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On the institutional innovation process: EU regulation through an evolutionary lens*

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Abstract

The focal point of this paper is the study of the process of emergence of novel institutions and the identification of factors that may influence the outcome of this process. We view institutions as commonly accepted sets of rules that influence actors' decisions and focus on state-mandated sets of rules i.e. regulations. We consider regulations as endogenously emerging institutions that evolve in accordance to other socioeconomic factors and analyze the regulatory process at each of its stages adopting an evolutionary approach. Evidence shows that the regulatory process resembles the innovation process as it can be viewed as a process of knowledge accumulation and transmission that is facilitated by purposeful actors. The study is empirically contextualized in the European political system, the detergents industry and specific regulations formed at European level. Data is drawn by secondary resources and in-depth interviews with different types of public and private stakeholders participating in the process.

Keywords: evolutionary theory, institutions, regulation, policy

JEL Classification: K20, L50, L65, O25, O43

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1. Introduction

The fact that institutions evolve across time and differ across contexts has been translated into a well developed and intriguing research topic that lies at the boundaries of political science, economics and sociology. Within this research field, the focal point of this paper is the study of the process of emergence of novel institutions and the identification of factors that may influence the outcome of this process. Being aware of the broadness of the concept of “institution”, in this paper we view institutions as “commonly accepted sets of rules that influence actors decisions” and focus on state-mandated sets of rules i.e. regulations.

We consider regulations as endogenously emerging institutions that evolve in accordance to other socioeconomic factors and seek to identify the mechanism that facilitates the emergence of new regulations as well as the factors that determine the outcome of the regulatory process. The regulatory process is a formal policy process whose analysis primarily belongs to the sphere of political science and this is where our quest for existing research on institutional emergence and change commences. Seeking to understand the nature of, initially, any policy process we begin with Hogwood and Gunn (1984), who suggest that any public policy “needs to have been generated or at least processed within the framework of governmental procedures, influences and organizations” (Hogwood and Gunn, 1984: 24). This approach implies two basic points; firstly that any type of public policy is a result of a timely and cumulative process and, secondly, that any policy process involves purposeful interactions among different types of actors. These two premises have already been argued for: the cumulative nature of the policy process has long been argued for as policy institutions change by building on their own history (March and Olsen, 1998) and hence current changes in the political sphere can be seen as part of a sequence of earlier changes and as setting the scene for future evolutionary developments (Nelson and Winter, 1982). In turn, the centrality of interactions between agents representing different interests and beliefs has been pointed by views suggesting that the policy process is one characterized by the dynamics of agents’ mobilization, persuasion and negotiation (e.g. Slembeck, 1997). Some important implications arise from these characteristics of the policy process; the first one refers to path dependencies and possible lock in phenomena attributed to the cumulative nature of the process and the second involves learning effects, and power interplays that are linked to, both, the cumulateness and the continuous interactions of agents.

Path dependencies are increasingly becoming part of the political science vocabulary when describing the policy process especially aiming to emphasize the notion of self-reinforcing processes (Pierson, 2000). Path dependencies are possible sources of lock-in phenomena which are common in politics due to inherent aspects of the policy process; more specifically, in politics agents rarely achieve important changes acting individually rather collective action is fundamental to policy change. Hence, individuals might be exposed to information that has been selected from other agents and therefore they may be “victims” of agenda-setting effects (Witt, 2003) which in turn result in unintentionally biased policy choices. Further, changes of rules and patterns are mostly dependent on authority rather than exchange and contracts (as in economics) while the existence of rigid institutions orchestrating the policy process make reversals and changes increasingly unattractive (North, 1990). Finally, even if mistakes become apparent, policy change requires long time periods due to the variety of stakeholders with sporadic participation and minor (individual) influence and because of the difficulty of evaluation of policy action in the short term (Pierson, 1993, 2000). Yet, the lack of perfect information and the constraints on available knowledge posed on all types of agents (voters, bureaucrats, policy makers, representatives of interest groups) are likely to induce agents to make further efforts to improve their

knowledge, alter their choices and induce purposeful action. Then political evolution can be seen as a learning process whereby agents improve their knowledge capacity and are able to influence and change the set of rules surrounding their action. Hence, changes of political perceptions and beliefs can be justified on the grounds that politics are a subtype of social evolutionary process that relies on knowledge accumulation for its evolution (Modelska, 1996).

The above considerations direct us to propose that the policy process is an evolutionary process fueled by knowledge accumulation and transmission that is facilitated by purposeful actors whose perceptions and choices vary and evolve. Such a process resembles the innovation process that is as well described as an accumulation of knowledge-seeking activities, stressing the interest of agents to gain knowledge about their environment and about the opportunities it offers (McKelvey, 1996). In this paper we shall carefully draw a parallel between the innovation and the regulatory process and seek to understand how institutional innovations come about, what are the types of interactions and negotiations that shape common approaches to policy problems and how are new policies diffused and implemented into a system comprising of heterogeneous agents.

Considering the above as the core attributes of the process of evolution and seeking to analyze the European regulatory process through an evolutionary lens, we expect this process to be characterized by a variety of actors whose interactions contribute to the accumulation and transmission of knowledge and lead to continuous changes and improvements based on existing conditions. Our expectations are met considering the structure of the political system within which this process takes place as well as the characteristics of the process itself. Section Two provides the empirical context of our analysis; Section Three discusses the evolutionary attributes identified in the regulatory process; Section Four continues with the in depth analysis of the European regulatory process which we investigate in each of its steps and Section Five discusses the manner in which evolutionary mechanisms guarantee the facilitation of the emergence and evolution of institutions.

2. Empirical context

This paper is empirically contextualized in the European political system, the detergents industry and specific regulations formulated at European level. Data has been collected through secondary resources (i.e. policy reports, existing studies for the industry, archival documentation of governmental agencies) and 26 in-depth interviews (13 private companies (large and small), 4 industrial associations (national and European), 7 policy makers (national and European) and 4 NGOs (national and European branches)).

The European political system is characterized by its non-hierarchical institutional design (implying different levels and arenas that are characterized by a high degree of institutional and functional interdependence due to intense interlocking between supranational and national institutions), the non-majoritarian mode of decision making (which places negotiations among the relevant actors at the core of the decision making process) and the dynamic relationship between various decision-making levels (Grande, 2001).

The consequences from this list of characteristics are summarized in a high demand for policy coordination and a partial redistribution of power between the organizations involved; this creates advantages for those actors who act at the interfaces between levels and arenas of decision making and significantly increases the number of strategic options for the actors involved. Placing actors and their interactions at the core of the decision

making process, the European system of multi-level governance has produced a distinctive type of interest representation with a high number of points of access and increased possibilities of interest groups to influence public policy making.

Within this fragmented and continuously transforming system (Coen, 1997; Knill, 2001) the regulatory process is a dynamic institutional structure that evolves to meet challenges posed by developments such as globalization, technological change and crisis situations. Nowadays, EU regulations are an outcome of the co-decision process that was introduced in 1992 after the Maastricht Treaty, built on the rationale of enhancing the democratic functioning of the EU (Crombez, 1997), namely increasing participation and transparency. The co-decision process applies to most of the regulations related to the Internal Market program and, briefly, works on the rule that a legislative proposal, after its introduction by the European Commission, can only become EU policy with the approval of both the Parliament and the Council (see Annex One for the detailed steps of the process).

The co-decision process increased the steps of the legislative process, increased the density and frequency of interactions, and created new access channels to various interest representation groups (i.e. NGOs, industrial associations or individual firms). This institutional change provided a further and more formal guarantee that a variety of interests are actively represented in the regulatory process and was accompanied by a redistribution of institutional responsibilities and influencing power. The large scope and number of issues to be solved through this process combined with the understaffing of the public apparatus (Bouwen, 2001) has been increasing the demand for expert knowledge available by non-governmental actors. Within this setting, agents that possess the most relevant and reliable information are the ones granted access to the regulatory process and the ones most likely to influence its outcome. Given the stage and timely character of the regulatory process from its initiation to its implementation, the evaluation of the quality of information provided by private agents takes place at various stages via formal consultations and expert group meetings, or informal communication among the participants. Broscheid and Coen (2003), suggest that the institutional structure of the European political system has inbuilt incentive and sanction mechanisms with regards to the transmission of valuable and false information; incentive mechanisms can take the form of privileged access to information about policy intentions, grants and favorable term contracts, while sanctions mechanisms to restrict opportunistic behavior are usually imposed by future exclusion from the negotiations.

The non-governmental protagonists of the regulatory process in our case represent the detergents sector. This industry dates back to the first half of the century and the extended use of its products has induced regulatory activity since the sixties. The strong link of the industry with the general public and the early exposure of its representatives to governmental controls in the form of regulations justify why the industry is an interesting case for analyzing the mode of participation of private agents in the regulatory process and consequently the changing boundaries between market and non-market organization. The incorporation of the detergents sector in the chemicals industry and the domestic use of its product, guarantees the continuous interest of public authorities in the activity of companies, and hence public intervention remains a relevant issue until today, offering a more than forty years period for inquiry.

Seeking to understand and explain why existing pieces of regulation ended up taking their current form and identify the factors that contributed to their pattern of evolution we use the most relevant regulations for the operations of the detergents industry. These are the 2004 Detergents Regulation, the new chemicals regulation dealing with the Registration, Evaluation, Authorization and Restriction of Chemical substances (REACH) and

the Globally Harmonized System for Classification and Labeling (GHS). A brief overview of their content as well as their historical evolution are presented in Appendixes Two, Three and Four respectively.

3. Evolutionary attributes of the regulatory process

3.1 Path dependence, legal paradigms and learning

The concept of institutional path dependencies has been recognized by institutional economists as useful for explaining the long-term persistence of institutions even when they are considered inefficient (North, 1990) and has been used for the analysis of legal change to describe the persistence of differences in legislation between different political systems on the grounds that national political systems persist and resist harmonization (Heine and Kerber 2002). The European regulatory process has inbuilt elements of path dependence due to the strong interrelation and dependence of institutional structures on the existing legislative plexus and the fact that legislative change takes the form of legislative succession and the revision of clauses and annexes of existing legal texts. The examples of the 2004 Detergents Legislation and REACH are indicative of this case¹.

These examples also highlight that regulations and policies evolve in response to the changing nature of problems and the problem-solving heuristics. The latter is the underlying notion of a paradigm developed initially by Kuhn (1970) and developed later by Dosi (1982). Applying the notion of technological paradigms to the case of legislation Heine and Kerber (2002:57) interpret legal rules as “socio-technological instruments” that attempt to solve problems of human interaction in societies and develop the concept of “legal paradigms” as structures “embodying an outlook, a definition of the relevant, problems and trade-offs, and a certain pattern of enquiry and heuristics for solving, new emerging problems”. The analogy between technology and legal rules has also been used by Eckardt (2004) who describes new statutory laws as “legal innovations” that are generated within a legal paradigm. For Eckardt (2004) legal paradigms refer both to the cognitive frame within which novel legal problem-solutions are looked for, as well as to the methods used to generate and disseminate legislative innovations. We find that shifts into new legal paradigms may be attributed to, both, advancements of knowledge as well as arising legislative inefficiencies. Political accountability enhances the incentives of policy entrepreneurs to improve their knowledge and develop new problem-solving heuristics, as in politics losses are not restricted to financial resources but also to the loss of governing power.

The case study material revealed three examples of shifts to new legal paradigms. The first example relates to changes in the existing process of rule formation, i.e. the review and reformulation of the European legislative process towards more participatory models and the consequent alteration of decision making processes and instruments for the enforcement of European law. In the early days of European level regulatory activity, decisions were mostly promulgated in the form of Directives and such an approach resulted in the proliferation of versions of legal texts dealing with the same issue in different countries. Consequently administrative difficulties, bureaucratic overload, ambiguity and opportunities for non-compliance became frequent phenomena. Considering these constraints, European public institutions have recently consciously shifted their

¹ As shown in Annex Two and Three, the latest detergents legislation is the outcome of several revisions of the 1973 Directive regulating the biodegradability of surfactants, while the REACH agreement is the descendant of the Dangerous Substances Directive (1967).

approach to legal intervention towards the promulgation of new legislation through the conversion of existing Directives into Regulations that are directly applicable -namely they create rules with immediate effect similar to a national instruments in all Member States and without any further action on the part of the national authorities (EUR-Lex, 2008).

A second example relates to changes in the problem-solving heuristics, and more specifically, the manner in which responsibility is allocated between authorities and addressees. REACH is considered by the industry representatives to have *“set a totally new paradigm in the way we look at the problem”* as it reversed the normal process of product regulation. Prior to REACH, companies were able to market launch a product and were only obliged to provide safety information if public authorities identified a problem related to the product and challenged them. Hence, the responsibility of testing new products against environmental protection and human safety criteria belonged to public authorities and the provision of information was only a case of reaction to public challenges. However this proved to be a very inefficient way of tackling the matter and its failure was attributed to lack of resources (in the authorities’ view) and bureaucratic reasons and lack of competence (in industry’s view). The new chemicals regulation, REACH, came to substitute the existing legal paradigm and shift the responsibility to the producers of new technology by reversing the onus of proof. Under the new regime companies can commercialize a chemical substance only if they demonstrate in advance that its use is safe. This transition is considered by the industry as a major revolution in the management of chemicals as it prolongs the time required for new products to enter the market, increases the production costs, and creates possibilities that challenges might originate from more stakeholders whose expertise on the issue can sometimes be questioned.

Thirdly, shifts between legal paradigms can be considered in terms of changes in the scope of regulation. In the case of GHS, the globally harmonized requirements for labeling required by the regulation, demanded the development of a transnational and intercontinental regulatory process as no single existing national or transnational regulatory process was adequate or sufficiently dominant to support the development and implementation of such regulation. This resulted in a new legal process based on international collaboration.

These examples indicate transitions to new legal paradigms due to arising inefficiencies and the continuous improvement, accumulation and transmission of knowledge between the increasing variety of stakeholders involved in the regulatory process. Changes in legislation are the combined results of advances located in various scientific disciplines and embodied in individuals belonging to various social groups. In our case, changes have been induced on the one hand by advances in chemistry and consequently the development of new substances as well as the development of testing methods to assess the properties of the new substances. The penetration of such knowledge into the policy circles and especially into the regulatory agencies resulted in responsive efforts on the part of regulators and policy makers to develop processes and instruments appropriate for the mediation of issues related to the assessment of chemicals. On the other hand, political and legal science has also been evolving following its own momentum in response to the changing characteristics of the European political system. Policy objectives based on the rationales of integration and harmonization are translated into efforts for the development of policy processes, institutional structures and policies aiming to facilitate the governance of this multi-actor and multi-level system which offers a fertile ground for interaction and information exchange. Then the provision a “commonly accepted basis of collective action” Slembeck (1997: 227) becomes the major task of politics and hence, similarly to innovation, the legal process can be seen as a problem solving process whose resolution is determined and dependent upon the

mobilization of various types of agents that share knowledge and heuristics and that collaborate to achieve their targets.

3.2 The variety-selection-retention triptych

There are three sequential mechanisms that lie at the heart of evolutionary processes and that we expect to find at work in the regulatory process. Loasby (1999: 25) notes that evolution comprises of “the generation of variety, the reduction of variety (selection) and some persistence (retention) both in the characteristics of the variants and in the environment in which they are selected”.

The **generation of variety** in evolutionary applications in social sciences is ensured by the fact that agents are capable of experimenting and discovering new rules and, thus, continuously introduce behavioral novelties into the system (Dosi and Nelson, 1994). In politics variety refers to policy strategies, programs and instruments and is attributed to the diversity of ideas, preferences and interests of policy agents that compete to bring their concerns onto policy agendas (John, 1998; Slembeck, 1997; Modelski, 1996). Regulations can be considered as formal expressions of rules whose variety is guaranteed by the array of policy problems that arise from interactions of agents with different political preferences and beliefs which themselves evolve in response to existing institutions (Rubin, 2002) and introduce new knowledge into the political system. Following Dopfer *et al.* (2004), the introduction of new knowledge carried by an agent with a new understanding and with skills of persuasion into a system of actors is the initial phase of an evolutionary process generating new rules, an idea which offers us a clear starting point for analyzing the process of emergence of regulations.

Certainly not all newly introduced issues are or can be resolved by regulatory action and hence **selection** must take place to reduce the variety and number of issues likely to attract policy resources. An aspect that distinguishes biological and social sciences models of evolutionary analysis is that in the social sciences both variation and selection processes are largely dependent and controlled by purposeful individuals (Pierson, 2000) or following Loasby (1999), are channeled by human institutions. This implies though that selection criteria may evolve in accordance to the forces influencing agents’ beliefs, perceptions and preferences and hence, which given the social context of politics selection criteria, may confront the question of “endogeneity” (Dosi and Nelson, 1994: 156) and potential political capture.

The third building block of an evolutionary process is the existence of “inertial forces that provide continuity to what survives the winnowing” (Nelson, 1995: 56), namely the existence of a mechanism that facilitates the adaptation and maintenance of novelties introduced in the system. Interpreting novelties as new sets of rules, (Dopfer *et al.*, 2004) refer to this stage as “**retention**” which involves the maintenance of the novel rule and its replication; retention describes a phase in which the new rule is normalized and new divisions of labor emerge including structures of knowledge as well as regional and industrial organization. In our view, the entrance of a new rule at this stage, constitutes a proof of fitness and signals the commencement of a period of relative stability in the sense of the temporary cease of struggle of ideas and interests related to a particular political problem. In politics the adoption and maintenance of novel rules in the system is ensured, at least for a considerable period of time, due to the characteristics of the institutional structures within which they evolve. Namely, once a regulation reaches the stage of implementation, its diffusion and retention in the system is guaranteed by the principle of compulsory compliance and, then, novel regulations can be seen as legal innovations that are the outcome of a collective problem solving process (Eckardt, 2004).

4. The regulatory process through an evolutionary lens

Seeking to explain how the variety-selection- retention triptych facilitates the regulatory process at each of its stages, in this section we identify four phases of the emergence of new regulations. In doing so we build upon the “cognitive evolutionary framework” developed by Slembeck (1997), who analyzed the process of policy formation and implementation as a collective process of mobilization and problem solving, triggered by the emergence of policy issues based on individual beliefs and perceptions; ambiguity or discontent are considered the main drivers that induce actors to take action and bring their ideas onto the policy agenda.

The cognitive evolutionary framework is based on the distinction of three policy levels, the “individual”, the “collective” and the “constitutional”. The constitutional level defines the institutions, rules and procedures of the policy process; the collective level is where the actual problem-solving process takes place, while the individual level is where the initiation of policy change begins. This three layer analytical approach is a helpful guide for our analysis though some distinctions need to be drawn. Firstly, the regulations under study do not address individual citizens so the individual level is as micro as the organizational level (i.e. a firm, a NGO, a governmental department). Secondly, the collective level does not solely refer to the public domain (as in Slembeck’s analysis), but describes the state where a problem has been acknowledged as worth the investment of resources by a variety of stakeholders. Finally, the constitutional level is the institutional environment within which policy processes take place. A useful way to think about the three levels is to relate the individual with a space where a variety of ideas exist embedded in actors organized in groups; to consider the collective level as a space where intense interactions take place aiming to solve a policy problem; while the constitutional level is a space comprising of structured sets of rules.

The initial phase of the process begins with **the emergence of a policy problem** and its acknowledgement as requiring regulatory action. Regulators are faced with a variety of issues to be resolved while the type of policy issue to be tackled will partly determine the type of solution, namely the type of regulation. In this sense and seeking to explain why regulations have the form they have, the first thing we need to investigate is the source and type of problems that induce legal change.

The stage following the acknowledgement of an issue is its incorporation in the collective agenda, which implies acknowledgement of importance. Considering the participatory nature of the characteristics of the European regulatory process, policy issues to be resolved with regulatory action become part of the agendas of different stakeholders public and private (i.e. firms, NGOs, industrial associations, national governments, etc.). Hence we identify an intermediate step between the emergence of an issue and the commencement of its solution, which is its **inclusion in multiple agendas**. At this stage we expect to find a variety of decision making processes that relate to the different structure of organizations and which yield the stakeholders’ approach to the definition and level of importance of the arising regulatory issue and determine the course of action they adopt. Conflicts and tensions may arise within each of different stakeholders’ groups and an internal winnowing of varieties of ideas must take place before stakeholders define their positions and attempt to communicate and defend their decisions to other groups. The externalization of stakeholder’s positions is related to what Slembeck calls “initial mobilization” which refers to actors’ efforts to “mobilize others in order to promulgate their own perception of the problem” (p.231).

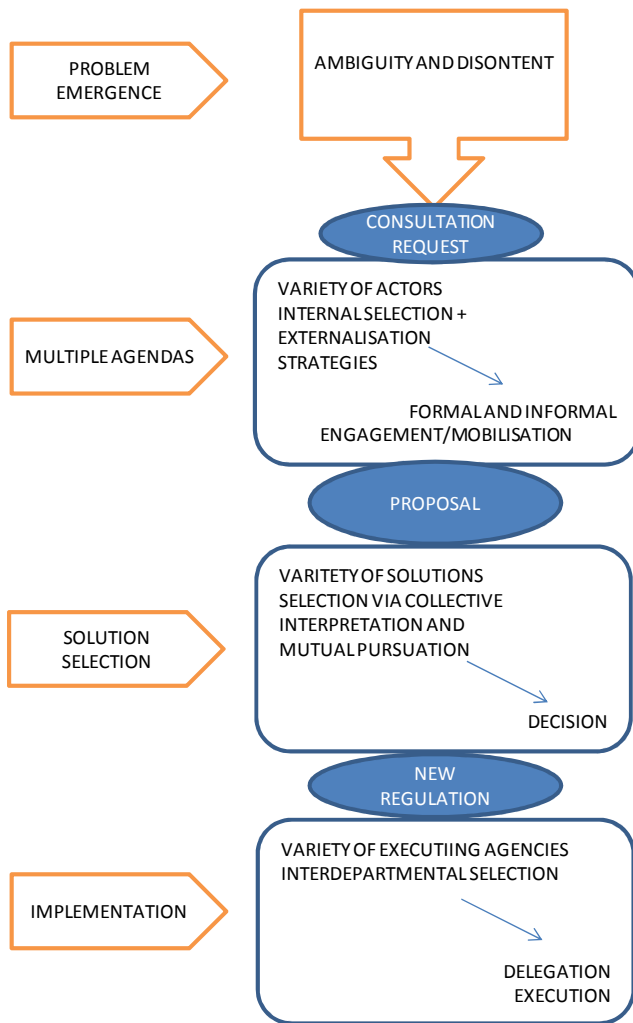
After the definition of the problem has been finalized and stakeholders have revealed their initial position to the issue, what follows is the **selection among possible solutions**. Modelski (1996) refers to this process as the

“macro-decision” describing the selection process that determines which policy strategies will persist and be followed. Solutions to policy problems are chosen among a variety of potential policy measures and are dependent on (i) the type of problem in question and (ii) the distribution of relevant to the problem knowledge among participating stakeholders. Slembeck (1997) distinguishes problems between “novel” and “routine”; the former mobilize formal decision making mechanisms (e.g. legislative processes) and the latter are tackled by following bureaucratic procedures. In this paper the analysis is concentrated on issues that ignite the regulatory process and that entail negotiations mostly focused on influencing the content of the measure rather than its type. As mentioned in Section 2 the institutional structure of the EU regulatory process increases the demand for expert knowledge which in our case is mostly located outside the policy circles. Such a demand, combined with differences in knowledge capabilities of participants, suggests that the solution of the problem is dependent on “who holds the most relevant information”.

The concluding stage of the regulatory processes is the **implementation** of the selected measures which also entails a selection process seeking to define the rules, procedures and delegated governmental agency essential to enforce the novel rule. This is the *“reinforcement/execution”* stage (Modelska, 1996) in which policy innovations and selected strategies are diffused within the policy system. At this stage agency conflicts may arise and regulation authorities need to ensure that the selected delegates are the ones equipped with relevant knowledge.

So far we have identified four distinct phases of the regulatory process within which the mechanisms of variation and selection manifest themselves. These phases are depicted in Figure 1 that is our conceptual map for the empirical contextualization of these processes, which is the focus of the remainder of this section.

Figure 1: EU Regulatory process through an evolutionary lens



4.1 Problem emergence

A variety of potential policy issues emerges in response to interactions between agents with different perceptions, preferences and beliefs while the initiation of the policy process that will possibly result in regulations is dependent on the mobilization of individual agents and fuelled by discontent and ambiguity. The differences between individual perceptions and preferences of actors are the source of a variety of problems that can be characterized according to their source, the size and type of social group they address as well as their mode of solution. Regulations might be attached to predetermined policy targets (e.g. market integration) or can arise in response to unexpected issues relating to market activities, bureaucratic procedures and so forth. The pieces of legislation discussed in this paper have different sources and have arisen at different policy levels. In what follows we present three cases of regulations that are indicative of the variety of sources and levels of initiation of legal change. Following our evidence, legal action might be induced by ambiguity triggered by environmental externalities (as in the case of the 2004 Detergents Regulation), discontent attributed to inefficiencies of existing legal regimes and lack of information (as in the case of REACH) and institutional mismatches (as in the case of GHS).

4.1.1. Environmental externalities and the 2004 Detergents Regulation

The example of the detergent regulation is indicative of cases in which novelties in the socioeconomic environment bring about novelties in the political agenda and more specifically the legislative aquis. The transition from soap and synthetic detergents during the 1950s was accompanied by public concerns related to the properties of the new products. The two points most commonly discussed by scientists, the public and the authorities (at individual level), were the effects on the skin of the user and problems of the disposal of the materials after their use. The first developments towards the formal interpretation of such phenomena and the resolution of concerns were expressed through public reports (e.g. the UK report by the Committee on Synthetic Detergents appointed by the Ministry of Housing and Local Government) that protected the then infant industry, reassuring the public that there was no cause for alarm with regards to the skin related problems, while, concerns about the effects of the disposal of synthetic detergents through sewage were considered justified but not irresolvable (Corlett, 1958). The first evidence of negative externalities of the new technology became obvious in the 1960s, when many Member States experienced foaming problems in rivers and lakes that were attributed to the fact that surfactants were not completely degraded by the bacteria naturally present in effluents. The technical character of the issues increased demand for expert scientific knowledge in order to resolve ambiguity and discontent regarding the connection of pollution phenomena with detergents. The attribution of foaming phenomena to the non-biodegradability of polyphosphates and the existence of scientific proof for what was to become a policy issue accelerated the interpretation and definition of the issue and solved differences in perceptions, while it comprised the common basis for the inquiry of its solution. Combined efforts of the industry and the authorities contributed to the development of testing methods which were incorporated as clauses in subsequent regulations.

4.1.2. Lack of information, administrative inefficiency and REACH

Discontent and ambiguity were also the drivers for political action in the case of REACH. Political discussions about changes of the chemicals regulation and the introduction of a new regime, commenced in 2003 due to the so far poor results of the evaluation process for dangerous substances and the observed lack of information. More specifically, out of the 141 substances prioritized for comprehensive risk assessments with the 1993 Existing Substances Regulation (ESR) only 28 were completed by 2003, while during the evaluations that actually took place it was commonly noticed that the producers of compounds and formulations were not fully aware of the potential applications and subsequent harmful effects of the substances included in their products. Such lack of information was translated into difficulties to determine the acceptable levels of exposure to consumers and the environment and provide adequate guidance. Discussions and concerns about the existing legislation were initiated among stakeholders already participating in the policy process about an issue that was already in the agenda of public authorities (collective level). Interpretations of the observed inefficiencies were formally sought and based on evaluations of the previous policy, a case that shows that the initiation of radical legal change does not always require novel issues to be brought onto the political agenda, rather legal innovations can arise from successive changes.

4.1.3. Institutional mismatches, lack of information and GHS

GHS is a case of regulation whose origins are related to the existence of multiple standards (sets of rules) and differences in institutional structures (constitutional level). The process for the formulation of a Globally Harmonized System for classification and labeling was triggered by the initiative of surfactant manufacturers

outside the EU to classify their products according to existing legislation in their region as “substances with serious damage to eyes”. This information raised concerns among regulatory and standard setting authorities in other continents and resulted in intense negotiations about the characterization and classification standards of such substances. Leading the discussions in terms of the stringency of requirements and following the existing European standards of classification, the responsible working group of the European Commission stated that any formulation containing more than 10% of this substance, regardless of its application, should be classified under a more stringent characterization. Following the precautionary principle, further discussions were stimulated resulting in a reduction from 10% to 3% of acceptable proportions of this substance. The United Nations working group that coordinated the negotiations brought to the attention of the participating experts the fact that there was a disparity of labeling symbols across continents and as the European one was not universally applicable, an alternative needed to be developed. The new labeling system is already finalized and has entered the process of implementation. This is an interesting example of the unintended mobilization of the policy process in the sense that the actors who change their perception of an issue (i.e. the manufacturers of surfactants changing the characterization of their product) have no incentive or objective to initiate policy process leading to legal change.

4.2 Multiple agendas

An integral part of the EU regulatory process is that the acknowledgement of an issue requiring legal action is formally expressed by a proposal for action composed and announced by the European Commission. The Commission’s proposal is the result of an extensive consultation process in which various types of stakeholders (national experts, international organizations, non-governmental organizations as well as different Commission departments) are formally requested to participate. Following this procedure, the policy issues considered relevant for legal action immediately become part of multiple agendas. For instance, the biodegradation issue became part of the agenda of the industry producing suspect substances, the industrial associations representing this industry, the non-governmental organizations and environmental groups concerned with the implications of pollution phenomena, special technical groups within the European institutions, national experts and so forth.

At this stage, non-governmental stakeholders have two types of decisions to make. The first is related to the importance of the issue for the organization and the respective internal allocation of tasks in order to provide the information required by the provisions of the Consultation process. The second decision is related to the selection of additional means of external communication of the organizations’ positions, given the fact that actors are prone to try to alter the outcome of the process for their own benefit. We find that the processes of internalization of forthcoming regulatory activity as well as externalization strategies differ according to the type of stakeholder and partly determine the means of their further engagement into the process.

Simultaneous processes of agenda setting take place in *three distinct stages*. The first stage involves the *internal process of interpretation and management* aiming at improving each stakeholder’s position against the expected changes in their environment. The criteria for assessing whether issues are sufficiently important attract resources are partly individual, partly induced by the economic and political system and also depend on the availability of resources, opportunity costs, etc. Once individual (in the sense of organizational) positions are crystallized, stakeholders interact with co-actors (i.e. firms interact with other firms, NGOs with other NGOs) and aiming to strengthen their influencing power, they establish *coalitions*. *Coalitioning* is the second stage of the process of agenda setting and confirms the argument that individuals rarely act in isolation against

economic and political challenges (Modelska, 1996) i.e. individual knowledge gradually becomes a population property (Metcalf and Foster, 2004; Scharpf, 1997). Equipped with more knowledge and increased bargaining power, coalitions of actors then *enter the policy arena* to promote their interests. Contextualizing the stage of multiple agenda setting, next we present some empirical evidence for the non-governmental actors that participated in the negotiations for the regulations under study.

4.2.1 *Private firms*

The internalization process of regulation varies across firms and mostly depends on the availability of financial and human resources, which are in turn related to size. Large firms usually have in place established departments or units dealing with regulatory matters, as well as well planned strategies and respective allocation of human resources. In contrast, smaller firms tend to shift existing staff members to different positions and rely more on external support as their stance is formulated by the creation of coalitions, participation in national associations and constant exchange of information with the authorities. Information and knowledge asymmetries between firms of different size are usually tackled by governments and legislators who set up supportive services (e.g. the helpdesks established for REACH), aware of the limited access of smaller size firms to valuable information about the requirements and management of regulation and driven by their own interest to successfully implement a novel measure.

The externalization of companies' decisions and positions can be achieved through various channels and is usually not immediate. With the exception of large multinational firms, the communication of individual companies' opinions does not reach the policy makers directly; rather, an intermediate communication process takes place within the industrial circles. Communication is orchestrated by industrial associations and facilitated by organized workshops and formal or informal meetings aiming at the formulation of common positions to be presented and supported in negotiations with other types of stakeholders. Knowledge and information asymmetries are present also in this process during which information exchange at industrial level is mostly beneficial to firms lacking information, while the value added, in terms of new information, for knowledgeable firms remains low. Clearly, knowledgeable agents may confront the trade-off between active participation in the process and disclosure of valuable information, especially in instances where the agents they interact with are of lower knowledge competencies and hence free-riding phenomena may be likely.

4.2.2 *Industrial associations*

Internal decision making in national and European industrial associations follows more strictly defined procedures that are formally outlined in the memorandum of the associations. Following the most common structure, the management committee of the association decides on the degree of importance of emerging issues and proposes the respective action required. This can take the form of a commissioned study, an organized workshop, an internal meeting, an inquiry letter to the authorities and the members, etc. In the case of an anticipated new regulation which is considered relevant and important to the operations of the industry, a specific working group within the association is formed chaired by a specialist member of the technical group. This working group assesses the implications that the forthcoming regulation might have for the industry, proposes possible amendments to the text and provides suggestions regarding the manner in which the industry could participate to improve the workability of the legislation and/or state its concerns. In the case of inadequate human resources associations invite member companies to volunteer and support them with extra personnel.

Once the positions of the industry have been crystallized, what follows is an intense communication activity. National industrial associations of sectors affected by the same regulation coordinate their action and contact the national authorities (i.e. ministries and competent authorities specifically dealing with the regulation), communicate their views to national representatives in European institutions, discuss their views with national NGOs and interact with their counterpart European associations to provide them with information about the national characteristics and outcomes of negotiations. In turn, European associations, equipped with information about the general trend in Europe, focus their action towards the European institutions involved to the regulatory process, namely the specific units of Directorate Generals (DGs) (Detergents unit, Chemicals Unit, REACH Unit), the Parliament (MEPs, and specialized Committees for instance Environment, Internal Market, Energy and Trade), the Presidency, the representatives of multinational firms and the international representations of NGOs. In addition to the regular meetings organized by the European institutions, industrial associations engage in the process via accumulating and disseminating information through media publications, statement positions as well as informal communications. The positions of associations are of special value to the authorities since they represent considerable population of private agents and include aggregations of opinions.

4.2.3 NGOs

NGOs are organized interest groups, who aim to take action on specific issues and hence their orientation with regards to the issues they engage with is to an extent predetermined. Most of the NGOs acting at international level have established agendas comprising global priorities within which they set specific targets selected on the basis of observations and scientific developments in fields related to their action (e.g. aquatic life, chemicals, human health). Nevertheless their agenda is active and evolving as new knowledge and emerging issues may be translated in opportunities of action, as for instance in the case of growing public attention surrounding the operations of the chemicals industry. The decision of whether to engage in a new issue is closely related to the availability of human resources, while considering the more loose management structure of such organizations (in comparison to private firms), national NGO branches have the freedom to decide whether they wish to participate in newly emerging issues and determine their degree of involvement.

In the case of NGOs, “non-participation” to public debates and negotiations may sometime prove to be more strategic than active involvement as, following their testimonies, there are instances in which their presence in meetings on economic and industrial related issues is considered by the media or other stakeholders as a proxy of general agreement to the issues under discussion. Although NGOs follow a less rigid structure of decision making and agenda setting they keep open channels of communication between themselves and organize frequent intra-organizational meetings in order to establish common positions, common strategies and common modes of action and pressure towards the authorities. Communication between the industry and NGOs is weaker as they usually stand on opposite sides though some examples of good will exist.

Hence, following various channels of communication and equipped with new knowledge, crystallized agendas and strategies, and a better potential to influence the outcome of the process, coalitions of stakeholders enter the arena of negotiations aiming to select between alternative solutions.

4.3 Solution selection

The results of the consultation process yield a variety of opinions on the possible solution of the policy issue awaiting resolution through regulation. A specialized working group of the Commission is required to assess

stakeholders' contributions and prepare the text of the proposal. While this is being prepared, non-governmental stakeholders exercise their strategies of influence and engagement on a more informal and bilateral basis. Informal interactions between public and private agents continue during the reading of the legislative proposal by the Parliament and the Council and the possible amendments proposed for the legal text. At this stage, individuals need to convince and mobilize as many actors as possible, in order to put forward their ideas and concerns to a wider group of agents; processes of collective interpretation and mutual persuasion are then at work aiming at the creation of a commonly accepted basis for action (Slembeck, 1997). The time required for the selection of a widely accepted solution is depended on the source of the policy issue and the level of codification of related information. For instance policy issues stemming from environmental externalities (e.g. foaming attributed to non-biodegradability of polyphosphates) are resolved faster than persisting social phenomena, due to the existence and codification of scientific proof; this reinforces the argument that the influencing power of agents is also a function of their interpretative competences and the availability of information (Bowen, 2001; Slembeck, 1997; Sharpf, 1997). An illustrative example is the determination of the testing methods for the assessment of the biodegradability of surfactants. In this case, manufacturers of surfactants developed testing methods for biodegradability when the first concerns about foaming incidents resulted in pressure on the industry and while no regulatory requirements existed yet. When the issue of biodegradability entered the agenda of European Institutions and the assessment of particular substances was considered essential, the opinion of the industry pioneers was highly valued and smoothly combined with existing OECD practices without long negotiations or conflicts. Due to the concentration of expertise outside the policy circles, public action and negotiations concentrated on the level of stringency of restrictions and the type of policy measure that would impose the decided thresholds on biodegradability, while the actual solution, the substitution of the harmful substance, was realized by private agents driven by additional market incentives. But this is not where the story ends; interestingly, the dynamic nature of knowledge accumulation is reflected on the evolution of political solutions, and ideas about solutions for public problems are continually emerging (John, 1998). Returning to our example, evaluation and assessment methods for substances contained in detergents have been increasing in terms of sophistication and effectiveness. Research on biodegradability assessment methods is ongoing and an increasing volume of studies are conducted by experts of the field, commissioned and financed by public authorities who are interested in updating relevant regulatory provisions.

4.4 Implementation

Once a common position on the legal text has been agreed between the Parliament and the Council, the negotiation process is concluded, leading to the implementation of the decided text. A different sort of selection process commences, which entails the delegation of the responsible governmental agency to enforce the regulation. In this case, national governments need to decide internally and propose to the Commission the relevant department (Competent Authority) that will be responsible for the implementation of the new legal requirements. The identification of relevant ministries is usually straightforward. Nevertheless, due to the multiple objectives of European regulations there are instances where more than one ministry needs to be involved. This selection is usually done on the basis of resource availability and synergies of operations but can sometimes be timely.

The UK example for the 2004 Regulation is indicative of the multitude of parallel negotiations and discussions at the implementation stage. In 2002, the announcement of the forthcoming Detergent Regulation by the European authorities and the respective responsibilities of national governments initiated policy discussions

between the Department of Trade and Industry (DTI) and the Department for Environment, Food and Rural Affairs (DEFRA) concerning the responsibility for implementing the proposed Regulation. Initially both departments posed resistance to the responsibility of implementing the forthcoming regulation and after a series of negotiations DEFRA was appointed as the responsible ministry. It was then that a second round of negotiations began, this time internal to the department. The reluctance of the Water Quality Division (the agency so far responsible for detergents) to undertake the responsibility on the grounds of administrative burden made essential the quest for alternatives. DEFRA sought advice from the private sectors and consulted the national industrial association for cleaning products (UKCPI) which pointed to the competence of the Pesticides Safety Directorate (PSD). PSD was asked for any objections and finally appointed as Competent Authority in 2004.

The implementation stage signals the commencement of the diffusion of legal innovations into the system while it also defines a new structure for the interactions between public and private actors. Interactions may become complicated and implementation difficulties may arise due to false expectations on the part of the bureaucrats as well as dual roles delegated to a single authority. The case study material revealed two examples attributing empirical context to such issues. The first refers to the management of the derogation provision of the Detergents Regulation; false signaling about to the number of firms and substances addressed by the regulation, created to the Competent Authorities anticipation of large piles of applications due to arrive at their premises as soon as the measure was promulgated. In the light of this expectedly big workload, heated negotiations took place over who should administer the issues and the budget to be allocated for the completion of the task. Several interdepartmental meetings took place and tens of emails were exchanged, only to be confirmed as a proof of false expectations by the low number (less than ten) of applications for derogation throughout Europe.

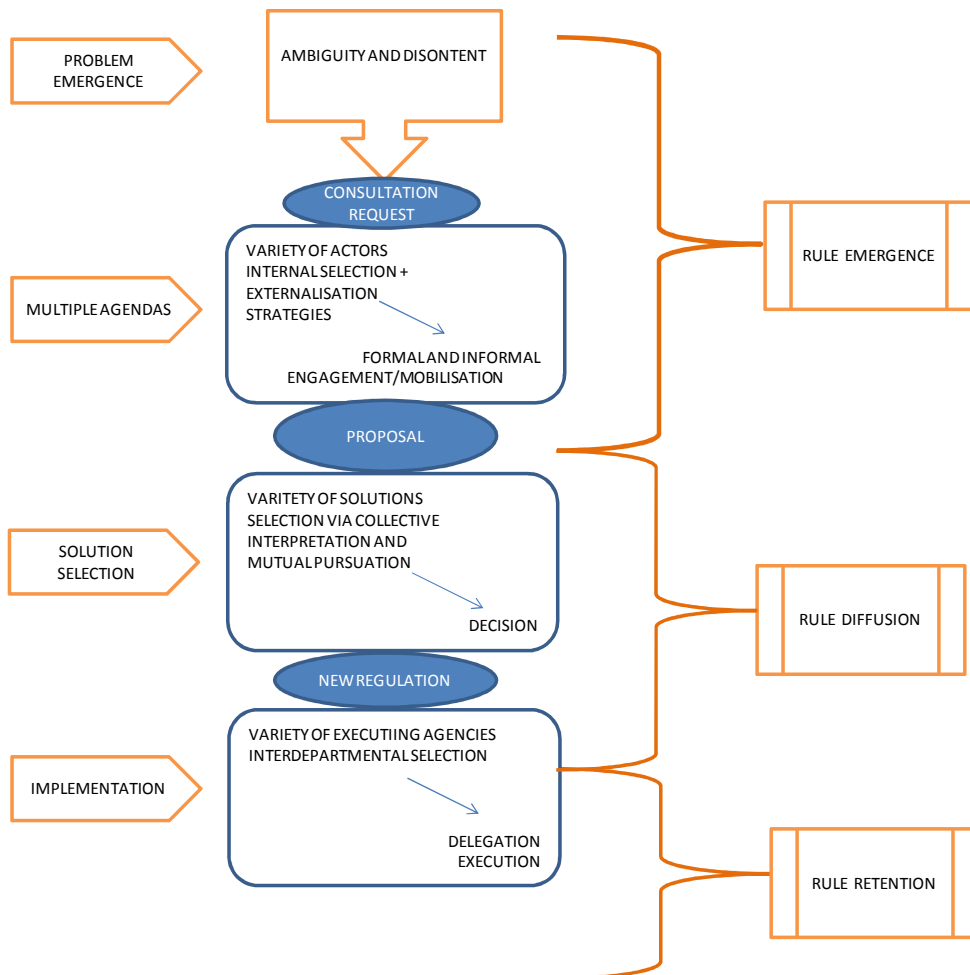
The second example of implementation difficulties is connected to the establishment of national “help-desks” which aim to support and guide actors with regards to the provisions of REACH. The selection of the departments to provide such a service resulted in two structures; some Member States established new departments, independent of, but working in collaboration with the Competent Authorities for REACH, while others (the majority) established the help desks as a separate team within the Competent Authorities. The latter type of arrangement resulted into concerns in industrial circles since the governmental department offering the information on the specifications of the regulation was also the one responsible for the enforcement and control of the measure. Firms admitted their reluctance to seek advice from REACH helpdesks as this would involve them disclosing information based on which they could be judged on. Such conflict gave rise to the need of intermediary organizations i.e. consultants specializing on regulatory matters, who have now established their role in the implementation process.

5. Regulation: an institutional innovation process

In analyzing the process of regulation formulation, an evolutionary process of rule emergence is observed. In its first stage, once an issue has attracted the attention of the regulating authorities, there follows an array of simultaneous internal selection processes and the subsequent externalization of their results (fit solutions, positions) triggered by the authorities request for consultation and demand for specialized knowledge. This situation fits the notion of the **emergence** of a new rule, described by Dopfer *et al.* (2004:271) as the phase of the evolutionary process “where an agent develops an idea/rule that leads to the design of an organization of

people, energy and materials”. Indeed, the anticipation of the introduction of a new rule into the existing institutional structure triggers an intense period of interactions and information dissemination among different agents (individual level) who need to incorporate the new rule into their agendas, establish a position on the matter and represent their view at a higher level (collective level). The next stage of the process is characterized by the adoption and adaptation of the newly proposed rule by a variety of stakeholders that through competition, interact and create variants of the rule (variants of legal provisions to be included in the final text), which constitutes the “**diffusion** phase” in the Dopfer *et al.* (2004) framework. Finally, the new rule enters the third stage of the process, its “**retention**”, in which it is further diffused and maintained in the system through its implementation by the delegated authorities, who need to ensure that the regulation is properly implemented and retained perpetually or at least until a new institutional challenge arises. Within this framework the regulatory process resembles an innovative process that yields new sets of rules, new “technologies of governance” (Voss, 2007) or “legal innovations” (Eckardt, 2004). In this vein, Figure 1 can be extended to incorporate the three stages of an evolutionary processes mentioned above (see Figure 2).

Figure 2: Regulation: an evolutionary process

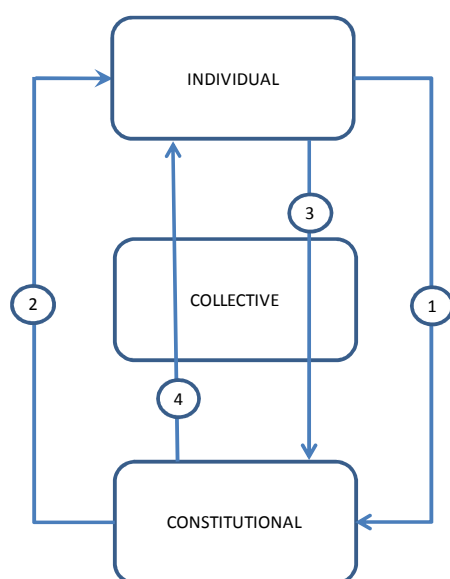


The lower part of the figure is intentionally left open to denote that this process is iterative and dynamic, fuelled by learning processes that are prone to resolve (or even reinforce) institutional lock-ins. It has become evident that interactions among agents take place at all stages of the policy process and between varieties of

stakeholders who have incentives to improve their knowledge and hence, learning processes are present throughout the whole regulatory process. Following the traditional political science accounts, this process reaches its peak at the implementation stage where it is considered to have accomplished its objective to tackle a policy problem through the promulgation of a new regulation. Nevertheless, in our view and through an evolutionary lens to politics, the implementation of a new regulation signals the diffusion of a novel rule and reconfigures the existing institutional structure.

Changes in the institutional structure will result in changes in the perceptions of individuals and their consequent mobilization to alter constitutional elements; in turn changes in the constitutional environment will have implications for the individual perceptions hence giving new momentum to the policy process (flows 1 and 2 in Figure 3). In addition, individuals and evolving constitutional arrangements can affect the political constellations located at the collective level, and thereby influence the possibilities, limitations and outcomes of the political processes (flows 3 and 4 in Figure). This may alter individual perceptions once more and hence refuel the process described.

Figure 3: Regulatory dynamics²



Overall, the outcomes of the policy process at each stage incorporate novel knowledge that feeds back into the system through learning and which contributes to its evolution. Throughout the whole process of policy formation and implementation, the basic mechanisms of evolution are at work and essential for the transition of ideas and knowledge between different levels of the political system, which itself evolves, fuelled by knowledge accumulation and transmission.

Describing the regulatory process through an evolutionary lens, what we actually witness is a course of knowledge originating from individual ideas and perceptions and its transformation into constitutional rules through collective problem solving activities. Hence, the process of emergence of a new policy –regulation- can be viewed as a process of knowledge accumulation, organization and transmission, resembling the innovation

² Numbers do not denote the sequence of interactions; they used only to assist explanation.

process. Politics offer a forum where a variety of stakeholders interact and purposefully reveal their preferences. Policy targets and demand for well articulated policy instruments encourage efforts for a combination of knowledge distributed among various interest groups; such efforts result in institutional innovations in the sense of novel structures of knowledge with implications for the behavior of all agents that participated in their construction. The issue of knowledge concentration and its relevance to bargaining power that directs policy discussions becomes very interesting and is one worth further investigation.

6. Conclusions

This paper focused on the study of the process of emergence of new institutions and sought to identify factors that may influence its outcome. Placing this study within the European political system and by drawing evidence from regulations framing the activity of the detergents industry, we found that the evolutionary approaches to the policy process offer a useful guide in explaining the emergence, diffusion and retention of new regulations.

Considering regulations and institutions as sets of rules we argue that the regulatory process resembles the innovation process as it exhibits the attributes an evolutionary process and can be viewed as a process ignited by the continuous emergence of a variety of issues that stem from ambiguity and discontent and that seek regulatory solution. Following a selection process, issues worth attracting political resources then become part of multiple agendas, an element emphasizing the variety of stakeholders involved in the process and the hazy nature of boundaries between public and private decision making within the specific institutional context. Agenda setting and mobilization comprises the second stage of the process where variety and selection are again present. Here, a variety of internalization and externalization strategies were observed denoting that differences in the competences and orientation of stakeholders partly determine the nature of their engagement in the regulatory process as well as their relative influencing power. Hence, different types of stakeholders guarantee variety in terms of means of engagement in the process and pursuing strategies and participate actively in the selection between alternative policy solutions. During this stage of the process we found that (i) the source of the problem, (ii) the policy level of its emergence and (iii) the distribution of relevant information among the participants to the process, are important factors that may influence its outcome. More specifically, regulations induced by environmental externalities tend to be accommodated easily by pioneers in the technological front due to the accumulation of technical expertise, while regulations in response to administrative inefficiencies that require the reallocation of responsibilities tend to cause tensions and take longer to be internalized by their addressees. At this stage the comparative advantage of knowledgeable agents becomes apparent and confirms the idea of resource dependencies between policy agents that in its negative expressions might result in political capture.

In addition, the policy level (i.e. individual, collective or constitutional) in which the policy issue is first observed influences the manner in which the issue will be resolved and corresponds to different directions of knowledge flows and interactions. For instance, the essential information for the resolution of the foaming issue was transmitted from social groups to the public authorities (bottom-up direction) as initial observations were made by the public and scientists (individual level). Conversely, in the case of REACH inefficiencies were identified by authorities (constitutional level) who initiated the process of legal change and information dissemination towards the industry and the general public (top-down).

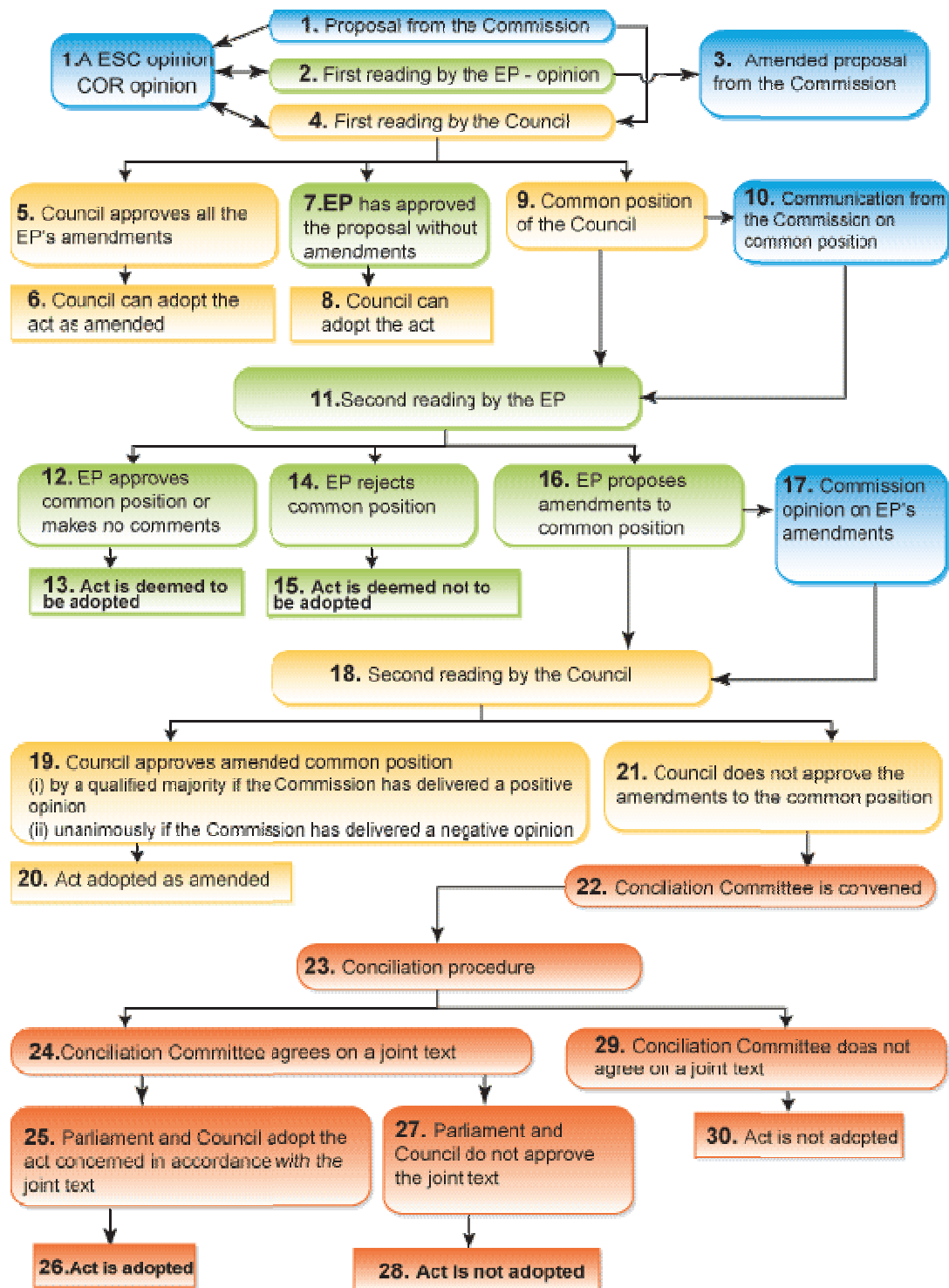
The final stage of the process is the implementation of new rules and signals the phase of diffusion and retention of the institutional innovations. The variation-selection mechanisms reappear at the implementation stage and determine the procedures and agents responsible for the enforcement of the regulation. Implementation difficulties arise in response to false expectations driven by limited information as well as situations in which public actors can incorporate two different roles simultaneously, relating to the well known principal agent problem. In spite of the practical difficulties, the implementation stage also heralds the further diffusion and retention of the novel rule into the system that is accompanied by changes in the existing constitutional structure. Changes in the institutional structure that frames agents' activities (the constitutional level) are expected to be accompanied by changes in agents' perceptions and preferences; these changes refuel the regulatory process and guarantee the continuous evolution of institutions, under the condition that learning processes resolve institutional lock-ins.

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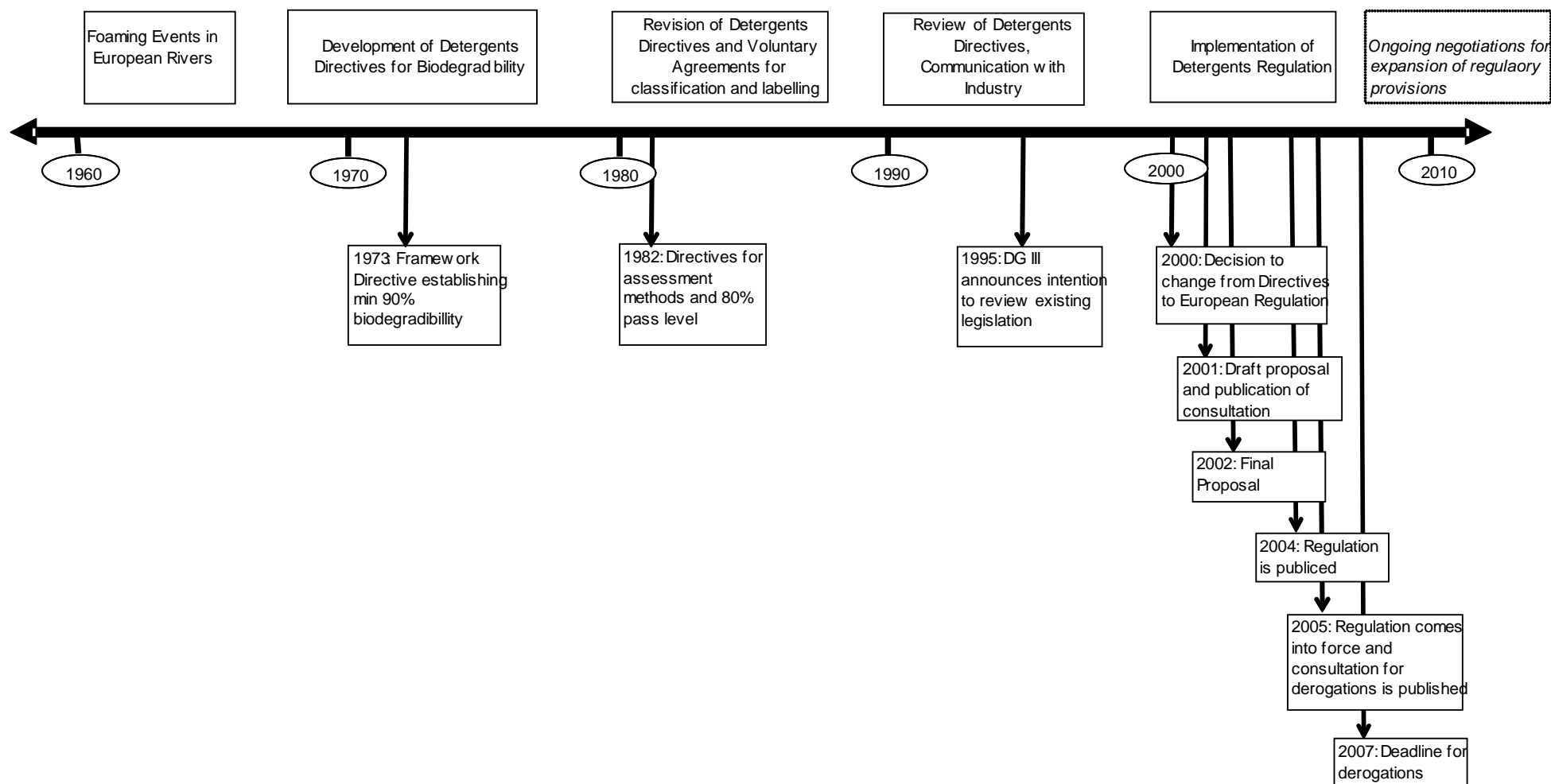
ANNEX ONE: THE CO-DECISION PROCESS³



³ http://ec.europa.eu/codecision/stepbystep/text/index_en.htm

ANNEX TWO: THE 2004 DETERGENTS REGULATION

The 2004 Detergents Regulation is the improved and expanded descendant of the 1973 Framework Directive on Biodegradability promulgated by the European Authorities and is an indicative case of smooth legislative succession supported by collaboration between authorities and industry. Its policy aim was described as “ensuring the free movement of detergents and surfactants for detergents in the internal market and a high degree of protection of the environment and human health” (EC 648/2004). The latest review of existing legislation aimed to meet global environmental targets, consider technological advancements related to the product, formalize existing voluntary agreements and level regulatory differences among Member States. The 2004 Detergents Regulation introduced a new testing regime on the biodegradability of surfactants while it distinguished requirements for surfactants for domestic use on one hand and industrial/institutional applications on the other. According to the legal test, surfactants for domestic use that fail to pass the stringent biodegradability test have to be withdrawn from the market unless the manufacturers are granted derogation by the European Commission. Apart from the tighter biodegradability testing requirements for the active ingredients of detergents, the regulation requires fuller contents information to be provided on detergents labels and repeals the previous legislation on detergents (Directives: 73/405, 73/405, 82/242, 82/243, 86/94 and Recommendation 89/542) (Oliver, 2005). Initiated in 2001, the formulation of the new regulation followed the co-decision process. This was also the year when consultations were incorporated formally in the European regulatory process and hence the opinion of different stakeholders was officially requested. The figure below presents the legislative background of the 2004 Detergents Regulation.



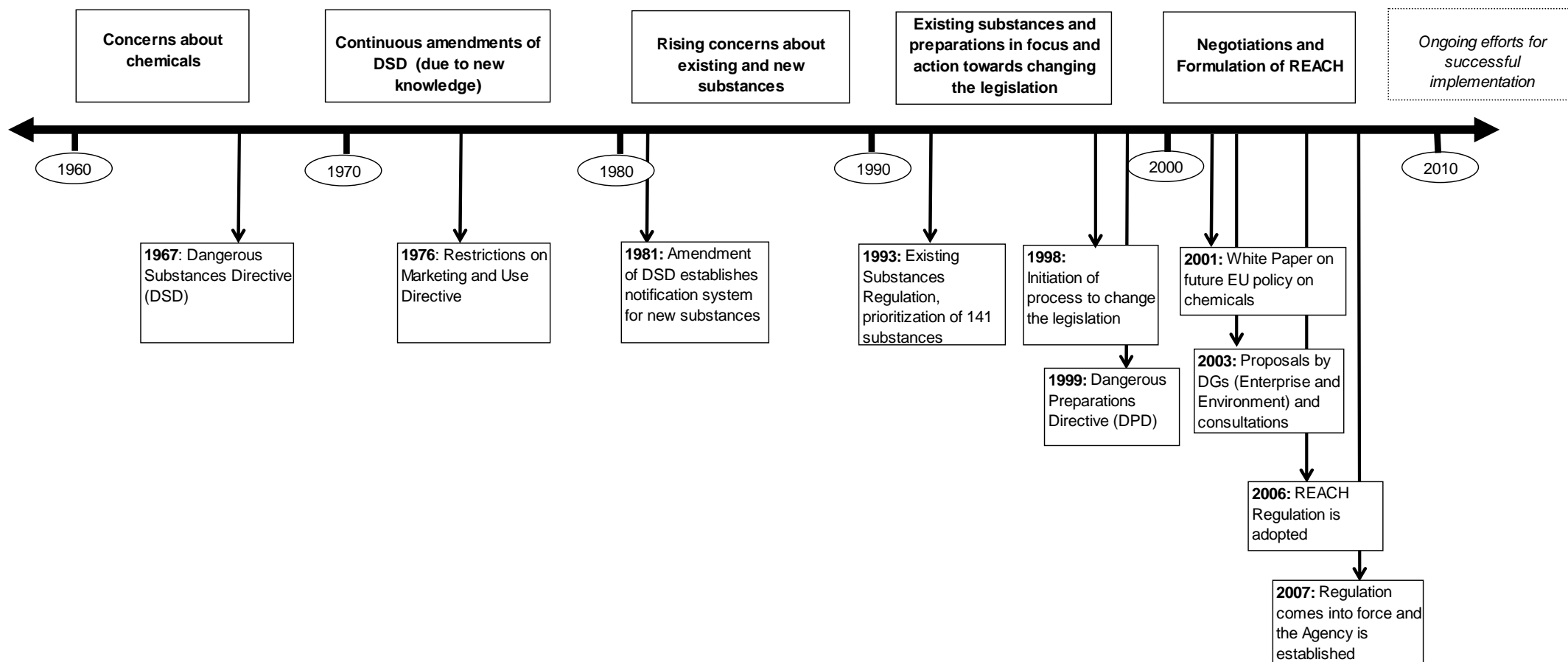
ANNEX THREE: Registration, Evaluation, Authorization and Restriction of Chemical substances (REACH)

The new Chemicals Regulation deals with the Registration, Evaluation, Authorization and Restriction of Chemical substances (REACH) (EC 1907/2006). REACH affects the whole chemical industry and respectively the detergents sector while it consolidates and harmonizes the hitherto national and European pieces of legislation regulating chemical substances. REACH is the descendant of the Dangerous Substances Directive of 1967 (67/548/EC), which was reviewed several times mainly with regards to its annexes. Briefly, the development of this regulation occurred as follows. The 1981 6th Amendment of the Dangerous Substances Directive made compulsory the notification of new substances to a system that required testing and risk assessment prior to their marketing. In 1993, the Existing Substances Regulation (ESR) prioritized 141 (out of 30,000) substances for comprehensive risk assessments based on rising concerns about existing substances. The ESR provided guidelines for the testing, risk assessment and risk management of existing substances based on existing data without further requirements. In 1999, the Dangerous Preparations Directive (DPD) filled the gaps of the Dangerous Substances Directive (DSD), by regulating preparations and finished products accompanied by the 2001 General Product Safety Directive which sets safety requirements for consumer products and is of a very wide scope.

The above regulation placed most of its emphasis on new chemicals and much less on the existing ones. In April 1998, the Council of Environment initiated the process for changing the legislation. Since 1998 and for most of the following three years there has been increased activity on the part of the authorities, including consultations with relevant stakeholders as well as preparation of reports and formal texts. In 2001, an EC White Paper titled “Sustainable Development in the EU Chemical industry within the framework of Single Market” was published and heralded the beginning of a whole new era for the chemical industry in terms of the legislation framing its activity and the roles attributed to different stakeholders. The current legislation is considered to have set a whole new paradigm in the management and orientation of chemical firms and its main features involve:

- a single system for existing and new substances;
- a duty of care for all manufacturers, importers and downstream users of chemicals;
- shift of responsibility/ workload from the authorities to the industry;
- shift of onus of proof from the authorities to the industry;
- authorization system of substances of “very high concern”;
- strict deadlines (Scailteur, 2001);
- safe use of chemicals across the supply chain.

The figure below presents the legislative background of REACH.



ANNEX FOUR: Globally Harmonized System for classification and labeling (GHS)

The Globally Harmonized System for Classification and Labeling (GHS) (COM (2007) 355) deals more with information dissemination rather than the properties of chemical products and aims at a common basis for the characterization of chemical substances with regards to their hazardous properties. The aim of the proposed regulation is to enable judgment on substances and/or mixtures with respect to their hazardous properties, provide hazardous chemicals with appropriate labeling and information on safety measures, reduce the need for testing and evaluation of chemicals and facilitate international trade. GHS was developed to overcome inconsistencies in classification and hazard communication at international level (RPA, 2006). The proposed system presents similarities as well as differences to the existing EU system; differences refer mainly to criteria, additional substances and hazards to be considered, evaluation of mixtures, concentration limits and some symbol changes. The harmonization of systems is not considered as a novel idea since other harmonization efforts were already in place. GHS targets not only the consolidation of national and continental differences in semantics, but also seeks to provide a common basis for classification and hazard communication for all audiences along the supply chain (i.e. workers, transporters, emergency responders, consumers, etc.). The figure below presents the legislative background of REACH.

