

Chapter 1

Challenges to Designing Regulatory Policy Frameworks to Manage Risks

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Greater emphasis on risk-based approaches to the design of regulation and compliance strategies can improve the welfare of citizens by providing better protection from hazards and more efficient services from government. Improvements to risk and regulatory policy are also consistent with the Better Regulation Agenda of most Governments and can reduce costs for business. However, across OECD only a few governments have taken steps towards developing a coherent risk policy framework for managing regulation. For the most part there is little or no central oversight or guidance to ensure that approaches being taken are efficient and effective, adequately account for risk-risk tradeoffs, and/or diffuse the lessons from individual agencies to other parts of government. This chapter argues that central guidance and a review role is necessary if progress is going to be made to improve risk governance systems right across the administration.

Introduction

OECD governments have come to recognise the critical importance of, and the need for, effective policies to identify, measure and respond to risks. Public servants deal regularly with risks in many public policy domains – economic, financial, health, safety, environmental and national security. With increasing frequency, officials face decisions about policies, programmes and services where future uncertainties are economically significant and unavoidable. Thus, they need to assess, appraise and manage risk in an overall effort to develop suitable policy responses. Moreover, in a context of growing complexity and interdependence, they need to inform the public about the nature of risks and the inherent tradeoffs between specific policy choices.

The problem-solving capacities of government administrations have often been inadequate in the face of the major risks facing society today. The range of policy responses to risk in the public sector comprises a broad picture. Not only does it include what has been termed risk management or risk analysis; it also looks at how risk-related decision making unfolds when a range of actors is involved. Effective responses to risk require co-ordination and possibly reconciling between differing policy objectives. Significant risks such as those related to climate change, terrorism or critical infrastructures call for co-ordinated effort amongst a variety of government agencies.

Because of its focus on improving the performance of government and reducing the costs of regulation, the systematic identification and treatment of risk is complementary to the better regulation agenda of many OECD governments. In this respect it is popular with business and governments seeking to reduce the costs of regulation. However, the tools and institutions that underpin an improved approach to risk are still being worked out. The effective treatment of risk across government demands a co-ordinated, policy driven approach but there is limited practical evaluation of the experiences of governments in establishing a comprehensive approach to managing risk and regulation. In principle guidance can be found as to what governments should do to improve the co-ordination of risk and regulatory policy, but in many areas of regulatory policy the design of appropriate governance arrangements are still being developed and tested and there appear to be some practical problems with its implementation. Nevertheless, there are valuable lessons from thinking about the policy problems that risk approaches try to address, looking at how particular countries are responding and considering the various elements of governance systems to improve the treatment of risk.

How can a risk approach improve regulation?

A risk-based approach to regulation explicitly acknowledges that the government cannot regulate to remove all risks and that regulatory action, when taken, should be proportionate, targeted and based on an assessment of the nature and magnitude of the risks and of the likelihood that regulation will be successful in achieving its aims. Regulatory responses are therefore to be informed by an assessment of the probability of

harm expected to arise from, for example, a market failure, where this can be known. Where the probability of harm cannot be calculated, a risk-based approach would require a rational and transparent consideration of other relevant factors that for want of evidence remain uncertain. Risk-based approaches have application to the formulation of regulatory proposals and to the development of compliance strategies to enforce regulation.

Governments face increasing demands to react to crisis and to reduce or eradicate risks and there are incentives for government to respond to these demands with attempts to resolve problems through regulation. In many areas including the preservation of the environment, protecting human health or facilitating markets, regulation clearly has a role in reducing the incidence of hazardous events or their severity. But governments may also respond with reactive regulation, usually after a problem has received significant media and political attention, by drafting regulations which may give the public the impression that the causes of the problem have been addressed, but are in fact not effective and efficient at addressing the risks.

There are costs to this sort of regulatory failure. Obviously there is a cost when governments fail to regulate when there is a need, but there can also be significant opportunity costs if governments regulate when there is no clear benefit to society. In a perverse way, poorly designed regulation that fails to address risk at the right level in society may actually increase the vulnerability of society creating situations of moral hazard and inhibiting innovation through the development of new and better methods to reduce risks. Good governance arrangements are fundamental to promoting the successful design and implementation of effective regulation and addressing the causes of regulatory failure. Risk assessment and risk management tools have an important place in these governance arrangements in particular to guide governments when choosing whether and how to regulate.

The opportunity costs of risk regulation

Governments (and in fact societies generally) have limited resources available to them to address market failures and to achieve policy goals. The regulatory resources that are applied to one problem are not available for use elsewhere. This applies to the public fiscal resources that the government allocates directly to address policy goals as it does to the private resources that are required to be diverted to fulfil regulatory obligations. Governments can improve the welfare of citizens and maximise the benefits of regulation to society through the efficient allocation of regulatory resources. This implies only regulating where the benefits of regulation outweigh the costs and applying the limited regulatory resources to those areas where the maximum benefit to society can be achieved. In both cases risk assessment can assist with the challenge of identifying these areas.

Clearly when governments fail to manage risk appropriately, the costs to society can be politically significant and these costs can impact at many levels, both sensational and prosaic. Governments are blamed when they fail to avert crisis, and will also be criticised for tying up the lives of citizens and business in red tape. Governments are expected to regulate to respond to and prevent the factors which lead to crisis, but should not stifle innovation, entrepreneurship and opportunities for markets and consumers through unnecessary bureaucracy.

Another way to classify this is as economic opportunity costs: the opportunity costs which arise from governments failing to anticipate and avert the consequences of emerging risks; and the opportunity costs from governments giving an unnecessary degree

of attention to risks that are better managed in another way, or by another part of society. As a matter of principle, regulation should be set at the minimum level necessary to achieve a regulatory objective to reduce unnecessary regulatory costs.

In regulatory parlance therefore these two categories of costs can be referred to as resulting from Type I or Type II errors. A Type I error is failing to regulate where there is a need, such as permitting unrestricted use of a product or medicine that will have unexpected dangerous consequences for consumers (approving bad products). A Type II error would describe the proscription of a product or activity that would have a social net benefit, for example by preventing patients from receiving medicine products where the therapeutic benefits exceed the costs (rejecting good products).

This general categorisation can be applied beyond product approvals to all cases of regulatory action or inaction. Type I errors are likely to occur when the attention of government agencies are diverted. They can have significant costs and result in public demands to know why regulation failed to prevent the adverse consequences. But governments are more routinely accused of having a greater propensity to commit Type II errors, of being risk averse and prone to over regulate. Clearly, society benefits when governments are better prepared to make judgments and the opportunity costs from both types of these errors are minimised.

There is a range of negative effects on social welfare which can result from the opportunity costs of the irregular treatment of risks in the following ways:

- Failing to set risk priorities – not all risks are equally important. A systematic approach is necessary to identify which risks are likely to be of significant magnitude to allow governments to apply sufficient resources to address the most serious risks.
- Over regulating risks – intervening in markets or the lives of citizens in a disproportionate manner to the scale of the risk is wasteful of resources. On the one hand regulating to attempt to insulate persons from risks which are more effectively addressed at an individual level may have the perverse effect of creating a moral hazard. That is it may increase the incentives that individuals have to take risks and therefore increase rather than reduce their public impact. On the other hand, unnecessary government action that is ineffective in removing risks can interfere with the live of citizens, increase the costs to consumers and impose obligations without a net benefit to society.
- Unequal treatment of risks – treating regulatory problems that represent equal risks differently can create barriers to trade between jurisdictions, increasing business compliance costs and reducing the welfare of citizens.

In principle, improving the capacity of governments to correctly identify and respond to risks has significant potential benefits to society in a broad range of ways. These include more targeted use of public resources resulting in reduced fiscal cost for the delivery of a wider range of services. It should also include higher rates of regulatory compliance.

What are the key elements of risk policy framework?

In general, risk can be defined as an uncertain consequence of an event or activity with respect to something that humans value. Practically the treatment of specific risks will require very specific mechanisms. At a high level, however, and for the purposes of discussion certain generalised features of risk policy which apply to all risk-based policy

approaches can be described. Analytical models divide risk policy into three sequential phases; assessment, management and review with all three stages linked to communication (OECD, 2006a).

Risk assessment involves framing and forecasting the probability and consequences of identified hazards. Framing involves constructing a conceptual model of the risk, taking into account the variety of issues that the public may associate with the risk. Forecasting involves undertaking a scientific assessment of the likelihood of the risk and its economic, environmental and social implications. A particularly important element of risk assessment is risk/risk analysis and the identification of risk tradeoffs; where reducing risk in one area may have the effect of creating an equally unacceptable risk in another area. In general terms the analytical methods of benefit cost analysis and regulatory impact assessment should include within them components of risk assessment when applied to determine the nature of policy problems and to evaluate the likely effectiveness of regulatory solutions.

The second phase, risk management, aims to design and implement actions and remedies to address risks through a consideration of potential risk treatments and the selection of the most appropriate. An extensive range of available regulatory and compliance strategies are employed by governments to deal with risks. Put broadly in the language of risk management, the range of responses can be classified into four categories:

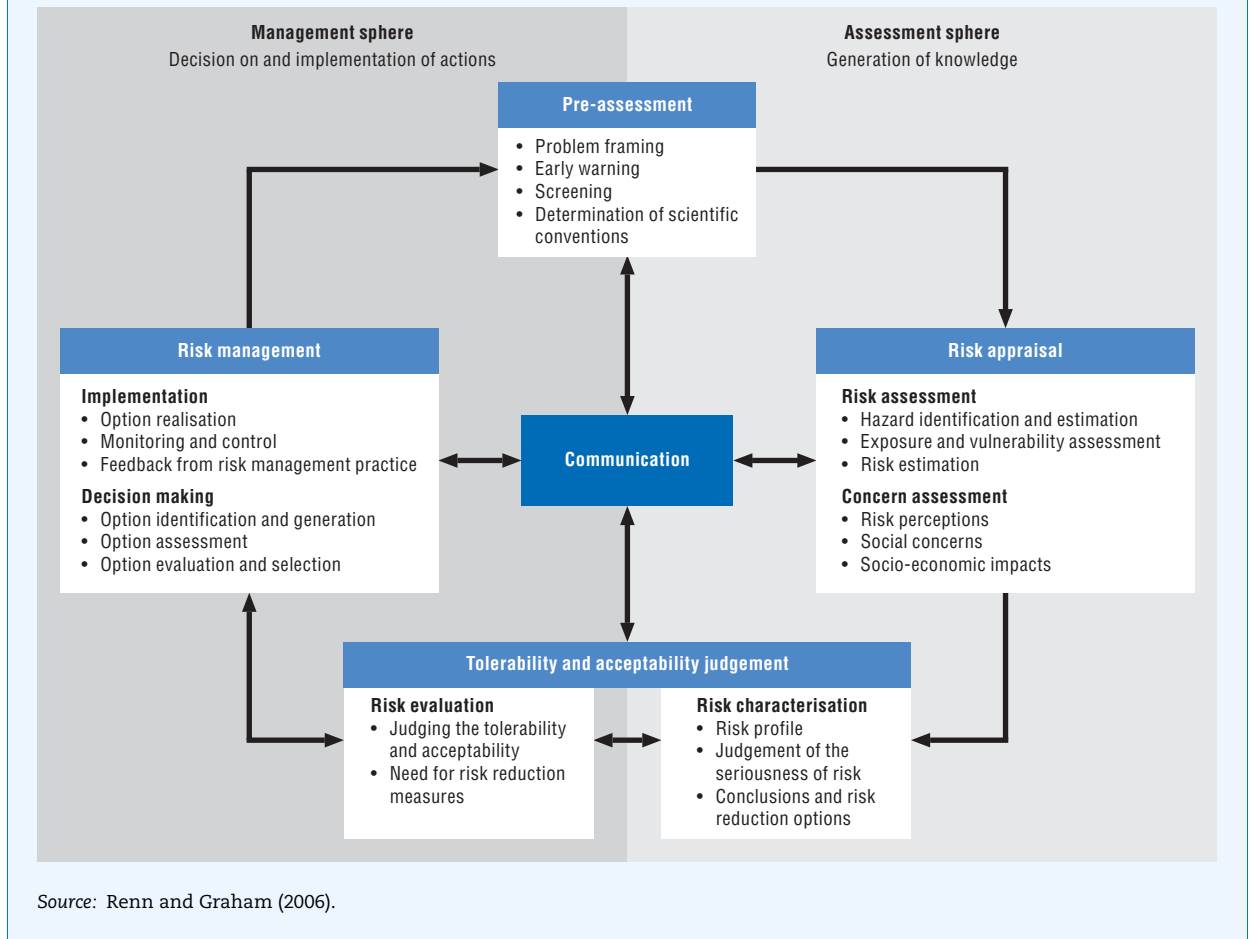
- Risk avoidance: not performing an activity that would create the risk (proscription, prohibition).
- Risk reduction: strategic methods to reduce the probability and severity of the impacts of a risk event (licensing, codes and standards, enforcement and compliance strategies).
- Risk retention: accepting the loss arising from the risk event (self insurance, retaining responsibility for functions within government).
- Risk transfer: cause another party to accept the risk by contracts (compulsory insurance, privatisation, public private partnerships).

The third phase of review and evaluation is an essential element of good policy process. Effective governance requires that decision making processes must be transparent and open to revision in light of new information. Effective risk management requires a policy cycle based approach that has both *ex ante* and *ex post* features. *Ex post* evaluation of the effectiveness of policy solutions is necessary for the development of future responses and adaptive management within governments. To achieve optimum results from a risk policy cycle, risk management would be fully informed by risk analysis.

Risk communication and consultation is fundamental to the entire risk policy cycle. Communication assists in identifying the nature and extent of the risks, educating and informing the public about the scale of risks when making risk tradeoffs (where the reduction of one risk may give rise to another) and building trust in the proposed responses and the institutions that administer them. Public transparency is also important to increasing the predictability of the business environment and promoting an effective investment climate. Improving public understanding of the nature of the risks and the risk management process can increase the public acceptance of the risk elements that cannot be further reduced through management.

There are many examples of this model of risk treatment. For instance, this is illustrated and elaborated in the framework formulated by the International Risk Governance Council – IRGC (Renn and Graham, 2006) which is based on a cyclic sequence

Box 1.1. The IRGC risk governance framework



for the various stages of pre-assessment, risk appraisal, risk characterisation, risk evaluation and risk management. The risk process has “communication” linked to all phases of addressing and handling risk. The presentation of these stages is intended to be illustrative of the logical phases and steps in the administration of a proper process of risk governance, even if in practice the sequence is slightly different.²

1.1. Challenges to a coherent risk policy

Despite the in principle benefits to a more coherent treatment of risk, there are a number of reasons why the governments are likely to face difficulties with the development of processes to improve the consideration of risk when developing regulatory policy. Developing and implementing risk-based approaches to regulation is complex and subject to particular challenges inherent to public administration including the following among them:

- *The interrelated nature of many risks.* Many risks are so complex as to require a multifaceted treatment, particularly as the suppression of risks in one area of society may give rise to risks elsewhere. However, the otherwise rational and efficient structure and organisation of governments necessarily results in the atomisation and fragmentation of responsibilities.

This can work against the identification and development of risk responses across government and incorporating the private sphere that are required to embrace the totality of risk consequences.

- *The manner in which governments encounter risks and how the awareness of the risks enters the policy cycle.* The treatment of significant societal risks is always a political issue. Good risk assessment procedures will anticipate and evaluate emerging risks and have prepared possible responses. However, where risks are identified through a crisis situation an immediate political response will usually be demanded. Hastily prepared responses may fail to address the causes of the problem and have unintended consequences leading to regulatory failure.
- *Failure to properly assess risks from the outset.* To be of assistance with the development of regulatory responses, risk assessment needs to inform the consideration of the scope and magnitude of the regulatory problem, market failure or policy objective before a regulatory solution is proposed. The timing of the consideration of risks and the extent to which risk assessment informs the regulatory response is therefore of critical importance.
- *The subjective perception of risks.* Many risks are not easily quantified and the subjective perceptions of regulators and of segments of society as to the magnitude of the risk do not always align. Public risk perception can and most likely will vary from that of the experts. [The public tends to overestimate lower probability events (floods, etc.) and underestimate higher probability events (car accidents)] (Majone, 2006). Risk perceptions can also vary among neighbouring countries resulting in the irregular treatment of risk across national boundaries.
- *Problems of communicating risks and risk responses to the public.* Even where risks are able to be measured and quantified and appropriate risk assessment procedures are in place there can remain a deep distrust of formalised risk assessment and the risk management process. This is particularly the case if cost benefit analysis is not believed to be a politically neutral tool or that it is not capable of delivering a solution that is able to adequately address the risk. There is the further problem of Governments being expected to respond to the public perception of risks and to reduce risks to zero, which is not always possible and may not be cost effective. Demands for a certain reduction in risk may not be made if the associated economic costs were known.
- *Difficulties of separating risk assessment and risk management.* As a matter of principle risk assessment and risk management are two distinct exercises, which should be undertaken separately to ensure that the assessment is objective and informs the risk management decisions. In a practical context, risk assessment may need to be appraised of risk management options and be institutionally joined to be effective.

Coping with uncertainty: data, accountability, co-ordination and evaluation

There are a number of potential practical obstacles to embedding a comprehensive risk assessment process within government regulatory policy processes.

A significant constraint on undertaking risk assessment and analysis is the availability of reliable and comprehensive data. Collecting data imposes a burden on government. It can be costly and time consuming and may require rare and expensive scientific expertise. Furthermore, even where scientific evidence is available, its conclusions may be contentious within the scientific community making it difficult to use effectively for informing decision making. The literature on risk assessment reflects extensive debate on

the technical construction of scientific procedures for assessing risk and uncertainty in particular technical domains, for example; assessing health and safety outcomes, impacts on the environment and applying valuation techniques to the measurement of intangible costs and benefits.

Even where data is available, risk analysis may be subject to criticisms of spurious accuracy. Risk analysis that includes significant technical complexity may be subject to the allegation that it obscures important policy issues rather than improving transparency – in effect promoting analytical paralysis. In this regard risk analysis cannot be taken to provide automatic answers or solutions to regulatory problems but rather has to be constructed as a source of information that informs policy decision making within properly designed institutional arrangements.

The authorising environment (expressed in legislation and political will) may limit possibilities for the use of risk assessment. For example Majone (2006) argues that the use of the precautionary principle (which is employed where the risks of actions or of a failure to act may result in irreversible damage to the environment or other goods) acts as a rule constraining the conduct of risk assessment because it does not focus on the entire range of possibilities but on losses. It therefore does not incorporate risk decision rules because it places too much weight on the outcomes without considering the costs and benefits. He also argues that the varying definitions of the precautionary principle in a number of statutes further reduce its effectiveness as a general principle to guide decision makers. However, it is noted that other commentators have taken a different view. Herwig (2006) for example, argues that the precautionary principle is a flexible instrument which usefully guides the reasoning of regulators, stating that “the only constraint that the precautionary principle introduces is that the evidence upon which decisions are based must be reasonable or that a threat could actually exist”. Regardless of the merits of the principle, its use as a guide to decision makers will be surely be enhanced by more clarity in how it should be applied.

Risk assessment can present significant co-ordination issues. Where risks are required to be managed by more than one department risk identification and the evaluation of priorities for the treatment of risk have to be looked at from a whole-of-government perspective. This is made acute by the potential for risk reduction strategies in one area to increase risks in another noted above.

As with all aspects of regulatory impact analysis risk assessment needs to be incorporated early in the policy process if it is to be effective. Once regulatory or policy solutions have been identified and become owned by stakeholders it is extremely difficult for alternative approaches to be given serious consideration even if their merits are supported by robust analysis.

While good risk policy processes require *ex ante* and *ex post* evaluation of risk assessment and management strategies it is a challenge for governments to undertake this evaluation systematically and in a timely manner. Some explanations for this are that governments may not be willing to accept the conduct of reviews as an appropriate allocation of limited resources, or may be concerned about the political consequences if reviews of responses to risk are highly critical.

Finally, risk assessment has been criticised for not being sufficiently nuanced and for failing to take into account distributional impacts or to provide guidance on how risk trade-offs should be made. This is a criticism which is also levelled at benefit cost analysis

generally, and is a matter to be considered in the design and use of risk assessment methodologies. Risk assessment must be promoted and understood in the same way as regulatory impact assessment and cost benefit analysis, as an input to assist decision makers. Clearly, while it may not be able to direct a certain policy choice particularly in a political context, robust risk assessment is an important tool for assisting with distinguishing and making transparent the consequences for different groups if certain trade-offs are selected over others.

The risk governance deficit

The goal of embedding risk management in public governance is to find a balance between the opportunities for greater flexibility and innovation in government service delivery, and limiting the adverse consequences of mistakes. The case for a risk-based approach to regulation can be easily made on efficiency and effectiveness grounds. Regulation should be proportionate to the problem that it seeks to address; therefore a risk-based approach would be underpinned by scientific evidence and a robust decision methodology. This is necessary if governments are to balance the tension towards reactive regulation to public responses to risk.

Adequate technical capacity is therefore a feature of risk-based approaches. A model is required which influences decision making, to make it more evidence based. Given the complexity of risk problems some sort of filtering mechanism has to apply on the reaction to risk events and the response of political decision makers. The obvious place for this is in the bureaucracy, as the role of the administration is to build up the technical capacity for this to occur. There is however, no one model for the design of this administrative capacity. Breyer (1993) proposed setting up a functional body for evaluating risks, like the OIRA but with a broader mandate to advise on the magnitude of risks. A key difficulty of Breyer's proposal is that it places a heavy emphasis on technical expertise at the expense of legitimating decisions through democratic policy making and the legitimacy of decisions is important to their effectiveness and support. Without legitimacy the public may view a reliance on the views of experts as no more rational than the views of lay persons. Majone (2006) also suggests giving the administration considerable independence and autonomy, but using a model of a reserved but transparent authority of a Minister to intervene in risk regulatory decisions as it is currently used, for example, to intervene in the decisions of competition authorities in relation to merger cases for those areas where a ministerial involvement may be required.

In practice it would be difficult to conceive of a single right model of public sector administrative reform for the improved treatment of risk in regulatory policy. It is, however, possible to identify some specific features that are likely to be common across all administrative arrangements and to conceive of proposals for incremental reform that are likely to improve the treatment of risk.

1.2. Steps towards the development of better risk assessment processes

When undertaken at the right stage, risk assessment and analysis can assist in overcoming some of the tensions inherent to the regulatory policy process and improve government responses to regulatory problems. To do this it must be incorporated in the

policy cycle and supported by appropriate institutional and practical arrangements. These include but are not limited to:

- Providing adequate political and statutory authority to the conduct of the process of risk assessment and analysis and the development of risk management approaches to regulation compliance and enforcement. This would include giving the necessary statutory direction and resources to regulatory agencies to develop risk-based policy. It would be supported by the role of gatekeepers to scrutinise regulatory proposals to ensure that risk assessment has been done prior to the development of regulatory proposals.
- Providing regulators responsible for the conduct of risk assessment with appropriate support in the form of training and guidance material. In particular this would include access to adequate data and information as well as training on the technical aspects of conducting risk assessment and benefit cost analysis or providing appropriate resources to acquire the necessary expertise.
- The *ex post* aspect of the risk assessment requires (built in) monitoring and review arrangements. There are different ways to do this including mandatory sunset clauses, or specific reviews of sectoral regulation.

On a broader scale, governments are increasingly being called upon to respond to emerging risks to society across a variety of policy domains where those risks are not amenable to resolution through regulatory solutions. This suggests that more overarching governance arrangements are required to deal with this more general area of risk policy to manage risk, make tradeoffs and to co-ordinate private and public resources in response to risk. To put it another way, risk assessment is not just something to be considered in the regulatory context, but in the government policy apparatus more generally.

The interrelated nature of many risks calls for a whole-of-government risk scanning exercise supported by some form of central co-ordination to set overall risk priorities. This would also seem to suggest a need for a more overarching co-ordination role for implementing risk assessment across government. This is necessary to identify and draw links between those risks which regulation has a role in managing and those which require other policy instruments.

The Canadian report on Smart Regulation³ illustrated such an approach when it recommended that the federal government develop a federal standard that included among other things:

- A strategy to “systematically and strategically access the best scientific information and knowledge to support regulatory decisions”.
- Periodic government-wide risk scanning exercises to ensure that regulatory programmes and resources are allocated to address the jurisdiction’s (countries) risk priorities. Prevent subjective risk strategies by putting in place mechanisms to build consistency in the risk assessment processes and provide guidance to regulators on the assessment of risks.
- The classification and prioritisation of risks, including the identification and publication of the risk priorities of each regulatory department.

Institutional benefits of a risk-based approach

A robust system of risk and regulatory governance needs not only the tools of risk assessment and management, but also an institutional structure to guide and oversee these analyses. Effective risk regulation needs implementation and enforcement.

Institutions for this component vary widely across countries. In addition, decisions are needed about where responsibility lies for assessing and managing particular risks.

At the level of regulatory agencies the potential benefits of a risk-based approach to regulation come from a more efficient resource use through resources being applied to highest risk issues and the equal treatment of like risks. Whether or not they are made transparent, decisions about risk are always being made by regulators. Even in the case of the most subjective of risk judgements, a transparent risk assessment process will reveal opportunities for measuring and refining the implicit assumptions that are held by regulators and inherent in the regulation of risks.

This is particularly relevant to stakeholder management by multi-sector regulators. Multi-sector regulators have to make judgements about which issues to give greatest attention and priority to in circumstances where not all policy problems within the regulator's domain will necessarily require equal or like treatment. Risk assessment provides a basis for regulatory agencies to communicate and consult with the public and within government as to how they are going to allocate their limited resources to ensure maximum public benefit. In this way it can contribute to building trust in government institutions and regulatory authorities through the transparent substantiation of the legitimacy of agencies and their role in regulation.

A risk-based approach can also assist in measuring performance and building accountability within agencies. Risk analysis relies on a transparent process for analysing alternative decisions in the face of risk and uncertainty. Rather than simply rewarding (or punishing) the performance of government agencies for outcomes which may be unrelated to their actions, a risk-based approach can reveal the sources of success and failure in the processes of regulatory decision making. This in turn can feed back into improvements to the rigour of future decision making processes through *ex post* evaluation of the regulatory responses.

The careful allocation of responsibility for risk management has the potential to produce greater economic benefits by allowing risks to be managed at the level of society where it will be most effective. This can include reducing unnecessary reliance on government involvement in individual's lives, thereby building a more resilient society and allowing opportunities for adaptive behaviour. Regulation has to be examined for its potential to displace entrepreneurial activity which can potentially address risks and minimise negative externalities more effectively through the development of private or market based solutions. This is a principle theme of the United Kingdom Better Regulation Commission paper, *Risk Responsibility and Regulation – Whose Risk is it Anyway?* (BRC, 2006). The BRC argues that:

The state should not intervene and assume responsibility for risks that are better managed by individuals, families, businesses, organisations or local communities... We can think about the management of risk in terms of a Risk Management Hierarchy. At the top is the individual, at the bottom the EU and other international organisations. The policy-making task should be unequivocal – to push as far up the hierarchy as prudence permits on each and every single occasion (United Kingdom Better Regulation Commission, 2006, p. 31).

The roles of central agencies and regulators

Risk and regulatory policy relates to the interface of risk governance with systems of regulatory management. As such it is concerned with the systems which governments use to organise themselves to deal with risk issues when considering regulatory policies. This has the potential to better align technical solutions with policy and political aims, improve the development of government's capacity to build and maintain public trust, and to improve the efficiency of government operations.

A key aspect relevant to the promotion of risk-based regulation is the supervision tools that central agencies and oversight bodies use to promote a consistent approach across government. The centre of government has responsibility for overall policy design, including developing and administering guidelines and meta-regulation and it includes the functions of central oversight bodies. It also includes whole-of-government regulatory management practices to influence the behaviour of regulators and to improve the design of regulations.

The role of regulators is important because of the autonomy that regulators exercise in the design, administration and enforcement of regulation. The processes that regulators engage in influences both the shape of regulation, and the substantive compliance costs and administrative costs imposed on business and citizens. Regulators are also responsible for the overall effectiveness of the implementation of regulatory initiatives. The examination of risk and regulatory policy is concerned with understanding how regulatory authorities put into operation risk-based approaches to achieve their regulatory goals and how successful these initiatives are in practice. This latter aspect is important because the experiences of one regulator can have lessons for practices that can be implemented by another regulator. This may apply to other regulators operating within another sector in the same jurisdiction, or in the same sector in a foreign jurisdiction.

In the academic literature there is a growing focus among commentators on government activity on the relationship of risk management and public governance arrangements. Evidence is emerging, at least in some countries, of an increasingly specialised focus on risk in government. For example, Black (2005) describes the combined impact of the development of internal risk management and risk-based regulation in the United Kingdom as the new public risk management where a focus on risk overlays without supplanting the tenets of new public management.

Black ascribes different motivations to the two facets. The former, internal risk management in government, is motivated by an aspiration to deliver the modernising government agenda, as an administrative consequence in response to high profile losses from public finance contracts, and from a general interest in emulating private sector corporate governance and risk management. The latter facet which focuses on risk and regulatory management *stems from political and organisational pressures arising within regulatory agencies [...] and demands from central government for more effective, particularly cost effective, implementation of regulation and deployment of regulatory resources* (Black 2005, p. 514). A significant objective of incorporating a better treatment of risk in regulatory management is to improve regulatory design and administration, to reduce the fiscal costs of administering regulation and minimise the burden that regulation imposes on business and the community.

A focus on risk then has the potential to improve the design and operation of government activities. In the public sector risk, defined as the potential failure to achieve objectives or deliver public services, is analogous in some ways to the risk to profitability

that is the motivation for private sector risk management. According to Power (2004), a focus on risk is emerging as the basis upon which public organisations, which are not otherwise subject to the disciplines of competition, profitability and share values, can self-challenge and improve their own management practices.

1.3. Challenges to the co-ordination of risk-based regulation

Understanding the functions and performance of public institutions is vital to interpreting how governments achieve their policy goals. In the context of risk and public policy key institutional functions are performed by central agencies, regulators and line departments. Increasingly it appears that the management of risk is an intrinsic (if not necessarily overt) feature of these agencies. It is open to examination how these risk functions should be organised within government and how well they are being performed. One area for examination is the extent to which risk management practices by regulatory agencies are effective in achieving policy goals.

As noted above, many of the features of a risk-based approach to the organisation of regulatory agencies have been adapted from the private sector in an effort to improve efficiency. Power (2004) supposed that the role of risk management may be seen as an organisational principle for government agencies in the same way that the discipline of competition drives the private sector. However, while governments have an incentive to reduce risks, it is not clear that risk and its consequences can be relied upon to have the same efficiency driving effect for government as the pursuit of profit does for the private sector. Nevertheless, the consideration of parallels between the management of risk by the private sector and by the public sector is instructive looking at where risk-based approaches may go wrong.

Trying to shoe horn equivalent approaches from the domain of private sector risk management onto the public sector produces its own problems. There are potentially significant pitfalls to the inappropriate adoption by government of the risk management practices that business uses to protect the firm because of the different objectives of government. Hood and Rothstein (2002) identifies that the principal business risk management approaches are intended to focus on three things: the profit centre of the organisation; improvement to shareholder value and; to provide decision tools linked to corporate strategy.

There is no easy equivalent found in government for these three features of business risk management. First, governments are primarily concerned about citizen interests rather than the well being of clients of any one agency. For many policy issues this requires a *cross organisational approach* to risk management, instead of maximising the success of any one profit centre. Secondly, governments are responsible for delivering public value, not shareholder value. *Public value* is more diffuse than shareholder value, relating not just to financial calculations but an assessment of what the public wants overall. Thirdly, government is more concerned with the *risks to services and systemic risks* than risks to the organisation. Finally, government's needs for risk decision tools differ from the private sector. They require a multi organisational rather than single enterprise approach and they are subject to requirements of transparency and accountability. Governments therefore face different issues than the private sector in dealing with potential threats and opportunities without the screen of commercial confidentiality.

From this, Hood (2002) also identifies potential pitfalls of adapting a business risk approach to the public sector, which indicate areas for examination and analysis. The first is that an emphasis on risk management can accentuate existing tendencies for public sector agencies to engage in blame avoidance:

Systems that put too much stress on limiting downside business risk at organisational level can trigger risk displacement processes among different organisations that create nil (or negative) public value. Such processes can result in the greatest exposure to risk being borne by organisations that are politically weakest rather than those best placed (through knowledge or resources) to assume responsibility for risk (Hood et al., 2002, p. 26).

Second, if applied in a mechanistic or token way risk management approaches can disguise policy inaction. Procedural form filling can be a substitute for government taking a proper role as a risk bearer. Thirdly, business risk management approaches that are focused on the organisation may encourage organisations to limit revealing information about mistakes or criminality; this in turn limits transparency and the opportunities for adaptive learning by the organisation.

Considering the potential principle agent problem, an important part of an assessment of the practices of a risk-based approach to regulation is to examine the extent to which the risk management practices of regulatory agencies are aimed at achieving the government's public value objectives and not just the agency. This is particularly relevant as agencies are given discretion to target scarce resources to reduce the most significant risks through risk-based regulation. Theoretically, the inappropriate adoption by regulators of risk-based techniques based on private sector models is a potential area in which agency failures can arise. Here Hood's analysis points to a number of areas for examination.

Hood (2002) suggests a number of areas for strengthening the risk management systems of governments. The first is the need for an integrated approach. Referred to as "getting the whole system in the room", it is intended to overcome bureaucratic interests and blame avoidance. The second is a focus on systemic risks, described as risks that affect a whole industry or service as distinct from any individual organisation. The third is a need for a deliberative process that gives consideration to "likely second order effects as well as first order effects of risk management and to 'reflexive practitioner processes'". This final element is particularly challenging to promote the requisite level of transparency and reflection by the organisation. It requires the instigation of a consultation process that gives careful consideration to the balance between open and confidential discussion, with a role for professional expert input as well as wider public participation in determining risk priorities.

Risk-based regulation and the role of regulators

For regulators, a risk-based regulatory approach can have at least three benefits: it contributes to regulatory efficiency by targeting the approaches of the regulator to allocate resources where risk is greatest; it can systematically improve decision making processes by providing new evidence and insights into potential risk, and; it can assist in providing defensible rationale for decision making, that can withstand external challenge from the courts, or potentially the media.

However, risk-based approaches to regulation can also present very difficult challenges. Some of these noted by Rothstein (2006) are: they may give impressions of scientific accuracy and create regulatory conflict; they may be more costly and time consuming for regulatory agencies and businesses, requiring a high up-front investment in

data to build confidence in a risk-based approach; they may conflict with traditional ways of doing things and established relationships with stakeholders, and; they may fail to generate social consensus if, for example, regulatory standards set at a national level are not accepted at a local level.⁴

The particular example of where this last effect can occur is in the case of high probability/low impact risks which may be socially and politically tolerable, and low probability/high impact risks (catastrophic) which may not be acceptable. Although the two categories of risks can have the same collective consequences their social and political effects can lead to very different agency behaviour in the two circumstances. The prevention of catastrophic risk places greater challenges on the regulatory agency. There is not the regular feedback loop that comes from responding to routine risk events, and agencies have to design and justify the budgets for research programmes to identify and respond to the precursors which occur early in the chronology of an emerging risk.⁵

Box 1.2. **What are the organisational structures for effective risk management?**

The panel appointed by the US Secretary of Transportation to review the FAA's Approach to safety reports that the essential organisational structures and procedures for effective risk management include the following:

- The ability to identify hazards or risk-concentrations early in their life cycle, using a broad range of detection, notification and reporting methods.
- A commitment to scan proactively for emergent and unfamiliar risks, using a broad range of analytic and information gathering techniques.
- The organisational fluidity to elevate risks identified to the appropriate level, so that the organisation can gather relevant resources and attention around them, taking care to respect the natural size and dimensions of the risk itself.
- A willingness to engage in an open-minded search for tailor-made solutions, sufficient to mitigate the risk to an acceptable degree in a resource-efficient manner.
- A formal managerial system for managing and monitoring a portfolio of risk mitigation projects.
- A system for organisational learning, so that those engaged in risk-mitigation projects can access the experience and knowledge accumulated by others as a result of similar or related projects.

Source: Managing Risks in Civil Aviation: A Review of the FAA's Approach to Safety, 2 September 2008. Report of the Independent Review Team. A Blue Ribbon Panel Appointed 1 May 2008 by Secretary of Transportation Mary E. Peters to Examine the FAA's Safety Culture and Approach to Safety Management Panel Members: Ambassador Edward W. Stimpson (Chair), J. Randolph Babbitt, William O. McCabe, Professor Malcolm K. Sparrow, Hon. Carl W. Vogt, available online at www.dot.gov/affairs/IRT_Report.pdf.

Rothstein (2006) further notes that regulators responsible for managing risks to society are also subject to institutional risks in going about their own business. Regulators face significant consequences of reputational risk if they fail in their enforcement goals, even to the extent of threatening the legitimacy of the regulatory institution itself. To be effective, regulators have to maintain a level of confidence from the public, the courts and the government.

Risk-based regulation as applied by regulatory institutions therefore has two related dimensions which may be in conflict: managing the *business risks* associated with delivering regulatory objectives, as well as; managing targeted and proportionate compliance and enforcement responses commensurate to the risks imposed on society by the regulated community. There are possible positive strategies which regulators may employ for managing this conflict, including an increased emphasis on risk-based communication to build consensus, and a greater focus on the qualitative and subjective concerns of stakeholders to build confidence. However, a further possible strategy which may be adopted by regulators is to intentionally bias decision making criteria for issues that pose the greatest institutional risks to the regulator.

Governance arrangements for managing risk have to be cognisant that the increased pressures for transparency and accountability in risk and regulation regimes can increase the threat of blame and liability for failures (Hood, 2001).⁶ This can make regulator's work more stressful and conflict laden which may lead to blame avoidance mechanisms instead of improved processes. As a consequence an analysis of risk-based regulatory institutions should look out for particular strategic responses that may prevail in response to these pressures. At an agency level, these institutional blame avoidance responses can include: delaying the release of information; simple rebuttal of demands for public disclosure; organisational reorientation to disguise responsibility for risks; service abandonment to avoid the consequences of a wrong decision; the adoption of a procedural checklist approach as a substitute for substantive action, and; finally just making excuses.

Because many regulatory initiatives depend upon the co-ordination of the roles of a number of regulatory agencies blame avoidance behaviour by a single regulator can have wider systemic effects across government. An analysis which looks at the participation of a number of institutions in the success of a regulatory regime may identify areas where, despite the openness followed by some institutions, the lack of transparency by other participants makes the effectiveness of an entire regulatory regime opaque. In cases where the delivery of regulatory goals requires the participation of a number of regulatory agencies, the behaviour of all players in the system will be connected and will therefore have to be examined for their impact on the system as a whole.

The identification of these issues underscores the need for guidance on the design of regulatory management strategies which anticipate the potential pitfalls for risk-based regulation. The above analysis points to some of the potential problems of a risk-based approach and to their solutions. Of course, the counterfactual to be considered is the extent to which agencies would be better at achieving their public value goals in the absence of a push for greater transparency and accountability in risk-based approaches.

1.4. Improving the design of risk-based approaches: implications for regulatory policy

As referred to above, one of the dilemmas of a risk-based approach to regulation is the choice faced by regulators in conditions of uncertainty. Because implications from regulatory interventions are not always clear, the selection of the correct regulatory solution is not always clear cut. Sometimes a regulator will be caught between the choice of erring on the side of a Type I, or a Type II error; to regulate or not to regulate? In such cases, should a regulator err on the side of assuming that a firm poses a risk when it does not, or that a firm does not pose a risk when it does? The regulator will have to make a judgement as to which error, should it arise, is less likely to undermine the public benefit.

Practically, these are decisions that regulators undertake all of the time. Under a risk-based regulatory regime however, the choices that have been made implicitly within a regulatory body will be made explicit (Black, 2005, p. 541). A risk-based regulatory approach implies that there will be an informed analytical approach, but also an acceptance at some level of a policy of non-zero regulatory failure.

For regulators, resolving the dilemma of which type of error to avoid; Type I or Type II, is often not going to be a case of stark choices, but will depend upon having in place robust and effective processes for guiding decision making. Agencies must be equipped to make an assessment of the consequences of risks, to select the right regulatory tools and implement effective compliance strategies.

One area where this is already being addressed by a few OECD countries is the development of risk assessment tools for the consideration of the case for regulation, and the documentation of this assessment in the preparation of regulatory impact analysis (RIA). A few countries require risk assessment to be included in RIA, but there is scope for improving the guidance that is available to regulators to do this. The risk assessment guidelines developed by the US set out the matters to be considered when evaluating the risks of regulatory problems and processes for risk assessment. This memorandum addressed to the Heads of Executive departments and Agencies lists six principles for risk assessment and also covers general principles for risk analysis as well as the principles for risk management. Canada is also undertaking a process for developing its own guidelines. There could be considerable merit in promoting a consistent approach across jurisdictions, particularly among trading partners. Practical issues which could be addressed include:

- Guidance on methodologies for undertaking Risk Assessment including analytical techniques and sources of information.
- Identification of acceptable risk thresholds (for example common approaches to the statistical valuation of human life across different regulatory sectors).
- Guidance on the identification and assessment of subjective *versus* objective risks.
- Guidance on the use of the precautionary principle in Regulatory Impact Analysis.
- Practices for promoting the use of independent rigorous scientific advice and peer review.
- Strategies for consultation and communication with the public on risk issues.

The potential for risk-based approaches to impose a paperwork burden on the regulated sector should be noted. Because risk-based decision making relies on an assessment of the probabilities of harm and the likelihood of non-compliance it usually depends on the regulator having access to a substantive knowledge base of the regulated sector. Risk-based regulators may move from broad regulation to more tailored arrangements which rely more heavily upon the internal risk management systems of the firm to report and prevent emerging risks. However, this requires that the regulator engages in information gathering from regulated entities, perhaps as a substitute for directive regulatory action, at least at the beginning until a solid body of evidence is collected. This creates a conflict between the need to obtain information from regulated entities and the better regulation directive to reduce the administrative burden of compliance costs. This, among other things, may be a source of tension in a risk-based approach.

Given the potential for tensions to arise in designing and administering transparent risk-based approaches, there is considerable scope for providing guidance to regulators on the incorporation of risk assessment in the development of regulation, risk management

Box 1.3. Risk-based approaches to regulation

Risk-based approaches to regulation may lead to a review of information obligations and administrative burdens. For example an effort to reduce administrative burdens may help to avoid heavy inspections for all firms, and follow from a risk-based approach which will focus on a sub-set of firms with the highest risks. This may also result in a review of compliance with regulations, developing a compliance strategy which allocates responsibility for risks where they can be best managed, even if this is within the firm. From this perspective, governments need to understand the behaviour of firms and individuals, to arrive at enforcement and compliance more efficiently and effectively.

Good governance arrangements are fundamental to promoting the successful design and implementation of effective regulation and addressing the causes of regulatory failure. Risk assessment and risk management tools which help to guide governments when choosing whether and how to regulate can contribute to any strategy to help countries face global challenges. Increasingly, such arrangements are likely to involve cross-border regulatory co-operation.

in the design of regulatory enforcement strategies and risk communication to maintain the effectiveness of regulatory agencies. The benefits from this guidance could be more effective and responsive regulation and regulatory institutions.

In summary the key regulatory management challenge for governments seeking to improve the governance of risk is to improve the evidentiary basis on which regulatory decisions are made and regulatory programmes are delivered. Without prescribing just how governments should organise their administrations to achieve policy goals, each of the following elements remains an important factor in designing better approaches to assessing and managing risk.

- *Put systems in place to deliver sound science for the estimation of risks* – This requires processes to obtain scientific information and to use this information to evaluate the extent of regulatory problems. Ensuring the accuracy of scientific evidence depends upon having open and transparent processes for the formulation and collection of scientific evidence and independent criticism and peer review of scientific claims.
- *Set regulatory priorities taking account of risks* – An overall risk programme should be developed based on an examination of significant risks. An agenda should be set for regulatory development identifying the policy priorities and how it is proposed to respond to these based on the weight of evidence. Associated with this would be the establishment of processes for identifying and evaluating possible policy responses to a crisis.
- *Where possible the design of regulatory solutions should be risk-based* – Risk-based regulatory strategies are designed to be targeted based on an assessment of the risk that they are intended to address. To achieve this, risk assessment should inform all aspects of the regulatory cycle, through data collection, the selection of regulatory instruments, the scheduling of inspection and the allocation of resources for prosecution. The use of cost benefit assessment can identify opportunities for increasing net welfare by introducing more regulation as well as reveal cases of over regulation. Creative and flexible regulatory approaches to achieve regulatory objectives may deliver better outcomes than traditional approaches.

- *Examine policy proposals for their potential risk-risk tradeoffs* – Efforts to bring about a reduction of risks in one policy area can inadvertently give rise to an increase of risk in another policy area. The instrumentalist and compartmentalised nature of governments can result in too narrow a consideration of the consequences of policy. A failure to consider the interconnected nature of government activities and public value objectives can result in the unexpected transference of risk across government. This results in the full costs of regulation not being properly considered and overlooks the potentially creative opportunities for “joined up” policy solutions.
- *The design of policy institutions can encourage innovation* – Policy settings should be cognisant that risk taking is a source of creative innovation in society; risk can have negative consequences but it can also produce rewards. Governments need to recognise that they are not always best placed to manage risks and to be cautious about regulating to remove opportunities for informed risk taking by citizens, and which may also depress opportunities for innovation. A considered approach to risk is also a key source of innovation within the public sector.
- *Consider the trade and competition impacts of standard setting and regulating risks* – The identification of local risks may have a self interested bias. Before regulating to remove risks; systems are required to consider the potential competition impacts of localised risk reduction measures on potential trading partners and to consider the implications of increased costs for consumers through the establishment of higher standards.
- *Incorporate communication in all aspects of the policy cycle* – An increased focus on risk-based regulation increases the challenges for regulators to establish and maintain effective communication with stakeholders. Risk communication is an integral part of the risk assessment and management frame work, both for collecting evidence and building support for the results of policies.

Conclusion

Greater emphasis on risk-based approaches to the design of regulation and compliance strategies is of significant interest to OECD countries that are seeking to improve the welfare of citizens by providing better protection from hazards and more efficient services from government. Improvements to risk and regulatory policy can reduce costs for business and reduce the opportunity costs of government action.

However, while at a general level the principles of improving the approach to risk are persuasive, evidence of adoption of these practices within OECD governments remain limited. A 2007 survey of all OECD country practices to which only nineteen OECD countries responded found that few countries had taken steps towards developing a coherent risk policy framework for managing regulation.⁷ This is not to say that countries did not have mechanisms for managing and responding to risks rather that the capabilities tended to be decentralised throughout government. This common approach may be appropriate to the administrative culture and particular circumstances of many countries. However, in the decentralised model there is little or no central oversight or guidance to ensure that approaches being taken are efficient and effective, adequately account for risk-risk tradeoffs, and/or diffuse the lessons from individual agencies to other parts of government. It is probably not sensible to centralise many risk functions, but the general lesson from reform strategies is that this central guidance and review role is necessary if progress is going to be made to improve governance systems right across the administration.

The challenges of global systemic risks, such as climate change, place increasing pressure on governments to find coherent policy solutions domestically that apply across a number of sectors and agencies. Assisting governments to improve the evidence base for regulation to address these challenges through better systems and techniques for impact analysis is a goal of the OECD Regulatory Policy Committee.

The absence of a coherent policy framework across OECD countries suggests the need for further study of how countries can improve their capabilities to design higher quality regulation through better risk governance processes. Risk-based approaches to regulation should lead to the development of processes to evaluate environmental, social and economic impacts. Measuring all possible consequences, particularly over the long-term, is usually not practical, but there is a need to integrate potentially important impacts. Accordingly, regulators will require compatible methodologies for sectoral risk assessments to compare risks and prioritise interventions on the basis of their relative efficiency.

Far from being a black box controlled by scientific experts and technocrats, the design of risk-based regulation can be a vehicle for open, transparent and inclusive decision making inside the government. The aim should be to gather and address all relevant viewpoints regarding value questions in the light of scientific facts and economic evaluations.

There is a need for better information about country practices regarding stakeholder participation and public deliberation in the elaboration of risk-based regulations, with particular attention to the use of scientific and economic assessments in these processes. Such work would help diffuse good practices among countries, in spite of cultural and institutional differences.

It is important to account for incomplete information in the design of risk-based regulations, in particular by favouring flexible approaches, creating linkages with information collection and research agendas, and planning revisions based on updated assessments. Such a dynamic process of risk-informed regulation appears superior to static – and somewhat artificial – distinctions between some risk issues that regulators would consider highly uncertain and others that they would assume to be fully understood.

The OECD Secretariat could take stock of national practices in the handling of informational gaps in risk regulations, with particular attention to institutional design and to pro-active interactions between regulation and scientific research. This would have particular application to the development of regulatory approaches to issues such as climate change.

Further work on risk and regulation at the OECD through a consideration of the relationship of regulatory impact analysis and the promotion of policy coherence could investigate these methodological issues and identify emerging solutions, in particular through:

- A comparison of country practices in promoting risk-based approaches to regulation across sectors.
- The development of guidelines for the evaluation of socio-economic consequences and its integration with scientific risk assessment.
- A regulators' toolbox of decision-support methods (cost-benefit analysis, multi-factor analysis, scenario analysis, etc.) highlighting their merits and limits for different regulatory contexts.

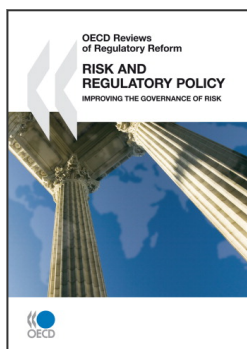
Notes

1. This chapter was written by Gregory Bounds, Policy Analyst, Regulatory Policy Division, OECD, Paris.
2. A slightly different, but equally valid example of this cycle can be found in the *Risk Management Guidelines: Companion to the Australian New Zealand joint standard Risk Management AS/NZS 4360:2004*.
3. "Smart Regulation: A Regulatory Strategy for Canada – External Advisory Committee on Smart Regulation", September 2004, www.smartregulation.gc.ca.
4. H. Rothstein, P. Irving, T. Waldon and R. Yearsley (2006), *The Risks of Risk-based Regulation: Insights from the Policy Domain*, *Environment International* 32, pp. 1056-1065.
5. For a general discussion of the difficulties faced by agencies tackling catastrophic risks, in particular the problems associated with demonstrating performance, justifying budgets and defining the role of analysis, see: Chapter 10, "Catastrophic Harms" in *The Character of Harms: Operational Challenges in Control*, Malcolm K. Sparrow, Cambridge University Press, 2008, pp. 217-229.
6. Christopher Hood and Henry Rothstein (2001), *Risk Regulation under Pressure: Problem Solving or Blame Shifting?*, London, LSE Research Articles, available online at <http://eprints.lse.ac.uk/archive/00000335>.
7. GOV/PGC/REG(2007)12ANN1, "Risk and Regulation: Progress Report on the Stock Take of Country Responses and the Development of Case Studies", annex draft summary of responses to the questionnaire on risk and regulation.

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