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CONCLUDING REMARKS

FROM RISK REGULATION TO AN INNOVATIVE RISK GOVERNANCE

by Lorenzo Allio[1]

Over the past two centuries, societal problems and citizens' concerns for safety and security have mainly been addressed through public forms of risk management. Today, government action mainly seeks to manage risks posed by technologies, products, economic and financial activity, and lifestyle choices. To be effective, **public risk managers must strike a balance between fostering innovation and prosperity on the one hand and maximising security and equity on the other** – a balance that changes over time.

Like any other actor facing globalisation, **regulators are called upon to grasp and react to increasingly inter-connected and intricate problems** whose emergence, type, scale and evolution are difficult to anticipate and control. What more, they have to do so in a context of higher demands from stakeholders and the public with regards to transparency, accountability and participation in all stages of the risk management cycle – from the identification of the mischief to formulating options and assessing impacts, to sharing implementation and enforcement tasks and review.

Traditionally, governments have so far responded to the growing sophistication of the societal challenges by engineering increasingly refined technical solutions without denaturing the intrinsic organisational and cultural rationale of the public sector. The model based on ever more specific and numerous silos of deep expertise and on typically command-and-control regulation is no longer the only model fit for purpose – it needs to be refined and complemented, and **governments now work at the intersection of multi-disciplinary and multi-actor knowledge, to integrate various perspectives**.

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1. Grasping approaches to improving risk regulation

This publication looks at different approaches that have emerged across various policy areas and on the initiative of various actors over time, which may set the basis for designing innovative risk governance. On the basis of the collected papers, these concluding remarks try to shed a light on how to 'read' them and how to internalise key lessons from those experiences. They result in an embryonic roadmap to renovate risk management by public authorities – a stimulating agenda ahead. The ambition is to **contribute to improving the exercise of the regulatory power (through co-decision, shared responsibility and transformation) and, by so doing, restoring trust and confidence between regulatory authorities and the regulated**.

The rationale for public risk management is expanding both in nature and scope – from economic and discrete to also social and systemic.

Regulatory interventions are no longer exclusively dictated by the willingness and necessity to curb economic inefficiencies and market failures, as modelled by neo-classical economic theories. Regulators still seek to intervene when in presence of non-competitive markets, externalities and sub-optimal supply of public goods. Yet, social regulation is increasingly adopted. It strives to achieve societal objectives, shifting for instance from guaranteeing minimum standards for public safety to achieving 'well-being' in a more normative way. This is not at all wrong per se, but it clearly raises the stakes of what regulators ought to do and can do (well).

The desirability and indeed **necessity to widen the remit of risk management to embrace more comprehensive approaches** is a recurring theme of the publication. Indeed, various perspectives of such an 'expanded risk management' are presented across the papers.

▶ **Colin Scott**'s analysis of transnational private regulation regimes stresses the intrinsic potential of private arrangements, either in terms of direct efficiency gains compared to traditional risk management solutions by public authorities, or because of socially-driven incentives to enhance risk management options – what he labels 'community solidarity'. Societal added values may be swifter and smoother coordination and functioning of markets and more generalised and effective implementation of risk management solutions. In addition to the stakeholder collaboration highlighted by Yosie, Scott's paper draws the attention also to the competitive nature implicit in much of the transnational private regulatory regimes – and how this needs to be managed to avoid distortions or detrimental re-allocation solutions. In any event, the examples brought forward show the leadership of private actors in topping government action across national boundaries.

▶ **Terry Yosie** reviews private sector initiatives for the management of systemic risks, presenting approaches to private public partnerships based on well-defined goals, flexibility to reach these goals and an effective checks and balances control system. He highlights how piece-meal or discrete approaches might

no longer suffice and that systemic risk management is an attempt at clustering various (types of) risks so as to better manage a system. It is simplistic to imagine effective management through individual and disconnected actions, if we acknowledge that economic, social, geo-political and environmental risks co-exists and affect simultaneously both the 'micro' and the 'macro'.

There are then risks that individually have the potential of disrupting entire systems through cascading or ramification effects. Energy black-outs and natural disasters are points in case. They can interrupt production or distribution chains that paralyse whole organisational systems. Public managers face moreover the challenge of the unpredictability of the occurrence of such risks and subsequently the urgency to deploy contingency plans. Stress tests are therefore applied periodically to ensure the readiness and effectiveness of the planned management options and anticipate bottlenecks. Diversification by using right asset allocation mix strategies or insurance helps mitigate such systemic risks but it is usually almost impossible to completely avoid them.

Like in Yosie's line of argument, **the trans-boundary nature of systemic risks (and the related risk management schemes) testifies here of the virtual impossibility to confine interventions within discrete jurisdictions and limit them to public actors**. We face by definition multi-actor, multi-disciplinary networked governance. The next step will be to design schemes to measure success of private and public-private initiatives to deal with systemic risks, including through benchmarking, and to monitor progress of coordinated action. There is a variety of evaluation or monitoring schemes, such as those of the Global Reporting Initiative[2], but robust standard approaches to measure progress in systemic risk management and sustainability is yet to emerge. The relatively recent origin of system-level risk assessments that incorporate sustainability account for the high interconnectivity of the technological, organisational, social and political dimensions offers the private sector great opportunities to develop more effective and efficient management solutions than in the past.

A further expansion of the traditional risk management concept draws from the imperative acknowledgment that any risk management intervention is, by its nature, designed to trigger behavioural changes in citizens or companies, or both.

▶ As **Ortwin Renn and Marie-Valentine Florin** report, regulators are increasingly considering insights from behavioural sciences to best exploit the marginal potential for change in behaviour. The authors underscore the importance of making risk management interventions align well with how people behave spontaneously, hence leveraging on existing (revealed or latent) preferences and incentives. This not only helps overcome inefficiencies linked to command-and-control regulation but it also shifts the emphasis on incentive-based, performance-based and outcome-driven solutions. Understanding the root causes of individual behaviour and preferences becomes increasingly important to achieve effective risk management and to address management trade-offs. The challenge is for risk managers to then be able and capable to exploit the acquired knowledge and leverage on our heuristic and cognitive biases and shortcuts.

[2] See www.globalreporting.org.

Public regulators need to enrich their risk management portfolios – from being direct managers to serving as catalyst platforms – but they must assert themselves as the guardians of transparent and rigorous evidence-based decision-making

Systemic, private-driven (multi-stakeholder) risk regulation presents many challenges and it might be utopic to foresee its implementation at a global level. It has in particular to pass two arduous tests.

- The first test is about trade-off choices: what needs to be given up for what? Who should be affected and how? Solutions to these questions may well vary from region to region, from issue to issue, but in a systemic perspective the calibration of the management solutions might be limited and certainly is controversial.
- The second test is about the wide-spread lack of trust between the private sector (and multinational corporations in particular) and NGOs and the citizens, and the often difficult communication between these actors and public authorities. On individual technologies, products or 'issues', barriers can be (and indeed have been) levelled down. However, many systemic policy issues are admittedly still majorly controversial – such as authorisation of GMOs, biocides, antibiotics and endocrine disruptors or exploitation of non-conventional fossil resources (e.g. shale gas).

Contemporary risk management needs therefore to rely on ever more porous interfaces and thicker dialogue among all involved actors.

▶ This is clearly an issue that emerges from the insights offered by the discussion on adaptive licensing in pharmaceutical regulation and the search for ever better performing risk management systems, which **Ken Oye and colleagues** highlight in their conference report. The innovative licensing approaches developed by EU and US drug regulators take great account of the rationales, constraints and motivations of the affected actors, while risk assessment practices remain grounded in high quality scientific evidence, and cost-benefit appraisals inform risk management decisions. The authors stress how greater adaptability of management solutions can address risk acceptance of specific (individual) patients that await new but not yet accessible treatment. This results from the integration of feedback from patients groups and the deployment of mechanisms for policy learning from past experience along the entire life-cycle of research, product development and licensing.

The new forms of risk management presented in the papers stretch the limits of conventional wisdom when it comes to defining the legitimacy of the solutions deployed. So dwell Renn and Florin on the very legality of nudging, coming to the conclusion that behaviourally-informed risk regulation to prevent or restrict risky behaviour in fields where freedom is protected by the law may be legitimate, as long as it is rooted on democratically (socially) agreed societal goals. In turn, the adaptive licensing case study illustrates how such an approach is an attempt to walk the thin line trading off uncertainty about cost effectiveness and safety on the one hand, and access to new therapies and investment cost recovery on the other. While stemming from different

rationales, both approaches allow for a conceptual shift from the traditional risk management towards more or less controlled forms of what might be labelled 'enlightened experimentalism'. Both behaviourally-informed and adaptive regulatory designs are applied to increasingly refined target groups, thereby fragmenting solutions that traditional risk regulation has by contrast tended to apply erga omnes.

Flexible, adaptive and responsive forms of risk regulation bear great potential for effectively meeting societal demands and stimulating innovative and efficient solutions. They nonetheless also raise the question about the capacity of public regulators to institutionalise and replicate these approaches in such a way that public risk management still meets other compelling imperatives for government action like the principles of legitimate expectations and legal certainty. The issue of precaution remains the elephant in the room in this respect. Risk managers are hence invited to invest in continuous re-evaluations of the risks as a function of changing contexts – be the latter determined by advances in (scientific) knowledge, by changes in individual exposure to the risk or by re-definition of the underlying trade-offs. In the case of drug authorisation processes, for instance, between the expectations and risk perceptions among patient groups on the one hand, and structural constraints by the public health care systems and the need for return in investment by industry on the other hand. There hence is a reiterated need to ground all risk management choices, no matter their nature, in robust, transparently and timely accessible evidence.

2. Revisiting risk regulation – Towards a roadmap

How can then regulatory action be improved on the basis of the practices currently in place? What follows are initial elements of a possible roadmap which urges public risk managers to work along four distinct yet intimately intertwined strands of action:

1. **Creating and maintaining favourable framework conditions** – Public regulators need to deepen their understanding of, and facilitate, the competition–collaboration dynamics that characterise the interaction between stakeholders, with a view to create a positive 'race to the top' in terms of conceiving or implementing superior risk management solutions. Such solutions are superior if they prove their effectiveness but also their credibility and legitimacy.

   One way forward would be developing forms of participatory decision-making, exactly to reap the potential of stakeholder comparative advantages, to achieve early acceptance (if not consensus) and enhanced legitimacy by addressing and eventually internalising potential conflicts.

   This has impacts on the way public policies are designed – i.e. how strategically decision-makers link policy objectives across the various government interventions and how consistent and proportionate the instruments regulators deploy are with respect to those objectives and the related impacts.

2. **Using the best available and impartial (scientific) evidence** – Recourse to the best evidence should be determined by the underlying scientific rigour, irrespective of its origin. Regulators must ensure that excellence and independence are the two key criteria to be applied when producing and using scientific advice.

   Excellence is achieved by sticking to the principles of the scientific method (replicability and verification of assumptions, methodologies and findings through internationally respected and validated standards); independence is essentially achieved by ensuring full transparency of interests and biases. Only this way can evidence of risk and harm be assessed and presented along with other legitimate factors that inform risk management decisions.

3. **Better understanding the wider impacts of (regulatory) risk management decisions** – Eventually, the effectiveness of harm prevention measures is assessed by each of us individually but public decision-makers must strike a balance between macro and micro consequences. Impacts of risk management decisions on innovation for instance, which is the single most powerful factor for economic growth in Western economies and on job creation, must be investigated alongside various aspects including public health, consumer welfare and the preservation of the environment.

   In practical terms, this calls for regulators to appropriately identify and measure societal benefits to gain from risk management options while at the same time grasping the indirect implications that their decisions may have for instance in terms of changes in capital allocation by private sector actors across an industry's value chain (e.g. in relation to R&D investment patterns). Such changes induced by regulatory choices may significantly impact innovation, job creation, and subsequently societal prosperity.

   This strand of action also corroborates the need for making risk management as flexible as possible through timely integration of feedback from stakeholders and the affected actors and by allowing for scaling up of solutions and for continuous learning from new scientific or empirical insights.

4. **Organising the communication of risks and risk management decisions** – This action does not mean monopolising risk communication. Rather, it refers to bridging domains as wide but necessary as the ones of scientists, regulators, decision-makers, stakeholders and laymen (the public), not least with respect to the notion of uncertainty and innovation, and the impossibility of managing everything and reducing risk down to zero.

   This takes the shape, for instance, of explaining that high quality harm management ensues from making decisions on the basis of risk (i.e. they should be proportionate to exposure, based on real world experience) as opposed to hazard.

When it comes to risk management, policy-makers must be fully aware of – and objectively communicate – what factors took priority in their decisions next to scientific evidence and why, and what are the consequences of those decisions onto society and the economy as a whole. Due process is required through the regulatory cycle, ensuring compliance with the principles of transparency, accountability, predictability and proportionality.