

Risk governance and risk-based regulation

A review of the international academic literature

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State of the Art in Regulatory Governance Research Paper 2019.02

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June 2019



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To cite this research paper:

van der Heijden, Jeroen (2019). *Risk governance and risk-based regulation: A review of the international academic literature. State of the Art in Regulatory Governance Research Paper – 2019.02*. Wellington: Victoria University of Wellington/Government Regulatory Practice Initiative.

Earlier publications in the State of the Art in Regulatory Governance Research Paper series:

- van der Heijden, Jeroen (2019). *Behavioural insights and regulatory practice: A review of the international academic literature. State of the Art in Regulatory Governance Research Paper – 2019.01*. Wellington: Victoria University of Wellington/Government Regulatory Practice Initiative.

Abstract

This research paper presents findings from a broad scoping of the international academic literature on the use of risk governance and risk-based regulation. It addresses six themes: (1) the evolution of thinking about risk, risk governance and risk-based regulation, (2) examples of risk governance and risk-based regulation, (3) evidence of the performance of risk governance and risk-based regulation, and (4) the epistemic challenges and (5) ethical challenges that come with this approach to regulatory governance and practice.

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1 Introduction

In regulatory governance and regulatory practice, 'risk' is probably one of the topics most talked about and least understood. The notion of risk is like the notion of time or happiness: we all know perfectly well what it is, until we try to explain it to others (or to ourselves, for that matter). Risk is intangible. It becomes somewhat unreal when we try to discuss and unpack it (Beck, 1992). The following ten definitions of risk illustrate this well:

- Risk is the product of the sum of money placed on a bet in a game and the probability of losing that money (De Moivre, 1756).
- Risk is the product of the probability of an event occurring and the consequences of that event (Kaplan & Garrick, 1981).
- Risk is a situation or event where something of human value (including humans themselves) is at stake and where the outcome is uncertain (Rosa, 1998).
- Risk is the probability of an adverse effect in an organism, system or population caused by exposure to an agent (IPCS and OECD, 2003).
- Risk is a situation when circumstances may turn out in a way that we do not wish for (Steele, 2004).
- Risk is an uncertain (generally adverse) consequence of an event or an activity affecting something that humans value (IRGC, 2005).
- Risk is uncertainty about the severity of the consequences of an activity concerning something that humans value (Aven & Renn, 2010).
- Risk is, objectively, the probability of exposure to harm or loss over time, and should at the same time be subjectively defined based on experience and context (Clark, 2013).
- Risk = Hazard x Dose (Exposure) (Burgess, 2016).
- Risk is the effect of uncertainty on objectives (ISO, 2018).

One set of easy questions, three sets of complex answers

An example of how quickly a 'simple' risk becomes complex when it is unpacked is the following: does a huge boulder that may fall off a cliff always pose a risk, or does it only pose a risk if it could damage or destroy something that is of value to humans? To estimate the risk, is it enough to know the objective probabilities of the boulder falling, or are other forms of knowledge (say, the political and societal consequences of the boulder falling) also required? Whose knowledge is going to be used in this estimation – that of a professional boulder expert, that of the humans directly affected by the boulder falling, that of others, or a combination of the knowledge of all these people?

The first question yields two broad answers. On the one hand, there are those who argue that the danger or uncertainty of the boulder falling is real, but that there is only a risk in human or societal experience. These people can be considered to hold a constructivist ontology of risk. That is, they argue that risk is a social construct and only exists in human perception. On the other hand, there are people who say that risk is a state of the world and that, whether or not a specific risk is experienced by humans, risks are real. These people can be considered to hold a realist ontology of risk (Rosa, Renn, & McCright, 2014).

The second question also yields two broad answers. Again, we see on the one hand those who argue that risks and their consequences can only be known subjectively and that our understanding of risk is a social process. This reflects a constructivist epistemology of risk. On the other hand, we see those who argue that the probability of a risk materialising, as well as its consequences, can be objectively

known. This reflects a realist epistemology, and these people believe that risks can be objectively mapped, and therefore 'perfectly' governed and regulated (Rosa et al., 2014).

The third question, finally, again yields two broad answers. On the one hand, there are those who consider that only quantitative, technical knowledge, collected by experts and professionals, and economical benefit–cost analysis, should be relied on when estimating risks. This reflects a reductionist approach to risk estimations. On the other hand, there are those who consider that, besides such 'hard' data and knowledge, other forms of data and knowledge should also be included in risk estimations. These other forms of data and knowledge may include the perspective of lay people or policymakers on the risk or on the non-economic impacts if the risk were to materialise. This reflects a systemic approach to risk estimations (Ansell & Baur, 2018).

Why it matters to reflect on these questions

In sum, relatively easy questions about the risk of a boulder falling quickly yield a set of complex answers. Of course, the 'correct' answer to these questions will lie somewhere in the middle. More and more, scholars are beginning to point to the 'fluid nature of risk', particularly in how we understand risk (Poortvliet, Duineveld, & Purnhagen, 2016, 217). It is often difficult to draw precise lines between the abovementioned realist and constructivist ontologies and epistemologies, and, likewise, it is difficult to point out where the abovementioned reductionist approach to risk estimations ends and the systemic one begins. It is more than likely that the way in which people understand risk will be somewhere on a continuum that is limited by the above answers. Similarly, it is more than likely that the way in which people understand risk will vary from one situation to the next.

Still, these questions are at the core of every process of risk governance and risk-based regulation. They are often skimmed over all too quickly in regulatory governance and practice. Under pressure from their superiors or society at large, policymakers and regulatory practitioners want to get going and solve a risk regulation problem. They are on the lookout for risk governance models and risk-based regulation tools that have proved to be effective in the past or in another place, and they want to apply those to the problem in the here and now. There is then a risk that, in seeking to address risk, inadequate tools, processes and solutions are implemented. This holds for New Zealand and elsewhere, as will become clear in the chapters of this paper.

Because the foundations of risk, as an approach to regulatory governance and to its practice, application and performance, are not always well understood by those who are keen to implement this type of governance, the Advisory Board of the Chair in Regulatory Practice has asked the Chair in Regulatory Practice to review the academic literature on risk governance and risk-based regulation as it relates, in particular, to regulatory practice. This report is the result of a systematic review of that literature, carried out between January and April 2019; Appendix B explains the methodology of the review.

Conceptual boundaries and roadmap of this paper

From the above, it is clear that it is not easy to say 'simply' what risk governance and risk-based regulation is all about. In this paper, the central focus is not so much risk as a problem or situation to be solved, but risk as encapsulating a way of governing and regulating problems and situations, and the processes, techniques and instruments applied in that governance. Within this paper, we will

move backwards and forwards between considering risk, risk governance and risk-based regulation in a narrow sense and in a broad sense.

In a narrow sense, the central premise behind risk governance and risk-based regulation is the 'adoption of apparently rational, objective, and transparent ways of prioritizing work, and the deployment of limited regulatory resources' (Hutter, 2017, 103). In a broad sense, the central premise behind risk governance and risk-based regulation is that they are a 'paradigm of administrative constitutionalism [that] promotes a model of public administration that is designed to address the factual and normative complexities of ... risk evaluation by granting to public administration substantial and ongoing problem-solving discretion in relation to particular issues. This power is needed so that the processes of ... risk evaluation can adapt to the [technical, political, economic, societal and other] uncertainties and issues involved in relation to specific ... risks' (Fisher, 2010, 30).

Likewise, in a narrow sense, risk governance and risk-based regulation is 'an "aspiration to control" future events [and] regulation is one manifestation of a modern belief that risks can be anticipated and controlled' (Hutter, 2017, 102). In a broad sense, risk governance and risk-based regulation is open to acknowledging that fully reducing risk to zero is impossible, and it works 'to instil processes and practices – training programmes, regular simulations, audits, crisis management units – that help prepare public and private organisations to recognise and manage these potentially catastrophic events' (Boin, 2010, 248).

With this in mind, let us now turn to the problem that risk governance and risk-based regulation seek to address: to what extent and in what way can risk be regulated and reduced? The chapters that follow touch on the evolution of thinking about risk, risk governance and risk-based regulation (Chapter 2), examples of risk governance and risk-based regulation (Chapter 3), evidence of how risk governance and risk-based regulation work (Chapter 4), and the ethical and epistemic challenges that come with this approach to regulation (Chapter 5). Each chapter discusses key insights from the literature, and in the final chapter (Chapter 6) conclusions are drawn from the full review.

2 The evolution of risk

It is safe to say that humankind has always been subject to risk. For a long time, however, humans considered risk along the lines of fate and determinism. Our ancient ancestors thought of risk as something they could not influence. Their future was set in stone, regulated either by the forces of nature or by spirits and deities. Risk as a way of thinking about a makeable and thus changeable future is a rather recent development (Burgess, 2016; Hutter, 2017; Macrae, 2010). One of the world's leading risk scholars, Eugene Rosa, has captured this well by stating: 'Risk has a very long past, but very short history' (Rosa, 1998, 15).¹

Risk from the twelfth to the eighteenth century

Rudimentary risk assessment and management

The contemporary understanding of 'risk' can be traced back to twelfth century Italy. It was in Italy at that time that merchants needed control over the future gains and losses of the goods they were trading. Early developments in probability theory and a documented history of trade allowed for rudimentary estimates of the uncertainties of investments. This was a major development, as it allowed the risk of trading in a good (the uncertainty of loss or gain) to be separated from the good itself, and the risk to be traded for a price. Suddenly, the unknown future 'could be estimated, commodified and exchanged' (Doron, 2016, 20). In short, it had become clear that 'risk is a choice rather than a fate' (Bernstein, 1996, 8).

Of course, this process did not happen overnight. It took some 600 years, from the twelfth to the eighteenth century, to move from a rudimentary understanding of risk as something that is not merely fate or determinism to the idea that risk can be captured, calculated, and to some extent controlled by humans. Once this notion was accepted, the development sped up incredibly quickly. During the Enlightenment, public authorities in Europe became expert in systematic data collection at the population level. Combined with the ongoing developments in probability theory and mathematics at that time, the fundamentals were laid for risk as an object of public governance (Alemanno, 2016; Huber, 2010).

Towards welfare states

From the eighteenth century onwards, risk became a fundamental concept that allowed for 'rational' governance, particularly at the population level. The idea arose that 'state policy should be shaped by administrative and arithmetic knowledge of the population' (Doron, 2016, 21). In other words, governance should be performed through the calculation of probability. Another idea that arose was that, on the individual level, people are often unable to control the risks to which they are subject, but, at the aggregate level, these risks can be controlled, either by pooling the risk through public insurance and state-organised welfare or by minimising the risk through modifying and deterring it in its origins.

The Industrial Revolution that started in the second half of the eighteenth century brought about a range of changes that were unprecedented—if not in terms of substance, then at least in terms of

¹ For an excellent history of risk assessment and risk management, see Peter Bernstein's book *Against the gods: The remarkable story of risk* (1996). The book is also an excellent history of probability theory and statistical mathematics.

scale. Industrialisation led to a novel distribution of risks through rapid urbanisation, negative externalities, and the working and living conditions in which large groups of working class people suddenly found themselves. In Europe in particular, insights into these new risks led to a growth of risk-pooling initiatives, such as public pensions, unemployment insurance, and public health schemes (Pierson & Casteles, 2006).

Risk in the nineteenth and twentieth centuries

A range of developments in the nineteenth and twentieth centuries has affected our thinking of risk and risk governance, and ultimately led to risk-based regulation. Some of these happened in sequence, and some in parallel.

A gradual change in the law

It became obvious that many of the 'new' risks that resulted from industrialisation were too complex to be addressed through a traditional understanding of the law (Steele, 2004). In particular, the system of tort law in the United States, in which the evidentiary burden is on the plaintiff, was unable to deal with many of the indirect or slow-to-materialise risks that arose from industrialisation. By the second half of the twentieth century, the United States Congress determined that the tort system 'was incapable of providing an effective response to the increasing threats to the public health and safety and the environment attributable to new technologies and development' (Shapiro & Glicksman, 2003, 3).

Between the 1960s and the 1990s, this led to a move in the United States away from minimal federal regulation towards an approach to risk governance in which the government often took action to regulate anticipated health, safety and environmental harms. Risk technologies (particularly risk estimation) were seen as a way of providing public security. Regulation thus moved further away from restoring harm done in the past and towards preventing harm from occurring in the first place. Countries elsewhere, particularly in Europe and the Asian Tigers,² followed suit, and, around the world, it was accepted that managing risks and public safety had become a task for government—the 'regulatory state' was born (Hood, Rothstein, & Baldwin, 2001; Majone, 2016).

A gradual change of governance

A more critical reading of this period is provided by 'governmentality' scholars (Foucault, 2009). They argue that the new risks, or, more precisely, the new understanding of risks, allow those in power to push for a way of governing that is ever more intrusive. That is, risks have become more than being the 'mere' objects of public governance through government-led regulation. In this critical reading, of interest to those in power are the underlying practices of these risks and 'how to most effectively govern the conduct and actions of populations to minimize identified risks' (Edge & Eyles, 2015, 189). That is, rather than seeking to reduce a risk, governments have become interested in reducing the behaviour that may result in the risk.

Thus, not only can the government hold individuals responsible for having *caused* harm, but the government can hold individuals responsible for engaging in activities and behaviours that *may* cause harm. To these critics, regulating behaviours such as driving when over the limit for alcohol, smoking in public places, or consuming fatty foodstuffs because they *may* cause harm, particularly at the

² Singapore, Hong Kong, Taiwan and South Korea.

aggregate level of society as a whole, allows governments to limit individual freedom even more than they have before (Dean, 2009). In sum, the new understandings of risk have moved the object of public governance from substance and matter to human conduct, and the modes of governance from restoring damage and preventing harm to imposing on and internalising in people norms of 'accepted' behaviour.

A utilitarian approach to regulation

The above discussion captures the birth of risk governance, but what about risk-based regulation? It is often argued that risk-based regulation is a specific way of looking at risk governance. In risk governance, risk is the object of governance (including regulation), as explained above. In risk-based regulation, the focus is on the allocation of resources based on risk levels (Macenaite, 2017). Risk is used as a decision-making resource that allows for a reasoned response to a possible harm or gain when there is a lack of knowledge in qualitative or quantitative terms (Steele, 2004). Examples of risk-based regulation will be discussed in chapter 3 of this paper. For now, it suffices to define risk-based regulation as 'an evidence-based means of targeting the use of resources and of prioritizing attention to the highest risks in accordance with a transparent, systematic, and defensible framework' (Black & Baldwin, 2010, 181).

In the 1980s in particular, under President Ronald Reagan in the US and Prime Minister Margaret Thatcher in the UK, there was a call on government departments to become more cost-effective and efficient—the turn to New Public Management (Hood, 1995; McLaughlin, Osborne, & Ferlie, 2002). For government departments and regulatory agencies, the tools of risk assessment and risk management allowed them to follow a utilitarian approach to 'allocate regulatory resources in proportion to the risks and interventions they require' (Davies et al., 2010, 963) and 'explicitly explain their selective decisions based on the assessment of the risk that the regulated actors (companies or individuals) present' (Macenaite, 2017, 512). It should be noted here that risk-based regulation is not the same as Professor Malcolm Sparrow's problem-oriented approach to regulation—that is, to find the biggest problem and fix it (Sparrow, 2000). The latter is less systematic and structured than risk-based regulation (Baldwin & Black, 2016).

Risk in the twenty-first century

By the end of the twentieth century, writings by a range of influential thinkers on the role of risk in modern society entered mainstream debate in the wake of large disasters—including the Chernobyl nuclear disaster in the Soviet Ukraine in 1986, the BSE (bovine spongiform encephalopathy) crisis in the UK in 1996, and the 9/11 terrorist attacks in New York in 2001. Among the best known thinkers are Ulrich Beck, who coined the term 'risk society', Anthony Giddens, Aaron Wildavsky and Niklas Luhmann. While the details of their arguments differ considerably, their main lines of thought show striking similarities, and run as follows: in current times, people have become preoccupied with risk and taming the future, and, despite all the controls that have been put in place to reduce, pool, mitigate or prevent risk, risk causes anxiety at the societal level (Beck, 1992; Giddens, 1997; Luhmann, 1991; Wildavsky, 1988).

The risk society perspective

To Beck, this preoccupation exists because we are faced with greater risks than ever before: risks are global, outlast generations, and affect all, regardless of class, culture, or citizenship. To Giddens, we have this preoccupation because we now 'live on a high technological frontier which absolutely no

one completely understands and which generates a diversity of possible futures (Giddens, 1998, 25). To Wildavsky, it is because of the paradoxical situation that risk prevention requires risk-taking and risk exposure (Wildavsky, 1988). To Luhmann, finally, it is because large risks loom in different systems (such as the economy, the environment, or politics) that are difficult for those outside those systems to mitigate but that may have detrimental consequences across systems (Luhmann, 1991).

The notions of new risks (and amplified existing ones), as well as the notions of systemic risks, raised by these thinkers echo particularly in the risk governance models we see around the globe today. New technologies (such as developments in ICT, nanotechnology, genetically modified foodstuffs and artificial intelligence) are considered to bring huge opportunities, but they come with risks that cannot be (objectively) estimated (Florin & Bunting, 2009; Giorgi, 2013; Hodge, Maynard, & Bowman, 2014). At the same time, many of today's major risks, such as climate change and the interconnectedness of global finance, are systemic, meaning that they are embedded in the larger context of societal processes. 'Systemic risks have therefore a growing potential of harm since effects can be amplified or attenuated throughout the prolongation of effects based on a complex system of interdependencies' (van Asselt & Renn, 2011, 436).

From uncertainty to probability and back again

Thus, while our understanding of risk, risk evaluation and risk management has grown tremendously over the last decades, it has also become clear that it is exceptionally difficult to reduce, pool, mitigate or prevent many of the risks that we are facing today. The power of risk governance and risk-based regulation as a means to safeguard society may very well have come to its absolute limit. Over recent years, critical questions have been raised about whether risk governance and risk-based regulation may perhaps provide a false sense of security. The way in which risk governance and risk-based regulation have become routine, which is observed around the globe, 'may obscure the conceptual foundations and limitations of this method' (Renn, 1998, 53).

The conceptual foundations and limitations to which critical scholars point bring us back to questions about the ontology and epistemology of risk, and the broad range of definitions discussed in the first chapter of this paper. More and more, the leading scholars of risk are calling for a move away from, or at least a softening of, the high value assigned to 'hard' probabilities based on 'objective', quantitative data, collected and processed by technical experts. They call for the inclusion of 'subjective', qualitative data and knowledge of lay people in the assessment and management of risk. The definition of risk as 'the objective probability of harm multiplied by the objective impact of harm' has quickly lost its mythical status. After centuries of statistical development in which we saw uncertainty captured in 'clean' probabilities, risk scholarship has moved back to the 'fuzzy' language of uncertainty (Aven & Renn, 2010; Renn, 2008; Renn & Klinke, 2013).

This brief history of (our thinking about) risk indicates that risk is not a static object that can be reduced, pooled, mitigated or prevented with stable, one-size-fits-all governance interventions and regulatory tools. In the chapters that follow, examples will be given of what is considered the current state of the art. Over time these will, no doubt, need updating.

3 Examples of risk governance and risk-based regulation from around the world

Inspired by the insights from risk studies, governments around the world have begun to develop and implement risk governance and risk-based regulation. Following these developments, scholars have begun to map, explore and interrogate risk governance models and strategies and risk-based regulatory approaches and instruments, and their performance. There appears to be no area in which governments have not trialled this approach to regulation.

The literature addresses examples of risk governance and risk-based regulation in the aviation, offshore oil and nuclear industries (Binz, Bronte Razavian, & Kiparsky, 2018), in infrastructure such as large dams (Escuder-Bueno & Halpin, 2016), in bioengineering (Florin & Bunting, 2009), in food safety (Giorgi, 2013), in nanotechnology (Hodge et al., 2014), in urban resilience (Sanchez, Van der Heijden, & Osmond, 2018), in banking after the global financial crisis (Briault, 2010), and in sexual regulation and blood donations (Belavusau, 2016)—to give but a few examples.

It is beyond the scope of this paper to review this approach to regulation on a sector-by-sector basis. The discussion that follows maps some of the frameworks for risk governance and risk-based regulation that are broadly considered to be ‘good practice’ by scholars or are dominant in some parts of the world. These frameworks are: holistic frameworks; frameworks that focus on high-occurrence but low-impact risks; and frameworks that build on the precautionary principle, benefit–cost analyses, or both.

Holistic frameworks

Around the turn of the millennium, risk scholars began to point out that ‘a strict separation between risk assessment and risk management is counterproductive’ in governing and regulating risk (van Asselt & Renn, 2011, 442). More and more, they began to present a vision of integration between risk assessment and risk management (Assmuth, Hildén, & Benighaus, 2010). Likewise, regulatory scholars began to argue that, while there was much debate about standard setting in risk-based regulation, information gathering and behaviour modification had received too little attention, and even less attention was paid to ‘linking those three components together—which is often the Achilles heel of control systems’ (Hood et al., 2001, 24).

These debates have resulted in suggestions for holistic risk governance frameworks. The most elaborate holistic framework that has emerged is that of the International Risk Governance Council (IRGC)³ (Aven, 2011; Aven & Renn, 2010; Renn, 2008; Renn & Klinke, 2016). This builds on four phases of risk assessment and management, and a set of cross-cutting aspects. The four phases build on and inform each other.

- Pre-assessment

This phase includes risk identification and framing. In this first phase, early warnings or (periodic) monitoring may point to deviations from the norm in activities or events. Perceptions, interpretations, heuristics, biases, and framing affect what is considered a risk *and* whether a risk is worth considering (Renn & Klinke, 2016). Likewise, how people think of risk (ontologically and epistemologically—see the introduction to this paper) affects what they

³ The IRGC Framework is available online: <https://irgc.org/risk-governance/irgc-risk-governance-framework/> (13.05.2019).

consider to be a risk that requires attention. Finally, various forms of data may point at such deviations from the norm, but not all forms of data are necessarily given equal attention. In this early phase, there is a danger that scientific and technocratic data will be given more attention than socio-political data (Nygaard & Aven, 2010).

- **Appraisal**

This phase includes the assessment of the technical and other causes of a risk, and the consequences of the risk. Ideally, risk estimation consists of: '(1) *risk assessment*: producing the best estimate of the physical harm that a risk source may induce; and (2) *concern assessment*: identifying and analysing the issues that individuals or society as a whole link to a certain risk' (Renn & Klinke, 2016, 207, original emphasis). Here, the challenge is to deal with often incomplete data (Shapiro & Glicksman, 2003), and to balance 'hard' technical data with 'soft' public and political perceptions (Renn, 1998). Specific dangers in this phase are: missing, ignoring or exaggerating early signals of risk; lack of adequate knowledge about a hazard, including probabilities and consequences; failure to consider variables that influence risk appetite and risk acceptance; lack of appreciation or understanding of the potentially multiple dimensions of a risk; and a failure to reassess in a timely manner quick and/or fundamental changes in risk systems (Aven, 2011).

- **Characterisation and evaluation**

This phase includes the making of judgements about risks and the need to manage them. Often this phase will result in a risk matrix in which risks are classified according to the urgency of the need for intervention. A distinction can then be made between risks that need to be addressed and risks that do not need to be addressed—or, at least, do not need to be addressed now. The suggestion is that risks are classified on a sliding scale, rather than as a dichotomy. For example, when using a 'traffic light' model of 'acceptable', 'tolerable', and 'intolerable' risks, it is immediately clear that the first need little engagement and the latter need to be addressed as soon as possible (Aven & Renn, 2010). Highlighting risks that are tolerable now but may slide into the intolerable category over time helps to keep track of them and to develop and implement preventive risk management measures such as 'actions that render these [tolerable] risks either acceptable or sustain that tolerability in the longer run by introducing risk reduction strategies, mitigation strategies or strategies aimed at increasing societal resilience' (Renn & Klinke, 2016, 210). In this phase, the same dangers are present as in the previous phase.

- **Management**

This phase includes decision-making and the implementation of risk management options. Actions to reduce, pool, mitigate or prevent risks have to be tailored to the specific situation at hand—the literature, unfortunately, does not present one-size-fits-all solutions. Herein, however, lie the core dangers of this phase: failure to design risk management strategies that adequately balance alternatives or address a reasonable range of options; inability to reconcile the timeframe of the risk with the timeframes of decision-making and incentive schemes; inappropriate management of conflicts of interests, beliefs, values and ideologies; failure to muster the necessary will and resources to implement risk management policies and decisions; failure to build or maintain an adequate organisational capacity to manage risk; and failure of the multiple departments or organisations involved in the management of the risk to act cohesively (Aven, 2011).

- Cross-cutting aspects

These include the involvement of stakeholders, ongoing communication with stakeholders, and consideration of the regulatory context in all of the above phases.⁴ They require regulatory policymakers and practitioners to remain vigilant of biases to which they may themselves be subject in risk assessment and management,⁵ and of changes in the political and physical environment of the risk. Perhaps the most important thing is to ensure a high level of communication throughout the risk assessment and management process: ‘The crucial task of risk communication runs parallel to all phases of handling risk: it assures transparency, public oversight and mutual understanding of the risks and their governance’ (Aven & Renn, 2010, 238).

It is best to consider the IRGC framework as a checklist (rather than a blueprint) for regulators interested in this approach to regulation, and for those who already have risk governance in place. The IRGC framework challenges regulators to think beyond a strategy of ‘pick the biggest problem and fix it’ and to develop and adhere to transparent, legitimate and accountable processes for both the ‘picking’ and the ‘fixing’ of problems. The IRGC framework does not spell out how this needs to be done but provides helpful starting points for thinking through important choices.

High-occurrence, low-impact risks and low-occurrence, high-impact risks

One of the issues the IRGC framework does not address is the difference between regulating and attending to high-occurrence low-impact risks (Ho/Li) (such as car break-ins, tax fraud by households, and unhygienic practices in restaurants) and regulating and attending to low-occurrence high-impact risks (Lo/Hi) (such as the British BSE crisis in the late 1990s, the 9/11 terrorist attacks in New York City in 2001, and the crashes of two Boeing 737 Max aeroplanes less than a year apart in the late 2010s). There is a tendency in regulatory policy and practice to focus risk attention on the latter (Lo/Hi risks) at the expense of the former (Ho/Li risks) (Black & Baldwin, 2012a, 2012b).

Of course, it is understandable that Lo/Hi risks tend to get more attention in risk governance than Ho/Li ones. If they materialise or enter the public debate as a possible reality, they result in a great deal of media attention, heightened levels of public fear, and calls on policymakers to act. It is also in this space that we are experiencing many of today’s systemic risks that ‘are at the crossroads between natural events (partially altered and amplified by human action, such as the emission of greenhouse gasses), economic, social and technological developments, and policy-driven actions, all at the domestic and international level’ (Renn, 2008, 5).

When too little attention is given to Ho/Li risks, they may, over time, accumulate and then gain the ‘capacity to produce both significant harms and political contention’ (Black & Baldwin, 2012b, 2). It is perhaps more interesting, from a regulatory perspective, that in regulating and attending to Ho/Li risks, lessons from other regulatory theories become highly useful. After all, it is in this area that we see many regulatees who are likely to be engaged only in one-off encounters with regulators (such as

⁴ Particularly insightful here is the risk-based regulation heuristic provided by Professors Christopher Hood, Henry Rothstein and Robert Baldwin. This links three core components of regulation (information gathering, standard setting, and behaviour modification) with the regulatory context and the content of the regulatory regime (Hood et al., 2001).

⁵ See the first State of the Art in Regulatory Governance Research Paper on behavioural insights for a more extensive discussion: van der Heijden, Jeroen (2019). *Behavioural insights and regulatory practice: A review of the international academic literature. State of the Art in Regulatory Governance Research Paper – 2019.01*. Wellington: Victoria University of Wellington/Government Regulatory Practice Initiative. Available online: https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3332699 (13.05.2019).

‘mums-and-dads’) rather than the small number of regulatees who professionally and repeatedly interact with regulators (‘repeat players’ such as corporations). For these specific risks (Ho/Li) and this group of regulatees, the Good Regulatory Intervention Design (GRID) framework developed by Professors Julia Black and Robert Baldwin (both London School of Economics, UK) provides guidelines.

- GRID framework

The GRID framework builds on the insight from regulatory studies that people and organisations have different motivations and capacities to comply with regulations (Parker & Lehman Nielsen, 2011; Tyler, 1990), and introduces three innovations to risk governance. First, it moves away from considering subjects of risk governance and risk-based regulation as a homogeneous group. The GRID framework classifies them into four types: (1) regulatees who are well-motivated to comply and have the capacity to do so, (2) regulatees who are well-motivated but lack capacity, (3) regulatees who are less motivated but have the capacity to comply, and (4) regulatees who are less motivated and lack capacity.

Second, the framework distinguishes between risks resulting from an activity or event engaged in by a regulatee (‘inherent risk’) and risks resulting from the management of that activity or event by a regulatee (‘net risk’). Thus, a regulator may seek to regulate an activity or event directly, or may seek to regulate the engagement of a regulatee in that activity or event. This challenges regulators to think of the various aspects of risky events and behaviours and the best ways to intervene to address them. For example, safety belts in a car are a means to regulate the risk related to driving a car, whereas alcohol checks on New Year’s Eve are a means to regulate how well regulatees ‘manage’ the risk related to driving a car.

Third, the framework challenges regulators to think carefully about whether a risk is stable (within a set timeframe) or whether it is volatile. Volatile risks may accumulate over time if they are not attended to. This could be simply because regulatees engage in more risky events and activities, or it could be because they manage existing risky events and activities less well.

Combining these three insights allows for highly detailed risk matrices. For example, sophisticated risk matrices could indicate that a specific volatile net Ho/Li risk is low for well-motivated regulatees with a high capacity to comply but is high for those regulatees that are less motivated and lack capacity to comply.

The precautionary principle

Another aspect that the IRGC framework does not explicitly touch on is the precautionary principle. The precautionary principle can best be understood as an expansion of the prevention principle that underpins many traditional regulatory interventions—it ‘requires those who wish to carry out an activity to prevent any related harm to the environment or human health’ (Tosun, 2013, 40). The precautionary principle is an ethical principle ‘saying that if the consequences of an activity [or event] could be serious and are subject to scientific uncertainties, then precautionary measures should be taken or the activity should not be carried out at all’ (Aven, 2010, 215). Discussions on the precautionary principle quickly turn toxic. Critics argue that it gives policymakers and regulators a motive for far-reaching and intrusive regulatory interventions, in which the costs of regulation outweigh its benefits (Majone, 2016). Advocates argue that it is the most sensible approach to regulating possible harm in the absence of sound knowledge of the possible occurrence or impact of the risk (Taylor, 2018).

Debates over the precautionary principle often boil down to risk appetite. When facing a situation of uncertainty and risk, one can either err on the side of Type I errors (false positives) or err on the side of Type II errors (false negatives). Doing the former implies that a non-existent harm triggers regulation so that, for example, safe products are blocked from entering the market; doing the latter implies that existing harm will not trigger regulation so that, for example, unsafe products are not blocked from entering the market (Lodge & Wegrich, 2012; Viscusi & Zeckhauser, 2015).⁶ In risk assessment, the role of, and the weight given to, ‘hard’ scientific data as compared to ‘softer’ societal and political data and knowledge have a strong impact on the choice between these two types of errors.

Globally, governments appear unstructured in when and why they err on either side of this line. For example, it is often argued that, across the board, Europe is more precautionary (i.e., erring on the side of safety at the cost of opportunity) than the US. No evidence is found to support this argument, however, in direct comparisons of regulation in various policy areas in Europe and the US (Shapiro & Glicksman, 2003; Tosun, 2013; Vogel, 2012; Wiener, Rogers, Hammitt, & Sand, 2011). Even within single countries such as the UK or the US, scholars find it difficult to trace patterns of the systematic application of the precautionary principle (Hood et al., 2001; Majone, 2016).

Rather than marrying the precautionary principle to a specific type of public administration or to a political philosophy that one espouses or opposes (Fisher, 2010), it is more fruitful to think of a ‘continuous variable to measure the degree of relative precaution’ of a policy or regulatory intervention (Wiener et al., 2011, 529). Thinking in this way allows a transparent, systematic, and defensible framework to be implemented in decisions about applying or not applying the precautionary principle. A brief reflection on the application of the precautionary principle in Europe and the significant risk doctrine in the US provides illustrations.

- **Application of the precautionary principle in Europe**

The development of the precautionary principle can be traced back to the 1970s, but the principle has been influential in European regulatory systems (at EU and Member State level) since the early 2000s (Vogel, 2012). Over time, the role of the precautionary principle has changed. It is ‘now more accurately understood as an element of risk management; a measure invoked temporarily, pending further scientific information. This is crucial, for it anticipates in the regulatory process *not a lowering of the evidentiary bar*, but its elevation: an absence of a scientific consensus (uncertainty) offers not an opportunity to invoke precaution ... but forms the basis from which to *resist* regulatory intervention’ (Taylor, 2018, 467, original emphasis).

The application of the precautionary principle in Europe can best be understood as a sliding scale of four levels: (1) ‘non-preclusion measures’, which specify action that can be taken to control risk-generating activities; (2) ‘safety measures’, to establish certain cautious limits to actions or events; (3) prescribed criteria for activities or products such as the Best Available Technology Not Entailing Excessive Cost (BATNEC)⁷; and (4) ‘prohibitory measures’, which ask

⁶ The framing of Type I and Type II errors as errors of commission or omission, or as errors of risk appetite or risk avoidance, strongly affects people’s perception of the type of action that needs to be taken. This relates directly to insights from the behavioural sciences that people, generally speaking, struggle with processing complex data and probabilities. See further footnote 5.

⁷ Comparable measures are the ‘As Low As Reasonably Practicable’ (ALARP) principle in a variety of regulatory regimes in the UK (Jones-Lee & Aven, 2011), the ‘As Low As Reasonably Achievable’ (ALARA) principle in radiation exposure and protection in the US (Shah & Platt, 2008), and the ‘So Far As is Reasonably Practicable’ (SFAIRP) principle in the New Zealand and Australian health and safety sectors (Enright, 2014).

people not to undertake activities that could be presumed to be risky unless there is no appreciable risk (Taylor, 2018; Tosun, 2013). Because of this broad variety in how the principle can be applied, it 'has not been as aggressive as its advocates urge and its critics fear' (Wiener et al., 2011, 555).

Scholars sometimes distinguish between 'weak' and 'strong' versions of the precautionary principle. The weak version places the burden of proof on those advocating precautionary action; the strong version places it on those who argue that the proposed activity or event does not cause significant harm (Aven, 2010). Others consider how early the decision is made in the knowledge collection process, as well as how stringently it restricts a risk, as a measure for the strength of the precautionary principle that is being applied: 'Earliness is a measure of precaution because it measures the willingness to act in the face of greater uncertainty about future outcomes and understanding. Stringency is a measure of precaution because it measures the degree of aggressiveness, weight, or sacrifice that society is willing to bear to prevent the risk' (Wiener et al., 2011, 530).

- Application of the significant risk doctrine in the US

The development of risk governance in the US is sometimes described as a long-term learning process that started in the 1960s. An early approach to risk governance, the 'least-feasible risk approach', which is comparable to the precautionary principle, was considered too strict by the US courts and regulators in the 1980s and 1990s. In response, the 'significant risk doctrine' emerged, in which some sort of quantification of costs and benefits is required (Majone, 2016). There is considerable discretionary space for regulatory agencies in developing risk governance and risk-based regulation, but they must follow a 'statutory trigger' or 'statutory standard'.

Statutory triggers establish 'the evidentiary burden that an agency has to meet in order to regulate [an anticipated risk]' (Shapiro & Glicksman, 2003, 33). Four levels are specified for the threshold of the minimum evidence required: (1) 'no threshold', which requires the agency to demonstrate that there is a risk, without setting a particular threshold for when to consider an activity or event to be a risk; (2) 'risk-based threshold', which requires the agency to demonstrate that the risk exceeds some threshold; (3) 'significant risk threshold', which requires the agency to prove that the risk is unacceptable; and (4) 'unreasonable risk threshold', which requires the agency to prove that the risk is unacceptable when comparing costs and benefits.

Statutory standards establish 'the level or stringency of regulation [and] what factors an agency is to take into account in setting the level of regulation' (Shapiro & Glicksman, 2003, 35). Five types of standards exist: (1) a 'standard based on risk or ambient quality', for which the cost of achieving the standard is considered irrelevant for its establishment; (2) 'phase-out', which is a phase-out ban that takes into account the cost of the phase-out; (3) a 'constraint balancing standard', which is based on a benefit–cost analysis but allows agencies to regulate beyond the point where the benefits and costs are equivalent; (4) 'open-ended balancing', which stipulates a benefit–cost evaluation and an evaluation of other economic values for which the agency can choose the weighting for each value in its final decision; and (5) a 'benefit–cost standard', which requires an agency to make a direct comparison of the economic benefits and costs of the regulatory intervention.

This chapter has put some meat on the theoretical bones of risk governance and risk-based regulation presented in Chapter 2. The chapter that follows zooms in further and explores the evidence of the performance and experiences of this approach to regulatory governance.

4 Evidence of the performance of risk governance and risk-based regulation

Now that we have a better understanding of the foundations of risk governance and risk-based regulation and have looked at some examples of their application, it is time to ask the hard question: do they work?

Answering that question is anything but easy. Only a small minority (16%, n=21) of the 133 peer-reviewed articles evaluated for this paper (see, further, Appendix B) address an example or examples of risk governance and risk-based regulation in practice. Most articles are conceptual and discuss the foundations of this approach to regulation (52%, n=69) or address the motivations for governments to turn to this approach to regulation (32%, n=43). Also, a large part of the world is under-represented in the scholarly debate: only a few articles are written by scholars from Asia, Africa or Latin America (11%, n=14), and only a few articles focus on these world regions (9%, n=12).⁸

In sum, when looking at the full set of articles, it becomes clear that, by and large, the debate on risk governance and risk-based regulation is driven by scholars from the UK, the USA and Europe, and that, by and large, they engage with theoretical and policy questions, rather than matters of regulatory implementation and practice. The following sections cluster the empirical findings under three themes: the perceived lack of homogeneity in the application of risk governance across countries and sectors, the observed changes in the understanding and drivers of risk governance, and the perceived risks of risk governance and risk-based regulation.

Little homogeneity in the application of risk governance across countries and sectors

In line with the findings of this review paper, scholars have mainly observed risk governance and risk-based regulation in the UK, the US, Australia and New Zealand, and continental Europe (Huber, 2010). Some argue that risk governance may be a specific conceptualisation of regulatory governance that fits well within the context of these liberal western democracies, but perhaps less well elsewhere (Smismans, 2017). That said, they consistently point out that there is little homogeneity in risk governance and risk-based regulation within these countries—or, as one scholar, states: ‘Risk regulation is a messy world’ (Hutter, 2017, 106). It is relevant to stress here, once more, that even within single jurisdictions scholars find limited homogeneity in the application of governance and risk-based regulation across policy sectors (Anderson, 2014; Hood et al., 2001; Power, 2004; Tosun, 2013).

Particularly popular in the empirical literature are comparisons between risk governance and risk-based regulation in the US and the UK on the one hand and continental European countries on the other. Typically, scholars describe risk-based regulation and risk governance as more salient in the US and the UK than in continental European countries (Allen & Koshima, 2018; Rothstein, Borraz, & Huber, 2013). The US and the UK are considered to prefer a rational–instrumental form of risk

⁸ Most articles reviewed come from scholars based in continental Europe (n=53, 40% of all 133 articles), the UK (n=33, 25%) or the USA (n=17, 13%). Scholars from other western countries were also highly represented, including Australia (n=9, 8%) and Canada (n=7, 5%). Empirical articles also mainly focus on Europe (n=23, 36% of the 64 empirical articles), the UK (n=9, 15%) and the USA (n=6, 9%). Again, cases from other western countries were highly represented, including western countries in articles with a ‘global focus’ (n=7, 11%), Australia (n=4, 6%), and Canada (n=2, 3%).

governance that puts a great deal of weight on 'hard' scientific data. Other European countries are, in turn, considered to prefer a deliberative–constitutive form of risk governance 'that is designed to address the factual and normative complexities of technological risk evaluation by granting to public administration substantial and ongoing problem-solving discretion in relation to particular issues' (Fisher, 2010, 30). In a similar vein, the US is considered more prone to err on the side of Type I errors (to prevent overly restrictive regulation) and European countries on the side of Type II errors (to prevent harmful under-regulation) (Vogel, 2012).

However, other scholars argue that these cross-country comparisons may too quickly result in caricatures of risk governance. They warn that there may be too much emphasis on the individual differences in how countries apply risk governance and risk-based regulation. For example, when studying the application of the precautionary principle in the US and Europe (see Chapter 3 of this paper), scholars sometimes tend to forget that the differences between these jurisdictions are rather small when compared to how these jurisdictions differ from other jurisdictions around the world (Wiener et al., 2011).

A changing understanding and changing drivers of risk governance

Scholars have observed that the politics of risk governance have changed substantially over the last two decades. They repeatedly point to changes in public perceptions of risk, and increased public pressure on policymakers to govern risk (Vogel, 2012). More than they did before, governments are found to respond with regulatory interventions to these changes in the public perception of risk and public opinion about risk (Scott, 2017). This has resulted in a significant shift in regulatory governance. No longer are governments purely regulating the direct risks stemming from activities and events: 'public risk perceptions are ... a reality that must be engaged with on its own terms. Perception has become, in a sense, as important as the hazard to which it relates' (Burgess, 2016, 8).

As a result, risk governance now understands risk in more broad societal terms—as opposed to considering risk as a purely technical probability. Risk is no longer considered an absolute certainty, because of the societal complexities that come with measuring risk (Burgess, 2016; Hood et al., 2001). This has resulted in a shift from scientific and technocratic risk models that base risk probability calculations on 'hard' data to socio-political models that acknowledge the impossibility of 'perfect' probabilities and instead rely on knowledge-based or subjective probabilities (Nygaard & Aven, 2010).

In short, among academics and regulatory policymakers there now is 'consensus that while the standard model of scientific investigation remains a necessary form of risk analysis (especially in the tasks of risk identification and estimation), it is no longer a sufficient form (especially in the areas of risk evaluation and management)' (Rosa, 1998, 8). As a direct result of this shift, deliberative and consensus-oriented approaches to regulatory governance are promoted as holding more promise for 'good' risk governance than traditional rational–instrumental approaches (Baldwin & Black, 2016; Fisher, 2010). That said, 'questions remain as to the extent to which traditional, often technocratic, cultures of risk regulation are able to permit meaningful interaction between publics and decision makers' (Jones & Irwin, 2010, 185).

The risks of risk governance and risk-based regulation

A final theme to which scholars regularly return when studying risk governance and risk-based regulation is that ‘risks’ come with this approach to regulatory governance—see Wildavsky (1988) for a taxonomy of risk errors. A frequently observed undesired effect is that of a ‘risk spiral’. Using the language of risk in regulatory governance alters the general public’s understanding of risk and heightens their risk anxiety. This may result in the general public having increased expectations about how much risk they ‘ought’ to be subject to, and the extent to which risk should be reduced, pooled, mitigated or prevented by government. In response, governments will increase their risk governance activities and interventions and increase the use of the language of risk. That increases the anxiety about risk among the general public, resulting in more calls for risk reduction, pooling, mitigation and prevention—ad infinitum (Giddens, 1998; Lloyd-Bostock, 2010).

In a related vein, scholars point out that governments often show ‘an overreaction ... to a risk or (public safety) incident by issuing more regulation and more oversight than necessary to control the risk at an acceptable level’ (de Ridder & Reinders, 2014, 4). This can result from responses being made too swiftly, and from the incoherent addition of risk-based regulation elements to an existing regulatory regime, which may cause regulatory failure in the future; an example is the post-global financial crisis risk-based regulation interventions (Anabtawi & Schwarcz, 2011). It may result from a tendency of regulators ‘to be drawn to their highest risks and ... pull back resources from lower risks’ (Black & Baldwin, 2012b, 2). Lower risks may, over time, produce significant harm and political contention (see also Chapter 3 of this paper). Finally, it may result from regulators’ desire to achieve ‘full’ safety and address ‘the last 10 per cent’ at all costs. In such a situation, the costs of reducing small risks, in particular, can quickly become excessive (Breyer, 1993).

Other scholars point out that risk as an approach to regulatory governance has resulted in the process of ‘responsibilisation’ in which citizens are increasingly expected to take the responsibility to protect themselves (Ansell & Baur, 2018). Risk as an approach to regulatory governance is then seen to fit a neo-liberal policy agenda and to be a justification for undermining (social) welfare (but for an opposing view, see Lodge, 2011). In a somewhat related way, making risk and the rational–instrumental approach central to risk governance creates an illusion of the manageability of risk. That may result in a false sense of security about how well future risks can be reduced, pooled, mitigated or prevented (Burgess, 2016; Power, 1999). Other challenges of this approach to regulatory governance are epistemic and ethical (Aven, 2016; Renn & Klinke, 2016). These are central to the chapter that follows.

Take home lessons for regulatory policymakers and practitioners

While the findings summarised here are insightful, they fall short in addressing the pressing questions of *what* forms of risk governance and risk-based regulation yield desirable outcomes, *where* and *why*. An understanding that governments take different approaches to risk governance, even in different policy areas within a single jurisdiction, helps to stress that there is no one-size-fits-all model for risk governance and risk-based regulation. The current evidence base is, however, too small to conclude whether risk governance and risk-based regulation is desirable in the first place. In the light of all the publications on risk as an approach to regulatory governance, the limited number of evaluative, comparative case studies—either comparisons between different types of risk governance or comparisons between risk governance and other regulatory governance approaches—is shocking (for

a promising exception of an ex-ante evaluation, see Rodenrijs, Kraaij-Dirkzwager, van den Kerkhof, & Runhaar, 2014).

Equally important to keep in mind for those interested in applying this approach to regulatory governance is that it produces a paradox. Risk governance and risk-based regulation may, at first glance, seem to be a rational, transparent and accountable way to allocate limited regulatory resources to address the most pressing risks. However, the efficiency gains of that utilitarian motivation for choosing this approach to regulatory governance may quickly be undone if risk governance and risk-based regulation is not taken seriously. Both rational–instrumental and societal–political risk assessments ask for substantial investment in time and resources. Deciding on the right level of risk management to implement will be equally time and resource intensive. However, without taking these steps seriously, the risks of risk governance and risk-based regulation may outweigh the benefits.

5 Epistemic and ethical challenges

Like any approach to regulatory governance, risk governance and risk-based regulation present considerable epistemic and ethical challenges. What is the minimal knowledge required for ‘good’ risk governance and risk-based regulation? Who decides how much knowledge is enough for risk assessment, and who chooses the ‘right’ risk management strategies? Do risks affect all citizens equally, and should regulatory governance responses reduce their risks equally? In what follows, we address the epistemic and ethical challenges most commonly discussed in the broader regulatory governance literature.

The epistemic challenges of risk as an approach to regulatory governance

Many of the epistemic challenges discussed in the literature address the limits of and differences in knowing what constitutes a risk and how best to respond to it. Scholars agree that sound risk assessment and management builds on multiple sources of knowledge regarding a range of elements. These elements include, but are not limited to, the extent of harm, the probability of occurrence, the remaining uncertainties (incertitude), the geographical and temporal spread of harm (ubiquity), the duration of harm (persistence), the reversibility of harm, the delay effect between the trigger and the occurrence of harm, and the potential for mobilisation of those affected (Renn & Klinke, 2016). However, obtaining sound knowledge on these elements and applying it well is anything but easy.

When risk governance and risk-based regulation backfire

Sometimes, risk governance and risk-based regulation backfire and do more harm than good. Scholars are critical of over-technocratic applications of the models and guidelines presented in the previous chapters of this paper, and of overconfidence about what this approach to regulatory governance may bring (Black & Baldwin, 2010; Renn, 1998). ‘Expectations that risks can be anticipated and managed may lead organisations to convey impressions that they are in much greater control than is in reality feasible, and the pressure may be on them to be seen to be doing something in response to the identification of risks’ (Hutter, 2010, 252). With the growing knowledge of risk assessment and risk management, risk governance has become ‘something of a cult. Today, an almost magical aura surrounds the estimation of probable harm’ (Durant, 1998, 73).

It is particularly problematic that risk assessment and risk management require the simplification of complex data and a reliance on proxies where data are lacking (Hutter, 2017). The data that exist often do not allow for risk assessment, historical data may be outdated, and too much weight may be given to probabilities derived from incomplete data (Aven, 2016). Data can be compromised at the political level by partisan or other interests, and biases may colour how data are interpreted or even provided (Aven, 2011). For example, in risk governance benefit–cost analyses are often used to understand whether people are willing to be subject to a specific risk. The exact framing of questions is critical. The answer to the question of how much people are willing to pay to reduce the risk of losing income/health/happiness/etc. will be substantially different from the answer to how much they would pay for the certainty of maintaining their income/health/happiness/etc. (Renn, 1998; Shapiro & Glicksman, 2003).

The changing nature of knowledge

More and more, claims to know what constitutes a risk and what constitutes an appropriate response are disputed. Often, a distinction is made between ‘objective’ and ‘perceived’ risks (Cedergren & Tehler, 2014). Over recent decades, scholars have put to the test the objectivity of technical risk assessments and have identified a range of biases and ethical and sociocultural influences that affect risk identification and estimation (Rosa, 1998; Viscusi & Zeckhauser, 2015). In response, more weight is now given to the knowledge of risk held by people other than technical experts, such as the general public affected by the risk (Poortvliet et al., 2016). It should be kept in mind, however, that a larger knowledge base of what constitutes a risk and what the response to the risk should be by no means provides a blueprint for effective risk governance (Shapiro & Glicksman, 2003; van Asselt & Renn, 2011).

Again, our bounded cognitive abilities come into play. One of the core epistemic challenges of risk governance is that humans have a limited capacity to deal with uncertainties and probabilities. We quickly jump to conclusions based on partial or misunderstood information about risk (Van Coile, 2016). To prevent poorly designed risk governance interventions being made that lean too heavily on either ‘objective’ or ‘perceived’ risks and risk knowledge, scholars urge a move away from a static understanding of risk towards a more dynamic understanding of degrees of uncertainty. They further urge a move away from risk aversion towards trial-and-error risk taking that allows for learning from adversity and promotes resilience (de Vries & Boeckhout, 2011; Wildavsky, 1988).

Limits to how much can be known about risks

Many risks are relatively simple in structure, their probabilities of harm are well understood, and their risk governance interventions have become conventional. Over recent decades, however, other risks have rapidly grown in complexity, ambiguity and uncertainty, and these pose challenges for regulatory governance (Renn, 2015; Renn & Klinke, 2013). This is particularly true for ‘systemic risks’ (see pages 9 and 12 of this paper). Strikingly, it is often not the activities and events underlying these systemic risks that have become more complex, but the way in which they interact.

Interactions between different activities and events in complex systems may multiply risks, or trigger synergies where the total of the risk is larger than the sum of its individual parts (Broberg, 2017; Van Coile, 2016). Depending on how tightly activities and events are coupled, an accident (of high magnitude) may be unpreventable. For example, sometimes ‘two or more failures, none of them devastating in themselves in isolation, come together in unexpected ways and defeat the safety devices – the definition of a “normal accident” or system accident. If the system is also tightly coupled, these failures can cascade faster than any safety device or operator can cope with them, or they can even be incomprehensible to those responsible for doing the coping’ (Perrow, 1999, 356-357).

The ethical challenges of risk as an approach to regulatory governance

When overviewing the range of ethical challenges discussed, two broad issues stand out. The first is a call on governments to reduce risk inequalities across different groups in society; and the second is a call on governments to improve the legitimacy and accountability of risk evaluation and risk reduction, pooling, mitigation and prevention.

Reducing risk inequality

One of Ulrich Beck's better-known statements in his paper *Risk Society* is that '[w]ealth accumulates at the top, risk at the bottom' (1992, 35). Beck was concerned that risks disproportionately affect groups in society that are already marginalised. Other scholars are less dystopian, but still argue that risks do not affect everyone equally. Often, they warn, risks are not chosen by individuals or groups but are imposed on them by the actions of others (Lodge & Wegrich, 2012). Likewise, risk responses desired by some may have negative consequences for others. '[R]isk-related decision making is not about risks alone or about a single risk usually. Evaluation requires risk-benefit evaluations and risk-risk trade-offs. [There] are competing, legitimate viewpoints over evaluations about whether there are or could be adverse effects' (Renn & Klinke, 2016, 208). It is partly because of these insights that scholars have begun to call for more inclusive and participatory risk governance processes.

Such participatory processes allow for risk assessment and the development of interventions that build on the knowledge of technical experts, expert bureaucrats, scientists and lay people (Lodge & Wegrich, 2012). They call for a move away from a rational-instrumental model of regulatory governance towards a societal-political one (see Chapter 4 of this paper). This, of course, does not imply that all risk governance interventions require extensive participation. The changing levels of risk knowledge and the changing nature of risks allow for different types of participation. For example, relatively simple and conventional risks can be addressed by expert bureaucrats, technical experts and scientists. When the risks that are faced are more complex and ambiguous, affected stakeholders and sometimes even civil society at large may need to be consulted (Renn, 2015). Not only does this allow for a broad knowledge base to be obtained, but it also helps to make affected stakeholders aware of the risks to which they are subject and the actions they can themselves take to reduce their exposure (Steele, 2004).

Improving legitimacy and accountability

Scholars also call on regulatory policymakers and practitioners to keep in mind that risk governance '[is not] a free-standing and technical guide to regulatory intervention [but a] particular way to construct the regulatory agenda' (Black & Baldwin, 2010, 210). Risks are not value free. Their construction, packaging and identification involve political choices, and this gives considerable power to decision makers (Baldwin & Black, 2016; van Asselt & Renn, 2011). At the same time, heightened public awareness of risks asks decision makers to 'justify not taking action rather than taking action' (Tosun, 2013, 42). A challenge for regulators in risk governance is that they may 'be criticized for being too harsh when things are calm and being too lax when risks have been realized' (Hutter, 2017, 107). To put this differently, the growth of risk regulation may raise legitimacy problems for a government: how can it demonstrate its effectiveness if the problems it seeks to address do not occur (Ansell & Baur, 2018)?

Governments engaged in risk regulation may also face accountability challenges. The aura of objectiveness and rationality that comes with this approach to regulatory governance may shift blame away from government, or result in symbolic responses with little practical value (Macenaite, 2017; Rothstein & Downer, 2012). Risk governance can also change the dynamics of regulatory capture, particularly when governments are highly reliant on third parties for technical risk assessments and other knowledge (Jansen, 2017). To help to improve the legitimacy and accountability of risk

governance, scholars therefore call on governments to increase the openness of their risk governance regimes (Hood et al., 2001). That can be done by, for instance, increasing public participation in risk assessment and the development of interventions, as discussed above. Alternatively, governments may wish to provide greater transparency in information-gathering and processing, as well as about the making of decisions on the kind of risks that are accepted and the kind that are not.

6 Conclusion

This research paper has reviewed a large collection of academic literature on risk governance and risk-based regulation. It has addressed the evolution of thinking about risk, risk governance and risk-based regulation (Chapter 2); examples of risk governance and risk-based regulation (Chapter 3); evidence of the workings of risk governance and risk-based regulation (Chapter 4); and the ethical and epistemic challenges that come with this approach to regulation (Chapter 5). Each chapter has discussed key insights from the literature. Three broad conclusions can be drawn from the review.

First, over recent decades, risk has become a dominant *approach* to regulatory governance. Of course, risk has always been an *object* of regulatory governance. As an approach to regulatory governance, it does, however, rest on a set of assumptions about how regulatory resources can best be allocated to achieve desirable societal outcomes—or, to put it better, how resources can best be allocated to prevent harm in the first place or to respond to it adequately when it arises. Generally, risk governance and risk-based regulation do not aim for zero harm for all observed risks: ‘the aim is not to develop absolutely fault-free systems but systems which are capable of handling faults quickly when they develop’ (Hutter, 2010, 259). Keeping these insights in mind, regulators have begun to complement their risk governance strategies and risk-based regulatory tools with risk response plans. These include preparedness plans that stipulate how to act to minimise harm during a disaster, resilience thinking about how to ‘bounce back’ or ‘fall forward’ after a disaster, and explicit precautionary strategies that clearly state when zero harm (‘better safe than sorry’) is required and when it is not (O’Malley, 2016; Sanchez et al., 2018; Wildavsky, 1988).

Second, risk governance and risk-based regulation come with their own risks. ‘Our faith in risk management encourages us to take risks we would not otherwise take’, Peter Bernstein argues (1996, 335). Others have stated that risk as an approach to regulatory governance may result in a false sense of security, in modelling that looks good on paper but would not stand the test of practice, or even in a means of resource allocation that is captured by political or private interests (see Chapter 4 of this paper). Keeping these insights in mind, regulators need to realise that risk provides a *utilitarian* approach to regulatory governance. It may make resource allocation more transparent and accountable, and perhaps more systematic and rational. It will not make resource allocation less political or contested. How to allocate resources under risk governance and risk-based regulation ultimately depends on ‘how risk is defined and on the chosen (declared) rationale justifying regulatory action. There exists indeed an important, and yet often neglected, linkage between conceptualisation of risk and proposed solutions of risk-related policy problems’ (Alemanno, 2016, 197).

Third and finally, regulators who make risk an approach to regulatory governance will quickly encounter the tension between a rational–instrumental and a deliberative–constitutive understanding of risk assessment and risk management (Fisher, 2010). The former calls for ‘more science’ in risk governance and risk-based regulation, the latter for ‘more democracy’ (see Chapter 3 of this paper). For a long time, marrying risk governance to the rational–instrumental approach made sense because it aligned well with a neo-classical rational choice model in which humans were considered to make predictable decisions within bounded contexts. Since the 1980s, however, the behavioural sciences have pointed to the limited predictive value of the neo-classical rational choice

model.⁹ Likewise, since the 1980s, it has become clear that many of today's most pressing risks transcend traditional regulatory boundaries. These insights indicate that siloed agencies and nation states can no longer regulate risks independently, and they also point to the limits of a rational–instrumental understanding of risk assessment and risk management. The review presented in this paper stresses that risk as an *approach* to regulatory governance calls for tailored solutions and bespoke applications. 'Good risk governance rests upon a combination of best available interdisciplinary knowledge, including the awareness of its limitations and uncertainties, and careful synthesis of public concerns, values and visions' (Renn, 2008, 368).

⁹ See the first State of the Art in Regulatory Governance Research Paper on behavioural insights for a more extensive discussion: van der Heijden, Jeroen (2019). *Behavioural insights and regulatory practice: A review of the international academic literature. State of the Art in Regulatory Governance Research Paper – 2019.01*. Wellington: Victoria University of Wellington/Government Regulatory Practice Initiative. Available online: https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3332699 (13.05.2019).

Appendix A – Suggestions for further reading

Serving the rapid growth of interest in risk governance and risk regulation from policymakers and practitioners, scholars from various fields have begun to publish ‘popular science’ books and ‘easy to read’ academic books. Many of these provide superb introductions to various areas of risk, risk governance and risk-based regulation. The following six (in no specific order) are of interest to those who seek a further introduction into risk governance and regulation.

Risk management and governance: Concepts, guidelines and applications (Aven & Renn, 2010)

Professor Terje Aven (University of Stavanger) and Professor Ortwin Renn (Potsdam Institute for Advanced Sustainability Studies) are two leading risk theorists and (regulatory) researchers. They have been studying risk, risk governance and risk management for well over two decades. In *Risk management and governance: Concepts, guidelines and applications*, they join forces and present key lessons from their work and that of others. While the book is now close to reaching its tenth anniversary, it is still among the best in the field for policymakers, practitioners and academics interested in a substantive introduction to the topic.

Against the gods: The remarkable story of risk (Bernstein, 1996)

Peter Bernstein goes back to twelfth century Europe to understand how the notion of risk emerged, and how precisely advances in game theory, probability theory and statistics have shaped risk assessment and risk management. This is probably the easiest to read of the available books on the topic—and one of the few books on risk that has become an international bestseller.

The government of risk: Understanding risk regulation regimes (Hood et al., 2001)

With *The government of risk: Understanding risk regulation regimes*, Professors Christopher Hood (University of Oxford), Henry Rothstein (King’s College London) and Robert Baldwin (London School of Economics) were among the first regulatory scholars to explore systematically the evolution and growth of risk regulation since the 1990s. The book seeks to understand why there is so much variety in how risks are regulated across and within policy domains. What makes the book of specific interest is that the authors are interested not only in risk regulation in theory (i.e., standard setting) but also in risk regulation in practice (i.e., information gathering and behaviour modification). In other words, they are interested in the different control components that make up risk regimes. This is one of the few books on risk governance that provides regulators with hands-on lessons.

Regulatory crisis: Negotiating the consequences of risk, disasters and crises (Hutter & Lloyd-Bostock, 2017)

In *Regulatory crisis: Negotiating the consequences of risk, disasters and crises*, Professors Bridget Hutter and Sally Lloyd-Bostock (both London School of Economics) seek to understand when a disaster becomes a crisis for regulators. They provide in-depth case studies of five disasters that became regulatory crises in the UK: the BSE epidemic of the 1980s and 1990s, the case of Dr Harold Shipman, the terrorist suicide bombings of 7 July 2005 in London, the financial crises of 2007-2009, and the volcanic ash crisis of 2010 that resulted in the closure of much of Europe's airspace. The book takes a slightly different view of 'risk' from the way it has been presented in this paper. It considers risk as an object for regulatory governance, rather than an approach to it.

Risk regulation and administrative constitutionalism (Fisher, 2010)

Professor Elizabeth Fisher (University of Oxford) presents a fresh reading of, and engagement with, the risk governance and risk regulation literature in *Risk regulation and administrative constitutionalism*. Her starting point is that too often this literature is concerned with either the democratic decision-making process or the scientific decision-making process that underpins risk regulation. Instead, she argues, it is better to understand the argument over how to govern risk as a dispute about the legal validity of public administration and its orientation. Put simply, debates about risk-based regulation are debates about what is good public administration.

Risk society: Towards a new modernity (Beck, 1992)

It is impossible to understand the debates surrounding risk-based regulation fully without reading *Risk society: Towards a new modernity*. In this book, Professor Ulrich Beck (1944-2015; University of Munich) explores what he termed the 'risk society'. The book was originally published in German in 1986, in the immediate aftermath of the Chernobyl nuclear disaster. It is considered to be one of the most important works exploring the shift in modernity from industrialisation to the global state of affairs in which we have found ourselves since the 1990s. Note: this is probably not the easiest read on this list.

Appendix B – Methodology

To understand the potential of insights from the academic literature on risk governance and risk-based regulation, this article takes stock of the literature as it has engaged with broader questions of public governance over the last ten years. It builds on a systematic review peer-reviewed publications from the fields of law, political science and public administration published in English between 2009 and 2018.

Publications were systematically sourced from the Web of Science database, using key word searches. The key word searches were: (risk AND based AND regulat*), resulting in 417 documents; (risk AND regulat*), resulting in 130 documents; (“risk regulat*”), resulting in 80 documents; (risk AND based AND govern*), resulting in 89 documents; (risk AND govern*), resulting in 553 documents; and (“risk govern*”), resulting in 148 documents. The asterisk (*) operates as a wildcard—for example, the term ‘regulat*’ allows the search to find ‘regulation’, ‘regulating’, ‘regulate’, ‘regulator’, etc.

After removing duplicates, this initial search resulted in a set of 1,126 peer-reviewed journal articles and book chapters. All abstracts and summaries of these were read to identify those publications that explicitly engage with regulatory governance. This step resulted in 133 publications. This set was complemented with 26 relevant publications cited in the publications traced (‘snowball sampling’): 23 academic books, two foundational articles published before 2008, and one foundational article that was not initially identified in the *Web of Science* database search.

These 159 publications were read, and notes (including the key insights reported, the area of study, and the type of research project undertaken) were kept in a working document. The document was coded to capture the ‘repetitiveness’ and ‘rarity’ of themes and findings reported across the various publications (cf., Bearfield & Eller, 2008; and Sutton, Papaioannou, & Booth, 2016).

Of course, the initial focus of the review on publications in the areas of ‘law’, ‘political science’ and ‘public administration’ will have somewhat skewed the set of source publications underlying this review. That having been said, the search includes publications from ‘typical’ journals oriented towards regulatory governance, such as *Governance, Regulation and Governance*, and *Public Administration*.

An unformatted Excel file of the 1,126 identified peer-reviewed journal articles and book chapters and the 159 coded publications is available upon request. Please reach out to: Professor Jeroen van der Heijden, jeroen.vanderheijden@vuw.ac.nz.

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