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The Role of Law in Managing the Tension between Risk and Innovation

Introduction to the Special Issue on Regulating New and Emerging Technologies

Maria Weimer* and Luisa Marin**

Technological innovations are crucial drivers of economic, social, and environmental progress.¹ While innovations lead the evolution of our societies and permeate all domains of human life, they also pose significant risks both to humans and the environment. Law and regulation are expected to enable innovation, while at the same time protecting society from unintended consequences.² However, assessing new technological risks confronts deep uncertainty and limited knowledge. In contrast to simple risks (e.g. car accidents), technological risks (such as risks stemming from new health technologies, nanotechnology, biotechnology, or robotics as discussed in this special issue) cannot be calculated according to traditional technocratic models, namely as a statistically foreseeable function of probability and effects.³ It is widely recognised that regulating new and emerging technologies is challenging for law due to problems of uncertainty and limited knowledge in the assessment and management of technological risks. To address this challenge it is crucial to study the ways in which law and regulation can successfully respond and adapt to technological progress.

As a social institution crucial for managing societal expectations, law plays a pivotal role for the so-

cial embedding and acceptance of new technologies in society. Above all, law is crucial for managing the tension between innovation and risk by ensuring a high level of protection, providing safety nets, and assigning responsibility for potential damage. At the same time, law is often considered either as an obstacle to innovations or as unable to protect society from their risks. Traditional law-making is often seen as both inefficient and unequipped to govern technological change, which evolves at a high pace. This has triggered the emergence of new approaches to law and regulation in both theory and practice. Scholarly work on new modes of governance,⁴ risk regulation,⁵ risk governance,⁶ responsive regulation,⁷ just to name some prominent examples, has contributed to rethinking traditional categories of government, law and regulation. Yet, while the problem of law's 'backlog' has been extensively discussed,⁸ the implications of technology and innovation for law, regulation and governance deserve further attention.

This special issue explores the ways in which law and regulation respond to emerging technologies, and how this in turn can lead to innovations in law and regulation. It therefore recognises that the rela-

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1 Innovation and progress are mirroring concepts. See Ulrich Beck, *Risk Society: Towards a New Modernity* (SAGE Publications 1992) 200 according to whom progress is an institutionalized 'extra-parliamentary structure of action for the permanent changing of society'.

2 On technological risks as unintended consequences of late modernity see Beck (n 1).

3 Marjolein BA van Asselt and Ortwin Renn, 'Risk Governance' (2011) 14 *Journal of Risk Research* 431.

4 See Charles F Sabel and Jonathan Zeitlin, *Experimentalist Governance in the European Union: Towards A New Architecture* (Reprint, Oxford University Press 2012); David M Trubek and Louise G Trubek, 'New Governance and Legal Regulation: Com-

plementarity, Rivalry or Transformation' [2007] University Wisconsin Law School Legal Studies Research Paper Series <<http://papers.ssrn.com/abstract=908229>> accessed 5 July 2016.

5 Ellen Vos and Michelle Everson, *Uncertain Risks Regulated* (Taylor & Francis 2008); Maria Weimer, 'Risk Regulation and Deliberation in EU Administrative Governance—GMO Regulation and Its Reform' (2015) 21 *European Law Journal* 622; Maria Lee, 'Beyond Safety? The Broadening Scope of Risk Regulation' (2009) 62 *Current Legal Problems* 242.

6 Asselt and Renn (n 3).

7 Julia Black and Robert Baldwin, 'Really Responsive Risk-Based Regulation' (2010) 32 *Law & Policy* 181.

8 Roger Brownsword, *Regulating Technologies: Legal Futures, Regulatory Frames and Technological Fixes* (Hart 2008); Jonathan B Wiener, 'The Regulation of Technology, and the Technology of Regulation' 26 *Cambridge Quarterly of Healthcare Ethics* 483.

tionship between law and technology is more complex than one-directional accounts are able to tell.⁹ By framing technology regulation in a certain way law itself is able to shape technological innovations thereby encouraging or discouraging different types of innovations.¹⁰ At the same time, the need to regulate emerging technologies triggers the evolution of new legal concepts. In what way does scientific complexity and the increasing reliance on both non-legal expertise and non-state actors affect the nature of law-making and enforcement including the task of judicial control?

By addressing these questions, the articles in this special issue are contributing to a promising research agenda, which studies law not merely as an obstacle to technology, but as an institution that is crucial to managing the tension, inherent in emerging technologies, between risk and innovation, between anxiety and promise. The issue therefore contributes to studying legal and regulatory transformations in the technological age.

The EU is a particularly productive site for the emergence of such legal and regulatory transformations.¹¹ As part of its 2020 strategy, the EU strives to accomplish an Innovations Union, defined as ‘a strategy to create an innovation-friendly environment that makes it easier for great ideas to be turned into products and services that will bring our economy growth and jobs.’ While not uncommon, this framing of innovation as a market commodity and a perspective for growth in the economy is further strengthened by the internal market underpinnings of the EU regulatory state. The EU intervention in the field of technology regulation (both on the side of risk and on the side of innovation) takes place within the particular multi-level legal and institutional framework of internal market integration.¹²

On the one hand, the functional necessity to assess and manage risks (e.g. to public health, environment and consumers) in a coordinated way in the EU’s internal market led to re-regulation, and therefore the expansion of the EU regulatory state. On the other hand, that expansion has been accompanied by problems of both EU law (e.g. principle of conferral, competences, institutional balance) and legitimacy.¹³ The latter is particularly contested in view of multi-level conflicts of authority (who decides on acceptable risks and levels of protection?) as well as democratic and political contestation over the desirability of particular technological innovations. Such con-

flicts and contestation also create problems of enforcement and implementation of EU legal frameworks at the national level.¹⁴

Because of the need to meet these challenges, EU law and regulation of technology has been an on-going process of crisis, learning, and adaptation. The public health and food safety scandals of the 1990s, for example, have paved the way for the consolidation of a EU approach to risk regulation based on the precautionary principle.¹⁵ Moreover, the socio-economic diversity in the Member States and hence the difficulty of implementing one-size-fits-all approaches has also allowed for regulatory experimentation and more de-centralised approaches.¹⁶ At the same time, the most visible challenge in EU law and regulation of technological risk has been to manage the tension between internal and external pressures.¹⁷ The latter is due to the transnationalisation of EU regulation as well as the need to comply with legal obligations of external economic governance regimes, such as that of the World Trade Organisation. The current controversies surrounding the negotiation of a new generation of regional trade agreements such as CETA and TTIP can be seen as a continuing manifestation of that external pressure. All this emphasises the need for EU law and regulation to continuously learn from past regulatory experiences and failures in order to meet the challenge of

9 Sheila Jasanoff, *States of Knowledge: The Co-Production of Science and the Social Order* (Routledge 2004). See also Maria Weimer and Anniek de Ruijter (eds) *Regulating Risks in the European Union: The Co-production Between EU Expert and Executive Power* (Hart Publishing, forthcoming).

10 On how regulatory experience with previous ‘new’ technologies shapes the frameworks for the next generation of technologies, see Elen Stokes and Diana Bowman, ‘Nanotechnology: Looking Back to the Future of Regulating New Technologies: The Cases of Nanotechnologies and Synthetic Biology’ (2012) 3 *European Journal of Risk Regulation* 235.

11 Sabel and Zeitlin (n 4).

12 See Christian Joerges and Ellen Vos, *EU Committees: Social Regulation, Law and Politics* (Hart Pub 1999); Ellen Vos, *Institutional Frameworks of Community Health and Safety Legislation: Committees, Agencies, and Private Bodies* (Hart 1999).

13 Vos (n 13).

14 Weimer (n 5).

15 European Commission, *Communication from the Commission on the Precautionary Principle* (EUR-OP 2000). See also Patricia Stapleton in this issue.

16 See Mini-Symposium on the EU GMO Reform in *European Journal of Risk Regulation* 4/2015 (Vol. 6).

17 See Grace Skogstad, ‘Contested Accountability Claims and GMO Regulation in the European Union’ (2011) 49 *JCMS: Journal of Common Market Studies* 895.

regulating new technologies in a transnational multi-level governance setting.

Against this background, this special issue points to several important lines of inquiry for interdisciplinary research on law and regulation of new and emerging technologies. The first important line of inquiry that emerges from the articles in this special issue is trust. This issue shows that trust is a crucial factor in stimulating regulatory learning among different stakeholders.¹⁸ Moreover, trust in the availability of legal protection in case things go wrong contributes to societal acceptance of innovation.¹⁹ Finally, breach of trust significantly shapes future institutional paths and legal reforms. For example, past regulatory and public health scandals in the European Union (e.g. mad cow, HIV-contaminated blood and dioxin contamination scandals) have undermined public trust in law and regulation.²⁰ Experience with these scandals has thus paved the way for significant EU legal reforms in the field of product safety including the emergence of the precautionary principle as a general principle of EU law. It has also shaped the political and institutional context for the introduction of the next generation of technologies (e.g. biotechnology²¹ and nanotechnology²²).

Another important line of inquiry relates to the insight that technological risk and uncertainty contribute to regulatory uncertainty, which can in turn hinder innovation. Therefore regulators should recognize their mission to enact future-proof regulation, i.e. regulation which contributes to the societal embedding of newly emerging technologies.²³ The reg-

ulation of responsible innovation should ensure a fair redistribution of risks connected with the emergence of new technologies. Furthermore, responsible innovation requires a broader approach that considers the ethical aspects of the governance of new technologies. Such a broader approach could positively contribute to increasing the social acceptance of newly emerging technologies.

Finally, this issue shows that technology might not only create risks, but also the opportunities to address these risks. For example, Tracing Technologies (TT), as described by de Bruin,²⁴ can contribute to addressing some of the regulatory questions created by Automated Intelligent Cars (AICs), such as problems of liability. This, however, might entail trade offs and raise follow up questions as to the societal preferences between conflicting interests: are we willing to give up some of my privacy if TT contributes to less regulatory uncertainty in cases of hybrid traffic? We should therefore consider societal preferences, for example with regard to privacy, not as static, but as constantly changing and dynamic: we might be increasingly willing to trade-off some public goods for others on the premise that regulatory strategies strive for a fairer distribution of risks arising from newly emerging technologies.

This special issue comprises four articles.²⁵ Every article contributes to the discussion on law and regulation of emerging technologies from different perspectives and backgrounds, and taking different case studies as starting points.

The first article by *Marta Morvillo* offers an original approach that combines a science and technology studies (STS) perspective with a constitutional law perspective to study the dialectic between law and science in the case law of the Italian Constitutional Court. Morvillo shows how 'scientific expertise' has permeated all traditional branches of public powers: neither the legislative nor the judicial powers can be considered as immune to the need of relying on a new source of legitimacy, namely scientific legitimacy. This in turn leads to the emergence of a new legal paradigm in the constitutional adjudication of scientifically complex issues.

In the theoretical part of her article, Morvillo sketches the difficulties in reconciling law and science as two fundamentally different realms: on the one hand, law as the realm where different interests and choices must be composed; and on the other hand, the scientific realm, which seems to be guided

18 See Aline Reichow in this issue.

19 See Roeland De Bruin in this issue.

20 See Patricia Stapleton in this issue.

21 See *ibid.*

22 See Aline Reichow in this issue.

23 P. Ruebig, 'The Changing Face of Risk Governance: Moving from Precaution to Smarter Regulation' (2012) 3 *European Journal of Risk Regulation* 145.

24 See Roeland De Bruin in this issue.

25 Earlier drafts of the articles have been presented and discussed at the panel "Regulatory challenges of new and emerging technologies" of the UCall conference "Law and the Risk Society", held at Utrecht University on 9-10 April 2015. The panel has been convened jointly by dr. Evisa Kica and dr. Luisa Marin. The Guest Editors wish to thank several colleagues who, in different roles, have contributed to the quality of the articles, by giving comments during the panel session of the UCall conference and by providing comments to earlier versions of the articles: Prof. Diana Bowman, Dr. Roderick van Dam, Dr. Frøydis Gillund, Prof. Michiel A. Heldeweg, Dr. Melinda Mueller, Prof. Henry Rothstein, Prof. Elen Stokes, Prof. Ramses A. Wessel (in alphabetical order).

by its immanent legitimacy based on scientific knowledge. Here the STS perspective helps Morvillo to reveal the naivety of the legal (community) attitude toward science, since the former has for long perceived the latter as a mere provider of neutrality and objectivity, whereas “the dialogue between technical-scientific knowledge and legal regulation” should be framed “as one of bi-directional influence”.²⁶ This is even more so when science is not able to provide certain answers, but rather unveils uncertainties.

Against this background, Morvillo analyses case-law of the Italian Constitutional Court, in which the Court carries out a constitutional review of technical legislation. By studying the reasoning behind six judgments, delivered from 1998 to 2014, Morvillo presents the reasoning of the Court when reviewing the constitutionality of the balance stroke between different concerns and interests in Italian technical legislation in fields such as clinical trials on new (‘Di Bella’ and ‘Stamina’ treatments) and controversial therapies (‘electroshock’ and ‘lobotomy’) as well as in the field of medically assisted reproduction.

Morvillo’s work argues that the Constitutional Court recognizes a significant space for a “technical reserved competence”, represented by the contribution of technical expertise, which is considered as essential and capable of limiting the political space of manoeuvre. Furthermore, Morvillo shows the emergence of “scientific reasonableness” as an evolving constitutional paradigm governing the interaction between science and political discretion. Scientific reasonableness is not a totally new legal category, but is rather a new declination of the reasonableness principle, a cornerstone of constitutional adjudication in Italy. The focus of the Court on scientific expertise was also determined by the fact that the legislative processes in the cases at hand were charged with ethical, political and values-oriented issues. Morvillo’s analysis shows that without needing to transform themselves in scientific experts, judges can rely on traditional legal principles as a toolkit for solutions of most contemporary issues.

The second article, by *Roeland de Bruin*, constitutes an ahead-of-the-curve exploration of European law and regulation of Automated Intelligent Cars (AICs) – an innovation currently still under development, but likely to transform transportation as we know it.

De Bruin focuses in particular on the question of whether the current legal frameworks for liability for

damages and of informational privacy and data protection in Europe are sufficiently equipped to address the AIC challenge. This question is particularly relevant for the integration of this innovation in our societies as well as for its societal acceptance.

More specifically, De Bruin discusses the EU Products Liability Directive as well as the road-liability regimes of France, the Netherlands and the United Kingdom. All the legal regimes analysed rely on causality for determining and allocating liability. The author shows the way in which the *autonomy* and the *intelligence* of AICs puts into question the traditional category of causality and its relevance for the future: “Autonomous intelligence makes it harder to pinpoint the exact cause of damage”, and therefore to determine liability. Which solutions could law offer? A strict no-fault liability regime for damage caused by AICs, which might be borne by producers and be perceived as an impediment to innovation? While the regulatory discussion is still open, technology, by offering tracing mechanisms, might contribute to finding a solution to the causality problem.

The other issue analyzed by de Bruin is the challenge posed by AICs to informational privacy and data protection. As is known, privacy and data protection are of fundamental relevance in the EU’s and the Member States’ legal orders. As two distinct but connected fundamental rights they shape the regulatory landscape in which AICs will operate. Data collected by AICs’ tracing technologies can be considered as personal data, when such data can identify, even indirectly, a natural person. Here de Bruin signals a paradox: on the one hand, the autonomy of AICs challenges liability regimes; this can however be ‘fixed’ with tracing technologies. On the other hand, the latter represent a challenge to informational privacy. Both regulatory aspects influence the societal acceptance of AICs, in the sense that consumers would request a high level of protection of legitimate interests, both in areas of liability and of privacy. De Bruin offers some suggestions on how regulators could strike an adequate balance between these conflicting interests.

The third article by *Aline Reichow* addresses another challenging issue, namely, how to ensure the effective regulation of nanotechnology in the Euro-

26 For a similar reflection, see also Gustavo Zagrebelsky, *Moscacieca* (Laterza, 2015).

pean Union. Her findings show most vividly how scientific uncertainty and limited knowledge surrounding this technology force law and regulation to rethink traditional ways of rule-making and implementation, above all the traditional conceptual distinction between these two categories. Reichow also illustrates the crucial role of learning and trust in the regulation of new technologies, as well as in the development of adequate legal rules and standards in this area.

More specifically, her contribution studies learning processes in nanotechnology regulation, which occur during the process of implementation of EU legal frameworks for occupational safety and health (OSH). The challenge posed to law and regulation in this field is that both regulators and employers are facing scientific uncertainty regarding potential health risks of nanotechnology as well as lack of knowledge regarding suitable risk assessment methodology in this field. At the same time, in order to comply with existing EU regulations, employers need to carry out risk assessments while regulators need to assess whether existing health and safety frameworks are evidently protecting employees' health. However, 'the prevailing scientific uncertainty means that we do not know whether existing rules evidently mitigate risk and protect employees or whether companies are able to comply with these rules'. The effectiveness of regulation (i.e. the degree to which policy goals have been achieved through the rule compliant behaviour of the regulated parties) therefore depends on the ability of both types of actors to organize processes of collaborative mutual learning in the practical application of EU OSH rules. The article therefore confirms the importance of studying processes of rule implementation which in fact constitute another layer of concretisation of legislative rules and frameworks, and the outcome of which feeds back into EU legal frameworks. Reichow's contribution lies in her offering a theoretical framework for studying such learning processes based on literature on network governance. This framework helps crystalizing three types of learning, namely substantive learning, which leads to the generation of scientific expertise, strategic learning, which generates trust, and institutional learning, which generates rules. By applying this framework to the case of nanomaterials regulation in Germany (which implements EU rules), she analyses the conditions under which learning has occurred in the col-

laboration between various actors (i.e. regulators, industry, federal research institutes). An important contribution of this article is that it indicates new avenues for empirically studying trust in collaborative activities. Moreover, it also raises interesting questions for law, such as whether law can play a role in facilitating trust in collaborative governance of new technologies, for example by offering procedural guarantees of independence. Furthermore, Reichow's analysis challenges the distinction between rule setting and implementation pointing to the recursive nature of law making.

The last article by *Patricia Stapleton* is dedicated to contemporary debates over risk regulation in Europe, and especially over agricultural biotechnology. Adopting the lens of Ulrich Beck's risk society, the author provides for a reflection on the political and cultural context of risk regulation in the EU. Stapleton's analysis is very informative in that it sheds light on the question of how prior scandals in Europe, from the HIV-contaminated blood scandal, to the mad cow crisis, and the dioxin contamination scandal have shaped the social, political and institutional context into which GMOs arrived in Europe, and which shaped EU regulation of agricultural biotechnology. She shows the way in which these prior scandals have created policy linkage in the public mind during the 1990s and the early 2000. Stapleton describes these public health and food safety scandals as exemplifying the side effects of modernization as outlined by Beck, and as revealing the tension between a globalizing market and public anxiety in late modern risk society. The negative experiences during these scandals, which have seriously undermined trust in the respective national regulators and their ability to act in the public interest, have set a new stage for the development of a new risk regulatory law and policy at the EU level. Stapleton's contribution helps us to better understand the emergence of the EU approach to the regulation of new technologies including to the precautionary principle as well as the gradual shift of regulatory competence in the field of public health and food safety from the Member States to the EU. These developments have significantly shaped the EU approach to the regulation of GMOs. In the words of the author 'This article demonstrates how the evolution of the precautionary principle reveals the entrenchment of Beck's risk society, and how the push for incorporation of the precautionary principle into food safety regulation represents the institution-

alization of concern about the distribution of risks.’ It also shows, that failure to address uncertainty surrounding a new technology in an open way can cre-

ate a backlash in public perception, if things go wrong, and create a stricter regulatory environment for future legal frameworks.