

INTRODUCTION

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1. Setting the context: contemporary risk regulation

Designing and implementing public interventions to effectively understand, prevent or mitigate risks has never been straightforward. In contemporary governance, nonetheless, public risk management activities appear to be particularly challenged. Because of the prevalence of systemic risks that span across sectors, actors and countries, and of societal expectation to manage emerging risks, risk assessment, management and communication are being questioned. Established approaches to understanding and addressing risks with impact on the environment, the economy or society may no longer be effective or fully legitimised. Also a major instrument that Western society has adopted to address risks – regulatory interventions – is under the spotlight and its performance and cost-effectiveness is sometimes challenged.

Traditional regulatory risk management – its nature, scope and efficiency – is being tested against changed framework conditions, which emerged because of the concomitance of a number of new global phenomena.

- **Multiple, multiplying and interdependent linkages** – Globalisation is not a mere keyword. The 21st century world is characterised by faster interactions between various actors across levels of established governance. Wiener (2011) describes three dimensions of increasing interconnectedness and risk regulation: (i) the faster and wider propagation of risks across globalising networks (for instance the transmission of pandemic disease, financial crises, terrorist attacks, or cyberwar); (ii) so-called “multi-risk impacts” generated by any intervention to address one risk, including ancillary harms and benefits (because the world is a web of multiple interconnected risks); and (iii) the increasing diffusion of regulatory ideas and learning across regulatory systems, potentially helping to address the first two dimensions. Well-defined and contained territorial and jurisdictional units of governance are no longer the reference system. No single, clearly identifiable and legitimated (public) actor can address complex societal problems. Globalisation has brought unprecedented opportunities for both developed countries and emerging economies but it requires a reorganisation of actions at the local, national and international level, as well as across various types of public and private organisations (Nye and Donahue, 2000; Vogel and Kagan, 2004; Camilleri and Falk, 2009).

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- **Greater complexity and salience** – Regulators are called upon to tackle increasingly complex and multi-faceted challenges. In the past problems have tended to be tackled singularly as definite entities, today we recognise the presence of – and expect solutions to – risks that cover the widest possible spectrum of the observable (Power, 2004). Action expected from public risk managers ranges from overarching societal problems (such as climate change and population ageing) to specific exposures to single chemicals (e.g. an endocrine disruptor) and the use of novel technologies or processes (for instance, nano- and bio-technologies). Regulators are moreover called upon to manage proven or potential risks which may involve fundamental ethical issues (e.g. application of stem cells research) or pertain to life-style (determined by individual nutritional, smoking or alcohol consumption patterns), which stretch the boundaries of the role of the state (Asveld and Roeser, 2009; Alemanno and Garde, 2013). Furthermore, emerging risks are constantly brought onto the regulators’ radar screen (IRGC, 2015). To a greater extent than in the past, risk regulators are now asked not only to react but also to anticipate future risks, deploying diversified rational risk management strategies (Viscusi, 1998; Sunstein, 2002; Hutter, 2010). Finally, the management of systemic risks is also increasingly relevant and in demand – both from the point of view of controlling catastrophic events and system-disruptive threats and as a means, by clustering various (types of) risks, to find suitable approaches to manage an economic and social system (OECD, 2003; Helbing, 2010; Alemanno, 2011).
- **Evolving processes and tools** – Evolving governance modifies decisional processes. The pivotal actor for public risk management is no longer only the ‘regulatory state’ (Majone, 1996). Increasingly, the goals and standards set out in primary legislation are interpreted and implemented through rule-making by non-state actors as well as administrative decisions or adjudication (Craig, 1990; Fisher, 2007). An “administrative state” has emerged in which the executive frequently acts as the regulator, the administrator and the arbiter, sometimes confusing the traditional separation of powers designed to protect citizens from poor quality or arbitrary decision-making (Richardson, 2002). So-called ‘Better Regulation’ principles and practices have been widely diffused internationally (OECD, 2015),² but their application has yet to fully reflect this development. The development and adoption of substantive guidance, for instance, tends to escape process management standards.³ Against this background, moreover, new tools for interpreting and managing risk situations are being tested. Insights from behavioural sciences have for instance opened new possible avenues to design and organise public risk management interventions using cues or ‘nudges’ (Shafir, 2013; Lunn, 2014) or deploying

² The diffusion of regulatory impact assessment – initially ex ante and nowadays increasingly ex post as well – is a point in case (DeFrancesco, 2013; Wiener, 2013).

³ A form of “soft law”, substantive guidance is used to set out detailed technical, scientific, or procedural requirements that must be met to fulfil obligations laid down in legally binding acts and to provide detailed interpretations of statutory obligations thereby defining requirements or impacts for affected entities. In many sectors, and for a wide range of risks, substantive guidance is one of the most important means used to implement secondary legislation. It is used to define, for instance, the technical or scientific requirements that businesses must meet if their products, processes, materials, or services are to satisfy standards of safety or quality or efficacy or environmental impact. Substantive guidance may also define complex hazards or clarify the scope and impact of major risk management laws (European Risk Forum, *forthcoming*; Graham and Broughel, 2014).

more experimental approaches such as design thinking and prototyping (Brown, 2009; Bason, 2010; Allio, 2014). Accountability, predictability, the rule of law and the quality of decision-making – and even its very legitimacy – may suffer when public and private decision-makers are dis-jointed from those affected by their decisions.

- **Higher expectations and weaker confidence** – Trust and confidence in government tend to be directly correlated to the public's expectations, and the more citizens are educated and mature, the higher are the demands on high quality and timely policy interventions. This naturally creates gaps between the pace at which institutions and decision-making structures evolve and how societal values and technology evolve. Tensions emerge between preserving stability and acquired affluence on the one hand, and accompanying (or prompting necessary) change on the other. From this perspective, public institutions in general always experience structural variations in public confidence (Fukuyama, 1995). The financial and economic crisis of 2008 has arguably only highlighted and accelerated the steady decline in trust, but it has not triggered it (Blind, 2007; Bouckaert, 2012). The post-crisis recovery context, however, significantly determines how public policy is implemented – and often in negative terms. Despite continued sophistication, accuracy and timeliness in detecting potential harm, the public is increasingly exposed to social amplification of risk that considerably affects public perception and acceptance (Renn, 2008). Winning the challenge of regaining and maintaining trust is crucial for contemporary governments (Lofstedt, 2005; OECD, 2013).

In response to the sophistication of contemporary challenges, governments are revising their analytic and management tools, including for their ability to address unintended negative consequences that arise from regulatory activity, such as so-called 'risk-risk trade-offs'.⁴ While the task to manage new forms of risks becomes more formidable, governments are held responsible for both the regulatory costs of detecting and addressing the risks as well as the costs of failing to prevent the risks.

At the same time, risk regulation offers an opportunity to public authorities because it provides ways for public authorities to revisit their role, organisation and functioning and be better equipped to address the double challenge of responding to ever increasing demands by the public for efficient action on the one hand while facing declining levels of trust and resource constraints on the other.

Risk regulation has yielded both successes and failures, and faces pressures to improve in several ways – including by learning from past experience to improve future design and performance. Scientific risk assessment by expert committees is increasingly complemented by assessment of concerns of affected parties, in an open and multi-stakeholder process. Society no longer contents itself with “being told” but requires to “be shown” how risk management options are chosen and are likely to have an impact – and it aspires to “be involved” in decisions (Rothstein et al., 2006).

⁴ Decisions taken to manage one single risk may create other countervailing risks (Graham and Wiener, 1995).

2. Rationale and purpose of this publication

If the traditional organisational and procedural frameworks so far used by regulators are put into question, it is imperative to explore various fields and experiences with public and private risk management solutions.

The decision to embark on this publication was stimulated by the high-level annual conference that the International Risk Governance Council (IRGC) organised on “*Improving Risk Regulation. From Crisis Response to Learning and Innovation*”, in collaboration with the Organisation for the Economic Co-operation and Development (OECD) and Duke University in October 2014.⁵ The conference identified, evaluated and discussed the relevance and effectiveness of new approaches to improving risk governance, both as they result from responding to and learning from crises, and as deliberate innovations in how regulatory power is exercised and shared. The research project organised by Duke University and presented on the first day of the conference will produce a book on policy learning from crises, with the title *Policy Shock: Regulatory Responses to Oil Spills, Nuclear Accidents and Financial Crises*. The sessions on the second day of the conference examined several kinds of regulatory innovations and framed the focus of this IRGC publication.

This publication thus explores new insights for addressing contemporary risks. It rests on the definition of ‘risk regulation’ as the body of law intended to prevent, reduce or re-allocate the likelihood of harm to individuals and society, and protect health, safety, security, and the environment from a variety of risks (UK Royal Society, 1992; Hood et al., 2001; OECD, 2010) – to then provide an overview of different forms and approaches to risk management by public authorities and the private sector based on interdisciplinary risk governance and multi-stakeholder processes. The publication highlights some innovative approaches to how governments and the private sector collaborate to improving the overall performance and efficiency of regulatory frameworks. **It seeks to stimulate reflection among (public and private) regulators as well as those who are regulated on how best to design and implement risk regulation so as to enhance its impact and efficiency.** In addition, the publication identifies innovative approaches that governments and the private sector may follow to exploit synergies and collaborate to ameliorate public risk management.

⁵ The conference programme and the presented slides can be accessed at irgc.org/event/annual-conference-2014-summary

3. Structure of the publication

This publication is the result of a collective effort by several international experts with various backgrounds. It is divided into four chapters, each of which introduces relevant issues and perspectives to modern public risk management. Taken together, the distinct dimensions and approaches presented in the chapters provide insights into how to possibly enhance the effectiveness and legitimacy (credibility) of risk regulation in the 21st century.

The first essay, authored by Colin Scott (University College Dublin), explores the private-public interface in organising and managing societal interactions. Transnational private regulation regimes may provide promising complementary approaches to the governance of risk and innovation. For instance, transnational industry associations may help design technical standards that are voluntary but set performance requirements that are subsequently adopted and enforced by governments. The essay presents illustrative examples of the potential that transnational private regulation has on innovative governance, notably in relation to addressing market coordination problems, to complementing inadequate and inappropriate public regulation, and to building community solidarity (understood here as willingness by all actors to achieve higher societal goals).

Terry Yosie (World Environment Center) explores emerging strategies to manage system-level risk through enhanced collaboration between public and private actors, including non-governmental organisations (NGOs) and leading global companies. The paper presents examples of collaborative arrangements that help understand and manage at various governance levels risks to public health and the environment triggered by contemporary global mega-trends. Such collaboration – the paper argues – yields insights on the scale of risks, new governance models, opportunities for innovation, and specific risk management strategies that incorporate sustainability. Accordingly, regulators should closely examine these dynamics, for they provide relevant information and case studies for the design of future regulatory strategies by modifying the scope and locus of decision-making; improving scientific tools and methods; identifying opportunities for collaboration across government, NGOs and private sector institutions; and developing a future research agenda.

Ortwin Renn (University of Stuttgart) and Marie-Valentine Florin (IRGC) address one of the emerging approaches to public intervention design – applying insights from behavioural sciences. Their essay investigates the scope and challenges for behaviourally-informed risk regulation as not only effective but also legal and legitimate means to achieve desired behavioural change. Dwelling on insights from behaviourally-informed interventions, the authors highlight how management decisions can preserve individual choice, for instance through default rules, smart disclosure and simplification requirements. They argue that the moral and political legitimacy for collective actors to shape human behaviour is granted only if the overarching policy goals have been agreed through the democratic and inclusive process.

The final essay constitutes a case study highlighting a practical sectoral application of new thinking emerging on how to improve regulation on the basis of enhanced collaboration between regulators, industry and the public (patients in this case). It refers to adaptive approaches to pre-market drug authorisation and the essay reports on the related panel organised at the IRGC conference of October 2014 mentioned above. The essay is authored by Kenneth A. Oye (Massachusetts Institute of Technology, MIT), Mark Pearson (OECD), Hans-Georg Eichler (European Medicines Agency), Theresa Mullin (US Food and Drug Administration) and Anton Hoos (Amgen). Against the background of a sector marked by rapid advances in science and technology, the authors highlight the main drivers of the adaptive licensing debate – growing patient demand for timely access to address unmet medical needs; emerging science of precision medicine leading to fragmentation of treatment populations; healthcare systems' budgetary constraints and rising payer influence on product accessibility; and pressure on pharma/investors to ensure sustainability of drug development. The authors focus on international regulatory initiatives to foster innovation while improving use of pre-market and post-market information, thereby striking a better balance over the full life cycle of drugs in the trade-off between uncertain effectiveness and safety of the treatment and its timely application.

The concluding remarks draw lessons from the various approaches and policy areas presented in the publication. They propose possible elements for advancing the risk regulation agenda internationally with a view to improving the performance and efficiency of risk management regulatory interventions. In that light, **public regulators might need to 'reinvent themselves' into providers of platforms that catalyse various approaches to risk management. In doing so, however, they cannot abdicate their role as guardians of transparent and rigorous evidence-based decision-making.**

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