to the refusal to confront contradictions inherent to multiple goals, and to accept trade-offs, then "scapegoating" regulators and calling for stronger rules and enforcement is a way to continue this refusal. It is convenient for politicians, who avoid confronting their own failures (see for instance the case of the *Deepwater Horizon* in Carrigan 2013), and in a way for citizens as well, who do not have to make hard choices (at least not consciously). Achieving a more risk proportionate, approach to regulation and regulatory enforcement would thus start by making tensions and contradictions between different goals and aspirations clear and visible. From this, a rational conversation could be had regarding the potential trade-offs, the possible ways to reconcile conflicting goals to some extent, and the limits of this. On this basis, rational policy decisions can then be taken, with a clear view of what upsides and downsides they entail.

The uses and limitations of science in relation to risk and regulation

Risk-based regulation aims to rely on evidence and data in order to assess risks and decide on the adequate response, and this applies to risk-based inspections of course as well. In most areas, assessing risks in a "non-subjective" way requires the use of scientific findings – but this is not always as easy as many would think it is, because science is complex, incorporates uncertainty, and cannot answer all questions (and in particular cannot answer values-based questions).

A cursory review of developed countries in particular (but even many emerging economies) will easily show that "scientific advice is found almost everywhere in our technological cultures" and that, for many scientific advisory bodies, "the emphasis is on translating the state of scientific knowledge to make it useful for politics and for policy making" (Bijker, Bal, Hendriks 2009). Even though some of the institutions involved in scientific advice go back a very long way in time (like the Netherlands' Health Council, the *Gezondheidsraad*, which was founded in 1902), there does appear to have been an increase in the reliance on scientific advice in public policy, or at least the push for increased reliance, in the past three of four decades. This can be linked at least in part to major incidents – as a way to react to these not in a "reflex" way, but by improving the adequacy of policies and regulations in particular, through the incorporation of the "best available" science. In the case of the EU, around the mid-90s "amid scandals over industrial safety (Seveso), 'mad cow disease', dioxin contaminated food and oil vessels safety, the EU reconsidered the role that scientific evidence could and should play in its decision-making system" (Alemanno 2014). More broadly, the increasing emphasis on scientific advice in policy making can be tied to the increasing complexity of technologies employed both by businesses and in the private sphere, and the need to take decisions in front of issues where prior experience or a decent education are clearly insufficient guidance.

The increased reliance on science, part of the broader trend towards more "evidence based" policy making (of which RIA is a particularly characteristic example), is not only the result of technological change, however – and it is also not fully uncontroversial. On a fundamental level, one can argue that founding policy decisions exclusively or primarily on scientific evidence is in itself a major policy choice, reflecting a utilitarian ideology, and not (as it is often presented) a "neutral", "non-ideological" approach. Very often, in fact, "on contested topics (…) science, values and politics collide". The "utilitarian" perspective, which would have science be the primary guide for policy choices, and statistically predicted impact on human life the key indicator, has been

vehemently criticized from many corners (from, say, the religious right to the radical left) as reductive and as ignoring the role of "higher" (or at least "other") values in policy choices (for an early example of such criticism, see e.g. Slama 1993). The reason it is essential to remind of this here is that science can in any case not give the answer as to "what should be the right policy" – it can only, at best, indicate *which instruments and specific norms* are likely to be most appropriate *for given policy parameters*. For instance, if safety and health are the policy priorities, smoking bans and all measures against smoking will be welcome. But if individual freedom of choice is considered a higher value, then such bans and policies will be opposed (see Slama 1993). The only things science can say are (a) what the impact of smoking on health is (medicine and biology) as well as, to some extent, (b) what measures and tools are more likely to lead to reduced smoking (behavioural science, psychology, socio-legal studies etc.).

In addition to this fundamental limitation, there are many situations (and indeed, often in the "hottest" topics) where science is simply uncertain. Of course, at its heart, science always includes an element of uncertainty, in the sense that a better understanding of reality may always emerge – but "stronger" uncertainty is what matters here, that which is at stake in issues which are still only imperfectly understood, and where as a result diametrically opposing viewpoints can both claim to be based on "science" (as in the Endocrine Disrupting Chemicals – EDCs – "controversy", even though the vast majority of scientists appear to be on one side, i.e. the one that points out the hazards of EDCs[451]).

To summarize, there are several fundamental, intrinsic limitations to what "answers" science can give to public policy issues:

- Science cannot address conflicts between values, or respond which values to prioritize
- When a policy choice is likely to have conflicting impacts on different aspects or indicators, science cannot answer on which one should be given priority
- In fields where important uncertainty remain, it can only give answers which are affected by this uncertainty, i.e. based on probabilities
- Thus in all cases science cannot make choices – scientific advice can, rather, be a "honest broker" or "cartographer" that "helps decision makers to choose wisely between the available options" or at least understanding the implications of different "policy paths" (Wilsdon 2014).

The specific case of "scientific uncertainty" – dealing with uncertainty, dealing with risk, two different but connected problems

In many situations where regulators are under pressure to act, but also subject to criticism for over-reacting, science is in fact not fully clear. Whereas scientific issues are not in debate for instance in the *Deepwater Horizon* disaster or in the Foot-and-Mouth crisis (and the questions are only about the proper tools to address technological or epidemiological issues, and trust deficits), they are or were very much openly debated or at least "not fully solved" in cases like the BSE ("Mad Cow") crisis, or EDCs and the right response to give them.

There is, indeed, a tendency (on many sides) to present scientific opinion or advice as "one" – and to see problems only in terms of ensuring that scientific evidence gets accepted and acted upon. Quoting an influential report on *Enhancing the role of science in the decision-making of the European Union,* for instance (Ballantine 2005), the only limitations it sees to scientific evidence are "policy-makers and decision-makers [being] often unable to make use of scientific advice", "lack of public confidence in the utility of scientific evidence, particularly in managing risks to human health, which limits its effectiveness", "difficulties in

[451] The controversies on GMOs would of course be another example, but their complexity and the passions at stake are even greater, and in addition the "scientific arguments" used by both sides tend to show that they (on purpose or not) do not even speak about the same issues – many proponents of allowing GMOs cultivation and sale emphasize studies showing innocuity on human health, but many GMO opponents do not focus on human health effects but rather on the environmental impact.

obtaining 'independent' and 'excellent' scientific advice" and the fact that "some influential groups[452] do not accept that scientific evidence is an appropriate input". We contend here that this is an exceedingly restrictive and "technocratic" view, that assumes the answer is clear and beyond doubt, and the only problem are "people" and "politicians" not listening or unable to act upon scientific advice. The reality is far more complex.

Scepticism is often grounded in major failures in the past

If many people (or "groups") show limited trust in what is presented to them as being the state of science, it can be not only because they conflict with their values or "ideologies", but because past experience has shown the limits of claims of safety of technologies based on "science" [regardless of whether or not the claims were indeed based on science or just presented as such].

Chemicals or drugs later found to be highly toxic (and remaining actively toxic for extended periods) remained in some cases on the markets for decades – with both instances of their toxicity having long been known, or of their being originally seen as safe and knowledge of their toxicity only gradually emerging. Infamous cases that have made history in the worst way include thalidomide, which was marketed as perfectly safe for several years in a number of countries, and led to around 10,000 birth defects leading to infant deaths and phocomelia. Diethylstilbestrol likewise was prescribed for three decades to pregnant women in the mistaken belief it would reduce the risk of pregnancy complications and losses – and not only had no positive health effects, but led to cause a variety of significant adverse medical complications during the lifetimes of those exposed (in particular genital tract diseases, e.g. vaginal tumours and uterine malformations). PCBs and other chlorinated hydrocarbons were recognized early as toxic due to a variety of industrial incidents, but serious regulation was only introduced nearly forty years after the first studies, in the 1970s. DDT was used for decades before serious attention was given to its adverse effects, which had been hitherto noticed only by a few scientists. Significant campaigning against the massive use of this chemical only started in the early 1960s, after several decades of massive use worldwide. Asbestos and lead, two naturally occurring chemicals, had harmful effects on health that were known in part since ancient times (at least for lead), but serious regulation of their production and use took often decades to be imposed (with the United States only banning lead-based paints in 1971, Europe lagging at least a decade after the US to ban lead in gasoline etc.) – industry associations during this whole time made considerable efforts to resist regulations and try and discredit scientific expertise that showed the hazards caused by these materials.

We have chosen these few examples on purpose, as particularly well known. They have in common massive adverse effects, and the fact that they were marketed as perfectly safe and warranting little or no precaution (thalidomide and diethylstilbestrol were indeed specifically targeted as pregnant women, the most vulnerable population of all). In some cases, active dissimulation was involved – adverse effects were well known and hidden. In others, adverse effects were not really known, but no efforts were made to investigate whether the compound was really safe, and it was intensively marketed as such. They should remind us that, when individual citizens, NGOs or indeed scientists are sceptical about claims of innocuity, they are not refusing "scientific advice" (as Ballantine and others would put it) but showing legitimate caution in front of statements that probably overstate the confidence we should really have in many products' harmlessness. Being sure of the (absolute or relative) harmlessness of chemical compounds that are novel and are being put into massive production is extremely difficult, if not impossible, at least in a short timeframe. Deciding between a precautionary stance and a more "growth oriented" one is a matter of balancing risks, opportunities, and uncertainty – it is a matter on which a rational conversation can be had, and rational people on both sides can

[452] Given the make-up of the Steering Group for this report, with many industry representatives, the "groups" are clearly meant mostly to refer to NGOs – but could also be understood more broadly.

disagree. It is not a topic where a simple "scientific truth" can be told and any disagreement should be seen as baseless obscurantism.

Openness and transparency are indispensable to build trust

Using "science" as a foundation for risk-based regulation, and specifically risk-based inspections and enforcement, is thus not a simple matter of following "science" as if it were just one clear set of directives. We would argue that the first step is building real trust through transparency, including transparency about uncertainties and disagreements. Not paying attention to uncertainties, full transparency and the need to clearly show divergences of opinions may have been one of the causes for the controversy surrounding the former Chief Scientific Advisor (CSA) to the President of the European Commission, whose office was not renewed under the new Commission: "if her mission is to strengthen the role of science within the policy process, it is manifest that the CSA cannot and should not do that alone. It is only by rendering public a possible divergence between her advice and the political decision that the CSA's ontological mission to promote science in government could be accomplished. Of course, this is not to suggest that scientific input should prime over other sources of advice, but that when a tension exists between the two this should be rendered public" (Alemanno 2014)[453].

If scientific advice is to be any use in making the public trust the risk-based approaches of inspectorates, and their claims to an adequate balance of costs and benefits, the scientific advice itself needs to be trusted. However, in some instances, this trust has been harmed considerably by prior experience (see above), and by what is seen as attempts to push policy decisions that result from choices and prioritizations as "the only choice". Transparency is needed on what are the uncertainties, the options and the costs associated with each one. Scientific advice should not mean advocating only one policy option, at least in many or most cases, but rather laying out clearly the upsides and downsides of different options. When significant uncertainty is involved, different scenarios should be sketched out, the costs of different options clearly presented, as well as their potential benefits.

If we take an issue like EDCs, simply stating that their risk to human health is "hypothetical at best, possibly illusory, and certainly never scientifically established[454]" appears to be an overstatement that is damaging to the cause being advocated, because in front of the evidence already collected (WHO UNEP 2012, which comes on top of 10 years of research after the first 2002 report), this appears at best as an overstatement, at worst like as fully misleading. It does not ensue that the decision should be an "outright ban" (which Julie Girling is advocating against) – but certainly the policy debate cannot simply be dismissed by trying to disparage or dismiss the findings of what appears to be the clear majority of scientists specialized in this field.

In conclusion, while scientific advice is an indispensable element of proper risk-based approaches to inspections and enforcement, it can in no way provide the sole source of rules, decisions, guidelines and practices. It is essential to understand and acknowledge that political decisions will be needed, based on values – as well as "technical" decisions by inspection officials, based also on values, combined with experience and a variety of heuristics. Combining a form of "precautionary principle" with a risk-based approach to inspections is not necessarily a contradiction. Precaution can be understood as a tool to use in the face of uncertainty, and it would not be impossible for a regulator to decide to be precautionary in the face of risks that cannot be assessed with certainty, but to otherwise make its approach proportional to risks in terms of requirements and enforcement decisions, and targeted on risks in terms of resources. The precautionary principle would just be in this way a heuristic tool to assign a rating to hazards that are subject to high uncertainty. A

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[453] See Blanc, Macrae and Ottimofiore 2015 p. 59 for a summary on this controversy.
[454] Julie Girling in the *Wall Street Journal* on 23 January 2014: http://www.wsj.com/articles/SB10001424052702303947904579336611208924306

"precautionary" regulator would give a higher rating to these than a non-precautionary one, but could still adopt and practice a risk-based approach overall.

In addition, in order to ensure trust and thus build support for their approach, regulators need to ensure that, whenever a decision is based on scientific advice or findings, they also set forth clearly what are the different values at stake, and if there is any actual or potential conflict between them. Acknowledging such conflicts is far more conducive to constructive engagement from all stakeholders with the advice given, whereas denying them by presenting the implicit values that form the advice's foundation as the only possible approach is creating strong negative reactions[455] (most scientific advice takes it as a given that safeguarding as many lives as possible is the main goal – but there are other values, like freedom or specific religious rules, for instance, that many citizens may see as deserving as much, or more, consideration – in other cases, advice incorporates an implicit "cost effectiveness" element, without discussing the alternatives, etc.).

In addition, it is important that "scientific advice" is understood not only as input from natural sciences into policy decisions involving technological and natural risks, but also as taking into account social sciences. This means first having social sciences give input into the policy advice on those policies aiming to address technological and natural risks, to ensure that issues related to behaviours, compliance etc. are adequately addressed, and that thus the presentation of policy options and their likely effects is realistic (see Wilsdon 2014). This is of major importance because, as a result, policies in social matters tend to be in many cases based far more on preconceptions and ideologies and far less on evidence. This also has serious implications for the legitimacy of all scientific advice and public support to evidence based policy: as long as it appears to be "cherry picked" and apply only to some issues, it is far more difficult to build broad-based consensus for it[456]. Considering findings from social sciences in regulatory matters is, precisely, what "smarter inspections" are about.

c. Applying risk-based approaches to inspections

Having attempted to summarize some of the main issues pertaining to the interactions of risk and regulation, and before we turn to examining in more details practical examples, it is time to consider the application of risk-based approaches to inspection from a general, part-theoretical and part-practical perspective. We will first consider the rationale for specifically basing *inspections* on risk (as distinct from "regulation" more broadly), then look at what are the main elements that appear to characterize "risk-based inspections" in the existing literature, and from there try to conclude on the theoretical basis for risk-based approaches in inspections and enforcement.

i. From risk regulation to risk-based inspections

[455] A policymaking process where the values and voices of stakeholders are not adequately represented will lose legitimacy – in contrast, procedural justice (irrespective of what the final decision is) will build legitimacy and thus acceptance of the policy decision in the end – see e.g. Maguire and Lind 2003.

[456] At the risk of being somewhat over-simplistic: much (but certainly not all) scientific advice on the risk of different products and technologies may end up showing that risks are acceptable and support broadly speaking "pro-business" policies. Broadly speaking "left-wing" groups tend to be skeptical of scientific advisory bodies as a result. Were scientific advice to also include social issues and social science, a quick look at the prevailing scientific evidence and consensus suggests that it may often result in supporting policies that are supported by these same groups that oppose the "pro-business" policies. By demonstrating that scientific advice and evidence is not "cherry picked" but used throughout all policy areas, it could contribute to broader support and acceptance, based on procedural justice effects (see above).

Risk-based inspections are not just a narrower field, a sub-section of a broader "risk and regulation" field – they are also one that has specific drivers, concerns and tools. While overall it is not only possible but legitimate to put them in the perspective of the broader risk regulation studies, it is also essential to understand this specificity.

BRDO's 2012 *Common Approach to Risk Assessment* outlines the different levels at which "risk assessment" (and, more broadly, risk-based approaches) can be applied in the regulatory sphere: "strategic risk", "priorities between national and local risk", "operational risk", "risk assessment of individual businesses" and "sanctioning according to risk" (pp. 3-4). In this outline, "strategic risk" corresponds to the overall strategy of the regulatory body, the key risks that it is its mandate to control. The setting of national or local priorities is in some ways UK-specific, given the importance of local regulation in the British system (though this articulation of different priorities can also be relevant to many other countries). "Operational risk" refers to the level where interventions are designed, the choice of regulatory instruments and tools made. The two last stages correspond to the classification of establishments according to risk (which is the basis for risk-based inspections, but can also be used for e.g. licensing), and to risk-proportionate enforcement.

We want to suggest here a slightly modified version of these different levels of risk-based regulation[457]: strategic risk assessment, operational risk assessment, risk-based targeting and risk-proportionate enforcement. The first deals with the policy-making level: what risks to regulate, and how. The second deal with the choice of implementation methods: what regulatory tools to use for which risks and situations. The third covers the targeting of inspections (and possibly of other regulatory tools). The last one deals with enforcement. While this classification is clearly based on that elaborated by BRDO, we think it introduces useful nuances and is more broadly applicable.

Mertens (2011) suggests a classification that focuses more on the risk assessment and management stages that take place within an inspectorate (p. 271). His classification has two broad levels. First a systemic one, which corresponds to the strategic inspection framework, defining priorities and programming. The output of the systemic stage is a classification of categories of risk level per type of establishment, and an action programme. Second, an operational level, which corresponds to the operational organization of inspections, involving information gathering and definition of specific focus. The output of this stage is an overview of results of prior inspections for each establishment, and an inspections plan.

There are several fundamental differences between what one could call the "macro" (strategy), "meso" (operational) and "micro" (targeting, enforcement) levels. While at the first level policy-makers operate at a rather high level of abstraction, and take decisions based on overall highly "aggregated" risk assessments, the "meso" level is already concerned with more concrete situations, and decisions that will translate into concrete differences for businesses – depending on which regulatory instruments are selected for different categories. The "micro" level, in turn, deals with individual cases (businesses, establishments), allocates them in one or the other category, and takes decisions based on findings on the ground. Thus, the first crucial difference is that one goes from abstract categories to individual cases.

The second essential difference is that the operational and "individual cases" levels all operate *within* the framework given by the strategic risk assessment. If the policy decision has been taken that a given category of risk will be addressed through regulation, then this is a given, which forms the environment within which lower level assessments and decisions will be made. The strategic level is where analysis such as Regulatory Impact Assessments can take place. At the operational level, the question is not anymore whether to regulate, but what instruments to use in order to best implement a regulatory decision already taken, with the available

[457] This relies on an internal World Bank Group paper, which was developed jointly with Wafa' Aranki and Lars Grava, both of the World Bank Group. They deserve equal credits for this.

resources, and taking into account what is known of the target groups, of compliance drivers, etc. Finally, at the individual cases level, the decision concerns first allocation of resources (given finite staff-hours, where will they be most useful) and how to respond to a given situation.

Whereas policy makers can, in practice, decide to regulate even if a realistic assessment would indicate that resources are insufficient, the regulation ill-designed, the goals unachievable – inspectorates cannot stretch resources beyond what they have. Thus, if they do *not* prioritize they will generally end up having to visit an unrealistically high number of premises (or check an unrealistically high number of products), meaning that each inspection will have to be very short. There are only three possibilities in the absence of risk-based planning: "blanket" coverage (every establishment/product is controlled), random inspections, or selection on a basis other than risk. In the first case, each inspection will have to be so short (except in rare cases of inspectorates dealing with a very small field) that it will be essentially useless – and, in fact, *within a given establishment* inspectors will be unable to control everything, hence there will be selectivity anyway (by default). In the second, there is formal "equality" (everyone has equal chances of being visited), but no uniformity in fact (some are visited, some not), and a clearly less-than-optimal resource allocation. In the third case, in the absence of a rational, somewhat objective instrument for selection, inspections end up being targeted based on convenience of inspectors, potential for flattering numbers (of fines, for instance), or rent-seeking. In other words, risk-based inspections are not an alternative to "non-selective" inspections, but to "selective by default" (see e.g. Blanc 2012, p. 31).

ii. Understanding what "risk-based inspections" entail

We have used so far a variety of related expressions to refer to our field of research, reflecting the diversity that is in use among both scholars and practitioners, and the different aspects that "risk-based approaches", broadly speaking, can take when applied to inspections. It is time for us to both specify more narrowly how we understand these different terms, and to consider what practices these refer to in the inspections field, based on the existing literature (both academic and originating from international organizations or state institutions).

"Risk-based inspections" are the broadest term: it refers to inspections approaches and practices that, generally speaking, are based on the notion of risk, and the idea that the regulatory response should be linked to the assessment of risk. "Risk-based planning" or "risk-targeted inspections" refer to the practice of linking the planning of inspection visits to the risk assessment of individual establishments (or, at least, of groups of establishments) – in one form or another, it is probably the most widespread form of "risk-based inspections", and also the meaning that most authors and practitioners are likely to associate immediately with the qualification "risk-based". "Risk-proportionate" inspections and/or enforcement refer to practices linking what is checked during the inspection visit, the importance given to different issues, as well as the way the inspection is followed up on (including enforcement decisions, if any) to the level of risk as assessed "on the ground".

Finally, there is a more comprehensive understanding of "smart", risk-based inspection practices that has not really been named adequately to date, and includes risk-based planning as well as risk-proportionality, but also goes beyond to incorporate a risk-differentiated approach in terms of selecting tools for compliance promotion (i.e. not only relying on inspection visits), and a far greater emphasis on information and guidance. This approach is grounded on a complex vision of compliance drivers, and seeks to make use of all of them at the same time. It corresponds to what the British now call "better regulatory delivery" (for which the Better Regulatory Delivery Office is responsible – but this is *even broader* since it includes other regulatory

instruments than inspections, e.g. licensing etc.). In specific discussions (when we try and "disaggregate" terms), we will refer to this as "smart inspections" – but in other cases, we will understand this to represent the "fullest expression" of "risk-based inspections". In other words, a *fully risk-based* approach to inspections will include *targeting* based on risk-assessment, *focus during visits* and *enforcement decisions* proportional to risk, and *compliance promotion approaches* which are differentiated based on risk (and on compliance drivers analysis). We will now take a slightly closer look to these different elements.

Risk-based targeting and planning

Before discussing the specifics of the criteria and tools used for risk-based targeting, a short preliminary discussion is required of a closely-related issue: the question of *reactive* versus *proactive* planning of inspections.

Reactive and *proactive* inspections

Inspection agencies can visit establishments either because they respond to a complaint or request (or a tip-off of some sort), or on the basis of their own planning, without any external trigger. Following a distinction introduced by Black (1970) for police work, Tilindyte (2012) refers to these two ways in which inspections can be initiated as "reactive" and "proactive", and this is a terminology used by a number of regulatory agencies themselves, at least in the EU. In other parts of the world, different labels may be used – in former Soviet countries, "proactive" inspections are known as "planned", and "reactive" ones as "unplanned". Whatever the words used, the distinction is widespread, and the vast majority of inspection agencies we have studied had a combination of both reactive and proactive work – but with very different proportions of each. In some rare cases, inspectorates even function nearly exclusively on the basis of complaints (reactive inspections).

Having reviewed the existing literature, as well as considered the issue from a theoretical perspective, Tilindyte (2012) comes to the provisional conclusion that complaints are more cost-effective, but that "only a small proportion of OSH violations are likely to come to the labour inspectorates' attention through private complaining". By contrast, "proactive policies (…) enable a more comprehensive, preventative and systematic approach to inspection" (pp. 42-43). Considering the specific experience of England and Wales, she concludes that inspectors mostly "do not view complaints as especially helpful" as "many of them are ill-informed" (p. 120). Inspectors in Germany reported problems linked to a "high number of complaints" coming from "disguised competitors" (p. 180). In other words, the *quality* of complaints-based information is frequently problematic in the OSH sphere.

If we consider other areas, the information basis for reactive inspections appears just as problematic, although in different directions. As shown by Bentata and Faure (2015), environmental complaints by private persons tend to be strongly biased towards "nuisances" rather than very significant pollution issues, and cannot form a sound basis for enforcement activity (and while their work shows NGOs picking up a significant amount of the serious cases in France, it cannot be assumed that this will be the case everywhere). In consumer issues, van Boom and Loos (2007) show that in the cases of repeated infringements with only limited loss for consumers ("trifle loss" problem), there is generally under-litigation (and, frequently, under-reporting). The propensity to complaint, in addition, is strongly linked to a number of social and cultural parameters. A recent OECD study of regulations in Lithuania (2015) shows that there is a real problem of excessive use of reactive inspections by the market surveillance inspectorate, and that the vast majority of complaints are trivial, or relate to issues that are not regulated by law (pp. 133-134).

"Proactivity" and "reactivity" are linked to the issue of risk-based targeting (or its absence), but in a somewhat complex way. In principle, complaints and other "tip-offs" *can* and *should* be integrated within a well thought-through risk-based targeting model. In practice, however, inspectorates that rely very strongly on complaints tend to have a very weak risk-orientation, if any. While Black (1970) focused on the bias in registering crime, there are a variety of major biases in *complaints*. These biases result from different cultures and perceptions, cost-benefits issues, social position (conditioning ease of access to "formal channels"), relationships with the objects of the complaint, etc. It can in no way be assumed that complaints will yield valuable information: many of them may be trivial, some are likely to be malevolent and dishonest, and if an agency simply follows up on each and every one of them, it will be stretched so thin that it may be unable to properly respond to the important ones.

As we will consider in more details in the third part of this research, inspectorates such as the Lithuanian market surveillance for which reactive work makes up more than half of all inspections tend not to be the "best practice" around. Systematic follow up of all complaints by an inspection tends to be frequent in post-Soviet or post-Communist systems, e.g. in Mongolia where more than 60% of the visits conducted by the General Agency for Specialized Inspections (GASI)[458] are "unplanned", i.e. complaints-based.

Rather, external sources of information can and should be incorporated into a risk-based analytical mode. As Tilindyte (2012) shows, this is the case for OSH in England and Wales, where the Health and Safety Executive handles complaints based on a series of factors, which allow to determine whether an investigation should take place (p. 119), and which include the potential or actual harm, past performance of the establishment, enforcement priorities, etc. A risk-based consideration of complaints can also take into account the existence of other (previous) complaints relating to the same establishment (which can be part of "past performance"), as well as the degree to which the complaint is substantiated. Conversely, in order to have up-to-date risk information on each establishment, an inspectorate needs to try and incorporate not only complaints, but other sources of information – coming from other inspectorates, the media, internet monitoring etc.

On balance, however, it appears clear that a risk-based approach to inspections means that an overwhelming majority of inspections would be proactive, and data-driven, rather than reactive and complaints-driven. It is worth noting that this relates to one of the key differences between regulatory inspections and police work (and more broadly crime-fighting work): most of the objects of inspections (establishments) are known, and the issue is to manage to estimate their risk level – whereas in criminal matters, identifying the culprits is precisely the main problem (and, in "victimless crime", identifying the crime itself). This is not to say that detection problems are not important (cf. Baldwin and Black 2008), but (at least for the most relevant inspection functions in terms of numbers), the universe of establishments is known, and the planning task is to determine where to go in priority. The primary objective is prevention, not response (even though response also matters). By contrast, even though police work aims *overall* at preventing (reducing, containing) crime, its operational focus is to a large extent based on *response* (even though of course there is a large amount of preventive action, e.g. patrolling). For these reasons, the significance of the *reactive* work as identified by Black (1970) for police work is far lower for inspections[459]. Bardach and Kagan (1982) make this very same point that "enforcement of protective regulation by inspectors is different" from typically law enforcement as

[458] The GASI gathers most inspection functions, except fire safety and revenue (tax, customs). Based on internal (unpublished) GASI data for 2013 and 2014.

[459] We posit here a strong difference between "regulatory inspections and enforcement" and "police work/criminal law enforcement". This difference is far from always being obvious, there are many "grey areas" and complex interrelationships, but on balance we think that the difference in fundamental focus is meaningful. It would have to be further investigated and discussed in future research. It is worth noting that we are far from the first to make this point, and to note that criminal law approaches are not necessarily the most effective or efficient for regulatory issues (see for another perspective on this Simpson 2002, investigating what she calls the "punitive model of corporate crime control" (p. 10), and concluding to its inadaptation to business regulation issues).

"inspectors sometimes respond to complaints, but they usually come on their own initiative to enterprises that have not been accused of any wrongdoing. They search for *ongoing* violations, things that might go wrong in the future" (p. 31). The question then is how best to select these places to proactively visit.

Targeting and planning in practice – the data issue

Selecting enterprises to be (proactively) inspected based on their risk profile is so essential to risk-based approaches that the two are often identified, i.e. that many lose sight of the fact that a proper "risk-based approach" includes *more* than targeting. We have already outlined above that the foundation of risk classification for inspections is to combine the *likelihood of harm* with its *potential severity and magnitude.* Doing so in an effective way requires disaggregating the processes that may lead to harm, in order to understand what are the causes of the harms that the inspectorate seeks to prevent, and to ensure focus on the right issues and establishments (cf. Mertens 2011 pp. 272-273).

There are different ways to structure the classification that is to form the instrument for planning. One approach (BRDO 2012, World Bank Group 2013 a) is to form a matrix with two axes – one corresponding to the likelihood of harm (including the likelihood of non-compliance, but not limited to it – World Bank Group version) or the likelihood of violation (BRDO version), and the second to the potential severity and magnitude. In such an approach, intrinsic risk and management risk are somewhat aggregated in the way they are presented (even though, analytically, they are to be handled separately). Another is the approach presented by Mertens (2011, pp. 273-274) where the risk classification is done purely on the basis of intrinsic risk, and *then* a level of inspection priority is determined by crossing the resulting risk level with the compliance history or expectation (management risk).

In any case, a fully-fledged risk-based targeting is to take into account a set of risk components that includes (a) intrinsic risk of the activity (hazardousness), (b) scope/size of the activity (number of people who could be affected, or other relevant indicator), (c) additional relevant vulnerability factors (e.g. types of populations affected, location etc.), (d) likelihood of harm. This last element can be itself split between intrinsic likelihood (which can be combined into "intrinsic risk", or not – in which case intrinsic likelihood and intrinsic severity are handled separately) and management-related likelihood, or "compliance risk". The relative weight that is given to each of these factors can vary (even though most "matrix" models suggest that severity and likelihood should overall be given equal consideration, precise methodologies are diverse). The ways in which these are rated, graded, measured etc. also varies considerably, with some agencies having far more sophisticated and "data-driven" models, some far more "qualitative" approaches (see Baldwin and Black 2010). The use of "qualitative" indicators does not mean the rating systems are necessarily simple – the Food Standards Agency in England and Wales has indicators that are mostly not data-driven, but a rating system that incorporates a number of dimensions and a sophisticated set of check-lists (cf. Blanc 2012 p. 33).

Once a classification has been created, as well as a grading/rating tool to assign a risk rating or category to each establishment (or product, or more generally "inspection object"), *targeting* involves assigning a category or rating to each *concrete* object, and to decide on an actual *plan* of inspections. These are two conceptually separate processes (whichever way they are actually conducted in practice).

If we look first at the question of *planning*, it involves matching resources to the needs, establishing "typical frequencies" for different risk categories, and also adding (or not) an element of "random selection". Here the most practically logical approach would involve deciding first only on an optimal frequency of visits for the highest risk category, then adjust it downwards if existing resources do not allow to implement it, and only then look at *factually possible* frequencies for lower categories, given existing staff and average duration of inspections. There are, however, many cases of frequencies assigned for all categories based on more-or-less

arbitrary estimations of what is "adequate", which then may or may not be feasible given available resources. In any case, the guiding principle of a risk-based approach is that high risk establishments should be visited far more regularly and frequently, that low-risk ones may not even warrant regular visits at all, and that the classification should be done in a way that results in only a minority of businesses being at the "peak" of the "risk pyramid" (World Bank Group 2013 a). In order to keep a "reality check" of whether the classification and ratings are adequate, and to avoid creating incentives for non-compliance for low-risk businesses, it is often accepted that keeping some level of (rare) randomly selected inspection cases for the low-risk category is a valid approach (see Baldwin and Black 2010, Sparrow 2008 *et al.*).

While the classification and the "indicative frequencies" for each category provide the tools for the actual planning, replacing abstract categories with actual "targets", establishments to be visited, requires *data* as a foundation – at a minimum, a list (database) of all establishments under supervision, with at least some fundamental information on the most important parameters that allow to determine the risk level. In some cases, the database can be very sophisticated, and be paired with an automated case selection system (which also takes care of matching frequency of visits with available resources, etc.) – in most cases, the systems are less sophisticated and require a significant human input. In any case data is, in a number of jurisdictions and agencies, the weakest link. There are, however, frequent misconceptions around this, so it is important to distinguish what is absolutely necessary from what is "good to have", and to understand what is the real level of operational challenges and resources involved.

A common assumption is that putting in place effective data systems for risk-based targeting and management of inspections would be very costly, and that moving to a risk-based approach is thus a major investment for an inspectorate – which, in turn, can be a reason to settle for avowedly inferior approaches to inspections. Such an assumption underlies for instance Tilindyte's statement that "proactive monitoring" has "generally high costs", "especially if it is to be based on a comprehensive risk assessment" (2012, p. 42). Baldwin (2007) expresses similar concerns, with more specifics: "a further tension (…) may arise out of the Government's desires (a) to reduce quite significantly the burdens of supplying information (…) and (b) to ensure that regulators target their enforcement activities more precisely (…) The problems are, first, that the targeting of enforcement demands that inspections and other actions are based on intelligence and, secondly, that if the obligations of businesses to supply information to regulators are reduced, it is increasingly difficult for regulators to engage in targeting without generating intelligence independently. Such independent generation of data may, of course, prove hugely expensive for regulators – indeed far more expensive for them than for the businesses that they are controlling" (p. 40). There are many points here, which all deserve to be properly addressed.

First, *in theory*, it may be true that building an information database on objects under supervision and a risk-based targeting system *from scratch* may be expensive. Similarly, regularly gathering information "in a vacuum", i.e. launching extensive investigations, would certainly be costly for an inspectorate. In fact, *any form* of information gathering has costs (even processing data submissions by businesses), and there is no doubt that making a planning system *more data-driven* will increase somewhat data-related costs. Finally, *assuming the information submitted by businesses is adequate*, it is clearly cheaper for the regulators to push the information collection burden on them. All these points, however, rely on assumptions that are fundamentally at odds with reality, at least as observed in most cases.

The first inaccurate assumption is that such information database would have to be built from zero – in fact, most inspectorates around the world have been operating for years or decades and, at least in OECD countries, the vast majority already have databases of objects under supervision, even if these may be managed through sometimes outdated software, or be partially incomplete etc. Furthermore, gathering data on establishments under supervision is something that *naturally occurs anyway* as part of each inspection. Given that, in fact, the inspection coverage tends to be far higher than suggested by studies focusing on only one agency (sometimes

"marginal" in terms of volume of activity), inspectorates gather each year a considerable volume of data simply as part of their normal control activities. The problem is that this data is often not managed properly, i.e. not entered into systems that would make it useful for further analysis and planning. Another difficulty is that in many contexts inspectorates do not share information among themselves, which reduces the number of establishments they can cover in a given year (cf. Blanc 2012 pp. 21-25 and 77-80). In other words, the already are considerable "sunk costs" whereby inspectorates have collected or are regularly collecting information, through their main activity i.e. inspections – the problem is how to best make use of this existing data.

A second highly problematic assumption is that whatever information is filed by businesses will be accurate (if not fully, then at least mostly). This is, based on our experience, unlikely to be always true, and in fact unlikely to be the case *precisely on some of the businesses where information is most needed*. Indeed, if we come back to our compliance models, and the proposed typology of different profiles, precisely the establishments which are the least likely to comply are also the least likely to submit truthful information, as they will correctly understand that this information may be used for risk-based profiling[460]. As for those who are inclined to voluntary compliance, burdensome information collection is likely to create resistance and to overall lead to a *decrease* in compliance. Thus, it is unlikely that relying strongly on information submitted by businesses themselves is ever a very good idea. It is, in some cases, relevant and necessary – but it should remain simple, and certainly not be the sole (or even the main) source of data[461]. This is not to say, again, that business-reported data cannot be useful – but that in any case it never could be sufficient. This is particularly obvious if one thinks of the case of "fly by night" businesses, i.e. those who try to stay invisible and operate partly or fully illegally, and without control. Both Sparrow (2008) and Baldwin and Black (2008, 2010) discuss in some depth these cases. Clearly, detection of such businesses will not be improved by relying on reporting obligations[462]. Rather, inspectorates need to rely on a combination of tools to "spot" businesses operating "under the radar": tip-offs and complaints, "physical" monitoring (verifying whether visibly operating premises are listed in the database), online monitoring (looking for signs of activity, e.g. websites, advertisements or social media comments, and checking whether the business is listed), and information sharing between regulators (if one of them detects an unregistered business, all of them should be notified). This shows how much active data collection is, in any case, a condition of effective supervision, with or without risk-based approach.

More effective sharing of information between different state bodies (and in particular between those which have a regulatory and/or supervisory function) is indeed an essential element of "smarter regulation", if by this we understand a way of regulating that would be *both* more efficient and more effective. This is particularly true when it comes specifically to risk-based inspections – information sharing is key to improving data on establishments/products under supervision, and making sure risk information is comprehensive and up-to-date. It is important to remind that, again, this is not *only* linked to the introduction of risk-based inspections. A number of governments have put in place, or are trying to introduce, policies or tools to avoid duplicating information requests, and ensuring that information collected once is shared across all of the public administration[463]. Some examples include the abolition of the use of certificates in the relations

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[460] See a detailed account of such problems in Bardach and Kagan 1982, pp. 90-91 – they write, in summary: "Documentation, by its very nature, is a declaration of innocence, and most of it is received by officials who ignore it almost entirely" (p. 90).

[461] Enterprise-submitted information is primarily useful to simply notify existence of an establishment – through business registration (for all establishments) or for specific activities (e.g. EU-wide notification of food business operations). These are also relatively "risky" for the business to evade, at least if the activity is easy to detect. Another case where information is more likely to be truthful is high risk, large scale businesses where inspections are frequent. In fact, for such businesses, relationships with regulators tend to be "ongoing", and this is not really the target group for reducing reporting requirements.

[462] One could argue that punitive sanctions for non-reporting could strengthen deterrence, but for all the reasons exposed in the compliance section, this is not very likely to work for most cases.

[463] As much as privacy legislation allows. In some cases, privacy concerns and/or applicable laws have been making information sharing more difficult, but this is a concern that is stronger in the case of citizen rather than business information, and in any case goes beyond

between private persons and the public administration in Italy[464], or the Netherlands' *Stelsel van Basisregistraties* ("System of Basic Registrations", in other words a system of unified registries[465]). More recently, France has embarked in a similar direction with the programme "*Dîtes le nous une fois*", which aims at avoiding duplicate requests and submissions of similar information[466]. At the EU level, important instruments have long been helping with exchange of information on emerging hazards in food and non-food product markets (RASFF for food and RAPEX for non-food[467]).

Specifically in the inspections field, information sharing can be done in a number of ways. At the local level, the fact that most inspection fields are under a single department under local authorities in the UK means that there is a good amount of information sharing going on between them, and there is ongoing work to develop information systems that will make this sharing more systematic and easier – and also ensure that sharing happens *between different regions*[468]. In the Netherlands, two systems have been developed to allow for more effective sharing of information between inspectorates (*Inspectie View*[469]) – and to allow inspectorates to access a trove of data on the business, avoiding duplicate submissions, specific queries etc. (*Ondernemingsdossier* – "Enterprise File"[470]). In Italy, a somewhat similar system has been created, first at the regional level (in Emilia Romagna since 2011) – with an extension to the national level now decided upon – the *Registro unico dei controlli* ("Unified Registry of Inspections") for the agricultural (and agricultural processing) sector, which allows inspectors of all relevant agencies to see records of all inspections, even by other agencies[471]. Clearly, much is happening in this direction – however, the existence of many legacy systems and institutional barriers mean that integration is done *ex post*, in a relatively uneasy way, and without automation (it all relies on inspectors actually using the system to make queries). The *Inspectieloket* portal even suggests that the decision to have different *Inspectie View* for different domains was done to avoid

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the scope of our research at this stage. The very real trade-off between privacy and burden is often poorly perceived, and this is clearly an area where more efforts should go both in terms of research and of policy discussions.

[464] Requesting certificates is in fact *prohibited* and would be a violation for civil servants – as per Law n. 183 of 12 Nov. 2011. See explanation on the website of the Office for Administrative Simplification: http://www.funzionepubblica.gov.it/lazione-del-ministro/decertificazione---direttiva-n-142011/la-direttiva-del-ministro-per-la-pubblica-amministrazione-e-la-semplificazione.aspx.

[465] See detailed presentation of the system here: http://www.digitaleoverheid.nl/onderwerpen/stelselinformatiepunt/stelsel-van-basisregistraties.

[466] A principle that is inspired e.g. by previous experiences in the Netherlands. On the French programme, see the following website: http://www.modernisation.gouv.fr/les-services-publics-se-simplifient-et-innovent/par-des-simplifications-pour-les-entreprises/dites-le-nous-une-fois-un-programme-pour-simplifier-la-vie-des-entreprises.

[467] See on the European Commission website: http://ec.europa.eu/food/safety/rasff/index_en.htm on RASFF, and http://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/index_en.htm on RAPEX. See also the first chapter of this research on the creation and development of RASFF.

[468] Which, in the past (and even currently), has been a significant problem at least in some areas. See e.g. Ogus, Faure and Philipsen (2006) p. 40, which underlines the problem with various risk-assessment models (something the 2012 BRDO *Common Framework* was precisely created to address).

[469] The system has gradually developed over several years and was created to allow any inspector to access data from other inspectorates on a given establishment/object – in particular prior inspection records. There is a general level (*Inspecte View Bedrijven* – "Inspection View for Companies") which can be used for planning and aggregates inspections and results from Social Affairs, Environment and Transport, Food and Non-Food Products Inspectorates. There are then several "specialized *Inspectie View*" with a deeper level of information sharing (greater wealth of information, e.g. on permits etc.) – for inland transport and environment (for now). For more information, see *Inspectieloket* portal: http://www.inspectieloket.nl/organisatie/index/ - and detailed files at the project webpage: http://www.informatieuitwisselingmilieu.nl/publicaties.php?id=11.

[470] The "Company File" allows to access all the information the company decides to make available – it is being rolled out gradually, by sub-sector of the economy, as it is run by businesses, not by the public administration. More information is available at: http://www.ondernemingsdossier.nl/. The "Company File" can be seen as an attempt to not only avoid duplication of reporting requirements, but also to access *more* information from businesses and thus make overall planning and targeting more effective (see Baldwin and Black 2008 p. 31 on the importance of mobilizing the private sector in gathering information).

[471] For the Emilia Romagna experience, see on the Region's portal: http://agrea.regione.emilia-romagna.it/servizi/accesso-agli-applicativi-1/registro-unico-dei-controlli-ruc. For the decision to expand it nationally, see on the Ministry of Agriculture's portal: https://www.politicheagricole.it/flex/cm/pages/ServeBLOB.php/L/IT/IDPagina/8631.

"unnecessary and excessive complexity and size of data". This appears, if one considers the "state of the art", to be more of a fig leaf than a genuine problem.

In fact, several jurisdictions have gone much further and created fully integrated databases for most inspection types (generally excluding fiscal ones), linked to a management system that directly uses the data and risk management guidelines to produce an inspection plan (and in some cases even assign cases directly to inspectors) – not to mention other features for inspections results recording, data analysis etc. These cases and best practices, which are mostly to be found in reports prepared by international organizations such as the World Bank Group (2014 b) and the OECD (cf. Blanc 2012 pp. 77-80), mostly (though not exclusively) come from emerging markets (broadly defined). With a lower presence of legacy systems, relatively lower institutional resistance, and the rapid technological progress (which lowers costs from year to year), it has been possible to set up systems that are far more advanced and effective. In fact, what appeared particularly difficult and costly a few years ago is now far more feasible (e.g. having a fully integrated database across most inspectorates) – but it requires significant decisions (political and technical), and good management.

In short, the important conclusion is that even really advanced and integrated systems are increasingly "feasible", and with certainty simpler systems of data collection and management are fully possible to implement even with relatively constrained budgets. Of course, any data collection and management system will have costs, and implementing analysis-driven planning will have costs relative to "rule of thumb" targeting – but these costs are far from being as considerable as suggested by several authors (which maybe relied too much on the testimony of regulators themselves, who may have their own motives for being reluctant), many data collection activities are anyway necessary (and it is just about using this data more efficiently), and there are considerable costs (in effectiveness) in the *status quo*. As we have noted above, such efforts to achieve more consolidation and sharing of data can be challenged based on privacy concerns (and privacy and data protection legislation, in some cases). There are very different perspectives on what is the appropriate level of privacy and data protection in different countries, and it is obvious that implementing such new systems would be more difficult e.g. in Germany than in the UK, from this perspective. Because the information at issue is *corporate* rather than *personal*, and because of the overwhelming case to be made from an efficiency and effectiveness perspective, we do not think such concerns should stand in the way of data sharing in the field of regulatory inspections of economic activities (as distinct from other areas where data sharing may be considered, and which are not the object of our research). Indeed, in countries where efforts at data consolidation and integration have been made (the UK, the Netherlands with *Inspectie View* and the "Company File", Italy with the *Registro Unico Controlli*, etc.), the parties directly affected (the businesses) have been in favour of the change, and have not generally voiced concerns. It remains that it may be different in other contexts (e.g. regarding the publicity of inspection findings such as is the case for food hygiene ratings), and that the issue is not uncontroversial. Technically feasible does not mean legally feasible, and does not mean desirable either (though, from an instrumental perspective, it clearly is).

Risk-based inspections "on the ground" – risk-proportionate enforcement

As we indicated above, targeting and planning are but the first element of risk-based inspections, and the way inspections are actually conducted "on the ground", as well as the way inspectors and their management *follow up* on them, are just as essential if one is to have an approach that is really founded on risk. While there have been very important scholarly works focusing on how inspectors take decisions and interact with regulated entities, there has been rather less on *what they check* (and what skills, experience and culture influence it). There has been considerably less work on inspections and enforcement practices *specifically focusing* on risk-based approaches, how inspectors understand them, and how they are translated into practice. Hawkins's very important work on enforcement practices in Britain's Health and Safety Executive (2002) considers in great detail and depth the practices of inspectors, the framework which influences their

decisions, the ways in which the agency's management attempts to shape them. It does this, however, without a specific focus on the question of *risk*, but rather at the notion of *discretion* and with a very open investigation of all the drivers that may be at play – and with a specific focus on the enforcement rather than on the inspection phase[472]. Overall, a relatively "diffuse" notion of risk permeates both Hawkins's work and the culture and framework in which he sees inspectors as operating – but not (and this was not his research's purpose) a "picture" of what "risk-based inspections practices" may look like. Baldwin and Black (2010) seek to define "really responsive risk-based regulation", but focus more on the intermediate, operations management level, than on the inspecting stage. Similarly, Sparrow (2008) considers more problems identification and "harm control/reduction projects" than the work of control at the "end phase". May and Winter (2012) consider the relative effectiveness of "enforcement styles", but not whether risk considerations may play a role in it, and without really looking at the inspection phase. The same could be said in general of much of the work on enforcement, including Ayres and Braithwaite (1992) and others: the main interest is the effectiveness of different interaction and enforcement strategies, not what inspectors actually check when they conduct an inspection visit.

Among major earlier works in our field, the closest to our question may be Bardach and Kagan (1982), since their consideration of "regulatory unreasonableness" to some extent looks at what inspectors check (at least through the prism of "what they then decide to enforce"), and does it with a prism that is closely related to "risk-based approaches". Their definition of "unreasonableness" can be read as, in a way, the opposite of "risk proportionality": "a regulatory requirement is unreasonable if compliance would not yield the intended benefits (…) Further, a regulatory requirement is unreasonable if compliance would entail costs that clearly exceed the resulting social benefits (…) Finally, unreasonableness means cost-ineffectiveness" (p. 6). One of the book's first examples illustrates how "unreasonableness" could also be less effective *in absolute terms*, i.e. distract attention and resources from more important problems, when a business operator (aluminium smelter) says of the "worst case scenario" which OSHA uses to justify its requirement: "Of course it *could* happen. Almost anything *could* happen. Never mind that it's more likely that an earthquake could happen. (…) This is a total misapplication of resources. I could use that money for real risk reduction in plenty of other places" (pp. 4-5). The same interviewee in fact refers clearly to the question of risk assessment: "Never mind that in the 15 years the plant has been operating nothing like that happened, or even *any incidents that suggest it might happen*" (p. 4 – emphasis ours).

While Bardach and Kagan use the word "risk" only rarely, and do not use the "risk-based" concept (which was yet to emerge at the time), the portrait they make of the "good inspector" encompasses many of the fundamental aspects of risk-based inspections "on the ground". First, they present precisely the problem that is one of the key justifications for a risk-based approach to select *what to inspect*: "the inspector who walks through a factory and faithfully enforces each regulation may not detect or do anything about more serious sources of risk that happen to lie outside the rulebook; at the same time, he alienates the regulated enterprise and encourages noncooperative attitudes" (p. 123). Indeed, at the core of risk-based inspection work on inspected premises is the idea of effective investigation, looking for the key risks, which requires to know how to prioritize, what to look for, and how to stimulate cooperation in order to get insider information (or, barring this, to detect dissimulation, and act accordingly). Bardach and Kagan introduce their vision of the "good inspector" by analogy with the "good cop", whose goal is to "reduce serious crime, particularly crimes of threat and violence" (p. 125). Translated into the regulatory field, this corresponds to a strong focus on risk, on "harm reduction". In order to achieve this, the police and regulators both need *cooperation* – "good community

[472] We will return to the findings of Hawkins's work in the third part of this research, looking at current HSE practice and considering whether there has been any evolution compared to the period his work considers.

relations is an essential element of effective law enforcement" because "citizens must be willing to inform the police of serious law violations" (*ibid.*).

From these premises emerge the vision that a good inspector "must have sufficient knowledge and understanding" but also at the same time "certain personality traits and communications skills". S/he must have "the capacity to empathize with those subject to the law and to understand their concerns, problems and motivations" (p. 127). These "communications skills" and understanding of the establishments s/he regulates should enable to (as much as possible) gain "compliance without stimulating legal contestation" (p. 128). This requires a "critical ingredient": "the capacity to be reasonable, to distinguish serious from nonserious violations, and to invest effort in the former" – which, in turn, requires "technical competence" (including understanding "the technical and economic problems of compliance", so as to be able to "evaluate the businessman's excuses or complaints" – *ibid.*). The inspector must have "tough-mindedness to probe", "be willing and able to exercise authority", and be "patient and persistent in the face of resistance" (pp. 129-130). S/he must be ready to offer "forbearance to elicit compliance" (p. 136), being lenient on minor issues to achieve progress on more important ones. Gaining cooperation may also involve supplying information: "drawing on its cumulative experience with a variety of firms", the inspectorate "can provide information about risks and abatement techniques", and inspector can advise "about significant hazards that have escaped the attention of company officials" (p. 143). The advice will be particularly well received if it "enables to make reforms more cheaply, and with less disruption of routine" (p. 144). The key, in other words, is to have inspectors that are able to spot and help solve *problems* rather than focusing on *violations* (p. 79-80).

The problem is then how to *enable* such inspectors to arise, and to work? First, of course, this way of working should not be forbidden: "good inspection can flourish only in an organizational and political environment that cultivates it, or at least permits it" (p. 151). Further than this, there should be tools to help inspectors do their work, which involves making "intuitive judgments about the motivations and capabilities they deal with" (p. 71), and developing a "specialized vision, more sensitive to possible risks and deceptions than the average person's" (p. 82). Risk-based approaches have been developed *precisely* with the intent to enable inspectors to be more along the lines of the "good inspector" defined by Bardach and Kagan, to help them have more effective tools for detection, but also better skills and approaches both for investigation and to stimulate cooperation and compliance. We will give here just a few examples of what can be done to make such "good inspectors" better equipped, and more numerous – considering the examples of the Health and Safety Executive (HSE) in Britain (*Enforcement Policy Statement* and *Enforcement Management Model*), the UK Better Regulation Delivery Office (BRDO) *Common Approach to Competency for Regulators*, and Lithuania's experience with risk-based check-lists.

Through its *Enforcement Policy Statement,* the HSE sets out the goals of inspections and enforcement activities, and their key principles – with risk as an essential foundation. First, the goals: "The ultimate purpose of the enforcing authorities is to ensure that dutyholders manage and control risks effectively, thus preventing harm" and "The purpose of enforcement is to: - ensure that dutyholders take action to deal immediately with serious risks; - promote and achieve sustained compliance with the law; - ensure that dutyholders who breach health and safety requirements, and directors or managers who fail in their responsibilities, may be held to account" (p. 2). Addressing risks is thus the most important, ultimate purpose. Then, the *Statement* lists the tools to these aims: "The enforcing authorities have a range of tools at their disposal in seeking to secure compliance with the law and to ensure a proportionate response to criminal offences. Inspectors may offer dutyholders information, and advice, both face to face and in writing. This may include warning a dutyholder that in the opinion of the inspector, they are failing to comply with the law. Where appropriate, inspectors may also serve improvement and prohibition notices, withdraw approvals, (…), and they may prosecute" (*ibid.*). Proportionality is immediately put forward. The *Statement* goes on to define the *principles* on which inspectors (and the whole organization) should base their actions (and their choice of tools): "HSE believes in

firm but fair enforcement of health and safety law. This should be informed by the principles of proportionality in applying the law and securing compliance; consistency of approach; targeting of enforcement action; transparency about how the regulator operates and what those regulated may expect; and accountability for the regulator's actions" (p. 3). The principles are then defined in further detail: "Proportionality means relating enforcement action to the risks" and "In practice, applying the principle of proportionality means that enforcing authorities should take particular account of how far the dutyholder has fallen short of what the law requires and the extent of the risks to people arising from the breach" (p. 4)[473]. Targeting, while it relates primarily to planning (see previous section), also has implications for how inspections and enforcement are conducted in practice: "Targeting means (…) that action is focused on the dutyholders who are responsible for the risk and who are best placed to control it – whether employers, manufacturers, suppliers, or others". In order to address the problem of excessive discretion and lack of equal treatment, HSE has a principle of *consistency*: "Consistency of approach does not mean uniformity. It means taking a similar approach in similar circumstances to achieve similar ends" (p. 5). Finally, "Transparency means helping dutyholders to understand what is expected of them and what they should expect from the enforcing authorities" (*ibid.*).

Such statements may be quite difficult to put into practice and, in fact, Hawkins (2002) suggested that, while official enforcement policy was *one of the elements* forming the framework for enforcement decision-making, they were but one of many, and in practice they left much to interpretation by inspectors (and their managers). In the meantime, the HSE developed a highly detailed, specific and practice-oriented tool to implement its enforcement policy: the *Enforcement Management Model (EMM).* The EMM's purpose is to "promote enforcement consistency by confirming the parameters, and the relationships between the many variables, in the enforcement decision-making process", to "promote proportionality and targeting by confirming the risk-based criteria against which decisions are made" and to "be a framework for making enforcement decisions transparent, and for ensuring that those who make decisions are accountable for them" (p. 5). While it does not replace or limit inspectors' discretion, it aims to guide it (in particular for less experienced inspectors). The EMM includes a number of "decision trees", rating tables and matrices helping inspectors to make decisions based on risk. We will quote here only some of the most important elements. As a first step during inspections, "inspectors collect information about hazards and control measures. From this, they make judgements about the health and safety risks associated with the activity under consideration. Inspectors should prioritise specific hazards and consider common root/underlying causes to ensure they deal immediately with serious risks. They should consider how best to achieve sustained compliance with the law" (p. 8). Then, inspectors should *assess* risk: they "should always deal first with matters that give rise to risk of serious personal injury. They have the power to either prohibit the work activity, or seize and make safe the article or substances that are creating the risk. Sometimes they will do both. When considering the immediacy of risk, inspectors should

[473] Proportionality is also a guiding principle in more targeted documents, eg. the Health and Safety Executive's *Enforcement policy in respect to iron gas mains* (2005). The context of the adoption of this enforcement policy was public risk concern: "In September 2001 HSE published its enforcement policy for the replacement of iron gas mains for the period 2002 - 2007. This followed a high level of societal concern about the potential consequences of gas mains failure. At that time records showed there were about 91 000 km of iron mains within 30m of property ('at risk') which may be a risk to people. (…) Given the uncertainty about this issue, HSE undertook to review the policy before the end of the first five years so that an agreed programme could be confirmed for the following period. The HSE's conclusion was that it was unrealistic to replace all iron gas mains in a short timeframe, but that at the same time "there is currently no feasible alternative to maintaining the network other than to decommission it and replace it with a more suitable material, usually polyethylene. This is the basis of HSE's enforcement policy, which requires iron gas mains within 30m of property to be decommissioned and replaced at the latest by March 2032 ". Basically, the enforcement policy offers gas network operators the option of developing a replacement programme and, if HSE approves it (for which it must be ambitious enough), they will have serious benefits in terms of enforcement: "if pipeline operators have an approved programme, they have a defence from prosecution if they are complying with it and a failure occurred on a pipe which was not yet due for replacement under the programme. However, the defence would not apply if the operator had knowledge which would indicate that the particular pipe was likely to fail". The solution adopted does not remove the legal obligation to overall replace all these pipes, but accepts that there must be a timeframe to do so, and offers defence from prosecution to firms that work in good faith on addressing the issue. See the policy on the HSE website available at: http://www.hse.gov.uk/gas/supply/mainsreplacement/irongasmain.htm

use the principles of 'risk gap analysis'" (p. 9). This "gap analysis" is then explained: once inspectors have determined the "actual risk (where the dutyholder is)", they should "compare this to the risk accepted by the law or guidance and decide the benchmark risk(the level of risk remaining once the actions required of the dutyholder by the relevant standards, enforceable by law, are met). The difference between where the dutyholder is and where they should be is the risk gap" (p. 12). The risk gap is then combined with the "authority of the standard" (level of clarity, specificity, strength of the rule) in order to give an "initial enforcement expectation" (p. 24). Then, the inspector should consider "dutyholder factors" and "strategic factors" (p. 31), "the factors specific to a particular case which may vary the initial enforcement expectation". "Dutyholder factors" include the compliance history, prior enforcement (or lack thereof), whether the violations were caused deliberately to seek gain, what are the general conditions in the establishment, behaviour of the operator ("responsive" perspective) etc. (pp. 31-34). "Strategic factors" are considerably more vague, essentially meaning that inspectors should check whether "the proposed action will produce a net benefit to the wider community in terms of reducing risks, targeting public resources on the most serious risks and the costs of pursuing a particular course of action" (p. 40). For instance, public expectations of a "tough response" may lead to a more severe action, but socio-economic impacts may also suggest in some cases a less severe one.

The EMM is a significant step (and, to our knowledge at least, unique – at least in its specificity) in making inspections and enforcement simultaneously more risk-based, more responsive, and more consistent. To put such tools to good use, however, competent inspectors are needed. In fact, the more flexibility is introduced, the more discretion is needed, the finer the assessment of risk required – the more competent inspectors are indispensable[474]. This notion of "competency", however, includes more than only *technical* skills (relating to food safety, occupational safety and health, environmental protection etc.), but should also encompass skills relating to risk assessment, investigation, relations with business operators and their staff, compliance promotion etc. In the UK, a model has been developed in recent years, building on work done within HSE. This effort involves a number of regulators and professional associations of regulatory staff is led by BRDO and has produced a *Competency Approach.* This is based on a set of "core skills" that are complemented by "technical skills" (rather than seeing core skills as "soft skills" they are put first). Among the core skills are: "assessing risks", "planning", "promoting compliance", "advising and influencing", "interventions", "enforcing legislation", "work with business", "work with partners", "using knowledge", "personal development" and "IT Literacy and Numeracy". The importance of skills relating to risk-based approaches broadly understood, including the choice of interventions, cooperation and persuasion, risk assessment etc. is particularly clear. The approach is fundamentally turned towards practice, and is thus not articulated in any lengthy document (only short summaries exist), but rather is supported by two web portals. The first is used for self-assessment (Regulators Development Needs Assessment – RDNA[475]) and the second for information and training (Guidance for Regulators – Information Point – GRIP[476]).

We have presented examples of clearly sophisticated approach, from a country where arguably risk-based approaches to regulation and inspections are the most established. It is important to consider whether such approaches are also applicable and realistic for countries where leaving discretion to inspectors can be associated with greater fears of abuse, where competency and professionalism are somewhat lower, and where the legal and regulatory culture generally is different. While we will present more examples and discuss this issue in greater depth in the third part of this research, looking at one short example will help complete this section. In Lithuania, since 2010, an ambitious programme of inspections reform has been underway,

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[474] Badarch and Kagan (1982) showed that, conversely, insufficiently competent inspectors tended to "go by the book" (pp. 128-129) and be both more "unreasonable" and less effective at managing risks.
[475] http://rdna-tool.lbro.org.uk/
[476] http://www.regulatorsdevelopment.info/grip/

openly modelled on the UK experience (and drawing more broadly on international experience and lessons – see OECD 2015 b). As part of this reform, the Government has promoted the development and use of check-lists by inspectorates, in particular for inspections of SMEs. This was first requested by a Government decree, and is now also part of the amended Law on Public Administration. In addition, the Ministries of Economy and Justice adopted guidelines for inspectorates on how to develop such check-lists, emphasizing the need to design them based on risks, and not by compiling all applicable legislation. The aim is to have problem-oriented check-lists, that guide inspectors to look at the most essential issues, where the most risk can arise, and take them away from "paperwork-focused" inspections[477]. Interestingly, check-lists for inspectors are not seen positively in more "advanced" inspectorates (e.g. in the UK, or in some agencies in the Netherlands) precisely because they are seen as excessively limiting discretion, leading to a "tick box" approach, insufficiently promoting professionalism. In Bardach and Kagan's (1982) account, check-lists were in fact a tool that had been introduced as part of the more rigid, more "protective" regulatory approach that emerged in the 1970s (pp. 74-75), and check-lists were generally examples of "zero discretion" practices, leading to "regulatory unreasonableness". Here, two factors are essential to consider: context, and contents of the check-lists. Context, first: a system where risk-based approaches run against deeply engrained practices of inspectors, and where resources are not necessarily available for in-depth retraining or to attract new and more qualified staff. In such a case, well designed check-lists, while not "optimal", can represent a major improvement by pushing inspectors to a somewhat simplified but still adequate risk-based practice. Contents, second: poorly designed check-lists will indeed end up with hundreds of items, a laundry list consisting of many paperwork requirements and lending itself to "by the book" enforcement – but a well-designed one will be the opposite, focusing on key risks, corresponding to the logical flow of an inspection visit, and clarifying requirements for duty holders.

"Smart Inspections" – using all compliance drivers and differentiated tools

As we have seen with the example of the HSE's *Enforcement Policy Statement,* a balanced inspections and enforcement approach involves the targeted use of a range of instruments – "information, and advice, both face to face and in writing", warnings, and an escalating range of sanctions. A really "smart" approach to inspections includes of course this differentiation in dealing with problems found during inspections, and it also consider inspection visits themselves as but one of a range of possible interventions. Not only are inspections primarily targeted at high risk (and, to a lesser extent, medium risk) objects, but there is also an effort to understand which tools and approaches will be effective to achieve improvements in compliance (and, more broadly, in safety) in particular groups of establishments. In its own "risk-intervention" pyramid, the UK BRDO sees the default type of intervention in low-risk establishments as information and guidance[478]. Even in cases where risk is not trivial, but inspections would be ineffective, looking for alternative interventions is essential. Faced with a problem of unsafe practices in mobile food traders (selling on the highway's side) in South West England in the late 2000s, the Local Better Regulation Office (LBRO – BRDO's predecessor) supported local authorities in developing a "Trader Information Pack". The recognition was that inspections would be ineffective anyway, since mobile traders were, by definition, mobile, and there could be no meaningful follow up, long-term interaction etc. Rather, the key issue was seen to be lack of knowledge, and this was actively tackled. This was linked to a voluntary light-touch "certification" scheme, which allowed to

[477] As Badarch and Kagan (1982) already showed, the emphasis on paperwork is not only ineffective in terms of reducing harms, but also tends to provoke resistance in the regulated entities – and it is most frequently practiced by inspectors with limited competence, and agencies with "no discretion" policies.

[478] Internal documentation, unpublished presentations, interviews with management.

identify "better practices" mobile traders (and notify consumers about them). This was voluntary, but traders who did not join got more checks, hence there was a clear incentive to take part[479].

Another example of a "smart" approach is the development and roll out of the "Safer Food, Better Business" (SFBB) toolkit[480], which we will discuss in greater detail in the third chapter. The development of the toolkit was a response to the entry into force of the new EU "Hygiene Package", and the approach taken stemmed from the finding that many catering businesses had fundamental problems with compliance because of ignorance or misunderstanding of safety requirements, and that this required an approach based on guidance and compliance promotion. In addition, UK food safety authorities had identified the importance of outreach to the many non-English-speaking professionals working in the country's food industry. One of the experiments leading to this acknowledgement was made in Chinatown by the Westminster City authorities[481]. After finding that non-compliances in restaurants were not only frequent, but not improving after repeated inspections, the Westminster regulatory team attempted to understand why. They found out that chefs mostly did not really understand English well, were not aware of local safety regulations, changed repeatedly, and that an inspection with negative findings resulted in a loss of face that made compliance, if anything, even less likely. The response was to emphasize prior training, and to use the chefs' language as much as possible. Along these lines, the SFBB toolkit exists in 16 languages, those most widespread among chefs working in the UK.

In other words, inspections are not a one-size-fits-all. In some cases, they can be a waste of resources, *even* if risks are not negligible. They need to be the appropriate tool to the problem at hand. If the problem primarily stems from lack of knowledge, then punishment will not help, but even an inspection that is not sanctions-oriented but rather primarily consists of advice and guidance may not be the most efficient or effective. Not the most efficient, because it makes more sense to give the knowledge first, through a lower-cost alternative, rather than sending out an inspector immediately. Not the most effective, because in many cases people will listen better to whom they hold to be their "peers" – and they may not accept inspectors as such (depending on whether there is a history of interaction, what are the prevailing regulatory culture and perceptions etc.). Channelling information and guidance through business associations may be in fact more effective. It is partly in recognition of this fact that the UK BRDO has now expanded the "Primary Authority" scheme to small businesses, through their associations. Under Primary Authority, a business that operates in multiple localities in Britain could request to be assigned a "primary" one, which would audit its operations, make recommendations, and issue guidelines on how to inspect and enforce in a given regulatory area, which would be binding for other local authorities also supervising other premises of this business (costs for this in-depth work are to be borne by the business). The scheme has now been extended so that even small businesses operating in one locality only can benefit from it, through their business association. It is the association that will request a primary local authority, and the authority will then issue guidance on how to operate, and how to inspect and enforce, for this given class of small businesses. The expectation is not only that it will make inspections more transparent and consistent (and more risk-based, as BRDO ensures that only the most competent local authorities can be selected as primary) – but also that this will help spread best practices among small businesses, through the guidance given by their associations[482]. With a similar aim, but different means, Lithuania put in place a system of phone and online consultations, whereby businesses can ask their questions about regulations and how to apply them, and get authoritative answers, which they know they can act upon with no fear of inspectors coming up later with a different interpretation (OECD 2015 b). In short, a

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[479] Unpublished presentation by Graham Russell, LBRO CEO (and now BRDO Director).
[480] See the Food Standards Agency portal: http://www.food.gov.uk/business-industry/caterers/sfbb
[481] Short case study by the Chartered Institute of Environmental Health: http://www.cieh.org/library/Knowledge/Food_safety_and_hygiene/Case_studies/Westminster%20CHIP.pdf
[482] See Policy Paper *Primary Authority extension and simplification* (BRDO 2015), available at: https://www.gov.uk/government/publications/primary-authority-extension-and-simplification.

“smart inspection” approach is one that recognizes both the importance of inspections (and the need to conduct them in the most professional, efficient and effective way) but also their limitations – and accordingly uses other tools as well to promote compliance and public welfare.

Having sketched out a picture of “risk-based” and “smart” inspections, which includes targeting resources and interventions based on data and risk analysis, increasing inspectors’ professionalism and focus during inspection visits, making enforcement responses proportionate, and using a variety of tools apart from inspections to address the diversity of situations and problems, we will now turn to consider some examples from the practice, and try to understand to what extent applying such approaches is relevant to different countries’ situations, whether it is realistic, and what results it appears to produce.

The third part will consider data in greater depth. First, its theoretical and actual limitations in terms of allowing us to capture the effects of inspections and of changes in methods. Then, specifically considering the evidence for the contention that risk-based inspections are more effective and more efficient, i.e. produce better (or constant) public welfare outcomes at constant (or reduced) costs. Finally, we will briefly look at what further work could be undertaken in order to produce better, more conclusive data and findings.

4. Inspections and enforcement – a view from the practice

"What we need is to be told what is needed within the law and sound advice on how to complete certain things."

"No business gets everything right all the time. Where we fail despite our best efforts we would hope that we are not treated as if our non-compliance was deliberate."

LBRO, From the Business End of the Telescope *(2010)*

…reduction in scheduled inspections and other visible shifts away from enforcement activity (…) is sending a clear, calculated message to corporate criminals that (…), they will be even freer to kill and injure with impunity.

Steve TOMBS and David WHYTE, A Crisis of Enforcement *(2008)*

Street-level bureaucrats dominate political controversies over public services for (…)street-level bureaucrats have considerable impact on peoples' lives.

Michael LIPSKY, Street-Level Bureaucracy *(1980)*

While considering the many theoretical and scholarly accounts of inspections, enforcement, compliance and risk regulation, we have on occasion inserted references to current practices, and hinted at what could be learned from it. Before that, we also took the historical overview of inspections development up to the latest developments, and sketched out some of the main traits of different systems. We have not, however, investigated current practices as such, looking at the strengths and weaknesses of different regimes, and at whether we can assess their relative effectiveness (or to what extent we can do so).

In this chapter, we will attempt to give a "view from the practice". Not a comprehensive account, which would be an impossible task given our comparative focus, and already a very challenging task even if we only took one jurisdiction. Some have already proposed very rich accounts of inspections practices in one country (e.g. Mertens 2011). Others have offered detailed comparisons of one function, in at most a few jurisdictions (e.g. Tilindyte 2012). What we undertake here is both much less, and significantly more. Less, because we will have to limit ourselves to "snapshots", glimpses of different regimes and practices – no comprehensive account of any particular country or function. More, as we will try and have a broader reach, looking at a larger number of countries, and several functions.

First, we will sketch out several cases of inspections practices – both risk based (to varying extents and degrees), and clearly *not* risk based. We will try to show briefly both what these practices involve, and what their effects are. To the extent made possible by available data, we will try and compare some of the results and outcomes between different jurisdictions, to attempt to draw some lessons (however tentative) on the relative effects of contrasted approaches. Then, we will review and discuss some of the data issues, trying to

shed light on the limitations and constraints, as well as on possible ways forward – both regarding the use existing data, and the potential production of new data. Finally, we will conclude this chapter by trying to make sense of the different findings, considering what they can teach us about the problems inspections regimes face (or even contribute to create), the reform experiments that have been undertaken, and the results of both inspections practices and their transformations.

4.1. Case studies – views from the practice, comparative assessments

In this section, we will successively present three sets of case studies. The first will center on the British practice in inspections and enforcement, which can with some justice be presented as an exemplar of risk based approaches in general (Blanc 2012, Rothstein, Borraz and Huber 2013 etc.), and thus a good place to start to consider what these approaches look like in practice, and how they appear to perform. The second will consider the experience and problems of post-Soviet countries, as well as the contrasted reform trajectories and their apparent outcomes. Finally, the third will take somewhat shorter looks at the experience of several EU countries, including reforms and their limits.

We have attempted to keep the presentation of these case studies relatively short, because the overall scope of this research, and its length, were already significant. Significant work has gone into gathering and analysing the quantitative data that is presented in these case studies, and in particular in trying to make data comparable across different jurisdictions in spite of differences in sources, definitions etc. Considering that we have already exposed much of the historical and institutional background that is relevant to these case studies in chapter 2, however, we have sought to focus them on the essential aspects: description of methods (in particular in relation to risk, and to compliance management), presentation of available data, and discussion of findings.

A last word on the selection of these case studies. The intent of the research is to try and find an answer (even tentative) to the question of whether risk-based and "smart" inspection methods can yield "win-win" results, i.e. better outcomes in terms of public welfare and reduced burden from inspections for businesses. We have attempted to select cases that are meaningful to shed light on this question. First, the European cases (focusing primarily, but not exclusively, on OSH) build upon the historical research in chapter 2, with some variations in scope that correspond to the difference in focus (the intent is to look specifically at *diverging practices* to see whether they yield contrasting results), and to limitations in data availability. Second, the post-Soviet and post-Communist cases are useful because they cover a far larger set of countries and institutions (i.e. they add "scale" to the research), and they are a very strong illustration of non-risk-based approaches and their outcomes. In addition, significant attempts at reform (at least in some countries) mean that they offer an unrivalled opportunity to compare "before and after" (the move towards more risk-based inspections) in terms of both public welfare and administrative burden. Overall, we have a picture that combines focused research (OSH cases in Britain and Germany, with a less-detailed look at France and Italy as well), which shows very sharply contrasting results in both effectiveness and burden, with broader country-level pictures that provide a possibility of confirmation of the validity of findings in a broader context (larger set of jurisdictions and regulatory areas). Taken together, and because results appear strongly consistent, they offer a first element of response to the research question. Not a definitive one, of course, for which selected case studies could never be sufficient (and a definitive answer may well be out of reach in any case) – but at least a tentative one, suggesting that certain approaches yield consistently worse results than others, and that this should at least be ground to question them and look with greater attention to what makes more successful approaches work better.

a. Risk-based inspections in Great Britain – methods, practices, outcomes in OSH (and beyond)

Considering all the different aspects of inspections practices even in a single jurisdiction like Britain[483] would require a book unto itself. Rather, we will first focus on a function that is simultaneously one of the best studied already (e.g. Hawkins 2002, Tilindyte 2012), one where risk-based approaches have been developed for the longest time, and where data is relatively easy to access: occupational safety and health (OSH). To try and assess the effectiveness of OSH approaches in Britain, we will attempt a comparison of outcomes data with Germany[484], and see what lessons we can draw from it. In the conclusion to this comparison, we will also include highlights of some key aspects of risk-based approaches in food safety inspections, trying to show in what ways it most strongly differs from (to use a simple moniker) more "traditional" approaches in other EU countries. In so doing, we will also indicate when such approaches are used *beyond* food safety and OSH.

i. Context and evolutions in the past two decades – the consolidation of "risk based approaches"

We have sketched out, in the first chapter, the birth and evolution of the OSH regulatory system in Britain, and how it resulted in a dual structure – the Health and Safety Executive (HSE) responsible for (broadly speaking) "high risk" categories (at least as they were traditionally defined) and "major hazards" (in particular those covered by EU directives), and local authorities (LAs) dealing with "lower and medium risk" categories (again, based on what was understood as such several decades ago). In recent years, spurred by successive reports (e.g. Löfstedt 2011), the HSE has also taken a stronger role of guidance and coordination of methods, even though it does not have direct authority over LAs officers. Even prior to this recent trend of growing HSE involvement in guidance for LAs, a level of consistency was already ensured – both by the HSE's role in issuing clarifications and guidance on how to comply with regulatory objectives (which were used by businesses, and inspectors, regardless of which supervisory authority they reported to), and by the common background shared by many inspectors. Indeed, most LAs inspectors and a significant share of the HSE's[485] are "Environmental Health Officers" (EHOs), certified by the Chartered Institute for Environmental Health (CIEH)[486].

The existence of a specific profession of EHOs, with a broad perspective on environmental health risks rather than a narrow technical focus, as well as the large share of this profession employed in the regulatory sphere, are in themselves a specificity and have no correspondence in most other countries. Elsewhere, by contrast, such inspectors would stem from distinct technical fields, and have a background that is not linked to

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[483] Because of the complex structure of the United Kingdom, regulatory structures are distinct in its different constituent parts – England, Wales, Scotland and Northern Ireland. In practice, England and Wales share national-level agencies, and also have similar structures at the local level. Scotland shares *some* of these with England and Wales, and the similarities are sufficient to speak of "British" practices (see details further in the text to justify this). While Northern Ireland's regulatory bodies tend to use similar approaches, their structure is sufficiently different to make it difficult to cover "UK practices" as a whole, hence our choice of "Britain" as the jurisdiction being considered.

[484] We will also make a partial comparison with France, but data on this country is incompletely available and does not allow for a full comparison. The choice of Germany is primarily due to Tilindyte's 2012 work comparing OSH in Britain and Germany, to which we are much indebted, as well as to the full availability of data, and the relative "proximity" of the two countries – but also to some other (real or imaginary) characteristics of Germany, as we will discuss further.

[485] Consistant with its missions, which focus far more on manufacturing industry, in particular heavy industry, and major hazards, the HSE also has a significant number of enginees and other technical specialists on staff, whereas LAs rely primarily on Environmental Health Officers.

[486] For an overview of its history and role, see CIEH's website at: http://www.cieh.org/about_us/history.html - for Scotland, CIEH's role is assumed by the Royal Environmental Health Institute of Scotland (REHIS) – see: http://www.rehis.com/about/about-rehis

regulatory issues. This specificity clearly has major significance in ensuring greater consistency, and in giving inspectors a sense of the existence of an "inspection and enforcement" field as such that cannot be reduced to the technical issues covered. Because food safety inspectors (at least those dealing with the processing and retail stages[487]) and environmental inspectors in the UK also generally are EHOs, this unique training and qualification model also ensures some consistency of approach and sharing of views beyond the OSH field.

Ensuring further coherence, and culminating in the recent evolution giving a stronger guidance role to the HSE, there has been a succession of policy steps to achieve greater consistency in enforcement. In 1997, an "Enforcement Concordat" was launched by the Local Government Association (LGA) and the Government (Secretary of state for the Environment, Transport and the Regions). This concordat was proposed for adoption by LAs, and established a number of "principles of good enforcement policy" (Davey 2011, pp. 263-264): clear *standards* for the level of service and performance, *openness* including information/advice and consultations, *helpfulness* based on a "prevention is better than cure" approach, effective and timely *complaints* procedures, *proportionality* of both requirements and enforcement actions and *consistency* (including with other enforcement bodies) to balance necessary inspector discretion. We have already reviewed above the HSE's Enforcement Policy Statement (see 3.3.c), and it is clear that there is a strong alignment between the two documents. In spite of institutional fragmentation (only one national-level body for OSH, but 433 local councils in the UK, including 407 in Britain, as of 2009[488]), there is thus a significant level of shared principles across all of Britain (and the UK).

This was further reinforced by successive developments from 2005 onwards. In 2005 was released the report of the review led by Philip Hampton: *Reducing administrative burdens: effective inspection and enforcement* ("*Hampton Review"*). OSH was of course among the major regulatory functions reviewed, both at the national and local level (see list of main regulatory functions pp. 14 and 17). This report was very influential and led to a series of Government initiatives. As a conclusion of the review of the existing situation and challenges, it proposed a series of principles, including: the need to use *comprehensive risk assessment* to target resources, *accountability* for efficiency and effectiveness combined with *independence* in operational decisions, regulations should be *clear* and based on *consultation*, inspections should be *justified*, information should only be requested *once* and when strictly *needed*, sanctions should *proportionate* but also *meaningful* and *prompt* for repeat offenders. Regulators should "provide *authoritative*, *accessible advice* easily and cheaply". In addition, the *Review* recommends consideration of enforcement issues from the policy drafting stage, avoiding the creation of new regulators when not needed, reviewing their "size and scope" compared to their missions, and recognition by regulators that "a key element of their activity will be to allow, or even encourage, economic progress and only to intervene when there is a clear case for protection" (p. 7). The *Hampton Review* has often been seen as being the starting point of a drive for more risk-based inspections in the UK. As we have seen, while it certainly put an increased emphasis on risk-based targeting and proportionality (and on the burden-reduction and economic growth angle) it built on a much longer tradition, and reiterated many of the principles already present in the 1998 concordat, for instance.

The *Hampton Review* resulted in a series of policy initiatives, which included the adoption of the 2008 *Regulators' Compliance Code* (see Davey 2011 p. 264). It was followed up by another review on sanctions and enforcement (*Macrory Review* 2008), which in turn led to the Regulatory Enforcement and Sanctions Act 2008, itself resulting in the creation of the Local Better Regulation Office (LBRO), in particular with a view to administer the new *Primary Authority* scheme. LBRO's mandate was to introduce more consistency in

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[487] See our first chapter on the historical factors that led to the unusually weak role of veterinarians in food safety in the UK. Even though veterinarians are in charge of the Meat Hygiene Service (under the Food Standards Agency), the bulk of inspections remains handled by LAs, and primarily by EHOs.
[488] See LBRO 2009 (p. 25)

inspections and enforcement, in a spirit of risk-based regulation, reduction of administrative burden and compliance promotion. Further developments then included the transformation of LBRO into the Better Regulation Delivery Office (BRDO) in 2012, with a mandate now including national regulators in addition to local ones, and the adoption of the 2014 Regulators Code, superseding the 2008 one. These successive developments further consolidated the emphasis on the "Hampton Principles": risk-based targeting, proportionality, guidance and advice, attention to economic growth etc.

Several specific reviews were conducted of the Health and Safety regulatory system – the first in 2008 (done by the Better Regulation Executive) and a second one (after the change of majority) in 2011 (by R. Löfstedt). The 2008 review showed, among other issues, that the split of responsibilities between HSE and LAs, based on a rigid legislative formula[489], resulted in a misallocation of resources from a risk perspective that has been nicknamed the "twin peaks" problem. Both HSE and LAs targeted their resources based on a "risk pyramid", but the top of the LAs risk pyramid tended to be "lower" from a risk perspective than the base of the HSE one (see pp. 59-66). Thus, some premises with actually higher risk tended not to be inspected at all (or insufficiently) because they were in the HSE's remit, and some premises with in fact lower (though not inconsequential) risk were being inspected far more intensively. This showed the limits of the rigid allocation of responsibilities (which has upside from a clarity perspective and avoids overlaps, but cannot accommodate a full risk-based approach). As for the 2011 review, it emphasized the inconsistencies created by the division of responsibilities and the large number of LAs involved (pp. 78-83) – and as a result recommended giving HSE a much stronger coordinating role. It also, again, highlighted the "twin peaks" problem and called for a much narrower focus on high-risk premises (pp. 5 and 82-83).

The *Löfstedt Review* recommendations were translated into the 2013 *National Local Authority Enforcement Code*[490] issued by the HSE and applicable to all LAs enforcement activities relating to health and safety. Its purpose was summarized by the Government as such: "local authorities are being banned from unnecessary health and safety inspections" and "will instead target proactive council inspections on higher risk activities in specified sectors or when there is intelligence of workplaces putting employees or the public at risk"[491]. The *Code* sets out to impose on all LAs a series of principles and rules, all emphasizing the need to focus resources on higher risks, and to use methods proportional to the risk level[492]. In particular, "proactive inspection" should be used "only for premises with higher risks or where intelligence suggests that risks are not being effectively managed" (p. 2). The *Code* emphasizes the importance of "choosing the most appropriate way of influencing risk creators and by targeting their interventions, including inspection, investigation and enforcement activity, on those businesses and sectors that represent a higher level of risk to the health and safety of workers and the public" (p. 4). It also lists a number of roles for the HSE in relation to LAs, in particular making its advice and guidance "authoritative", and giving it a far stronger role of strategy definition, priorities setting, support and guidance for LAs (p. 5). The *Code* specifically requires LAs to have "risk-based intervention plans" and use "proactive inspections" only in "sectors specified by HSE" or where "intelligence" suggests problems with risk management (pp. 6-7). It also emphasizes the importance of proportionality, and instructs LAs to follow the HSE's *Enforcement Management Model,* as well as HSE's criteria for dealing with complaints on a risk basis (pp. 7-8). It also underlines the importance of the Primary Authority scheme as a way to provide more guidance and consistency, and more risk focus – as well as the need to develop LAs inspectors competences in line with

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[489] The precise split is set out in the 1998 Enforcing Authority (Health & Safety) Regulations but "remains largely as it was in the early 1960s" (BRE 2008 p. 57).

[490] See the HSE website for an introduction and the full text: http://www.hse.gov.uk/lau/la-enforcement-code.htm.

[491] Taken from the Government website's summary page on the Code – see: https://www.gov.uk/government/news/new-code-curbs-unnecessary-council-safety-checks

[492] The *way* in which this is done raises a number of problems, which we will discuss further. For now, we will just note that the *Code* explicitly strengthens the importance of risk-based approaches.

the "competency approach" (pp. 9 and 11). In conclusion, following the adoption of the *Code,* a relatively unified model of risk-based inspections applies, at least in theory, to all health and safety inspections in Britain.

Decreases in staffing and number of inspections

For a variety of reasons, which it would go far beyond our scope to explore, "health and safety" (as it is generally referred to in the UK, since the regulatory remit is broader than only *occupational* risks) has been particularly targeted by efforts to reduce regulatory costs (for the state) and burdens (for businesses and citizens). This has led to a significant decrease in staffing levels, and in the number of inspections, at least for the HSE (it is far more difficult to assess such trends for LAs). One possible explanation for this decline is political (pressure from employers to reduce workers' protection and the associated costs), but (apart from ideological motives, which are of course possible) this would not explain why the HSE in particular has been under constant pressure to reduce inspections, more (or so it appears) than other regulatory areas.

First, there are only few major national regulators conducting a significant number of inspections in Britain – mostly, the HSE, the Environment Agency, and Her Majesty's Revenue and Customs[493]. Thus, HSE inspections "stand out" far more than, say, food safety ones, which are conducted essentially by LAs (except the meat slaughter ones, which are EU-mandated and thus "immune" to "burden reduction"). Second, there may be (but this would have to be investigated further) a difference in perceptions by the public. While food safety requirements and inspections impose clear costs on businesses, they are rarely visible by the public, and do not *seem to* result in a reduction in food availability (even though, in fact, they do). By contrast, there is a significant proportion of OSH requirements that appear to have a high "annoyance" factor, and are seen as limiting or preventing activities that used to be possible (more) freely. This public perception issue appears serious enough that HSE has a dedicated set of activities to address it: "busting the health and safety myths[494]". There are additional issues at play. Perceptions of health and safety burden by businesses and the general public (and the resulting "health and safety myths") are very probably driven as much (or possibly far more) by the activities and recommendations of private consultants, insurers and other actors than by HSE inspectors, who are far more likely to come up with "realistic and reasonable" solutions, at least according to many practitioners. In the end, however, the public does not differentiate where messages come from, and end up complaining about "health and safety" generally – which the Government then tends to react to as if it were an indictment of regulatory bodies in charge, HSE in particular[495]. In addition, the position of the HSE as a non-departmental body under the Department for Work and Pensions likely plays a role as well. Indeed, the HSE's functions bear very little relation to the Department's primary focus (delivering benefits). Thus, in a context of budget restrictions, cutting staff and resources to the HSE is likely to be frequently the path of least resistance, as it will not be seen as threatening the Department's overall performance.

Whatever the causes, and regardless of how these trends may be interpreted, there has been a significant decline in HSE staffing and budget, and in the number of HSE inspections. We saw in the first chapter that, between 2002 and 2014, overall HSE staff went down by at least a quarter[496]. The decline in the number of

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[493] Tax inspections may also be on a downward trend but, given their link to revenue, they tend to be an area that Governments are less keen to make savings upon. Environmental inspections in England and Wales are also generally down, but primarily linked to changes in the permitting system, so in a different context from the HSE's.

[494] See on the HSE website: http://www.hse.gov.uk/myth/.

[495] See Dunlop 2014. Summary here: http://www.exeter.ac.uk/news/featurednews/title_427731_en.html

[496] Taking into account the spin-off of the Office for Nuclear Regulation (ONR) and thus not counting the nuclear safety staff in 2002 – the exact percentage is difficult to calculate given that the 2002 annual report provides nuclear safety staff separately, but only for operations, whereas the spin-off also included management staff for the ONR. Comparing "all of HSE" in 2002 with "HSE and ONR" in 2014, the decline is 24%. Taking only HSE without nuclear directorate in 2002, and HSE without ONR in 2015, the decline is 29%. Sources: successive HSE annual reports – this ans subsequent data from the HSE annual reports from 2001-2002 till 2014-2015 - see: http://www.hse.gov.uk/aboutus/reports/index.htm

inspectors is even sharper, particularly in recent years. They were 1,625 in 2002, and only 1,038 as of 31 March 2015[497] - a decrease of 36%[498].

While data on the number of staff is readily available, numbers of inspections have stopped being publicized by HSE nearly a decade ago, and have to be found in secondary sources (which obtained them e.g. through Freedom of Information requests) or "reconstructed" from different HSE publications. In the 2001-2002 financial year, there were 75,237 inspections (out of which 65,000 by the Field Operations Directorate). In 2002-2003, it went up to 84,234 (out of which 74,112). From there, it was a constant decline. In 2004-2005, Field Operations Directorate (FOD) inspections were down to 55,195[499]. In 2006-2007, the same number was only 41,496[500] - 44% less than in 2002-2003. The decline continued in later years. In 2011-2012, FOD undertook 21,603 proactive inspections. To these should be added around 4,000 reactive inspections (*HSE Annual Report 2011-2012,* p. 23) – 3,957 to be precise, even though not all of these were necessarily handled by FOD (but certainly the bulk of them were). HSE also "followed up circa 10,400 conventional health and safety complaints" (*ibid.*) – but not all of these "follow ups" were inspections.

The critics of this evolution, such as Tombs and Whyte or *Hazards Magazine* certainly have a point that the total inspections data is being dissimulated on purpose, making it difficult to track evolutions precisely. The question is, of course, whether HSE management (and the Government) are right that the number of inspections is simply misleading and irrelevant. Before moving to considering outcomes, however, let us try and look at the latest data to establish the current picture. HSE reported completing 5,004 investigations including a total of more than "over 3,260 incidents" meeting HSE criteria. The report also noted the "completion within agreed timescales" of 70% of complaints meeting HSE criteria and due to be followed up (*HSE Annual Report 2014-2015,* pp. 27-28) – meaning approximately 9,870 complaints followed up in a timely way. Though the report does not indicate it, only a minority of these follow ups involve inspections, and these are most probably counted within the 5,004 investigations noted above. A total of 20,200 proactive inspections were conducted (p. 16)[501], and "over 1,000 major hazard operators" were inspected (p. 31). Thus, while a grand total is not available anywhere, it can safety be assumed that the total number of all inspections conducted in 2014-2015 by the HSE did not exceed 30,000. Because each source of data and each year ends up giving us slightly different perimeters, we cannot do an exact estimate of the decrease for each year, but between 2002 and 2015 it was nearly two thirds (64%). This may somewhat over-estimate the decline, because 2002 itself came after several years of *increase* in resources and inspections at the beginning of the New Labour period. Still, it is quite a major decrease, and would still amount to a halving of inspections compared to 20 years earlier.

HSE inspections are, however, only a part of the total OSH inspections in Britain. While the HSE is responsible for a bit under half of total business premises, LAs are responsible for slightly more than half[502]. In terms of

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[497] Note that the annual report 2014-2015 differentiates between "frontline staff (total)", "frontline inspectors" and "inspectors in functions othe than frontline". The overall picture is similar whether one counts "frontline staff (total)" (1047) or "all inspectors" (1038).

[498] The majority of these inspectors are in the FOD, but a large number are in the different specialized departments within HSE. The number of Full Time Equivalent (FTE) inspectors may in fact be lower, though the difference is sharper for LAs (see BRE 2008 p. 58).

[499] *Hazards Magazine,* number 94, April/June 2006 – article available at http://www.hazards.org/commissionimpossible/hse.htm (quoting HSE data obtained through Freedom of Information appeal).

[500] Quoted in Tilindyte 2012 p. 117 – see also Tombs and Whyte 2010.

[501] Thus implementing a target of the Coalition Government to see HSE "reduce its proactive inspections by one third (around 11,000 inspections per year)" (*Good Health and Safety, Good for Everyone - The next steps in the Government's plans for reform of the health and safety system in Britain* - 21 March 2011 – paper by the Department for Work and Pensions, available at: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/66745/good-health-and-safety.pdf – p. 9)

[502] See *Good Health and Safety, Good for Everyone* p. 10, suggesting a 50/50 split, and BRE 2008 p. 59 indicating a 55/45 split LAs/HSE. HSE's own data gives a slightly different picture: "HSE has responsibility for securing compliance in over 740 000 establishments and

employees, the LAs-supervised businesses represent close to 50% (reflecting the fact that, on average, LA-supervised establishments are slightly smaller)[503]. As of 2008, LAs also had more inspectors than the HSE's FOD – a total of 1,100 FTE working on health and safety issues (BRE 2008 – 3,320 inspectors in total, but covering a range of issues). Parallel to the decrease in HSE staffing, this number has decreased to 2,390 in total and 800 FTE in 2013-2014 – still more than the HSE's FOD[504]. The rise in importance of LAs in health and safety inspections largely reflects deep transformations in the economy, whereby "since the late 1970s, levels of employment and numbers of businesses have grown in the sectors of the economy that are inspected by local authorities" (BRE 2008, p. 58). LAs overall conduct far more inspections of health and safety issues than the HSE – even though a number of these are not "pure" health and safety but cover other issues as well, taking opportunity of the fact that EHOs have a competence that also cover for instance food safety issues[505]. Still, even with this noted, LA inspections are far more numerous than HSE ones (though they may often be shorter). In 2006-2007, HSE conducted "around 36,000" preventive inspections and LAs "around 121,000" (BRE 2008 p. 58 – noting also that HSE inspectors spent "significantly more time" per visit). The decline, however, has also been significant in the past few years for LAs inspections – in line with the Coalition government's objective to reduce inspections by LAs by "at least a third" (out of 196,000 in total, proactive and reactive, as of 2009-2010)[506]. In 2013-2014, after several years of reduction, the total number of LAs inspections for health and safety was down to 86,900[507].

Interestingly, the implementation of these new guidelines and priorities seems to have been done with a certain degree of confusion in objectives and methods – or at least in statistics. The *Enforcement Code* for LAs called for a reduction in proactive inspections, and ensuring they were focused only on high risk premises (or on premises where 'intelligence' suggested a high probability of non-compliance). The Government plans called for a reduction of ⅓ of inspections in total. In practice, LAs reported[508] cuts so radical in proactive inspections that these all but disappeared: while they made up 60% of all inspections in 2009-2010, they barely reached 8% of the total in 2013-2014. Reactive inspections (including follow-up inspections where problems were identified) increased, from slightly over 30% to around 45%. The gap was bridged by the "other" category, which rose from 9% to around 47%. Considering such figures, it is clear that the new policy has generated a high level of confusion, led to an increase in reactivity vs. proactivity (which is generally *not* a good thing in an approach aimed at *preventing risks*, since reactive inspections come, by definition, nearly always "too late") – and also led to a collapse in the meaningfulness of reporting categories, since the "other" group (supposed to be used for rare cases that did not quite fit one of the main categories) now makes up nearly half of the total. This move may, judging by the experience of many other countries, reflect a defensive move by inspectors and LAs disagreeing with the new policy, and deciding to keep to the approach they consider correct but game the system by avoiding to report their visits as "proactive" and selecting "other"

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local authorities enforce the HSW Act in around 1 194 000 establishments" (*HSE Annual Report 2001-2002*), but successive reports have concluded that HSE's data was not fully accurate on this point.

[503] BRE 2008 p. 59.

[504] See *Data Collection – analysis of LAE1 2013/14 data from Local Authorities, Paper Number: H17/01*, Paper prepared for the HSE / Local Authorities Enforcement Liaison Committee – available at: http://www.hse.gov.uk/aboutus/meetings/committees/hela/

[505] See BRE 2008 p. 64 indicating that the number of inspections to catering premises reported included 60% of joint food inspections. Since 2011, such joint inspections have become the norm, see HSE, FSA and Local Government Regulation joint note: http://www.hse.gov.uk/lau/pdfs/combining-health-safety-and-food-safety-inspections.pdf

[506] See *Good Health and Safety, Good for Everyone* p. 10

[507] See *Data Collection – analysis of LAE1 2013/14 data from Local Authorities, Paper Number: H17/01*, Paper prepared for the HSE / Local Authorities Enforcement Liaison Committee – available at: http://www.hse.gov.uk/aboutus/meetings/committees/hela/ - also see latest detailed statistics on LA inspections at: http://www.hse.gov.uk/lau/enforcement-lae1-returns.htm - the detailed data only covered approx. 87% of local authorities. 86,900 is an extrapolation done by the paper's author (methodology unknown). Our own estimated extrapolation is around 85,000 (based on the number of enterprises or the population of the non-reporting LAs). The slight difference may come from the author using the employed population or another variable for extrapolation.

[508] See *ibid.*

instead. A more positive development appears to be the increasing focus on high risk objects – "inspection of higher risk premises has remained fairly constant but inspections of lower risk premises has more than halved since the introduction of the Code"[509]. This picture of increased focus is, however, unequal: "fewer than 10% of LAs account for over 77% of the lower risk inspections (B2/C) reported"[510]. Finally, it appears that many of the "other visits" are of advisory nature (a category of visits that the *Code* allows to continue without restrictions) – but in fact this again suggests that many of the former "proactive visits" (which were, to a large extent, aimed at advice and guidance to prevent risks) were mostly "renamed"[511]. While most of the evolutions more-or-less matched the guidelines issued by the Government, concern was expressed that, in nearly 20% of LAs, no inspections at all were undertaken[512].

Consequences of changes – disputed assessments

As Hawkins (2002) has shown in details, the use of prosecution has already long been a "last resort" for HSE inspectors – and we have indicated in the first chapter that this went back to the 19th century. Prosecutions, as a result, have always been rare, even though *in principle* health and safety violations are to a large extent "criminalized", i.e. *can be* subject to prosecution and (in case of conviction) criminal penalties. As a far more frequent alternative to prosecution, and in cases judged serious enough for simple advice to be insufficient, inspectors (HSE and LAs) can issue improvement notices (mandating the resolution of a given violation in a set time period) and prohibition notices (adding to this obligation the prohibition to use a given equipment, part of facility, entire establishment etc.). The latter, in particular, are quite powerful tools, as the economic damage imposed can be considerable. Tilindyte (2012) has concluded that the strength and flexibility of notices was such that HSE inspectors and management showed little interest to use the new Regulatory Enforcement and Sanctions Act 2008, and the possibility it offered to introduce new administrative penalties in addition to existing options of criminal prosecution and notices (see pp. 249-250 and 257-266). Many critics of the changes in health and safety enforcement in the past 15 years have spoken of a complete collapse in enforcement – *Hazards* magazine speaking of a "neutered watchdog"[513].

The data on *enforcement*, as distinct from that on *inspections*, is however far less clear than critics of successive reforms make it out to be. Tombs and Whyte (2008) show a significant decrease in HSE prosecutions from 2000-2001 to 2006-2007, but the picture is less clear on enforcement notices. These remained roughly constant for LAs, and the decline observed in HSE notices from 2002 to 2006 came after a significant increase from 1996 to 2002, and thus could be interpreted as a return to longer-term trends (p. 9). As Tilindyte (2012) shows, 2005-2006 was in fact (for whatever reasons) a low point in the number of notices, and these increased significantly afterwards, returning in 2009-2010 to a level that, while lower than the early years of Labour Government, was higher than in the years of Conservative Government in the first half of the 1990s (p. 140).

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[509] See *ibid.* p. 2.

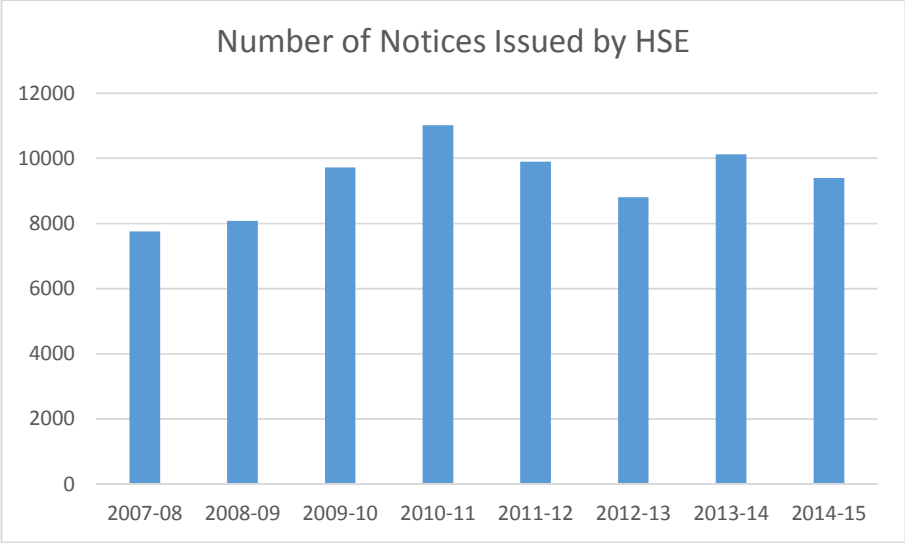
[510] See *ibid.* The note did not include a discussion of the *factors* that could lead to this difference in practices, and attempting to investigate it would have required considerable time. Experience from other countries would suggest that differences in "inspectors culture" and management vision could help explain it, as well of course as differences in the businesses themselves.

[511] See *ibid.* pp. 2-3. Advisory visits cannot result in sanctions in case of violations – but, as is well known from studies such as Hawkins 2002, BRE 2008 etc., health and safety inspections in Britain very rarely result in sanctions anyway. Hence, the "transformation" of many "proactive inspections" into "advisory visits" is mostly a case of change of label, rather than of substance, suggesting again the well known fact that excessively rigid quantitative targets, imposed without consideration to practice, often result in "gaming the system".

[512] See *ibid.* Once more, difficult to say how much it could have to do with local business circumstances (low-risk premises only) or with local priorities. In particular, even though LAs regulatory services are organized on a professional basis, they report to the local councils, which may have very different political views. One could imagine that Labour councils would support more health and safety inspections compared to Conservative ones (while having only limited ability to diverge from national trends due to legislative and budget constraints).

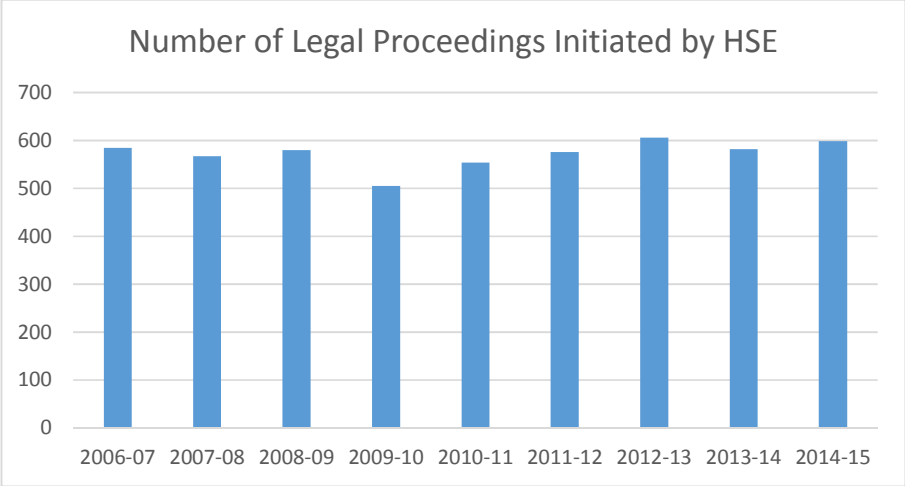
[513] *Hazards* issue 111, July-September 2010 – available at: http://www.hazards.org/votetodie/neutered.htm

Notices have continued to increase and decrease irrespective of the Government in place (as the chart below illustrates), and of reform trends – suggesting strongly that HSE inspectors are, in fact, quite independent in their assessments.



(Sources: *HSE Annual Reports 2011-12 and 2014-15* – data for 2014-15 is provisional)

As for prosecutions, as noted by Tilindyte (2012), there was first a noted increase in 1996-2000, followed by a decrease until 2006 (p. 142). Since then, the annual number of prosecutions has been relatively stable, between 500 and 600 a year, with fluctuations again seemingly not connected in any way with political changes (see chart below)[514].



(Sources: *HSE Annual Reports 2011-12, 2013-14 and 2014-15* – data for 2014-15 is provisional)

While HSE has always sought to focus its prosecutions on cases where it assessed that the chances of successful conviction were maximal (see Hawkins 2002, Tilindyte 2012), this has become an official

[514] Note: different sources and works use "informations" (one for each alleged offence) and "prosecutions" (one for each establishment) and thus give very different totals. The trends remain: notable decrease until 2006, stable since then – at a level lower than in the early 1990s.

performance target and the conviction rate is now regularly reported in annual reports. It has been around 95% for the past few years. While this speaks to an efficient use of resources from a narrow perspective, putting this as a performance target may twist incentives in a way that discourages inspectors to attempt prosecutions that may fit many criteria of relevance, but would be somewhat more difficult to conclude successfully. As Tilindyte indicates, there are "several set of explanations put forward" by HSE management for the decrease in prosecutions, in particular the "rebalancing of resources towards more advice and guidance" but also the fact that "the criminal justice system is seen as increasingly time consuming" (p. 143). This latter explanation may be the strongest one, since there is no long-term decline in notices, which could have occurred had the institution really "moved away" from enforcement altogether. In fact, HSE staff seems to have become increasingly focused and efficient at maximizing their enforcement effect. This is suggested by the percentage of conviction and average penalty per conviction, which are clearly on an upwards trend (Tilindyte 2012, p. 149) – and also by the increase of the ratio of notices per inspections (see Tilindyte 2012 p. 238 – the trend has strengthened since then, with inspections decreasing rapidly and notices remaining at a rather high level). The data provides significant support for the claim of stronger targeting.

Thus, the assertion that there has been a collapse in enforcement, and a trend of "under-enforcement" (Tombs and Whyte 2008, p. 8) does not fully hold up to scrutiny – even less, we would argue, the same authors' even more radical claim of "regulatory surrender" (2010). Still, their point that there has been a tendency to resort less to criminal prosecutions is held up by data – and is not disputed by HSE or any other scholar. In other words, it is "a feature and not a but". The question is whether such an approach – less inspection visits overall, more risk-focused targeting, emphasis on guidance and advice, risk-based enforcement with limited use of prosecution but substantial use of notices – delivers positive results or not for the country at large.

As said, critics of the evolutions in HSE (and LAs) practices tend to use dramatic language – "neutered watchdog", "regulatory surrender", "safety crimes". In a way, this can be understood as no more than the counterparty to "better regulation" slogans decrying "red tape", "stifling burden" and the like. Let us look, then, at the substance of what these critics say. First, they make a number of unproven assertions (or claims resting on very shaky ground at best). Hearings of the Parliament's Committee on Work and Pensions (2008) thus list claims that there is a "correlation between the decline in the inspection rate and increases in fatal injuries", basing it on data from only one year. In the same hearings, some "argued that it was essential that the rate of inspection was increased and that doing so would ultimately decrease enforcement and prosecution costs", but with as little evidence to support it (p. 27). Likewise, in the introduction to a paper by Tombs and Whyte (2008), the editorialists assert that "most safety crimes are either undetected or filtered out from official channels of resolution" – which, in fact, remains unproven through their paper (which does demonstrate other things, but not this claim). The authors then declare that "deaths and injuries suffered at work usually result from infractions of the criminal law" (p. 2), but give no data to back up this statement. They then proceed to claim that their estimates of "deaths and injuries caused by working" are "more accurate", but this claim of "accuracy" is highly debatable (they simply look at another "perimeter"). They also claim that "this process of decriminalisation is reaching crisis point" (*ibid.*) – but show no evidence of it.

In fact, their paper is remarkable for the absence of demonstration of any *trend* in work-related deaths and injuries, or any attempt at comparing their level in Britain with that found in other countries. Their 2010 work (*Regulatory Surrender*), though far longer, similarly avoids the question of trends, beyond claiming that official statistics are "not credible". It makes no effort to look at other sources of statistical information (for, we would contend, they would *not* support their claims). Finally, and this point we will discuss in more details, they pretend to "discover" some data that would have been "hidden" – in fact only reflecting different possible definitions of "work-related" – and similarly claim to "reveal" the unreliability of data (RIDDOR reported number of work-related accidents) that everyone (including HSE management) knows very well to be

incomplete[515]. Tombs and Whyte also suggest to include work-related traffic accidents in the total number of work-related deaths, which indeed increases the total but (absent consideration of chronological trends, of cross-country comparisons) tells us nothing about the performance of the health and safety system (even less so, considering that HSE or LA inspectors, or their counterparts in other countries, are not primarily responsible for road safety, which is under the supervision of other institutions). Finally, they criticize official data for excluding "deaths to members of the public sustained through working environments which are recorded by the HSE" (p. 2). While true, this is again a question of definition. In order to compare across countries OSH data, definitions need to remain comparable. The real question, i.e. whether the situation in Britain has gotten worse, or is worse than in other (more "strictly enforcing") countries, is never addressed.

In fact, the problem of the different definitions of "occupational injuries and deaths" is well known, and has been considered in a number of studies (Feyer *et al.* 2001, Australia's National Occupational Health and Safety Commission 2004, HSE 2014, US Bureau of Labor Statistics 2014 etc.). These differences can sometimes be reconciled so that comparisons are possible, but not always – in any case, they reflect different methodologies rather than some "plot" to hide the scale of a given phenomenon. Some countries (e.g. Germany) include work-related traffic-accidents, but this is more the exception than the rule. Since Britain (and Germany) both are EU members, the European Statistics Office (Eurostat) compiles statistics on key OSH indicators which are harmonized, i.e. where data has been recalculated to conform to a uniform definition. Such data allows easy comparisons between countries. It is noteworthy that none of the strident critics of changes in health and safety regulation in Britain has apparently seemed worthwhile to consider it. These show that the UK has one of the lowest rates of traffic-related deaths[516], strongly questioning the strength of Tombes and Whyte's claim that the number of work-related traffic accidents would be shockingly high. Overall, the UK has a life expectancy that is slightly below the EU average[517] - but not because of violent deaths, where it has consistently among the best EU indicators. Thus, while Tombs and Whyte's are probably right that broadly-defined "work-related deaths" are indeed higher than deaths caused by violent crime, this says nothing about the *evolution* of work-related deaths (however broadly defined), nor about the *relative importance* of this problem compared to other causes of premature deaths in the UK. To be fair, they make a valid point that "the ongoing moral panic that characterises social responses to most 'mainstream' violent crime" (p. 11) makes a strange contrast to the relative indifference to work-related deaths that are, depending on the definition taken, nearly as frequent, or maybe even more frequent (if we take the most expansive definition). They do not, however, prove the importance of work-related deaths in Britain. It may just be that the problem is opposite, i.e. that "mainstream" violent crime is emphasized far too much, and would deserve far less attention, and non-violent causes of death far more.

ii. Comparing health and safety outcomes: Germany and Great Britain

If we want to look beyond *outputs*, and also not base our assessment on assumptions but, as much as possible, on facts, considering Britain's health and safety outcomes *in a comparative perspective* seems unavoidable. It

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[515] Reporting of Injuries, Diseases and Dangerous Occurences Regulations (RIDDOR) is the official, mandatory system through which employers have to report to regulators any significant incident. Because RIDDOR reports frequently (for injuries) or even systematically (for fatalities) trigger inspections, employers have an incentive to under-report. While this is generally impossible for deaths (which end up criminally investigated in most cases), it is quite feasible for injuries, and results in very significant under-reporting. This is a very well known problem (and has similarities in many countries), and is e.g. covered by Tilindyte (2012), pp. 122-123. In its summary yearly statistics the HSE, well aware of this issue, reports both RIDDOR *and* the more reliable data from the Labour Force Survey (see e.g. http://www.hse.gov.uk/statistics/overall/hssh1314.pdf for the 2013-2014 statistical summary, reporting both figures).

[516] See summary document by Eurostat on causes of death in Europe: http://ec.europa.eu/eurostat/statistics-explained/index.php/Causes_of_death_statistics

[517] See Eurostat summary document on life expectancy: http://ec.europa.eu/eurostat/statistics-explained/index.php/Mortality_and_life_expectancy_statistics

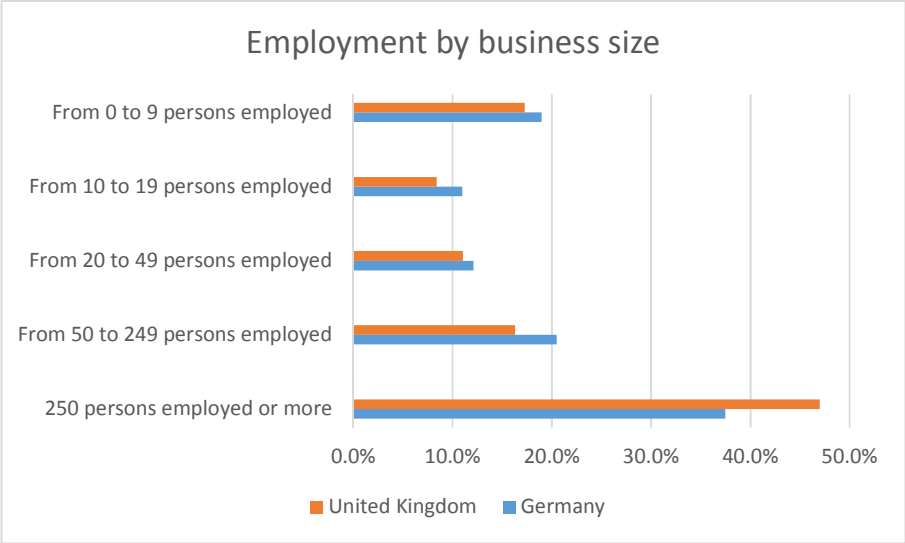
is, however, not so easily done. As Hawkins (2002) pointed out, determining and measuring the effects of health and safety inspections and enforcement is very difficult – for "it is very difficult for regulatory agencies to exhibit their effectiveness in terms of the numbers of injuries or deaths that did not occur" (p. 8). Even if one manages to overcome this problem by looking not at absolute numbers but at trends, remains the near-intractable issue of *attribution*: not only is it difficult to "see whether situations are improving or not", but even then "how much credit do you give to proper regulation, proper firmness, proper inspections?" (pp. 8-9). Overall, "reductions in occupational death, disease, and injury are hard to attribute to changes in law or its enforcement without having a clear sense of the extent to which other influences, such as technological or economic shifts (…) have contributed to any observed effects" (p. 9). These "problems are exacerbated where events are rare, or where latency problems make comparative analysis especially hard" (p. 10), as is the case with many cases of occupational-related illness, which can have decades of latency compared to the work situation which caused them.

We believe that these problems can, to some extent, be alleviated. First, by focusing our comparative research on indicators that have the least latency, and are most easily comparable – in particular fatal occupational accidents. While looking only at one single indicator does not allow to fully reflect on the performance of an institution or a system, we will try and see whether the findings hold constant when considering other (less reliable) indicators. If they do so, we will conclude that there is at least some level of likelihood that the findings do reflect the actual performance of the systems. Second, we will try and filter out the effects of other factors by comparing the outcomes of two countries that are sufficiently similar in terms of economic and social structures, and work methods, and see if there appears to be significant difference in inspection practices, and in outcomes.

The complex issue of "comparability"

The extent to which two jurisdictions can be said to be "comparable" or "similar" is difficult to define precisely, because of the number of variables involved, and the difficulty to assess the relative weight of these variables. Differences between Britain and Germany are quite real – but the average differences are in many cases smaller than the intra-country differences (e.g. on GDP per capita, where the gap between South-East and North England or between Bavaria and Sachsen-Anhalt is larger than the aggregate Britain-Germany difference). If we had the ambition to build a rigorous mathematical model, we would logically also have to try and quantify the most important differences, and attempt to correct for them. Since we have settled, for reasons we exposed above, for a more modest (and, to our mind, meaningful) approach, we will not do so. Germany and Britain are two advanced economies, two of the earliest to have industrialized, two of the earliest to have had a meaningful regulatory system for health and safety (even though Britain was far earlier on the two accounts). The population size and enterprise population is also sufficiently similar (Germany larger on both accounts, but clearly within the same "group" among EU countries). Looking for factors that could plausibly affect health and safety, climate and physical geography are also sufficiently similar (levels of flooding do differ, for instance, but again more between different regions of the country than overall, with the two countries in the same broad climatic zone). If there are meaningful differences that could bias the results, they could mostly be in two areas: employment structure (sectors, size of businesses etc.), and the more difficult to pinpoint field of "culture" and "social norms". While the first question can be relatively easily addressed by looking up the Eurostat website, the second is of course far more complex and disputed.

Let us start by employment structure. According to Eurostat data[518], in 2014 the two countries had active populations around 41.7 million (Germany) and 32.6 million (UK[519]) and employed populations of respectively 39.9 and 30.6 million. The structure of employment by size of business is not strikingly dissimilar, but does show the UK having significantly more employees in large businesses, and Germany more in middle-size ones (the famous "*Mittelstand*").



Unfortunately, neither the British HSE statistical publications nor the German *Sicherheit und Gesundheit bei der Arbeit* (SuGA) reports[520] present occupational accidents differentiated by enterprise size. While this data may be available, it is relatively peripheral to our topic, so we did not investigate further. Given that neither country appears to consider it a meaningful type of disaggregation, and considering that the difference in distribution by size is limited, we can consider its potential effects to be rather negligible. At most, the UK structure might give it a slight advantage, if we assume that large businesses have stronger safety procedures (which is not always true, even though it is often "received wisdom").

The distribution by enterprise sector is somewhat more different, but again is relatively negligible in its effects. As is well known, Germany has one of the highest rates of workers in manufacturing in Europe, while Britain has evolved far more towards a "service economy". Manufacturing, however, is not anymore the sector where work accidents (and in particular fatal ones) are the most frequent[521]. In Britain, fatal injury rates in manufacturing are only slightly above the average for the entire economy, nearly 20 times lower than in agriculture, more than 8 times lower than in waste and recycling, more than 3 times lower than in construction (HSE 2015, p. 3). Germany has a different methodology for calculating fatal accident rates (it includes transportation accidents related to work), and Eurostat does not have the same level of disaggregation, thus it is difficult to fully compare the figures, but the SuGA report for 2013 (BAuA 2014) similarly shows

[518] See Eurostat Labour Force Survey data at: http://ec.europa.eu/eurostat/web/lfs/data/database and Structural Business Statistics tables available at: http://ec.europa.eu/eurostat/web/structural-business-statistics/data/main-tables

[519] Eurostat statistics are for the UK and not for Britain only. The inclusion of Northern Ireland, given its small population and economic weight, is unlikely to change much to the overall picture.

[520] See BAuA 2014 (available at: http://www.baua.de/de/Publikationen/Fachbeitraege/Suga-2013.html;jsessionid=F408E48F5081F0A5F2FE529FC070E1E2.1_cid343) and HSE 2015 (available at: http://www.hse.gov.uk/statistics/pdf/fatalinjuries.pdf)

[521] Assuming it ever really was. As we have discussed in the first Chapter, the high accident rate e.g. in agriculture was for many decades left unaddressed, probably because of different risk perceptions ("traditional" activity against "disruptive" one). Still, manufacturing had very high accident rates a century ago, and even more two centuries ago, as seen in that same Chapter. This is not anymore the case.

manufacturing as slightly above average only, 40% less than in waste and recycling, twice lower than construction, nearly 2.5 times lower than in agriculture[522]. In conclusion, the differences in employed population distribution appear unlikely to result in a large effect on work-related accidents, and particularly fatal one. It may have a *small* effect, though – so the comparison can be valid, but not if it comes to drawing conclusions from small variations. Unfortunately, while Eurostat does collect and compute accident rates for each economic sector separately, the full disaggregation is not available online (only broad categories are available, lumping together all agricultural and industrial sectors). The differences between countries in terms of economic structure are, in any case, accounted and corrected for in the standardized injury/fatality incidence rates compiled by Eurostat, which are therefore fully comparable and can be taken to reflect the frequency of such injuries *irrespective* of differences in distribution of employed populations between sectors[523].

What, then, to think of the "cultural difference" between the two? Many sweeping generalities and unfounded assumptions circulate on the different cultures and their characteristics (and effects), but few (if any) are seen to hold when confronted with careful examination of facts and data. As Chang (2007) reminds us, the stereotypes that cast Germans are more hard working, more respectful of rules, were reversed in the 19th century, when British writers found them to be "lazy" and "lying" (pp. 179-183). The recent and still unfolding Volkswagen emissions scandal is, from this perspective, a welcome reminder that stereotypes have little to do with reality. From our perspective of making "modest" comparisons, not attempting to model or draw strict quantitative inferences, the similarities between Britain and Germany appear large enough. To many considering them from afar, certainly, they are significant: two societies in North-Western Europe, wealth, with a long history of state building, public administration, legal compliance, social services etc. Anecdotal evidence underlines the proximity, e.g. data on fatal traffic accidents. Out of many indicators, we selected this one because it reflects to a significant extent on attitudes towards compliance with rule and safety issues. Because the two countries have (once again) sufficiently similar size, population density, quality of roads, wealth etc., other factors that could lead to large discrepancies in traffic fatalities can be discounted for a first approximation. Both Britain and Germany end up belonging to the same group of low-fatality countries, with Britain performing slightly better, whichever indicator is used (fatalities per population, per motor vehicles, or per passenger-kilometres)[524]. Thus, again, we can for now hold that the similarities between the two countries are sufficient to allow for meaningful comparison, though certainly not for drawing excessive conclusions from small variations.

Health and Safety outcomes in Britain and Germany

Lets us first look at outcomes in both countries, and to this aim let us focus on the indicator that is the least susceptible to under-reporting (and thus to bias in reporting that could differ from one country to the other depending on specifics of regulations and practices): fatal accidents at work. Non-fatal accidents tend to be under-reported in Britain (as in many other countries), because they may lead to additional inspections, potential liability issues etc., and employers try and incite or coerce their employees in not reporting them

[522] It is likely that the fact that the rankings are similar, but the magnitude of the gaps far smaller in Germany, is linked to the inclusion of work-related traffic accidents. These can be expected to be somewhat more rare e.g. in construction, and more frequent in manufacturing or services, thus reducing the difference between lowest and highest rates. To fully explain the much lower gap between agriculture and the average, one would have to dig deeper in the data, but caution is needed because the total numbers are low anyway (and the agricultural working population quite small in both countries), thus meaning that variations of a very small number of actual cases can yield considerable changes in percentage points.

[523] See full methodological note on European statistics on accidents at work on Eurostat website here: http://ec.europa.eu/eurostat/cache/metadata/en/hsw_acc_work_esms.htm.

[524] See the Wikipedia page on *List of countries by traffic-related death rate*, with data for all the three indicators, available at: https://en.wikipedia.org/wiki/List_of_countries_by_traffic-related_death_rate.

either. By contrast, in Germany, the no-fault insurance system and the multiple control points (e.g. reporting obligations of medical doctors) mean that the reported level is expected to be far closer to the real one[525]. Accidental deaths also avoid the time-lag problem that makes it difficult to link occupational-related illnesses with *current* regulatory practices (as the effects today may often be related to practices one or several decades ago). Thus, even though the Labour Force Survey (LFS) provides more reliable accident figures for Britain (and they are indeed the ones used by both the HSE and Eurostat), fatal accidents appear the most convincingly comparable (also because, for non-fatal accidents, the question of the *severity* of the accidents would have to be taken into account).

As briefly noted above, fatal accident *rates* being very low, a change of a few units from year to year can lead to important changes in percentage points – thus it is important to compare not only rates for one given year, but averages over a longer period. A further difficulty arises when considering *which definition* of the fatal work related incidents rate to take. Eurostat's definition[526] of an accident is "a discrete occurrence in the course of work which leads to physical or mental harm" – and a *fatal* accident is one "which leads to the death of a victim within one year of the accident[527]". Crucially, the definition *since 2008* includes "all accidents in the course of work, whether they happen inside or outside the premises of the employer (…) in public places or during transport (including road traffic accidents or accidents in any other mean of transportation) and at home (such as during teleworking)" (though it excludes "accidents on the way to or from work"). The HSE's definition, by contrast, *excludes* accidents taking place during transport, which results in a markedly different picture (it corresponds to Eurostat practice up to and including 2007).

As pointed out by Tombs and Whyte (2008), the exclusion of traffic accidents involving "at work" vehicles is important – it does not only change the overall magnitude of the problem (which could be without consequence for comparisons, if the change was constant across countries), but in fact also changes the *difference* between British and German fatal injury rates, as well as part of their *evolution*. Because Eurostat still publishes data excluding traffic accidents, we are able to consider both alongside each other, as well as long-term averages. The tables below presents the evolution and averages of these standardized rates, as obtained from the Eurostat website (both excluding *and* including "at work" traffic accidents) – the former corresponding also to the data in the HSE publication *European Comparisons –Summary of UK Performance* (2015)[528] and *Statistics on fatal injuries in the workplace in Great Britain 2015*[529]. As we can see, while Britain performs *overall* better than Germany, the difference is far sharper when excluding traffic accidents, and even ends up slightly reversed in some recent years when including them. Because of changes in Eurostat procedures, there are pre- and post-2008 figures with different references and definitions[530].

Eurostat data *Standardized incidence rates, fatal occupational injuries – excluding traffic- and transport-related*	2008	2009	2010	2011	2012	2013	**1998-2007**	**2008-2013**	*1998-2013* [531]
Great Britain	0.59	0.59	0.69	0.73	0.58	0.51	**1.4**	**0.62**	*1.11*
Germany	1.11	0.66	0.81	0.94	0.9	0.81	**2.1**	**0.87**	*1.66*

[525] See Tilindyte 2012 pp. 122-123 (Britain) and 181-182 (Germany). On fatal accidents see pp. 121-122 for Britain specifically.
[526] See: http://ec.europa.eu/eurostat/cache/metadata/en/hsw_acc_work_esms.htm.
[527] Considerable harmonization work is needed because of this, as different Member States have very different durations being considered for their own definition of "fatal accident".
[528] Available on the HSE website, statistics section, at: http://www.hse.gov.uk/statistics/european/european-comparisons.pdf
[529] Available on the HSE website, statistics section, at: http://www.hse.gov.uk/statistics/pdf/fatalinjuries.pdf
[530] All standardised incidence rates for fatal accidents are per 100,000 workers. For the methodology, see: *European Statistics on Accidents at Work (ESAW) – Summary Methodology,* 2013, Eurostat – available at: http://ec.europa.eu/eurostat/en/web/products-manuals-and-guidelines/-/KS-RA-12-102. Pre-2008 data excludes traffic and transport accidents (even if work-related or during work time), while data since 2008 includes them (but Eurostat also offers tables for incidence rate *without* these).
[531] Due to change in methodology in 2008, this average is only for informational purposes. Last line is for EU 27.

EU 15	1.83	1.64	1.58	1.43	1.3	1.19	**2.4**	**1.5**	*2.04*
EU 28 *(EU 27 until 2008 included)*	2.31	1.94	1.87	1.59	1.46	1.3	**2.6**	**1.63**	*2.26*
Eurostat data *Standardized incidence rates, fatal occupational injuries – including traffic- and transport-related*	2008	2009	2010	2011	2012	2013		**2008-2013**	
Great Britain	1.02	1.55	1.61	1.8	1.52	2.05		**1.59**	
Germany	2.67	1.4	1.58	1.59	1.54	1.29		**1.68**	
EU 15	2.68	2.31	2.35	2.42	2.33	2.17		**2.38**	
EU 28 *(EU 27 for 2008)*	3.1	2.52	2.61	2.65	2.44	2.22		**2.59**	

In any event, Great Britain's performance in occupational safety and health, using fatal injuries as a proxy, is way better than the EU average, even using the EU-15 group only, i.e. the "oldest" (and wealthiest) members. It is vastly better, for instance, than France (2008-2012 average of 3.83 including traffic accidents or 2.62 excluding them) or Italy (3.64 and 1.52 respectively over the same period), a point worth coming back to later, considering the sharp differences in OSH inspections between Britain and these two countries (France in particular). The comparison with Germany is, however, slightly more complex. If we consider the definition *excluding* traffic accidents (which is the one used in Britain by the HSE and corresponds to its mandate, and is also the one for which longer-term data is available), then the gap is constantly in favour of Britain, and it has remained remarkably constant (33% lower over 1998-2013, 30% lower for 2008-2013, 37% in 2013).

In recent years, however, if we still consider this same definition, Britain's performance appears to have plateaued (and even worsens in 2013, with a Eurostat footnote indicating a "change in data series", meaning the trend should be checked again in 2014), whereas Germany's improved markedly between the beginning and the end of the period considered. While their performance is essentially similar on average over 2008-2013 (Britain's rate being 5% lower overall, a slight edge only), there are important swings from one year to the next, and Britain's rate goes from 60% lower to 60% higher than Germany's. Overall, swings in data including traffic accidents seems to be substantially stronger, possibly linked to the far higher number of factors that could influence the overall rate, and the potential for "catastrophic" road accidents having an influence on the data.

For a variety of reasons, we have concluded that the more meaningful figure to compare the effectiveness of the inspection and enforcement system in achieving good OSH outcomes is the incidence rate of fatal accidents *excluding* traffic-related accidents. First, this indicator is available on a longer timeframe, which is important because of the high year-on-year variability of the rate (given that fatal accidents are anyway rare). Second, and crucially, it corresponds to the sphere of responsibilities of the HSE and LA inspections in Britain (see below). Third, *even* if we consider the least-favourable indicator (*including* road traffic accidents), Britain's performance remains at least as good as Germany's, while relying on a far smaller number of inspections. If we consider data *excluding* traffic accidents, not only has Britain long had among the best OSH performance in Europe, but its edge over Germany has held in spite of strong improvements in Germany's performance. – but also suggest that this edge has been eroding, not because Britain's performance worsened, but because Germany's improved. Over the period 2008-2013, Britain retains on average the lowest fatal injury rate in the EU, with the Netherlands, Slovakia and Germany coming close (in that order). Finland, Denmark and Sweden also rank among very good performers, but with somewhat worse data. In the period 1998-2008, the best performance was Sweden's, followed by Britain, the Netherlands and Finland. Thus, Britain has confirmed its excellent performance over the long term, being one of the very best in Europe, but Germany has improved

its relative ranking – in a period where, in fact, inspections decreased in numbers, as we will see in the next section.

If we use the incidence rate *including* traffic-related accidents, the best performer is Greece (which is likely to reflect the collapse in economic activity since 2008, particularly in high-risk sectors for OSH such as construction), followed by the Netherlands, the United Kingdom (data for the whole of the UK rather than only Britain), Finland and Germany. Thus, changing the indicator would not meaningfully affect our conclusions.[532].

The significantly stronger difference between British and German performance when excluding traffic accidents, compared to when they are included, may reflect structural differences, with a stronger share of activities involving more intensive use of transportation during work. It also most likely reflects far less emphasis on reducing this kind of occupational accidents, which both justifies and questions HSE's reporting data excluding them. On the one hand, as HSE is *not* responsible for investigating such fatalities as per current legislation, it can be understood that they are outside of its remit, and that prevention of such fatalities is the province of other state authorities (those responsible for traffic safety more broadly). On the other hand, anecdotal experience suggests that there can be a lot of employer pressure on employees driving to "cut corners" in order to meet schedules and targets, and these should be recognized as "occupational", and addressed as such (by HSE and LA EHOs, as relevant). Overall, while this gap does not really affect Britain's excellent performance in OSH, and only marginally affects Britain's ranking, the continued exclusion of traffic- and transportation-related occupational injuries and deaths may be misleading, and make it more difficult to work effectively on reducing them. At the same time, this very difference actually goes a great way to demonstrate the HSE's (and LA inspectors') effectiveness: whereas Britain has established a major gap in its favour when it comes to occupational safety "on premises" (where their activities are focused), this edge is far less pronounced when traffic-related accidents are included, which suggests that, on traffic-related occupational accidents *alone,* Britain's performance is clearly worse than Germany's. While this suggests that it would be important to enlarge the scope of OSH supervision to further reduce accidents in Britain, it also demonstrates very clearly that the way HSE and LAs work is highly effective, and that the far lower number of inspections they conduct does not negatively affect this performance.

Health and Safety inspection practices in Britain and Germany

We can thus conclude from the above that, at least on the metric considered most reliable and most easily comparable (fatal occupational accidents), Britain has been performing generally significantly better than Germany, though the latter has improved its results in recent years. British performance is worse in areas where OSH inspectors are not involved (traffic-related accidents), but this only strengthens the evidence that these inspectors (and their institutions) are highly efficient and effective in their domain. Because of considerable problems with their reliability, we will not try and complement these data points with a comparison of non-fatal injuries (a quick look at Eurostat data shows massive under-reporting in a number of countries, making the whole data set unfit for use[533]). A glimpse at occupational health statistics would be useful, to balance the "short term" perspective (injuries) with the "long term" one (diseases), but again Labour

[532] Over 1998-2007, Greece's performance is far worse, suggesting that its excellent rating post-2008 may be (in a paradox frequently observed in OSH) linked to the brutal economic crisis, leading to a massive slump in some high-risk areas (e.g. construction).

[533] A look at the Eurostat tables for injuries resulting in more than 3 work days lost shows that the average rate (2008-2012) was lowest in Romania, Bulgaria, Latvia and Lithuania, with Romania's rate less than 1/30th of the EU average, and Germany's around 15% above EU average (Germany's system, as noted above, makes it likelier that work-related injuries will be correctly recorded). By contrast, on fatal injuries, Romania has the EU's worst performance (more than twice the average incidence), followed by Lithuania. Clearly, under-reporting is massive, even when Labour Force Surveys are used (work-related injuries are just not "perceived", and/or are actively hidden, and/or workers are simply unable to take days off for fear of losing their job, etc.).

Force Survey (LFS) data presents glaring inconsistencies, with some good performance pointing clearly to under-reporting, but certainly not *all* good performance. Let us just suggest here that, considering Britain's excellent record on fatal injuries, there is at least some plausibility that its good record on work-related health problems as reported by the LFS may reflect reality rather than under-reporting[534].

The second part of our comparison will now focus on OSH inspection practices in both countries – their numbers, targeting methods, and "style". As Tilindyte (2012) has shown, the structures and practices in Britain and Germany differ significantly, and it is precisely these differences, as well as the considerable distance in terms of inspections frequency, that matter to us. The structural differences mean, however, that comparisons are not as straightforward as one may wish. OSH inspections in Germany are conducted by two sets of bodies: state officials working for the federated states (*Länder*) in the Enterprise Supervision services (*Gewerbeaufsicht*), and employees of the mandatory insurance providers (*gesetzliche Unfallversicherungen*). While the latter focus exclusively on occupational safety and health issues (checking compliance with technical norms that are meant to reduce accidents and illness, and thus insurance payments), the former have a mandate that is less precisely defined. In some *Länder,* the *Gewerbeaufsicht* are assigned a number of non-OSH related missions, in some their organization has been devolved to the local (municipal) level (Tilindyte 2012, pp. 166-167). In some cases, the remit of these inspections includes consumer or environmental protection (*ibid.*, p. 175). These inspectors also control provisions of legislation relating to child labour, work time etc. – but *not* "provisions of collective agreements, and they do not enforce legislation in relation to social security and employment contracts, such as the payment of wages or dismissal"[535]. Thus, with the exception of cases where inspectors are responsible for consumer or environmental law, or market surveillance[536], their remit is roughly comparable to the HSE's (somewhat broader in terms of labour legislation, somewhat narrower in terms of health and safety, where the HSE is mandated to look in a holistic way and not only at the occupational perspective). In some *Länder*, the supervision of state laws on occupational safety and health has also been entrusted to the mandatory insurers, at least in some sectors[537] – but this has no incidence on the total number of inspections, only on who conducts them.

Thus, for Germany, in order to assess the total number of inspections we have to consider all the visits conducted by the mandatory insurers, as well as *most* (but possibly not all) of the visits conducted by the *Gewerbeaufsicht.* In fact, it is unlikely that some visits are *exclusively* focused on non-OSH issues, and most likely that all visits incorporate at least some elements of OSH, thus there is sufficient ground to assume that all of these visits can be counted as OSH-related. In any case, as we will see, even if we applied some discount, the gap between Britain and Germany would remain considerable.

The data from Britain is somewhat simpler to interpret, but also carries some degree of uncertainty at the local level, this time not because what is counted as OSH inspections may incorporate non-OSH visits (though this may also be the case), but because it is possible that environmental health officers (EHOs) conducting non-OSH visits (e.g. focusing on hygiene) also look "on the side" at OSH issues, thus conducting a form of monitoring that may improve the overall coverage and ability to identify risks. This is, in fact, "a feature, not a but" of the system – EHOs have a broad set of skills and competences, and a broad mandate, allowing them to cover inter-related risks in several areas during one visit, and joint inspection visits are encouraged, as we have seen above. In other words, the official count of OSH visits by LAs may be to some extent an

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[534] See HSE 2014, *European Comparisons* – p. 4.

[535] ILO's summary page on *Labour Inspection Structure and Organization* in Germany – available at: http://www.ilo.org/labadmin/info/WCMS_209470/lang--en/index.htm

[536] See ILO, *ibid.*

[537] See ILO, *ibid.*

underestimation – and it is difficult to put a figure on how significant it may be. Again, we will see that applying some correction to these numbers would not change the overall conclusion.

Germany (SuGA 2013, pp.286, 292-293)		Number of enterprises visited	Number of inspection visits
Länder inspections	2011	123252	297917
	2012	110207	267008
	2013	99999	242503
Mandatory insurers	2011	353360	639641
	2012	337345	603483
	2013	297941	599605
Total	2011	476612	937558
	2012	447552	870491
	2013	397940	842108

Great-Britain	Local authorities	HSE	**Total**
2006-07	*200000*	50000	*250000*
2009-10	196000	45000	241000
2010-11	194200		
2011-12	151000	*37000*	*188000*
2012-13	106200	33000	139200
2013-14	86900	30000	116900
Sources: HELA Paper H15/01, LAE1 return forms, HSE annual reports, Löfstedt 2011, "Focus on Enforcement" data for 2012-13. Since HSE does not publish aggregate inspections data, the HSE column represents the author's own extrapolations based on incomplete data, experts opinions (direct interviews with OSH enforcement officials in Britain) and breakdown of inspections in earlier years for which full data is available. Numbers in italics denote author's extrapolations based on trends (no data source available for that year).			

The above tables show that there are currently more than 7 times more OSH inspections in Germany than in Britain, and that even in earlier years (when OSH inspections were more frequent in Britain), the ratio was around 3.5 to 4 times more in Germany. This is quite a striking difference. Of course, the number of active businesses (and of establishments to be visited), and the active population, are also different, and significantly larger in Germany – hence it is important to look at inspection *rates* rather than absolute numbers. Ideally, like Eurostat data, the inspection rates should be normalized correcting for different economic structures, but the British data is not sufficiently differentiated to allow for this (SuGA reports give data by economic sector and would in principle allow for such corrections). We will have to accept this limitation, considering (as indicated above) that the two countries' economic structures are, though by no means identical, sufficiently close.

Adjusting for population requires to take a decision as to which population to use (workers or establishments), and (if the latter) which definition of establishment, enterprise (or business) population to adopt. This is all the more important as Britain has seen an important shift from salaried employment to self-employment, i.e. an important rise in the number of individual businesses, most of which are *not* being controlled by the HSE or by LAs[538]. There is no perfect choice in this matter, so we will present below the different possibilities, as well as the results obtained with each of them. The best variable for adjustment would be the number of "establishments (premises) under supervision", but this is not available in either country (though some reports in the UK present estimates, which we also refer to below).

	Great Britain	Germany	ratio Germany/Britain
Total population (millions)	62.70	82.70	1.32
Active population (millions)	33.01	44.70	1.35
Employed population (millions	31.09	42.70	1.37
Persons employed in private businesses	25,354,000	31,914,340	1.26
Total number of businesses	5,272,530	3,629,666	0.69
Number of businesses with 10 employees and more	236,830	339,087	1.43
Persons employed in non-zero employees businesses	20,996,000	29,914,278	1.42
Persons employed in businesses with 10 employees or more	17,093,000	24,176,805	1.41
average ratio (excluding total number of businesses)			1.37

(Sources:

Great Britain: Office for National Statistics (ONS): Labour Market Statistics – September 2015 release; ONS: Population Estimates for the UK, England and Wales, Scotland and Northern Ireland, mid-2014 release; Department for Business, Innovation and Skills (BIS): Business Population Estimates for the UK and regions, 2015

[538] Löfstedt (2011) has recommended *not* inspecting businesses with no employees except when their type of activity could pose a significant risk to outsiders. This policy, while not having the force of law, is widely implemented (and in fact was most probably widely implemented already before the report).

Germany: *Statistiches Bundesamt* website: *Konjonkturindikatoren, Volkswirtschaftliche Gesamtrechnungen* and *Arbeitsmarkt*; *Statistiches Bundesamt* online database "Genesis": tables 52111-0001 and 52111-0014[539])

If we exclude the total number of businesses, which is much higher in Britain due to the far larger number of self-employed (as mentioned above), the ratio between Germany and Britain is relatively stable, mostly between 1.3 and 1.4. Since most of these self-employed fall outside of the HSE's and LA's OSH inspections remit, we decided not to count this number and consider only the other ratios. The rationale for considering specifically the number of workers in businesses with at least one employee and with more than 10 employees is that they tend to be those (particularly those with at least one employee, as opposed to purely individual entrepreneurs) on which OSH inspections focus. Overall, excluding the total number of businesses, the smallest gap is on the total number of persons employed in private businesses, the largest is in the number of businesses with 10 employees or more. As indicated above, there is another number which would be most relevant to consider, the number of *premises under supervision* (i.e. at least potentially covered by inspections). Unfortunately, this number only exists (as estimate) for Britain. As indicated in the BRE report *Improving Outcomes from Health and Safety* (2008), there were over 2.5 million such premises in 2008 (BRE estimate), with over 26 million workers (HSE estimate) (BRE 2008, p. 59). In Germany, the SuGA 2013 (p. 291) report (BAuA 2014) indicates over 3.2 million businesses and 31.5 million workers as reported by the mandatory insurers, which *may* correspond to the same definition (approximately at least, though the number of *premises* is likely to be higher than that of *businesses*) – but the *Gewerbeaufsicht* may have another "universe" of premises under supervision. Using these numbers, the respective ratios would be 1.28 and 1.21. This would suggest a *smaller* gap between the scope of supervision in Britain and Germany, and actually *strengthen* the case that OSH inspections in Britain are considerably less frequent. We thus decided to keep a ratio of 1.37 for further calculations, which corresponds to that of the employed population.

	number of OSH inspections			
	Germany	Great Britain	ratio	ratio adjusted for population
2006	*1100000*	*250000*	4.4	3.2
2009	*980000*	241000	4.1	3.0
2011	937558	*188000*	5.0	3.6
2013	842108	116900	7.2	5.3

(N.B.: data in italics are estimates – for Great Britain, author's own extrapolations based on available data – for Germany, based on Tilindyte 2012 p. 177)

Once adjusted for the difference in population, we see that for a number of years the frequency of OSH inspections adjusted for population was 3 or more times higher in Germany. In the most recent years, the gap has considerably increased, and the inspections rate is now above 5 times higher in Germany. While inspections have overall become less frequent in both countries, the gap has remained, and recently (in line

[539] Reconciliation of data for Germany was very difficult, with various sections and tables of the Federal Statistics Office giving different totals with apparently similar definitions. These two tables were taken as being the most reliable, and also match best the data available p. 291 in the SuGA report (BAuA 2014), which is based on mandatory insurers reports. It should be noted that, for Britain, ONS and BIS have different statistics, apparently based on different definitions and sources. We have used the BIS reports as being the most up to date and corresponding best to our definitions. *Pro memoria,* in Germany there are also statistics on the number of *Betriebe* distinct from those on *Unternehemen,* i.e. a broader "establishments" definition including public sector ones, with a total of 3,835,716 – we did not use it because it differs from the UK definitions, and would change little to the ratio. There also are discrepancies between "employed" and "subject to social security contributions" numbers in some cases. The numbers quoted in the table are "subject to social security contributions" as per the Federal Statistics Office tables referenced.

with post-2010 reforms in Britain) increased. Even if we discount this recent increase (since, as we will discuss below, the reforms may in some respects have gone further than what risk-based principles would recommend), the long-term ratio of more than 3 times is very high. As we indicated several times above, considering the many ways in which the two countries differ, a small variation in inspections frequency (or in outcomes) could be discounted. Three times more frequent inspections (and more), for outcomes that have been in the long term generally far worse and (at best, if taking the most favourable indicator) are now equivalent appears like a strong indication that inspections and enforcement practices in Germany are clearly less efficient than in Britain[540]. This example clearly shows that the naïve assumption that "more inspections" will automatically mean "better outcomes" is mistaken, it also leads to ask *what* makes British regulatory delivery so much more effective.

iii. Explaining effectiveness and efficiency – risk-based approaches vindicated?

Conceivably, at least some part of this difference in efficiency could be explained by British inspectors having access to more effective deterrence tools than German ones – or having a more adequate "enforcement pyramid", making escalation more credible and therefore more effective at increasing compliance. Tilindyte (2012) suggests that this may be the case, after an in-depth review of the enforcement options available to inspectors in both countries, considering not only the letter of the law but the actual practice, and the extent to which theoretically available sanctions are used in practice (pp. 230-274). On administrative sanctions, her conclusion, on balance, is that administrative sanctions are relatively more frequently used in Britain than in Germany, and that although the HSE only has notices (and, to some extent, license terms modification) at its disposal, the publicity of the notices (public registers) adds a powerful "naming and shaming" effect. By contrast, German inspectors have in theory more varied and powerful administrative sanctioning tools, but in practice (for reasons both of complexity of procedures, of ignorance of the option to impose *corporate* rather than *individual* sanctions, and of "culture") use them very rarely (pp. 270-271). Concerning criminal sanctions, she likewise concludes that both probability and potential severity are somewhat higher in Britain – and that the lack of corporate liability could be a significant limitation in Germany (pp. 269-270). These relative weaknesses may indeed *to some extent* contribute to making German inspections less effective in terms of dissuasion – in particular, existing research indeed suggests that negative publicity may be a stronger driver than sanctions themselves, and the legal strength of the British "notices" is quite significant. The lack of corporate liability in Germany is clearly a significant problem. Nonetheless, these are unlikely to be sufficient to explain how an inspection rate more than three times lower results in equivalent or better outcomes in Britain, particularly considering that deterrence is (as we have seen in the second Chapter) a relatively weak compliance driver.

The answers can be found by looking more closely at data and practices, in particular concerning *targeting,* the way advice and guidance are *structured*, and the overall organization of the system. On the first point, Tilindyte presents (*ibid.,* pp. 238-239) historical data on inspections, "deficiencies" identified (for Germany), and enforcement measures. Though the data is partial (only HSE FOD for Britain, and only *Gewerbeaufsicht* for Germany), it is enlightening. While, for the periods considered, HSE FOD conducts only 12-13% as many inspections as the *Gewerbeaufsicht*, it issues 55-66% as many notices, and initiates from 2 to 7 times as many prosecutions (but the German authorities also have the ability to impose direct administrative penalties). In other words, German inspectorates visit far more premises, but seem to find problems that are sufficient to warrant enforcement action only very rarely. This should be considered also in light of the number of "OSH

[540] One could even use this as a possible indication that OSH outcomes have no relation at all to inspections and enforcement practices. For the many reasons exposed in earlier chapters and sections, we believe this would be an excessive claim – but surely this example shows once again that there is no direct correlation between more inspections and better outcomes.

deficiencies" identified in Germany, on average 1.5-1.6 per inspection. Thus, inspectors find a vast number of "deficiencies", but consider most of these to be too mundane for enforcement, or enforcement not to be the adequate response. There are several ways to interpret such findings, including that this may represent "reluctance" to adopt a formal approach (Tilindyte 2012, p. 239) – but there is also a distinct possibility that this reflects a "net cast far too wide". German inspectors may be over-inspecting, i.e. visiting a large number of premises where the risk level is low, then identify "deficiencies[541]" that reflect a large set of very prescriptive and detailed rules (which make non-compliance likely by their very nature), but decline to enforce because they clearly see that it would be disproportionate (and would likely trigger backlash from their own management or from the public, even if their own professional judgement did not discourage them from enforcing).

Interestingly, professional attitudes between German and British inspectors seem to have some similarities, at least in terms of emphasis on advice and "informal" rather than formal enforcement (*ibid.,* pp. 193-194 and 239-240). It does not appear to be a "lack of advice" overall that could explain the relative under-performance of German inspections, or constitute the key difference between the two systems. In fact, the fact that *both* Britain and Germany rank among the very best performers in terms of OSH in the EU (and, more broadly, in the world) suggests that "informal enforcement", rare use of sanctions and emphasis on advice and guidance may be working very well at promoting compliance and safety. Tilindyte quotes the EU's Senior Labour Inspectors Committee (SLIC) as reporting in 2005 as observing a "widespread, seemingly institutionalised, assumption that advice is more effective and preferable to [formal] enforcement" (*ibid.*, p. 239) – and suggests that this, at least, in "tension" with the SLIC principles which, while they foresee the use of "informal enforcement", also put some emphasis on adequate powers and formal enforcement (*ibid.,* pp. 98-99). However, the performance of systems that put heavy emphasis on formal enforcement, such as France's, appears considerably worse. As we have seen, France has a rate of fatal occupational accidents that is very high (2008-2012 average of 3.85, 50% above the EU 15's and 2.5 times more than Britain's or Germany's), with far more inspections than Britain[542] (though not necessarily than Germany's), and an enforcement approach that is well known for being very formal, enforcement-prone and "adversarial"[543]. Clearly, there is a "chicken-and-egg" question as to whether informal, cooperative enforcement fosters effective cooperation, or whether a cooperative climate is what makes informal enforcement possible – but these examples clearly show that equating "intensive, formal enforcement" with "higher effectiveness and compliance" is simply impossible[544].

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[541] Which do not necessarily amount to an offense – cf. Tilindyte 2012 p. 191.

[542] In 2010, France's Labour Inspection conducted 368,236 "interventions" (inspections, investigations etc.). In addition, each regional Medical Insurance *Caisse* has a corps of controllers (not unlike the dual system in Germany). While no consolidated statistics exist on their numbers or activities, anecdotal evidence suggests their visits are (at least in some sectors) not less frequent than Labour Inspectors'. While in 2011 there were over 2,200 inspectors (broadly defined, as there are two different statutory grades with inspection functions) in the Labour Inspection, an estimate based on data from a few regions suggests there should be close to 1,000 Medical Insurance inspectors at least. Assuming a similar inspection schedule, this would yield between 500 and 600,000 inspections per year, vastly more than in Britain, even though the two countries have a similar working population and number of enterprises. (Source: *L'Inspection du Travail en France en 2011,* officla report to the ILO, available at: http://travail-emploi.gouv.fr/IMG/pdf/Rapport_IT_2011_sans_table.pdf - cf. pp. 63 and 124). Note of course that France's labour inspectors check not only OSH issues but also the full employment legislation, and that this is a major part of their tasks (which may distract their attention from OSH). Still, health and safety are part of every inspection they conduct (in principle at least), and the Medical Insurance inspectors check *only* health and safety.

[543] There are reams of anecdotal evidence but evidence is provided by the same report to the ILO – remarkably little on outcomes, but strong emphasis on inspections and enforcement (pp. 70-102), far more than on advice and guidance (pp. 108-113). Also the same report (pp. 135-137) emphasizes the importance of "protection" (judicial) granted to inspectors in cases of conflicts (including violent ones). Such items are of course missing from e.g. HSE reports, and such situations generally unknown in Britain (or in Germany). The degree of conflict linked to labour inspections in France is particularly high, with inspectors widely known to be strongly politicized and both sides (inspectors and businesses) seeing the other more as "enemies" than "partners".

[544] As indicated, France has more inspections and far worse outcomes than Britain. As sketched out in the first Chapter, the roots of France's labour inspection challenges and practices go back to the 19th century, and combine political, legal, administrative and social

A key difference between the HSE's practices and advice provided by German inspectors appears to be the degree to which, in the UK, advice is provided pre-emptively and with a broad outreach effort, in a way that is designed to be easy to understand and implement. In other words, whereas German inspectors seem to primarily provide *ad hoc* advice based on their findings and their own experience and understanding, the HSE (and, increasingly, LAs) provide *guidance.* This guidance is not provided only when an inspection reveals problems, but proactively, to everyone who requests or looks for it (and HSE and LAs make efforts to ensure that as many people and businesses as possible are aware of this guidance).

As Tilindyte (2012) points out, advising businesses on how to comply with OSH regulations is a *duty* of the German state authorities (p. 190). As she underlines, inspectors "see themselves primarily as consultants, service providers" assisting to achieve compliance, and this is "particularly true for inspectors of the accident insurers" (*ibid.*). In fact, as we have seen, the SLIC's assessment considered that, if anything, the Germany system was too far on the side of "advice" and not enough on the "enforcement" side. Tilindyte further notes "numerous programmes of the individual authorities" that "reflect their aspiration to improve and strengthen education and advice" (p. 191). The "quantity" of advice thus does not seem (at least in recent years) to be an area where there is a meaningful difference between Britain and Germany. To the extent that Tilindyte underlines that evolutions started around 10 years ago led to a strengthening of the "service-oriented", advice component of German OSH structures' activities, it is conceivable that this change may have contributed to the significant improvement in outcomes that we have observed above (with Germany catching up gradually with Britain). Still, it appears that the primary vehicle of advice in German OSH practice remains the inspection visit itself. A (non-exhaustive) look at different government websites covering OSH suggests that significant efforts have been done to improve availability, accessibility and ease-of-use of information, but that much remains to improve – in terms of contents, as in terms of ease-of-use.

The German system's fragmentation may be part of the causes of the problem, meaning that there is a mix of federal and state-level websites to consider, each with a different structure and focus. For this research, we reviewed the information available on two state-level websites (Niedersachsen[545] and Nordrhein-Westfalen[546], the first as an example of a mid-size state with significant manufacturing industry and a

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elements. Still, it is remarkable that the lack of effectiveness of existing methods has been so little challenged. Even if existing practices of French labour inspectors may have come "in reaction" to "resistance" by businesses, they clearly seem to have the result to *strengthen* them rather than lead to transformations, thus the "chicken-and-egg" question is not useful when it comes to determining a course of action.

[545] See the portal of the *Gewerbeaufischt* for Niedersachsen (Lower Saxony), with the start page available at: http://www.gewerbeaufsicht.niedersachsen.de/. Detailed perusal of the portal shows that there are a number of specific pages e.g. on OSH organization in the workplace, protection against specific hazards etc. The portal also links to a certain number of practical tools – these include in particular a safety inspection check-list focusing on hazardous installations (available at: http://www.gewerbeaufsicht.niedersachsen.de/download/30099/Ausfuellbares_Pruefschema_fuer_Sicherheitsberichte.pdf), and (for the same type of safety visits) safety inspection guidelines (available at: http://www.gewerbeaufsicht.niedersachsen.de/download/81617/Niedersaechsischer_Inspektionsleitfaden_2012_zur_Durchfuehrung_der_jaehrlichen_Vor-Ort-Inspektion_entsprechend_16_Stoerfall-Verordnung.pdf). Practical, easy-to-use guidance is, however, rare. One example is a (rather short and not very user-friendly) flyer on asbestos (http://www.gewerbeaufsicht.niedersachsen.de/download/57589/Flyer_Entsorgung_von_Asbest_Stand_08_2013.pdf), but there is very little guidance overall for construction works, one of the highest risk sectors.

[546] See the portal for occupational safety in Nordrhein Westfalen (North-Rhine-Westfalia), at: http://www.arbeitsschutz.nrw.de/. The portal is well structured and it is easy to find pages helping employers with their risk assessment and explaining their responsibilities (e.g. http://www.arbeitsschutz.nrw.de/themenfelder/arbeitsschutzsystem_gefaehrdungsbeurteilung/index.php and http://www.arbeitsschutz.nrw.de/themenfelder/arbeitsschutzsystem_gefaehrdungsbeurteilung/verantwortung_des_arbeitgebers/index.php). It has practical tips e.g. on lifting heavy weights (see at: http://www.arbeitsschutz.nrw.de/themenfelder/arbeitsplaetze_arbeitsstaetten/heben_und_tragen/index.php) including a brochure (http://www.arbeitsschutz.nrw.de/pdf/themenfelder/sieben_schritte_zum_erfolg.pdf). The latter is, however, rather "conceptual" and targeting managers more than directly "visual" and practical. It has tips for builders (http://www.arbeitsschutz.nrw.de/themenfelder/baustellen/pflichten_des_bauherren/index.php) and a brochure on "safe building" (http://www.arbeitsschutz.nrw.de/pdf/themenfelder/baustellen/Fb_Mit_Sicherheit_Bauen_04_final.pdf), but again the latter is light

centralized OSH service, making research easier, and the second being the most populous and industrial state in Germany), the website of the Federal Ministry for Labour and Social Affairs[547], and that of the Federal Agency for Labour Protection and Occupational Medicine[548]. In comparison, for Britain, we have only had to peruse the HSE website, which acts as a unique portal for health and safety issues. The conclusions are that the German websites are often inadequate for the needs of business operators, managers and workers, having fragmented information, complex documents, lack of practical examples etc. It is also difficult to know which portal to use. Finally, when real efforts are made to make the information easier to find and to use (as in Nordrhein-Westfalen), this is done at the *Land* level, and thus likely to be ignored in other parts of the country. Each *Land* duplicates the others' efforts, and best results are not shared.

In Britain, by contrast, the HSE website is the single portal for all things "health and safety". One of the site's main tabs is "Guidance[549]" – which then leads into several clear sections e.g. "Industries" and "Topics", which makes information search easy. There is a specific section on "Risk Management"[550] including a set of interactive tools and check-lists for different types of premises. There are clear, detailed and practical brochures for a number of key types of risks, e.g. working with weights[551], "slips and trips" (one of the most frequent causes of accidents on the workplace)[552], or types of establishments such as construction[553]. In the latter page users can, crucially, find a guide to "absolutely essential" health and safety advice in construction, with very practical, clear, visual explanations. This short review leaves no doubt that finding information on OSH issues and good practices is considerably easier in Britain, and that the information is also far more usable. Sources of information in Germany are both dispersed and complex, and the best guidance documents are not available on national (federal) websites and thus are probably ignored in other regions. Of note is also that, while the HSE's efforts in developing and communicating advice and guidance are long standing, they are also part of an increasingly coherent government effort in the UK. In 2009, the Better Regulation Executive published the *Anderson Review* of regulatory guidance[554], which emphasized the importance of making guidance more accessible and clearer – areas in which clearly the available information in Britain is far superior

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on practical recommendations. The brochure on risk assessment is detailed and practical (though very text-heavy), and is one of the best examples of guidance we have seen on German websites, but the link included in the portal is indirect, and it takes efforts to eventually find and download it (https://broschueren.nordrheinwestfalendirekt.de/herunterladen/der/datei/bro-gefaehrdungsbeurteilung-april2014-pdf/von/gefaehrdungsbeurteilung-am-arbeitsplatz/vom/staatskanzlei/1650).

[547] *Bundesministerium für Arbeit und Soziales* – website accessed at: http://www.bmas.de/DE/Startseite/start.html - pages on labour safety issues e.g. http://www.bmas.de/DE/Themen/Arbeitsschutz/inhalt.html, and for legislation in this area see e.g. http://www.bmas.de/DE/Service/Gesetze/arbstaettv.html. On OSH, the website has primarily (a) general descriptions of issues and policy activities in different areas and (b) federal legislation. Practical guidance, if any, is very limited. There is also no easy collection of links to other institutions, federal and state-level. Hence this website is not really usable as an OSH portal.

[548] *Bundesanstalt für Arbeitsschutz und Arbeitsmedizin (BAuA)* (portal at: http://www.baua.de/). The portal is heavy on research papers and legislation, but also has guidance documents on topics that can be very useful, e.g. on handling heavy weights – but these documents tend to be very complex and break down the assessment and recommendations in many components. E.g. there are two brochures to cover the "heavy weitghts" – lifting and handling: http://www.baua.de/de/Themen-von-A-Z/Physische-Belastung/pdf/LMM-Heben-Halten-Tragen.pdf?__blob=publicationFile&v=3, pushing and pulling: http://www.baua.de/de/Themen-von-A-Z/Physische-Belastung/pdf/LMM-Ziehen-Schieben.pdf?__blob=publicationFile&v=3. There is a very detailed brochure also on handwork positions: http://www.baua.de/de/Themen-von-A-Z/Physische-Belastung/pdf/LMM-Manuelle-Arbeit.pdf?__blob=publicationFile&v=9. Overall, information is fragmented, and far from easy to use. It targets rather specialists than operators.

[549] Available at: http://www.hse.gov.uk/guidance/index.htm - see for "topics" http://www.hse.gov.uk/guidance/topics.htm and for "industries" http://www.hse.gov.uk/guidance/industries.htm

[550] See: http://www.hse.gov.uk/risk/index.htm - and tools at: http://www.hse.gov.uk/pubns/indg163.htm (guidance) and http://www.hse.gov.uk/risk/risk-assessment-and-policy-template.doc (template)

[551] See: http://www.hse.gov.uk/pubns/indg143.pdf (brochure with clear, visual guidance), http://www.hse.gov.uk/pubns/indg383.pdf (detailed version with assessment charts), http://www.hse.gov.uk/pubns/indg398.pdf (guidance on use of handling aids).

[552] See: http://www.hse.gov.uk/slips/index.htm including a number of assessment tools, practical tips and brochures etc.

[553] See: http://www.hse.gov.uk/construction/index.htm and "absolutely essential" health and safety brochure at: http://www.hse.gov.uk/pubns/indg344.pdf

[554] Available at: http://webarchive.nationalarchives.gov.uk/20090609003228/http://www.berr.gov.uk/files/file49881.pdf

to that in Germany. The Review also recommended to improve *certainty* and we will briefly discuss this aspect in this section's conclusion.

The gap in effectiveness between Germany and Britain could also have parts of its origin in the earlier development and adoption of a risk-based approach in OSH in Britain. Following the 1974 Health and Safety Act, risk assessment became the norm. In Britain, OSH risk was thus focused on identifying and preventing or mitigating risks, driving efforts to identify trends and evolutions, concentrate resources, provide guidance on the problems most commonly identified (including on problems affecting many different sectors). Rather than prescribing standards, the 1974 Act emphasized outcomes and left flexibility on how best to achieve them. By contrast, in Germany, OSH remained essentially based on sector-specific, detailed standards-based regulations. The 1989 EC Directive on health and safety at work (89/391/EEC), which introduced "general principles of prevention" based on risk (and on risk-assessment and risk-management) (cf. Tilindyte 2012, pp. 92-96) led to significant changes in the German legal order (whereas it ended up requiring remarkably little changes in Britain, as the Directive to a significant extent drew on the same principles as the 1974 Act)[555]. The Directive was translated in German law with the adoption of the 1996 Occupational Health and Safety Act (see Tilindyte 2012 pp. 165-166). While the current system (in particular the mandatory insurers' requirements and practices) is still largely based on pre-1996 principles, including detailed sector-specific rules, and while the uptake of risk assessment by businesses has been slow and difficult (*ibid.* p. 183), there is little doubt that this legal change had important consequences. Still, it is plausible that the more than 20 years gap in implementing risk-based approaches in OSH regulations may be one of the reasons for the gap in efficiency and effectiveness.

The fragmentation of the German system goes together with what appears to be a somewhat weaker management of information, and a less formalized risk-based planning system. German authorities, in fact, used to have regular, "individualized" supervision of businesses largely independently of risk (Tilindyte 2012 p. 182), before the reduction in resources and change in approach led to more targeting (p. 183). As Tilindyte notes, however, much of the targeting is done "in the absence of *formal* models or comprehensive risk assessment models" (*ibid.*), with some targeting based on sectors, other on issues, and many cases simply on the inspectors' "personal experience and expertise". The inspectors' previously very broad autonomy is gradually reducing, but formalized risk assessment models exist so far only in some *Länder* (*ibid.*, p. 184). By contrast, risk-assessment and risk-based targeting are far more clearly formulated and more strongly and consistently implemented in OSH inspections in Britain (though not without room for improvement) – and this is evidently a decisive factor in the fact that Britain manages to achieve excellent OSH outcomes (comparing to EU average for instance) with far less inspections than Germany.

OSH inspections in Britain are explicitly planned on a risk-assessment basis[556], and meaningful risk-assessment requires both *data* and an *information management system.* On this count, the dual structure of OSH enforcement (HSE and LAs) leads to a sub-optimal structure. HSE records inspection activity and findings (and enforcement follow-up) using a database called COIN (Corporate Operational Information System)[557]. Every intervention is recorded in the system and the findings result in an "inspection rating" – taking into account "past performance as well as demonstrated attitudes towards health and safety" (Tilindyte 2012, p. 125). These inspection ratings are then combined with the sector-based prioritization to determine which premises

[555] This is of course a very much shortened account of the process, which was considerably more contentious. The Directive, though using the language of risk, imposes mandatory prescriptions and does not use any language comparable to the British "So Far As Reasonably Practicable" (SFARP). In fact, the "SFARP" clauses were challenged before the CJEU in 2005 by the European Commission, but the CJEU found in favour of the UK (Tilindyte 2012 p. 108). As a result, the British legal framework for OSH was little affected by this Directive (though further, specific directives e.g. on protective equipment have of course been taken up, but they belong more to the "conformity assessment" field than to the OSH field in terms of their implementation and enforcement mechanisms).

[556] See further for a discussion of the changes in terms of targeting introduced by Government policy in recent years, in particular the notion that there could be "high risk" activities but where inspections have been demonstrated to be ineffective.

[557] See on the HSE website: http://www.hse.gov.uk/statistics/data-quality-statement.htm and also Tilindyte (2012) p. 125

will actually be targeted. Significant efforts are made to ensure the integrity and quality of the COIN database, however recent reports suggest that it may not be fully adequate to ensure optimal targeting. In particular, in the 2014 research report conducted by the Health and Safety Laboratory as part of the review of the new "Fee For Intervention" scheme (see also below on this), inspectors reported significant issues with COIN data: "challenges for both [proactive and reactive visits] related to the quality of information available on COIN. For proactive visits, a major challenge discussed was that the intelligence provided was not targeting a sufficient number of organisations with poor health and safety standards" (p. 2). The report further details that "challenges associated with the preparation for proactive visits related to the quality of site information that was available and, more broadly, the intelligence provided to inspectors. In particular, inspectors expressed frustration with the availability of company information on COIN. It was described that very often company information (such as previous inspections or investigations) is not available on COIN because details get deleted for companies that have not been inspected for seven years" (p. 28). It appears that the HSE's targeting system is hampered here by a double challenge. First, inspections are becoming more rare because of decreases in staffing and of a political drive to reduce their number, which means that inspectors are more rarely visiting premises, and thus that updated information on establishments under supervision becomes rare. Second, the quality of targeting suffers from a well-known problem affecting organizations that moved early to computerized data: problems linked to legacy systems. In this case, the information system (COIN) is set up so that data older than seven years is deleted, which means that prior track record will be lost (for companies that have been visited more recently), and that other establishments see all their data disappear altogether from the database (if they have not been visited for the last seven years).

As for LAs, each one uses its own IT system, and they only provide consolidated summary data to the HSE each year (over 90% of LAs effectively do it). While the lack of data sharing between LAs and HSE is in principle not a problem (since supervision and enforcement are clearly divided between them, and there is no establishment where both could be involved in OSH supervision), the fragmentation of data among different LAs is an issue for companies that operate in a number of localities. Efforts to address this problem exist, e.g. as part of the *Primary Authority* scheme (see further below), but this remains a real limitation.

Overall, in spite of these limitations, there is significant evidence that greater emphasis on use of data (in particular records of previous inspections) and clear criteria for risk-based targeting are instrumental in making Britain's OSH inspections more efficient than German ones, i.e. better able to cover key risks for a given number of visits.

Finally, and though there is at this stage no evidence of this link (other than correlation), it is plausible that the way enforcement is structured, and discretion is framed, has some influence on the results. Indeed, we have seen that in Britain OSH inspectors' discretion is exercised within a particular set of institutions, practices and cultures (Hawkins 2002) but also, increasingly, within an "enforcement management framework" that gives more transparency and predictability, and explicitly links the exercise of discretion to an assessment of risk. Post-enforcement discretion of course exists in Germany (Tilindyte 2012 pp. 187-188), within the limits of Administrative Procedures Law (*Verwaltungsverfahrengesetz*), and depending on the wording of the law being enforced (much like in Britain and elsewhere) – but there are no specific guidelines to help inspectors take decisions, and make these more transparent. There are a number of general principles, notably "equal treatment", "proportionality", "necessity" etc. (*ibid.,* p. 188). All of these, however, require interpretation, and leave considerably more leeway and uncertainty than the very specific guidance included in the HSE's Enforcement Management Model (EMM). There are two ways in which the clarity, predictability and transparency introduced by the EMM could have positive effects in terms of safety. First, it could plausibly have a positive procedural justice effect, by making it clearer for duty holders how they will be assessed, and how decisions will be taken – resulting in an increased likelihood of voluntary compliance. Second, because the EMM emphasizes the importance of *risk assessment* and of the "risk gap", it may push businesses to focus

on critical issues and concentrate their compliance efforts on the points that are likely to have the greatest safety impact. In other words, if the EMM is understood (at least in general) by businesses, and if they can reliably expect that enforcement decisions will be risk-based, they will have a strong incentive to focus on improving the points that may cause the most harm and thus (assuming limited resources and inevitably imperfect compliance) maximize the safety outcomes for a given "percentage" of compliance. By contrast, German businesses, left with far more uncertainty and far less clarity of what inspectors expect, are more likely to try and increase compliance in all directions, or focus on points that appear clear but may have less impact. At this point, we do not have any specific data that could prove these relationships, but this would be an interesting area to explore in future research.

iv. Areas of potential concern

We have seen above that there is very strong data suggesting that Britain's OSH inspections system and approach are significantly more efficient than Germany's (comparable safety outcomes with several times less inspections), and that this appears to be linked to a more consistent use of *risk* in planning and decision-making, and more emphasis on *guidance and advice*, as well as a system that is generally more *structured.* This does not mean, however, that all is perfect in the British system and that there are no areas of concern. First, we have seen that Britain's OSH performance *used to be* significantly *better* than Germany's, but that the latter has partly caught up (because Britain's has not continued to improve) – although the trend is less clear when traffic-related accidents (which are not supervised by the HSE) are excluded. Second, we have noted some concerns related to the quality of data used for risk-based targeting. We have also discussed above the many critics of the latest years' evolutions. We have also indicated that there seemed to be serious under-performance in the area of work-related transport accidents. We will first discuss the "data quality" issue (and also respond to observations made in Germany's case), then consider the question of transport-related accidents, and conclude by considering the most recent reforms and their likely effects on OSH effectiveness in Britain.

Data quality, IT systems and low frequency of visits

A relatively frequently made claim is that introducing a comprehensive database of establishments, including their risk profiles, is far too resource-intensive and costly, and this is often used to resist pushes to introduce risk-based planning. Tilindyte (2012) thus writes (in respect to Germany) that "clearly, the effort necessary to establish, maintain and implement such models is substantial" (p. 185), and goes on to emphasize the number of workplaces supervised in each *Land.* Like Baldwin (2007), she goes on to suggest that the costs "to collect, to process and evaluate information on all of them" are a "mammoth task", imposing "high costs" – and that the necessary regular updates will again imply further high costs (p. 185). As we have already noted in the theoretical discussion on risk-based targeting, there is reason to believe that such concerns are overblown (and, possibly, not expressed in an entirely candid way). In reality, as we have seen, German inspectors (if we consider both mandatory insurers and *Land* inspectors) visit nearly 400,000 enterprises each year. Granted, this is only a bit more than 10% of the total number of businesses, but this is more than all the enterprises having 10 employees or more. In other words, German inspectors, assuming that they pool their efforts and all (mandatory insurers and *Gewerbeaufsicht*) enter data in a unified system, could cover all the most "meaningful" enterprises in one year, and all the enterprises with at least one employee in at most a couple of years, simply by conducting their existing number of visits. We have observed the experimental verification of such an undertaking's feasibility in Mongolia. In 2010, the World Bank Group took a group of officials from the General Agency for Specialized Inspections (GASI) to Bosnia and Herzegovina, and they observed the

effectiveness of the unified database and information management system in place in the State Inspectorate of the *Republika Srpska* entity. Over the next couple of years, GASI's management instructed all inspectors to henceforth conduct a risk assessment during every inspection visit, and to enter the data from this risk assessment in a computerized database[558]. After only a couple of years, GASI built up a comprehensive data of all establishments, with their risk profile, and it is being regularly updated. It appears difficult to believe that German inspectors could not do the same – but it would require the setup of a unified system for OSH inspections, and also a clear decision to focus on premises with significant risk (i.e. premises with at least 10 employees at first, moving on afterwards to premises with more than 5, and eventually to those with at least 1 employee – and essentially leaving out those with no employees).

The situation is different in Britain – better for now, but with the perspective for getting worse. Indeed, in contrast to Germany, OSH inspections are now *really* rare (equivalent to less than half of the enterprises with 10 employees or more, and a small fraction of those with at least one employee). Because computerized databases already exist for HSE and most LAs, the problem is one of *updating* – and of *maintenance* for the HSE system, given that premises with no inspection in the last 7 years get "reset" to zero. As we have indicated above, there is a dual information technology problem (a "legacy" system in HSE, fragmented systems in LAs) – combined with an operational challenge created by the decrease in the number of inspection visits overall. It is not the purpose of this research to develop detailed responses to the challenges identified, but this one deserves consideration for, if it was impossible to address it, this could seriously undermine the viability of a risk-based approach. In fact, even assuming that inspections remain at a sustained low rate as is currently the case, there would be practical means to get more regular updates on the risk profile of establishments. This would involve the replacement of current legacy systems (at national and local levels) by a new *integrated* system with a common database for several types of inspections (involving several national agencies and all the different regulatory areas covered by LAs) or, at a minimum, a system enabling regular data sharing between the different existing systems and databases. We have discussed above the existing models and systems that exemplify such approaches (cf. also World Bank Group 2014b and Blanc 2012, as well as OECD 2015 b), and there is no doubt that such data sharing is feasible with existing technology. The challenges involved in Britain would be institutional and political, particularly when it comes to building a system connecting national and local institutions. So far, significant efforts at data sharing between different inspection areas have been done in some local authorities, but broader integration would involve significant steps politically and administratively. In addition, while the idea that other agencies can act as "eyes and ears", that compliance problems in one area can often be predictors of issues in another areas, that the fundamental characteristics of an establishment can be assessed by one inspector for the benefit of several agencies are all correct, it may still be important to reconsider the current trend towards ever-decreasing HSE inspections.

Transport-related accidents

We have seen above that the fatal accident rate reported by HSE, i.e. *excluding* transportation-related accidents, has Britain as the EU's best performer, and with a far lower rate than Germany. When considering the rate of fatal accidents *including* transportation-related "at work" accidents, Britain still features among the "best in EU", but not anymore quite at the top, and not better than Germany, at least in recent years. The fact that HSE reports generally the rate *excluding* transportation accidents has been criticized (e.g. by Tombs and Whyte 2010) as leading to under-estimation of the seriousness of OSH problems, and indeed it tends to distort reality and present a picture more flattering than should be the case. The source of the issue, in fact, appears to be regulatory provisions rather than a specific attempt to understate the issue (and, in fact, this

[558] Sources: interviews with GASI management and GASI central risk assessment unit, review of internal GASI reports for 2012-2014, direct consultation of the database in September 2014.

regulatory requirement much predates the reforms of the past few years). Under the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR) which govern occupational accidents reporting, work-related accidents on public roads are *not* reportable to HSE, for responsibility for investigating them lies with the police. HSE would only get involved if the police identify any serious management failings that they feel led to the accident and as a result refer it to the HSE – and such referrals are, in practice, quite rare[559]. However, even when work-related transport is taking place on public roads, health and safety law still applies and employers are under a duty to manage occupational road risk in the same way as any other risk – and HSE and LAs inspectors could perfectly include this risk in their preventive and inspection work.

In practice, it seems the absence of a reporting requirement to HSE has been an incentive for health and safety inspectors to avoid focusing on occupational road risk. This issue has been known for a long time: the Royal Society for the Prevention of Accidents (RoSPA) has been lobbying for a greater focus on road accidents "at work" for many years, and laid out findings and recommendations in a 2002 report. This report estimated that between ¼ and ⅓ of road fatalities in Britain may be work related, and that "at work" road accidents may make up more fatalities than all other occupational injuries (Eurostat data indeed suggests the two to be roughly equivalent, or road accidents possibly a bit more numerous than all other types). It suggested that "car and van drivers who cover 25,000 miles a year as part of their job" were working in the equivalent of "acknowledged high hazard sectors such as construction and quarrying" (p. 1). It found, however, that "health and safety law is not applied on the road" in spite of existing legal duties (*ibid.*). Among the changes considered in the report was making road accidents reportable under RIDDOR (p. 2) and ensuring that employers manage risk on the road as part of health and safety (p. 3). To this aim, the report suggested that HSE provide guidance to employers, to conduct a major awareness campaign, and to link more effectively police and HSE enforcement (p. 3). More than a decade afterwards, however, none of these recommendations has been implemented, and the additional resources the report called for have given way to a sharp reduction in resources.

What is particularly important here is that this is an illustration of the well-known adage "what gets measured gets done". In spite of limited (and shrinking) resources, there is solid evidence that the HSE and LAs in Britain have had very good results in keeping fatal occupational injuries at what is, seen from an international perspective, a very low rate. It seems, however, that they have devoted at best minimal attention (or in many cases probably none at all), and that this has had very real effects in terms of sustained rates of "at work" road accidents that are on par with countries that overall have far worse OSH performance than Britain. In spite of limited resources, which would mean that any investment in preventing road accidents may reduce resources available elsewhere, there is some reason to suspect that at least a moderate investment in awareness and prevention, and the inclusion of road safety issues when reviewing risk management plans, could have a net beneficial impact. Rather than concluding, with Tombs and Whyte, that the non-inclusion of these accidents is deliberate and deceitful, we would rather find that it is the result of poor initial regulatory design (RIDDOR), institutional inertia and the unavoidable effect of incentives – if HSE's performance assessment does *not* include road accidents, then it would not be logical for HSE to invest resources in preventing them (to the possible detriment of other areas where its performance is being assessed). The importance of adequately defining *performance indicators* and the *scope of the risks* that an agency is supposed to work on preventing is thus demonstrated.

"Fee For Intervention" and the reduction of proactive inspections

[559] Author's interview with experienced H&S inspectors in Britain.

We have seen above that the significant decrease in inspections that took place in the past 10 years did not seem to harm Britain's OSH performance in aggregate, but this does not means that some of the evolutions do not present some ground for concern. This is the case in particular with the recent drive to reduce all inspections further and *particularly* proactive one, and to introduce a scheme known as "Fee For Intervention" (FFI). This scheme was introduced in 2012 with the aim to "shift some of the cost of health and safety regulation from the public purse to businesses and organisations that break health and safety laws"[560]. The scheme's principle is that if inspectors, when visiting a business "see material breaches of the law", the duty holder "will have to pay a fee[561]". The introduction of FFI was based on the Government's policy paper *Good Health and Safety, Good for Everyone*[562]. This policy paper had three main components: clamping down on "rogue health and safety advisers", reviewing and simplifying regulations (and providing clear and simple guidance, in particular for SMEs) – and "shift the focus of health and safety activity away from businesses that do the right thing, and concentrate on higher risk areas and on dealing with serious breaches of health and safety regulation". FFI pertained to this last objective[563], and resulted from its further articulation in the following way: "this will mean a very substantial drop in the number of health and safety inspections carried out in the UK. We will also shift the cost burden of health and safety away from the taxpayer, and instead make those organisations that gain competitive advantage by flouting the rules pay for the costs of putting things right". While the objective itself may be uncontroversial (reduce burden on compliant businesses, focus on high risks and "repeat offenders"), the *ways* proposed to achieve it ("substantial drop" in inspections, and shifting of the cost burden) are neither obviously logically connected to the goal, nor necessary to achieve it – and quite possibly may in fact work contrary, at least in part, to this stated objective. To understand this better, we need to consider separately the questions of "cost burden" (FFI), and of the number of inspections.

"Making offenders pay" is one of these mottos that has the appeal of its simplicity. It reminds one of "make polluters pay", and superficially could be thought to rely on a similar economic logic – just as charges for pollution aim at ensuring negative externalities are priced in, charges for OSH offenses could do the same, and make compliance more frequent by tilting the economic incentives in its favour. However, as we have discussed at length in the second chapter, there is at best weak evidence that various forms of deterrence (i.e. tilting economic incentives) are really effective at promoting compliance, and the (unequal, relatively weak) effects of deterrence frequently conflict with opposite effects caused by deterrence strategies harming voluntary (ethics-based) compliance. It is thus far from clear that the introduction of FFI should be expected to have a positive effect on compliance (and, ultimately, safety levels). The level of the fees (GBP 124 per hour charged[564]) is in any case most likely too low to create any significant incentive for large businesses, while it may on the contrary end up being perceived as a major (and unjust) burden if applied to SMEs.

The purpose of FFI's introduction clearly appears to be reducing budget expenditures rather than "fairness" or "effectiveness". Even the report by the "Independent FFI Review Panel" (2014)[565], which was written clearly from a "positive" perspective[566], had as its first conclusion that in spite of "challenges associated with FFI" they could "see no viable alternative to it within the current environment for public expenditure" (p. 2). In other words, considering the Government's budget policy, and the seemingly low priority put on HSE budget by the

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[560] HSE, *Guidance on the application of Fee for Intervention (FFI)*, 2012 (latest revision 2014) – available at: www.hse.gov.uk/pubns/hse47.htm - p. 1

[561] *Ibid.,* p. 6

[562] 2011 – available at: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/66745/good-health-and-safety.pdf

[563] Listed in second position in the policy paper, p. 3

[564] See the FFI page on the HSE website: http://www.hse.gov.uk/fee-for-intervention/index.htm

[565] Available at: http://www.hse.gov.uk/fee-for-intervention/independent-ffi-review-panel-final-report-2014.pdf

[566] A comparison of the report text with the appendices shows that the drafters took the conclusions as far into positive territory as possible considering the (limited) evidence collected

Department for Work and Pensions (for which HSE's mandate is far from its core 'business' of managing and delivering benefits), FFI was the only remaining option to fill a major funding gap. If we look at the total fees collected so far under the FFI scheme[567] they amount (for October 2012 to May 2015) to a modest GBP 2 Million, to be compared with a total HSE expenditure in financial year 2014-2015 of over GBP 152 Million (HSE Annual Report 2014-2015). Thus, it seems that the cost/benefit value of the scheme may be very unfavourable, considering the significant time costs of administering it for staff[568], and the very real risk of unintended, negative consequences.

To sum up these, we will briefly quote the independent review report – its very euphemisms pointing out the many problems FFI is still expected to pose, and the authors being keen to note that they have not materialized *yet* (which, after only a year and half, is not surprising): "the consistency of approach adopted by HSE inspectors has minimised the detrimental effects", there is "a cost to pay in terms of the relationship between dutyholders and inspectors, particularly with respect to the advice that inspectors feel able to offer businesses, and that they are motivated to seek from inspectors. But the evidence we have considered suggests that this cost has not been as high as was predicted before the introduction of FFI" and finally that the review "could find no compelling evidence to suggest that HSE is using FFI as a 'cash cow', solely to generate revenue". In other words, the very solid and structured professionalism of HSE, and the strength of the existing relationships with duty holders, minimized the harm done by the scheme to HSE's ability to be effective at promoting compliance through guidance and advice, and the ability of its inspectors to keep their professional judgement unaffected by funding considerations. This does *not* mean that FFI, if extended long enough, would not seriously undermine HSE's professionalism – it only means that it has not done so yet. The limited amount of fees collected, making FFI income a marginal source overall, certainly contributed to this.

FFI is different from previously existing cost-recovery areas of HSE's work (e.g. the "major hazards" work under Control of major accident hazards regulations – COMAH), or from similar risk- or complexity-based fees levied e.g. by the Environment Agency of England and Wales or the Swedish Fire Inspection, because FFI is linked to the discovery of problems, and is thus a quasi-automatic "fine" in case of violations, and one that is proportional not to the seriousness of the issue, but to the time HSE will spend on the case. While there is a safeguard, namely that FFI should only be imposed when there is a "material breach[569]" of health and safety regulations, i.e. a "contravention of health and safety law" that is serious enough to require the inspector to issue a written notice. In a way, this is an automatic fine added to the improvement (or prohibition) notice, but one that is proportional only to time spent, and not to risk or harm (or to undue profit), thus being at odds with the overall HSE enforcement approach. Because it is specifically linked to time spent, it endangers the focus of HSE on advice, and the readiness of duty holders to ask for and receive such advice.

The risks posed by FFI may seem minor, considering the review's results and the HSE's well established practices and professional standards. Still, it is important to keep in mind that the effects of such perverse incentives as built in by the FFI scheme work over time, and can lead to quite dramatic results. We have already discussed above the terrible effects caused by a number of municipal police forces in the United States relying primarily on fines and penalties for funding, resulting in police actions that aimed not at securing citizens and maximizing compliance, but at maximizing recorded and penalized violations. We have observed closely a number of agencies that were allowed to keep a part of the fines they issued (or other mandatory payments they imposed, e.g. testing), and in every case it led to a clear worsening of practices, creating strong incentives

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[567] Available on the FFI page of the HSE website – direct link: http://www.hse.gov.uk/fee-for-intervention/ffi-invoice-oct12-may15.pdf
[568] See Appendix 1 to the Review Panel Report, available at: http://www.hse.gov.uk/fee-for-intervention/ffi-review-appendix-1.pdf
[569] See HSE, *Guidance on the application of Fee for Intervention (FFI)*, 2012 (latest revision 2014) – available at: www.hse.gov.uk/pubns/hse47.htm - p. 8

to maximize the number of violations found[570]. The fact that the Government imposed at the same time a target to reduce the overall number of inspections means that FFI cannot (in such a context) result in the HSE trying to maximize the number of inspections, but it distorts the relation with duty holders, and the incentives for inspectors, with very few benefits (even financial ones being marginal).

The other element of the new strategy that was meant to "reduce burden" on compliant businesses was the reduction in proactive inspections. This is one more decision which has a very weak link with the stated goal, and only can appear logical if considered very superficially. It is, in fact, very problematic. First, as we have discussed extensively above, *proactive* inspections are in fact widely considered to be the more effective, more efficient kind, as opposed to *reactive* ones which (as Tilindyte 2012 noted) have for them to be the "low-cost" option (since they require no targeting and no intelligence gathering and rely on accidents, complaints or findings of previous visits). A proper risk-based approach can, by definition, *not* be primarily based on reactive inspections, as we have noted. In fact, HSE constantly conducted far more proactive inspections than reactive ones over all the years we were able to consider, and this was a fundamental part of its risk-based approach. While the ratio remains clearly in favour of proactive inspections in HSE (which are 3 to 4 times as numerous as reactive ones in the latest available annual report for 2014-2015), this Government priority on reducing proactive inspections has led to their collapse in LAs inspections (but as we noted above, the "other" category ballooned, suggesting that many visits were just "re-labelled"). Reactive inspections may be "justified" in a "punitive" vision of inspections, but they are simply not the most effective from a risk-based prevention perspective[571].

A valid question would be whether reducing OSH inspections in Britain, at this stage, makes any sense – from a burden perspective, and from an effectiveness and efficiency one. We have seen above that OSH inspections in Britain are several times more rare than in Germany, and also far below the levels found in France. We have also noted that this may be reaching (or be close to reaching) the point where too rare visits make it difficult to maintain a robust risk-based targeting system (though there may be solutions in sharing data with other regulators). How, then, do health and safety inspections compare to *other types of inspections* within Britain, when they are thus singled out for reduction? In order to do so, we looked at the data compiled as part of the "Focus on Enforcement" initiative of the Department for Business Innovation and Skills[572] - with the latest available year being 2012-2013. Four agencies[573] stand out as making up the bulk of "business inspections": the Environment Agency (EA), the HSE, the Food Standards Agency (FSA) and the Animal Health and Veterinary Laboratory Agency (AHVLA). Unfortunately, whereas the FSA reported the inspections made by local authorities on its behalf, the EA did not (HSE also did not, but we have this data from their website, and we have already presented it. Thus, we can only say that the EA inspections are slightly less frequent than the HSE's (around 25,000 per year), but the EA uses another regulatory instrument far more often (permits, with around 500,000 permit holders). It can be expected that LAs environment inspections add a significant tally to

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[570] This was true of course in countries and agencies with major corruption problems (e.g. Ukraine's Tax Service and State Committee for Consumer Protection and Standardization in 2006-2009, Tajikistan's Tax Inspectorate in 2004-2007 etc.) but also in agencies with a real commitment to reform and making significant efforts to reduce corruption and increase effectiveness (e.g. Mongolia's GASI in 2014-2015). In all cases, funding incentives meant that inspectors tended to inspect more frequently than needed from a risk perspective, and to find as many violations as possible (and impose fines in every case).

[571] Again for comparison, the General Agency for Specialized Inspections (GASI) in Mongolia has been making progress in introducing risk-based targeting, but its inspectors keep being distracted from it by the practice of following up on every single complaint through an inspection, resulting in over 60% of inspections being reactive. There is no doubt that it results in major inefficiencies. The HSE of course has solid criteria to filter out complaints, and only conducts reactive inspections in cases worthy of investigation, but the general idea that proactive inspections should be reduced by executive fiat is clearly *not* in line with risk-based principles.

[572] See Focus on Enforcement website at: http://discuss.bis.gov.uk/focusonenforcement/ and the link to the data for 2012-2013 at: http://discuss.bis.gov.uk/focusonenforcement/regulator-data-201213/

[573] The initiative did not cover Her Majesty's Revenue and Customs (HMRC), which of course conducts a significant number of inspections.

this number. But OSH inspections are dwarfed by the number of food safety visits: more than 540,000 for the FSA, and over 100,000 for AHVLA. Most of these visits were in fact conducted by third-parties and reported by the national regulator (for the FSA, these third-parties are LAs). Thus, in 2012-2013, OSH inspections made up less than 140,000, and broadly "food-safety related" ones over 640,000. In this perspective, it is not clear that targeting a reduction of OSH inspections made sense even from a pure burden-reduction angle.

It may be that food safety issues warrant a higher level of control from a risk perspective (this would require detailed research on the prevalence of OSH and food risks in Britain, which is beyond our scope), but it may also be that food safety inspection numbers are "shielded" from reduction by a combination of popular perceptions of risk (food safety being usually high among public concerns), EU regulations, and the fact that nearly all inspections are done by LAs. By contrast, it appears that "health and safety" gets targeted for reductions because of a combination of mistaken beliefs ("health and safety myths"), lack of strong interest in the topic from the HSE's parent department (Work and Pensions), and possibly the vagueness of the term ("health and safety" is so broad that many people may attribute to HSE regulations and controls that are completely unrelated to its activities). Whichever the causes, in any case, it seems reducing what is already clearly a very "lean" inspection number is unlikely to have positive results. As we have discussed in the second chapter, there is some evidence suggesting that there may be a lower "threshold" under which the perceived probability of detection is so low that violations *do* increase (breakdown in deterrence). While there is no evidence that this has been reached yet, this pitfall should be taken in consideration for the future.

v. Conclusion – Risk-based and "smart" inspections in Britain

From the above, we can conclude with some confidence that OSH inspections in Britain are indeed a valid example of risk-based, risk-proportionate inspections (both in terms of planning and of enforcement decisions). Indeed, the ways in which the HSE in particular emphasizes guidance and compliance support appears to make this a real example of "smart inspections" in the full sense of the word: risk-focused in inspections, risk-proportionate, transparent, aiming at promoting compliance rather than maximizing "outputs" such as inspection visits, violations identified etc. The comparison of both outputs (inspection visits) and outcomes (rate of fatal occupational injuries) with Germany strongly suggests that Britain's OSH systems is considerably more efficient (at least similar outcomes, with far less inspections) – and even that it was, at least until a couple of years ago, apparently more effective (significantly better outcomes).

While attributing these outcomes fully to the inspections and enforcement system is impossible, and we cannot thus exclude that Britain's better performance is largely or partly due to other factors (still to be specified), there is reason to think that at least some significant part of this higher efficiency is due to "smarter inspections" – and, before that, to a much earlier regulatory focus on *risk*. As we have seen, the emphasis on risk assessment and risk management in OSH dates back, for Britain, at least to the 1974 Act, and translated into very different practices not only for inspectors, but for businesses. A similar evolution, as yet unfinished, did not start in Germany before the 1996 Law translating the 1989 EC directive into German legislation.

At the same time, we have seen that this does not mean that Britain's OSH inspections regime is "optimal" from a risk and "smartness" perspective. First, because of some limitations in the quality and interconnection of data used for targeting. Second, because some of the evolutions in recent years (e.g. FFI) are causes for concern, and may be running *against* a sound risk-based approach rather than being (as they purport to be) its continuation. Third, of course, because perfection in such matters is never possible, and there will inevitably be areas where practices could be improved – the non-inclusion of road accidents "at work" being one of the most obvious areas for improvement.

To put these findings in the perspective of the broader inspections and enforcement system in Britain, it is worth looking briefly at some interesting practices and observations in another regulatory sphere, food safety, which we have selected along with OSH as one of our areas of focus – and also at recent changes that affect inspections and enforcement in all regulatory areas.

"Safer Food, Better Business" and Food Hygiene Ratings

We have noted briefly above that food-related inspections in Britain are far more numerous than OSH inspections. It is difficult, without considerable further research, to draw any conclusion from this in terms of whether this means that risks are significantly higher in food, and/or that "high-risk" premises are more numerous – or whether it reflects a lower level of focus and an approach that is more "inspections heavy". There may be elements of both, considering the large number of food handling premises where risks are not negligible (hospitality and catering), and at the same time the existence of EU legislation that mandates a significant level of inspections (e.g. in slaughterhouses). Rather, we will consider two important examples of "smart approaches" – the "Safer Food, Better Business" toolkit, and the use of Food Hygiene Ratings.

"Safer Food, Better Business"

The 2009 Anderson review stated that Government guidance to businesses should be clear, accessible and consistent. While the review looked at health and safety and employment law guidance, and we have seen that the HSE has made significant efforts in this direction, one of the most interesting examples of guidance is in the food safety field. The origins of the "Safer Food, Better Business" (SFBB) toolkit[574] are to be found in practical experience, and feedback from inspectors on what they found. These resulted in the development of a toolkit that essentially "translates" all essential requirements for catering businesses (including all the EU Hygiene Package provisions, and thus including – crucially – the "HACCP" approach) in a way that is readily understandable by cooks and other employees. The SFBB guide (which exists as a printed pack, PDF or online tool) makes all guidance visual, explains the logic of requirements, and structures them in categories that correspond to the fundamental dimensions of food safety in the kitchen (cross-contamination, cleaning, chilling, cooking, management). It includes a diary (refillable) to keep all mandatory records.

The approach taken in SFBB can be traced back to the finding that many catering businesses had fundamental problems with compliance because of ignorance or misunderstanding of safety requirements, and that this required an approach based on guidance and compliance promotion, including outreach to the many professionals working in the UK but speaking a foreign language. One of the experiments leading to the development of SFBB was made in Chinatown by the Westminster City authorities[575]. After finding that non-compliances in restaurants were not only frequent, but not improving after repeated inspections, the Westminster regulatory team attempted to understand why. They found out that chefs mostly did not really understand English well, were not aware of local safety regulations, changed repeatedly, and that an inspection with negative findings resulted in a loss of face that made compliance, if anything, even less likely. The response was to emphasize prior training, and to use the chefs' language as much as possible. In consequence, the SFBB toolkit exists in 16 languages, those most widespread among chefs working in the UK.

The development and launch of SFBB came in response to the entry into force of the EU "Hygiene Package" and of Government concerns that compliance could prove very difficult for SMEs and in particular small catering businesses – and that this difficulty could come more from difficulties in understanding the

[574] See the portal: http://www.food.gov.uk/business-industry/caterers/sfbb
[575] Short case study: http://www.cieh.org/library/Knowledge/Food_safety_and_hygiene/Case_studies/Westminster%20CHIP.pdf

requirements, than from material challenges[576]. Both national and local evaluations showed strongly positive results after the first year of the scheme already. First, "perceptions of external assistance were very positive. The FSA information packs were very well received with the vast majority wanting to see these continue in future. There were equally positive about local authority interventions, particularly one to one coaching and training courses" (Jigsaw Research 2007, p. 4). The implementation of Food Safety Management appears to have strongly benefited from SFBB. From an evaluation's survey of food business operators, "based on their own perception, 93% of businesses claimed to have FSM in place, and of those, around three-quarters claimed it was fully implemented" (*ibid.,* p.3). Direct evidence from local authorities' inspections provided somewhat lower numbers (unsurprisingly), but still clear confirmation of positive effects: "Compliance with the food safety management requirement for all food businesses has improved from 30% in 2002 to 45% in March 2006 to 48% in March 2007. These figures are based on local authority inspections. Many businesses that have been helped using SFBB have yet to be re-inspected (as the average inspection frequency of the target businesses is once every 18 months). The 48% figure for compliance in March 2007 therefore under-reports the effect of the programme moving businesses towards full compliance. In addition, many businesses are close to compliance and actively working toward it. Evidence from the local authority grant projects shows that where support has been provided, 66% of businesses are broadly compliant shortly after the intervention in the business" (FSA 2007, p. 3).

Assessing and evaluating more precisely the degree to which SFBB has improved (or not) food safety levels in Britain compared to other EU countries, and the extent to which it has helped food businesses (and particularly small ones) make the transition to the new EU legislation, would both require considerable efforts, in particular given the vast number of other factors affecting both indicators. What is important is the strong emphasis put by the British authorities[577] on this approach, and the scarcity of similar examples elsewhere. The only similar guidelines we could find in the EU were developed in the region of Lombardy (Italy) and published in 2014[578]. This Italian document (*Manuale di buone pratiche di igiene per le microimprese alimentari* – "Good Practice Handbook for Hygiene in Food Micro-Businesses") is very interesting in that it covers also food processing, and is adapted to the specifics of Italian food, but it is somewhat less "granular" than the SFBB toolkit and does not as conveniently break down the control steps and points. Still, it remains a very interesting document, that is unfortunately sub-optimally publicized (it is available on a variety of regional and

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[576] See Hogg (2007): "In response to the new Food Hygiene regulations (EC Regulation 852/2004 on the hygiene of foodstuffs) for the UK, which came into effect on 01 January 2006, the Food Standards Agency (FSA) introduced a new food safety management system based on the principles of HACCP (hazard analysis critical control point) called Safer Food Better Business (SFBB). This system is much simpler than the traditional HACCP methodology in that it cuts out all of the jargon and can be tailored to meet each individual food business needs throughout the country. It is also a very simple system for food businesses to put in place." (p. 4) – available at: http://www.torridge.gov.uk/CHttpHandler.ashx?id=265&p=0 - and from the first official FSA evaluation of the scheme: "The aim of the programme is to help micro1 and small catering and retail businesses comply with the 2006 food hygiene regulations that require businesses to put in place effective food safety management procedures. There are over 400,000 micro food premises in England. Research has shown these businesses previously found food safety management difficult to implement and that improving their standards would have a positive impact on public health by reducing food poisoning. Given the numbers of premises, the scale of activity represents a significant challenge for the Agency and its partners." (FSA 2007, p. 2 – available at: http://tna.europarchive.org/20120419000433/http://www.food.gov.uk/multimedia/pdfs/board/fsa071204.pdf)

[577] Note: the Food Standards Agency that used to work in all of Britain has now been replaced by a Food Standards Agency for England and Wales, and Food Standards Scotland– because Scotland disagreed with the narrowing down of the FSA mandate by the Coalition Government. Food Standards Scotland has the same emphasis on guidance and risk-based approaches and to all intent and purposes this institutional change does not affect the points we discuss here. Among existing nuances in approach, Scotland has had since 2006 a guidance for implementation of HACCP approaches that is somewhat different from SFBB, though similar in concept, called "CookSafe" – see http://www.foodstandards.gov.scot/cooksafe

[578] The publication date is estimated from the date of publication of the different webpages referencing the guidelines, as well as the dates of local authorities' decisions given for context – see e.g. The page on the site of the Azienda Sanitaria Locale (Monza and Brianza): shttp://www.aslmonzabrianza.it/ita/Default.aspx?SEZ=1&PAG=135&NOT=979. The toolkit can be downloaded here: http://www.aslmonzabrianza.it/user/download.aspx?FILE=OBJ02262.PDF&TIPO=FLE&NOME=manuale_buone_pratiche_microimprese_alimentari_RL or here: http://www.asl.lecco.it/intranet/docs_file/6_6582%20allegato.pdf

local websites in Lombardy, but not on national websites, and it is not featured prominently, contrary to SFBB, meaning that many businesses are probably unaware of it). We were not able to ascertain if this Italian handbook was inspired by SFBB, although this seems highly likely. The SFBB toolkit has proven to be inspiring for national authorities in a number of countries where it was presenting, even though adaptation has been rare so far – beyond the Italian example, one more case is Mongolia, where the World Bank Group has supported the translation and adaptation of SFBB into Mongolian, and its distribution to inspectors and local businesses[579].

Food Hygiene Ratings

Assigning ratings to food businesses based on inspection findings in terms of hygiene is not a new idea, and it does not appear to have originated in Britain. The first example we are aware of, and which is documented in scholarship, is from Los Angeles County in the United States, and was introduced in 1998. An evaluation showed substantial beneficial effects on compliance of this scheme, which also involved a risk-based targeting approach (Fielding *et al.* 2001). Overall, the study found that "the development of risk categories has resulted in better targeting of high-risk establishments through more frequent inspections" and that "Retail food establishments behave as if achieving a high letter grade is sufficiently important to comply more strictly with food safety practices. Of particular note is the almost 75% decrease in establishments scoring below 70%, suggesting the impact not only of greater public access to inspection scores, but also of the revised program's more stringent penalty for establishments scoring below 70 twice in a 12-month period. The decrease in closure rates (…) also suggests improved adherence to public health standards for food handling" (*ibid.,* p. 242). Of particular importance for us here is, beyond the vindication of risk-based targeting and the note on the importance of deterrence for repeat offenders, the effectiveness of publicly available ratings at increasing compliance. Similar schemes were later introduced in other locations, e.g. in Denmark (from 2001), which has long been one of the best known such schemes[580]. Similar schemes have been introduced or discussed in countries as diverse as Nepal and China, Germany and France, Kyrgyzstan[581] etc. Thus, Britain's use of Food Hygiene Ratings is neither an isolated nor a "pioneering" case – but it deserves consideration in how it fits with Britain's approach to food safety inspections and enforcement more broadly.

Food hygiene ratings were introduced much later in Britain than in Denmark: "the FHRS[582] was launched in late 2010 and local authority uptake following that progressed rapidly such that the scheme is now well bedded in. All but one authority (Rutland County Council) in the three countries[583] is now operating the scheme and information is available on the FSA website on over 440,000 food businesses. The FHIS[584] is now operating across Scotland. The FHRS was put on a statutory footing in Wales in November 2013 to provide for mandatory display of FHRS ratings at food premises. The transition from the voluntary scheme to the statutory scheme is due to be complete in May this year. Northern Ireland is set to follow suit with draft legislation introducing mandatory display currently being considered by the Northern Ireland Assembly, and the FSA strategy for 2015 to 2020 highlights that pressing the case to extend this to England is a priority"[585]. As this report indicates, the display of food hygiene ratings is still not mandatory in England, though all businesses do get a rating after

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[579] Author's direct interviews with World Bank and Mongolian government officials involved.
[580] See overview of the system here: http://www.findsmiley.dk/en-US/Forside.htm and here http://en.fvm.dk/focus-on/smiley-food-inspection/.
[581] Author's direct observations (press reports, pilot schemes) in France, World Bank colleagues internal reports on Germany and China, author's direct involvement in pilot schemes in Nepal and Kyrgyzstan.
[582] Food Hygiene Ratings Scheme
[583] England, Northern Ireland and Wales.
[584] Food Hygiene Information Scheme
[585] Source: Food Standards Agency Board Meeting – 25 March 2015 (FSA 15/03/06), *Food Hygiene Rating Scheme – Update And Next Steps,* Report by Jason Feeney, Chief Operating Officer – available at: http://www.food.gov.uk/sites/default/files/fsa150306.pdf

each inspection, and consumers can freely access these on line. Furthermore, non-display of the rating is likely to indicate that the rating is low, and the FSA website logically advises caution to consumers in such cases.

There is an important difference between the FHRS (England, Wales, Northern Ireland) and the FHIS (Scotland), which is the number of possible different ratings. The FHRS has zero to five stars[586], whereas the FHIS only has "pass" or "improvement required"[587] (by comparison, the Danish scheme has four types of smileys, plus the "elite smiley" for those repeatedly obtaining a clean sheet). The FSA scheme thus provides more nuanced and detailed information (at the risk of some potential for confusion on the exact meaning of such nuances for consumers), whereas the FSS goes for a very simple system. In any case, what is noteworthy is that *ratings* are distinct from *enforcement* decisions, and introduce an additional tool for compliance promotion, with more flexibility than enforcement measures.

Indeed, as the FSA's "Frequently Asked Questions" on FHRS make clear, even a business with a low rating is not necessarily always shut down (or at least not immediately) – low ratings are not equivalent *ipso facto* to formal enforcement measures, but rather are a "stronger form" of informal enforcement, using the powerful incentive (market effect) created by the ratings' publicity. Quoting the FSA website: "Businesses given ratings of '0' or '1' must make urgent or major improvements to hygiene standards. The local authority food safety officer will use a number of enforcement tools as well as giving advice and guidance to make sure these improvements are made. (…) The Food Hygiene Rating Scheme means that people can choose instead to eat out or buy food at places with higher ratings and businesses with low ratings are in danger of losing customers and so will be encouraged to improve standards more quickly and to maintain these in the future. If the officer finds that a business's hygiene standards are very poor and there is an imminent risk to health – this means food is not safe to eat – the officer must take action to make sure that consumers are protected. This could mean prohibiting part of an operation or closing the business down[588]." This additional, intermediate form of "semi-formal enforcement" can be appropriate in a number of situations where the inspector thinks shutting down operations is inadequate (negative social impact, loss of revenue that will make improvements even more difficult to achieve etc.). The ratings are a tool whereby the administrative action (inspections and enforcement) uses market forces to ensure increases in compliance. They are interesting in that they offer high flexibility (because formal enforcement is not automatic, there is reversibility in the decision if things improve), and businesses can ask for a re-visit if they have made the required improvement. By offering transparency to consumers, less drastic measures than formal enforcement (and a chance for improvement) to businesses, food hygiene ratings thus are an instrument that seems to be able to combine a real "deterrence" effect (through reputational risk) and a high level of procedural justice.

The March 2015 report to the FSA's board includes the summary of an evaluation (conducted over 2011-2014) which shows that (i) "consumer awareness and reported use of the FHRS have steadily increased to 36% and 20% respectively, and 76% of people recognise the distinctive green and black branding", (ii) "there was a significant increase in 'broad compliance' (ratings of 3 to 5) in the first year, and a significant increase in 'full compliance' (rating of 5) in the second year in local authority areas after FHRS was introduced, compared with areas where the scheme was not yet operating" and "there was also a significant decrease in the proportion of very poorly performing businesses in the first two years after launch"[589]. Thus validating the findings of the 2001 survey of the Los Angeles County case, this FSA evaluation shows (including by comparing "treatment"

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[586] See FSA website at: http://www.food.gov.uk/multimedia/hygiene-rating-schemes/ratings-find-out-more-en/fhrs

[587] See FSS website at: http://www.foodstandards.gov.scot/food-safety-standards/food-safety-hygiene/food-hygiene-information-scheme

[588] "Why are businesses with poor ratings not closed?" in FAQ at: http://www.food.gov.uk/multimedia/hygiene-rating-schemes/ratings-find-out-more-en/fhrs

[589] Source: Food Standards Agency Board Meeting – 25 March 2015 (FSA 15/03/06), *Food Hygiene Rating Scheme – Update And Next Steps,* Report by Jason Feeney, Chief Operating Officer – available at: http://www.food.gov.uk/sites/default/files/fsa150306.pdf - p. 3

and "control" groups given phased introduction of the scheme) that public food hygiene ratings are (gradually at least) used by consumers, and have a positive impact on compliance.

Of course, it is important to remember that such food hygiene rating schemes are only useful if the professionalism and ethics of the inspectors assigning the ratings is such that (a) consumers will have trust in the ratings and pay attention to them (something that, of course, also requires adequate efforts to "advertise" the rating scheme) and (b) they will not abuse the power given by these ratings (since bad ratings can be highly damaging to businesses) for corrupt purposes. Such potential pitfalls are not limited to low- and middle-income countries. The 2001 evaluation of the Los Angeles County case pointed out that "Strong economic incentives to achieve higher grades increases the risk of bribery.(…) One confirmed episode of an inspector soliciting a bribe, captured in an investigative report on a local news station in November 1998, prompted DHS to review and revise measures in place to prevent illegal and unauthorized activities by inspectors" (Fielding *et al.* 2001, p. 244). Credibility and visibility can also be real issues. Some initial pilot schemes in France had little success, and it remains to be seen whether the new initiative to publicize the inspection results (as ratings in four letters) from July 2015 (to be extended country-wide in 2016) will be more successful[590]. Thus, food hygiene rating schemes are not a solution that can be implemented independently from a broader risk-based approach, and require to be successful a strong basis of professionalism among inspectors.

The *Primary Authority* scheme

The United Kingdom (and Britain, within it, in particular) present the specific situation of regulations that are primarily national (or, in some cases, European) with inspections and enforcement that are primarily conducted by officers hired by local self-governing bodies. In a 2009 report, the then-Local Better Regulation Office (LBRO – now BRDO) counted 433 councils administering regulatory enforcement across the UK (out of which 407 in Britain) – to which should be added 58 Fire and Rescue Authorities (57 in Britain) and 151 Port Health Authorities (141 in Britain)[591]. Reviews for a number of years, such as those conducted by Hampton or Löfstedt, have been pointing out the issue of consistency as a key area for improvement. The Regulatory Enforcement and Sanctions Act (2008), apart from establishing the possibility of introducing new types of administrative sanctions (as recommended by the Macrory review) also created the "Primary Authority" statutory scheme, to be administered by LBRO (and, from 2012, by BRDO as its successor body). Though we will only discuss it in a very cursory way, Primary Authority is interesting because it seeks to address several issues: consistency of enforcement between different localities, transparency and clarity of regulations, certainty of advice.

Primary Authority can apply to "a single business that is regulated by multiple local authorities, or to a business that is part of a group of businesses that are collectively regulated by multiple local authorities, where these businesses share an approach to compliance" that "might be demonstrated, for example, through membership of a trade association that provides regulatory guidance, or through a franchisee relationship with a business that specifies compliance controls"[592]. The business(es) enter(s) a partnership with a single local authority ('primary authority') which has to be approved by BRDO, which will validate it only if it has assessed this particular authority as adequately competent in the regulatory area(s) under consideration. The role of the primary authority is then to be a "key point of contact" in relation to the business' interactions with

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[590] See newspaper reports: http://next.liberation.fr/food/2015/07/01/quel-niveau-d-hygiene-dans-les-restaurants-pres-de-chez-vous_1340907 and http://next.liberation.fr/food/2015/07/01/y-a-t-il-vraiment-un-probleme-d-hygiene-dans-les-restaurants-asiatiques_1313183 - official news release and data here: http://agriculture.gouv.fr/experimentation-de-la-mise-en-transparence-des-controles-officiels-en-restauration-commerciale-paris

[591] LBRO 2009, pp. 25-27

[592] BRDO, *Primary Authority Statutory Guidance,* September 2013 – p. 3

local authorities that regulate it and to coordinate the regulatory enforcement efforts in relation to this business[593]. It does this e.g. by providing "advice and guidance on compliance to the business (known as 'Primary Authority Advice') in areas of regulation covered by the partnership, on which the business can rely" and also by providing advice and guidance to *other local authorities* in regard to this business. It may "publish an inspection plan" to guide and co-ordinate their enforcement activities. Crucially, the advice given by the primary authority to the business can be opposed to another local authority: "where the business faces potential enforcement action by an enforcing authority, the primary authority will assess whether the proposed action is inconsistent with any Primary Authority Advice given. If the action is inconsistent, the primary authority is able to direct the enforcing authority not to take the action". If the primary authority has published an inspection plan, other authorities have to follow it. They also must "notify the primary authority of enforcement action in relation to the business" and "in most circumstances this notification is required before the action can be taken" (except for emergencies)[594]. In other words, the primary authority for a business can give it in-depth advice that, if it then follows, it can be assured will be found to be valid by other authorities – and it establishes a significant degree of consistency and coordination in inspection plans and enforcement responses. Because of the significant amount of work involved for the primary authority, its work within such a partnership is done on a cost-recovery basis.

The benefits for businesses are clear: they get assurance that, if they behave in a certain way, this will be found to be in compliance with the law – and that the way they are treated will be as uniform as possible across the country. There are significant benefits expected for citizens as well (be they consumers, neighbours, workers etc.): if key regulatory requirements are "internalized" in the internal directives and procedures of businesses, they are far more likely to be complied with. Ensuring that advice and guidance are given by the most competent local authorities in a given field is also expected to improve the overall regulatory outcomes. And, of course, higher certainty of regulatory interpretation should lead to some uptick in investment and growth – and lower regulatory burden to (marginally) lower prices.

Primary Authority has been the subject of several evaluations and studies – a first evaluation in 2009-2011 (conducted by RAND Europe), a second in 2013 by acl Consulting, and an evaluation of the impact of training sessions on primary authority for inspectors, by Dunlop, Kamkhaji and Radaelli in 2013-2015. As the scheme is not universally applied (contrary to, say, the food hygiene ratings) and uptake is voluntary, and since it is in many ways a very significant change, it is not surprising that evaluation results were not one-sided. The 2011 review found that positive effects on consistency were not reported by more than 22% of businesses, but many noted that it was "too early", and for most participants it had not been a major concern or primary reason to enter the scheme anyway. The evaluation noted differences between a more "thorough" primary authority relationship (with an inspection plan) and "lighter" ones: when an inspection plan was present, consistency was more strongly increased, and satisfaction levels were higher (in any case ¾ of businesses were satisfied). The study was not designed to really capture compliance levels, but noted that a significant share of local authorities had changed the way they dealt with businesses in case of problems, far more often going to the head office rather than branches (pp. 43-47). The 2013 evaluation found again ¾ of businesses satisfied, but only 45% of local authorities considering the overall impact positive (versus 30% negative and 25% neutral). Businesses generally noted a reduction in time spent on regulatory issues, better relationships with regulators, more consistency in advice and guidance. On the compliance side, it was found to reduce "instances where action is necessary in respect of non-compliance by promoting informal discussions between primary authorities and enforcing authorities" – but the authors noted that most participants in the scheme were already businesses with a "positive approach" and "positive interest" in compliance, making it difficult

[593] *Ibid.*
[594] *Ibid.,* pp. 3-4

to see a clear impact on that front (pp. 5-7). As for the study by Dunlop *et al.* (2015), it did not look at the scheme itself, but at the trainings provided by BRDO to inspectors, and found that they had a significant impact on the extent to which inspectors understood the logic and the relationships with the scheme, and thus their ability to make the most of it (p. 3). Because both evaluations (2011 and 2013) noted that there remained many implementation and understanding issues, this finding on the effectiveness of training is important.

Overall, Primary Authority is a very important innovation conceptually, and there is a large amount of anecdotal evidence of its benefits[595], but there is not yet a set of very strong evaluation findings on its effects. In any case, from our perspective, it demonstrates the importance of considering inspections and enforcement issues comprehensively, not only in terms of targeting or numbers, but of methods, consistency, relations with duty holders, guidance etc. Primary Authority is not yet old enough (and, maybe, not yet widespread enough in use) to make strong conclusions, but does appear to be an approach that has the potential to bring improvements in terms of compliance, interactions between inspectors and enterprises, and overall procedural justice.

Summary conclusion

As we can see from the above OSH case study, and from the snippets presented from inspections and enforcement practices in other areas, Britain (and, more broadly, the UK) can be taken as a valid example of risk-based approaches and, at least in some areas, of "smarter approaches". This does not mean, of course, that inspection practices in OSH or other areas in Britain are "perfectly risk-based" (if such a thing were possible). There are areas where significant improvement from this perspective would clearly be possible, for instance data quality in OSH, or the "twin peaks" created by the distribution of premises between HSE and LAs. In food safety, SFBB and food hygiene ratings seem to be very promising initiatives, but their impact remains to be more fully evaluated, as should be the frequency of inspections. Primary Authority is innovative and seems to have the potential to solve major contradictions and issues in inspections and enforcement, but is still in its growth phase. In addition, institutions, methods and practices are all vulnerable to changes driven by short-term budgetary considerations more than by sound evidence, and the introduction of FFI and sharp reduction of proactive inspections in the OSH area are causes for serious concern, and seem likely to lead to a worsening rather than an improvement of the efficiency and effectiveness of the system.

Still, when considering the overall performance of Britain's OSH system compared to Germany's, the magnitude of the efficiency gap is such that it strongly suggests that Britain's risk-based approach seems to have real benefits. With several times less frequent inspections, Britain has consistently performed at least as well as (and, until a few years ago, significantly better than) Germany. This is certainly not a result that is due entirely to different inspection practices (and, for instance, the far earlier emphasis on risk-management *within enterprises* in Britain probably also played a role), it also seems unlikely that Britain's far more risk-focused approach is not one of the reasons for this difference in performance. Investigating whether such greater efficiency and positive results can be seen in other areas (e.g. food safety) would thus be a very valid area of future research.

b. Post-Soviet and Post-Communist Experiences

[595] See BRDO (2014), *Primary Authority: A Guide for Officials*, available at: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/348664/14-1058-pa-guide-for-officials.pdf

The "post-Soviet" or "former Soviet" world (or, to use a convenient moniker, the Former Soviet Union or FSU[596]) continues, in spite of the more than 20 years elapsed since the USSR's collapse, and of the obvious deep differences between its constituents, to share a number of common characteristics, particularly in the structures and workings of the public administration. This is true also, albeit to a lesser and more unequal extent, for countries that were never part of the Soviet Union, but were under its direct influence (Comecon members)[597]. Decades of shared institutions, legal systems, practices and experience (longer for some, shorter for others) resulted in regulatory systems that were, at least at the onset, very close. Of course, various backgrounds in terms of earlier history and social structure, economy, culture and geography meant there were major differences between all these countries – but also considerable similarities, among which was precisely the way economic activity was organized (and, at it gradually became private, regulated).

These countries' shared history and structures did not end all of a sudden in 1989-1991, but rather in many cases have effects that can still be easily observed. Nor were privatization (with the many challenges it represented, and the many ways in which it went socially, economically and politically "wrong") or "shock therapy" (where it was attempted) enough to comprehensively transform the relations between state administration and economic operators[598]. In fact, at the end of the 1990s, business regulation, and as part of it inspections and enforcement, were a significant issue in practically all FSU countries, and most if not all other former Communist countries (including some outside of the group we are considering, e.g. former Yugoslav republics). As a result, reforming business regulations and specifically, in a number of cases, business inspections and enforcement, started to become an important priority – both for national governments, international organizations and, in the case of candidate countries, for the EU.

Problems with regulatory systems stemmed from a number of aspects of the Communist-era inheritance. A hostile attitude to private ownership and private businesses fostered confrontational approaches geared at punishing violations that were expected to be numerous, with businesses seen as criminal by essence. The way the law was for decades systematically made to mean whatever was in favour of the authorities left a very weak rule of law and highly problematic ethics in the state administration (and outside of it too), and courts that tended to rule in favour of the most powerful (and, in particular, in favour of the state). Institutions left over from the previous period were strongly specialized, heavily staffed, with a strong technical bend, and a risk-averse approach, resulting in a tendency to try and achieve total control over each and every risk, and also in each risk dimension being controlled repeatedly from several different angles. Of course, this common background was nuanced by country specifics. The Baltic States, for instance, drew on a more liberal tradition, and on the legislative traditions from the inter-war period. Russia, by contrast, had a dreaded figure of 'inspector' long before Soviet times, as exemplified in Gogol's *Inspector General* (in Russian "*Revizor*"). In most of these countries, however, and definitely in all former Soviet ones, the term "inspection" (in Russian

[596] This includes the following fifteen internationally recognized independent countries: Armenia, Azerbaijan, Belarus, Estonia, Georgia, Kazakhstan, Kyrgyzstan, Latvia, Lithuania, Moldova, Russia, Tajikistan, Turkmenistan, Ukraine, Uzbekistan

[597] This includes the following: Bulgaria, Czech Republic, Hungary, Mongolia, Poland, Romania, Slovakia. Former Yugoslav Republics had a completely different legal and administrative system, and so had Albania (though the latter was far more "statist" than the former). Vietnam could also be considered, as well as Cuba, but they were considerably more "remote" from the Soviet Union, and present major specificities. We will thus limit ourselves to the seven listed above. East Germany was incorporated into the Federal Republic of Germany and took over "wholesale" its regulatory structures. Some differences may linger in practices of various *Bundesländer* but studying them is beyond the scope of this research.

[598] See e.g. EBRD *Transition Report* for 1999 and 2000. These reports, however, focused on a very limited set of "liberalisation" indicators (e.g. price and quantitative import/export controls) and, while they occasionally mentioned broader "market access" issues, did not really investigate them. In the first decade of "transition", the importance of technical, safety etc. regulations (and their enforcement) was not always perceived, with more "fundamental" aspects of a market economy being still in the forefront.

"*proverka*") and its derivatives were well known by all, and elicited prompt responses from any interviewed citizens, business operator or not[599].

While European integration ensured that, to a large extent, underlying regulations were transformed in candidate countries, it left regulatory procedures largely untouched. Indeed, as we will outline in the next section, the level of harmonization of "regulatory delivery" is overall relatively weak in the EU, even in areas where regulations themselves are partly or strongly harmonized, with the partial exception of food safety and, of market surveillance of non-food products. This means that, in many areas, inspection structures and methods were left largely untouched by the EU accession process (while corruption in "street level bureaucracy" did overall decrease as a result of across-the-board institutional reforms, but was clearly not eliminated). While the stronger level of harmonization in food safety meant that inspection structures and practices did change in this area, this did not necessarily lead to changes in other instruments, e.g. licenses and permits, which were able to remain "on top" of EU requirements. Harmonization in conformity assessment for the "New Approach" directives in regard to non-food products was likewise strong, but did not prevent the persistence of pre-reform inspection practices, additional licensing requirements etc. In short, while EU accession did result in significant changes (particularly if comparing new EU Member States with other former Soviet countries in Eastern Europe, e.g. Ukraine), it did not (by far) transform all pre-existing practices[600].

The salience of the problem was evidenced through action taken by governments in Eastern Europe and Central Asia, with or without the support of international organizations – Latvia was one of the very first, with an inspectorate improvement programme supported by the World Bank Group in 1999-2003[601], Armenia passed a law on inspections in 2000, and Russia a law on the protection of business operators during inspections in 2001. Romania attempted to consolidated a number of inspection functions in 2003, and Poland set procedural guarantees for businesses during inspections in 2004[602]. Lithuania embarked significantly later, but in a more ambitious way, in a thorough reform of inspections (2010 onwards)[603]. Evidence of the prevalence of the problem is also evidenced in the responses to the business surveys that the World Bank Group started running in a number of countries, in support of business environment reform programmes (which increasingly included inspections as well as permits and licensing reforms), from the end of the 1990s. Countries covered by these surveys (at various dates) include Azerbaijan, Belarus, Georgia, Kyrgyzstan, Mongolia, Tajikistan, Ukraine and Uzbekistan[604]. All of them showed, at least before reform (and often after several years of it, in spite of some improvements), the prevalence of inspections-related problems.

The wealth of data collected by these surveys (as well as by some country-specific ones, e.g. those run by the Lithuanian government since 2010)[605] will be a very important source for the outline of inspection practices,

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[599] See for instance Coolidge, Grava and Putnina 2003 on the situation in Latvia in the late 1990s.

[600] For an example of how such regulatory practices can survive in a new EU Member State, see e.g. OECD 2015 b on Lithuania. The whole report is sub-titled "focus on the delivery side", emphasizing the importance of regulatory procedures and processes rather than only the text of regulations. See in particular chapters 7 (inspections and enforcement) and 9 (construction permits). Lithuania also has a large number of other licenses and permits, including approval requirements for food business operators that are stricter than mandated by EU regulations (source: direct interviews with and presentations by senior officials). Several other OECD reviews of regulatory reforms covered post-Communist countries (Czech Republic, Russia, Kazakhstan) – see: http://www.oecd-ilibrary.org/governance/oecd-reviews-of-regulatory-reform_19900481.

[601] See Coolidge, Grava and Putnina 2003 as well as Putnina 2005 and Coolidge, Grava and Liepina 2008.

[602] See Putnina 2005 and World Bank Group 2010.

[603] See OECD 2015 b, chapter 7.

[604] The surveys covered the following years: Azerbaijan: 2008 (a later survey remained unpublished) – Belarus: 2003, 2004, 2005 and 2008 – Georgia: 2003 and 2005 - Kyrgyzstan: 2008 and 2010 – Mongolia: 2009 and 2015 (forthcoming) - Tajikistan: 2003, 2005 and 2007 (a later survey remained unpublished) – Ukraine: yearly from 2000 to 2004, then 2006, 2008 and 2010 – Uzbekistan: yearly from 2001 to 2007. All these surveys see bibliography IFC (various years).

[605] See OECD chapter 7 for a summary of these surveys. Other surveys covering businesses' experiences in the region are those run jointly by the EBRD and World Bank Group and known collectively as BEEPS (Business Environment and Enterprise Performance

effects and changes in former Communist countries that we will briefly draw below. The other key source will be our own experience – being involved as an advisor to governments in a number of these countries since 2004[606], which resulted in countless discussions and interviews with both government officials, businesses and external experts.

i. Inspections pre-reform: burden and attempt at "total control"

Geographically, this section focuses on several countries of the Former Soviet Union (Armenia, Azerbaijan, Belarus, Georgia, Kyrgyzstan, Tajikistan, Ukraine and Uzbekistan), to which Mongolia (which was very close administratively to the Soviet system) is added. We also consider one EU Member State that is also at the same time a former Soviet republic (Lithuania). There are several reasons to consider this particular set of cases. First, the Former Soviet Union, and more broadly former command-economies of the Soviet block, have been (for many still are) characterized by rigid and heavy regulatory systems which aim at preventing "all risks, all the time, everywhere" – in effect, a direct opposite of the risk-based approaches we are considering in this research. Second, most of these countries have undertaken significant regulatory reforms (often focusing specifically on inspections, and with a risk angle) in the past ten or even fifteen years, and many have reached important results, but also faced significant limitations – thus presenting interesting lessons on how such reforms can succeed (or not), and with what effects. In all these countries, business inspections used to be, and often still are, a major problem, and thus have been a key area of reform – which allows to investigate specifically this aspect, and the impact of changes. Because of the salience of these issues, and of the need to have reliable data to design, steer and evaluate reforms, the International Finance Corporation of the World Bank Group, and the World Bank Group Investment Climate Advisory Services, have conducted business surveys in most of these countries (and the Lithuanian government has done likewise, and with similar questions and methods), focusing on regulatory procedures and instruments, in particular inspections, which provide a wealth of data.

Before reform, the regulatory approach in these countries was (and still is in part in many cases) extremely prescriptive, with detailed "specification-type" rules setting out exactly what material should be on the walls, how a shop or factory should be laid out, what recipe to use to preserve cucumbers, how many coat-hangers should be in a hotel room etc. Not only were these rules highly prescriptive and detailed, but they were hugely numerous, and came from a large number of different regulatory bodies, without coordination (and quite often with contradictions). In order to ensure adherence to these norms, and to control business activity more broadly, most activities were (and often still are) subject to *ex ante* controls: businesses and citizens require hundreds of permits, approvals, licenses etc., which must frequently be renewed. In addition, once operating, businesses are subject to numerous inspections regardless of the actual risk level of activities, and likewise customs, traffic police etc. attempt to control each and every person, truck, shipment.

Evidently, most of these countries (or, probably, all of them, but to varying extents) present clear links between "petty corruption" (that of "street level bureaucrats" rather than major top-level corruption involving large contracts) and frequent inspections (and permits, licenses etc.). This link is not only seen in the circle of

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Subject). We discuss later in this research issues with the reliability of these surveys, but in any case they essentially do not cover inspections (except in a very marginal way) and thus are of limited relevance to our work.

[606] Working in this period in Armenia, Azerbaijan, Georgia, Kazakhstan, Kyrgyzstan, Lithuania, Mongolia, Tajikistan, Ukraine and Uzbekistan. It should be added that, before that, we also experienced first hand government inspections in Tajikistan as a non-profit entity, while working as Central Asia coordinator for the French NGO ACTED. In 2003, a shipment of WHO-recommended insecticide to be used for malaria preventionwas delayed over a month at the border for spurious technical reasons (and very real corrupt demands), until it got escalated by the funding party (the EC) and cleared at the highest political level. This resulted in serious harm (the insecticide only arrived after the start of the malaria transmission season), and definitely drove home to us the importance of the issue.

more inspections resulting in more bribes resulting in continued frequent inspections. It is also observed in that it appears that burdensome and intrusive controls, unfair treatment and constant inspections breed disrespect for the law on the side of the controlled persons and entities. Thus, it appears that even in cases where individuals are not corrupted, these practices tend to "corrupt" the system, i.e. make it inefficient and ineffective. The relevance of these (tentative) findings may be challenged by arguing that the regimes of Central Asia, Russia or Ukraine, are "inherently" authoritarian, plagued by 'cultural issues'. Many (over more than a century) have argued that authoritarian rule is endemic to the 'Russian character'. Others may suggest those governments' are unable to manage modern administrative systems because of lack of resources. This is too easy a way to dismiss the significance of post-Soviet (post-Communist) cases.

Clearly, lack of resources is not the reason. Russia's, Kazakhstan's, Azerbaijan's or Mongolia's GDP per capita, thanks to natural resources wealth, increased rapidly during most of the 2000s (even though Mongolia has slowed down, and Russia and Kazakhstan suffered from drops in oil prices and exchange rates)[607], and are on par with at least some European countries. Belarus (even though this is partly due to its industry still benefiting from a *de facto* energy subsidy from Russia) also has higher PPP GDP per capita than the poorest EU Member States. Even though other countries in our study group are mostly poorer (with the exception of Lithuania), it is sufficient to show that lack of resources cannot be the explanatory variable – particularly given that corruption problems in regulatory issues are definitely not lower in the resource-rich group (except for Mongolia, which has a significantly more open and more democratic system). Nor can the old fallacy of "cultural specificities" explain away the "control and corruption nexus". This fallacy is in fact used most frequently by corrupt senior officials themselves to justify the lack of reforms. In the 19th century, Germans were derided by Britons as lazy and corrupt – and laziness was also one of the main Japanese characteristics according to Western observers in the early 20th century[608]. Nowadays it is held that the German and Japanese cultures embody hard work and that corruption is low in Germany because it is abhorrent to the national culture.

Cultural differences exist, and the way the Soviet Union applied its laws (as tools to root out dissidents, meaning the law would always be against you no matter what it appeared to say) is definitely a key factor in the corruption problem. But one should look closer: most Russians, Ukrainians, Tajiks etc. complain about corruption and see it as a problem[609]. Most officials, for their part, go to great lengths to appear to comply with the laws. In many cases at least, based on numerous conversations with businesses in all these countries, officials generally make references to applicable norms and highlight violations that are at least partly credible, rather than outright asking for a bribe (though at the lowest level, with micro-businesses e.g. in Tajikistan, directly asking rather than bothering with pointing out norms is frequently observed). Most people, both citizens, businesses and officials, clearly see corruption as an evil – even if it is widely practised, even if they

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[607] In 2014, Russia and Kazakhstan both had higher nominal GDP per capita than Romania and Bulgaria (the poorest EU Member States), and only 10% lower than Hungary. Mongolia's was much lower but catching up already with Tunisia and Albania, for instance. At PPP, Russia was even above Poland and around 10% below Slovakia, Kazakhstan was above Slovakia and Mongolia less than 10% below Serbia
(Source: World Bank – see:
http://data.worldbank.org/indicator/NY.GDP.PCAP.CD?order=wbapi_data_value_2014+wbapi_data_value+wbapi_data_value-last&sort=desc and
http://data.worldbank.org/indicator/NY.GNP.PCAP.PP.CD/countries?order=wbapi_data_value_2014+wbapi_data_value+wbapi_data_value-last&sort=desc).

[608] See Chang (2007), Chapter 9

[609] Even though surveys as BEEPS sometimes report the percentage of respondents rating corruption as a "major" or "serious" problems to be decreasing, this is neither because of a decrease in the phenomenon, nor (based on considerable evidence, including successful revolutionary movements in Kyrgyzstan and Ukraine, and unsuccessful movements elsewhere) because of growing acceptance of it, but simply because of the way such questions tend to elicit unreliable responses because of the way respondents may perceive "problems" as meaning "unusual or somewhat solvable issues", as opposed to endemic and permanent ones. See for this our section discussing data reliability issues in surveys such as BEEPS.

benefit from it themselves. They may be profiting from corruption (on any side) but they are not advocating the practice as being "good" or even "normal". Crucially, and by contrast, there is a wide consensus about the way the system *should* work: there should be *effective total control*. Citizens long for it, businesses assume this is how things should work and inspectors are partly pretending, partly genuinely trying to enforce rules (taking bribes is not necessarily in contradiction with thinking one is trying to enforce laws, and sometimes actually enforcing them). Our argument is that this *objective of total control* is precisely a core element of the problem, and one that is therefore worthy of reform – and of study.

All the countries that we are considering here have attempted, with varying levels of commitment, different approaches and unequal success, to reform their inspection systems. These reforms were driven by the recognition that there were blatant problems with existing practices, and they also were part of an international context, where reforms in some countries of the region inspired others, and where the World Bank Group (and, to a somewhat smaller extent, other international assistance actors such as USAID, for instance) promoted such reforms and worked on trying to spread risk-based approaches. Crucially for our purpose, in most of the countries where it implemented programmes to support inspections reform, the World Bank Group ran representative business surveys to capture the frequency, duration and a number of other aspects of inspections (and of a number of other administrative procedures). While there were some variations in sampling structure and in precise wording of questions, these surveys offer a sufficient level of homogeneity to make meaningful comparisons on inspections incidence and frequency, and their evolution, both between the different countries surveyed, and over time. Given the large sample sizes used for most of these surveys (1 to 2 thousand respondents in general), and the relatively high engagement of World Bank Group teams in these countries in quality control, the reliability of data is rather high, at least when one considers simple "objective" questions such as the number of inspection visits. Unfortunately, no equivalent data exists to track the regulatory outcomes such as food safety or occupational safety (for reasons that we will briefly discuss), hence a full comparison of "before" and "after" reform will be impossible, but this will still enable us to get a first impression of the impact of changes.

ii. Data perspective: reform results and international comparisons

How much a regulatory agency inspects is a fundamental metric – be it relative to its staff's other tasks, or from the inspected establishments' perspective (what percentage of them are inspected every year, and how often on average). Data on the share of resources and staff-time spent on inspecting is mostly lacking. Even in OECD and EU countries, many agencies are loath to release such figures, or simply do not track them. It is even more so in the focus countries for our paper, even though discussions with officials suggest that *most* resources and time are spent on inspecting[610].

All the countries in our "surveyed group" shared initially a high level of inspections "volume", i.e. most businesses[611] (75% to 100%[612]) were inspected[613], usually several times a year. Post-reform data, in a majority

[610] Close to 100% of resources spent on inspecting in FSU. Confidential data from regulatory agencies in some OECD countries suggests that, there, at least 20% is spent on analysis and back-office work (and regulatory work includes not just inspecting, but informing).

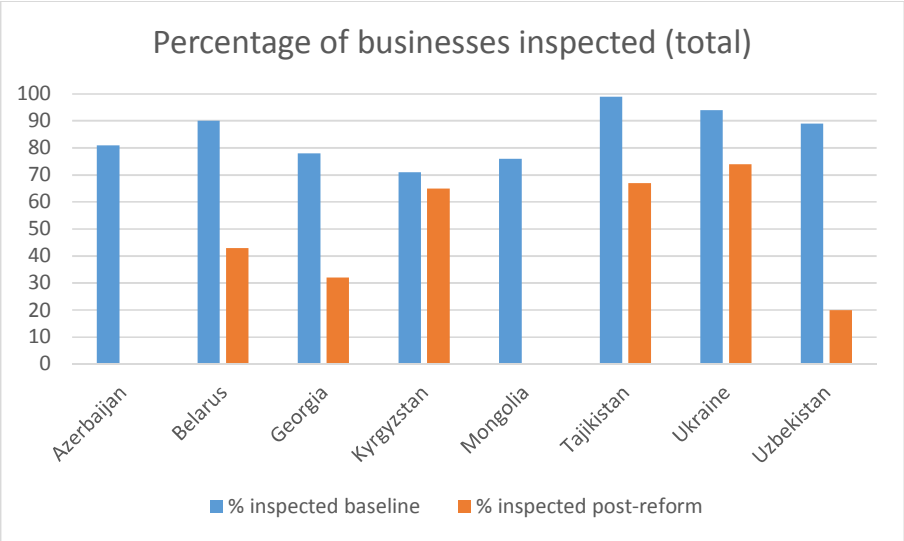
[611] Looking at percentage of *establishments* would be more accurate, as a single business may operate several. In surveyed countries, however, the majority of businesses (and the near-totality of SMEs) correspond to only one establishment. Since, for sampling reasons, surveys were based on *business* population [because business registries are based on entities, not premises), the two are assumed to be essentially equivalent here.

[612] The populations surveyed are not entirely identical, due to differences in the registriation of sole proprietors (and the possibility, or not, to combine their sample with legal entities'), the inclusion or not of agricultural producers, etc. Nonetheless, the general picture is comparable. See survey reports for detailed methodologies.

[613] To assess *targeting*, it would be better to have data on the percentage inspected *out of the supervised population*, i.e. the establishments that the regulator effectively has competence upon, but in most cases, for the countries considered, this population can be equated with the general business population, as regulators have very broad mandates, and make full use of them.

of countries where it is available (i.e. where reform has progressed for long enough, and where new surveys have been conducted), shows a significant decrease. The extent of this decrease, however, varies considerably depending on the character of the reform (more or less radical and/or well implemented, with Georgia the most, and Tajikistan, Kyrgyzstan and Ukraine the least), and on its duration. It appears also that strong, authoritarian governments can (when they are set on doing so) achieve significant decreases in inspections incidence, frequency and duration more easily, in some instances, than relatively weaker or more democratic regimes. These strong decreases, however, often do not reflect profound improvements in the environment for business creation and growth, or real changes in practices, but rather formal compliance with orders from the top. Thus, changes in the percentage of businesses inspected (incidence), the number of annual visits (frequency) or the duration are interesting indicators – but far from the whole story.

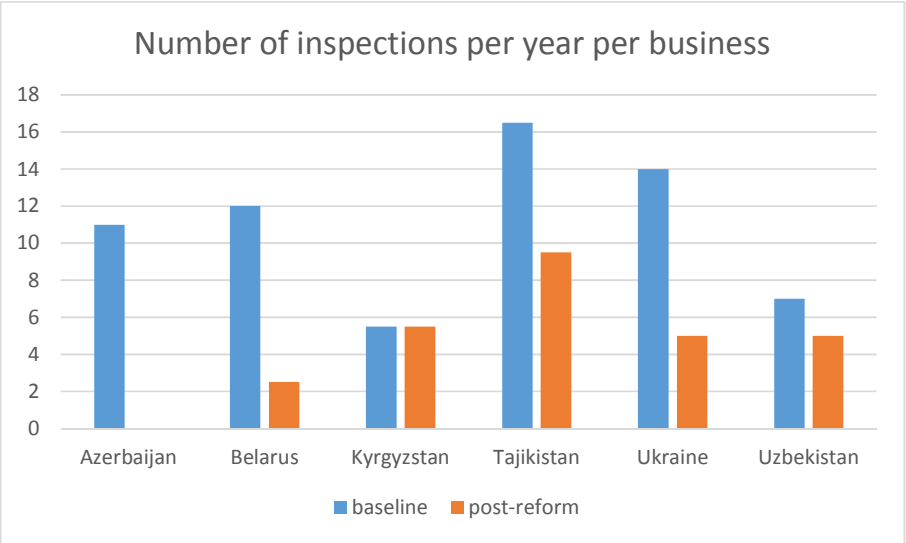
The graph below gives a general picture – with "baseline" and "post-reform" corresponding to different years for each country[614] [note that reform continued in Georgia, and inspections volumes went down much further, but no subsequent survey was conducted, hence the figure below is the latest available]. It shows both the very high incidence of inspections all across our group of countries pre-reform, and the significant decreases in most cases.

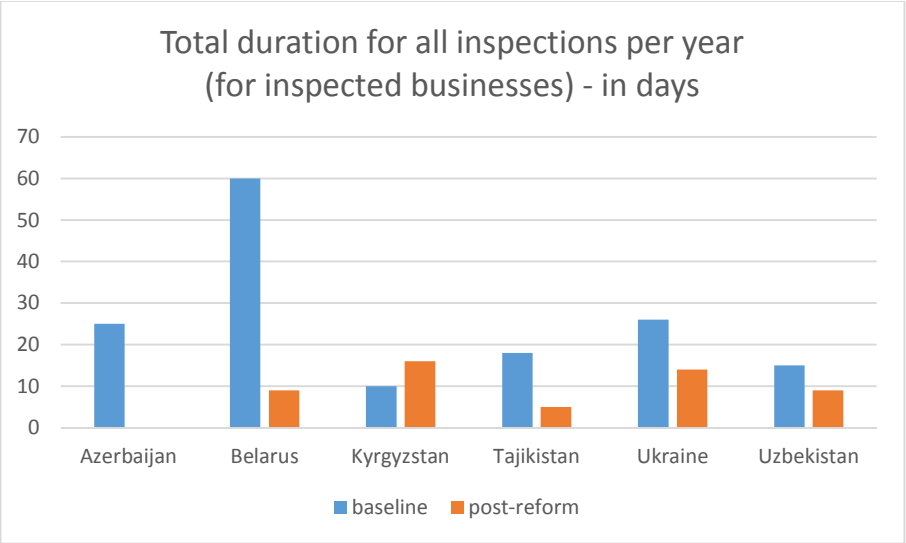


Percentage of businesses inspected in a given year, by country

Incidence is, of course, not the only relevant indicator. Other data, such as the number of inspection visits and their aggregate duration, generally give the same picture, with the same countries displaying strong (or weak) performance, and generally high baselines (though with significant differences) in all cases.

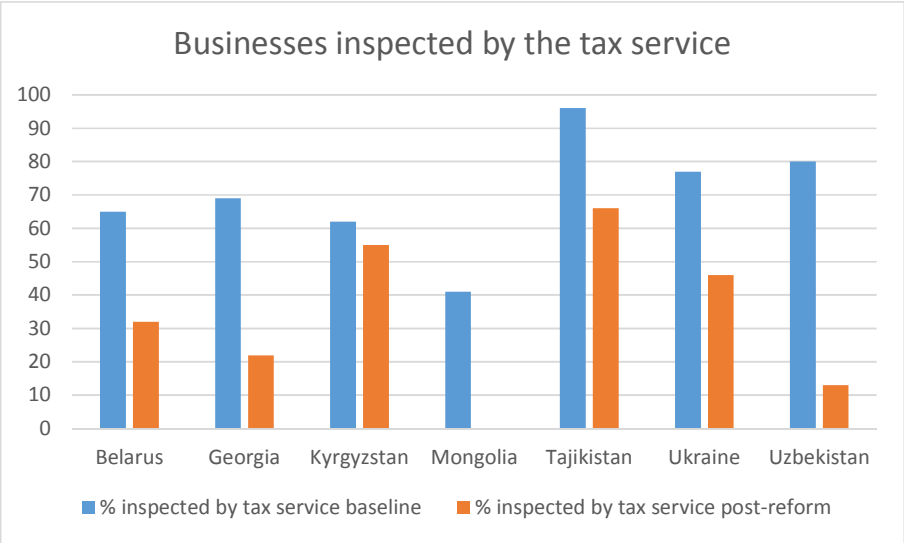
[614] Azerbaijan: 2007 [a subsequent survey was planned but did not take place], Belarus: 2003 and 2012, Georgia: 2003 and 2005, Kyrgyzstan: 2008 and 2011, Mongolia: 2008-9 (Q4 to Q3) [a follow up survey is planned in 2016], Tajikistan: 2003 and 2010 [the 2010 data was presented publicly but not published, it suffers from lower quality than previous years – last published report is 2007], Ukraine: 2006 and 2010, Uzbekistan: 2001 to 2007. Reforms started in: Azerbaijan 2011 only, Belarus 2006, Georgia 2001 with acceleration in 2003, Kyrgyzstan 2005 but stalled several times because of political events, Mongolia 2003 but stalled and resumed in 2009 only, Tajikistan 2006 with slow implementation, Ukraine 2007 with similarly difficult implementation, Uzbekistan 1998 deepened from 2002.

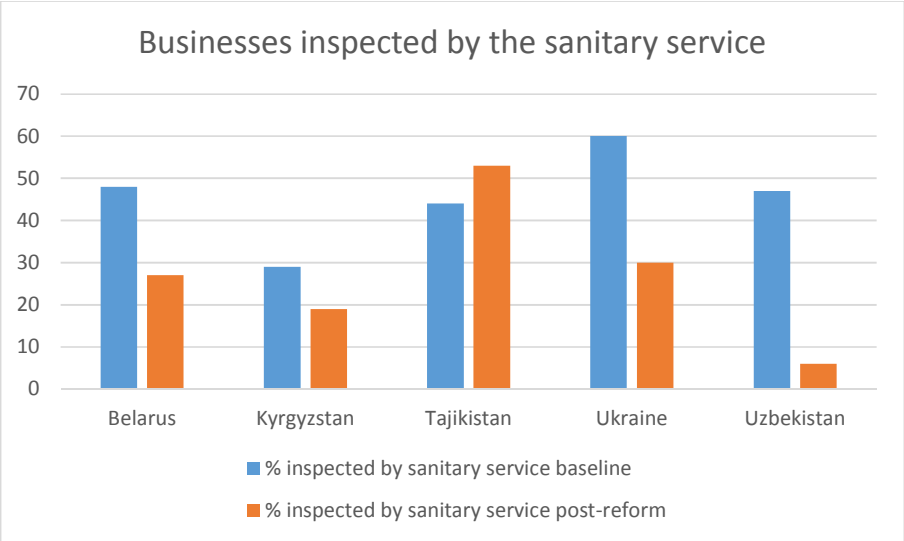




These figures aggregate *all* inspectorates but the bulk of inspections are conducted by one to five (at most ten) agencies, while the remainder[615] are far less active, because of limited staff and resources. Overall, in all countries, tax inspections, fire safety inspections, hygiene and food inspections formed the bulk of the visits. Survey results show the prevalence of these inspections, as well as mixed reform results, corresponding to different degrees of implementation by different agencies.

[615] Just a couple in Mongolia, where most agencies were consolidated in a "single inspectorate" – around 20-30 in Tajikistan, Kyrgyzstan, Uzbekistan – around 80 in Ukraine. This compares with around 70 in Lithuania, similarly with only a few being really active and most of them being very small, or less than 15 in Latvia or Slovenia. It is often difficult to ascertain the number of inspection agencies because many can be small, or local/regional. Thus, while in the Netherlands there is now only a dozen of national inspectorates, an inventory a couple of years ago identified nearly 70 bodies with inspecting powers.





It would be optimal to compare this data to that of EU countries, but it is difficult to do so for, unfortunately, most agencies do not publish data on the percentage of businesses inspected, and very few countries have conducted surveys on this issue[616].

It is in some cases possible to estimate inspections incidence based on (a) the published number of inspections and (b) the total number of businesses in the country[617], but again it is only possible for those who publish their inspection numbers (a small minority). We have to explain here why we think it possible to use data published by inspecting agencies themselves in this case, whereas for FSU countries we have preferred to rely

[616] The data from these surveys is of a different nature, and scope, from the data used in the function-focused case studies. While in the OSH studies (Britain, Germany, and further down France) we have inspectorates' own data, covering only one regulatory function, here we look at survey data with responses from businesses, covering a number of different functions. In countries where there are reasons to doubt the quality of inspectorates' data (which is frequently the case, even in the OECD, as we illustrate below in the case of France OSH – but is far more the case in a post-Soviet context, for instance), business surveys are a superior alternative. Considering percentages inspected, rather than raw number of inspection visits, allows to make easier comparisons country-to-country, regardless of their size. Finally, the ability to look at the overall prevalence of inspections across all functions allows to give a picture that goes beyond a specific function, and reflects the general situation in the country in terms of inspection practices.

[617] This *over-estimates* the percentage of businesses inspected, since some may have visited twice, and this this data is not usually available. This still allows to get an order of magnitude.

on representative surveys. The reliability of data on inspections numbers provided by inspectorates relies on at least three preconditions: adequate information systems to record the data, high compliance with internal rules by frontline officers, and alignment of incentives for the agency, the inspectors and the management (i.e. absence of incentives to manipulate the data one way or another). These conditions are broadly met in the case of the EU-based examples we use below[618], but not in the FSU countries. There, by contrast, not only are information systems frequently absent (except in tax services, records tend to be only paper-based), and compliance with internal processes is far from assured[619]. Most crucially, while there are strong incentives to conduct as many inspections as possible in practice (inspectors and their managers frequently draw illicit income from this, and some inspectorates are also allowed to keep a percentage of the official fines), there is an incentive to report less, since political authorities generally want to at least have appearances of business friendliness, so would react negatively at the very high numbers of inspections that would be reported. Considering official reports by the French tax service[620], and official data from the Latvia tax service[621], they both appear to inspect less than 5% of all businesses, a sharp contrast with the very high percentages observed in the FSU. As for British Occupational Safety and Health inspections, we saw in the previous section that there are less than 200,000 of them per year, for more than 5 million businesses, resulting in a percentage inspected of less than 5% as well.

Doing comparisons for an entire country (all types of inspections together) requires, however, business survey data, for no EU country currently has consolidated data on all inspections conducted in a given year by all agencies. While some have good quality data, this is far from the case for all of them, many do not publish inspection numbers, and there is in any case no way to avoid double counts and deduct from these numbers an aggregate incidence and frequency. Only very few EU countries have conducted representative surveys that we can use for our purpose. While the UK's National Audit Office and Better Regulatory Delivery Office conduct regular surveys of businesses about regulatory matters (in recent years jointly), these do not directly ask whether a business was inspected in a given year, they do not include tax services, and overall do not provide data that would be comparable[622]. The governments of Italy and Lithuania, by contrast, have both conducted surveys that yield (with some minor *caveats*) directly comparable data.

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[618] When an inspectorate thinks the inspection numbers may be "too high" or "too low" for some important stakeholders, it usually simply refrains from releasing them in the EU. This is e.g. the case of the British HSE in recent years, which prefers to avoid releasing aggregate figures to avoid criticisms one way or another.

[619] Both because of archaic management practices (heavy on authoritarian approaches, weak on real control) and because of incentives (low salary and high prevalence of corruption), actual compliance is low at all levels.

[620] See: Direction Générale des Finances Publiques (DGFIP), *Rapport d'activité 2014 – cahier statistique,* available at: http://www.economie.gouv.fr/files/files/directions_services/dgfip/Rapport/2014/RA_2014_cahierstats_0107_web.pdf. See page 13: in 2014 there were less than 48,000 on site 'accounting verifications' (tax inspections) as well as less than 70,000 checks of compliance with the public television service contribution. Even assuming (though it is highly unlikely) that all these targeted different businesses (whereas in fact a large overlap is likely), the total number receiving any form of "on site" controls was only around 100,000. In the same year, France had more than 3 million non-agricultural enterprises, and over 500,000 agricultural enterprises, hence somewhere between 2 and 3% of enterprises (at most) received an on-site tax inspection [enterprise population see INSEE website – accessed at: http://www.insee.fr/fr/themes/document.asp?ref_id=if4 and http://www.insee.fr/fr/themes/document.asp?ref_id=T13F172]. By contrast, the number of checks conducted remotely (documentation checks) was far higher – but still covered no more than around 10% of all businesses (even assuming that each individual control measure affected a different enterprise, which is again highly unlikely).

[621] Unpublished case study prepared for the International Finance Corporation of the World Bank Group in 2009, showing that less than 5% of enterprises in Latvia received a tax inspection in the most recent year.

[622] Several EU countries have initiated programmes that could yield a consolidated view of inspections, but so far they cover only some sectors, regions or inspectorates, and never all inspectorates in a country (though a few examples of this exist worldwide, e.g. in countries where most inspectorates have been consolidated in one single agency, like in Bosnia and Herzegovina). In Italy, the Registri Unici dei Controlli cover only the agricultural production and processing sector, and so far only at the regional level (though a nationwide extension has been decided). In the Netherlands, the *InspectieView* programme covers only national inspectorates (and not all of them fully at this stage). For more on this topic, see World Bank Group 2014 d.

In Italy there was (so far) a single survey covering 2011 and whereby over 1,500 respondents were interviewed, covering businesses with 5 to 250 employees. Because very small businesses were excluded, there may be a non-insignificant bias in the results (they may be inspected less frequently and, because of their high number in Italy, this would reduce the mean incidence and frequency). The exclusion of large businesses is likely to have less of an impact given their small number (though the mean incidence and frequency of inspections in these businesses is likely to be high). Though detailed results of the survey were presented in a number of events in 2012 by the *Dipartamento della Funzione Pubblica* in charge of administrative simplification, only some excerpts are available on line[623]. This survey showed that the percentage that had received at least one inspection in 2011 was slightly above 36% - hence, far lower than in FSU countries (even though, by many metrics, the Italian authorities considered the inspection burden to be far too high, in particular because of many duplications in controls, and of the high concentration of inspection visits on a few sectors, which received a far higher burden than the average may suggest[624]).

In Lithuania, the percentage inspected pre-reform was high, though somewhat lower than FSU countries that have not joined the EU, at around 60% in 2011 (see OECD 2015 b, p. 122). Initial gains (decrease to less than 45% in 2013) have been partly reversed due to a lower focus on reform under a new administration. If one considers not only incidence but also the combined frequency of visits and duration, the overall inspections burden fell around 30% in the first years of reform and, even after the partial reversal in recent years, this burden remains around 20% lower that at the baseline (*ibid.*, p. 124).

iii. Assessing outcomes of inspection systems – and of reforms

Ideally, in order to properly assess the effectiveness of inspection systems in FSU countries, and of reforms, we would take an approach similar to the one we used to compare British and German OSH inspections, using publicly available data on key outcomes such as food-borne diseases, occupational health etc. Unfortunately, such data is generally highly unreliable in most FSU countries, partly for the same reasons that official data on inspection numbers is not reliable. First, information systems are often lacking entirely, or are limited in scope and usage. Second, political priorities may make under- or over-reporting a much better strategy for managers than giving accurate data. In addition, challenges such as detection (e.g. for food-borne diseases) that apply in all countries are even stronger in countries where the public health system has been in upheaval for a couple of decades and is frequently plagued by corruption. Thus, it is impossible to look for precise correlations at the level of one inspection field, except possibly in taxation, where data on tax income (and on tax income as percent of GDP, and on collections vs. plans) are significantly more reliable (though not perfect).

Being able to compare data on food safety would be very valuable, for it is an area where, in spite of major differences in conditions (natural, economic), changes in practices can make a very strong difference, and one could expect better inspections and enforcement practices to deliver positive results (at least over some years, by supporting changes in how business operators and consumers behave). Unfortunately, except in cases of major outbreaks, food-borne diseases tend to be under-reported: not all patients will see a doctor, and few doctors will prescribe tests to identify the pathogen, except if the case is particularly serious. To this must be added very different practices in terms of health care (in some countries, most patients will go to a general practitioner, if they consult at all – in others, many will go to hospital), different reporting rules and standards. In addition, the consolidation of data from local sources is, in some countries, very problematic – with cases of "sloppiness", but also cases of outright manipulation of data in order to either show better performance

[623] See: *Dossier – I Controlli*, Dipartamento della Funzione Pubblica – Ufficio per la Semplificazione Amministrativa – available at: http://www.funzionepubblica.gov.it/media/1023751/dossier_controlli.pdf (see pp. 21-23).

[624] Our estimates based on the published data suggest that, for businesses with more than 10 employees, the mean number of inspection visits for those having been inspected at least once was around 10 per year in 2011, a very high number indeed.

than is the case or, in other circumstances, make the situation look worse to obtain more funds[625]. While food-borne diseases are *in aggregate* a serious issue, and they rank among the foremost public concerns in developed countries, they are rarely among the most salient risks, or gravest epidemics, and are thus not even reported separately in global health statistics compiled in WHO reports[626]. These WHO reports do however include incidence of under-5 mortality due to diarrhoea (not all of which is linked to food-borne diseases, but which can be a somewhat acceptable proxy), and WHO statistical tables (unfortunately with data over 10 years old, from 2004)[627] include estimates of Disability Adjusted Life Years (DALY) loss for diarrhoeal diseases (which is again an acceptable proxy, and this time for the whole population). The WHO also provides statistical tables with somewhat more recent data (2008) for standardized death rates from diarrhoeal diseases[628] - these are somewhat less helpful (effectiveness of health care system will impact the death rate more than the DALY, and some diarrhoeal diseases will rarely be deadly, so DALY is a better reflection of the actual food safety situation), but combining the two sources allows to cross-check if the situation has evolved significantly between 2004 and 2008.

Reviewing the available data on diarrhoeal morbidity and mortality from WHO tables shows that its reliability is far from perfect[629]. This is unsurprising given what we have noted above. More precise data (on specific causes of disease) is, when available at the national level, even less reliable. Detection of even the most prominent causes of disease, such as *salmonella*, is problematic in most countries. To compensate for detection and reporting biases, advanced regulatory systems such as the EU's are underpinned by systematic monitoring programmes in order to assess (based on sampling and testing) the actual prevalence of key contaminations[630]. Since such monitoring is not conducted in a comparable way (neither in terms of sampling, nor of reliability of tests or consolidation) in countries of the Former Soviet Union (excluding, of course, those that have joined the EU), it is impossible to *precisely* assess their food safety levels[631]. Still, combining WHO statistics and other sources (anecdotal evidence, expert reports, audit reports on the food safety system) it is possible to draw some tentative conclusions.

First, several of the countries with very high food safety and hygiene inspection rates (and which have had such high rates for many years) have clearly dismal records in terms of food safety. This is the case e.g. for Tajikistan, Kyrgyzstan or (demonstrating that this cannot be explained only by low income levels) Azerbaijan.

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[625] We have witnessed first hand all of these problems in the years 2001-2004 in Tajikistan, not for food-borne diseases but for malaria, a disease that is normally higher profile and thus more systematically diagnosed and reported (and where data quality problems are thus likely to be *less salient* than for food-borne diseases). First, an epidemilogical survey showed that there was very considerable under-detection at the local level. Second, review of the hospital-level data and comparison with aggregated national data showed that there was strong under-reporting once consolidated. Third, sharp variations in consolidated levels year-on-year suggested active manipulation of data for fundraising purpose (while keeping the overall under-reporting to protect the Ministry's image).

[626] See WHO database available at: http://apps.who.int/gho/data/node.home and consolidated reports on World Health Statistics (WHO, yearly) available at: http://www.who.int/gho/publications/world_health_statistics/en/

[627] Available at: http://www.who.int/healthinfo/global_burden_disease/estimates_country/en/

[628] *Ibid.*

[629] For instance, Ukraine has DALY loss for diarrhoeal diseases that is only 30% higher than in the UK and othe EU countries (2004) and even reports age-standardized death rates for diarrhoeal diseases (2008) that are significantly *lower* than e.g. the UK, France or Germany. While this is not *impossible*, other available evidence does not suggest this to be true, but more likely the result of under-detection and/or under-reporting, as the food safety situation in Ukraine is widely agreed to be worse than in these countries (of course, some of this could translate in longer-term health problems rather than diarrhoea, or less easily categorized symptoms, e.g. in case of chemical contamination). Among the "high incidence" countries, there are also very sharp variations between otherwise relatively comparable countries, that all point to the need for caution in using these statistics. They are, however, quite helpful for a first approximation.

[630] See in particular EFSA's monitoring programmes at: http://www.efsa.europa.eu/fr/topics/topic/monitoringandanalysisoffood-bornediseases and summary reports at: http://www.efsa.europa.eu/fr/node/952441

[631] National-level data, when it exists, should be treated with great caution. While working in Ukraine, in 2008, we heard a very senior official of the country's Sanitary and Epidemiological Service deny any problems with food safety regulations in the country by stating that their *salmonella* prevalence was lower than Switzerland's or Norway's. It may very well be that the *officially reported* prevalence was lower, but it was obvious to all that this did not reflect in any way the real situation in the country.

All three have high (>900 per 100,000 for Kyrgyzstan till >1,900 for Tajikistan) DALY loss from diarrhoeal disease (2004) as well as high age-standardized death rates from these same diseases (>9 per 100,000 for Azerbaijan till >26 for Tajikistan – 2008). The US Food Safety and Inspection System has not conducted any audit of any of these countries[632], Tajikistan has never been audited by the EU either, Kyrgyzstan was only audited in 1998 for horses (and the findings were negative, i.e. exports to the EU were not authorized)[633]. Azerbaijan received a few audits, focused on fishery products (2002, 2007) and equidae (2009)[634]. The audits' conclusions on the food safety system as a whole were negative, even though some establishments were found satisfactory. Of course, the EU FVO reports (or their absence) reflect not only on the food safety regulatory system, but on private sector capacity. Very poor countries, landlocked, like Tajikistan and Kyrgyzstan, also simply little that could be of interest to the EU, and no establishments that could meet its requirements – but the negative findings on Azerbaijan show the lack of connection between frequency of inspections and effectiveness. This is confirmed by the many difficulties Kyrgyzstan and Tajikistan have faced in recent years for their exports to Russia and Kazakhstan because of food safety concerns[635].

Further evidence of the disconnection between heavy inspections regimes and effectiveness of the food safety regime is provided by the examples of Georgia and Ukraine. As indicated above, Georgia dismantled most of its regulatory agencies and drastically curtailed regulatory inspections following the "Rose Revolution". With EU assistance, and as a requirement for the conclusion of the Deep and Comprehensive Free Trade Agreement with the EU[636], Georgia has gradually built up a new National Food Agency (NFA). However, in keeping with the market-friendly orientations of government policy, as of 2014[637] the NFA was still conducting only very few inspections (at most a couple of percent of all businesses were being checked yearly). In spite of this "light touch" approach, successive EU FVO reports showed strong improvements (in the fisheries sector, which was the one for which approval for exports was requested) between 2010 and 2014[638]. As for Ukraine, it has received many successive EU FVO audit visits over the year, being a major agricultural producer and food processor, neighbouring the EU, and with a major export potential. While until 2007-2008 most reports highlighted very serious deficiencies, there have been marked improvements in the past 8 to 10 years, with increasing market access in particular for certain Ukrainian eggs and dairy producers (though it is worth noting that this applies only to a few of the best firms in the country, and most of the sector is still excluded, reflecting unequal private sector capacity). In spite of inspections that remain overall very frequent[639], important reforms took place in the years 2008-2014 (and are being continued), in particular the consolidation of all food processing inspections under one agency (State Veterinary and Phytosanitary Service of Ukraine, formed and

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[632] See on the USDA website: http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/importing-products/2000-2003-foreign-audit-reports and http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/importing-products/eligible-countries-products-foreign-establishments/foreign-audit-reports. The US FDA audit reports are not systematically published and only available on the basis of Freedom of Information Act (FOIA)requests, so this evidence could not be used for this research – see answer on availability of reports on the FDA website: http://www.fda.gov/Food/ComplianceEnforcement/Inspections/ucm211823.htm#q33

[633] See report on the FVO website: http://ec.europa.eu/food/fvo/audit_reports/details.cfm?rep_id=471

[634] There are also 2 reports on aflatoxin contamination in hazelnuts, which are less useful as proxies for the whole food safety system. See reports on the FVO website: http://ec.europa.eu/food/fvo/audit_reports/details.cfm?rep_id=894 - http://ec.europa.eu/food/fvo/audit_reports/details.cfm?rep_id=1894 and - http://ec.europa.eu/food/fvo/audit_reports/details.cfm?rep_id=2378.

[635] Russia is well known for using food-safety based import bans for geopolitical purposes, but the two countries are rather firmly in its sphere of influence and in these cases the bans or threats seemed to at least partly reflect very real concerns. Kazakhstan's measures on meat and dairy from Kyrgyzstan seem to primarily reflect real concerns. Russia's and Kazakhstan's food safety systems are themselves far from perfect, but the overall situation is markedly better than in Tajikistan and Kyrgyzstan, giving some credibility to the assessment. See e.g. several instances of bans on Kyrgyz dairy by Kazakhstan: http://www.akipress.com/news:564986/ and http://en.tengrinews.kz/politics_sub/Kazakhstan-to-lift-ban-on-dairy-products-imports-from-7842/.

[636] This Agreement (DCFTA) was achieved as part of the signature of the Association Agreement in 2014 – see: http://www.eeas.europa.eu/factsheets/news/eu-georgia_factsheet_en.htm

[637] Interview of senior management of the NFA of Georgia by the author, June 2014.

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[639] See World Bank Group (2011), *Investment Climate in Ukraine as Seen by Private Businesses* – pp. 39-42

reorganized in 2010-2012[640]), the abolition of mandatory certification of food products by the State Committee for Standardization, etc. Overall, these changes resulted in a significant decrease in inspections and enforcement (and in other mandatory procedures), even though the post-reform level remains high (average number of inspection visits per year down around 30% between 2006 and 2010 as per World Bank Group survey data). Thus, while it is obvious that Ukraine's inspections system remains closer to the "old post-Soviet" norm than to EU practices, significant improvements in regulatory performance as recorded in successive EU FVO reports[641] took place alongside a significant *decrease* in inspections coverage and frequency.

A further confirmation of the disconnect between inspections "intensity" and public health and safety outcomes is provided by looking at aggregate data for Georgia compared to its neighbours Armenia and Azerbaijan – three countries which, in spite of their differences (in particular very rapid growth in the past 15 years in Azerbaijan due to its massive hydrocarbon resources), share many similarities in terms of starting conditions and level of development. Considering that inspections affect many areas of public safety and health, and that precise indicators are hard to come by and/or present reliability issues, we can take the opposite approach and consider high-level aggregates. Following Helsloot (2012) and Helsloot and Schmidt (2012 a), we can use life-expectancy as a proxy for overall physical safety in the broadest sense, and look at trends in life-expectancy in these three countries. Considering the period before any regulatory reform started (i.e. the late 1990s), life-expectancy at birth was (WHO data[642]) 72 years in Georgia in 2000, 71 years in Armenia and 66 years in Azerbaijan. The same source indicates 74, 71 and 72 years respectively in 2013. World Bank data gives very similar figures[643]. Georgia had a slightly longer life-expectancy at birth before the reforms started, and it still does, with a slight improvement over 2000. Armenia has remained stable. Azerbaijan has experienced a rather strong improvement, which is likely to be primarily linked to the massive increase in wealth over the past 15 years[644] (and possibly the phasing out of some very highly polluting chemical industries inherited from the Soviet period). While Azerbaijan has not done significant reforms in regulations, inspections and enforcement, this is beside the point because their effects would in any case be dwarfed by the increase in incomes (and income is the primary driver of physical safety, cf. Helsloot 2012). What matters to our research is that Georgia, which did very radical reforms resulting in a very sharp drop in inspections and enforcement "intensity" did not see any worsening of life expectancy (and even a small improvement), in spite of the period also being characterized by internal and external warfare, as well as a partial economic embargo imposed by Russia, which heavily weighed on economic recovery. In spite of disaster warnings by some that cutting such inspections would have dramatic safety consequences[645]. Both President Saakashvili and Minister of Economy (and then of Reform Coordination) Bendukidze stated during the reform process that risks were minimal from disbanding these institutions and stopping their activities, because they had hitherto been corrupt and using ineffective approaches. Facts appear to have mostly vindicated them.

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[640] See EU FVO report on dairy products (2014) available at: http://ec.europa.eu/food/fvo/audit_reports/details.cfm?rep_id=3377

[641] See e.g. meat 2009: http://ec.europa.eu/food/fvo/audit_reports/details.cfm?rep_id=2344 – animal health 2010: http://ec.europa.eu/food/fvo/audit_reports/details.cfm?rep_id=2651 – salmonella in eggs 2013: http://ec.europa.eu/food/fvo/audit_reports/details.cfm?rep_id=3159 – dairy 2014 : http://ec.europa.eu/food/fvo/audit_reports/details.cfm?rep_id=3377

[642] See WHO Global Health Observatory data repository: http://apps.who.int/gho/data/node.main.688

[643] See in World Bank data repository: http://data.worldbank.org/indicator/SP.DYN.LE00.IN

[644] See World Bank data repository, GNI per capita (PPP in current US$): Azerbaijan 2000 = 3,340 – 2014 = 16,910. By comparison, Georgia 2000 = 2,690 – 2014 = 7,510 and Armenia 2000 = 2,380 – 2014 = 8,450. The impact of war (internal secessions, external war with Russia) and of Russian embargo (on key export products) is highly visible in Georgia and has severely curtailed growth. Data available at: http://data.worldbank.org/indicator/NY.GNP.PCAP.PP.CD

[645] In 2007-2008 for instance the OIE warned about potential dramatic impact from disbanding the previous system of veterinary inspections. The dire warnings did not as yet materialize (which does not mean nothing could happen, of course).

A last example can be taken from the tax inspection field. As part of its 2007 *Business Environment in Ukraine* report, the IFC of the World Bank Group conducted several calculations to look at comparative "tax yields" in jurisdictions with varied tax inspection levels, both inside and outside of Ukraine. The international comparison (p. 56) showed Latvia as having a far better "yield" (compared to tax potential) by employee with far less inspections than Ukraine. The internal comparison (focusing on SMEs) showed that, between different regions of Ukraine, there was no link whatsoever between the tax revenue per SME and the percentage of SMEs inspected. Additional research showed that most tax inspections in Ukraine brought negligible revenue, while a very small percentage (10% at most) brought roughly 90% of the additional tax assessments and penalties.

As we have acknowledged from the start, none of these data points is enough to fully prove the case, data reliability, attribution and other issues being limitations that cannot be overcome, at least at this point. Taken all together, however, they build a strong picture of how the volume of checks, their coverage and frequency, are essentially uncorrelated to public welfare outcomes – be they safety, health or tax revenue. Equating "more inspections" or "more stringent enforcement" with "higher effectiveness", as is still too often done, is simply not supported by evidence. While one could argue whether the findings from Former Soviet countries can be transposed to an EU or OECD context (considering in particular the different situation in terms of petty corruption – though it is far from unknown in EU or OECD too), these findings should be a warning to those who think that "stronger enforcement" is a priority in developing countries and emerging market, in front of problems such as environmental pollution, or health and safety issues. Indeed, sometimes at least, *more effective* enforcement may be direly needed. This does not mean, however, that "more" or "stronger" enforcement will prove to be effective.

c. Short overview of a few EU countries: Lithuania, France, Italy

As indicated in the introduction, the scope of this research did not allow us to rely exclusively on case studies, nor to undertake a comprehensive review of each and every case that would be possibly relevant. Our aim was not to demonstrate with full certainty a causal relationship (one way or another) but to challenge established assumptions and to check whether, based on available data and findings, some evidence in support of risk-based inspection practices and "smart inspections" could be found. The above examples appear to rather strongly support our hypotheses: there clearly is no positive correlation between "more inspections" and "increased safety", and Britain (using risk-based targeting, risk-proportional enforcement, and putting much emphasis on guidance and support) achieves significantly better results (and/or similar results with far less costs) than countries relying on more "traditional" approaches to inspections and enforcement, such as Germany or France.

Similar analytical work would need to conducted in other regulatory areas to confirm these preliminary findings, but it is rarely easy to find reliable effectiveness data (as we have discussed above at some length), and consolidated statistics on inspections are also hard to come by. Taking a short look at some of available data points from other countries can, however, be done in order to this review of evidence from the practice.

i. Lithuania – OSH, reforms and challenges

In Lithuania, as we have seen, post-2010 reforms led to a significant decrease in the overall frequency and duration of inspections. They also led to important changes in enforcement practices. Because Eurostat standardised data on fatal occupational accident rates is, as explained above, one of the most reliable

indicators to compare effectiveness, it is worth considering briefly labour inspections in Lithuania and their evolutions.

First, the country's performance in terms of occupational safety appears overall poor. The standardised incidence rate for fatal accidents[646] was 6.62 in 2008 (4.56 excluding traffic-related accidents) and only slowly and unsteadily crept down (5.06/3.79 in 2013). By comparison, the EU-28 average is 2.22 in 2013 (1.3 excluding traffic-related accidents), France (which we saw has practices in sharp contrast to Britain, and worse-than-average performance) achieved 3.71 (2.94) in 2013, and Germany 1.29 (0.81). As we have seen, year-on-year variations should be treated with caution (because of the small number of observations, which can result in sharp variations in the incidence rate), but the 6-year trend is clear: poor performance, with slow improvements[647].

Second, inspections pre-reform appeared to be at a relatively high level in terms of frequency, and to be rather "heavy handed" in terms of enforcement, at least compared to the British and German cases studied above. The Lithuanian State Labour Inspectorate's (SLI) annual reports[648] give data on the number of inspections that is not easy to compare, because they include in the "total number of businesses" under supervision all farms, that amount to more than 50% of the total (but with the breakdown only available for most recent years). Unfortunately, the SLI does not indicate how many inspections were conducted in farms versus non-farms. 2012 data, for instance, would suggest a rate of approximately 5% of businesses inspected (if taking the entire population, farm included) but as high as 11% if assuming that nearly only non-farms were inspected – and even more if assuming that mostly *private* businesses (rather than "all economic entities")[649] were visited. Comparing with data from business surveys conducted by the Ministry of Economy (see OECD 2015 b, p. 123) show that in 2012, close to 15% of surveyed businesses reported receiving at least one labour inspection. While comparisons are complex due to different economic structures and uncertain quality of the data, such a coverage would be more comparable to Germany's than to Britain's, particularly considering that the 2012 rate already reflected a strong decrease (from 16,000 inspections in 2008).

In terms of enforcement, in 2008 the Lithuanian SLI issued 10,980 improvement notices, far more than the British HSE, in spite of covering a considerably smaller economy, and nearly as much as in Germany (12,693 for 2008, cf. Tilindyte 2012 p. 192). In that same year, it suspended operations over 2,400 times (against approximately 3,000 in Britain, again for a vastly larger economy), and issued or proposed 2,500 administrative penalties (twice more than in Germany). These numbers suggest that, in addition to a rather heavy coverage by inspections (possibly reflecting a lack of risk-focus), the enforcement approach was heavy on sanctions and rather "confrontational". Data from 2014 suggests there has been a significant change, with only 1,723 notices (down from still 5,192 in 2012, meaning the decrease has accelerated in recent years), only 43 suspensions of work activity, and 511 administrative fines. The collapse in the number of suspensions was particularly marked in 2012 (only 9, down from 230 in 2011) – and it is likely that the uptick in fatalities in that same year led to a partial reassessment (with approximately 40 suspensions per year since then).

This data, combined with the review of practices done by the OECD (2015, pp. 127-130), suggests that the SLI has strongly changed its practices since 2011, in reaction to reform efforts by the Government, to its own assessment of methods and results, and to the economic crisis (which to a large extent explains the collapse in suspensions of operations[650]). The decrease in inspections coverage is less clear (OECD 2015 b, p. 123:

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[646] Eurostat data available at: http://ec.europa.eu/eurostat/web/health/health-safety-work/data/database

[647] Lithuania has the EU's second-worst performance on fatal accident rates (including or excluding traffic accidents), just after Romania. Neighbouring Latvia has rates that are nearly as high, suggesting long-term trends linked to the post-Soviet context.

[648] Available for 2008-2014 at: http://www.vdi.lt/English/VDI_English.aspx

[649] See detailed enterprise statistics on the Statistics Lithuania website, at: http://osp.stat.gov.lt/en/temines-lenteles51

[650] Both because of the slowdown in the high-risk construction sector, and because of a deliberate policy by the SLI to minimize suspensions – direct interviews with senior SLI officials, december 2014.

decrease in 2013, but uptick in 2014), but seems nonetheless real over the last 6 to 7 years. At the same time as the SLI thus reduced its inspections coverage (at least somewhat) and turned away from heavy sanctioning to embrace a far more "compliance supporting" enforcement approach, key effectiveness indicators showed overall a slight improvement. Even the 2012 "surge" in fatalities just brought their level back to 2008. Thus, it seems that at the very least it is possible to conclude that the move towards a far more risk-proportionate and more compliance-supporting approach, while it clearly meant far less burden on private businesses, did not have any negative results on effectiveness – and probably had some limited positive impact. It is still too early to say whether time will strengthen this positive trend, but it is at least clear that the heavy-handed approach used for many years did not have any positive impact in terms of safety, and that a change was clearly in order.

ii. Labour inspections in France: conflicts, data issues, and disappointing results

Many "old Member States" of the EU (i.e. those who joined before successive "eastern enlargements", up to 1995) have disappointing OSH results, i.e. data that is significantly worse than the EU-28 average. This is the case for instance of Luxembourg, Belgium or Spain if excluding traffic-related accidents – and of Ireland, Italy or Austria if including them[651]. We elected to look briefly at only one of these, namely France, because labour inspections are a highly contentious issue there, with important political forces considering that any decrease in frequency of inspections or any laxity in enforcement would have dramatic consequences for workers (and other forces seeing labour inspections as a major impediment for business development). While the fatal accidents data is clear, however, it is not the case of inspections data. The Ministry of Labour publishes yearly reports to the International Labour Organization that include relatively detailed statistics on labour inspections and enforcement[652], these statistics are based on reporting in a unified information system by labour inspectors, and the annual reports repeatedly point out the variations in reporting rates and accuracy of reporting[653], meaning that the data should be considered as more indicative than authoritative. In addition, as we have pointed out above, other institutions inspecting OSH issues are not accounted for in these reports, which mean they seriously under-estimate the overall inspection and enforcement activities in France on this issue.

Considering the uncertainties surrounding the data, it is difficult to make definitive assertions, but there seems to be no real trend in terms of frequency of inspections, or of enforcement measures, over the period 2000-2013. According to the annual reports for the years 2000, 2003, 2008 and 2013, the key indicators were as follows:

	2000	2003	2007	2011	2012	2013

[651] Austria has a particularly high fatal accidents incidence when including traffic-related accidents, averaging more than 5 over 2008-2013 – since its performance excluding traffic accidents is just barely worse than average, this suggests a specific and very acute transport-related problem.

[652] See links to reports since 2000 on the Ministry's website, available at: http://travail-emploi.gouv.fr/ministere/documentation-et-publications-officielles/rapports/article/l-inspection-du-travail-en-france-en-2013

[653] See in particular the 2000 report: *l'inspection du Travail en France en 2000 - les chiffres clés. Rapport au Bureau International du Travail*, Ministère de l'emploi et de la solidarité, Paris, 2000. This report indicates that all statistics on inspections and other interventions published in the 1990s are essentially worthless because of erratic reporting rates and low reporting accuracy (p. 190).

Number of visits to businesses[654]	295,930[655]	295,899[656]	239,542[657]	356,200	265,300	294,000
Official letters (warnings)	N/A	N/A	161,114	226,300	163,000	183,500
Improvement notices (*Mises en demeure)*	9,621	7,921	5,017	6,573	5,515	5,375
Prosecutions	N/A	N/A	N/A	8,345	7,624	6,374

While there seems to be some decrease in the most stringent form of improvement notices (*Mises en Demeure*), there appears to be no noticeable trend in any of the other indicators (some of the data is very differently reported in different years, explaining the repeated "not available" mentions). The quality of reporting data seems to be a real issue, with software problems compounded by inspectors' refusal to use the new procedures. The 2003 report (pp. 220-221) outlines a long-term decrease in the total number of interventions, but this appears based on incomplete data, and partly reversed in recent years. The high number of warnings and prosecutions (compared e.g. to Britain or Germany) reflects the overall climate surrounding labour inspections in France, characterized by distrust on both sides (inspectors and employers).

During the same period, no improvement trend is visible in our key safety indicator, i.e. fatal accidents incidence, as the table below demonstrates[658]. France has the 9th worst average over 2008-2013 if including traffic-related accidents, the 7th worst if excluding them. It seems to be sliding in relation with the performance of other "old Member States", since over 1998-2007 had the 11th best performance – which meant 4 of the EU-15 had worse performance. Since 2008, only Portugal (and Austria, if including traffic-related accidents) has worse performance among the EU-15 group.

Eurostat Data	**Fatal occupational accidents, France**								
	1998	**2001**	**2002**	**2003**	**2004**	**2005**	**2006**	**2007**	**Average (98-13)**
Pre-2007 *(excludes traffic accidents)*	4	3.2	2.6	2.8	2.7	2	3.4	2.2	**2.97**
			2008	**2009**	**2010**	**2011**	**2012**	**2013**	**Average (08-13)**
2008 onwards *(excludes traffic accidents)*			0.5	2.07	2.59	4.99	2.64	2.94	**2.62**
2008 onwards *(includes traffic accidents)*			1.84	2.9	2.91	8.11	3.51	3.71	**3.83**

654 In France, there are many types, among which "control visits" (inspections *stricto sensu*) are only the most frequent, around 60% according to the most recent annual reports. For greater simplicity, and because the proportions appear more-or-less stable, we use here the total number of visits, whichever their legal nature and cause.

655 Extrapolated from the report's figure of 216,029, based on the note that this represents approximately 73% of the real number of interventions, cf. p. 162 of the 2000 Report to the ILO. Extrapolation for improvement notices is based on indication (p. 163) that only 55.7% of agents reported on this indicator.

656 Extrapolated from the report's figure of 253,386, based on the note that this represents approximately 85.7% of the real number of interventions, cf. p. 219 of the 2003 Report to the ILO. Same extrapolation done for all data in the 2003 column.

657 Extrapolated from the report's figure of 215,588, based on the note that this represents approximately 90% of the real number of interventions, cf. p. 155 of the 2008 Report to the ILO. Same extrapolation done for all data in the 2007 column.

658 As for data presented above on Britain and Germany, there is a break in time series after 2007, meaning that data up to and after 2007 is not directly comparable.

What these findings suggest is that OSH inspections in France seem to suffer from sustained problems: poor data (making it difficult to track evolutions), lack of questioning of prevailing practices and their effects even confronted with repeated poor performance, high reliance on formal enforcement measures but without evidence of positive impact on compliance. Data suggests that there is neither a trend in reducing the inspections incidence or the amount of enforcement measures, nor a positive evolution in safety. This suggests that the reliance on a "traditional", confrontational and non-risk-proportional approach does not seem to yield positive results.

iii. The inspection system in Italy – structures, crises, attempts at reforms

The survey conducted in Italy in 2012 on businesses' experiences with inspections offers a level of insights on inspections coverage and patterns that is unfortunately available in very few countries[659]. There are, however, some limitations in the uses that can be made of it, at least without considerable further research. Since no subsequent survey was conducted (or at least published), it is not possible to check for any changes in the most recent years. As most other EU countries have no comparable data, it is not possible to directly compare levels of inspections or patterns. And, because of all the limitations in effectiveness data discussed above, it is very challenging to easily assess the effectiveness of these inspections. That said, there are a number of interesting points in the data, which at least allow to confirm the relevance of some of the questions raised in this research.

In terms of coverage, in spite of inspections being conducted by a large number of agencies, in a variety of fields, the bulk of the control visits (and also documentary controls) are done by a small sub-set of them, focusing on a narrow set of domains: food safety and public health (*Aziende Sanitarie Locale* – ASL, Local Public Health Establishments, controlled the highest number of businesses), fiscal issues (the *Guardia di Finanza,* i.e. tax and customs police, was second, and the tax agencies fourth – cumulated, they controlled more businesses than even the ASLs), OSH and labour law (Labour Inspectorate and INPS, *Istituto Nazionale Previdenza Sociale* – National Institute for Social Prevention plus INAIL, *Istituto Nazionale per l'Assicurazione contro gli Infortuni sul Lavoro* – National Institute for Insurance against Labour Accidents – again, the combination of Labour Inspectorate, INPS and INAIL totalled more controls than the ASLs). A fourth group was made up by controls of the various police forces (excluding the *Guardia di Finanza,* GdF), which can cover a variety of issues (food and hygiene, environment, "nuisances" and public order etc.). In total, there were (in 2011, for businesses with 5 to 250 employees) more than 115,000 businesses controlled tax and duties, around 100,000 for labour and OSH inspections, over 80,000 by ASLs, close to 50,000 by police forces (excluding GdF) – but only around 10,000 by the Regional Environment Agencies (*Agenzie Regionale per la Protezione Ambientale*, ARPA), around 17,000 by the Fire Service, and less than 10,000 by the Forest Corps.

Many of these inspections in fact covered repeatedly the *same* businesses, as we have already pointed out earlier. Data shows a considerable amount of overlap between ASLs, Labour Inspectorate, GdF, tax service and INPS. Thus, a given business, if it was inspected, was likely to receive repeated visits on very closely related issues, or even on the same subject, from different (unrelated and uncoordinated) agencies. While some

[659] The survey results were presented in several public events in April and May 2012, as well as later in the year, but are not available in a published form. The below is based on data distributed during these presentations, which the author attended. The survey was conducted by the Italian State Statistics Agency ISTAT on behalf of the Office for Administrative Simplification in the Department for Public Administration under the Presidency of the Council of Ministers
(see their website at: http://www.funzionepubblica.gov.it/uffici/ufficio-la-semplificazione-e-la-sburocratizzazione)

reforms were initiated to try and address this situation (e.g. by taking away the inspection function of the INPS), it is unlikely that this situation has altogether changed since 2012.

As a result, it appears that inspection resources are in many instances fragmented and not used in the most efficient way (with repeated controls on the same topics by agencies that do not share planning or results), a concentration on some issues (e.g. labour/OSH) that produces mixed outcomes (as we have seen above, Italian performance in OSH is below EU-28 average at least when including traffic-related accidents – when excluding them, it is below EU-28 average, but still above EU-15 average[660]), and possibly a lack of resources for some important risk areas. This is particularly the case of environment, which we discuss briefly below. To conclude on the data, however, it is also important to note that the survey also included questions on the number of hours required to deal with inspections by each authority. These showed without surprise that tax and duties controls took the most time (1 to 2 days each), but the average time for labour-related and health-related inspections (around 5 hours each) was also not insignificant, particularly considering that the survey focused on SMEs.

Several major scandals affecting environmental protection, public health and occupational safety and health have broken out in recent years in Italy – and both are still ongoing issues. The first is the waste-management crisis in Southern Italy (leading to very serious public health concerns), and the associated food safety issue when it was found that illegal waste disposal had led to dioxin-contamination in *mozzarella di bufala*.[661] The second is the pollution scandal linked to the Ilva Taranto steelworks (long the largest in Europe), which exceeded applicable norms for decades, with major effects on public health in the area (both workers' and general population's) and the environment more broadly.[662] At first glance, these scandals could point towards some serious gaps in environmental protection inspections and enforcement – however it is not clear how much they are linked to what one could call "regular" inspections and enforcement, or whether they rather reflect very specific political and criminal contexts, on which regulatory agencies have very little influence (if any). In Campania and other Southern Italian regions, indeed in principle regular inspections could have helped to spot problems early on (particularly illegal waste dumps), but it is unclear how much inspectors could have done in a context where such illegal waste operations were managed by organized crime. As to the lack of adequate investment in proper, legal waste management, this went back to political decisions (and, again, criminal influence) – not issues on which any "business inspections" could have helped. The Ilva Taranto case is different[663]: environmental inspectors did their work, found out about the (major) violations, notified the need for improvement, attempted to withdraw the environmental permit allowing the factory to continue operating – but the political connections and wealth of the Riva family (which owned the plant) and the huge social importance of the plant (the main employer, by far, for Taranto and its region) meant that there was constant political backing (from otherwise opposite political camps) to adopt special legislation allowing it to continue operating. Only once the case was taken over by criminal prosecutors did it become possible, as part of the criminal case, to suspend operations. Thus, the problem was not the environmental inspectors failing at the task (they did not), but politicians overriding them (for a variety of reasons). Both of these cases show

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[660] Though Eurostat data on fatal accident rate suggests a trend for improvement – the 1998-2007 series (excluding traffic accidents)saw Italy's rate decline from 5 to 2.5, and the 2008-2013 series a decline from 4.5 to 3.06 (including traffic accidents) and from 1.89 to 1.24 (excluding them). It may thus be that some results are seen from sustained efforts, but the overall performance remains worse than EU-15 average (though better than results in France). The Ilva Taranto disaster (see below) also shows that long-term occupational health risks may be a serious issue at least in some parts of Italy.

[661] See Pasotti (2010) on the waste management crisis, and Borrello, Brambilla, Candela *et al.* (2008) on the mozzarella contamination scandal.

[662] See Pascucci (2013)

[663] There exist many summaries of the case, which has developed over a couple decades – see e.g. the Wikipedia article in Italian, which is regularly updated and has a number of links (https://it.wikipedia.org/wiki/Ilva#Taranto) or articles in *La Repubblica* such as http://www.repubblica.it/ambiente/2015/03/03/news/good_morning_diossina_il_libro_di_angelo_bonelli_sul_caso_taranto-108646777/ or http://temi.repubblica.it/micromega-online/ilva-uno-scandalo-di-incompetenza-e-malapolitica/?refresh_ce

how important it is not only to distinguish between "regulatory enforcement" and "criminal enforcement", but also the importance of having *effective links* between them – as there are cases which cannot adequately be addressed from a regulatory compliance perspective.[664]

Considering available data on key performance indicators e.g. in food safety[665] or environmental protection[666] does not suggest that Italy has very serious structural problems of regulatory compliance "across the board". Still, performance in food safety (at least from EFSA/ECDPC reports) is not outstanding, and neither is environmental performance. Occupational safety performance is, as we have seen, below par. Considering that this happens against a background of inspections that are overall rather frequent, and particularly "concentrated" on a limited number of businesses (many repeat inspections), with significant institutional overlaps, there seems to be a real case for improving risk analysis, targeting, compliance promotion methods, and overall coordination of inspection activities. All these areas belong to the reform work that the Government has undertaken since 2012, but it is still too early to see whether the situation has changed significantly.

4.2. Data challenges – inherent limitations in considering factual evidence

As we have briefly discussed earlier in this research, the question of whether regulations pose a significant burden on economic growth and competitiveness cannot be fully responded to based on available research. Investigating whether regulations deliver their expected benefits in terms of public welfare is likewise complex, and existing research gives conflicting answers (which often reflect different regulatory approaches and goals, but may also correspond to limitations in research design). The focus of our research is markedly more modest and limited: attempting to find out whether different approaches to inspections and enforcement appear to have different effects in terms of public welfare, while also considering the level of administrative burden they create (which is an admittedly very imperfect proxy for the impact on business growth, but is an indicator that can be more-or-less easily available), and the degree to which they include compliance-supporting activities or not. All through the different cases exposed above, we have relied on

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[664] Note that such effective interaction can be through integration of prosecution in the regulatory agency itself (British HSE) or by coordination between distinct institutions.

[665] See for instance the *European Union summary report on trends and sources of zoonoses, zoonotic agents and food-borne outbreaks in 2014*, European Food Safety Authority and European Centre for Disease Prevention and Control, available at: http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/4329.pdf (and see generally EFSA monitoring and other reports at: http://www.efsa.europa.eu/en/topics/topic/monitoringandanalysisoffood-bornediseases). While EFSA and ECDPC warn against limitations in comparability, and there are many indicators for which reporting bias is an issue, data from monitoring campaigns done according to specific EU regulations (where comparability is maximal) do not suggest any systemic weakness in Italy – e.g. in terms of *Salmonella* control, it overperforms in some areas (e.g. contamination in breeding flocks, p. 44, is below average), underperforms in other (e.g. contamination in laying eggs flocks, p. 47, is somewhat over average). The situation is somewhat worse in broiler flocks before slaugher (pp. 48-49). Overall, Italy is rarely among 'best performers' (though it is in some indicators), but the situation does not appear to be cause for concern either.

[666] Italian compliance levels in key areas such as EU regulations on water and air do not seem out of line with other Western European Member States. For instance, the most recent report on water quality is Synthesis Report on the Quality of Drinking Water in the EU examining the Member States' reports for the period 2008-2010 under Directive 98/83/EC (COM(2014) 363), available at: http://ec.europa.eu/environment/water/water-drink/pdf/report2014/1_EN_ACT_part1_v3.pdf shows Italy having no problems in microbiology, and some (isolated) issues in chemical contamination, but not more than Germany or Spain (pp. 4 and 10). There is no equivalent report for air quality, but the closest comparison we found is the In depth analysis of the NEC national programmes - Final Report, prepared by ENTEC (2005), available at: http://ec.europa.eu/environment/archives/air/pollutants/pdf/final_report.pdf. The Executive Summary (page iii) states that "only four Member States are currently projected to comply with all of their NEC targets by 2010 without the need for further actions" – suggesting a far lower level of compliance with the targets. Specifically for Italy (pp. 87-88), the report highlights some limitations on public action, but again not different from what is found in many Member States, and reflecting broad public policy issues rather than specific shortcomings in inspections and enforcement.

aggregate, country-level, average data, and not attempted to do any statistical analysis of possible correlations – be it across countries (using country-level data) or within a country (using e.g. firm-level data).

There are several reasons for this. First, the purpose of this research is rather to look at the issue in as broad a way as possible, considering a large number of countries and regulatory areas, and combining a review of existing research and explanatory models with evidence from the practice. The time and efforts required to attempt a statistical analysis of the data would be substantial, and would have required to curtail other parts of the research. Second, and more fundamentally, there are reasons to doubt that such work would produce conclusive results. These doubts are grounded both in the fact that existing statistical research on the effectiveness of inspections has yielded rather conflicting research, and on the many limitations and shortcomings of the datasets that could potentially be exploited. Before concluding on this chapter considering examples from the practice, we will briefly present some of the examples that led us to avoid engaging in statistical analysis of data (in spite of the benefits it could potentially provide if conclusive results were within reach).

a. Limitations and contradictions in studies attempting to investigate effectiveness

As a preliminary remark, it is essential to note that existing data-based research purporting to investigate the effectiveness of inspections was formulated as looking into the effectiveness of "regulation", with inspections seen the primary means of translating this regulation into practice, but not considered in their specificities. Thus, this research did not specifically look at the methods used to target these inspections (and whether some may be more effective than others), or the approach used during inspections (and whether they may have different impact), but only at whether there was a statistically significant effect of having had an inspection, versus not having had any. Given that the topic of our investigation was to see whether there was a *differential* impact between different methods and approaches for targeting and conducting inspections, the findings of these studies are anyway interesting but not directly conclusive. Still, they are interesting as an illustration of the pitfalls existing when attempting to base such research on strict statistical analysis.

The studies we will now consider focus on occupational safety and health, a regulatory area that has been subject to a number of studies, primarily in a US context, largely because of its high level of "political salience", with political parties sharply divided about its costs to the economy, positive impact on welfare, and overall policy choices in this regard. Because many other countries have less of a political conflict on this topic[667], there have been less such studies elsewhere. This means that in many other countries researchers have rather assumed that having occupational safety and health regulations was in and of itself likely to have positive effects on workers' health and safety, and research has thus focused on the approach and "style" of regulation and enforcement, but not on whether having regulations (as opposed to having none) had an impact, and which ones[668].

Interestingly, two significant studies on this issue have very similar approaches – but end up with findings that *appear* contradictory at first (we will see that "deconstructing" the findings allows to understand, if not solve, this contradiction) – even though the second survey references the first. We will start by summarizing briefly

[667] see e.g. Clark 1999 on the difference between US and Australia in matters of occupational safety and health regulations – but note that OSH and labour regulations are very "political" and "confrontational" in France and Italy, for instance (as illustrated in Italy by labour inspections being excluded from the scope of the inspections reform that started in 2012 – in France, yearly reports to the ILO regularly discuss physical conflicts involving labour inspections, and the need to request police protection, which is a good illustration of the level of conflict).

[668] This is possibly also because the Occupational Safety and Health Act of 1970 provided a convenient cut-off date for comparative research – before that date, researchers could consider that regulation was relatively minimal, federal inspections nearly absent, and overall the level of regulatory intervention was very low.

the two studies and their findings, before discussing their assumptions and conclusions, and seeing if we can draw some lessons from the apparent contradiction(s).

i. Inspections: effective, but not for their stated purpose?

In a first paper (Bartel and Thomas, 1985), the authors used official data from the Occupational Safety and Health Agency (OSHA) database, on inspections, (non-)compliance findings (and enforcement), and combined it with data obtained from the Bureau of Labor Statistics and Census Bureau, covering workers' injuries rate, firm size etc.. The data used covered the 22 states where *only* OSHA was enforcing the 1970 Occupational Health and Safety Act (and not the 28 others where state-level enforcement was also involved). The study intended to test two conflicting hypotheses on why previous studies had "failed to find any statistically significant impact on national injury rates due to the Occupational Safety and Health Administration" (p. 1) – the first is the "noncompliance hypothesis" ("because of limited statutory and budgetary authority from Congress, OSHA is unable to compel industrial compliance with its own standards") and the second the "inefficacy hypothesis" ("Since OSHA standards address only part of the problem, these standards can have at best minimal effect[669]") (pp. 1-2). The authors aim to explain what they consider a paradox – that in spite of apparent ineffectiveness (since there is no impact on national injury rates), and in spite of "enormous financial burdens on industry" , "OSHA safety regulations and their enforcement were continuously supported and funded by Congress throughout the decade 1970-80 despite significant Congressional controversy" (p. 2).

Among the study's major findings are that "the negative and significant coefficient on the inspection probability (…) indicating the responsiveness of firms' compliance decisions to OSHA's enforcement efforts" and that "noncompliance is also strongly affected by increases in the penalty structure (…). Indeed, increases in the penalty structure are a more efficacious means of achieving greater compliance than increases in inspection rates. Hence we have quite strong evidence that the noncompliance hypothesis is false" (pp. 20-22). However, "the result of a doubling of the inspection rate is only a 2.5 percent reduction in the lost workday rate because of the weak relationship between compliance and safety" (p. 22). The authors further note that "large firms (…) clearly choose lower violation rates because of lower marginal costs of compliance. These findings demonstrate the presence of significant economies of scale in compliance for large firms and, therefore, the opportunity for redistributions of wealth from small to large firms through OSHA enforcement" (p. 22). Finally, they note that "industries with higher injury rates (holding constant compliance levels) and industries with higher profit rates are inspected more frequently" and that "unionization has a negative and significant coefficient; this implies that unionized firms use OSHA as a tool for imposing costs on nonunionized firms. In addition, industries with larger average firm sizes have lower inspection rates, although this enforcement asymmetry disappears by 1978[670]".

The authors conclude that "our study has found only weak linkages between noncompliance and workplace accidents, indicating that the inefficacy hypothesis is largely correct, although the statement that OSHA standards achieve no reductions at all in injuries is probably invalid. In contrast, there are significant effects of OSHA enforcement on industry violation rates, indicating that the noncompliance hypothesis is false" (p. 25). In other words, they find that inspections and sanctions are effective at increasing compliance, but that the rules are inadequate and thus compliance ends up having little positive impact on safety. Their second conclusion is that "indirect effects of OSHA regulations exist, are significant in magnitude, and may well

[669] "It is important to recognize that OSHA standards are not performance requirements that specify some maximum accident rate for each firm, but rather are design requirements for the workplace itself. Most OSHA standards are in fact capital equipment standards dictating, often in great detail, physical characteristics of plant and equipment." (p. 4)

[670] Possibly because of greater political attention given to complaints by small businesses, referred to in the study.

dominate any direct effects (certainly direct benefits). The apparent beneficiaries of these indirect transfers of wealth are unionized and large firms, who would reasonably provide political support for the agency, so long as OSHA has some cost impact-and so long as this impact is asymmetrically distributed against nonunion and small firms" (p. 25). The overall conclusion of the study is thus to validate a "regulatory capture" vision of OSHA standards and enforcement strategy, as well as a "deterrence" vision of inspections (but with a lack of effectiveness to improve safety, the stated objective of the rules and of the institution).

ii. Inspections: effective, and with "lagged" effects?

In a second paper (Scholz and Gray 1990), the authors built upon past research (including Bartel and Thomas, which we just summarized), but were able to use a different dataset "merging OSHA enforcement records and Bureau of Labor Statistics (BLS) injury data for 6842 manufacturing plants", which "provides richer information than has been available to other studies" (p. 284). The data covers 1979-1985, i.e. a different period than the previous study. It combines data on inspections and enforcement actions, characteristics of the plants inspected (including size, but also some qualitative data on the workforce), injuries (not aggregated rates, but at the plant level). The study was predicated generally on the same deterrence-based compliance model (as originally formulated in Becker 1968), but incorporating major elements from the "behavioral theory of the firm" (p. 283), as well as findings from research on "decision making under risk and uncertainty" (coming from Kahneman, Slovic and Tversky 1982 in particular) (p. 285). Thus, the model being used is somewhat more sophisticated (in that it incorporates more findings on behaviours and decision making), but still founded on deterrence theory. The authors investigate four hypotheses: that firms respond to accidents (by attempting to correct the safety risks they have revealed), that firms respond to perceived increases in "enforcement risk" (OSHA enforcement activity) but "over several years", that OSHA imposing penalties against firms has an additional, "specific deterrence" effect – and that firms react independently to the two "dimensions of expected penalty (probability and amount)" and "respond more to changes in probability".

A key difference with other studies (and one that the authors think explain a substantial part of the difference in findings) is that the sample is not representative of the general enterprise population but, rather, corresponds to types of plants which are an area of focus for OSHA. This is due to the BLS over-sampling large plants. As a result, the sample had firms with on average nearly 10 times more workers than the general enterprise population, and far more regularly inspected ("27% of them inspected in 1979, compared with 8% for all manufacturing plants", p. 288). While not representative, this lent the sample "more analytic power" (*ibid.*) to try and investigate responses to enforcement activities.

In their conclusions, the authors note that "the number of lost workdays and (…) injuries decrease significantly after increases in general enforcement and after specific contacts with enforcement agencies" (p. 302), i.e. there is both a general effect of OSHA enforcement existing (and increasing), and a specific effect of OSHA visits (the authors consider this a deterrence effect but one could argue that it may be a broader effect, and not only deterrence). They also note "relatively long lags between enforcement changes and changes in injury risks" (p. 302), and that "our estimates suggest that the effect [of changes in enforcement] continues into later years" (p. 295). In addition, "the results confirm that changes in probability and penalty are not symmetrical (…) increase in inspections reduced injuries and lost workdays more than a comparable increase in penalty" (p. 297). However, "enforcement effects are relatively modest, as other studies have found; a 10% increase in enforcement would reduce injuries by around 1% for the large, frequently inspected firms represented in our sample" (p. 302). In short, while inspection effects are small, they are clearly present, and produce effects over a couple of years (which can be both because the behaviour effects last a couple of years before reverting to mean, and because the positive effects of capital investments in safety take some time to produce results).

iii. *Making sense of the findings: "how" rather than "whether"?*

At first glance, the difference in findings may partly be explained by the sample composition and more detailed data: Scholz and Gray had more detailed data (with injuries etc. *per plant*), and in any case the effects are small, thus looking at a sub-sample of larger, more frequently inspected businesses, magnifies results that may otherwise be too small to be significant. Revisiting these two studies from the perspective of practical experience in inspections across many countries allows us, however, to challenge a number of the underlying assumptions for the two studies, and to suggest possible alternative interpretations of their findings.

First, both studies rely fundamentally on the same model of compliance – though a slightly modified (or "enhanced") version in the case of Scholz and Gray. The fundamental driver is seen as deterrence, with compliance entirely (or mostly) determined by rational calculations of costs and benefits. For Barthel and Thomas, "firms will elect to violate OSHA standards whenever such noncompliance is profit maximizing. Even apart from OSHA enforcement efforts, the level of noncompliance by a firm will have several distinct effects on profits" (p. 5) – probability and cost of enforcement actions intervene by modifying the cost-benefit calculation. In their study, Scholz and Gray use the same model but with additional considerations for "risk-induced" behavioural responses (reaction to accidents etc.), "based on observations of business decision making processes, in particular observing that firms' behavior deviates systematically from optimal performance (which would simultaneously maximize expected profit over all possible behaviors) because of limitations on the firm's decision-making ability" (p. 286). There is no consideration that firms' behaviours (and the behaviours of individuals who work within the firm) may be driven by a variety of other factors (social, cultural, psychological etc.), values, and thus may not be strictly determined by a combination This is all the more striking considering that, as the authors themselves write, "most empirical studies have investigated the deterrence hypothesis" but "the results of these studies have not consistently demonstrated the linkage [between deterrence and compliance] (…), although the insignificance of effects is sometimes interpreted as a sign of ineffective or inadequate enforcement rather than of a weak theory" (pp. 283-284). The inconsistency of findings, as well as the modest magnitude of deterrence effects observed even in Scholz and Gray's study (in spite of its sample "bias" towards more-heavily inspected firms) would, rather, appear to us to strongly support the view that deterrence is *not* the only or even the main compliance driver (at least in most cases), and that the modesty of the observed effects simply reflects this. Putting too much emphasis on deterrence, regardless of the sophisticated economic models developed for these studies, flies in the face of daily evidence. Every day, most individuals will comply with rules and norms for which the probability of detection, were they to violate them, is vanishingly small – and thus the deterrence effect very low[671]. A more sophisticated model of compliance is clearly necessary.

Second, while the authors have attempted to control for a number of factors, the way they have done it is not entirely convincing, which has to do with their overly schematic compliance model, with insufficient consideration of the specifics of the phenomena studied, and with data limitations. Because of the deterrence model, they did not look at the potential influence of factors such as information about regulations, type and quality of interactions with inspectors. Because of data limitations (or at least so we have to assume), they did not look at the question of costs of compliance, and whether there appears to be significant differences in compliance between firms which would have substantially different costs (in fact, both studies repeatedly refer to the question of costs, but always with assumptions and never with data). Even on factors for which they *do* attempt to control, one can but notice that they do so with some lack of attention for the specifics of

[671] Quoting Tyler (2003): "In most actual situations, the objective risk of being caught and punished is quite low. For example, according to an analysis of crime and arrest rates, the objective risk of being caught, convicted, and imprisoned for rape is about 12 percent; for robbery 4 percent; and for assault, burglary, larceny, and motor vehicle theft 1 percent". Even if a number of people over-estimate the probabilities, the fact that the vast majority of us do *not* steal cars is sufficient evidence that a large part of compliance cannot be explained by deterrence effects only.

the issue. A perfect example is the question of reporting of accidents and injuries. This is a fundamental variable for both studies, but barely gets any discussion. Bartel and Thomas write that "an analysis of worker injuries must take account of the role played by the workers' compensation system. The benefit structure varies across states and over time, and previous research by Butler and Worrall has shown that reported injury rates are higher in those locations and those years when benefit formulas are the most liberal" (p. 13) and they therefore opted to correct for this by using the "expected benefit measure for a representative wage earner" in each industry, and a "weighted average of the waiting period for receipt of benefits". Scholz and Gray make no mention of this issue at all. However, we know from many other settings and studies (e.g. Tilindyte 2012 pp. 122-124) that there are many situations of under-reporting of incidents, for a variety of reasons (mostly employers' pressure and/or attempts to reach an informal settlement and avoid any possible liability, sanctions etc.). There may be reasons why these do not apply to the US, but none of the authors even discuss them.

Third, the two studies make a number of somewhat "heroic" assumptions and/or downright *non sequiturs*. A strong example of this is to be found in Bartel and Thomas (p. 14): "Violations of OSHA standards are much like victimless crimes in that they are not automatically reported, but rather must be uncovered and verified by inspections. Not violations per firm (VF) but only registered violations (R) generated by inspections (I) are observable. The variables are related as follows: R = VF I. Hence registered violations per inspection (observed noncompliance) is a proxy for violations per firm (actual noncompliance)." In fact, this makes a number of (hidden) assumptions and there is no logical link from the premises to the conclusion. It assumes that each inspection finds all violations in the establishment, and that violations (and/or inspections) are distributed randomly so that indeed one variable can be used as proxy for the other. There is no reason to assume that this is correct.

Fourth, the fact that the effects of inspections (on compliance, and safety) are found to be small, but appear to increase (or be more significant) when one "focuses" more (e.g. through Scholz and Gray's sample of larger firms), actually suggests that the line of inquiry should be different. The question is not so much "do inspections achieve anything" but "under what circumstances, with which methods, do inspections work better?" If we take a different (or complementary) interpretation of the persistence of OSHA funding in spite of disappointing aggregate results in the 1970s, i.e. that Congress knew that the public wanted more protection, how do we make this protection more effective? Thus, we would argue that the question asked was maybe not the most relevant one – and that rather than asking "is there an impact from inspections", the question should rather have been "are there more efficient and effective ways to reach the desired impact".

In any case, these two studies show the limits of statistics-based investigations in our field. Rather than yielding conclusive and solid findings, two successive studies considering the very same issue result in largely opposite findings, partly reflecting differences in the data, but also to a large extent differences in the methodology and underlying assumptions (different weights, coefficients etc. given to different variables and phenomena). Considering the very considerable resources required for this type of work, the cost/benefit ratio does not appear very favourable.

iv. Broadening the view: US OSHA in international perspective

Let us attempt to draw a couple of lessons from these two studies, their strengths and shortcomings. Overall, they are "on the verge" of making a significant contribution to understanding inspections' impact on safety but, in our view, do not quite reach that point because they adopt a narrow model and neglect a number of aspects of the problem – and because they remain too far from the practice to actually consider how the institution selects targets, how the inspectors conduct their work.

To some extent, this problem is exacerbated by the specific characteristics of occupational safety and health (OSH) regulation in the US. For a number of reasons (in particular the fact that the OSH reform movement was more linked with broad social movements, environmental and consumer activists etc., than with organized labour), in the 1970 OSH Act "cooperation, discretion and flexibility were designed out, while adversariness and strict adherence to rules and procedures were designed in" (Clark 1999, p. 99). In line with this, "OSHA's deterrence philosophy involves a much greater emphasis on citations and penalties. US compliance inspectors are accorded little discretion" (*ibid.,* p. 96). In addition, "the courts are highly involved in the development and interpretation of US health and safety regulation" (*ibid.*) – which means OSHA will be keen to adopt rules that prescribe as much as possible "objectively verifiable", material standards, rather than practice-focused / safety outcomes requirements, to protect itself against judicial review. At the same time, "the operations of OSHA have continued to attract an intense amount of scrutiny, controversy, challenge and criticism in Congress, the courts, the executive branch (…) and the media" (*ibid.*, p. 98). It would be understandable, in this context, that researchers gave less attention to "enforcement style", since it is so obviously constrained – though in fact Scholz himself has written elsewhere on the importance of enforcement methods (Scholz 1994)[672].

Looking at the practice, here, would have meant trying to understand how OSHA was selecting inspection targets, and if some selection methods gave better results, for instance. It could also have meant comparing OSHA's results with that of other agencies where inspectors are given more flexibility and discretion, to investigate whether the benefits of discretion can outweigh the risk of capture. Even with the very rigid regulatory framework that surrounds OSHA, there is clearly scope for improvements in data analysis, targeting, outreach and information, and development of inspectors' skills – all these can have a major influence on results, and looking only at aggregate results in one agency tells us relatively little. In fact, to the extent that Scholz and Gray's results indicate a stronger effect than Bartel and Thomas's, and that this seems at least to a large extent due to their more focused sample, these studies in a way show "by contrast" that a more focused selection approach (e.g. a risk-based one) would produce more effects on safety – but this point is not really seen, as the focus is on validating a set of theoretical hypotheses rather than on understanding how practice works.

A last point of interest considering the US OSHA case would be whether its practices appears to deliver better, or worse results than other, more "responsive" ones. There is no easily available conclusive evidence on this topic, but we can look for some indications. Ayres and Braithwaite (1992) wrote of OSHA's regulatory strategy that it was "poorly conceived", with inspectors that "constantly nip at firms with flea-bite fines", where "petty punitiveness is in the foreground and no big guns are in the background" (p. 49). By contrast, Clark (1999) wrote that "there is evidence to suggest that, in terms of workplace outcomes, Australia's current occupational safety and health performance is, at the very least, *no better* than that of the USA" (p. 102) – but unfortunately she did not indicate any of this evidence.

The only relatively "easy" indicator that is available to compare the performance of OSH systems across countries is the fatality rate, which suffers from less distortions (and under-reporting) than the rate of (non-fatal) injuries – even though one of the studies used here reports that "limited or incomplete information on the death certificate and variation in certifier interpretation of the "injury at work?" item contribute to an estimated under count of occupational injury deaths of between 10% and 30%" (Feyer, Williamson, Stout, et al. 2001, p. 23). With this *caveat* then that one should not exaggerate the precision of rates of fatal occupational accidents, there are at least four published papers or reports comparing these rates across a

[672] See also Kagan (1989, 1994) for another example of US-based research emphasizing the importance of different "enforcement styles".

number of advanced economies (and online data allows to complement older studies by seeing how rates have evolved).

Feyer *et al.* in 2001 compared New Zealand, Australia and the US, and showed the US as having somewhat better results than Australia (and New Zealand performing worst), but "because the United States data collection method likely underestimates the occurrence of work related fatal injuries, the true difference between the United States and the other two countries is probably less" and "much of the difference between countries was accounted for by differences in industry distribution" (the differences within a given industry being far smaller, and sometimes going in the opposite direction) (p. 26). It should be noted that Australia's performance appears to have improved strongly over the decade and more since this paper was published, as the most recent data shows that "The 191 fatalities in 2013 equates to a fatality rate of 1.64 fatalities per 100 000 workers. This is the lowest fatality rate since the series began 11 years ago. The highest fatality rate was recorded in 2004 (2.94)" (Safework Australia 2013, p. vii).

The next study was done by Australia's National Occupational Health and Safety Commission (2004). It decided to exclude the United States "as their data, particularly at industry level, would require significant manipulation before it could be included" (p. 23). The report added that "as the USA's incidence rate (4 deaths per 100,000 employees per year) is considerably higher than the countries selected, it is unlikely its inclusion would alter the findings of this report. This is in contrast to the report by Feyer *et al*. (2001) which concluded using 1989–92 data that the USA performed better than Australia. Since this time Australia's performance has improved substantially whereas the USA's rate appears to have remained fairly constant based on data supplied to the ILO" (though methodological caution applies). In this 2004 report, "Sweden and the UK [had] the lowest fatality rates" (p. 24).

The last two studies (one prepared by the UK HSE, the other by the US BLS) are both from 2014 and can be used to complement each other. The BLS's Wiatrowski and Janocha (2014) compare aggregated European (EU) OSH data with US one, while the HSE looks at the UK in comparison with other major EU economies. The US rate appears to be somewhat higher than the EU's in aggregate, and sometimes far higher at the sector level (Wiatrowski and Janocha 2014, p. 3). Within the EU, the HSE study (p. 2) shows that "the UK consistently has one of the lowest rates of fatal injury across the EU. In 2011 the standardised rate was 0.74 per 100 000 workers, which compares favourably with other large economies such as France (2.74 per 100 000 workers), Germany (0.94 per 100 000 workers), Italy (1.5 per 100 000 workers) and Spain (2.16 per 100 000 workers)".[673] Indeed, the UK's rate was roughly half the EU-15 average for most of the past decade and more.

Considering this data, it appears that both Australia (which has a fatality rate that in most recent years appears to be 40 to 50% lower than the US) and the UK (which has less than a third of the US's fatality rate) perform significantly better on at least this most easily comparable (and telling) measure of OSH. Differences in economic structure are substantial, but even when corrected for, the difference still exists, in the same direction. Australia and the UK both have two of the "enforcement styles" that most emphasize responsiveness, flexibility, promotion of compliance and overall focus on achieving safety outcomes rather than registering and sanctioning each and every violation. As we have seen, by statute and by design, OSHA's practice is in sharp contrast to this.

It would be difficult to conclude, however, on the relative level of effectiveness of OSHA's practices without considering the number of staff it can mobilize, and the number of inspections they conduct. As it states on its own website, and considering the size of the US economy and labour force, "federal OSHA is a small

[673] As discussed in earlier sections, these are the rates *excluding* fatal occupational accidents which took place in transit or transport.

agency"[674] – with "approximately 2,200 inspectors responsible for the health and safety of 130 million workers[675]". Part of the 50 US States have inspections and enforcement delegated by OSHA to State-level authorities, under an agreed plan – other have direct OSHA inspections and enforcement, hence the 2,200 inspectors include "state partners". By comparison, as we have seen earlier, the total number of (full-time equivalent) staff in the UK HSE and in Local Authorities working on OSH issues made up around 1,900. Britain, however, only has (latest Eurostat data) around 29.5 million workers overall (including self-employed), out of which slightly over 25 million *employees* (the main focus of OSH inspections in Britain). Thus, the ratio of inspectors to employees would be approximately 4.5 times higher in Britain, were there no other agencies involved in the US. In fact, there are agencies and structures at the local level that may be involved in OSH and are not summarized in OSHA's numbers, and there are some other federal administrations (most notably the US Mine Safety and Health Administration, MSHA) involved. These agencies are, in some cases, responsible for a distinct set of workers, but taking them into account may significantly change the ratio. For instance, the MSHA's 1,000 staff[676] are responsible for at most the slightly over 700,000 workers in the "Mining, Quarrying, and Oil and Gas Extraction" sector[677].

Likewise, while OSHA and its state-level partners conducted in 2015 slightly less than 80,000 inspections (federal inspections: 35,820 – StatePlan inspections: 43,471 – OSHA "Commonly Used Statistics" data), there were inspections conducted by other agencies (such as MSHA). These amount to approximately 43,000 visits per year on average over 2011-2014[678], including all kinds of visits (spot inspections on one single topic, reactive inspections, planned/regular inspections, information-focused visits etc.). Even accounting for such additional inspectors and inspections, however, it remains that their numbers appear low compared to prevailing levels in major EU countries, and even to Britain (where they have steadily decreased, and are far lower, as we have seen, than in Germany), at least considering the far larger working population. Indeed, a rough estimate would suggest that OSH inspections are at least 4 times less frequent in the US than in Britain, pro-rated to the working population. Things can look different, however, if we consider another unit of analysis, i.e. the number of active businesses (or of business establishments), and particularly those that are "above micro-size", since OSH inspections mostly focus on those where a significant number of workers is employed. Indeed, the US have, for a number of reasons, a very different enterprise structure from Europe, and a far smaller share of SMEs among the total number of businesses.[679] Britain has as of 2015 more than 5.2 million businesses, compared to 5.77 million in the US[680]. On this basis, the difference in the number of inspections per business would be negligible. If one considers only the businesses with at least 10 employees, the difference is however far larger (1.2 million in the US, around 235,000 in Britain). Thus, the ratio between the two countries will be very different depending on what is measured: inspections per workers, inspections per businesses, or inspections per businesses *above a certain size*. Overall, the total number of inspections in the US and Britain is relatively similar (around 120,000 if considering both OSHA and MSHA, and both HSE and

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[674] Quote and data (including in next paragraph) from the "Commonly Used Statistics" of the OSHA website – available at: https://www.osha.gov/oshstats/commonstats.html

[675] Out of a total labour force of close to 160 million (see US Bureau of Labor Statistics data available at: http://www.bls.gov/news.release/empsit.t01.htm)

[676] Staffing numbers could not be found on the MSHA's website (http://www.msha.gov/) and were therefore obtained from the Wikipedia article: https://en.wikipedia.org/wiki/Mine_Safety_and_Health_Administration

[677] And in fact the MSHA is *not* responsible for all workers in this sector – data from the US Bureau of Labor Statistics available at: http://www.bls.gov/iag/tgs/iag21.htm

[678] MSHA does not publish anywhere a consolidated report on its number of visits. We had to extract this by analyzing the bulk data on all MSHA visits since the agency's creation, available at: http://ogesdw.dol.gov/views/data_catalogs.php (select "MSHA data" and then on next page "MSHA inspections"). Between 2011 and 2014, the total number of visits (all kinds) ranged from 41,174 to 46,366.

[679] See successive editions of the OECD's *SME Outlook* for details on this (the latest *SME Outlook* dates from 2015 but findings on this structural difference are still valid).

[680] US Census data for 2013 – see: http://www.census.gov/econ/susb/

LAs respectively, in most recent years) – but the ratio of working population (US/GB) is around 4.4, and the ratio of businesses with 5 employees or more is similar (4.44).

Thus, because on most measures OSH inspections in the US are roughly 4.4 times less frequent than even in Britain (itself a "low coverage" country by European standards), it is difficult to make any conclusions on the relative effectiveness of different inspection approaches between the US and countries with more risk-proportional, compliance-promoting countries. This has not prevented the fatal accidents rate to decrease in the US[681], but it has remained (as we have seen) significantly higher than in comparator countries. The fatal injuries' rate decrease was also slower than e.g. in Britain, where the HSE's figures put it at 84% between 1974 and 2015[682] (but of course the HSE had more staff, not only different methods).

What conclusion, if any, can we draw of this? Unfortunately, the existing studies and data tell us little about the relative effectiveness of US OSHA's approach compared to the British HSE – and tell us nothing about possible differences within the US (between federal OSHA and state partners, for instance). This also tells us very little about the question of focus and targeting. From Scholz and Gray (1990), we know that OSHA primarily targets larger firms. From OSHA's own website, we know that inspections heavily rely on "reactive" scheduling, while also incorporating an element of risk-based targeting.[683] The existence of a distinct administration (MSHA) also means that a very substantial share of the total OSH inspecting workforce is looking at a very small sub-set of the working population (admittedly, one that works in a high risk sector – but the institutional separation means that there can be no reallocation based on evolving risks). There are also risk factors that are US-specific, and which the action of OSHA inspectors is unable to affect. As US Bureau of Labor Statistics data shows[684], nearly 10% of fatal occupational injuries were homicides – whereas the number in Britain is nearly negligible.

There is, however, one area where it is possible that OSHA's approach, as mandated by its statute, may have had specific (negative) effects – it is in reinforcing political polarization around the agency's activities. While it is likely that (given the specific political climate in the US) *some* political polarization would have been present, the contrast with the US FDA (which elicits significantly less opposition) suggests that there may be some element of reaction to what Bardach and Kagan (1982) called "regulatory unreasonableness[685]". Since the low level of OSHA's staffing (and the resulting low level of inspections) are partly a factor of political opposition by the Republican party to any increase in OSHA's funding, and since hostility to OSHA among businesses was likely reinforced by the agency's "enforcement style", there may be a negative feedback loop between its approach and its effectiveness, not directly but mediated through its effect on the political and social acceptance of the agency's actions.

Overall, this short glance cast at the US situation and US-focused studies has raised more questions than it has yielded answers. Possibly, the decrease in fatal injuries would have happened regardless of regulatory interventions, given technological, economic, managerial and social change. The sharper decrease in the UK may reflect more resources, better methods, a different context – or all of the above. To our mind, this all strengthens the case to start by making more systematic comparisons – of resources, activities, methods and outcomes – before "drilling down" into statistics-based analytical work. This way, we may be better able to ask the right questions.

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[681] By over 2/3 since 1970 and OSHA's creation – see: https://www.osha.gov/oshstats/commonstats.html
[682] See "historical picture" in the HSE statistics section: http://www.hse.gov.uk/Statistics/history/index.htm
[683] See "Inspections Fact Sheet" available at: https://www.osha.gov/OshDoc/data_General_Facts/factsheet-inspections.pdf
[684] See set of charts on fatal occupational injuries at: http://www.bls.gov/iif/oshwc/cfoi/cfch0012.pdf and a summary article on this topic (which has been the object of increasing public discussions) at: http://www.vox.com/2014/9/14/6139883/how-americans-die-on-the-job-in-5-charts
[685] And precisely OSHA examples formed a large part of Bardach and Kagan's book.

b. Real correlations or "noise" – assessing the quality of available data

We indicated above that there were two key reasons (apart from, obviously, limited time and resources) that we did not engage into systematic statistical analysis of data (looking for correlations in particular): inconclusive evidence from studies based on these methods (with conflicting findings) was the first, that we discussed in the previous section. The second was significant issues with data quality and reliability in many datasets – issues that become rapidly overwhelming once one attempts to correlated several insufficiently reliable data points, or to combine several insufficiently reliable sources.

Even in the OSHA study by Scholz and Gray (1990) that we have just discussed, not all data points are fully reliable. The records of inspections are most probably correct, but there is no absolute certainty that additional visits have not happened that were not recorded – while this may be insignificant in the case of OSHA, this is far from being negligible in other countries or institutions. Assessments of safety and health effects rely on reporting of injuries, diseases etc. that are inherently far less reliable, as we have discussed. As soon as a study seeks to take into account not only such relatively "objective" indicators but also more "qualitative" ones such as enforcement style, or some "hidden" ones such as corruption (broadly defined), or even "objective but hard to measure" such as burden – then the data becomes considerably less reliable. As a result, we would argue that studies that attempt to perform statistical analysis and establish correlations (let alone causalities) from such datasets tend to err, not because of their methodology, but because they apply what may be sound methods to profoundly unsound (or at least insufficiently reliable) data.

i. The difficulty of measuring corruption

Let us consider one simple example. At the onset of this research, we were hoping to include considerations of links between certain inspection and enforcement systems and practices on the one hand, and corruption prevalence in inspections on the other. Indeed, inspection and enforcement power can be abused by those who hold or oversee it, regardless of where orders come from, of what the law actually prescribes, of the existing safeguards etc. Such a possibility will always exist, and it would have been highly interesting to see whether certain systems seemed less corruption-prone than others. As we have discussed in earlier sections, there are reasons to believe for instance that performance management for inspection agencies based on public welfare outcomes decreases incentives for a particular form of "institutional corruption" whereby the agency tends to have an interest to find as many violations as possible to bolster its performance rating or its income (if they are linked to the number of inspection visits and of violations sanctioned). Systematically investigating this as well as other hypotheses on corruption would have required, however, some data that we could trust. Unfortunately, corruption is a very difficult phenomenon to *measure* (though it is easy to know it exists from anecdotal evidence). Indeed, the actual prevalence of corrupt behaviour is inherently difficult to measure and track. Corruption is by nature hidden, and most victims will be reluctant to report it for fear of reprisals - and in some cases the "victims" may in fact be rather willing to engage in corrupt behaviour, because it may be easier and less costly than compliance. Thus, it is very difficult to find adequate and reliable measures of corruption, and what data exists inevitably suffers from a number of limitations, regardless of the apparent precision given by scores and indices

Going further, establishing any causality between certain inspection regimes' features and corruption is even more problematic, at least if we look at demonstrating causality in a statistically- and quantitatively-grounded way. That would require not only assuming that responses to corruption-related questions were sincere (or at

least that under-reporting bias was constant in different jurisdictions and cases, which is highly unlikely), but also having databases which have been adequately checked for consistency and quality.

Considering the existing surveys which underpin the various indices on corruption (or exist as stand-alone), there are at least three different kinds of questions aiming at assessing corruption:

- Direct questions on whether the respondent has had to pay a bribe (or engage in corruption in any other way, e.g. gifts etc.), either in general to "facilitate" relations with authorities, or in direct relation with a given procedure (e.g. in our case an inspection);
- Indirect questions on whether the respondent considers that corruption is "prevalent" or "common" in a given situation (or in general in relations between enterprises and the state, or citizens and the state);
- Qualitative, rating questions, where respondents are asked to indicate how "severe" corruption is, or how much of a burden it is for their business (or businesses in general), or how "important" they consider corruption to be as a problem, etc.

Unfortunately, all three of these types of questions have shortcomings. The third category is the most obviously problematic: ratings are highly subjective, and depend on expectations, prevailing behaviours, existence or absence of comparison points, etc. They rarely correspond to what a data-driven analysis (e.g. growth or productivity factors) would indicate. They also rarely reflect the actual differences in prevalence of corruption, as examples in the following table will show. Possibly the only advantage of such questions is that answering them may be considered less "dangerous" by respondents, and so they may be relatively more open. But there are clearly major downsides in terms of reliability, particularly when trying to establish fine differences (i.e. between relatively similar countries, and not between "worst case" and "best case").

The first and second types of questions are somewhat similar, and only differ in that in the second case the question is asked more generally, and not necessarily in respect to the respondent. The second type of question is thus less precise (and, if we assume full truthfulness of replies, theoretically less reliable), and it is not possible (or at least more problematic - it depends on the exact wording of the question, as it may be restricted to "firms similar to yours") to use it to correlate corrupt behaviours with specific procedures, types of business, sectors etc.

By contrast, the first type of question is in principle the best one: it is unambiguous, precise, specific. It lends itself perfectly to quantitative analysis of any kind. The problem, however, is that available evidence suggests it is rarely fully honestly or truthfully answered (for reasons that are easy to comprehend), and also that its very precision lends itself to answers that are not "technically" false but in fact "hide" the reality. The first problem is linked to fear: in situations where corruption is prevalent, respondents (business, citizens) will frequently (but not always) fear for their safety if they report information that may be seen to be critical of the regime, or damaging for power holders. Since not all respondents will have full confidence in the strict confidentiality of the survey (whatever the assurances enumerators give them), a proportion of them will not respond truly - and this proportion varies, which makes any assumption to correct this error highly problematic, at best. The second problem is linked to the diversity of corruption - direct bribes paid during an administrative procedure or inspection are not the only form corruption takes, far from it. People may give gifts or payments at other times, support a higher official's child studying abroad, rely on friends or relatives' support to influence administrative decisions, etc. All these are *in fact* corruption of the proper working of the law, regulations, administration - but are not "making a payment to the official". Experience unfortunately suggests that most surveys do not take this issue adequately into account. And most reports analysing corruption-related questions tend to look for correlations and trends while taking all data at face value.

Formulation of questions, and truthfulness or accuracy of answers, are not the only issues affecting negatively data quality on corruption. The main problems that affect some, if not all, surveys are sample size and structure, and quality control and data cleaning. Since statistically representative surveys are a costly exercise, most such surveys are based on sample sizes that are set at the smallest possible size to produce statistically significant results on some key questions. That does not mean, however, because number of respondents may be lower for some questions, that the results are significant on *all* questions. And it is even less ensured that *variations* between different years or between countries can be measured accurately. In fact, such variations are often above the margin of error - and, contrary to a frequent situation with political polls, there are no additional measurements over several days or weeks to confirm or infirm the trends. Again, most analytical reports tend to avoid considering this issue too closely, and indeed it may not affect general conclusions (regressions over a number of countries, regional trends) too strongly, but it does preclude very precise comparisons between years or countries.

Quality control and data cleaning are possibly even more serious issues. Many surveys covering corruption issues are implemented across several countries, some of them in most of the world, which is essential to allow for comparisons. At the same time, budget constraints generally mean that the resources available for quality control (of translations of questions, of enumerators' training, of interview practices, of data entry and consolidation etc.) are limited. Practices also vary in terms of data cleaning (verification of outliers, possible exclusion of extreme outliers that cannot be explained by available knowledge or verification, etc.). This can result in aberrations being recorded as correct data, and this may be extremely difficult to spot. As a result, when data appears strongly at odds with "expert opinion", i.e. knowledge of the country based on first-hand experience and feedback from a number of direct personal interactions, it is not always clear whether this is due to the data being right and the "expert opinion" being based on biased experience, or whether the "expert opinion" is rather correct and the data happens to be of poor quality.

ii. Methodological and implementation limitations with available surveys

We have made use, in the section on the practical experience of post-Soviet and post-Communist countries, of business surveys conducted by the World Bank Group. Having been directly involved in the preparation and implementation of 5 of these, and indirectly in the supervision or analysis of many others, we are well aware of both the strengths and the limitations of these surveys. In terms of data quality overall, these surveys have benefited from large sample sizes, and strong supervision (not only by the survey firms, but by the World Bank Group teams in country), and extensive efforts to clean data by verifying consistency and cross-checking or eliminating outliers. When it comes to corruption data, however, there have repeatedly been serious problems that the survey teams were able to observe as respondent data came in. Unaccountably (at first glance), the percentage of respondents answering that corrupt practices had taken place during inspections (or other regulatory procedures) could suddenly drop from one survey to the next, whereas first-hand observations and numerous off-the-record interviews suggested this was by no means the case in reality. When attempting to cross-check the data in Tajikistan (where such a drop occurred between the 2003 and 2006 surveys), and following additional phone interviews with several hundred respondents, it became clear that the apparent drop was illusory. Many respondents did not respond "yes" because corruption took place *outside* of the inspection procedure itself (they used relations, or money, or gifts to ensure positive regulatory results – but did so *pre-emptively* and not during a particular procedure). Others were simply not convinced by assurances of confidentiality, and feared to answer truthfully. We have similarly observed very low levels of answers on corruption-related questions in regimes that were strongly authoritarian. A further limitation of these surveys (and the reason we have not tried to use them to study other possible correlations) is that they cover only a limited set of countries (several post-Soviet republics, and Mongolia), with a limited number of years (frequent surveys for some countries, like Ukraine, but only a few for others, like Mongolia or Georgia).

By contrast, another group of surveys, called worldwide the "World Bank Enterprise Surveys[686]", and known as Business Environment and Enterprise Performance Surveys (BEEPS) in Eastern Europe and Central Asia (where they are run jointly by the European Bank for Reconstruction and Development and the World Bank Group – the EBRD taking the lead[687]), offers global coverage (including a number of EU/OECD countries), and regular iterations. These surveys have been used for a very large number of research pieces[688], including many focusing specifically on regulatory issues, and on corruption.[689] Some research has in fact tried and use the large coverage of the Enterprise Surveys dataset to assess whether patterns of corruption under-reporting can be found, and indeed found under-reporting to be higher under more authoritarian regimes (Jensen, Li and Rahman 2007) – but most others have looked at corruption data as being reliable, and used it to investigate correlations with other variables.

Some of these papers reach results that are "challenging" or even difficult to understand. Knack and Kisunko (2011) thus report at face-value changes in use of bribes, and end up with (relatively free) Kyrgyzstan having far higher levels than (far more authoritarian) Azerbaijan or Tajikistan – something that is clearly difficult to reconcile with first hand observations in these countries. The answers to different questions were also seemingly difficult to reconcile for some countries (e.g. Kosovo, where many respondents both answered that bribes were rare, and that corruption was a major problem), leading the authors to elaborate complex interpretative theories, without first considering whether data quality issues may play a role. For their part, Blagojevic and Damijan conclude among other points that "results suggest that foreign owned firms are more likely to engage in informal payments" (p. 20), not considering whether they may not in fact just be more forthcoming with their answers (something that would be quite likely in our experience). They also write that most negative effects of corruption on firm performance "dissipate after 2004, indicating the general improvements in the business environment" (*ibid.*). This *might* be true but could also indicate a decrease in the level of corruption reporting by respondents (something we have repeatedly observed).

To conclude on this issue, and demonstrate more clearly why we decided *not* to attempt any systematic statistical analysis (least of all on corruption, but not on other issues either), let us look more closely at some examples from Enterprise Surveys data.

Enterprise Surveys have been conducted every few years since 2002, relying on face-to-face interviews of business operators in up to 135 different countries (the exact number can vary between different iterations). The methodology has been fully harmonised since 2005-06. The survey instrument covers a number of aspects of business operation - legal and regulatory environment, infrastructure, technology and skills, access to finance etc. The sections that are of interest to us here are the ones on "Corruption" and "Regulations and Taxes".

The WBG Enterprise Surveys (and EBRD-WBG BEEPS) have the advantage of covering a large sample of countries, including some developed (OECD, EU) ones, which allows to compare very different regulatory regimes. They have a range of questions covering corruption, but have no questions directly on inspections. They have questions on the regulatory environment e.g. licensing and construction permits (but these are rather bad proxies for inspections, as one part of the regulatory system is not always a predictor of another), and a question on "interactions with tax authorities" that *includes* tax inspections, but is not limited to them (visits to the tax authorities, e.g. to file or pay taxes, are also included). Thus, this survey can mostly be useful

[686] See website: http://www.enterprisesurveys.org/
[687] See website: http://ebrd-beeps.com/
[688] See databases of research done using these surveys – on World Bank website: http://www.enterprisesurveys.org/research - on EBRD website: http://ebrd-beeps.com/research/
[689] To name but a few examples: Knack and Kisunko 2011, Blagojevic and Damijan 2012, Denisova-Schmidt and Huber 2014

to provide data points on corruption for a large number of countries, though if no other data is available on a given country the "interactions with tax authorities" question can be used as an imperfect proxy.

There are however very significant methodological issues with the Enterprise Surveys. The first is the extensive use of "qualitative", "opinion" questions, asking respondents to rate the importance or severity of a constraint. We provide below examples of how such questions can provide results that simply do *not* reflect the real condition in a given country. The second is the relative weakness of the control on survey implementation, and also the lack of attention to whether questions are actually phrased in a way that *can* give meaningful results (i.e. if the questions simply *make sense* in a given country, or not). The third is that sample size is rather small, and that the sample does not include micro-businesses and individual entrepreneurs (which, typically, are quite affected by "petty corruption") - thus, the statistical reliability of the data (in terms of providing a reliable picture of the whole economy of a country) is not fully assured. The table below illustrates the problems with corruption-related data in the Enterprise Surveys.

Corruption data and its inconsistencies – WBG Enterprise Surveys / BEEPS

Economy	Year	Bribery incidence (percent of firms experiencing at least one bribe payment request)	Percent of firms expected to give gifts in meetings with tax officials	Percent of firms expected to give gifts to get an operating license	Percent of firms expected to give gifts to get a construction permit	Percent of firms expected to give gifts to public officials "to get things done"	Percent of firms identifying corruption as a major constraint
Armenia	2002	...	34,0	...	...	25,0	15,3
Armenia	2005	...	70,5	...	...	25,9	21,4
Armenia	2009	15,5	13,3	11,3	21,7	16,0	39,6
Germany	2005	...	14,8	...	...	...	3,9
Kyrgyz Republic	2002	...	79,1	...	...	63,3	17,5
Kyrgyz Republic	2003	...	49,5	25,0	56,3	77,4	50,5
Kyrgyz Republic	2005	...	83,8	...	...	68,3	34,3
Kyrgyz Republic	2009	42,5	39,0	25,7	56,3	47,8	58,9

Kosovo	2009	9,0	7,7	5,8	5,7	7,5	73,4
Lithuania	2002	...	29,1	...	...	49,1	18,7
Lithuania	2004	...	3,8	8,2	5,6	...	27,6
Lithuania	2005	...	35,4	...	...	43,4	16,6
Lithuania	2009	7,2	3,4	5,4	32,4	10,7	38,6
Latvia	2002	...	37,1	...	...	48,4	15,3
Latvia	2005	...	30,0	...	...	29,8	12,8
Latvia	2009	8,9	4,4	0,0	13,2	13,4	33,9
Slovenia	2002	...	15,8	...	...	15,0	4,9
Slovenia	2005	...	13,9	...	...	12,2	4,8
Slovenia	2009	2,3	0,0	0,0	3,6	5,8	9,8
Tajikistan	2002	...	84,4	...	...	68,5	18,9
Tajikistan	2003	...	44,4	84,8	86,7	55,3	23,5
Tajikistan	2005	...	71,5	...	...	51,1	20,9
Tajikistan	2008	37,9	33,0	38,5	42,3	44,6	37,8

Source – World Bank Group Enterprise Surveys for the years indicated

Through this table and subsequent ones, we have tried to show some of the problems with corruption-related data in Enterprise Surveys. To this aim, we have taken a few countries from the former Soviet Union (on which other data sources and information are available so as to cross-check the survey data), a few recent EU Member States (as "transition" comparators), and some Western European countries for reference[690].

A number of data points appear to be particularly problematic, which we outline below.

[690] Limiting ourselves to those available in the database, which does not cover all of Western Europe, and covers these countries in some years only, as they are only there as reference points and not as the survey's main focus.

First, in Kosovo, nearly ¾ of respondents rate corruption "a major constraint" but less than 10% respond positively on any of the other corruption-related questions (which are "objective" questions, i.e. of the type "did something – like paying a bribe – take place or not"). This suggests that answers to the "major constraint" may not be fully meaningful.

Second, in Germany, nearly 15% of respondents indicated that "giving gifts when meeting tax officials" was expected. This appears not to be supported by any other data, and is clearly not particularly consistent with what is usually known of the experience of firms in that country [note that the same indicator in Slovenia for that year was 0%]. It is unclear how reliable the answers are.

Third, in many cases, variations from one year to the other appear difficult to reconcile with any plausible explanation. To the author's best knowledge (with direct work experience in this field in these countries), there exists no particular set of reforms, changes or events which could explain these. For instance, the percentage of firms in Armenia reporting that they were expected to give gifts to tax officials first doubling (2002-2005) then decreasing 80%. This is compounded by internal inconsistency, as between 2005 and 2009 the percentage of respondents rating corruption "a major constraint" nearly doubled (suggesting an opposite trend). The same indicator on gifts to tax officials in Kyrgyzstan decreasing nearly 40% from 2002 to 2003, then nearly doubling, then halving again. In addition, still in Kyrgyzstan, we see the indicator "corruption as a major constraint" fluctuating wildly (nearly tripling first, then 30% down, then again up 75%) [note: major political changes did take place in Kyrgyzstan in this period, but not in 2002-2003, and in any case changes in tax administration and public administration overall were far from radical]. Likewise, in Lithuania we observe variations by a factor of 10 on the "gifts to tax officials" indicator between two consecutive surveys, repeatedly – and "wild" (if not quite as large) swings on this same indicator in Tajikistan.

In addition, internal inconsistencies are numerous – indicators on "gift to tax officials", "gifts to public officials" and "corruption as a major constraint" frequently move in opposite directions from one survey to the next (particularly in Tajikistan). Furthermore, some of the trends, even not considering all of the above, appear not to reflect reality as experienced and reflected through in depth interviews, daily experience etc. in various countries – and likewise for the relative level of indicators across different countries. Indeed, data from the most recent survey suggests that corruption in administrative procedures is higher in Kyrgyzstan than in Tajikistan, whereas most other evidence (country-specific surveys, in depth interviews, etc.) suggest that corruption in Tajikistan is *at least* as high as in Kyrgyzstan (and probably higher). While this does not in and of itself prove that the data is incorrect, when combined with the above, it certainly suggests that it could be the case. In a similar fashion, absolute levels in percentage of firms expected to give gifts to get a license or permit, even though high in Tajikistan or Armenia, seems far lower than what most in depth interviews and direct experience would suggest. This, again, raises additional doubts – particularly when combined with all the issues outlined above.

Taking a closer look at other modules of the Enterprise Surveys raises similar problems. These problems are worth considering because the Enterprise Surveys are, in fact, not worse than many other instruments routinely used for analytical reports, studies and papers – and possibly better than many. These flaws suggest that far too much confidence is routinely given to such quantitative data, resulting in researchers and analysis building complex models and testing causality, all on foundations that appear quite flimsy upon closer inspection.

Regulatory issues data and its problems – WBG Enterprise Surveys

Economy	Year	Senior management time spent dealing with the requirements of government regulation (%)	Number of visits or required meetings with tax officials	Days to obtain an operating license	Days to obtain a construction -related permit	Percent of firms identifying tax administration as a major constraint	Percent of firms identifying business licensing and permits as a major constraint
Armenia	2002	1,9	...	...	...	37,1	7,6
Armenia	2005	3,1	2,8	...	...	46,7	16,8
Armenia	2009	10,3	2,1	20,0	26,3	21,1	5,6
Germany	2005	1,2	1,3	...	...	23,2	4,0
Spain	2005	0,8	1,5	...	...	12,8	12,9
Estonia	2002	2,1	...	...	...	5,1	11,8
Estonia	2005	2,1	0,3	...	...	3,6	3,6
Estonia	2009	5,5	0,4	8,3	29,0	3,1	3,4
Kyrgyz Republic	2002	5,1	...	...	...	23,7	9,4
Kyrgyz Republic	2003	6,6	16,6	43,9	115,6	52,5	13,4
Kyrgyz Republic	2005	5,1	3,5	...	...	34,2	11,8
Kyrgyz Republic	2009	4,9	2,1	18,0	64,6	31,6	16,3
Kosovo	2009	9,8	4,5	18,8	47,7	10,4	7,5
Lithuania	2002	5,4	...	...	...	22,7	9,4
Lithuania	2004	25,9	9,5	55,5	63,4	36,8	13,4

Lithuania	2005	4,5	2,2	...	...	15,0	9,3
Lithuania	2009	9,3	0,8	65,5	44,6	28,0	23,4
Latvia	2002	5,8	...	...	...	28,4	9,8
Latvia	2005	3,2	1,4	...	...	27,9	8,4
Latvia	2009	9,7	1,5	11,5	70,0	25,0	14,4
Slovenia	2002	3,8	...	...	...	7,1	2,4
Slovenia	2005	2,4	0,4	...	...	15,4	1,6
Slovenia	2009	7,3	0,3	56,0	117,0	5,7	4,6
Tajikistan	2002	5,8	...	...	...	25,2	15,0
Tajikistan	2003	1,5	6,2	15,3	17,2	9,5	9,0
Tajikistan	2005	4,2	2,5	...	...	22,9	14,3
Tajikistan	2008	11,7	1,4	22,6	62,0	17,0	16,6

Source – World Bank Group Enterprise Surveys for the years indicated

As we can see looking at this table, data on administrative and regulatory procedures is quite problematic as well. We summarize below some of the main difficulties.

First, one of the indicators is "days to obtain an operating license" – however there is no clear definition of what an "operating license" is. The Enterprise Survey has some of its origins in work on Latin America, and "operating licenses" are quite frequent in that region. There, they are an additional approval that is mostly given out by municipalities, and comes on top of the business registration (and of tax registration too). They are "universal" in the sense that they apply to all businesses, regardless of sector etc. The Enterprise Survey team decided that from 2005-06 they would have a fully harmonised (unified) methodology worldwide, and not only kept this indicator for all regions, but adopted guidelines that prohibit any clarification of indicators by enumerators, to avoid any variation between countries (at least this is the intent, if not the result). The problem (and this is not a minor one) is that "operating licenses" of this kind do not exist in all parts of the world (though they exist in much of Africa, in addition to Latin America). Notably, they rarely exist in Europe (both inside and outside of the EU), with the exception of Greece (where they are not fully universal, but close to it). Nor do they exist in the Former Soviet Union, for instance. This does not prevent the surveys from asking the questions, recording responses, and then does not prevent research articles or reports from analysing this data. It is likely that either translators in each country will give a different meaning (one that "seems to make sense"), or each respondent will answer based on whatever s/he assumes to be meant (probably taking whichever license he has recently obtained for a particular activity – but not all businesses obtain licenses, so

many respondents must answer based on their experience with other procedures). This introduces major scope for data errors.

Second, several countries show massive increases in the "senior management time spent dealing with government regulation" over time, particularly in the 2009 survey. Again, this happens without any known event or change which could be a credible explanation. On the contrary, in most countries affected by this increase, important regulatory simplification reforms took place. Even assuming very imperfect implementation of these reforms, a radical worsening of this kind is surprising, and is more likely to indicate low reliability of the indicator. Indeed, the question is difficult to answer reliably for many respondents. It could also reflect the effects of an unreliably low sample size. For instance Armenia sees this indicator triple from 2005 to 2009, and Tajikistan is also close to tripling, as well as Latvia, Slovenia. In Lithuania, there is first an increase (by a factor of 5) from 2002 to 2004, then a decrease (by the same factor), then a doubling. Such variations suggest that the indicator is essentially random (i.e. respondents answer "whatever comes to mind").

Finally, "number of visits or required meetings with tax officials" is an indicator that could be useful for our purpose (as a partial proxy for "inspections"). Unfortunately, the quality of this indicator is doubtful. For Tajikistan, it shows a very rapid decrease that is not confirmed through any of the other available surveys (which have larger sample sizes and a narrower focus on the topic). In addition, the reported number of interactions in Tajikistan is several times lower than only the number of inspections (as measured by the more detailed World Bank Group surveys we presented earlier, which had a far larger sample size and more "intensive" quality control), without even counting the many visits to the tax authorities needed to file for many taxes there. In Kyrgzystan, the scope of the decrease appears far larger than what other available data, as well as the contents of reforms, would suggest.

A final look at another part of the Enterprise Survey data (infrastructure, including access and quality) will allow us to further justify our refusal to engage in complex statistical analysis on the basis of any of this data, and to consider all "subjective" questions (asking respondents to rate the importance of a problem) with the utmost caution. Looking at the questions on infrastructure indeed allows to compare such ratings with easily observable, objective reality on infrastructure quality in different countries.

Enterprise survey data on infrastructure – reality and opinion

Economy	Year	Days to obtain an electrical connection (upon application)	Percent of firms identifying electricity as a major constraint	Percent of firms identifying transportation as a major constraint
Armenia	2002	2,5	13,1	10,4
Armenia	2005	2,5	3,1	10,2
Armenia	2009	16,3	24,9	26,3

Germany	2005	3,2	1,0	1,6
Spain	2005	9,3	8,3	10,8
Kyrgyz Republic	2002	3,5	1,7	1,7
Kyrgyz Republic	2003	22,1	4,0	3,0
Kyrgyz Republic	2005	14,1	1,3	1,3
Kyrgyz Republic	2009	25,2	58,0	30,9
Slovenia	2002	9,6	0,8	0,0
Slovenia	2005	12,7	2,3	0,8
Slovenia	2009	60,8	23,3	12,3
Tajikistan	2002	12,5	15,0	3,8
Tajikistan	2003	11,6	22,1	5,2
Tajikistan	2005	5,3	10,8	2,2
Tajikistan	2008	28,3	39,2	22,9

Source – World Bank Group Enterprise Surveys for the years indicated

Once again, the data appears plagued by two combined problems: unreliability of data in terms of internal consistency (suggesting problems with data quality), and unreliability of "identification as a major constraint" questions as an indicator of the actual situation for businesses. Looking at a few examples makes it clear.

As a first problem, we see wild swings in the days needed to obtain an electrical connection in Tajikistan from one year to the next, again not related to any known change in the system and practices, suggest that the number of respondents is too low, or some outliers or data entry errors cause the average (mean) value to increase or decrease without reflecting the "actual average" in reality. The massive increases in days needed for such a connection in Armenia and Slovenia also appear difficult to explain. Since systematic checks of outliers are not necessarily undertaken by contractors, these may be enumerators' errors, data entry errors, or whatever else.

A second illustration can be seen on transportation. In practical terms, transportation in Tajikistan is a major issue (lack of paved roads and/or horrendous conditions of said roads, very limited rail links to the outside, rare international flights etc.) – but only 2-5% of respondents in 2002-2005 rated it as a "major constraint". While real improvements (however limited) took place after 2005, the percentage suddenly jumped by a factor of 10 (to nearly 23%). This suggests that people respond to such questions based on the salience of various issues for them at a given time, their expectations, their points of comparison (or lack thereof), possibly the

order of questions, etc. A roughly similar comment can be made for data on Kyrgyzstan and Armenia, which clearly understates the extent to which transportation is a problem in these countries. In the same vein, in 2005, nearly 11% of respondents in Spain rated transportation a major constraint – which is far more than in landlocked Tajikistan and Kyrgyzstan, more even than in Armenia. While this may correspond in some cases to different propensities to trade beyond an enterprise's home city (if no trade is undertaken beyond a few kilometres, transportation may indeed not be a "constraint"), it is nonetheless clear that these responses do not in any meaningful way reflect the objective situation in terms of quality of transport infrastructure, transportation times etc. As a result, such data is quite simply irrelevant when one tries to determine the "picture" for a given country in terms of constraints for economic development.

Considering these major flaws in available data (and the Enterprise Surveys are most likely not worse than most other "global" datasets – the easy accessibility of the detailed data just makes it easy to point out the problems), we have decided not to attempt any statistical analysis – regressions and any other tools pointing to correlation (or lack thereof), and more complex tools to try and isolate specific factors and causal links. We simply believe that such analysis would be close to meaningless considering the unreliability of the data, whether caused by poor data quality (insufficient samples, lack of data verification and cleaning etc.), excessively complex questions (to which respondents *cannot* reliably answer because they assume a level of knowledge they do not have, e.g. when asked about percentage of their time spent on something in a given year), or "inherently unreliable" questions (where people are asked to rate "major constraint", which will be answered based on salience of experience, which is not what is relevant to analyse the situation in the country).

We have, rather, chosen to limit ourselves to observing aggregate, country-level trends. We believe that the results thus achieved are clearly limited in terms of establishing correlations or causations, but that they are more solid in the sense that they are not built on fragile data. We have indeed chosen to rely only on surveys where we had a reasonably high level of confidence in the data quality, and within these surveys only on questions where the objectivity and straightforwardness of questions minimized the risk of bias or error. We have also taken official (inspectorates, Eurostat etc.) data, again selecting only those sources and indicators that were most reliable. In the way we used this data, we have avoided attempting to conduct statistical correlation or other analysis, but rather looked at high level, aggregate comparisons. Because they all leaned in the same direction, and in spite of the limitations of the approach, we hope these case studies have shed some light on the relative effects of different inspections and enforcement approaches, and indicated some directions for future research.

5. Conclusion

As suggested in our introduction, we have attempted throughout this research to try and bridge the gap between "theory" and "practice" perspectives, i.e. to bring together perspectives issued from decades of research on enforcement methods, compliance drivers and risk regulation – with knowledge, experience and data coming from practitioners of regulation and regulatory reform.

We set out to investigate whether risk-based approaches to inspections, and more broadly what one could call "smarter" approaches to inspections and enforcement, appeared to live up to their promises – namely a "win-win" result of higher effectiveness (or at least constant effectiveness with reduced costs and burden), higher efficiency, and better economic results. In so doing, we also sought to validate the consideration of inspections as a specific and distinct object, to present some of the main variations in inspections practices, and to define more precisely what risk-based, "smarter" inspections consisted of – and what exactly was to be understood under the word "risk". We also intended to look at the issue of trust (between market actors, in the regulatory system), and the extent to which different inspection methods may influence the trust level. Finally, we intended to look into the question of outcomes – how they are defined and measured, how differently formulated goals may influence actions and results, and what measurement challenges exist in order to assess the impact of inspection practices.

5.1. Testing our hypotheses

If we now consider our three main hypotheses, there are grounds to consider them validated to a significant extent. First, that inspections are a distinct object with their own range of effects, distinct from that of the regulations they aim at implementing, appears strongly demonstrated. This stems both by the historical perspective, which shows the specificity of the institutional development of inspections, independently from regulations, but also by the comparative perspectives, where jurisdictions with similar legislation (e.g. EU countries on food safety) have very different situations and results linked at least in part to different inspections and enforcement methods.

Second, risk is an important instrument to define goals and indicators, allocate resources, select priorities, decide on proportionate enforcement measures – but it is also a word fraught with polysemy, and a phenomenon that gives rise to conflicting perceptions. The effective implementation of risk-based approaches in inspections and enforcement requires an adequate definition of risk (combining not only probability of hazard, but its potential magnitude), as well as data to ground planning and prioritization of actions. It also requires an enabling legal environment, which is sometimes problematic, and a political environment that likewise allows it, and does not impose a risk-averse approach. We have seen that, while there appears to be a strong justification for enabling risk-based discretion, forces that push towards risk-aversion are strong, and risk-assessment is sometimes difficult (uncertainty, lack of data), and/or conflicts with common perceptions.

Third, to the extent that data is available and can be relied upon, and leaving aside for a moment the question of causality and attribution, there exists some preliminary evidence that risk-based inspections practices produce better outcomes than other approaches, and that lower inspection numbers and more supportive enforcement practices do not lead to worse compliance levels, but rather (if done in the context of better targeting, "smarter" enforcement, more guidance etc.) to better safety levels (at least in some cases). The difficulty, however, is that data is far from sufficient to deliver strong evidence and very robust findings. Detailed, firm-level data is difficult to access, unavailable in many cases, frequently unreliable. Aggregate data is not always of high quality, and presents attribution issues. In addition, the question of economic impact is very difficult to properly investigate.

5.2. The case for risk-based inspections

Considering one of the most striking cases that we reviewed (occupational safety and health inspections and safety levels compared in Britain and Germany, and – with less detailed data – in France), it appears that the British HSE has long been conducting less inspections, putting more emphasis on risk-management and compliance-promotion, and achieved considerably better results than comparator countries. If comparing with Germany (where data is more detailed), Britain has been having consistently several times less frequent inspections and overall better outcomes (though Germany has been catching up). If comparing with France, safety in Britain is far higher, and so appears to be the overall trust in the system and trust between the different stakeholders (though this is based on non-quantitative evidence, the level of conflict around labour inspections in France is very high, with police protection regularly necessary, while effectiveness is clearly in question).

Of course, none of these findings is fully "robust" – cases were not randomly selected but picked because of data availability and knowledge about the different systems, labour inspections in France (and to some extent in Germany) check also other issues than OSH, we did not consider other safety indicators than fatal accidents (because they are known to be less reliable and/or, for occupational diseases, have a very strong time-lag), and the differences in performance may have a variety of causes. In addition, data on the economic impact of inspections is limited, so we had to use the number of inspections as a simple proxy (though Britain also has inspections that are far more "supportive" of businesses, guidance-oriented, and not only less frequent, thus there is a strong likelihood that they indeed create far less economic burden). Overall, the case is strong in favour of more risk-based and "smarter" inspections, but it is not without flaws in terms of data.

5.3. Challenges with data, and methods

What can be hoped for is that, this research having established with some level of evidence that the inspection issue is worthy of specific study, and that certain aspects deserve particular attention (targeting and enforcement models, safety outcomes etc.), there could be successive research undertakings focusing on specific inspection functions and jurisdictions, and attempting to use firm-level data to investigate correlations and possible causations in a more quantitative way. There would, however, be significant challenges in strict data-based investigations. First, firm-level data may be impossible to obtain (confidentiality or faulty information systems), and/or may require significant resources to conduct *ad hoc* surveys. Second, as we have attempted to show, there may be substantial problems with the quality of data, and with the interpretation of answers to surveys.

Overall, it is not certain that attempting to conduct such studies would be the best way to increase knowledge and understanding of the field. Were more governments to conduct representative business surveys assessing overall coverage and burden from inspections, as well as collecting some key "qualitative" data, and were more researchers to consolidated available data from inspectorates, our collective understanding of inspection activities would already greatly increase. If, in combination, more governments were to conduct surveys allowing to test the situation in terms of key public welfare outcomes (safety levels, prevalence of certain diseases, etc.), our knowledge of outcomes would be far greater than it is now. Even absent such additional resources and surveys, a deeper look at existing data sources (e.g. epidemiological) could allow to better assess the relative performance of different jurisdictions. Thus, rather than a focus on firm-level data research (which, as we have seen, seems to produce conflicting results, for a number of reasons), the field may be better served by more investigation of existing (consolidated) data at the level of entire jurisdictions and agencies, at least in a first phase. It is not clear, given the state of social sciences research and the issues

posed by data concerning complex social phenomena, that studies based on statistical analysis of correlations (and on testing causal models) would necessarily produce more useful results[691].

5.4. Limits and downsides of inspections

We think that this research at least shows the relevance of investigations of inspection practices and their effects, purported and real, challenging assumptions and "established wisdom". Indeed, the default assumption is still too often that more means better (and that stricter also means better). In reality, on the contrary, the effect of inspections is far from obvious. If we consider historical developments, the Netherlands set up a labour inspectorate only decades after France, Germany or Britain – it would be interesting to see whether the evolution of occupational-related deaths and injuries was markedly different or not. Indeed, available data suggests that improvements in such indicators took place regularly in the United States long before inspectorates were created. Likewise, major improvements occurred in food safety even at times when inspections were few and far between, conducted with methods and techniques that would not be considered adequate today. Improved technologies, better science, social movements, prevailing cultural norms etc. were all major drivers of these changes. How much of a role regulations and inspections play is still difficult to assess, but it may not be as much as some of their staunchest advocates claim.

The string of factory disasters in Bangladesh (and other countries of Southern and South-East Asia), which had as its most salient tragedy the *Rana Plaza* collapse[692] killing upwards of 1,100 people, illustrates the limits of inspections and enforcement. Even though the international outcry following it included many voices calling for more stringent inspections and enforcement, a closer investigation of the events leading to the building's collapse suggested this was not as easy (or as certain to produce results) as it sounded.[693] Indeed, inspectors had in fact responded to calls by workers that warned about the building being structurally unsafe, and ordered its closing, but their orders were simply disregarded by the owners. Thus, the disaster (and its causes) pointed to far more structural issues: weak rule of law (particularly for certain categories of powerful people), deep social inequality in terms of enforcement of legal rights, prevailing social norms among factory owners etc. Better targeted inspections and stronger powers for inspectors may be part of the solution, but they were (and are) far from certain to be sufficient.

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[691] From our perspective, the current (disputed) "replication crisis" in social sciences reflects a number of issues, including less-than-optimal methods in a number of cases (bias against "null effect" reporting, excessively small samples, manipulation of samples to achieve statistical significance etc.), but is also likely to reflect the sheer complexity of the phenomena being studied, for which the variables measured may be inadequate proxies, and the difficulty to have reliable answers (or reliable interpretation of answers) on complex human behaviours and affects, when conducting surveys. We have already referred to the Open Science Collaboration (2015). Many other scholars have weighed in regarding replicability in psychology (and particularly social psychology). Pashler and Wagenmakers (2012) wrote that: "replicability problems will not be so easily overcome, as they reflect deep-seated human biases and well entrenched incentives that shape the behavior of individuals and institutions. Nevertheless, the problems are surely not insurmountable" (p. 529). Stroebe and Strack (2014) dispute the idea of a "crisis". For them, "because experiments are typically conducted with the aim of testing a theoretical hypothesis, the important question is not whether the original finding can be duplicated but whether it constituted a rigorous test of the postulated mechanism" (p. 62). In other words, if the original experiment was a poor test of the theory, replicating it will not give further "proof" of the theory – and not replicating it will not invalidate the theory either. Gilbert *et al.* (2016) have also challenged the Open Science Collaboration paper and findings, and write that they "did not take into account the multiple sources of error in their data, used a relatively low-powered design that demonstrably underestimates the true rate of replication, and permitted considerable infidelities that almost certainly biased their replication studies toward failure". Our tentative conclusion would be that, given the very high complexity of the interactions studied in the field of inspections, the very high chances for flaws in data or differences making replication impossible, the many ways in which design can have flaws that make the study inadequate to test the theory, this may simply not be the most productive approach, and a more modest approach using aggregate data and qualitative approaches may be more fruitful.

[692] See Wikipedia article: https://en.wikipedia.org/wiki/2013_Savar_building_collapse for a summary and sources

[693] Source: unpublished World Bank Group assessment in which the author was involved.

Increased inspections and "tough" enforcement may thus be neither strictly necessary to secure safety improvements, nor always effective at doing so either. They may in addition be harmful, if misguided because of a political "knee-jerk" reaction to a (real or purported) scandal. A recent illustration of what has been called in the Netherlands the "risk regulation reflex" can be seen in the nail salon "scandal" and its aftermath in New York City.[694] After the original reporting (by the New York Times) claimed rampant abuses, exploitation and unsafe working conditions, the City and the Governor responded with stepped up inspections and new regulations. These led to a significantly negative impact on businesses and their workers (closed salons, lost jobs), whereas further reporting a few months on showed the original report to have been nearly fully wrong (misrepresented facts, translation problems, exaggerations etc. led to its having little in common with reality). This is just an illustration of the fact that inspections are not a purely benign instrument – they can fail at their stated purpose, and they can also create actual harm. As such, their use needs to be carefully thought through.

5.5. Inspections and trust

To a significant extent, and this echoes one of our opening questions, an essential role of inspections and enforcement appears to create *trust*, and this may be the way in which their most positive effects are achieved – but even in this respect the risk of "overshooting" also exists. "Credible" inspections and enforcement are expected and requested by different groups of market participants and act for them as a guarantee that others will abide by the rules, and thus give them the appropriate assurance that they can engage in market interactions without excessive risk taking. In this respect, inspections and enforcement create a "floor" of confidence, and a risk-mitigation mechanism. They are also an important driver of compliance not only or even mostly through deterrence, but by reinforcing voluntary compliance: those who comply voluntarily have the confidence that the rules of the game are enforced and that those who are trying to undercut them through non-compliance do not have free rein. Credible inspections and enforcement reinforce the expectation of compliance, and thus increase trust among businesses (towards suppliers and buyers), workers (towards employers), consumers (towards sellers) etc. In an optimal situation, it reduces the reliance on litigation, reduces uncertainty, thus decreases costs and ends up having a positive economic and social impact.

There are however limits to the use of inspections to create trust. One of the earliest uses of regulations and inspections, as we have seen, has been to establish and enforce weights and measures, which in turn enable trade by simplifying transactions and reducing the risk for buyers[695]. This has early on started to evolve towards regulations and inspections covering the *quality* of goods, such as we have seen with the French *Inspection des Manufactures.* Such "quality inspections" are not, however, without problems in a market economy context. Defining quality is a very difficult proposition, at least when it goes beyond the definition of what a particular name should correspond to, and attempts to step into coercing sellers to provide only "good quality" wares. For instance, defining what can be called "olive oil" and what should only be called "vegetable oil", or what can be called "chocolate" and what should only be called "confectionary with cocoa" is a relatively narrow intervention, and can be grounded on clear norms, botanic and chemical definitions etc. By contrast, who is to determine (and how) whether garments, furniture or any other wares (or services) are of "adequate

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[694] See successive reporting by: the New York Times, exposing the "scandal" (May 2015) http://www.nytimes.com/2015/05/10/nyregion/at-nail-salons-in-nyc-manicurists-are-underpaid-and-unprotected.html?_r=0 – the New York Review of Books, exposing factual errors (July 2015) http://www.nybooks.com/daily/2015/07/25/nail-salons-new-york-times-got-wrong/, and Reason followed by the New York Post fully deconstructing the original reporting, and showing the strong negative consequences it produced (October-November 2015) http://reason.com/blog/2015/10/27/new-york-times-nail-salon-unvarnished - http://reason.com/blog/2015/11/10/new-york-times-nail-salons-ron-kim - http://nypost.com/2015/11/03/the-new-york-times-refuses-to-face-facts-on-its-bogus-nail-salon-expose/

[695] This function is also important for other regulatory instruments such as licensing, certification or registration – cf. Kleiner 2006.

quality"? If such powers are given to inspectors, there is a real risk of abuse, decisions that are not grounded in clear requirements, excessive market restrictions, and plain and simple waste of resources.[696]

5.6. Closing remarks and questions

It is clear, thus, that this research's conclusion opens more questions than it gives answers. We hope to have shown that inspection institutions and practices, and their evolution and variations, are important objects that deserve to be researched and considered independently rather than simply amalgamated into "regulation" or "law enforcement". There is evidence that the effect of inspections is ambiguous and can be positive (on trust, on compliance, and to a somewhat unclear extent on safety and other public welfare outcomes), but also negative (on economic activity, employment, and also on trust and compliance if inspection practices are poor).

There is also evidence that risk-based approaches to inspections planning and implementation, and to enforcement decisions, seem to produce better results *both* in terms of safety, compliance and other targeted outcomes – but also in economic terms. The role of "risk" appears particularly central, with risk-averse reactions tending to produce poor regulatory outcomes, but an adequate understanding and management of risk seeming essential to balance different priorities and improve results. As the instrument allowing to assess priorities and to decide on what action to take and which resources to allocate, risk can be seen as the "currency of regulation"[697], i.e. the common unit that allows to "trade" between different priorities.

Specifically, risk-focused and risk-proportionate inspections and enforcement, combined with an approach that seeks to promote compliance by drawing on all its drivers rather than a narrow deterrence angle, can result in significantly improved public welfare. It also appears that such approaches work best when they combine:

- High level of professionalism and skills, not only in the narrow technical sense but encompassing a variety of competences (relations with businesses, risk management etc.);
- Balanced risk assessment methodology combining intrinsic risk with compliance history and confidence in management – supported by data and information technology to effectively target inspections and manage follow-up actions;
- Responsive and risk-proportionate enforcement, where the emphasis is on achieving increased compliance overall rather than symbolic punishment (even if the latter can be used in some cases);
- Active efforts to promote compliance through clear and reliable guidance, advice etc.;
- Transparency in methods, criteria, processes, decisions, combined with giving a real "voice" to duty holders, so as to maximize the sense of procedural justice and resulting legitimacy.

Such approaches can only be fully established in a context of agreement about goals, i.e. consensus that the primary objective of inspections is to achieve reduced risks and/or improved public welfare (in particular through an increase in compliance with specific regulations, but not only). In the absence of such consensus, e.g. for instance when the primary objective is seen as identifying and punishing violations, this combination of elements will be impossible (even if, for instance, targeting of visits is "risk based") and the results will unavoidably be different. Hodges (2015) has shown how there can be a very direct tension between achieving increased safety results and "punishing violations" (see e.g. the case of aviation safety pp. 326-329, where the

[696] See e.g. the case of Lithuania's Non-Food Products Inspectorate, which is forced by poorly-worded legislation and ingrained practices to conduct inspections upon consumer complaints, even when no legal norm has been infringed, i.e. pure "quality" inspections. These mostly relate to trivial issues, and have little results, but waste considerable resources for the inspectorate (and for businesses). See OECD (2015) pp. 132-134.

[697] This expression courtesy of Graham Russell, Director, UK Better Regulation Delivery Office

promotion of what is called as a "just culture" where reporting safety incidents is incentivized cannot, by definition, be done in a context of systematic punishment of violations).

Finally, there is a complex set of activities that are directly connected to inspections and enforcement tasks and institutions, but are distinct from inspections *stricto sensu*, such as provision of information and guidance. We have deliberately included some coverage of these in this research, as it is indispensable to properly assess inspectorates' activities and effectiveness, but a better word than "inspections and enforcement" may be needed to designate this field and this set of activities and institutions. In the United Kingdom, the expression "regulatory delivery"[698] has been adopted for this purpose – which also includes other regulatory instruments such as permits or licenses. Researching not only how inspections and enforcement are organized and conducted, but also in what broader "regulatory delivery" system they fit, and how different "regulatory delivery" models perform, also seem like important areas of future research.

Just as the field of inspections research as such, and particularly from a comparative context, is still relatively new (even though some very important works were written several decades ago, the "field" as such only emerged gradually over the last decade and a half[699]), policy interventions specifically targeting inspections are also relatively recent. Considering more thoroughly the different reform experiments[700], the different practices and their impacts, is clearly needed. We hope to have provided here some first elements that allow to show the relevance of such research, and to point at some directions it could take.

In addition, the question of methods to promote, support and verify compliance is important also for other areas of legislation – for instance the implementation of EU legislation by Member States[701], but also the "delivery" of legislation and rules applying to private citizens. Just as this research has drawn considerably from research originally focused on interactions between "law enforcement" (judiciary and police) and citizens, there is considerable potential for findings from studies of regulatory inspections and enforcement having relevance in other fields.

As a final word we hope that, in spite of its many limitations, this work will have shown the importance of challenging assumptions and beliefs when it comes to inspections and enforcement, and that there is a real possibility of "doing things better", in a way that benefits all stakeholders. In this respect, spreading what we *already* know is maybe as important as conducting further research to increase our knowledge, or test its limits.

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[698] See the webpage of the UK's Better Regulation Delivery Office - https://www.gov.uk/government/organisations/better-regulation-delivery-office/about

[699] With "official recognition" internationally being achieved *inter alia* through the publication of the OECD's *Principles* (2014)

[700] As presented e.g. in Blanc 2012

[701] See Voermans 2015

Note on sources

To the extent possible, we have attempted to reference published sources to as to allow readers to cross-check our statements or to look for further details and information. This we have done even in cases where we had first-hand information or data on the issue, always preferring to refer to the published version. In the course of our work on inspections, however, we have had many opportunities to obtain first-hand insights into structures, practices, approaches, mind-sets etc. that are not reflected in any publication. This was not, however, typically collected as part of "research field-work" but as part of our work as a project manager or technical expert for inspections reform projects implemented by the World Bank Group, or during discussions with colleagues working on inspections issues (as inspectors or reformers) in various countries, but always in a professional capacity. In some countries, in spite of not being present "on site", we participated in online discussions and had access to unpublished reports. As a result of the vast number of these meetings and interactions, listing all of them or giving all of the dates would be not only tedious but impossible. We only, for the reader's information, give a short summary of our main direct interactions with government officials in charge of inspections below, including countries, years of involvement or interaction, and short comments on the frequency, as well as on the profiles of officials involved.

Country	**Dates**	**Interactions**
Armenia	2008-2016	Frequent, on site and remote– political, senior management, operational
Azerbaijan	2009-2010	Repeated, on site and remote– senior management
Bangladesh	2013	Occasional – remote work with World Bank Group staff and experts
Belarus	2009-2012	Occasional – remote work with World Bank Group staff and experts
Bosnia	2008-2009	One-off on site visit (senior management) and remote exchanges
Cambodia	2011-2013	Repeated, on site and remote – political, senior management, operational
Colombia	2008	One-off on site visits – operational/management
Côte d'Ivoire	2014-2016	Occasional, on site and remote – senior management, operational
France	2012-2014	Occasional, on site – political and senior management
Georgia	2014	One-off on site visit – senior management
Greece	2014-2016	Frequent, on site and remote– political, senior management, operational
Guinea	2012	One-off on site visit – senior management
India	2013	Occasional – remote work with World Bank Group staff and experts
Italy	2012-2016	Repeated, on site and remote – senior management
Kenya	2010-2012	Repeated, on site and remote – senior management and operational
Kyrgyzstan	2008-2016	Repeated, on site and remote – senior management and operational
Latvia	2004-2008	Three visits (senior management and operational levels) + remote exchanges
Liberia	2012-2014	Occasional – remote work with World Bank Group staff and experts
Lithuania	2011-2016	Frequent, on site and remote – political, senior management, operational
Mongolia	2008-2016	Frequent, on site and remote– political, senior management, operational
Nepal	2013	Occasional – remote work with World Bank Group staff and experts
Netherlands	2008-2016	Repeated, on site and remote– senior management, operational
Peru	2011-2014	Occasional – remote work with World Bank Group staff and experts
Poland	2008	One-off on site visit – operational/management
Slovenia	2012-2014	Occasional remote – one-off on-site visit (senior management)
Tajikistan	2004-2015	Frequent, on site and remote– political, senior management, operational
Ukraine	2006-2010	Frequent, on site and remote– political, senior management, operational
United Kingdom	2010-2016	Frequent remote, occasional on-site – senior management, operational
Uzbekistan	2004-2006	Repeated, on site and remote– senior management

Summary

Regulations edicted by governments to govern certain aspects of economic activities have existed for thousands of years, but have rapidly increased in number and expanded in scope and complexity over the past century and a half, with an acceleration in the last few decades. Given that these regulations generally have significant utilitarian goals (and often symbolic ones as well), it is not surprising that governments have also increasingly developed instruments to control and increase compliance with these rules: inspections and enforcement, generally conducted by specialized structures created (or transformed) for this purpose. Such regulatory inspections (and the institutions that conduct them) have not, however, appeared everywhere and in every area at the same time, nor have they developed in identical ways and at identical pace. There are considerable differences in history, structures, resources, and methods – both between countries, and within a given country between different regulatory domains.

Whether, and to what extent, these efforts at making businesses or citizens comply with regulations have been successful is also a complex issue. In most countries, outcomes in terms of health and safety have improved, but it is hard to tell how much is owed to increasing prosperity, and how much to regulatory compliance – or how much compliance owes to increased resources, skills and a changing society, and how much to enforcement efforts.

In recent years, following on concerns about "regulatory burden" and efforts to achieve "better" or "smarter" regulation, attention has also turned to inspections and enforcement. Government reform programmes have been launched, national and international institutions have developed guidance documents, and research has been done on whether, and how, inspections and enforcement could be made more effective, more efficient (less costly and/or burdensome), or both. Strong claims have been made that adopting risk-based approaches, i.e. focusing control efforts on establishments and issues presenting the highest risks, and taking enforcement decisions on the basis of risk, would reduce burden and costs, and increase effectiveness.

In spite of this, there is so far no conclusive body of evidence on the extent to which these claims are realised, and also no universally accepted understanding of what these "smarter" inspections would entail. There have been, in recent years, some important efforts to compare inspection practices and risk-based regulation between different countries, but generally not trying to look at effectiveness issues. Conversely, studies that have tried to look at compliance or effectiveness effects have rarely taken a comparative perspective. Academic literature on compliance also often remains divided between conflicting perspectives, emphasizing e.g. deterrence or voluntary compliance as primary drivers. Even though a number of scholars have developed more balanced, complex models of compliance, these are not always widely used by either academics or practitioners of regulation.

This research first considers the question of what exactly "smart inspection" practices, based on risk-based inspections, risk-proportionate enforcement, but also including efforts to promote compliance through other ("softer") measures, consist of. It seeks to examine the history of their development, and considers their theoretical underpinnings, as well as their legitimacy to the extent that they rely on a specific way of openly embracing organized regulatory discretion. Finally, and possibly most importantly, it attempts to look at whether evidence can be found regarding the effectiveness of such "smarter" approaches, and how it compares to other inspection methods which are not (or less) risk-based, and take less of a responsive approach to enforcement.

Consideration of the history of the development of inspection institutions and practices focuses on several cases – food safety and occupational safety and health (OSH) in Britain and the US, as well as France, Germany, the Netherlands, and the EU as a whole (for food safety).

The cases were selected for a combination of reasons: food safety and OSH were among the very first regulatory areas where inspectorates were created, they remain among the most high-profile and strongly resourced ones, and the countries considered were generally among the first to set up such institutions, among the most important economies of the period considered, and/or offer interesting contrasts in terms of trajectories and approaches.

This historical review leads to several findings, in particular that the creation and development of inspection structures and practices is generally linked more to risk perceptions than to scientific risk assessment, that path dependency plays an important role in determining today's setups and approaches in various regulatory fields and countries, and that some countries (and the EU, in food safety) have increasingly embraced risk-based approaches in inspections, while others remained (for a variety of reasons) more reluctant to do so.

The literature review covered several aspects: general perspectives on regulation and regulatory instruments, as well as their economic consequences, explanatory models for regulatory compliance, perspectives on regulatory discretion, and risk-based regulation.

Fundamental works on regulation and rules, including by the likes of Ogus, Diver or Baldwin, show the impossibility of achieving perfect rules, and the trade-offs that have to be accepted when chosing between more specifications-based or more outcomes-based norms, between more certainty and more flexibility. These lead to emphasize the importance of the enforcement stage.

Research on the economic consequences of regulation is complex, and often inconclusive. Porter and others have shown that, in some cases at least, higher regulatory requirements can actually go along with increased competitiveness. Rodrik, Djankov and many others have, however, concluded that poorly administered regulations, burdensome procedures, arbitrary enforcement etc. could have significant negative consequences – showing once more the importance of how regulations are "delivered".

Very different models of regulatory compliance have been put forward – from those focusing on deterrence and rational calculations (Becker), to far more complex models emphasizing procedural justice and legitimacy, but incorporating several other factors (Tyler, Lind). Experimental results tend to produce diverging results in a number of cases, but the complementarity of compliance drivers seems to be the most convincing perspective: capacity to comply (knowledge, finances) is fundamental, social conformity and legitimacy are strong drivers, and deterrence (rational calculations) is a driver of generally lower strength than conformity and legitimacy but can play a strong role for some people or companies, and/or in some circumstances (as not all rules are viewed in the same way by all people). This shows the importance of a balanced approach to enforcement – and a risk-focused one, to avoid pushing those who would willingly comply towards resistance, and to improve procedural justice as well (as criteria for decisions are made clearer).

Perspectives on the legitimacy of executive and prosecutorial (and, by extension, regulatory) discretion are highly conflicting – and, in addition, differ according to legal traditions. At least in the Common Law and Roman-French traditions, however, there is overall a strong deference to the opportunity principle, which offers room for regulators to adopt a responsive approach to enforcement, in line with a broader risk-based framework. Thus, while such discretion is not unproblematic, there is at least a significant body of legal writing and case law to support it.

Finally, risk and regulation research points both at the relevance of the issue, and at the very different ways in which risk is defined and managed. While some authors (e.g. Black and Baldwin) also point out the challenges existing in terms of having sufficient information for proper risk-based planning, practice suggests that, for a number of inspection functions, this challenge should not be overstated.

Overall, the literature review points both at the importance of the inspections and enforcement stage, at the need to have an approach that covers all compliance drivers in a balanced way, and at the crucial and complex role of discretion. It also shows that there are different understandings of risk, and that the meanings that have been used by some researchers differ significantly from what is commonly accepted e.g. by the OECD or government-level institutions – which may explain some apparently disappointing research findings.

Case studies form the last part of the research, and allow to try and test the hypotheses and look for an answer to the research question. The first (and most detailed) case study looks at OSH inspections in Britain and Germany (building in part on previous research by Tilindyte). The second considers inspections in countries of the Former Soviet Union, how they compare to practices in OECD/EU countries, and what have been the results of efforts to reform them in a more risk-based direction. The last one looks in a shorter manner at a few EU countries and at some salient aspects of existing practices and reform efforts. The chapter then considers available data and whether it could allow to search for correlations between inspection practices and outcomes, and concludes that the quality of data would not allow for robust findings.

The first case considers the evolution of OSH inspections in Britain in the past decade and a half, and compares the number of inspections, methods and outcomes with Germany. The case was selected because OSH is relatively unique among inspection functions in that at least one of the outcome indicators (fatal occupational accidents) has a high level of reliability and comparability. Harmonization of data by Eurostat makes it easy to compare. The case shows that British OSH inspections are strongly risk-focused, risk-proportionate and responsive in enforcement decisions, and also put a strong emphasis on guidance and compliance support. The data shows that whereas British OSH inspections are several times less frequent than German ones, outcomes are significantly better over the past 15 years and more. In addition, the frequency of inspections has gone down in both countries, but fatal accident rates have also gone down (more strongly so in Germany, where the level was far higher at the beginning). While this is not enough to prove that risk-based approaches caused this better performance, the case certainly suggests that they may have played a role, and in any case disproves the idea that more inspections would necessarily be correlated with better outcomes.

The successive cases lead to the same findings. Data from surveys conducted by the World Bank Group in the Former Soviet Union shows typically very high levels of inspections coverage, without this resulting in any way in high levels of compliance or positive outcomes. Moreoever, reforms resulting in a very significant decrease in inspections numbers do not lead to any worsening of outcomes. On the contrary, countries that underwent significant reforms of inspections towards a more risk-based, compliance-promoting approach (e.g. Lithuania) also tend to have better outcomes. A brief consideration of OSH inspections in France reinforces the findings from the Britain-Germany comparison: France has vastly more frequent inspections than Britain, combined with a “zero tolerance” approach grounded in a view of compliance as purely deterrence-driven, and has outcomes that are significantly worse than the EU-28 average (whereas Britain has among the best, or the best results, depending on the year considered). Survey data on inspections in Italy shows that inspections there tend to target many times the same businesses, resulting in a high level of burden for around a third of businesses, with limited positive effects.

In conclusion, and while the research has limitations that do not allow to produce decisive proof, there is a significant body of research and evidence that suggests that risk-focused inspections, risk-proportionate and responsive enforcement, and a balanced approach aiming at using all drivers of compliance does produce better results. In any case, the opposite idea to “smart inspections”, i.e. that any reduction in inspections numbers and reduced severity of enforcement would lead to lower compliance and worse results, appears to be clearly disproved. It is also clear that the issue lends itself to considerable follow-up research: deeper investigation of methods and outcomes, more systematic review of countries and regulatory areas, etc. Achieving more conclusive findings in terms of effectiveness of inspections and of specific approaches, however, may remain largely elusive given data limitations and the complexity of the phenomena studied. Focused experimental studies, if possible and adequately resourced, could alleviate the data quality problem – it would then remain to be seen how robust the results would be in terms of determining any causality.

Samenvatting

Van de jacht op overtreders naar het beheersen van risico's

Achtergronden, uitdagingen en ontwikkelingen van toezicht en handhaving

Overheidsregelgeving die aspecten van economische activiteiten regelt, bestaat al duizenden jaren. Het aantal regels is de laatste anderhalve eeuw echter snel toegenomen en de strekking en complexiteit ervan zijn veelomvattender, met een waarneembare tempoversnelling in de laatste decennia. Dit soort regels dient in het algemeen belangrijk geachte doelen vanuit een utilitaristisch en vaak ook symbolisch perspectief. Het is daarom niet verrassend dat overheden ook steeds meer instrumenten hebben ontwikkeld om naleving van deze regels te controleren en te vergroten. Toezicht en handhaving, in het algemeen uitgevoerd door gespecialiseerde structuren, zijn gecreëerd of aangepast voor dit doel. Inspecties en handhaving (en de instituties die ze uitvoeren) zijn echter niet overal en op elk gebied tot stand gekomen, noch hebben zij zich op identieke wijze en identieke snelheid ontwikkeld. Er zijn aanzienlijke verschillen in geschiedenis, structuren, middelen en methoden – zowel tussen landen als binnen een land tussen de verschillende domeinen van regelgeving.

Of en in welke mate deze inspanningen om bedrijven en burgers te laten voldoen aan regelgeving succesvol geweest zijn, is een complexe kwestie. In de meeste landen zijn gezondheid en veiligheid verbeterd, maar het is moeilijk om te bepalen hoe veel daarvan te danken is aan toenemende welvaart en hoe veel aan naleving van regelgeving – of zelfs hoe veel van de regelnaleving te danken is aan toegenomen middelen, betere vaardigheden en een veranderende mentaliteit van de samenleving, en hoe veel aan handhavingsinspanningen zelf.

Met de toename van het aantal regels bestaan er, de laatste decennia, ook toenemende zorgen over "regeldruk" en probeert men om "betere" of "slimmere" regelgeving te bereiken. Mede daardoor is recentelijk ook de aandacht voor toezicht en handhaving vergroot. Hervormingsprogramma's zijn gelanceerd door overheden, nationale en internationale instituties hebben richtsnoeren ontwikkeld en onderzoek is uitgevoerd over of en hoe toezicht en handhaving effectiever of efficiënter (minder duur en/of belastend) gemaakt kunnen worden, of beiden. Er zijn ook stevige claims gemaakt voor een risicogestuurde aanpak, dat wil zeggen een aanpak waarbij de toezichtsinspanningen geconcentreerd worden op bedrijven en activiteiten met de hoogste risico's, en waarbij handhavingsbeslissingen vervolgens genomen worden op basis van het risico, waardoor de lastendruk en kosten van regels verminderen en de effectiviteit van de regels wordt vergroot.

Ondanks al deze inspanningen is er tot nu toe geen afdoende bewijsmateriaal om te kunnen bepalen in hoeverre die claims ook bewaarheid worden. Bij nadere beschouwing blijkt er zelfs geen alom geaccepteerd begrip van wat "slimmere" toezicht en handhaving precies inhouden. In de afgelopen jaren zijn er een aantal belangrijke initiatieven geweest om de praktijk van (al dan niet risicogestuurde) toezicht en handhaving te vergelijken tussen landen, maar in het algemeen werd hierbij niet gekeken naar effectiviteit. Omgekeerd hebben studies die hebben geprobeerd om te kijken naar de effecten van toezicht en handhaving zelden een (internationaal) vergelijkend perspectief. Academische literatuur over motieven voor regelnaleving kiest vaak voor een enkel perspectief, bijvoorbeeld door de nadruk te leggen op het effect van afschrikking of juist

vrijwillige naleving als primaire drijfveer. Ook al zijn door een aantal academici meer gebalanceerde, complexe modellen van motieven voor regelnaleving gemaakt, toch blijkt dat deze niet altijd worden gebruikt door zowel andere academici, als door beleidsmakers en -uitvoerders.

Dit onderzoek beschouwt eerst de vraag wat “slimme” toezicht- en handhavingspraktijken, gebaseerd op risicogestuurde inspecties, risico-proportionele handhaving, maar ook inclusief inspanningen om naleving te bevorderen door andere (“zachtere”) maatregelen, inhouden. Het probeert als tweede de geschiedenis van die ontwikkelingen te onderzoeken en beschouwt hun theoretische onderbouwing, alsook hun legitimiteit voor zover ze vertrouwen op een specifieke manier van het openlijk omarmen van georganiseerde discretie in de uitvoering ervan. Tenslotte als derde, en misschien het belangrijkst, probeert het onderzoek te kijken naar de vraag of er bewijs kan worden gevonden voor een al dan niet hogere effectiviteit van zulke “slimmere” benaderingen, en hoe dat zich dan verhoudt tot andere (al dan niet klassiekere) inspectiemethoden die niet (of minder) risicogebaseerd zijn, en een minder responsieve aanpak hebben wat betreft handhaving.

De analyse van de geschiedenis van de ontwikkeling van inspecties en handhavingspraktijken richt zich, in dit onderzoek, met name op twee verschillende casusdomeinen – voedselveiligheid en arbeidsveiligheid & arbeidsgezondheid – in de volgende landen: Groot-Brittannië en de VS (voor beide casusdomeinen) en Frankrijk, Duitsland, Nederland en de Europese Unie (voor voedselveiligheid).

Deze domeinen en landen zijn geselecteerd vanwege een combinatie van redenen: voedselveiligheid en arbeidsveiligheid & arbeidsgezondheid behoorden tot de allereerste regelgevingsgebieden waarbij inspectiediensten werden gecreëerd. Zij blijven behoren tot de meest high-profile en van veel toezichts- en handhavingsmiddelen voorziene gebieden. De landen die beschouwd worden, behoren in het algemeen tot de eersten die zulke instituties opgezet hebben, behoren tot de meest belangrijke economieën van de betreffende periode, en/of bieden interessante contrasten in termen van trajecten en benaderingen.

De historische analyse leidt tot verschillende bevindingen. Zo blijkt onder andere dat de opzet, inrichting en ontwikkeling van inspectiestructuren en -praktijken in het algemeen meer gekoppeld is aan risicopercepties dan aan wetenschappelijke risicobeoordeling. Ook padafhankelijkheid speelt een belangrijke rol bij het inrichten van arrangementen, opzetten instituties en ontwikkelen van benaderingen in verschillende regelgevingsdomeinen en landen. Daarnaast blijkt dat sommige landen (en de EU, voor voedselveiligheid) steeds meer een risicogestuurde benadering hebben omarmd ten behoeve van inspecties, terwijl anderen huiveriger lijken te zijn om dit te doen (om verschillende redenen).

De in dit onderzoek uitgevoerde literatuuranalyse behandelt verschillende aspecten: een algemeen onderzoek naar regelgevingsinstrumenten en hun economische consequenties, onderzoek naar verklarende modellen voor naleving van regelgeving, en onderzoek naar perspectieven op de acceptatie van discretionaire ruimte bij de uitvoering regelgeving en risicogebaseerde regelgeving.

Fundamenteel onderzoek naar regelgeving, van bijvoorbeeld Ogus, Diver of Baldwin, laat de onmogelijkheid zien om tot perfecte regels te komen. Het laat zien dat compromissen moeten worden gesloten, die geaccepteerd moeten worden wanneer bijvoorbeeld gekozen wordt tussen 'middel'regelgeving en 'doel'regelgeving en in geval van een keuze tussen meer zekerheid of meer flexibiliteit. Deze bevindingen onderstrepen ook het belang van de toezichts- en handhavingsfase, waarin nog weer nadere keuzen worden gemaakt.

Onderzoek naar de economische consequenties van regelgeving, zoals hier uitgeveoerd, is methodologisch ingewikkeld en de resultaten zijn vaak ook nog eens niet erg overtuigend. Porter et al. hebben laten zien dat, tenminste in sommige gevallen, strengere en gedetailleerdere, goed beheerde regels, niet zozeer marktwerking verkleind (door regelingslasten e.d.), maar dat dit soort regels ook hand in hand kan gaan met het verbeteren van de concurrentiepositie en daardoor economische groei. Rodrik, Djankov en vele anderen hebben echter geconcludeerd dat slecht beheerde regelgeving, belastende procedures, arbitraire handhaving etc. significante negatieve gevolgen kunnen hebben op economische ontwikkeling. Dat laatste laat nogmaals het belang zien van de wijze waarop regelgeving wordt "uitgevoerd".

Er zijn veel verschillende modellen over regelnaleving in de literatuur te vinden – van relatief simpele modellen die zich richten op de rationele berekening door bedrijven en personen van het effect van straf als gevolg van niet-naleving (Becker), tot veel complexere modellen die procedurele gerechtigheid en legitimiteit benadrukken, maar ook verschillende andere factoren opnemen (Tyler, Lind). Experimenten om de modellen te toetsen en te valideren leveren meestal uiteenlopende resultaten op. Meest overtuigend lijkt dat de inzet van onderling aanvullende prikkels tot naleving het meest effectief is. Daaronder vallen voldoende toezichts- en handhavingscapaciteit (kennis, financiële middelen) en sociale conformiteit en legitimiteit zijn sterke aanjagers. Afschrikking is in het algemeen een minder sterke prikkel tot naleving dan conformiteit en legitimiteit maar het kan een belangrijke rol spelen voor sommige mensen of bedrijven en/of in sommige omstandigheden (omdat niet alle regels op dezelfde manier gezien worden door alle mensen). Dit laat het belang van een uitgebalanceerde benadering van handhaving zien: een risicogestuurde benadering is nodig om te voorkomen dat degenen die spontaan zouden naleven geduwd worden in de richting van weerstand, en aandacht voor procedurele gerechtigheid (waarbij criteria voor beslissingen duidelijker gemaakt worden) is nodig om de legitimiteit te verhogen.

De perspectieven in de literatuur op de legitimiteit van discretie bij toezicht en handhaving zijn zeer conflicterend. Een deel van de verschillen hangt samen met juridische tradities. Ten minste in de Common Law en Romeins-Franse tradities is er globaal een groot respect voor het opportuniteitsbeginsel, dat ruimte biedt voor een 'responsieve aanpak van handhaving' gebaseerd op feitelijke risico's.

Tenslotte benoemt onderzoek naar risico's en veiligheidsregelgeving de zeer verschillende manieren waarop risico gedefinieerd en gemanaged wordt. De consequenties daarvan voor toezicht en handhaving zijn niet altijd duidelijk. Auteurs als bijvoorbeeld Black en Baldwin wijzen op het theoretische probleem dat bij onduidelijkheid over definities het moeilijk is om een valide risicogebaseerde planning te maken. De praktijk suggereert echter dat dit probleem beperkt speelt.

Kortom, de literatuurreview wijst zowel op het belang van toezicht en handhaving, als op de noodzaak om een benadering te hebben die op een gebalanceerde manier met alle prikkels tot naleving rekening houdt, en op de cruciale en complexe rol van discretie bij de uitvoering. Het laat ook zien dat er verschillende definities zijn van risico, en dat de definities die gekozen zijn door sommige onderzoekers aanzienlijk verschillen van wat in het algemeen in de beleidspraktijk geaccepteerd is, bijvoorbeeld door de OECD of overheidsinstituties – wat mogelijk een aantal ogenschijnlijk teleurstellende onderzoeksbevindingen verklaart.

Casestudies vormen het laatste gedeelte van het onderzoek, en maken het mogelijk om de hypothesen te toetsen en te zoeken naar een antwoord op de onderzoeksvraag. De eerste (en meest gedetailleerde) casestudy kijkt naar arbeidsveiligheid & arbeidsgezondheid inspecties in Groot-Brittannië en Duitsland (gedeeltelijk voortbouwend op eerder onderzoek van Tilindyte). De tweede casestudie beschouwt inspecties in landen in de voormalige Sovjet Unie, hoe deze zich verhouden tot praktijken in OECD/EU landen en wat de resultaten zijn van inspanningen om ze te hervormen naar een meer risico gebaseerde richting. De laatste casestudie kijkt op een meer metaniveau naar een aantal opvallende aspecten van bestaande praktijken en hervormingsinspanningen in een aantal EU-landen. De overkoepelende analyse zet vervolgens alle beschikbare data op een rij. De conclusie is dat de kwaliteit van de data robuuste conclusies over correlaties tussen toezicht- en handhavingspraktijken en de resultaten ervan niet mogelijk maken.

De eerste casus beschouwt de evolutie van arbeidsveiligheid & arbeidsgezondheid inspecties in Groot-Brittannië in de afgelopen vijftien jaar, en vergelijkt het aantal inspecties, de methoden en de resultaten met Duitsland. Deze casus is geselecteerd omdat arbeidsveiligheid & arbeidsgezondheid relatief uniek is onder inspectie functies omdat ten minste een van de outcome-indicatoren (dodelijke arbeidsongevallen) een hoge betrouwbaarheid heeft en goed te vergelijken is. Harmonisatie van data door Eurostat maakt het makkelijker om te vergelijken. De casus laat zien dat Britse arbeidsveiligheid & arbeidsgezondheid inspecties sterk risico gericht, risico-proportioneel en responsief in handhavingsbeslissingen. Ze leggen ook een sterke nadruk op advies en ondersteuning voor naleving. De data laten zien dat hoewel Britse arbeidsveiligheid & arbeidsgezondheid inspecties minder frequent zijn dan Duitse, de resultaten significant beter zijn in de afgelopen vijftien jaar. Daarnaast is de frequentie van inspecties gedaald in beide landen, maar de cijfers van dodelijke ongevallen zijn ook gedaald (waarbij de daling sterker was in Duitsland, waar de cijfers veel hoger waren in het begin). Hoewel dit niet genoeg is om te bewijzen dat risico gebaseerde benaderingen hebben geleid tot deze betere prestaties, suggereert de casus zeker dat zij mogelijk een rol gespeeld hebben. In ieder geval ontkracht de casus het idee dat meer inspecties noodzakelijk gecorreleerd zijn aan betere resultaten.

De volgende casus leiden tot dezelfde bevindingen. Onderzoek uitgevoerd door de World Bank Group in de voormalige Sovjet Unie laat typisch erg hoge niveaus van inspectie-dekking zien, zonder dat dit op enige manier resulteert in hoge niveaus van naleving of positieve resultaten. Bovendien leiden hervormingen die tot zeer significante afname van de hoeveelheid inspecties zorgen niet tot enige verslechtering van resultaten. In tegendeel, landen die aanzienlijke hervormingen van inspecties ondergingen naar een meer risico gebaseerde aanpak gericht op de promotie van naleving (bijvoorbeeld Litouwen), hebben meestal ook betere resultaten. Een korte beschouwing van arbeidsveiligheid & arbeidsgezondheid inspecties in Frankrijk versterkt de bevindingen van de vergelijking tussen Groot-Brittannië en Duitsland: Frankrijk heeft vele malen frequentere inspecties dan Groot-Brittannië, gecombineerd met een “zero tolerance” aanpak, gegrond in een visie op naleving die volledig uitgaat van afschrikking, maar heeft resultaten die significant slechter zijn dan het

gemiddelde van de EU-28 (waar Groot-Brittannië telkens als beste of een van de beste scoort). Data over inspecties in Italië laten zien dat de inspecties zich daar meestal herhaaldelijk richten op dezelfde bedrijven, wat resulteert in een hoge mate van belasting voor ongeveer een derde van de bedrijven, met beperkte positieve effecten.

Concluderend, met onderkenning dat het onderzoek beperkingen heeft die ervoor zorgen dat er geen doorslaggevend bewijs geleverd kan worden, kan worden gesteld dat er een omvangrijke hoeveelheid onderzoek en bewijs is dat suggereert dat risicogerichte inspecties, risicogebaseerde en responsieve handhaving en een gebalanceerde benadering gericht op het gebruiken van alle prikkels tot naleving tot betere resultaten nalevingsresultaten kan leiden. In ieder geval lijkt het tegenovergestelde idee van "slimme inspecties" door deze studie duidelijk te worden ontkracht, dat wil zeggen de 'claim' dat elke verlaging van aantal inspecties en verminderde striktheid van handhaving zou leiden tot (rechtevenredige) verminderde naleving.

De studie maakt daarmee ook direct duidelijk dat er vervolgonderzoek nodig is: verdiepend onderzoek naar methoden en resultaten, naar meer systematische vergelijking van landen en domeinen van regelgeving, enzovoorts. Het trekken van meer ferme conclusies over de effectiviteit van inspecties en van specifieke benaderingen, zal echter altijd moeilijk blijven, vanwege de beperkingen van de data die tenminste deels samenhangen met de complexiteit van relaties tussen toezicht en handhaving via de mate van naleving met het effect van regelgeving in de werkelijkheid.

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Curriculum vitae

Florentin Blanc (born in Orange, France, in 1973) studied history in Paris (Panthéon-Sorbonne University and Ecole des Hautes Etudes en Sciences Sociales). After completing an MA and a *Diplôme d'Etudes Approfondies,* and being admitted (ranking 2nd) at the *Agrégation d'Histoire*, he spent several years teaching history and geography. He then moved to a career in international development, first with the international NGO ACTED, and then (from 2004) with the World Bank Group. Since that time, he has been working on regulatory issues, in particular assessment and reform of regulatory procedures, inspections and enforcement, risk-based regulation, in over 30 countries and in all parts of the world. He has written, led or contributed to a number of publications on the topic of inspections and enforcement, in particular for the World Bank Group and the OECD. Since 2010, he has been working as a consultant, primarily for the World Bank Group, but also for the OECD and a variety of national governments within the EU. This has allowed him to undertake academic research in parallel, which is focused on issues of relevance to his practice: regulatory inspections and enforcement, drivers of compliance, risk and regulation, regulatory impact and related issues.