OECD Reviews of Regulatory Reform

RISK AND REGULATORY POLICY

IMPROVING THE GOVERNANCE OF RISK

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Foreword

Governments have always relied on regulation to protect citizens from social, environmental or economic risks. In fact it may be because the amelioration of societal risk is such a pervasive activity of government that an assessment of whether governments have a systematic means of addressing risks tends to be overlooked. An OECD survey revealed that very few countries have attempted to develop a coherent policy on the management of risks through regulation. Yet it is precisely because regulation is so often relied upon to address risks that improvements to the risk governance frameworks has such potential to improve social welfare, by ensuring that regulatory approaches are efficient, effective and account for risk/risk tradeoffs across policy objectives. Risk-based approaches to the design of regulation and compliance strategies can also provide better protections from hazards, more efficient services from government and reduced costs to business.

The chapters in this publication aim to assist OECD governments to develop coherent frameworks for the governance of risk in regulatory policy. This topic is of high interest to the regulatory policy community. The chapters cover a series of topics including: diagnosing the challenges in designing risk policy frameworks; understanding the legal and cultural contexts for the application or risk regulation; strategies for improving the analytical models for identifying and addressing risks; designing regulatory governance institutions to address the joint effects of multiple risks; the design of innovative regulatory approaches to respond to hard to assess risks; the evaluation of risk-based regulatory frameworks used by regulators in the food safety, financial markets, environment and health and safety sectors across five OECD countries; and the salient features of government guidelines for risk assessment and management.

Each chapter seeks to provide concrete policy advice on how to improve the design and performance of coherent risk governance policy for managing regulation. The collected chapters are intended to assist policy analysts in OECD governments to consider how to develop, or improve, the design of a coherent risk governance policy for managing regulation and improving the welfare of citizens.

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List of Abbreviations

APRA	Australian Prudential Regulation Authority
ASIC	Australian Securities and Investments Commission
BRC	Better Regulation Commission
BSE	Bovine spongiform encephalopathy, commonly known as mad-cow disease (MCD)
CBA	Cost-benefit analysis
CCPs	Critical control points
DHS	US Department of Homeland Security
DNB	De Nederlansche Bank
EA	Environment Agency
EC	European Commission
ECJ	European Court of Justice
EFSA	European Food Safety Authority
EPA	Environmental Protection Act
EPA	Environmental Protection Agency
FDA	Food and Drug Administration
FSA	Financial Services Authority
GATT	General Agreement on Tariffs and Trade
GM	Genetically modified
HACCP	Hazards Analysis and Critical Control Points
HSE	Health and Safety Executive
IAs	Impact Assessments
IGAOT	A Inspecção-Geral do Ambiente e do Ordenamento do Território
IRGC	International Risk Governance Council
MEI	Maximum exposed individual
MSDs	Muscular-skeletal disorders
NIOSH	National Institute for Occupational Safety and Health
OFT	Office of Fair Trading
OIRA	Office of Information and Regulatory Affairs
OMB	Office of Management and Budget
Opra	Operational Risk Assessment
OSH	Occupational Safety and Health
OSHA	Occupational Safety and Health Act's
PAIRS	Probability and Impact Rating System
PP	Precautionary Principle
RIA	Regulatory Impact Analysis
SOARS	Supervisory Oversight and Response System
SPMs	Sanitary and Phytosanitary Measures

SPS	Sanitary and Phytosanitary Standards
TPR	The Pensions Regulator
TR	Target risk
VROM	Verantwoordelijk voor wonen, ruimte en milieu
VSD	Virtually safe dose
VSL	Value of a statistical life
WTO	World Trade Organization

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Executive Summary

There is a gap between the level of risk that is aspired to by policy makers and the level that is achievable through regulation. Not all risks can be reduced to zero and tradeoffs in risk reduction measures are inevitable. This publication aims to identify areas for the improvement of risk governance through an analysis of the legal, procedural and practical challenges for risk regulation. Each chapter provides advice on policy steps that governments can take to improve the efficiency and effectiveness of regulatory management arrangements for reducing risks.

Chapter 1 discusses a range of challenges faced by governments in designing coherent risk regulatory policy and steps to overcome these challenges. It describes the features of a deliberate risk-based approach to the design of regulatory management and compliance strategies, and argues that this can improve the welfare of citizens by providing better protection from hazards and more efficient services from government. A focus on risk and regulatory policy is also consistent with the Better Regulation Agenda of most Governments and can reduce costs for business. However, most OECD countries have not developed a coherent risk policy framework for managing regulation. The chapter argues that the provision of guidance and review is necessary if progress is going to be made to improve risk governance systems right across the administration. A central oversight role can for example ensure that approaches being taken by individual agencies are efficient and effective, adequately account for risk-risk tradeoffs, as well as share lessons from individual agencies with other parts of government.

Chapter 2 discusses risk regulatory concepts and the law. It describes the increased utilisation of risk regulatory concepts in administrative decision making in a wide array of contexts and in many different jurisdictions over the past decade. The concepts have been introduced for different policy reasons, regulate administrative power in a diverse range of ways and are not defined homogeneously. This complexity of risk regulatory concepts is reflected in the many different legal dimensions that they are applied. In addition risk regulatory concepts have been subject to specific criticisms which make clear that they should be used with care, critical reflection, and an awareness of the complexities involved. Chapter 2 reviews the relationships between risk regulatory concepts and different legal dimensions. It proposes a process of analysis that highlights the fact that the operation of risk regulatory concepts is not straightforward and is always embedded in a particular cultural and legal context. This has implications for models of public administration, and is useful in understanding procedural decision making and how a regulatory decision maker is held to account.

Chapter 3 discusses strategic issues in risk regulation and risk management focussing on the obligation of public officials to make decisions about policies where future uncertainties are economically significant and unavoidable. In this context there is a need

for clear and consistent principles for dealing with uncertainty. Chapter 3 argues that the theory of decision making under uncertainty provides the appropriate conceptual framework for thinking about uncertain events and their consequences, and thus also for thinking about risk. It illustrates the practical consequences of confused thinking about the principles of decision making under uncertainty, including a discussion of the limitations of the precautionary principle as a general decision rule.

Chapter 4 presents a critical overview of the key elements of risk regulation and governance institutions, regarding risks to health, safety, environment, security, finance, among other areas. It emphasises the challenges for risk regulation of increasing interconnectedness in a multi-risk world, including: the need to assess the joint effects of simultaneous exposure to multiple risks; the increasingly rapid spread of risks across networks; and the ubiquitous ancillary impacts of risk regulation such as risk-risk tradeoffs. A range of institutional responses are called for including: comprehensive regulatory impact assessment of the full portfolio of impacts of risk reduction efforts; both *ex ante* (prospective) regulatory impact assessment to inform initial policy decisions, and *ex post* (retrospective) regulatory impact assessment to inform subsequent policy revisions and to improve *ex ante* assessment methodologies; even-handed use of regulatory analysis both to discourage undesirable policy proposals and to encourage desirable policy proposals; greater use of economic incentive instruments in regulation; and better co-ordination and oversight of risk regulation policies across agencies within each government, and across governments internationally.

Chapter 5 discusses how management-based regulation can be used by regulators to achieve public risk management objectives at lower cost by giving greater flexibility to the private sector without sacrificing public health and welfare. Public policy challenges increasingly arise from new kinds of risks that seem to evade resolution through traditional forms of regulation. Management-based regulation may help regulators better address both existing risks and new ones by deploying regulatory authority in a way that leverages the private sector's knowledge about its particular circumstances and engages firms in developing their own internal procedures and monitoring practices that respond to risks. This flexibility also raises the question of whether this regulatory strategy can actually deliver value to society. The chapter argues that empirical evidence indicates that management-based regulations can lead firms to make risk-related behavioural changes and induce positive behavioural change within an industry. The chapter explains how management-based regulation fits within a government's overall policy toolkit and examines the conditions under which management-based regulation is both a viable and superior policy strategy.

Chapter 6 identifies key aspects of the risk-based frameworks of eleven regulators in four countries across four sectors. It is an empirical study of the choices, practices and lessons from the experience of regulators applying risk regulatory frameworks. Desk-based research (and selected interviews) was conducted with respect to food, environmental, and financial regulators in the UK, Ireland, the Netherlands, Portugal and Australia, and occupational health and safety in the UK and the Netherlands. Regulators implementing risk-based frameworks must make real choices as to the types and levels of risk they are prepared to tolerate. The risk-based frameworks that they adopt also have risks, and a regulator's risk tolerance is ultimately driven by the political context. The chapter explores the motivations for an adoption of risk-based frameworks, sets out the main elements of risk-based frameworks and explores key questions that arise in practice with respect to

each of these elements. The chapter concludes with an evaluation of the main issues and challenges which have arisen in the implementation of risk-based frameworks and identifies lessons from the experiences of regulators.

Chapter 7 proposes steps that governments can take to improve the integration of risk management with the design and management of regulations and the functions of regulatory bodies through the development of formal guidelines. Themes that should be addressed in guidelines include optimal risk taking, processes for preparing formal risk assessment reports, the analytic treatment of scientific uncertainty about risk, ranking risks and risk-reduction opportunities, precaution and the value of information, ancillary risks and benefits, transparency of governmental procedures, cross-department co-ordination, public/stakeholder participation and capacity building. The chapter notes that the governments of Canada, the USA and the UK as well as the European Commission have already developed formal policy statements on risk.

Individually, each chapter provides policy insights for improving risk regulatory approaches both in the design of regulation and its implementation. Taken together, the selection of themes discussed in the chapters is intended to provide countries with the materials to review or develop a governance framework for risk and regulatory policy across the administration.

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Chapter 1

Challenges to Designing Regulatory Policy Frameworks to Manage Risks

by
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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, entrepreneurism 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:

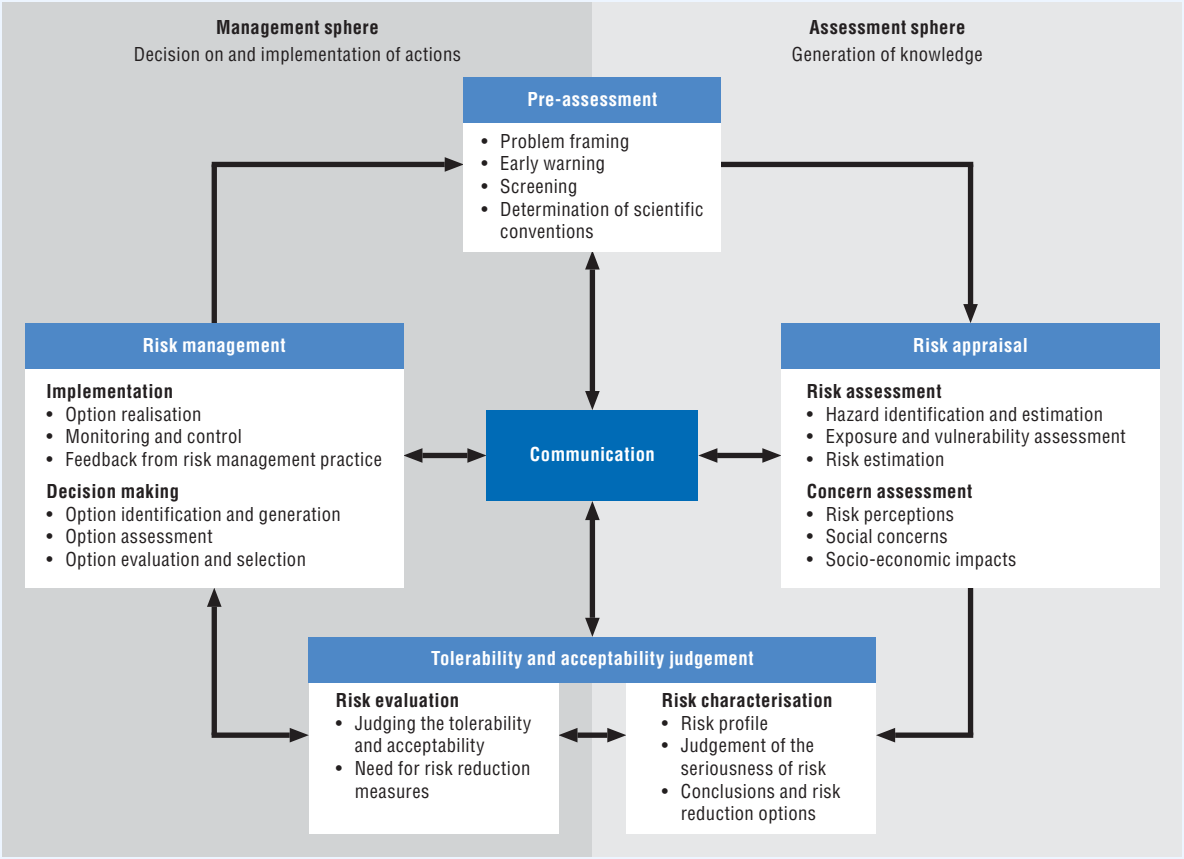
- Risk avoidance: not performing an activity that would create the risk (proscription, prohibition).
- Risk reduction: strategic methods to reduce the probability and severity of the impacts of a risk event (licensing, codes and standards, enforcement and compliance strategies).
- Risk retention: accepting 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**



Source: Renn and Graham (2006).

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 maybe 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 Regulation[3] 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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ANNEX 1.A1

Framing Risk in the Public Sector

Different conceptions of government and risk

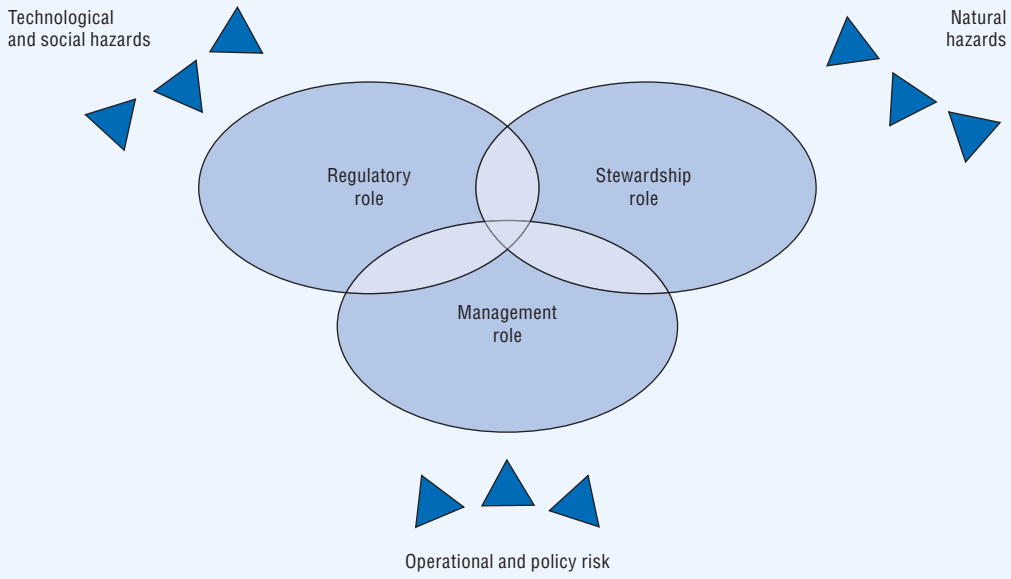
Because the reduction of risks is a pervasive part of government activity, the management of risks is a primary function embedded in the operations of capable governments. In practical terms, government action provides protection for citizens against myriad risks every day. However, this is clearly being done better for some risks (and in some countries) than for others. Meeting the challenges from new emerging risks is a constant source of pressure on government administrations that can result in reactive regulatory responses. The political consequences of failing to manage risks are significant. Elections can be won or lost on the public estimation of a government's capacity to manage particular risks, and the choices made at the administrative level about the treatment of risks are also under increasing scrutiny and pressure from interest groups, particularly when viewed retrospectively following a critical event. Governments can only benefit from a better understanding of how to assess, manage and communicate with the public about risks at both the political and the administrative level.

As the primary role of regulation is the reduction of risks an assessment of risk is a threshold issue for determining whether and how to regulate private activities. Risk is a key consideration in the selection among regulatory and non regulatory approaches, for guiding the assessment of costs and benefits of regulation to reduce the burden of regulation in its design and in developing models of enforcement and compliance. Risk assessment and risk management have an important place within regulatory quality management strategies and the better regulation policy agenda. The policy goal is to help integrate risk considerations in regulatory decision making to improve regulatory design and enforcement in order to reduce the economic and social costs of coping with risks.

Risk and public policy is obviously a broad topic with many dimensions; the objective of ameliorating risk underlies so much government activity, that inevitably there is overlap in any segmentation of the topic of risk in public policy. For clarity of the analysis some useful distinctions can be made. The UK Strategy Unit (2002)[1] identified that governments have three roles in handling risk and uncertainty: the regulatory role addressing potential technological and social hazards; a management role in relation to its own business operations and; a stewardship role to protect individuals, business and the environment from risks imposed from the outside.

Different conceptions of risk policy can be distinguished as follows: crisis management; the co-ordination and prioritisation by government of social risks, and; decisions on when and how to regulate.[2] Crisis management can be described as including

Box 1.A1.1. **Risk and the role of government**



Source: UK Strategy Unit, 2002.

the issues encountered by governments in preparing for and responding to large-scale incidents such as natural disasters. The second characterisation, the co-ordination of risk responses from the centre of government, covers multiple priorities and approaches, including internal risks and policy risks. The final issue concerns risk as a threshold issue for the consideration of whether and how to structure government intervention in private sector activities. For the purpose of identifying different implications for risk policy each of the above areas are briefly outlined as follows:

- Risk and crisis: Government has a stewardship role to reduce those risks to the public from natural disasters, threats to national security, disease and widespread systemic risks. Clearly there is some potential overlap with the regulatory role, although how governments organise their broad stewardship role cannot be allocated straightforwardly to any individual or agency. From a policy perspective governments must have strategies to identify risks, to respond to public perceptions about emerging risks and to make decisions about what level in society those risks may be best managed. Various strategies are employed, including pooling risks that individuals cannot address by themselves (for example third party motor insurance) and applying arrangements to protect critical networks.
- Risks to government: As a whole and within individual business units, governments have a role in identifying and addressing internal management risks. These risks relate to the potential failure to achieve policy and operational goals. They have impacts on the budget and the achievement of service delivery objectives. This is addressed by governance arrangements, accountability measures and other public management strategies. It can involve identifying and managing risk-risk tradeoffs, where the activities of one part of government increase the risks for another.
- Risk and regulation: As the primary role of regulation is the amelioration of risks, an assessment of risk is a threshold issue for determining whether and how to regulate

private activities. Risk is a key consideration in the selection among regulatory and non regulatory approaches, for guiding the assessment of costs and benefits of regulation to reduce the burden of regulation in its design and in developing models of enforcement and compliance. Risk assessment and risk management have an important place within regulatory quality management strategies and the better regulation policy agenda. The policy goal here is to help integrate risk considerations in regulatory decision making to reduce the economic and social costs of coping with risks.

These roles each present co-ordination and governance challenges. For example, regulatory practices have to be responsive to the nature of external risks, and government's management role has to deliver the capacity to enforce regulatory compliance. Government organisations need to be able to identify and communicate risks where they have wider effects than can be handled by a single agency and may impact on other agencies or the wider concerns of the country or state. This is particularly the case where there is a policy goal that requires co-ordination by more than one agency and may require a regime or system of responses rather than a single regulation or the actions of a single regulator.

Box 1.A1.2. **Categorising state sector risks**

In the Government of the state of Victoria, Australia, the Auditor General has identified a number of categories of state sector risk where risks may be joint or multiple, affect only one agency, a number of agencies, or impact at a whole-of-government level. Risks that have impacts that go beyond the interests of one agency require a systemic approach:

- Agency level risk: these can become risks to the state because of their size and significance, because of the wider impact of measures to manage them, or because of poor management by agencies.
- Inter agency risk: if unmitigated by one agency become risks for other agencies; and
- Statewide risks: are beyond the boundaries of any one agency and call for a response across agencies co-ordinated by a central agency.

Source: Auditor General's Office (AGO), Victoria Australia, *Managing Risk across the Public Sector: Good Practice Guide 2004*, p. 2.

In some cases there will be overlapping spheres of the regulatory, stewardship and management roles of government. Each of the above areas may also involve the same actors and processes (including Ministers, and risk management practices) in pursuit of different aims. Furthermore, the general techniques of risk assessment, management and communication have common elements that are influenced by the scientific knowledge and by the adaptation of the application of private sector risk management practices.

Risk policy in a broader context

Effective risk policy needs to go well beyond the generic elements of risk assessment and management. Equally important to the policy-making process are co-ordinating public and private responses to risk, the interdependent nature of risk, and strengthening and global responses to risk. As illustrated in the following box which draws on the work of the OECD, *Emerging Risks in the 21st Century* (2003), in many cases the role of the government in protecting society from risks is linked inextricably with the proper functioning of the private sector.

Box 1.A1.3. **Co-ordinating public and private responses to risk**

Over the last 20 years, the interface between the public sector and the market has shifted dramatically. For instance, in a majority of OECD countries, critical infrastructures – electricity grids and telecoms – have been privatised and are in private hands. Likewise, key public services – health care and pensions – have moved away from the exclusive domain of the public sector and are being provided by the market. Given this shift, a major challenge for public authorities is to define, apply and enforce appropriate regulations which shift a greater share of risk management to the private sector.

Such efforts would seem to stand a better chance of success when they benefit from high-level political backing, or indeed are initiated by political leadership.[1] This idea is clearly supported by the more widespread trend of the need for high-level support for regulatory reforms.

One way to structure such a partnership is to have government standards and regulations coupled with third party inspections and insurance to enforce these measures. Insurers can require – at least as a minimum condition for providing coverage – that safety rules and regulations are respected. By doing so, they benefit from the scale economies of a common system of norms and standards. In turn, regulatory authorities can rely on the insurance sector for enforcement. For example, insurance companies and other financial institutions could play a major role in the implementation and enforcement of norms such as building codes. Insurance coverage or mortgages could be made conditional on inspection, certification and, when necessary, the adoption of loss mitigation measures.

Another form of co-operation is to create funds financed jointly by the private sector and the government with the aim of promoting risk prevention in specific areas or industries.[2] Such funds could improve the handling of industrial risk in inhabited areas by assisting industries in their efforts to reduce risk and by furnishing the means to purchase threatened properties.

Another example is provided by the impact of certification on the implementation of safety measures in corporations. Such public/private co-operation can be an effective risk management tool, complemented when needed by liability law. For instance, an injurer can be held liable for damage even while complying with safety norms if the optimal level of care cannot be imposed through norms.

At the core of such public/private partnership is the need to get the incentives right, in particular by internalising to the extent possible the costs of risk-generating activities. Public/private co-operation can also aim at creating positive-sum solutions with regard to risk prevention.[3]

1. The United States is a case in point. In response to the findings of a presidential commission, a Presidential Decision Directive (PDD63) on "Protecting America's Critical Infrastructures" was issued in 1998, launching a major interagency initiative.
2. Such a scheme was suggested by the French Parliament after the Grande Paroisse chemical plant accident in 2001.
3. The Turkish Catastrophic Insurance Pool (TCIP), created after Turkey's 1999 earthquake disaster, illustrates how the combination of legislative measures (making insurance compulsory), public service (providing insurance up to a ceiling) and market forces (complementary insurance, reinsurance of the pool, possibly issuance of catastrophe bonds) can create the appropriate mix of regulation and incentive to better address risks. It is expected that the TCIP will help significantly improve enforcement of building codes and both prevention and coverage of earthquake risks in Turkey.

Source: OECD (2003), *Emerging Risks in the 21st Century*.

Notes

1. UK Government (2002), UK Strategy Unit, *Risk: Improving Governments Capability to Handle Risk and Uncertainty*, November, *www.strategy.gov.uk*.
2. This was also raised in a paper by the Secretariat to the working party on Regulatory Management and Reform GOV/PGC/REG(2007)12. A fourth dimension which has not been discussed here is the perception of political risk which in a more sophisticated assessment might be seen to overlay each of the three spheres.

ANNEX 1.A2

Risk Policy in Practice

Selected examples from country practices

The OECD has recognised that applied risk assessment is an important factor in the governance arrangements for regulatory quality systems. In its 2002 report[1] the OECD remarked that:

> Quantitative risk assessment improves the capacity of a government to focus on the most important risks and reduce them at lowest cost while identifying those risks that fall below a threshold justifying government action.

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. In OECD countries this function is largely decentralised. In 2007 a survey of OECD country practices was undertaken to identify the extent to which countries had developed and promoted a policy driven approach to identifying and managing risk. The questions were structured first to identify the extent to which policies and institutional approaches had been formulated and secondly to elicit information about these formalised approaches. Nineteen of the thirty OECD countries responded to the survey, and of these only four countries completed the entire survey. The results indicated that most OECD countries have limited integrated policies for the treatment of risk in regulation. In some countries risk assessment is applied in the formulation of RIA. The United Kingdom has also developed a formal policy on risk-based compliance and enforcement. However, these risk-based approaches are not routinely adopted among OECD countries. For the most part risk assessment is not routinely required in the development of RIA, nor is it applied systematically to the reduction of compliance burdens. Except in limited instances it appears that guidance material on the application of risk assessment is not usually prepared by the centres of government and provided to regulators.

For an example of some existing policies on risk-based approaches, a brief overview of some of the guidance provided to regulators in the United States and in the United Kingdom is summarised below.

The United States – applying risk principles to the development of regulation

The joint OMB OSTP Memorandum M-07-24 for The Heads of Executive Departments and Agencies issued on 19 September 2007 outlines clear principles for risk assessment, risk management, risk communication, and priority setting. The memorandum advises agencies to review their risk analysis practices and guidelines and incorporate these

principles as they develop, update, and issue risk analyses and guidelines. The following text reproduces the main headings from the memorandum. Further guidance not reproduced here can be found in the original document.[2]

Principles for risk assessment

- Agencies should employ the best reasonably obtainable scientific information to assess risks to health, safety, and the environment.
- Characterisations of risks and of changes in the nature or magnitude of risks should be both qualitative and quantitative, consistent with available data. The characterisations should be broad enough to inform the range of policies to reduce risks.
- Judgments used in developing a risk assessment, such as assumptions, defaults, and uncertainties, should be stated explicitly. The rationale for these judgments and their influence on the risk assessment should be articulated.
- Risk assessments should encompass all appropriate hazards (*e.g.* acute and chronic risks, including cancer and non-cancer risks, to human health and the environment). In addition to considering the full population at risk, attention should be directed to subpopulations that may be particularly susceptible to such risks and/or may be more highly exposed.
- Peer review of risk assessments can ensure that the highest professional standards are maintained. Therefore, agencies should develop policies to maximise its use.
- Agencies should strive to adopt consistent approaches to evaluating the risks posed by hazardous agents or events.

Principles for risk management

- In making significant risk management decisions, agencies should analyse the distribution of the risks and the benefits and costs (both direct and indirect, both quantifiable and non-quantifiable) associated with the selection or implementation of risk management strategies. Reasonably feasible risk management strategies, including regulation, positive and negative economic incentives, and other ways to encourage behavioural changes to reduce risks (*e.g.* information dissemination), should be evaluated. Agencies should employ the best available scientific, economic and policy analysis, and such analyses should include explanations of significant assumptions, uncertainties, and methods of data development.
- In choosing among alternative approaches to reducing risk, agencies should seek to offer the greatest net improvement in total societal welfare, accounting for a broad range of relevant social and economic considerations such as equity, quality of life, individual preferences, and the magnitude and distribution of benefits and costs (both direct and indirect, both quantifiable and non-quantifiable).

Principles for risk communication

- Risk communication should involve the open, two-way exchange of information between professionals, including both policy makers and "experts" in relevant disciplines, and the public.
- Risk management goals should be stated clearly, and risk assessments and risk management decisions should be communicated accurately and objectively in a meaningful manner.

To maximise public understanding and participation in risk-related decisions, agencies should:

- explain the basis for significant assumptions, data, models, and inferences used or relied upon in the assessment or decision;
- describe the sources, extent and magnitude of significant uncertainties associated with the assessment or decision;
- make appropriate risk comparisons, taking into account, for example, public attitudes with respect to voluntary *versus* involuntary risk; and
- provide timely, public access to relevant supporting documents and a reasonable opportunity for public comment.

Principles for priority setting using risk analysis

- To inform priority setting, agencies should seek to compare risks, grouping them in broad categories of concern (*e.g.* high, moderate, and low).
- Agencies should set priorities for managing risks so that those actions resulting in the greatest net improvement in societal welfare are taken first, accounting for relevant management and social considerations such as different types of health or environmental impacts; individual preferences; the feasibility of reducing or avoiding risks; quality of life; environmental justice; and the magnitude and distribution of both short- and long-term benefits and costs.
- The setting of priorities should be informed by internal agency experts and a broad range of individuals in state and local government, industry, academia, and nongovernmental organisations, as well as the public at large. Where possible, consensus views should be reflected in the setting of priorities.
- Agencies should attempt to co-ordinate risk reduction efforts wherever feasible and appropriate.

The United Kingdom – applying the principles of risk in compliance and enforcement

The United Kingdom Hampton review on reducing administrative burdens through better compliance and enforcement practices[3] was published in March 2005. In April 2008, the United Kingdom issued *The Regulators Compliance Code*;[4] a statutory code of practice intended to ensure that inspection and enforcement is efficient, both for the regulators and those they regulate and based upon risk principles. The Code gives the seven Hampton principles relating to regulatory inspection and enforcement a statutory basis and is binding on UK regulators. It requires the following of regulators:

- Regulators should recognise that a key element of their activity will be to allow, or even encourage, economic progress and only to intervene when there is a clear case for protection.
- Regulators, and the regulatory system as a whole, should use comprehensive risk assessment to concentrate resources in the areas that need them most.
- Regulators should provide authoritative, accessible advice easily and cheaply.
- No inspection should take place without reason.

- Businesses should not have to give unnecessary information or give the same piece of information twice.
- The few businesses that persistently break regulations should be identified quickly and face proportionate and meaningful sanctions.
- Regulators should be accountable for the efficiency and effectiveness of their activities, while remaining independent in the decisions they take.

It is important to review the success of these measures in practice and in July 2008, the United Kingdom National Audit Office reported on reviews of the performance of the five largest regulators in implementing the Hampton principles.[5] The regulators were the Environment Agency, Health and Safety Executive, Financial Services Authority, Food Standards Agency and the Office of Fair Trading. The general conclusion was that regulators had accepted the need for risk-based regulation and in most cases had established mechanisms to assess risk and direct resources accordingly. There were however a number of common challenges faced by regulators. Among these was the development of a comprehensive risk assessment system to deal with a wider range of risks including those applying to the regulated sector generally and at the level of the firm so that resources could be applied effectively. The review concluded that there was considerable value in regulators sharing their knowledge and experience.

Notes

1. OECD (2002), *Regulatory Policies in OECD Countries – From Interventionism to Regulatory Governance*, p. 130.
2. United States Government (2007), Memorandum of the Executive Office of the President, Office of Management and Budget, USA concerning the "Updated Principles for Risk Analysis", 19 September 2007, *www.whitehouse.gov/omb/memoranda/fy2007/m07%1e24.pdf*.
3. United Kingdom Government, The Hampton Review – Reducing Administrative Burdens Effective Inspection and Enforcement, March 2005, available online at *www.hm-treasury.gov.uk/media/7/F/bud05hamptonv1.pdf*.
4. United Kingdom, *Regulators Compliance Code – Statutory Code of Practice for Regulators*, Department of Business Enterprise and Regulatory Reform, 17 December 2007, available online at *www.berr.gov.uk/files/file45019.pdf*.
5. United Kingdom Government (2008), National Audit Office, *Regulatory Quality: How Regulators are Implementing the Hampton Vision*, *www.nao.org.uk*.

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Chapter 2

Risk Regulatory Concepts and the Law

by
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Over the last decade risk regulatory concepts have been increasingly utilised in administrative decision making in a wide array of contexts in many different jurisdictions. These concepts have been introduced for different reasons; are regulating administrative power in a range of ways; and are not defined homogeneously. Moreover, these concepts have not gone un-criticised and these criticisms make clear that the use of risk regulatory concepts must be done with care, critical reflection, and an awareness of complexities involved in their use. The complexity of risk regulatory concepts is reflected in the many different legal dimensions of risk regulatory concepts. A study of the interface between risk regulatory concepts and these different legal dimensions highlights the fact that the operation of risk regulatory concepts is not straightforward and is always embedded in a particular cultural and legal context.

Introduction

Over the last decade decision making in public administration has increasingly been characterised as an exercise in "handling risk" (The Strategy Unit of the Cabinet Office, 2002). A consequence of this is that public decision makers are now thinking in terms of risk, and utilising techniques of risk management and risk assessment. Moreover, numerous regulatory reform programmes are promoting an even greater emphasis on these and associated "risk concepts". An important dimension of these set of developments has been the role of law (Fisher, 2003b).

The speed at which risk and associated concepts have become central features of administrative decision making is breath-taking. Likewise, these concepts are now playing a role right across public administration in many different jurisdictions. In such circumstances it has often been difficult for policy makers and decision makers to be able to have an overall understanding of the role these concepts play in administrative governance and their implications for law.

This chapter provides a starting point for developing that understanding. The introduction and Section 2.3 are concerned with providing an overview of these risk regulatory concepts, and Sections 2.4 to 2.7 are a description of the different legal dimensions of them. Section 2.8 sets out a framework to aid policy makers and decision makers in the development and use of risk regulatory concepts. Overall the argument of this chapter is that the proper use of risk regulatory concepts requires a critical understanding of them which is grounded in an appreciation of the importance of context for how these concepts are interpreted and operate.

In the first section it is shown how the introduction of risk concepts has been on the basis that they *regulate* public administration. It is for this reason that this chapter refers to concepts such as risk, risk assessment and risk management as *risk regulatory concepts*. These concepts are also introduced to promote good decision making as defined by models of good public administration, and in particular the rational-instrumental model of good administration.

As shown in Section 2.2, these concepts are regulating administrative power as part of at least four different governance agendas. Thus risk regulatory concepts have been introduced because of public management reform; as part of the re-characterisation of regulatory subject matter; in relation to enforcement and criminal justice decision making; and as part of a general debate about the role of the state.

Due to this state of affairs it comes as no surprise that risk regulatory concepts can be defined in different ways and this is illustrated in Section 2.3. The definitions of risk regulatory concepts are heterogeneous because such definitions are derived from different disciplinary contexts for different administrative purposes. With that said, a common feature of many definitions is that they emphasise the need for decision making to be quantified and for it to be based on methodologies. Section 2.4 sets out five different criticisms of the use of risk regulatory concepts: that they are inaccurate; their operation

ignores important issues; such concepts are open to abuse; such concepts do not effectively regulate administrative power; and such concepts are normatively objectionable.

In Section 2.5 the focus shifts to describing the different legal dimensions of risk regulatory concepts. That section considers the interface between risk regulatory concepts and administrative law in general terms. In particular, it highlights that that interrelationship is mainly in relation to circumstances where risk regulatory concepts are being deployed to describe the subject matter of regulation. Section 2.6 discusses the importance of legal culture and highlights that not only will risk regulatory concepts be deeply embedded in a legal culture but legal cultures differ significantly between jurisdictions. Section 2.7 examines the role of law in constituting and limiting public administration through establishing the competence of a decision maker, limiting their discretion, and regulating the procedures by which they make decisions. Risk regulatory concepts have a role to play in all these things. Section 2.8 gives a brief overview of the role of accountability mechanisms and highlights that they involve four different steps: the setting of standards; the obtaining of an account; the judging of such an account; and finally a decision about the consequences that arise from such a judgment (Davies, 2001, p. 81).

In Section 2.9, a framework is set out to aid policy makers and decision makers in the development and use of risk regulatory concepts. That framework requires decision makers to critically consider five different questions: why are risk regulatory concepts being deployed or promoted?; what models of good public administration are being promoted by risk regulatory concepts?; what disciplines are needed for the operation of risk regulatory concepts?; what is the role of law in the operation of risk regulatory concepts?; and what does experience with risk regulatory concepts tell us? These questions encourage decision makers and policy makers to take a critical and contextual approach in thinking about risk regulatory concepts.

Four points should be made at the outset. First, as risk concepts are in themselves regulating power it is acknowledged at the outset that the line between law and non-law is not always easy to establish. For the purposes of this chapter, law is defined as referring to legislation, delegated legislation, case law, and regulatory schemes with a legal basis. Second, the focus of this chapter is upon the role of risk regulatory concepts in administrative governance and not the role of these concepts in other areas such as regulatory strategy,[2] private governance (Rosen, 2003) or private law (Cranor, 2006). Third, this chapter does not provide an exhaustive examination of all examples of where risk regulatory concepts are being deployed in administrative governance. The use of risk regulatory concepts is now so wide spread that that would be impossible to do. Rather examples are illustrative and are particularly drawn from the public health and environmental areas as these are areas which the author has particular expertise in (Fisher, 2006, 2007). Fourth, the purpose of this chapter is not to either argue for or against the promotion of risk regulatory concepts in administrative governance. In dealing with the future the use of such concepts is inevitable. With that said, there is a need to appreciate that these concepts are not neutral, are normative, and that a sophisticated and nuanced understanding of them if they are to be successfully deployed.

2.1. Risk regulatory concepts and the regulating of public administration

Put simply and very crudely, thinking about risk is about dealing with uncertain futures. As much of administrative governance and regulation is about trying to achieve better future outcomes it comes as no surprise that in the last decade there has been an

increased focus on the concepts of risk, risk assessment and risk management. For many this is blinding commonsense and has meant that discussion about these new "risk regulatory concepts" often quickly moves to the technical details. Yet to truly understand the nature of this development in administrative governance there is a need to take a broader view.

The paradoxical role of public administration

To understand the role of risk regulatory concepts there is a need to understand that the role of public administration is inherently paradoxical. In an advanced democracy, those who govern should be the subject to the will of the people. Yet the needs of an advanced, complex technological society mean that the process of governing requires ongoing, information-intensive and expert-based decision making. As such, much of the process of governing has been delegated to non-elected administrative decision makers – a state of affairs which is seemingly undemocratic. Whether it is the building of infrastructure projects, the regulation of financial markets, the management of the criminal justice system, or environmental protection regulation –, public administration dominates decision making (Fisher, 2007).

The paradoxical nature of public administration means that despite the fact that public administration plays such a significant role in governance, that role is not easily justified. As Cook notes the position of public administration begs the question of "how can a long-range, stable, even permanent exercise of governmental authority be reconciled with a regime of popular sovereignty?" (Cook, 1996, p. 3). The result of this situation is that there are ongoing attempts to explain, justify and legitimise administrative power which have resulted in a range of theories which often prescribe quite different roles to administrative bodies. These include attempts to democratise public administration (Dorf and Sabel, 1998) control it (Lowi, 1979) and/or to replace it with decentralised governance networks (Scott, 2000). A constant feature of the administrative state in nearly every jurisdiction has been a continuous reworking of its nature and role. Moreover, there is rarely agreement at any one time about what is reasonable and valid action on the part of administrative decision makers (Fisher, 2007; Chapter 1).

Risk regulatory concepts and "good" public administration

The increasing role for risk concepts including risk assessment and risk management must be seen as part of this debate over the legitimacy of public administration. This is because these new risk concepts have an important role in regulating administrative power (Fisher, 2003b; O'Malley, 2004). It is for this reason that this chapter refers to these concepts by the unwieldy phrase *risk regulatory concepts*. Included in this phrase are not only concepts of risk, risk management, and risk assessment but associated concepts such as comparative risk analysis, the precautionary principle, risk communication, security, uncertainty and hazard.

Risk regulatory concepts regulate regulatory decision making in three ways. First, such concepts play an important role in defining the competence of public administration. Requiring a decision maker to assess risk by a quantitative method vests them with a very different expertise than if they are given wide ranging discretionary powers to consider anything they feel relevant (Treasury Board of Canada, 1999; Treasury Board of Canada, 2001). Second, risk regulatory concepts limit administrative power (Applegate, 1995; Audit Commission, 2001, p. 49). This is because requiring decision makers to act on the basis of a

risk assessment or risk management strategy places boundaries on what they can and cannot do. This limitation is done on the basis that risk regulatory concepts will promote more "effective" decision making. This is particularly because risk management and risk assessment are decision making processes which introduce analytical methods into decision making and require decisions to be based on information. As such, a decision based on a risk assessment should theoretically be more rigorous than a decision that is not. Third, risk regulatory concepts are promoted on the basis that their operation will lead to more accountable and transparent decisions which are open to greater scrutiny due to the fact that such techniques require decision makers to explain their reasoning. There are many who question the ability of risk regulatory concepts to do these things (see Section 2.4) but the point is that risk regulatory concepts are being utilised in the belief they will result in better public administration (Graham, 1996; Sunstein, 2002b).

Most significantly, risk regulatory concepts are regulating public administration in accordance with understandings of good public administration. As seen above, however, there are no fixed understandings of "good" public administration and thus different risk regulatory concepts are often promoting different models of good public administration. These can also be called models of administrative constitutionalism in that they are models concerned with constituting, limiting and holding public administration to account so that it is legitimate (Fisher, 2007, Chapter 1). While, multitudinous models of administrative constitutionalism exist broadly speaking we can understand public administration to be dominated by two particular models – the deliberative-constitutive model and rational-instrumental model (Fisher, 2007). The former model conceptualises public administration as an institution constituted so as to be a permanent problem solving body with wide ranging and flexible discretion. Such a body is needed because of the perceived complexities of the problems administration must deal with, and the exercise of discretion involves a mixture of facts and values. In contrast, the rational-instrumental model conceptualises public administration is an "agent" of the legislature entrusted to carry out a series of finite tasks with as little discretion as possible. Such tasks also involve the consideration of facts and values but the consideration of each is seen as separate, and consideration of each is constrained as much as possible, ideally by analytical methodologies. This model has been promoted because it is perceived to result in greater legislative control of public administration. Both models thus require decision makers to engage with science and values but define these things differently.

There are three important things to note about these models. First, neither model offers perfect public administration. The deliberative-constitutive model promises effective problem-solving at the cost of forgoing a simple means of restraining public administration. In contrast, the rational-instrumental model promises accountability and control but at the cost of effective problem-solving in that discretion may be too constrained to actually address the complexity of the problems that public administration are dealing with. This is indicative of the fact that there are no utopias when it comes to public administration – whatever model is implemented will always have its disadvantages. The best model of public administration is one which is developed in awareness of that fact but is best suited to addressing the issues at hand. Second, both models of public administration will often be being promoted at the same time through different policies, laws, institutional structures and administrative cultures (Fisher, 2005). Decision makers can thus often find themselves subject to competing expectations about what is a "good" decision. This reflects the fact that administrative decision makers are subject to multiple accountabilities.

Third, risk regulatory concepts are capable of being interpreted in both rational-instrumental and deliberative-constitutive terms. Thus for example, the precautionary principle can be interpreted in deliberative-constitutive terms as enabling the exercise of flexible discretion in circumstances of scientific uncertainty or it can be interpreted in rational-instrumental terms as a limited exception to the rational-instrumental principle that decision making must be based on the facts (Fisher and Harding, 2006; Fisher, 2007, pp. 42-44). Likewise, risk assessment can be understood in deliberative-constitutive terms as a broad but rigorous reasoning process or in rational-instrumental terms as a particular quantitative and analytical method (Fisher, 2007, Chapter 5). With that said, the introduction of most risk regulatory concepts over the last decade has mainly been to promote a rational-instrumental model of public administration (Fisher, 2007, Chapter 7). The regulating role of risk regulatory concepts is thus often about controlling public administration and restraining administrative discretion as much as possible so that public administration is carrying out a set of very specific tasks in very particular ways.

2.2. The different areas in which risk regulatory concepts are being used

What the above highlights is that risk regulatory concepts are not objective or neutral concepts. This is not the only complex aspect of risk regulatory concepts to appreciate however. It is also the case that there is no fixed or monolithic understanding of risk regulatory concepts and they are being used in many different contexts. They are also relatively new concepts in the public administration context. Before the last two decades risk was mainly a topic for discussion in isolated specialist disciplines such as insurance and nuclear engineering (Health and Safety Executive, 1999; Covello and Mumpower, 1985).

There are at least four different ways in which risk regulatory concepts are being deployed in regulating public administration. First, these concepts are part of public sector management reform. Second, these concepts are being used in a variety of fields to regulate a regulator's discretion by re-characterising the subject matter of regulation. Third, risk regulatory concepts are being used to regulate enforcement and in the criminal justice context. Finally, the concept of risk is also playing a role in more general debates about the role of the state. These different uses of risk regulatory concepts do overlap and are not necessarily exhaustive but they do highlight that these concepts are being used in a variety of ways for a variety of reasons.

Public sector management reform

Risk has become an important concept in public sector reform (Better Regulation Commission, January 2008; Working Party on Regulatory Management and Reform, 2006, Treasury Board of Canada Secretariat, 2003, Barret, 2005). In this context it is strongly associated with new public management ideals (Hutter, 2005; and Black, 2005). Risks are understood as a threat to the successful operation of public administration and "[e]ffective risk management is then needed to enable the organisation to deliver its objectives in the light of those risks" (Audit Commission, 2001, p. 19). In particular, risk is significant because managing future risks is seen as an important part of effective public financial management and there is a perception that this was poorly done in the past (Audit Commission, 2001, p. 12). Reform in this area is often modelled on private sector techniques as there is a perception that this type of risk management is done well by private organisations (KPMG, 1999).

Reforms can take many forms. Thus for example, there may be the promotion by the central executive of general risk management frameworks where these frameworks primarily focus on financial risk management (ALARM – The National Forum for Risk Management in the Public Sector, 2007; Auditor General Victoria, 2004; HM Treasury, 2001; The Strategy Unit of the Cabinet Office, 2002; Treasury Board of Canada, 2001). The United Kingdom (UK) Treasury thus advocates the development of an overall "risk culture" within a public organisation (HM Treasury, November 2006b). Government Treasuries have also produced detailed guidelines setting out frameworks for carrying out risk management (HM Treasury, 2004). Risk regulatory concepts are also deployed as a specific concept in a particular public management strategy. Thus for example the "transfer of risk" to the private sector is a central feature of public/private partnerships used to develop public infrastructure (OECD, 2008).

Risk as the subject matter of regulation

The second way in which risk has become an important feature of public sector discourse is that the subject matter of regulatory activity is now being re-defined in terms of risk. Thus for example, environmental and public health regulation is now understood to be about regulating environmental and public health risks and financial regulation is now understood to be about regulating market risk. The term "risk regulation" has also become a common one.

For regulators, this has two practical implications. First, to regulate a "risk" must be identified.[3] Second, in assessing whether such a risk exists and how it should be regulated, a decision maker must use a range of analytical methodologies which assess and manage risk (Fisher, 2006; National Research Council, 1994; Sunstein, 2002a). The significance of this shift is that the goal of regulators is now more specifically defined than in the past. Thus for example, an environmental protection regulator is no longer broadly protecting the environment but rather reducing environmental and health risks (Science Advisory Board, 1990). Moreover, regulatory discretion is more constrained. A regulatory decision maker must justify their decision by doing a risk assessment or engaging in risk management.

The re-casting of regulatory activities in terms of risk has occurred in a variety of ways including the introduction of new legislation and policies, case law, as well as the emphasis on risk in general policy and academic debate. It has particularly occurred through the introduction of general regulatory reform initiatives such as the Better Regulation schemes in the UK and EU and the OMB regime in the United States (US) (Baldwin, 2005; Deighton-Smith, 2007; McGarity, 1991). Overall, this set of developments can be understood as the promotion of a rational-instrumental paradigm of administrative constitutionalism in that these concepts are being promoted on the basis that they will constrain discretion (Fisher, 2007 at Chapter Two; Fisher, 2000a). Such concepts, also seem to make decision making more objective and neutral – a fact which is attractive in an era of globalisation.

Enforcement and criminal justice

The third area in which risk regulatory concepts are being deployed is in relation to enforcement and criminal justice. Thus, risk regulatory concepts are now playing a role in decisions concerning how to apply and enforce regulatory schemes (Baldwin and Black, 2008). The most obvious example of this is the "risk-based" approaches to enforcement promoted by the Hampton Report in the UK which has resulted in different UK regulators adopting a range of "risk-based" policies which vary in their detail and in how much they

require decision makers to rely on analytical methodologies (Hampton, 2005; Financial Services Authority, 2006, Office of Fair Trading, November 2007, Environment Agency, 2005). Similar approaches can be seen in other jurisdictions (Australian Prudential Regulation Authority, 2000, Resource Safety, 2005). This is related to the first two developments above but is distinct in that the focus of these policies are upon what threat a particular regulated actor creates in not complying with the law.

More significantly, risk regulatory concepts are playing an increasingly important role in the criminal justice system and have closely been related to the re-characterising of that system as providing security (Goold and Zedner, 2006; Law Commission of Canada, 2006 HM Government, July 2006). Thus policing policies have been based on risk assessment and management strategies and the assessment of prisoners re-offending is now understood as a form of risk assessment. Similar developments can also been in relation to mental health and social services (Department of Health – National Mental Health Risk Management Programme, June 2007). As well, concepts of risk assessment and risk management have become key themes in terrorism prevention (HM Government, July 2006). All these different techniques are based on the premise that methodologies exist which can accurately assess and manage individual's future behaviour.

Risk and the redefinition of the role of government

Finally, risk regulatory concepts are being promoted as overarching concepts that regulate administrative action. On this basis, the role of the executive is understood to be about the "handling of risk" and the three trends above are largely seen as one development (Fisher, 2003b; Regulatory Impact Unit, 2003; The Strategy Unit of the Cabinet Office, 2002). Thus, the UK Cabinet Office has published a National Risk Register which identifies the major risks that the UK government may need to deal with. Government departments have also been encouraged to develop risk management strategies.[4]

Risk is also a major theme in discussions about what role the state should play in the private life of individuals and in regulating activities more generally (Better Regulation Commission, October 2006). Thus for example there are public policy discussions concerning what risks are within an individual's responsibilities and whether society as a whole is too risk adverse.

This understanding of the state "handling risk" is appealing in an era in which concepts of joined up and interconnected government are being promoted. It suffers however from the problem that the way in which risk is managed and assessed is very different in different contexts and, as such, is too general a statement to be meaningful. This can best be seen in the many different ways risk regulatory concepts are defined.

2.3. Defining risk regulatory concepts

What is clear from the last section is that risk regulatory concepts are being deployed in many different contexts for many different reasons, but particularly to regulate administrative power. This has three important implications when it comes to thinking about how risk regulatory concepts are defined. First, definitions of these risk regulatory concepts will vary from context to context. Second, risk regulatory concepts are regulatory constructs which have been developed for specific purposes. Third, because one of the most significant purposes of introducing these concepts is to regulate administrative power in accordance with the rational-instrumental model, definitions of risk regulatory concepts tend to emphasise the importance of analytical rigour and quantification.

Variations in definitions

Across public administration there is a multitude of different definitions of risk regulatory concepts in operation (Fisher, 2003b). This is because the types of uncertain futures administrative decision makers are dealing with are different in different contexts. Assessing the ecological impact on a wetland from industrial pollution is different from assessing whether a sex offender will re-offend and is different again from assessing the financial risks that arise from an infrastructure project. All present, "a situation or event in which something of human value (including humans themselves) has been put at stake and where the outcome is uncertain" (Jaeger *et al.*, 2001, p. 17) but beyond that there is little convergence in how different disciplines and/or groups define what is of human value, what is at stake, what is uncertain, and how any of these things are assessed (Bammer and Smithson, 2008).

Thus for example, in the environmental and public health regulation context, while there is considerable controversy over how risk is defined, a typical starting point is a definition taken from engineering. Risk in that context is defined as "a combination of the probability, or frequency, of occurrence of a defined hazard and the magnitude of the consequences of occurrence". It is also distinguished from hazard, which is defined as "a property or situation that in particular circumstances could lead to harm" (Royal Commission on Environmental Pollution, 1998, p. 51). In contrast, in the criminal justice sphere, risk is being used as a tool in the assessment of whether particular people are likely to commit crimes and is defined as the "probability that some undesirable event will occur" (Clear and Cadora, 2001, p. 52).

In relation to finance, the concept of risk is often derived from Knight who defined risk in this context as circumstances where you don't know it will happen but you know the odds (Knight, 1964). As such he distinguished it sharply from uncertainty where the odds were not known. Risk in these terms has developed out of probability theory in mathematics that has also been the cornerstone of insurance (Bernstein, 1996). This disciplinary background is reflected in the OECD's definition of risk as included in their guidelines on public/private partnerships:

> Risk, sometimes called measurable risk, is defined as a case where there is a range of possible outcomes that are each associated with an objectively (*i.e.* statistically determined) or subjectively ascribed numerical probability. Formally, risk is defined as the measurable probability that the actual outcome will deviate from the expected (or most likely) outcome. If sufficient data are available, the probabilities involved can be estimated statistically. Alternatively, based on experience, subjective numerical probabilities can be ascribed to the various possible outcomes (OECD, 2008, p. 48).

It is not just definitions of risk which vary however. There are also an array of different definitions of risk assessment and risk management in operation. Again this is not surprising. Risk assessment and risk management are techniques being utilised in many different contexts. Thus for example in discussions about risk management in the context of general public management the focus is upon both reducing *and* taking risks (HM Treasury, November 2006a). In contrast, in criminal justice risk management is primarily concerned with classifying people on the basis of what they might do in the future (Feeley and Simon, 1994; Garland, 2001). In contrast again, the regulatory focus in relation to public health and environmental protection is upon predicting whether a particular activity or substance will adversely affect the environment or human health (National Research Council, 1996; Royal Commission on Environmental Pollution, 1998).

Moreover, even within a particular field such as public health, risk assessment can also mean many different things. The US National Research Council makes this point well:

> Risk assessment is not a monolithic process or a single method. Different technical issues arise in assessing the probability of exposure to a given dose of a chemical, of a malfunction of a nuclear power plant or air-traffic control system, or of the collapse of an ecosystem or a dam. Thus, one size does not fit all, nor can one set of technical guidance make sense for the heterogeneous risk assessments undertaken by federal agencies (Committee to Review the OMB Risk Assessment Bulletin – National Research Council, 2007, p. 106).

Thus, for example a risk assessment of whether a chemical causes cancer is a very different enterprise from whether the release of a particular chemical into the environment will cause algae blooms.

What all this means is that conversations across administrative institutions need to be done with care. While decision makers may think they are deploying exactly the same risk regulatory concept because such concepts have the same label they may not be. Risk regulatory concepts cannot be transferred from one context to another in a haphazard fashion. An environmental definition of risk is nonsensical in the criminal justice sphere just as a concept of risk-based enforcement is meaningless in discussing the financial risks which may arise from a public/private partnership. With that said, a single decision maker may find themselves governed by different definitions of risk because regulatory regimes concerning public management, regulatory subject matter, and enforcement may simultaneously apply to them.

Risk regulatory concepts as regulatory constructs

The second implication of the many different ways risk regulatory concepts are being deployed in administrative decision making is that risk regulatory concepts will be often created for specific purposes and also be a product of particular regulatory environments. Different definitions are thus not just a product of different *disciplinary* contexts but also due to different *administrative* contexts. This can particularly be seen the public health and environmental regulatory fields. Rhomberg in 1997 wrote a 173 page survey of the different chemical risk assessment methodologies used by US Federal administrative agencies. The variations were enormous, often within the same organisation. He noted that these variations can be…

> … attributed to the different questions being asked of the risk assessment process in different regulatory contexts by different environmental statutes. In part it reflects different institutional judgments about the most appropriate methods and different scientific judgments about matters with high scientific uncertainty. And in part it reflects a simple policy choice made for the sake of consistency within each organisation (which, owing to independent histories, become inconsistent among organisations) (Rhomberg, 1997, p. 2).

How risk assessment is defined is not just due to scientific factors but also institutional ones as well (Fisher, 2006). Thus for example, the now common distinction between risk assessment as an objective scientific process and risk management as a political process was first formally set out in a US National Research Council report in 1983 and the catalysts for the report was a Supreme Court decision and the specific regulatory politics of that time (National Research Council, 1983; 1994). Likewise, "risk-based" enforcement policies in the

UK reflect the particularly important role enforcement plays in UK regulatory strategy (Black, 2005). Even, risk management techniques borrowed from the private sector take on a particular public sector understanding (HM Treasury, 2003). There is also considerable variation in the nature of risk assessment practices as part of regulatory impact assessment (Deighton-Smith, 2006, pp. 18-21). An implication of risk regulatory concepts being regulatory constructs is not only that they are defined and developed for specific purposes but they may also evolve over time in light of administrative experiences, emerging institutional concerns, political trends, and specific events.

The emphasis on quantification and methodological rigour

The last two sub-sections have emphasised the heterogeneity in how risk regulatory concepts are defined. With that said, many definitions have one thing in common – that is they emphasise the need for decision makers to quantify aspects of their decision making or apply some form of methodology in the analysis of an issue. Thus for example, risk is often defined in quantitative terms and risk assessment and risk management processes are often detailed methodological regimes.

While it is the case that not all definitions of risk regulatory concepts emphasise quantification and methodology it is not surprising that many definitions do. As seen above, a primary reason for the introduction of risk regulatory concepts is to promote a rational-instrumental model of public administration. Quantification is seen to do this by not only making decisions more objective and controlling discretion but also seemingly removing emotional and hysterical factors out of decision making. As Porter notes:

> In a political culture that idealises the rule of law, it seems bad policy to rely on mere judgment, however seasoned. … A decision made by the numbers (or by explicit rules of some other sort) has at least the appearance of being fair and impersonal. Scientific objectivity thus provides an answer to a moral demand for impartiality and fairness. Quantification is a way of making decisions without seeming to decide. Objectivity lends authority to officials who have very little of their own (Porter, 1995, p. 8).

Methodologies such as risk assessment and risk management should result in decision makers making more factually accurate and rigorous decisions. Thus for example, Cass Sunstein has argued that risk assessment contributes both to public reason and to promoting the idea of a cost/benefit state (Sunstein, 2002a; 2002b). Wiener has also argued that such techniques allow for decisions to be based on more information (Wiener, 2006, p. 9). Moreover, quantified and methodologically based definitions of risk regulatory concepts are also promoted on the basis that they make decision making more accountable because they seemingly make decisions more transparent. This is because decision makers must explain and justify their decisions in accordance with particular definitions and processes.

2.4. Why have risk regulatory concepts been criticised?

While risk regulatory concepts have become popular concepts they have also been highly controversial and have been subject to sharp criticism from many different quarters. Criticisms fall into five different overlapping categories. Such concepts are argued to be: inaccurate; distorting decision making; open to abuse; not properly regulating administrative power; and promoting the wrong normative understanding of administrative government. Each category is considered briefly below.

These categories do overlap. Thus for example a criticism about risk assessment methodology is often driven by a concern about the normative values that particular types of risk assessment promote. With that said, it is useful to see these objections as distinct. Moreover, it should be noted that many of these criticisms are concerned with how *quantitative* risk regulatory concepts operate. In particular, there is a constant emphasis of the dangers of relying on objectivity and science in delivering good public administration (McGarity, 2004). In other words, many critiques of risk regulatory concepts are, in essence, a critique of rational-instrumental models of public administration.

Risk regulatory concepts are technically inaccurate

The first major category of criticisms about risk regulatory concepts is those criticisms concerned with the technical inaccuracy of risk regulatory concepts. The most significant criticism in this regard is that in the operation of such regulatory concepts there has been a failure to properly take into account uncertainty (National Research Council, 1994; Shrader-Frechette, 1993). In particular, it is often argued that in promoting these regulatory concepts there has been a failure to appreciate that risk is about the future and thus is inherently uncertain. Rather, risk regulatory concepts are seen to be based on a naïve view of science, analysis, and the ability to achieve certainty. Uncertainty is not just a data gap but shorthand for a whole myriad of technical, methodological and epistemological problems in assessing and managing the future (Dovers and Handmer, 1999). Those that talk of "full" and "complete" risk assessments are viewed as failing to appreciate the fact that rarely can any risk assessment be full or complete because of the problems to do with uncertainty. These criticisms can particularly be evidenced in regard to health and ecological risk assessment where there have been many studies showing how risk assessments have been based on inadequate data or upon models in which value judgments have had a significant role to play but have not been acknowledged.

Many in these debates are not criticising the use of risk regulatory concepts generally but often specific methodologies, particularly when there is an attempt to impose general methodologies on a range of problems. The argument is often that there is a need to develop more nuanced methodologies that also assess and make sense of uncertainty (Committee to Review the OMB Risk Assessment Bulletin – National Research Council, 2007). This is one of the reasons why in recent years many public institutions have attempted to develop more sophisticated models of risk assessment and risk management which take into account these uncertainties (Royal Commission on Environmental Pollution, 1998; National Research Council, 1996; and Presidential/Congressional Commission on Risk Assessment and Risk Management, 1997). Likewise, many who promote the precautionary principle do so because they believe it forces decision makers to explicitly engage with scientific uncertainty in rigorous ways (Deville and Harding, 1997; Dovers and Handmer, 1999; Stirling *et al*., 2006). For them, the precautionary principle is not about making decisions on the basis on less information but about analysing the quality of that information more thoroughly. This group is often promoting a deliberative-constitutive interpretation of the precautionary principle and public administration in which the focus is on developing nuanced methodological approaches to specific problems.

Risk regulatory concepts distort decision making

Related to this first category of criticisms is a second category of criticisms that focus on the fact risk regulatory concepts distort decision making. This distortion is seen to occur in two main ways.

First, the operation of risk regulatory concepts is seen to narrow the range of issues a decision maker takes into account (Ackerman and Heinzerling, 2004; Rayner and Cantor, 1987; Tribe, 1973). In particular, there is a concern that such techniques tend to focus on what can be quantitatively measured ignoring those things that cannot be, such as management practices.[5] This is particularly in cases where risk assessment is being combined with cost/benefit analysis in that it is often argued the costs of regulatory action are easier to assess than the benefits. Further distortion occurs because of the failure for decision makers to properly take into account a range of uncertainties.

The second way in which risk regulatory concepts are seen to distort decision making is that their operation "frames" a problem in a way that privileges one understanding of the problem over another (Erikson, 1994). Thus for example, commentators highlight the fact that a focus on quantitatively assessing risk can lead to decision makers ignoring that the decisions they make raise significant questions about equity and fairness (Rayner and Cantor, 1987). This failure to identify aspects of a problem can also lead to greater outcry from the public. Likewise, some argue a rationalistic concept of "acceptable risk taking" is based on a flawed understanding of human decision making (Jaeger, Renn, Rosa and Webler, 2001). Moreover, some have criticised risk management strategies in the public finance field such as public/private partnerships on similar grounds (Freedland, 1998). As can be seen from these examples, the criticism is usually that problems are framed too narrowly. This is a common criticism of rational-instrumental models of administrative constitutionalism in that the focus is too much on the control of public administration and not enough on effective problem solving.

Risk regulatory concepts are open to abuse

A third category of criticisms of risk regulatory concepts is that they are open to abuse by specific interests. In particular there are those who argue that these concepts can be manipulated to ensure a particular regulatory actor's desired ends. This criticism is most common in the US where in recent years there have been a number of high profile examples of where industry has "manufactured uncertainty" as a way of stopping regulators establishing the required factual basis to regulate (Michaels, 2008). As administrative decision makers must establish a risk exists and so if industry can produce data showing such a risk does not exist then they can prevent regulation. This is even when the data produced is open to question and the risk is highly uncertain. Likewise, litigants have been "analytically opportunist" in litigation and regulatory processes by challenging any perceived analytical flaw in risk assessment processes. As nearly all risk-assessment processes will contain methodological flaws, this creates an open-ended opportunity for attacking decisions. Such attacks do not lead to better decisions but merely a longer and more drawn out decision making process – what Wagner has described as a "science charade" (McGarity *et al*., 2004; Wagner, 1995).

These and other opportunities for abuse are mainly felt to arise because there has been among general decision makers and those holding decision makers to account a failure to appreciate scientific uncertainty and the role values plays in scientific analysis.

Because science is understood to be objective all data is treated equally and any hint of uncertainty or methodological weakness is evidence that data is incorrect. Those that make these criticisms often argue the need for a far more sophisticated understanding of science and risk regulatory concepts to be developed.

Risk regulatory concepts do not effectively regulate administrative power or hold decision makers to account

A fourth set of criticisms about risk regulatory concepts is that their operation does not result in better or more accountable public administration (Wagner, 1995; Power, 1997). Again this criticism is often made in relation to risk regulatory concepts that promote a rational-instrumental model of public administration and such a criticism highlights the fact that while the rational-instrumental model promises accountability it does not necessarily deliver it.

This failure to control public administration can be seen in a number of different ways. Thus for example, there are those that argue that the use of risk regulatory concepts make decision making more opaque rather than more transparent. This is because decision making becomes highly technical and because those scrutinising the decisions can't always see the data on which it is based. Moreover, it can also become difficult to see the role that particular values may be playing in a decision. This is particularly in regard to the use of scientific models in risk assessment (McGarity and Wagner, 2003).

Risk regulatory concepts are also criticised for leading to a culture of "blame re-engineering" in which decision makers focus on ensuring they are not held responsible for decisions (Hood, 2002 and Hood *et al.*, 2001). The result is that public decision makers "expend material amounts of time in creating defendable trails of process" (Power, 2007, p. 190). Moreover, there is a danger that risk management frameworks become merely bureaucratic checklists which are superficial exercises that do not effectively regulate institutional power (Audit Commission, 2001, p. 21).

There are also those who argue that the use of risk regulatory concepts has led to decision making becoming too slow and resource intensive without any obvious improvement in the outcomes of decisions. This arises because decision makers must collect a considerable amount of information and carry out considerable analysis in the operation of these concepts. In the US, this slowing down of the regulatory process is known as "ossification" (Carnegie Commission on Science Technology and Government, 1993). One example of it can be seen in the fact that while the Occupational Safety and Health Administration's (OSHA) 1972 rule in relation to asbestos was 4.5 pages long, their methylene chloride rule published in 1997 was over 100 pages long,[6] had taken over ten years to develop, and had been based on a 48 000 page record. Likewise, criticisms have been made more recently in the US in relation to regulatory impact assessment where it has been argued that the regime has been based on incorrect assumptions about the regulatory process (Revesz and Livermore, 2008).

A further criticism is that this state of affairs has led to decision making becoming more informal so as to circumvent the heavy analytical burdens that risk regulatory concepts impose (Elliott, 1992; Mashaw, 1997; Pierce, 1997; Werhan, 1996). This is seen as problematic because the shift to more informal decision making is seen as a shift to less accountability. Other commentators have grown more cynical and argue that risk regulatory concepts have very little to do with good public administration and more to do with de-regulation (Schultz Bressman and Vandenburgh, 2006).

Risk regulatory concepts are normatively objectionable

The fifth set of objections to the use of risk regulatory concepts is from those that find the resulting relationship between the state and the individual as normatively objectionable (Douglas and Wildasky, 1982; Furedi, 1997; and Gill, 2007). This can particularly be seen in the criminal justice sphere where the concern is that the promotion of risk methodologies leads to a culture of control (Garland, 2001). Likewise, the use of risk in the public management field is criticised for distorting the role of public services. There are also those who are concerned that a focus on reducing risk leads to a nanny state and a litigious culture. These views about the appropriateness of relationships reflect a range of ideological and normative differences of opinion over the role of the state in the lives of individuals. It should also be noted that those that raise normative objections to risk regulatory concepts do not agree among themselves about the role of the state.

Normative disagreements also reflect the differences of opinion over what should be the role and nature of public administration. Indeed many disputes over risk regulatory concepts are really disputes over the legitimacy of public administration. In particular, as already noted, criticisms of risk regulatory concepts tend to be critiques of the rational-instrumental model of public administration, or at the very least, the inappropriate reliance on that model.

Reflecting on these criticisms

Before proceeding further it is useful to briefly reflect on three main features of these criticisms. This is particularly because these criticisms are catalysts for law reform and figure in legal disputes and legal debate.

The first thing to note is that these criticisms are often quite subtle and nuanced. While there are some examples of where actors wish to argue that risk regulatory concepts have no role in decision making much of the criticism is directed at naïve and unsophisticated utilisations of risk regulatory concepts. Not surprisingly then, in jurisdictions in which there has been some experience of risk regulatory concepts in practice there is often official recognition of a need for more careful application of these concepts (National Research Council, 1994; Presidential/Congressional Commission on Risk Assessment and Risk Management, 1997; Royal Commission on Environmental Pollution, 1998).

Second, these criticisms have come from a wide range of actors. Some are clearly from those pushing a particular ideological agenda, but many are from those working with these risk regulatory concepts day to day. Indeed, a striking feature of policy about risk regulatory concepts is that those using these concepts tend to be more explicit about their limitations than more general policy makers who tend to emphasise the potential of these concepts to regulate administrative power (Fisher, 2000a).

Third, these criticisms cannot be ignored or sidelined. They do point to the fact that risk regulatory concepts, like any aspect of public administration, are not perfect. As a means of regulating administrative power such concepts bring with them their own problems. In some circumstances, such problems may make the use of such concepts entirely inappropriate. In other situations, the use of such concepts must be done carefully and thoughtfully. In all cases, the use of such concepts must be in a reflective and sophisticated manner.

2.5. Risk regulatory concepts and the role of law: a descriptive account

The discussion so far has given an overview of risk regulatory concepts as they apply to public administration. It has highlighted that: they play a significant role in regulating administrative power; they promote ideals of good administration; they are used in a variety of ways; that many different definitions of these concepts exist; and that the deployment of these concepts has been the subject of a range of criticisms. In this section a descriptive account is given of the interrelationship between law and risk regulatory concepts. Such an account has two purposes. First, to illustrate that there are many different ways in which risk regulatory concepts regulate administrative power. The second purpose is to counteract the unfortunate, naïve and incorrect assumption often held among policy makers that the "law is the law".

Administrative law and public administration

The starting point for such a descriptive account must be the law that applies to public administration. This is usually described as administrative law or public law. The actual law, and how it is described, will vary significantly from jurisdiction to jurisdiction but the important point to appreciate is that in thinking about the interface between risk regulatory concepts and the law we are thinking about the interface between risk regulatory concepts and the specific area of the law that deals with public administration. As such, for this chapter that body of law will be described as administrative law. Moreover, the focus is not on other areas of law such as tort law, contract law or company law.

Administrative law is concerned with constituting, limiting, and holding public administration to account. Legislation and delegated legislation are the main means by which decision makers are constituted and limited although policy can play a role as well. The holding of decision makers to account can be done in a variety of ways including by ombudsmen, control by the legislature, central executive oversight, specialist tribunals, public inquiries and by the courts reviewing the validity of administrative actions (judicial review). Accountability mechanisms will generate their own principles that limit decision makers. Thus for example, in a common law jurisdiction a court case will become authority for what is a good decision.

Administrative law is not neutral and the processes of constitution, limitation, and accountability will reflect different understandings about what is and should be the role and nature of public administration. As such, administrative law shapes "administrative decision making in accordance with our fundamental (but perhaps malleable) images of the legitimacy of state action" (Mashaw, 1997, p. 108) and behind any body of administrative law lies a theory of the "good" administrative state (Fisher, 2007). As we saw above, there is little agreement over the role of "good" administration however, and thus administrative law has become an arena and discourse for disputing the role and nature of public administration. Legislative reform debates, judicial review cases, or other forms of calling to account are sites for determining and shaping what is, and should be, the role and nature of public administration. In particular, law will often provide the arenas in which administrative decisions can be challenged. Likewise, the law itself is the discourse through which this is done. Legal imperatives will shape understandings of the nature and role of public administration and the nature of the problems that public administration is dealing with. At the same time understandings of public administration, and the problems they deal with, will shape the law.

As this is the case, it comes as no surprise that in most jurisdictions administrative law is a dynamic and diverse body of law that is highly complex and reflects competing ideals about good administration including the rational-instrumental and deliberative-constitutive models discussed above. Moreover, administrative law scholars often highlight the fact that the substance of administrative law can vary dramatically from subject matter to subject matter due to the very specific nature of administrative schemes.

Administrative law and risk regulatory concepts

Administrative law has an important interrelationship with risk regulatory concepts because both administrative law and risk regulatory concepts are concerned with regulating administrative power so as to ensure good administration. As such, it should come as no surprise that many of the regulatory developments described in Section 2.2 have been legal developments. Thus for example, the requirement that a regulator should carry out a risk assessment has been included in many different pieces of legislation (see Section 2.7, Limiting discretion).

However, many risk regulatory concepts operate with little role for law. Thus for example, the new public management developments described in Section 2.2: Public sector management reform, have not been accompanied by legal reform in many jurisdictions, "risk-based" enforcement is mainly a policy, and more general debates about risk and the state have had few legal implications. The reason for this is that risk regulatory concepts can and do regulate administrative power independent of the law – a situation which reflects the fact that public administration is not only constituted, limited and held to account by the law but also by administrative policy, practices, and a general ethos. Whether risk regulatory concepts are included in the law or not is due to a range of factors including the general legal culture within a jurisdiction, historical practices and sheer accident.

With that said, it is mainly the regulatory developments concerned with re-characterising the subject matter of regulation in terms of risk (see Section 2.2, Risk as the subject matter) which have had a significant legal dimension. A study of the interface between law and risk regulatory concepts thus runs the risk of overlooking the fact that risk regulatory concepts are also playing roles in other areas in different ways. Yet at the same time, a study of how risk regulatory concepts operate within law also helps in gaining an understanding of just how complex risk regulatory concepts are. This is because such a study not only confirms the diverse and controversial nature of these concepts but also highlights that their operation is not straightforward. In particular, the role and nature of risk regulatory concepts is profoundly influenced by the surrounding legal and institutional context.

This is highlighted in the next three sections which examines three different aspects of the interface between administrative law and risk regulatory concepts. First, the law in any jurisdiction is not just a set of rules but rather a complex culture consisting of ideas, institutions, actors and principles. The operation of any risk regulatory concepts will be embedded and interact with that culture. Second, law is providing the framework for decision making through defining the competence of different institutions, limiting their power and creating decision making procedures. Finally, law provides a discourse and arena for challenging decisions made about risk.

2.6. Law is a form of legal culture

Law is often depicted in policy discussions as an instrument or tool to further particular policy ends. Yet this is an incorrect characterisation. Law is not just rules but a culture unto itself with its own institutions, operating concepts, rules, and principles which often take many novel forms. It is for this reason that a number of legal scholars talk in terms of "legal cultures" – a term that denotes legal norms, rules, and institutions and the interaction between them. It can, as Nelken notes, refer to everything from basic facts about a legal system to "more nebulous aspects of ideas, values, aspirations and mentalities" (Nelken, 2004, p. 1). Legal culture will determine the language, the priorities, the sites for dispute, and the remedies available.

The fact that law is a form of culture and not just instrumental has four different implications for thinking about risk regulatory concepts. First, risk regulatory concepts are embedded in complex cultures which will shape how such concepts operate and are defined. Second, legal cultures vary significantly between jurisdictions which means that risk regulatory concepts cannot be transplanted between legal cultures and operate in the same manner. Third, globalisation has led simultaneously to a proliferation of legal cultures and to a demand for greater uniformity. Fourth, the complexity of legal cultures means that unambiguous legal interpretations of concepts will often not exist. What all this means is that the very fact that a risk regulatory concept is given legal force results in complexity. For this reason it is useful to consider each of these implications.

Risk regulatory concepts and legal cultures

The operation of any risk regulatory concepts will be embedded in, and interact with, a complex legal culture. Risk regulatory concepts are not just rules that operate in isolation and how they are interpreted and operate will primarily be influenced by the institutions, laws, and ethos that surround them. Thus for example, the precautionary principle will have a different interpretation in different jurisdictions and contexts because it is operating in different legal cultures (Fisher, 2002). Moreover, embedded in different legal cultures will be different understandings of public administration and administrative constitutionalism.

This fact also has a number of other implications. As already seen in Section 2.3: Risk regulatory concepts as regulatory constructs, risk regulatory concepts are regulatory constructs which have been developed for specific regulatory purposes. In particular, the creation of new legal frameworks is because there is a perception that there needs to be reform in a specific area in a specific legal culture. Thus for example, the creation of the UK Food Standards Agency with its emphasis on risk assessment and management was a direct response to the perceived limitations of the more discretionary institutional structures that existed at that time for food safety (James, 1997; UK Government, 1998). The need for reform can also be derived from outside a legal culture. Thus for example, a catalyst for the European Commission's Communication on the Precautionary Principle was the World Trade Organisation (WTO) Sanitary and Phyto-Sanitary (SPS) Agreement (Commission of the European Communities, 2000a; Majone, 2005).

Moreover, when new risk regulatory concepts are introduced they will be interpreted in light of existing and established legal concepts and institutions. Thus for example, those enforcing regulation will interpret "risk-based" enforcement strategies in light of previous approaches to enforcement. The risk assessment powers of decision makers will be reviewed by courts in light of existing doctrines concerning how courts should review decisions (Fisher, 2001; Leventhal, 1974).

An important consequence of the fact that risk regulatory concepts are embedded in legal cultures is that the legal issues or disputes which arise in relation to them can be quite obscure and technical. Rarely will a legal dispute be over whether a risk regulatory concept is a "good" concept or not, but rather will concern a particular legal aspect of the concept's operation. Thus for example, in English planning law the issue of whether a local planning authority can take into account the perceived health risks from mobile phone masts has been litigated as an issue of whether they must follow a central government planning policy statement and how that statement should be interpreted.[7] Likewise, the ability of an European Community (EC) member state to ban genetically modified organisms from an area is not a legal dispute about the legitimacy of their risk assessment but rather about whether they have met the particular requirements of a specific Treaty Article.[8] Principles such as the precautionary principle can also be deployed in legal reasoning in a variety of legally technical ways (Scotford, 2007; Scotford, 2008). Those hoping to find in the law succinct discussions about the good and bad operation of risk regulatory concepts will be sorely disappointed.

Differences and overlaps between jurisdictions

If law is a form of culture then it obviously follows that legal cultures differ greatly between jurisdictions. Indeed, the ideas, institutions, and processes differ so markedly between legal systems that a lawyer from one jurisdiction will often find it difficult to understand how law operates in a different jurisdiction. Thus for example an inquisitorial civil law operates in a very different way from an adversarial common law system. Most significantly case law does not have the legal authority in the former that it has in the latter. Yet even between common law systems there are often significant differences. Thus for example, US legal culture, particularly in relation to administrative law, is often said to be dominated by adversarial legalism in that many disputes are litigated in the courts (Kagan, 2003). In contrast, the UK administrative law has been dominated by negotiation and informal agreements (Hawkins, 2002; Harlow and Rawlings, 2009). These differences can relate to different socio-political cultures but it is important to remember that law is not just instrumental. Moreover, such cultures are constantly evolving.

Evidence of the heterogeneity of legal cultures is the fact that risk regulatory concepts have played different roles in different legal cultures. Thus for example, risk assessment has dominated US environmental and public health regulation since at least 1980 and has given rise to hundreds of cases in which the legitimacy of decisions about environmental and public health risks has been the subject of judicial review actions. In contrast, in the UK, risk assessment has been only promoted since the mid 1990s but has not given rise to a large body of case law (Fisher, 2007 at Chapters Two and Three).

Moreover, as law is a "culture" then laws cannot be simply transplanted from one regime to another and expected to operate in the same way. Zedner notes the danger of borrowing from other jurisdictions and the…

> … [s]erious limitations of policy-oriented comparative research, not least for those who go abroad like some modern peripatetic surgeon in search of new medicine or organs with which to remedy domestic ills. Without proper regard for the social body in which apparently attractive procedures or institutions operate, the attempt to transplant may prove fatal (Zedner, 1995, pp. 11-12).

How risk assessment operates in relation to the US Environmental Protection Agency (EPA) is very different from how it operates in relation to European Food Safety Authority (EFSA) and that is different again from how risk assessment is understood and interpreted under the Australian Gene Technology Act 2000.

Globalisation and the rise of supranational and international legal cultures

Legal cultures are different but as seen above there is interaction and transfer between them. Much of this has been to do with economic, social and legal globalisation and these different forces have also led to the creation of supranational and international regimes such as the EC and WTO. The key point to appreciate about these new institutional and regulatory frameworks is that they too are embedded in their own legal cultures which are just as complex as national legal cultures. Institutions such as the WTO, European Commission, or Codex Alimentarius Commission are not objective or neutral and the law they produce is not just rules (Cass, 2005).

The emergence of these legal cultures creates two contradictory forces in the operation of risk regulatory concepts. On the one hand, these emerging international and supranational legal cultures results in a proliferation of different interpretations of risk regulatory concepts and different situations in which such concepts might operate. Thus for example, within the EU, at least six overlapping categories (Fisher, 2007 at Chapter Six) can be identified in which the precautionary principle is operating:

- The application by Community institutions in carrying out their international obligations.
- The application by Community institutions in exercising their power pursuant to a Community regulatory regime or competence.
- The application of the principle by member states when operating pursuant to Community regulatory regimes.
- The application of the principle by member states where there is a Community: regulatory regime but a member state wishes to rely on the principle in derogating from the obligations of that regime.
- The application of the principle by member states where there is no Community: Regulatory regime but application *prima facie* infringes other Community obligations.
- The application of the principle by member states in matters with no relationship to EU law.

Moreover, the number of categories multiplies when one also takes into account different subject matters as well as the different international regimes that govern EU decision making. In such circumstances, it is entirely legitimate that the precautionary principle will be given a range of different interpretations and be playing different roles. In other words, globalisation increases legal uncertainty by increasing the opportunities for multiple interpretations of concepts and overlapping regimes. Moreover, these different contexts are not operating independently from each other but rather a single decision maker may be subject to a range of different regimes operating in different legal cultures. Thus for example, thinking about food safety in France requires consideration of French, EC, and WTO law and the complex interrelationship between each which can result in different definitions of legal concepts and different regulatory obligations being imposed on a decision maker.[9]

On the other hand, a key feature of globalisation is the promotion of the uniform application and interpretation of concepts. Indeed, the promotion of risk regulatory concepts is one example of this and regimes such the WTO and EU have played a key role

in that process of promotion. Uniformity is valued because it creates legal certainty. Thus for example, within the EU, the European Commission has promoted a "common understanding" of the precautionary principle, despite the fact that as see above, it is operating in many different contexts (Commission of the European Communities, 2000a). The key point is that we should not be naïve and think that globalisation leads to uniform interpretation. Moreover, it should be recognised that the promotion of global approaches to risk regulatory concepts do raise some difficult questions about the interrelationship between different forms of public administration in different legal cultures.

Numerous legal interpretations

The fourth important implication of law being a form of legal culture is that within one jurisdiction there is not always one agreed interpretation of the law. Law is be interpreted in different ways with different outcomes. Thus while decision makers often wish for legal certainty it is not always possible, particularly in controversial areas.

This legal "uncertainty" is for a number of reasons. First, a law may apply differently in different factual contexts. Establishing a "significant risk" in relation to occupational risks from electrocution is different from establishing a "significant risk" from occupational HIV infection and is different again from establishing a "significant risk" from air particulates.[10] Likewise, in English planning law whether public concern about a health risk is a valid consideration for a planning authority to take into account depends upon the nature of the project, the nature of the concern, and the surrounding policy.[11]

Second, language, by its very nature is ambiguous and how it is interpreted will depend on context. As seen above, the concept of "risk" can validly have a number of different definitions and risk in an economics sense means something different from an engineering concept. Moreover, even in the same discipline, a concept can be validly interpreted two different ways. Thus for example, the WTO Dispute Settlement Panels and Appellate Body interpreted the concept of "risk assessment" in different ways in their early decisions concerning the interpretation of the WTO SPS Agreement (Fisher, 2007, Chapter 5).

Third, different legal actors will often promote different interpretations of the law either because such definitions promote the legal outcome they desire (*e.g.* pro or antiregulation) or because a particular legal interpretation accords with their normative or ideological values.[12] Thus for example, the precautionary principle has been given many different definitions by those pushing different ideological and academic agendas. Indeed, in controversial areas such as risk regulation there is often an ongoing dispute over how concepts should be interpreted because a different legal interpretation will lead to different factual outcomes.[13] Fourth, as already noted, the "same law" will be interpreted differently in different legal cultures (see Section 2.6, Differences and overlaps between jurisdictions).

In light of all of the above, an analysis of law must be done with care. A trawl through the case law for how a particular concept is defined without regard to context is pointless. Likewise, an exercise in spotting examples of risk regulatory concepts in different legal systems will remain no more than a game if not accompanied by careful legal analysis. Moreover, it is important to keep in mind that the law, particularly case law, is constantly evolving.

2.7. Law and the constituting and limiting of public administration

So far the discussion about law has focused on its background role. Law has two significant foreground roles however – in providing the framework for decision making by constituting and limiting public administration and by providing arenas for challenging administrative decision making. The former is considered in this section and the latter in the next section. Risk regulatory concepts will be deployed in relation to both roles. Thus risk regulatory concepts may play a role in constituting an institution, in limiting its power, and also in the process of holding it to account.

In limiting and constituting decision making law provides a framework for public administration in three main ways: by defining the competence of institutions; by placing limits on the discretion of decision makers; and by defining the procedures a decision maker must follow. These three roles for law do overlap. Procedures limit discretion and the limits placed on discretion do contribute to our understanding of the competence of an institution. Moreover, it is important to remember that not all these things need to be done through law.

Competence

Law provides a framework for risk decision making because it defines the competence of the institution making the decision. Different institutions will have different competences and this will result in risk being understood and handled differently. Thus an administrative body vested with economic expertise will have a very different competence from an administrative body staffed with toxicologists. There are two different types of competences that can be identified: institutional and constitutional.

Institutional competence

Institutional competence is the competence of a decision maker defined by the powers of the institution that that decision maker is operating within. In some cases, this will be done by a single piece of legislation creating an institution and setting out its power in an explicit manner.[14] A very simple example of this is the US Consumer Product Safety Commission that was set up in 1972. The Consumer Product Safety Commission Act states that the Commission is hereby established, that Commissioners will have expertise in consumer product safety, and lists the range of duties and powers of the Commission.[15] Likewise, the legislation setting out the powers of a number of Australian universities describe managerial risk management and risk assessment as one of the functions of their Councils.[16] There are also some examples where the role of an institution is to promote good risk management among private actors.[17] In other circumstances, legislation will give new powers and competences to existing institutions.[18] Thus for example, the US EPA was set up by Executive Order but different pieces of legislation vest it with different competences and powers (Harris and Milkis, 1989).

Institutional competence will not only be defined by legislation however. Policy can also have an important role. Thus, in the UK Part IIA of the Environmental Protection Act 1990 vests the Environment Agency in the UK powers to identify and deal with land contamination.[19] That legislation however, requires decision makers to have regard to central government policy guidance which sets out risk assessment guidelines.[20] Likewise, departmental policies can also play a role in defining institutional competence, as can more general policy guidelines (Fisher, 2000a; Fisher and Harding, 2006).

Case law can also be important in defining institutional competence. The most high profile example of this is the US *Benzene* decision.[21] The Supreme Court ruled in 1980 that OSHA must establish a "significant risk". The reason for doing this was the majority found it implicit in the Occupational Safety and Health Act's definition of safety standard. The consequences of this ruling was that not only that OSHA needed to develop expertise in risk assessment so as to establish that a significant risk existed before regulating but also that they could no longer use generic policies.

Constitutional competence

The second type of competence established by the law is constitutional competence. Constitutional competence relates to the more general principles of what is constitutionally valid for an administrative decision maker to do and highlighting the significance of it is a reminder that risk decision making is embedded in legal culture and that that legal culture has an important role to play in shaping the powers of risk decision makers.

Principles of constitutional competence vary significantly from jurisdiction to jurisdiction. Thus for example, in the UK there is a greater willingness to delegate discretionary power to administrative decision makers than there is in Germany (Fisher, 2003a). Likewise, within the EC, it is a strict principle that discretionary power cannot be delegated from the main Community institutions.[22] In this case, independent agencies such as EFSA and the European Chemicals Agency have very limited powers and risk regulatory concepts have played a significant role in limiting those powers, particularly in regard to the former. Likewise, the powers of a decision maker can also be limited by the constitutional division between federal and state power such as in Australia.[23]

The alleged lack of constitutional competence will also often be the basis for a judicial review action. Thus for example, in the US, the EPA's exercise of wide discretion under the Clean Air Act was challenged as being unconstitutional due to it offending the non-delegation doctrine although the Supreme Court ultimately upheld the Act.[24] Constitutional competence will also shape how courts review administrative decision making. This will be discussed in more detail below but a prime example is the way in which English courts have reviewed sentencing decisions. These decisions have been characterised as "judicial" in nature and therefore the courts have been willing to review them more intensely than they would "administrative" decisions.[25]

Limiting discretion

The second and most obvious important role that law plays is in defining the limits of decision makers' discretion through defining their duties, responsibilities, and discretionary powers. This role for law overlaps with competence and can be done in a variety of ways. It should be stressed that in many jurisdictions and in many contexts such limitations will not be placed on decision makers and whether they are or not depends on legal culture and historical accident. Moreover, the failure to place limits on decision making is not *prima facie* a bad thing. The history of public administration has highlighted the need for decision makers to have flexible discretion as well as the fact that the expertise of administrative institutions mean that generalist restraints can be inappropriate. As that is the case, few simplistic generalisations can be made about the need to restrain or empower decision makers.

Guiding principles and objectives of decision makers

First, legislation and/or case law may set out guiding principles or policies which decision makers must generally take into account in the exercise of their power. Thus for example, some legislation explicitly states an overall aim for regulation.[26] Take for example the Gene Technology Act 2000 (Australia). Section four states:

The object of this Act is to be achieved through a regulatory framework that:

- provides that where there are threats of serious or irreversible environmental damage, a lack of full scientific certainty should not be used as a reason for postponing cost-effective measures to prevent environmental degradation;
- provides an efficient and effective system for the application of gene technologies; and
- operates in conjunction with other Commonwealth and state regulatory schemes relevant to GMOs and GM products.

This section is separate from the provisions which define the functions of the Gene Technology Regulator and associated committees.[27] Another example is the Food Standards Agency in the United Kingdom. Section 23(2) of its legislation states:

The Agency, in considering whether or not to exercise any power, or the manner in which to exercise any power, shall take into account (among other things):

- the nature and magnitude of any risks to public health, or other risks, which are relevant to the decision (including any uncertainty as to the adequacy or reliability of the available information);
- the likely costs and benefits of the exercise or non-exercise of the power or its exercise in any manner which the Agency is considering; and
- any relevant advice or information given to it by an advisory committee (whether or not given at the Agency's request).

Depending on the legal culture, these overarching aims of legislation may be further interpreted in case law and/or policy. Thus for example, the Gene Technology Act empowers a Ministerial Council to publish policy principles (Section 21) and for the Gene Technology Regulator to establish Risk Analysis Frameworks (Office of Gene Technology Regulator, 2005). The UK Food Standards Agency is explicitly required to publish a statement of its objectives.[28]

Besides these specific pieces of legislation, decision makers may also be limited by principles that apply to a range of decision makers. The widespread inclusion of the principles of ecologically sustainable development in Australian legislation is a prime example of this.[29] Those principles include the precautionary principle (Peel, 2005). Another example is Article 174(2) of the Treaty of the European Communities. That article states:

> Community policy on the environment shall aim at a high level of protection taking into account the diversity of situations in the various regions of the Community. It shall be based on the precautionary principle and on the principles that preventive action should be taken, that environmental damage should as a priority be rectified at source and that the polluter should pay.

The practical implications of this legal provision is that these principles are relevant to a wide range of decisions involving health and environmental risks and it has given rise to a rich policy discourse and to a complex body of case law which concerns how these principles affect the discretion of Community institutions (Scotford, 2008).

Indeed, courts can play an important interpretative role both in relation to these general principles as well as the more specific principles guiding a decision maker.[30] The most high profile example in relation to risk regulatory concepts is the judicial interpretation of the precautionary principle in a number of jurisdictions (Fisher, 2001; Heyvaert, 2006).

Defining risk regulatory concepts

A second way in which the discretion of a decision maker can be limited is that the risk regulatory concepts that they are utilising are defined by legislation or case law. This is because in defining these terms, decision makers do not have the discretion to define those terms themselves. We have already noted that these definitions vary significantly (Section 2.3) and it is also the case that definitions may be included in legislation, case law, policy or emerge from a combination of all three. Indeed, the process of finding risk regulatory concept definitions is not always straightforward. Rarely, will a piece of legislation set out in explicit detail what these different terms mean. Rather, the legal definitions of these concepts can be developed in different ways.

A very simple example of where risk regulatory concepts are defined is in the Regulation creating the European Food Safety Authority. Articles 3(9)-(12) of that regulation defines what are meant by the terms risk, risk analysis, risk assessment, and risk management:

9) "risk" means a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard;
10) "risk analysis" means a process consisting of three interconnected components: risk assessment, risk management and risk communication;
11) "risk assessment" means a scientifically based process consisting of four steps: hazard identification, hazard characterisation, exposure assessment and risk characterisation;
12) "risk management" means the process, distinct from risk assessment, of weighing policy alternatives in consultation with interested parties, considering risk assessment and other legitimate factors, and, if need be, selecting appropriate prevention and control options.[31]

Such detailed definitions are the exception rather than the rule. Much legislation will often use terms without defining them or provide definitions which are open to numerous interpretations. Thus the Food Standards Act 1999 may require the Food Standards Agency to take into account "the nature and magnitude of any risks to public health"[32] but does not define risk. Likewise, the WTO SPS Agreement does not define risk and defines "risk assessment" in the following broad terms:

> The evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of an importing member according to the sanitary or phytosanitary measures which might be applied, and of the associated potential biological and economic consequences; or the evaluation of the potential for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs.[33]

Not surprisingly this term has been subject to different interpretations in dispute settlement proceedings (Fisher, 2007, Chapter 5). In particular, it has been interpreted as a narrow and very specific methodological tool, and as a more flexible concept concerned with a decision maker showing the reasoning of a decision.

Indeed, courts and other bodies holding decision makers to account can play an important role in interpreting these terms. Thus for example, the US Supreme Court decided in 2000 that the US Food and Drug Administration could not regulate tobacco because the FDA could not establish it fell into the definition of "drug" as defined by the Food Drug and Cosmetic Act.[34] Moreover, detailed definitions can often be found in policy. The guidance in relation to land contamination in the UK is an example here (Department for the Environment Food and Rural Affairs, July 2008).

Specific legislative provisions

The third way that the law limits powers is that the specific legislative provision granting power to a decision maker will often set out the basis and the limits of that power. The importance of these legislative limitations should not be underestimated. They will dictate what is and what is not relevant for a decision maker to consider and how such factors should be considered.[35]

In some cases, the legislation will give little guidance. Thus for example, Section 1(a) of the Animal Health Act 1981 (UK) states:

> The Ministers may make such orders as they think fit – generally for the better execution of this Act, or for the purpose of in any manner preventing the spreading of disease.

This is a very wide, albeit not unfettered discretion.[36] It is based on a deliberative-constitutive model of decision making in that it allows flexible decision making which is responsive to particular problems.

In contrast, other legislative provisions can set out how discretion should be exercised in considerable detail. Thus for example para. 655(b)(5) of the US Occupational Safety and Health Act states:

> The Secretary, in promulgating standards dealing with toxic materials or harmful physical agents under this sub-section, shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health and functional capacity even if such employee has regular exposure to the hazard dealt with by such a standard for the period of his working life. Development of standards under this sub-section shall be based on research, demonstrations, experiments and such information as may be appropriate. In addition to the attainment of the highest degree of health and safety protection for the employee, other considerations shall be the latest available scientific data in the field, the feasibility of standards and experience gained under this and other health and safety laws. Wherever practicable, the standard promulgated shall be expressed in terms of objective criteria and of the performance desired.

This is a very detailed legislative provision. It has also been interpreted by the US Federal courts so that terms such as "extent feasible" have been judicially considered at length.[37]

There are also many examples of where risk regulatory concepts are explicitly included in specific legislative provisions. Thus for example, some legislation requires a decision maker to *carry out* a risk assessment in the exercise of their power.[38] Likewise, there are provisions that require a decision maker to take a risk assessment *into account* in the exercise of their power.[39] Other provisions can require decision makers to take into account particular risk assessment techniques.[40]

General administrative law doctrine

The final limits that law places on administrative decision making worth noting are not specifically concerned with risk regulatory concepts but will have a profound impact upon how such concepts operate. These limitations are provided by general administrative law doctrine. We saw some examples above in relation to constitutional competence but there are also an array of doctrines in relation to how legislative provisions should be interpreted[41] and what is *prima facie* a reasonable exercise of discretion.[42] These principles will again vary significantly from legal culture to legal culture. Many of these doctrines will relate to the powers of the reviewing body in their review of an administrative decision maker and thus are discussed in Section 2.8. This is particularly in relation to the US.

There are however many examples, of where courts have developed doctrines that require decision makers to take certain factors into account. The doctrine of legitimate expectations is an example here as are the general principles of EC law such as non-discrimination and proportionality (Tridimas, 2006). Legislation can also do this such as Section 6 of the Human Rights Act 1998 (UK) which states that it is "unlawful for a public authority to act in a way which is incompatible with a Convention right". It is also the case that in most jurisdictions, there are general principles concerning how to determine what is, and is not, a relevant consideration for a decision maker to take into account.[43]

The importance of these general doctrines should not be underestimated. They will be the starting point that lawyers will use to assess the validity of any administrative action. Thus for example, in the UK there exists a publication which gives guidance to civil service decision makers about how the concept of good public administration is understood in administrative law terms (Treasury Solicitor, 2006).

Procedures

Besides establishing the competence of decision makers as well as limiting their power, law also plays a role in setting out the procedures that a decision maker must follow in making a decision.[44] These procedures may relate to the steps a decision maker must take in making decisions, the type of information and factors they must take into account, and the type of consultation they must engage in. Procedures may also relate to how a specific institution, such as a committee, must conduct itself.

The procedures for a decision will thus closely relate to the reasoning process that a decision maker must engage in as well as being a general limitation on the discretion of the decision maker. Moreover, there is a long tradition of requiring decision makers to engage in certain procedures as a means of regulating their decisions – environmental impact assessment being the first major example of this technique (Holder, 2005).

General procedural frameworks

In many jurisdictions there are general procedures that administrative decision makers must follow in the making of decisions. In some cases, these procedures are minimal,[45] but in other cases there procedures are quite substantive. The complex comitology procedures in the EC[46] and the procedures for formal and informal rulemaking under the US Administrative Procedure Act 1946 are examples of the latter.[47] Moreover, general duties concerning freedom of information[48] and committee procedure[49] are often imposed by overarching pieces of legislation.

Moreover, as part of general principles of administrative law there exists a large body of doctrine concerning valid procedure. Much of this has developed out of principles of natural justice and evolved into more general principles of procedural fairness.[50] These have a particularly important role in dealing with the application of risk regulatory concepts to individuals. Thus for example, in the UK it was held procedurally unfair for a prisoner not to be able to respond to the allegation on which a risk assessment of him re-offending was based.[51]

These general procedural frameworks are not only important because those utilising risk regulatory frameworks are often subject to them but also because it is these general frameworks which those calling decision makers to account use as blueprints for defining what is good decision making. Thus for example, in the 1970s there was considerable confusion caused among courts and legal actors by the fact that the rulemaking procedures under new public health and environmental protection legislation departed from established frameworks for decision making by adding extra public participation and analytical requirements.[52] Much of the problem arose because the departures from pre-existing procedures followed no common pattern and was not accompanied by much in the way of explanation (Fisher, 1997; Scalia and Goodman, 1973; Williams, 1976).

Procedural frameworks and risk regulatory concepts

Besides, general frameworks for administrative procedure, there exists more specific decision-making procedures in which risk regulatory concepts are being utilised. As noted in the last section, these procedures may be based on general frameworks but they also may be *sui generis*. Such procedural frameworks also vary significantly in their detail and in where the details of the procedure are set out. Thus for example, the procedures that EFSA's scientific committees follow are set down in internal guidelines[53] and are in delegated legislation for the committees operating under the Gene Technology Act 2000 (Australia).[54]

Besides these very specific legal frameworks for decision making it is also important to note that there has been considerable policy discussion about the overall procedural frameworks for making decisions about risks. While these frameworks are not in legal form they do influence how the law is put into operation. These procedural frameworks have tended to fall into two main categories. First, have been those frameworks which have tended to understand making decisions about risk as a *linear* procedure in which there is an objective process of risk assessment, a political process of risk management, and then a public process of risk communication (Codex Alimentarius Commission, 2004; Commission of the European Communities, 2000a; Commission of the European Communities, 2000b; National Research Council, 1983). A second and more recent procedural framework for risk decision making characterises it as a more *cyclical* procedure in which analysis, deliberation, and consultation are occurring in a symbiotic process (National Research Council, 1996; Presidential/Congressional Commission on Risk Assessment and Risk Management, 1997; Renn *et al.*, 2003; Royal Commission on Environmental Pollution, 1998).

Public participation

Over the last three decades, one of the most controversial aspects of decision making procedure has been the role and the rights of the public to participate in it, particularly in relation to collective decision making about public health and environmental risks. This chapter does not want to re-rehearse those arguments here but it is important to note three important features of public participation in relation to risk regulatory concepts.

The first is that some form of public participation is a feature of most regulatory frameworks that involve collective decision making about risks. Moreover, such public participation exists alongside a role for science and expertise. The depiction of risk decision making as being a choice between scientific or democratic approaches to decision making is thus a false one.

Second, and following on from this, the issue is not so much whether there is any form of participation or consultation in a regime but rather what form these rights take. Thus the public may be asked to comment on a proposal[55] or a decision maker may be under a duty to carry out public meetings.[56] Such meetings may themselves be informal or be governed by their own procedures.[57] Likewise, there may be more substantive participatory schemes. Thus for example, in the US a procedure for negotiated rulemaking was created in the early 1990s.[58] In relation to other regimes, there may be standing consultative committees set up where the role of these committees can be both representative or as a source of specialist advice.[59] How legitimate any of these schemes are understood to be will depend on the model of good public administration in operation.

The final point to note about consultation is that consultation is not only between public administration and the public but can also be required between different administrative bodies (including those in other jurisdictions).[60] Thus for example, under Section 11C of the Quarantine Act 1908 (Australia) in relation to decisions that are likely to result in a significant risk of harm to the environment, the Director of Quarantine must request advice from the Environment Minster as to the "adequacy of the risk assessment process that is proposed to be followed in assessing the risk of harm to the environment".

2.8. Accountability mechanisms and the challenging of decisions

Law is not only playing a role in framing the context in which risk regulatory concepts operate however. It is also providing a range of arenas in which the operation of risk regulatory concepts can be challenged. Such challenges will occur for a variety of reasons but mainly because particular actors do not agree with the outcomes of decisions and/or because they do find them legitimate decisions. As seen in Section 2.4, the operation of risk is often controversial and thus often challenged.

As already noted, public administration is subject to multiple accountabilities and risk regulatory concepts can themselves operate to promote accountability. Thus for example, risk regulatory concepts may be relevant to a range of accountability mechanisms including judicial review, merits review, public inquiries, regulatory impact assessment, and financial audit. Before however, looking at these different mechanisms it is useful to reflect on the concept of accountability which is a complex concept. In particular, it has been argued by some commentators that it is an Anglo-Saxon concept (McDonald, 2000). If this is the case, and if risk regulatory concepts are about promoting accountability, then care must be taken with their operation in very different legal cultures.

At its most basic, accountability is the giving of reasons or explanations for what one does (Normanton, 1966, p. 1). Davies notes that accountability has four major elements: the setting of standards; the obtaining of an account; the judging of such an account; and finally a decision about the consequences that arise from such a judgment (Davies, 2001, p. 81). Davies is identifying accountability as a process involving a series of different steps and different accountability mechanisms will often emphasise different steps. Thus for

example, a public inquiry will emphasise the importance of obtaining information about a decision (the second step) while judicial review will emphasise the importance of judging an account (the third step).

Setting standards

While much discussion about accountability focuses on the last three of Davies' steps it is really the first step of standard setting which is most fundamental. Before holding a decision maker to account a decision must be made about what is the standard that a decision maker will be held to *i.e.* what is a "good" decision. Risk regulatory concepts play an important role in establishing those standards. Thus for example, requiring a decision maker to carry out a risk assessment as part of a regulatory impact assessment is setting a standard that the quality of a decision will then be judged by.

At the same time however, it is important to appreciate that accountability mechanisms will also be used by a range of actors as a means of challenging these standards. In this sense, accountability mechanisms are often highly de-stabilising in that they act as a conduit for different actors to promote different definitions of good decision making (Fisher, 2004). This can particularly be seen in relation to risk regulatory concepts because their use has been so controversial and subject to criticism. The holding of a decision maker to account is in actual fact a process by which the concept of "good decision making" deployed by the decision maker is challenged. Thus in the *Benzene* case, OSHA had relied on a generic carcinogen policy to set the benzene standard and a consequence of the Supreme Court's decision was to make such reliance not valid.

Indeed, much of judicial review litigation is essentially challenges to the criteria of "good decision making" and litigants in judicial review are often arguing that a decision should have been based on different standards. Thus for example, decisions should have been based on a comparative risk analysis,[61] the precautionary principle,[62] cost/benefit analysis,[63] and/or it should have taken different factors into account.[64] It thus becomes the role of the court to determine the standards by which a decision should be judged by and they will do that with regard to the legislative framework and general administrative law doctrine (see Section 2.7). Thus for example, in ruling that the para. 655(b)(5) (see Section 2.7: Specific legislative provisions) of the OSH Act did not allow OSHA to take formal cost/benefit analysis into account, the US Supreme Court paid close regard to the legislative framework.[65] Complex and cryptic frameworks can make this task more difficult for courts.[66]

It is also the case that different accountability mechanisms can impose different standards of good decision making (Fisher, 2005). One example of this is that while the US Clean Air Act does not allow the US EPA to take costs into account in setting ambient air quality standards the OMB regulatory impact assessment process does require them to (Elliott *et al.*, 2001).

Obtaining of an account

The obtaining of an account is the second of Davies' steps. This second step highlights that there are many different means of holding decision makers to account. This was seen above. Legislation sometimes provides (albeit rarely) for particular or specific review mechanisms for certain types of decisions involving risk regulatory concepts.[67] Likewise, in Australia and New Zealand there exists a series of different specialist environmental courts that review planning and environmental decisions on their merits and which have developed special procedures for hearing expert evidence (Edmond, 2008; Fisher, 2008).

It is also the case that the processes in relation to each can result in decision makers having to provide very different explanations. Thus for example, accountability in relation to financial risk management will involve the audit of financial records while an inquiry carried out by a legislative committee such as a select committee may involve wide ranging questioning. In contrast again, judicial review hearings in the UK are done on the basis of written statements[68] while in an Australian environmental court it can involve the giving of concurrent oral expert evidence in a procedure known as "hot tubbing" (Downes, 2005; Edmond, 2008). It is also the case that procedural hurdles to litigants or regulatory actors bringing legal actions such as the rules of standing will impact on the number of cases being brought. Likewise, some decisions are held not to be reviewable. Thus for example, a risk assessment done by EFSA pursuant to Article 8(7) of Regulation 451/2000 is not reviewable because it is not intended to have legal effect (it is advice to the commission).[69]

Risk regulatory concepts can also play an important role in the obtaining of an account. Thus for example, the risk assessment requirements of a regulatory impact statement are laying down guidelines for what account a decision must give of their decision. Likewise, a requirement that a government department should develop a risk management framework is a requirement for that department to provide an account of how they manage all their risks.

Judging of an account

The next step after obtaining an account is the judging of the account. Again there are many different ways that this can be done. Thus for example, it can be done by assessing the analytical rigour and methodological quality of a decision as in the case of specialist peer review or in relation to impact assessments (Deighton-Smith, 2006, p. 21). It could be done by political actors in a political or legislative forum. It could also be done by vesting an appeal body with the power to overturn the decision and replace it with a decision they deem "correct" in a process commonly described as merits review (Fisher, 2008). The different ways in which a decision is judged is once again dependent upon legal culture and historical and legal context.

The most high profile example of judging of an account is judicial review. It should be stressed that this has tended to dominated in the US but not so much in other jurisdictions. In some jurisdictions the grounds of judicial review are codified in legislation[70] while in other jurisdictions they are a product of the common law. The technicality of judicial review doctrine also varies from legal culture to legal culture.

The key thing to note about judicial review is that a court carrying out judicial review has only the institutional and constitutional competence to judge a decision on the basis of whether it is legally valid or not and not whether the decision was a good or correct one (Jaffe, 1965; Jowell, 2000). In other words review of the facts is not seen as generally within the scope of judicial review. Likewise courts have also historically recognised the importance of deferring to primary decision makers in cases where decisions are complex and require specialist knowledge.[71]

These general principles have important implications for the review of decisions about risk because such decisions are fact laden, complex and require specialist knowledge. Indeed, the judicial review of decisions involving environmental and public health risks has given rise to a rich discourse about how such review should be carried out (Bazelon, 1977; Heyvaert, 2006; Leventhal, 1974). Moreover, even within the constraints of judicial

review there are very different ways that such review can occur. One excellent example of this is that two judges of the District of Columbia Circuit of the US Federal Court of Appeals, Judges Leventhal and Bazelon, developed two very different approaches to judicial review in the 1970s. The starting point for both judges was the "arbitrary and capricious" standard as set out in the US Administrative Procedure Act which allows for relatively extensive review.[72] Both judges interpreted this as requiring an administrative body dealing with environmental risks to take a "hard look" but in each case that hard look was of a very different kind.[73]

Leventhal argued that the best way of making sure that a hard look had taken place was to ensure that there was a firm factual basis for decision making.[74] As such, decision makers would also need to establish the reasonableness and reliability of their methodology.[75] Leventhal's concern in developing this approach was ensuring that "expertise is strengthened in its proper role as the servant of government when it is denied the 'opportunity to become a monster which rules with no practical limitations on its discretion'".[76] Expertise was defined narrowly because Leventhal was concerned with the abuse of power.[77]

In contrast Chief Judge Bazelon argued that the role of judicial review, and thus hard look review, was "to monitor the agency's decision making process – to stand outside both the expert and political debate and to ensure that all the issues are thoroughly ventilated" (Bazelon, 1981, p. 211). The focus of judicial review was not on establishing the reliability of the methodology but rather upon ensuring that "complex questions should be resolved in the crucible of debate through the clash of informed but opposing scientific and technological viewpoints".[78] For Bazelon problems about risk were highly socio-political and uncertain.[79] As such regulators were quite different from scientists as they were required to make decisions on "judgement calls"[80] and act in "spite of uncertainty" as opposed to scientists "who sought to conquer it" (Bazelon, 1981, p. 213).

Each of these judges was defining risk and expertise in quite distinct ways and these divergences were due to different concepts of what was the legitimate role for public administration in such circumstances. Leventhal was deploying the rational-instrumental model of good public administration and, for him, risk and expertise were highly rationalist so that public administration was kept under control by limiting its role to applying the facts to the legislative mandate, a process regulated by the rigour of risk assessment and other tools. In contrast, Bazelon was using the deliberative-constitutive model of public administration as his starting point. He recognised that decision making about risk was highly uncertain and ridden with socio-political conflict. Standard setting thus required a more substantive and constitutive role for public administration. Administrative agencies needed to rely less on pure science and rigorous methodology and more on reasoning and dialogue with interested parties. This led each judge to take a very distinct approach to judicial review and thus what can be seen are understandings of what is good administration can also impact upon how a decision is reviewed (Fisher, 2007, Chapter 3).

Consequences

The final thing to note is that the consequences that arise from a decision being judged as not meeting a certain standard can vary significantly. With that said, in the main there are usually few financial consequences as damages for administrative action are relatively limited. In terms of judicial or merits review, a consequence of review may be that a decision is struck down, remanded for reconsideration or replaced. In relation to other accountability mechanisms there may be more widespread political or institutional

consequences such as administrative or legal reform. Moreover, judicial review and merits review decisions will act as precedents for future administrative action and thus they can have a powerful role in shaping decision making.

2.9. A framework for a critical and contextual approach to risk regulatory concepts

This chapter has so far highlighted four features of risk regulatory concepts. First, these concepts are not neutral, instrumental nor objective. The primary purpose in introducing them has been to regulate administrative power and these concepts do so in accordance with normative visions of good administrative governance. In particular they have often been introduced to promote a rational-instrumental model of public administration. Second, risk regulatory concepts are playing a multitude of roles in public administration and at least four were recognised in Section 2.2 above. Risk regulatory concepts will also have a range of different definitions due to different disciplinary and regulatory contexts. As such to talk in universal terms of risk and public administration is naïve. Third, risk regulatory concepts have been subject to considerable criticism that highlights that the operation of these concepts can be problematic particularly in circumstances where decision makers do not have a sophisticated understanding of the quality of information they are dealing with. Finally, and most importantly, risk regulatory concepts are operating within particular contexts and legal cultures that influence how these concepts are defined and operate. Sections 2.5 to 2.8 particularly highlight that point and show how risk regulatory concepts interact in a variety of ways with different aspects of legal culture.

Overall, what this chapter argues is that, in both the design of public administration regimes which utilise concepts of risk, and the operation of such regimes, it is important to take a contextual and critical approach to such concepts. The need for a contextual approach arises because how risk regulatory concepts are defined and operate is dependent on context. A critical approach is needed because risk regulatory concepts are not perfect tools for regulating public administration and a non-sophisticated use of them is deeply problematic. This need to critically reflect does mean that any assumption that these techniques simplify decision making and make it more objective and streamlined is questionable.

The key question thus becomes how decision makers and policy makers should develop a critical and contextual approach to risk regulatory concepts? Below, are a set of five questions that decision makers and policy makers can ask themselves as a starting point in taking such approach. These questions are relevant to those developing risk regulatory concepts, to those utilising such concepts, and those reviewing decisions based on such concepts. Much of what is highlighted below, reiterates points made in the discussion above. These questions do overlap and each of them is really directed at requiring a decision maker or policy maker to know why they are deploying risk regulatory concepts and to understand the complexities and limitations of those concepts.

Why are risk regulatory concepts being deployed or promoted?

The first question to ask oneself is why a particular risk regulatory concept is being deployed or promoted. The purpose of this question is that an understanding of why a risk regulatory concept is being promoted will help in gaining an appreciation of the function, utility, and limitations of a particular risk regulatory concept, as well as what may be relevant in thinking about it. Most importantly, it is a reminder that risk regulatory concepts are tools for decision makers and do not define the whole decision making process.

For example, the European Commission's Communication on the precautionary principle places great emphasis on risk assessment and risk management, despite the fact that historically these procedural tools did not figure significantly in Community law.[81] The reason for this was twofold in that the Communication was both concerned with ensuring EC risk regulation decisions were compliant with the WTO SPS Agreement and that there was a perceived need to address a legitimacy crisis in Community governance (Fisher, 2007, pp. 224-229). As such, the Communication cannot be understood as a simple set of guidelines but rather a document reflecting a set of complex pressures within the Community, particularly because WTO law is ambiguous, and because the debate over the legitimacy of Community institutions is ongoing. In other words, as the Commission notes, the Communication must be understood as an "input into the ongoing debate" and not a set of guidelines set in stone (Commission of the European Communities, 2000a, p. 3).

Another example is the concept of "risk-based" enforcement in the UK which had as its impetus the Hampton Review. In promoting risk assessment, Hampton was hoping that risk assessment would reduce administrative burdens on the regulated while at the same time improve regulatory outcomes (Hampton, 2005). As such, the development of any risk-based enforcement techniques by a regulatory body must by ultimately concerned with those two purposes and if a particular risk-based technique is not delivering either of these things then it must be flawed. Being a "risk-based" technique is not enough for a technique to valid.

Appreciating the purpose of particular risk regulatory concepts is also relevant to those reviewing decisions so as to ensure that review is being carried out on a correct basis and to those relying on decisions that utilise risk regulatory concepts. The latter category is particular important because it ensures that reliance on a decision is not ill-founded. Thus for example, senior officials in the UK government and the members of the Southwood Working Party had very different concepts about the purpose of the Southwood report in relation to the health risks concerning BSE. That mismatch arguably contributed to the crisis in that senior officials relied too heavily on a report which was never expected by its authors to be given such authority (Fisher, 2007, Chapter 2). Early critical reflection would have stopped this occurring.

Reflecting on the catalysts for the promotion of risk regulatory concepts also requires appreciation of the fact that some reasons for promotion may be naïve and others may be problematic. In the former category are examples where it is hoped that risk regulatory concepts will simplify complex decisions to the point that complexities no longer exist. As seen above, that cannot occur. There are no quick solutions to difficult problems. In the latter category are examples where concepts are being promoted for a particular ideological end or to further purposes which are at odds with an accepted regulatory scheme. In all these cases, reflection and discourse may be required before going further.

What models of good public administration are being promoted by risk regulatory concepts?

The second question that decision makers and policy makers need to ask themselves relates to the first and concerns what models of good public administration are being promoted by particular risk regulatory concepts? As seen in the introduction, risk regulatory concepts are promoted on the basis that they will deliver good administration but there is disagreement about what is "good". With that said, over the last decade risk regulatory concepts have been primarily promoting a rational-instrumental model of good administration.

Appreciating the relationship between a particular risk regulatory concept and a specific model of good public administration enables a decision maker to delve deeper into the purpose for introducing a particular concept into decision making. Thus for example, the promotion of risk assessment is usually a shift away from discretionary decision making. Accordingly, while a risk regulatory concept is a tool, the effective application of the concept may require broader institutional reforms to legislation and institutional structures. Likewise, there is also a need to consider how appropriate any particular model of public administration is in particular circumstances. Thus for example, a rational-instrumental model of administrative decision making would clearly be inappropriate in cases of child welfare or mental health where good decision making heavily relies on flexible professional judgment. In contrast, the stationary purchasing decisions of an administrative body do lend themselves more to a rational-instrumental model of administration. In between these two extremes are many examples where a mixture of rational-instrumental and deliberative-constitutive models is what is needed.

Again, the model of public administration being promoted by risk regulatory concepts is also significant for those reviewing decisions and for those relying on decisions which utilise risk regulatory concepts. Thus for those reviewing decisions, it helps establish the standard of what is reasonable for a decision maker to do and thus how that decision maker should be judged (see Section 2.8, Obtaining an account). It may also highlight the fact that there is a mismatch between what a decision maker thinks is "good decision making" and what the person reviewing that decision thinks it is.

What disciplines are needed for the operation of risk regulatory concepts?

The first two questions outlined above are relatively abstract ones but the third question is a more practical one – what disciplines are needed for the operation of risk regulatory concepts? This question is important because it requires decision makers and policy makers to recognise that there are often quite onerous information and expertise needs which result from the introduction of risk regulatory concepts.

Thus for example, complex financial risk management instruments require considerable financial knowledge and those with experience and expertise in using such instruments. The introduction of risk regulatory concepts thus may require new staff, training, and greater resources for information collection. Demanding that a decision maker do a risk assessment is a waste of time if they have no information on which to base it. Likewise, it may be inappropriate to require decision makers to use particular risk regulatory concepts if such concepts are highly resource intensive. Thus for example imposing obligations on resource stretched local authorities may not be appropriate.

Likewise, there is also a need for decision makers and policy makers to think about the limits of both knowledge and expertise. Thus for example, there has been a failure of policy makers and decision makers to understand the fact that much risk assessment relies on modelling but modelling is a limited and malleable tool (National Research Council, 2007; Policy Foresight Programme, 2008). There has also been general lack of appreciation of the complex nature of scientific uncertainty. Moreover, there is a need to scrutinise any particular claims made about the predictive capacities of a discipline. One can understand the value of being able to predict who was going to commit crimes but anyone making such a claim is to be doubted as experience with predicting human behaviour tells us such an activity is a problematic enterprise.

None of this is to say that we should not rely on expertise and information but rather decision makers and policy makers need to appreciate the limits of both. In particular, it needs to be appreciated that a risk assessment or a particular expert may not provide a definitive answer to a question and substantive discretion may still need to be exercised in relation to a problem.

What is the role of law in the operation of risk regulatory concepts?

The fourth question for policy makers and decision makers to consider is what the role of law is in the operation of risk regulatory concepts. This question is useful for two reasons. First, it highlights that risk regulatory concepts may have direct legal implications and knowing what those implications are, is necessary to a decision maker as it provides them with a clearer picture of what is valid for them to do. Thus for example, knowing that how the concept of "risk" is defined will influence the legal boundaries of a decision maker's power is obviously important (see Section 2.7: competence; and: limiting discretion and 2.7.2). The same is true of being aware that the use of a risk regulatory concept may directly relate to how a decision maker is held to account (see Section 2.8, Setting standards). Appreciating the procedural steps that are entailed in a risk assessment can assist in reforming decision making processes.

Care must be taken however in ensuring that an assessment of the legal implications is not too simplistic. As discussed above, the legal implications of the operation of a risk regulatory concept may be different in different contexts and different legal cultures. Thus for example, the WTO SPS Agreement is relevant to food safety decisions but not environmental protection measures. Judicial review of regulatory decisions is common in the US but not in the UK. Likewise, the legal implications will often be ambiguous. One of the problems of current debate about risk regulatory concepts is that it is often based on a very crude understanding of law. Thus for example, legal issues such as tort liability may be relevant in the US but are not as relevant in the UK.

The second reason why analysing the legal implications of risk regulatory concepts is useful is that asking the question reminds that risk regulatory concepts are not operating in isolation and must interact with a range of other features of an administrative regime and those interactions may be quite complex. This is the bulk of what was discussed in Sections 2.5 to 2.8. An analysis of the law is thus a way for decision makers and policy makers to understand that the operation of risk regulatory concepts is rarely straightforward.

What does experience with risk regulatory concepts tell us?

The final question that a decision maker or policy maker must ask themselves is what does experience with risk regulatory concepts tell us? In other words, there is a need to monitor, review and reflect on how risk regulatory concepts are used and what the consequences of such use are. Monitoring has become a *cliché* in regulatory regimes but its importance cannot be overstated. Risk regulatory concepts are predictive tools and the quality of such tools can only be assessed in light of what happens after they are deployed. If risk-based enforcement results in widespread illegal action on the part of the regulated its utility is to be doubted.

In many jurisdictions such reflection has taken place, often by independent bodies (Royal Society, 1992; Committee to Review the OMB Risk Assessment Bulletin – National Research Council, 2007; Presidential/Congressional Commission on Risk Assessment and Risk Management, 1997; National Research Council, 1994; and National Research Council, 1996). The conclusion of nearly every single one of these reviews is that decision making

involving risk regulatory concepts is far more uncertain and value laden than was originally expected. As such, it is nearly always concluded that a less linear and more sophisticated approach should be taken. There is also considerable value in independent review of past disasters and controversies to understand what occurred (Inquiry into BSE and vCJD in the United Kingdom, 2000; Harremoës *et al.*, 2002; and President's Commission on the Accident at Three Mile Island, 1980). Again such reviews have tended to highlight uncertainty and the importance of organisational culture. Such reviews can also be frustrating in that they often provide little in the way of definitive answers.

In carrying out review and reflection it is important to note two important things. First, decision making can never be perfect and mistakes will happen. This is often difficult to accept in an era in which such mistakes can carry heavy legal and political costs but mistakes are a necessary feature of dealing with the future. The real issue thus becomes what are acceptable and unacceptable mistakes in light of a realistic assessment of the disciplinary and institutional context. Making that distinction is not easy but ignoring the importance of that distinction is not helpful.

Second, review and reflection need not necessarily result in a complete overhaul of a risk regulatory concepts but often adjustment and minor reforms (Committee to Review the OMB Risk Assessment Bulletin – National Research Council, 2007). The need for dealing with the future is a necessary feature of governing and the value of expertise and information in governing is obvious. What is important in review and reflection is to appreciate that there are many different ways to deal with the future and there are many different ways to define expertise and information, and to use them.

Conclusion

Non-lawyers often grow frustrated with the pedantry of lawyers and legal academics and their non-committal answers of "it all depends" and "you could argue it this way". There are many aspects of this chapter which will frustrate in this regard. As a study of risk regulatory concepts from a legal perspective it has shown that such concepts are neither simple nor straightforward. It is only by appreciating that fact however, that these concepts can contribute to improving public administration.

In this regard, it is important to remember that governing would be a lot easier if we did not have uncertain futures to deal with. Yet uncertain futures are an inherent fact of life. Moreover, as everyone who is engaged with administrative governance knows, there are no simple answers or utopias when it comes to public administration (OECD, 2008, pp. 48-54). Good public administration is not a product of a simple formula, just vesting discretion in the "wise", or enlarging public participation. Rather it is the product of ongoing debate, ongoing reflection and a constant balancing act between contradictory forces. The role of public administration in an advanced democracy is paradoxical and the operation of risk regulatory concepts reflects that fact.

Notes

1. This chapter was prepared for the OECD by Dr. Elizabeth Fisher, Fellow in Law, Corpus Christi College, University of Oxford.
2. Thus for example, the new EU chemicals regulation, by requiring chemical manufacturers and importers to carry out risk assessments results in chemical markets taking into account risk assessment information. See Regulation (EC) 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) 793/93 and Commission Regulation (EC) 1488/94. See also Examples of this includes. 165 Anti-Money Laundering and Counter Terrorism Financing Act 2006 (Australia); Section 29H Superannuation Industry (Supervision) Act 1993 (Australia). For a general discussion of dealing with uncertainty in regulatory strategy see Jones, 2007.
3. This can be seen in the environmental health context: *Industrial Union Dept AFL-CIO v. American Petroleum Institute*, 448 US 607 (1980), although this is not always straightforward see in Case T-13/99, *Pfizer Animal Health SA v. Council* [2002] ECR II-3305.
4. For examples see *www.hm-treasury.gov.uk/about/about_riskmanage.cfm* (HM Treasury) and National Probation Service, 2004.
5. This point is often made in the study of major industrial accidents. See Perrow, 1984; President's Commission on the Accident at Three Mile Island, 1980.
6. 37 Federal Register 8601 (28 April 1972). Note it was challenged. See *Industrial Union Dept, AFL-CIO v. Hodgson* 499 F 2d 467 (DC Cir. 1974) and 62 Federal Register 1494, 10 January 1997.
7. *T Mobile (UK) Ltd. v. First Secretary of State* [2005], Env LR 18 and *Harris v. First Secretary of State* [2007] EWHC 1847 (Admin).
8. Article 95(5). See Case T-366/03, *Land Oberosterreich v. Commission* [2005] ECR II-4005 and Case C-439/05, *Land Oberosterreich v. Commission of the European Communities* [2007] 3 CMLR 52.
9. For examples see Godard, 2006, Case C-6/99, *Association Greenpeace France v. Ministère de l'Agriculture et de la Pêche* [2000] ECR I-1651, Case C-1/00, *Commission v. France* [2001] ECR I-9989, and Case C-24/00, *Commission v. France* [2004] ECR I-1277.
10. *American Dental Association v. Martin* 984 F 2d 823 (7th Cir. 1993); *Alabama Power Co. v. OSHA* 89 F 3d 740 (11th Cir. 1996); and *AFL-CIO v. OSHA* 965 F 2d 962 (11th Cir. 1992).
11. *Gateshead Metropolitan Borough Council v. Secretary of State for the Environment* [1995] Env LR 37; *Newport Borough Council v. Secretary of State for Wales* [1998] Env LR 174; and *R v. Tanridge District Council, ex parte al Fayed* [1999] 1 PLR 104.
12. *Competitive Enterprise Institute v. NHTSA* 45 F 3d 481 (DC Cir. 1995) and Case C-321/95 P, *Stichting Greenpeace Council v. Commission* [1998] ECR I-1651.
13. Compare Justice Marshall's and the plurality's opinion in *Industrial Union Dept AFL-CIO v. American Petroleum Institute* 448 US 607 (1980) and compare the different judgments in the three cases concerning whether tobacco was a drug under the Food Drug and Cosmetic Act: *Brown and Williamson Tobacco Corporation v. FDA* 153 F 3d 155 (4th Cir. 1998); *FDA v. Brown and Williamson Tobacco Corporation* 529 US 120 (2000); and *Coyn Beahm Inc v. FDA* 966 F Supp 1374 (MDNC 1997).
14. Food Standards Act 1999; Fisheries Management Act 1991 (Australia) (as amended in 2008); Regulation (EC) 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority; and Protection of the Environment Administration Act 1991 (New South Wales).
15. Consumer Product Safety Commission Act 1972 15 USC, para. 2 053-2 054.
16. Section 15 (1B)(e), University of New South Wales Act 1989 (New South Wales).
17. Section 2A(c), Insurance Act 1973 (Australia).
18. Part 6, Resource Management Act 1991.
19. Part IIA, Environmental Protection Act 1990 (United Kingdom).
20. Sections 78B(2) and 78YA Environmental Protection Act 1990 (United Kingdom). For the guidance see Department for the Environment Food and Rural Affairs, July 2008 and Department for the Environment Food and Rural Affairs, 2006.

21. *Industrial Union Dept AFL-CIO v. American Petroleum Institute* 448 US 607 (1980).
22. Case 9/56, *Meroni v. ECSC High Authority* [1957-8] ECR 133.
23. For examples in the environmental sphere see *Commonwealth v. Tasmania ("Tasmanian Dam Case")* (1983) 158 CLR 1 and *Murphyores Incorporated Pty Ltd. v. The Commonwealth* (1976) 136 CLR 1.
24. *Whitman v. American Trucking Associations* 531 US 457 (2001).
25. *R v. Secretary of State for the Home Department Ex p. Pierson* [1998] AC 539 and *R v. Secretary of State for the Home Department Ex p. Venables* [1998] AC 407.
26. Sections 5-8, Resource Management Act (Nez Zealand); Sections 3-3A, Fisheries Management Act (Commonwealth); and Sections 3-6, Financial Services and Markets Act 2000. See also the role that preambles play in European Community Directives and Canadian legislation.
27. Sections 27, 1001 and 107 Gene Technology Act 2000.
28. Section 22(1), Food Standards Act 1999 and Food Standards Agency, 2000.
29. *BGP Properties Pty Limited v. Lake Macquarie City Council* [2004] NSWLEC 399 and 2007.
30. Thus for example consider the importance of the court's interpretation of the US Clean Air Act in *Small Refiner Lead Phase Down Taskforce v. EPA* 705 F 2d 506 (DC Cir. 1983) and *Whitman v. American Trucking Associations* 531 US 457 (2001).
31. Regulation (EC) 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.
32. Section 23(1) Food Standards Act 1999, discussed in Section 7: Guiding principles and objectives of decisions makers.
33. Annex A.4: World Trade Agreement Sanitary and Phyto-Sanitary Agreement.
34. *FDA v. Brown and Williamson Tobacco Corporation* 529 US 120 (2000).
35. See for example the analysis in Case C-14/06 and C-295/06, *Parliament and Kingdom of Denmark v. Commission of the European Communities*, 1 April 2008.
36. There being no such thing as an unfettered discretion in UK administrative law: *Padfield v. Minister of Agriculture Fisheries and Food* [1968] AC 997.
37. *American Textile Manufacturers v. Donovan* 452 US 488 (1981); *United Steelworkers of America v. Marshall* 647 F 2d 1189 (DC Cir. 1980); and *American Iron and Steel Institute v. OSHA* 939 F 2d 975 (DC Cir. 1991).
38. Section 74 Canadian Environmental Protection Act 1999, Section 16A Children's Act 1989 (United Kingdom); Section 67 Criminal Justice and Courts Services Act 2000 (United Kingdom); Section 50 Gene Technology Act 2000 (Australia); and Section 103(3)(a) Food Act 2003 (New South Wales).
39. Section 885J Corporations Act 1991 (Australia); and Section 266K Environmental Protection Act 1994 (Queensland).
40. Article 19, Regulation (EC) 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) 339/93.
41. In the US see *Chevron USA Inc v. NRDC* 467 US 837 (1984).
42. In the US see *Motor Vehicles Manufacturers Association v. State Farm Mutual Automobile Insurance Company* 463 US 29 (1983); in the UK see *Associated Provincial Picture Houses Ltd. v. Wednesbury Corporation* [1948] 1 KB 223; and in Australia see *Re Minister for Immigration and Multicultural and Indigenous Affairs; Ex parte Applicant S 20/2002 v.* (2003) 198 ALR 59.
43. *Minister for Aboriginal Affairs v. Peko-Wallsend Ltd.* (1986) 162 CLR 24.
44. Gene Technology Act 2000 (Commonwealth) or any of the rulemaking procedures in US risk regulation legislation.
45. Statutory Instruments Act 1946 (United Kingdom).
46. Decision 1999/468/EC laying down the procedures for the exercise of implementing powers conferred on the Commission (as amended).
47. 5 USC, para. 553-557.

48. Freedom of Information Act 5 USC, para. 552.
49. Federal Advisory Committee Act 5 USC 562.
50. *Ridge v. Baldwin* [1964] AC 41.
51. *R (Price) v. Governor HMP Kirkham* [2004] EWHC 461 (Admin).
52. For examples see Clean Air Act 42, para. 7607(d); Toxic Substances Control Act 15, para. 2605(c); and Federal Water Pollution Control Act 33, para. 1317.
53. Article 29(9) of Regulation (EC) 178/2002 of the European Parliament and of the Council of 28 January 2002, laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.
54. Gene Technology Regulations 2001 (Australia) (as amended in 2007).
55. Administrative Procedure Act 5 USC, para. 553.
56. Clean Air Act 42 USC, para. 7607(d).
57. Toxic Substances Control Act 15 USC, para. 2605(c).
58. Negotiated Rulemaking Act 5 USC, para. 561 et seq.
59. See the importance of the distinction in *Flue-Cured Tobacco Co-op. v. EPA* 4 F Supp. 2d 435 (MD NC, 1998) as discussed in Fisher, 2000b.
60. Article 17, Council Directive 96/61/EC of 24 September 1996 concerning integrated pollution prevention and control and Article 7, Council Directive of 27 June 1985 on the assessment of the effects of certain public and private projects on the environment (85/337/EEC).
61. *Competitive Enterprise Institute v. NHTSA* 956 F 2d 321 (DC Cir. 1992).
62. *R v. Secretary of State for Trade and Industry ex parte Duddridge* [1995] Env LR 151; *Friends of Hinchinbrook Society Inc v. Minister for the Environment* (1997) 142 ALR 632.
63. *American Textile Manufacturers v. Donovan* 452 US 488 (1981); *United Steelworkers Of America v. Marshall* 647 F 2d 1189 (DC Cir. 1980); and *International Union, UAW v. OSHA* 938 F 2d 1310 (DC Cir. 1991).
64. *Corrosion Proof Fittings v. EPA* 947 F 2d 1201 (5th Cir. 1991); *Gray v. Minister for Planning* [2006] NSWLEC 720; and *R v. Secretary of State for Health ex parte Eastside Cheese Company* [1999] 3 CMLR 123.
65. *American Textile Manufacturers v. Donovan* 452 US 488 (1981).
66. *Industrial Union Dept, AFL-CIO v. Hodgson* 499 F 2d 467 (DC Cir. 1974).
67. Section 181 Gene Technology Act 2000 (Australia) and Article 91 Regulation (EC) 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) 793/93 and Commission Regulation (EC) 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.
68. Part 54, Civil Procedure Rules.
69. Case T397/06, *Dow AgroSciences Ltd. v. European Food Safety Authority*, 17 June 2008.
70. 5 USC para. 706; Administrative Decisions (Judicial Review) Act 1977 (Australia); and Article 230(2) TEC.
71. *Federal Power Commission v. Hope Natural Gas Co.* 320 US 591 (1944); *R v. Chief Constable of Sussex ex parte International Trader's Ferry* [1998] 2 AC 418; Case C-331/88, *R v. Minister of Agriculture, Fisheries and Food and Secretary of State for Health, ex parte FEDESA* [1990] ECR I-4023.
72. 5 USC, para. 706(2)(A).
73. Although not always different outcomes. See *Ethyl Corp v. EPA* 541 F2d 1 (DC Cir. 1976).
74. *Portland Cement Association v. Ruckelshaus* 486 F 2d 375 (DC Cir. 1973) at 393. See also Leventhal, 1974.
75. *International Harvester v. Ruckelshaus* 478 F 2d 615 (DC Cir. 1973) at 643.
76. *Greater Boston Television Corp v. FCC* 444 F 2d 841 (DC Cir. 1970) at 850.
77. *Walter Holm and Co. v. Hardin* 449 F 2d 1009 (DC Cir. 1971) at 1016.
78. *International Harvester v. Ruckelshaus* 478 F 2d 615 (DC Cir. 1973) at 651.

79. His lengthiest analysis of this can be seen in *Natural Resources Defense Council v. Nuclear Regulatory Commission* 547 F 2d 633 (DC Cir. 1976).

80. *AFL-CIO v. Marshall* 617 F 2d 636 (DC Cir. 1979) at 651.

81. This is best illustrated in cases such as Case C-331/88, *R v. Minister of Agriculture, Fisheries and Food and Secretary of State for Health, ex parte FEDESA* [1990] ECR I-4023 and Case C-180/96, *United Kingdom v. Commission* [1998] ECR I-2265 where there was no discussion of risk assessment.

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Chapter 3

Strategic Issues in Risk Regulation and Risk Management

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Public officials are increasingly facing the need to make decisions about policies where future uncertainties are economically significant and unavoidable. Today the issue of risk looms so large that some observers speak of a "risk society", where problems of "risk distribution" replace those of income distribution which characterised industrial society. The need of clear and consistent principles for dealing with uncertainty is as urgent in the public sector as it was in the private sector a few decades ago. This chapter presents concrete examples of the practical consequences of confused thinking about the principles of decision making under uncertainty, pointing out, for example, the shortcomings of the precautionary principle as a general decision rule. A key element of this chapter is that the theory of decision making under uncertainty provides the appropriate conceptual framework for thinking about uncertain events and their consequences, and thus also for thinking about risk. One limitation of this theory, however, is that it has been developed for structuring the choice problems of an individual decision maker and so does not provide unambiguous advice for group decisions when different stakeholders have different attitudes toward risk. But the methodology is nonetheless helpful without providing formal solutions.

Introduction

Defining an appropriate analytical framework is of critical importance for effective risk policies. Public officials are increasingly facing the need to make decisions about policies where future uncertainties are economically significant and unavoidable. Today the issue of risk, in its multifarious forms, looms so large in public discourse and in popular perceptions that some observers speak of a "risk society", where problems of "risk distribution" replace those of income distribution which characterised industrial society.

In such a situation the need of clear and consistent principles for dealing with uncertainty is as urgent in the public sector as it was in the private sector a few decades ago. Perhaps the most convincing way of demonstrating this need is to provide concrete examples of the practical consequences of confused thinking about the principles of decision making under uncertainty.

This chapter will present numerous examples of such confused thinking. A number of such examples are in fact scattered throughout the present chapter. Sections 3.6 and 3.7 in particular, point out the shortcomings of the precautionary principle as a general decision rule, while Section 3.8. shows how, in the United States, early approaches to risk regulation have been progressively refined along the lines suggested by modern decision theory. This introduction considers an old, but still instructive, episode from the early history of risk regulation (Box 3.1).

Several lessons can be drawn:

- First it is obvious that risk regulators operate on the basis of great, and in many cases irreducible, uncertainty (see Sections 3.1 and 3.2). Such uncertainty is too important to be treated in a purely intuitive and qualitative way; rather, it should be expressed in terms of numerical probabilities. These probability estimates are necessarily subjective, but they are explicit, hence open to scrutiny by third parties, and can be revised in a logically consistent way when new information becomes available. The reluctance of medical doctors and health scientists to think in probabilistic terms, and to express subjective estimates has already been noted some time ago.[2] Since then, the situation has not greatly improved in this respect, while the idea of making net benefit assessments, rather than consistently favouring worst-case scenarios, if anything, has gained greater acceptance.
- A second important lesson is that a zero-risk approach is untenable practically as well as conceptually (such as is implied by the Delaney clause, but also by some versions of the precautionary principle). Since the FDA's saccharin ban the capacity to detect chemicals in foods in quantities as small as parts per trillion has been perfected. These scientific advances further complicate the regulatory task since the significance of such tiny amounts in carcinogenesis is generally unknown. What is clear, however, is that absolute safety cannot be a sensible regulatory goal.

Box 3.1. **An early example: the Saccharin case**

Moving away from full certainty towards rational decisions under uncertainty

This early episode refers to the Saccharin Ban imposed by the US Food and Drug Administration (FDA) in 1977, after a study sponsored by the Canadian government showed a significant increase in bladder tumours among male (especially second-generation) rats exposed to high levels of saccharin consumption. According to the agency, the ban was made necessary by the wording of the so-called Delaney anticancer clause to the 1958 Food Additives Amendment. The Delaney clause reads, in part: "No additive shall be deemed safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of food additives, to induce cancer in animal or man."

According to FDA officials, this proviso authorises the agency to exercise scientific judgment in determining whether a test is an appropriate one, and whether the results demonstrate induction of cancer. But once the agency has made its determinations concerning these two matters, no further inquiry is allowed. For example, the agency may not establish a maximum level of safe use, or authorise further use of an additive based on a judgment that the benefits of continued use outweigh the risks involved. The proposed saccharin ban was very controversial, particularly since an acceptable saccharin substitute did not exist at that time, and the possibility of developing a non-nutritive sweetener that was safe and economic, was judged to be remote. Actually, the evidence against saccharin was less than overwhelming. Laboratory studies of rats repeatedly showed a weak carcinogenic effect, but retrospective human studies failed to reveal a consistent link between saccharin consumption and bladder cancer. The weight of medical testimony before congressional subcommittees was that: *i)* saccharin is probably a weak carcinogen that could have substantial adverse effects on human health if consumed in large quantities over prolonged periods; but *ii)* a ban on saccharin could also pose risks, especially if saccharin users responded by substantially increasing their consumption of sugar or other high-calorie foods. Despite congressional awareness of the fact that saccharin might provide consumers with benefits as well as posing health risks, congressional hearings failed to produce any definite conclusion. The only outcome was continuing postponement of the ban, coupled with labelling requirements. The Food and Drug Administration did try, however, to modify in practice a conceptually flawed, but legally binding, decision rule. Thus, the agency has sometimes concluded that a substance is not a "food additive", and hence is not subject to the Delaney clause, even though it occurs in food, arguably through human agency. For example, FDA has refused to regulate compounds such as PCBs and aflatoxin. Proceeding in this fashion, by the mid-1980s the agency had effectively narrowed the application of the Delaney clause to direct food additives.

- Third, a good decision rule must take into consideration all the important elements of the risk problem: the level of uncertainty, the health and other risks, as well as the potential benefits of alternative measures. As is shown in Section 3.5, a decision rule that fails to consider all such elements tends to distort regulatory priorities. One of the most important issues facing legislators and risk regulators today is to move away from the *ad hoc* rules of the past (for example, uncritical use of "safety factors"), towards more inclusive and logically defensible principles. This presupposes a significant capacity for policy learning, and it is encouraging to observe that some countries have indeed been able to correct past mistakes in their approach to risk regulation (see Section 3.8).

Before concluding these introductory remarks it may be worthwhile to mention a fourth lesson: *this case suggests that people are quite prepared to trade off, at the margin, risks and benefits, as long as both sides of the benefit/cost equation are honestly and convincingly presented to them*. As already mentioned, the proposed saccharin ban was very controversial, particularly since an acceptable substitute did not exist. Congressmen reportedly received more mail on saccharin than on any other issue since the Viet Nam war. Representatives of health organisations testified at congressional hearings that saccharin provides enormous health benefits to persons, such as diabetics, who must restrict the intake of sugar. In response to widespread opposition to a regulatory decision which took the remote risk posed by a product, but not its benefits, into account, Public Law 95-203 was passed, providing for a moratorium during which period the National Academy of Sciences was asked to review federal food safety policy, with special emphasis on saccharin.

A gap often separates the public's risk perception from the assessment of the experts. According to a number of empirical studies, there is a tendency to overestimate events associated with lower-probability events, while ignoring potential benefits. But in the case of the saccharin ban we have, in a sense, the reverse situation: a public acceptance of some risk for the sake of well-understood benefits. This leads one to suspect that the exclusive concentration of some decision rules on (often negligible) risks, regardless of foregone benefits, may be politically inspired – for example, in the shape of "position taking" in parliament, or protecting special interests – rather than a reflection of genuine popular preferences.

Managing risks from a regulatory management perspective requires not only appropriate analytical foundations and institutional set-up, but also an appropriate communication strategy that will enable all individuals as well as society to accept the best rational trade-offs, with a clear and honest presentation of both sides of the benefit/cost equation.

3.1. The implications of regulatory science for risk management

Managing risks in a regulatory framework requires addressing a mix of analytical and institutional aspects. From the analytical perspective, significant aspects may have complex, and often unintended consequences, as rational decisions have to be taken in an *uncertain* world, where uncertainty cannot be eliminated. Uncertainty is pervasive in risk regulation, by definition. What seems to be less well understood is that in many cases, uncertainty is not only pervasive but also irreducible, as is illustrated by the example of potential chemical carcinogens. The heterogeneity of human populations, as well as the difficulty in finding the best close animal specie for tests leaves public authorities with an almost impossible regulatory task in terms of managing and fully securing the risks associated for potential carcinogens for the overall population, including high risk groups. The difficulty to produce solutions that are entirely and totally logical to the various problems of risk assessment leaves regulators dealing with scientific uncertainty, and with the need to search for various "safety factors" or conservative assumptions, which are nothing else than empirical rules of thumb, which is one reason that explains the origin of the so called "*precautionary principle*".

Typical regulation of carcinogens is based on laboratory tests involving animals. A major issue is the determination of the animal species that best predicts the response of humans. Would the same species be equally predictive for all carcinogens being tested? Do species differ in the degree to which they can predict toxicity for specific organ systems – kidney, liver, lungs, and so on? Which "animal model" best simulates the pregnant woman, the

new-born child, or individuals with inadequate diet or genetic deficiencies? There are no unequivocal answers to such questions. Thus, many researchers have criticised the excessive use of rodents as predictive models because rodents are phylogenetically further removed from humans than other species, such as the dog or the monkey. Yet, some years ago a scientific panel of the Unites States Food and Drug Administration on carcinogenesis did not recommend the general use of the dog in the testing of chemical carcinogenesis because of its large size and relatively long life span.

Several scientific as well as practical aspects have to be considered. There is, in fact, little hope that one species could provide the broad range of predictive potential needed to assess the responses of a highly heterogeneous human population to different types of pollutants. Predictions could be improved by using multiple species in toxicological experiments. But heterogeneity in human populations is often social in origin, and social conditions cannot be reproduced in the toxicologist's laboratory. The issue of human heterogeneity also arises in connection with the prediction of adverse health effects on individuals who are (or may be) at high risk with respect to certain pollutants.

Once the toxic dose for the "normal healthy" population has been derived, consideration must be given to high-risk groups: children and adults with vitamin C deficiency are hypersensitive to ozone and to a number of heavy metals; pregnant women, to lead and carbon monoxide; people with asthmatic and chronic respiratory diseases, to respiratory irritants such as nitrogen dioxide, ozone, and sulphur dioxide, etc. Standards developed for statistically "normal" individuals should be adjusted in order to protect the sections of the population at high risk. Unfortunately, for a variety of reasons such as lack of detailed exposure information, high-risk groups are seldom considered specifically and separately in setting environmental and health standards, except perhaps through the dubious device of "safety factors", see below.

Strictly speaking, each individual has a unique genetic composition and life history, and thus a unique response to carcinogens and environmental pollutants. This heterogeneity of human populations leaves public authorities with an almost impossible regulatory task, in securing a guaranteed "life time" response for specific products, using specific formal mathematical models, and facing the need to find the safest of all mathematical assumptions (Box 3.2).

What a distinguished statistician wrote in the late 1970s is still largely true today: "All present safety evaluation procedures… must be regarded as mathematical formalisms whose correspondence with the realities of low-dose effect is, and may long remain, largely conjectural" (Cornfield, 1977, p. 698) (see Box 3.2). It might be argued that if there is no firm scientific basis for choosing among different dose-response models, then one should prefer the *safest* or *most* "*precautionary*" procedure. One problem with this argument is that it is not clear where one should stop. A no-threshold model is more conservative than one that admits the existence of thresholds for carcinogenic effects. But within the large class of no-threshold models many degrees of precaution are possible. Again, in designing a toxicological experiment one could use the most sensitive species, the most sensitive strain within the species, and so on down to the level of the most sensitive animal. In short, it is difficult to be precautionary in a consistent manner, unless one is prepared to propose a zero level of exposure in each case. This dilemma, which Jerome Cornfield stated so clearly some thirty years ago, has not yet been resolved by the advocates of such decision rules as the *precautionary principle*.

Box 3.2. **Links between life time response and dose levels**

In an effort to find a way out of these uncertainties toxicologists and statisticians have developed several mathematical models expressing the probability of a lifetime response, P, as a function of dose levels, D: P = f(D). This is the dose-response function, and different choices of functional form – *i.e.* different choices of f – generate different models, such as: the traditional threshold (non-linear) dose-response model; or the linear (non-threshold) model, according to which adverse health effects occur at every level of exposure, and there is no obvious point at which a reasonable standard could be set; or again, a dose-response relationship could be expressed by a curve which is linear at high or moderate dose levels, but at low doses it could indicate more serious health effects than the linear model would have predicted. But how is the functional form f chosen? The usual procedure consists in fitting a curve (by one of several available methods) to the observations in the observable range, and then extrapolating downward to a "virtually safe dose" (VSD). A VSD is defined as a dose level such that the probability of a lifetime response at that level is less than some *preassigned* small probability such as 10 (exp - 8), the value favoured by many toxicologists, or 10 (exp - 6), the value used for example by the US FDA.

There are three major problems with such procedures for determining the shape of the function f. First, the choice of functional form has a major effect on the value of the VSD. Thus, under a threshold model it is possible to establish a "virtually safe" level of exposure (even though high doses produce adverse health effects) whereas, as we saw, this is impossible if one uses a linear model. Second, the different extrapolating functions often cannot be distinguished from each other in the range of the observable responses. Finally, no firm scientific basis exists for choosing among the different possibilities.

Unable to produce logically defensible solutions to the various problems of *risk assessment*, regulators deal with scientific uncertainty by means of various "safety factors" or conservative assumptions, which are nothing else than empirical rules of thumb. Often a safety factor of 100 is used, meaning that test animals should show no adverse health effects from a given pollutant or potential carcinogen when exposed to doses at least 100 times greater than the likely human dose. This particular rule of thumb is sometimes justified by the reasoning that humans may be ten times more sensitive than the experimental animals used, and that there may be in addition a tenfold variation in sensitivity among individuals. But then, how does one justify safety factors of 50 or 500 which are also in use? The consequences of such unsatisfactory methods of dealing with uncertainty are far-reaching, as will be discussed later on in the present chapter. At this point it suffices to point out that reliance on such subjective – but often practically unavoidable – judgments as "virtually safe doses", "acceptable risk doses", "virtual safety", and numerical safety factors, blurs the distinction between risk analysis and risk management. To anticipate a later conclusion: *although the two stages of risk regulation – analysis and management – are conceptually distinct, they are not separable in practice and, hence, should not be separated institutionally.*

The examples mentioned above only begin to give an idea of how pervasive is the uncertainty which faces the risk regulator. Thus, risks posed by drinking water regulated by the US Environmental Protection Agency could be ten times greater or ten times less than the mean estimate of the risk. Similarly, the risks posed by air pollution could be twenty times less than the mean estimate (Viscusi *et al.*, 1996, p. 673, Table 19.6). What is perhaps less well known is that for some problems, such as global warming, the main uncertainty

is with respect to the potential increase in the benefits of controls above current levels. Although temperature seems certain to increase by several degrees in the near future, for northern regions this may be a benefit, while for southern regions it will generally be a disadvantage. Again, the warming in the winter will be beneficial and will occur to a larger extent than warming in the summer, which will have an adverse effect, etc.

The analysis in this section illustrates the intractable aspects of risk analysis, and the pervasive nature of uncertainty. Given this pervasive nature, it may be difficult to draw a clear distinction between risk analysis and risk management, with significant implications in terms of institutional design of regulatory management systems, notably with regards to the need for an *integrated approach of risk analysis and management*.

3.2. Regulatory science and trans-science: scientific analysis *versus* popular perception

Uncertainty in risk regulation is not only pervasive but also irreducible. Careful analysis of old and new controversies about the analysis and management of risk shows a number of "trans-scientific" issues. This shows the boundary between science and "trans-science", for issues over which expert disagreement is most serious, and for which the gap between the available scientific evidence and popular perceptions of risk. "Trans-scientific" issues are beyond strictly scientific or technical issues. In Alvin Weinberg's terminology, trans-scientific issues are questions of fact that can be stated in the language of science but are, in principle or in practice, unanswerable by science (Weinberg, 1972). For both cognitive and practical reasons, intrinsic, irreducible uncertainty is a key feature of regulatory science. The gap between risk assessment and actual risk perception may have significant implications as well in terms of risk management as well as communication over risks. The difficulty in dealing with irreducible uncertainty often lead to a proliferation of such *ad hoc* methods, and to the reference to the so called "precautionary principle", which reveal a lack of understanding of the logic of decision making under uncertainty.

Irreducible uncertainty

For example, at present the choice of a particular dose-response function must be treated as a trans-scientific question since, as we saw, the relationship can be represented by many different functions, but with the experimental data usually available there is no firm scientific basis for choosing a particular functional representation. However, the choice can have a major effect on risk management. Also mentioned was the unreliability of extrapolations outside the experimental range, in particular downward extrapolation from the very high dose levels used in animal experiments. But why are test animals exposed to levels of toxic substances far in excess of those to which humans would be exposed under normal circumstances, thus making downward extrapolation necessary? The answer is that this is done in order to compensate for the small number of animals usually tested.

Thus, if we assume that a chemical agent will cause cancer in 1 out of 10 000 people who are exposed to it, and that humans and test animals do not differ significantly in sensitivity with respect to the given agent, it would be necessary to test 10 000 animals (but preferably something like 30 000 animals) in order to detect one case of cancer. With 1 000 test animals and an unacceptably low confidence level of 90%, the upper confidence limit for a negative experiment (no cancer induced at the given dose level) is 2.3 cancers

per 1 000 tests. It has been calculated that to reduce the upper limit of risk to 2 cancers per one million at a confidence level of 99.9% would require a negative result in somewhat more than three million test animals. In practice, no more than 50 or so animals are usually available per dose level, and this explains the use of high doses on small samples of animals. "Megamouse" experiments with extremely large number of animals have been proposed. Such experiments would allow reducing the experimental doses and hence the unreliability of downward extrapolations; but the costs would be prohibitive and the validity of the conclusions still doubtful because of the problems connected with human heterogeneity and extrapolations from animal test to humans. Analogous issues arise in the regulation of the risks of nuclear radiation – the area where the notion of trans-science originated. Thus, one of Weinberg's examples is the determination of the health effects of low-level radiation. He calculated that in order to determine by direct experimentation, at the 95% confidence level, whether a level of X-rays radiation of 150 millirems would increase the spontaneous mutation in mice by 0.5%, would require about 8 billion mice.

The time frame for decision making

Another defining feature is the necessity of reaching a decision within a reasonable time. Unlike the academic scientist, the regulatory scientist cannot refuse to decide, or postpone a decision while waiting for better evidence: s/he must come to some definite conclusion, however large the area of *subjective* uncertainty. How to deal rationally and consistently with *such irreducible uncertainty* in a limited time frame is the most basic problem of risk regulation.

Safety factors, risk classification ("similar risks should be treated similarly"), worst-case scenarios, least-feasible-risk rule, and the precautionary principle, are all attempts to come to grips with this basic problem. Unfortunately, these and similar attempts are not only *ad hoc*, but logically flawed, practically misleading (since they create a false sense of security), and prone to be misused for protectionist or other purposes having nothing to do with risk abatement. The very proliferation of such *ad hoc* methods of dealing with probabilistic events shows how widespread, even among scientists and regulators, is the ignorance of the logic of decision making under uncertainty.

How to formulate a coherent approach for risk analysis and management?

The rest of this chapter will try to go back to basic principles to see how they may help in formulating a coherent approach to the analysis and management of risk. The aim is not to provide ready-made solutions, but rather to demonstrate the usefulness of a clear understanding of a few fundamental ideas. General ideas must always be adapted to a multiform reality, but the adaptation should be made having in mind, that an approximate answer to the real question, which is often vague, is much to be preferred to a precise answer to the wrong question, in the spirit of John Tukey's.

3.3. Towards procedural rationality when facing uncertainty

Before introducing the basic ideas of probabilistic decision theory, it is useful to draw attention to the important, but often overlooked distinction, between *procedural* and *substantive rationality* (see Annex 3.A1). *Substantive rationality* tends to consider the final outcomes of the decisions themselves, and will be applied in cases of certainty. Uncertainty and more complex cases will lead to *procedural rationality*, with an emphasis on

process, and how decisions are made. This distinction will serve as a means of demonstrating the plausibility of certain key results of the theory, as well as making sense of certain practices in risk regulation, especially at the international level.

Generally speaking, the more complex a system, the greater the reliance on procedural rationality, for, as Talcott Parsons wrote: "Only on the basis of procedural primacy can the system cope with a wide variety of changing circumstances and types of cases without prior commitment to specific solutions" (Parsons, 1966, p. 27). Relatively simple situations – in particular, situations where certainty is assumed, involve an emphasis on emphasise on substantive outcomes rather than processes. Both the focus on substantive results and indifference toward procedures are understandable if one assumes that there exists an objectively best decision in a given situation. If the correctness of the outcome can be determined unambiguously, the manner in which the decision is made is largely immaterial: only results count. This is the reason why the key concept in the traditional theory of choice, whether in microeconomics or in management science, is *optimisation*.

The conditions for choice will differ in an uncertain context, with an increased emphasis on *consistency*, and *procedural rationality*. Optimisation has no well defined meaning when the consequences of a course of action are uncertain – one should not, for example, maximise expected profit without considering, at a minimum, also its variance. By contrast, the key concept in the theory of decision making under uncertainty is not optimisation but *consistency*, a characteristically procedural notion.

Procedural harmonisation provides a good illustration of the importance of procedures in the international regulation of risk. The purpose of harmonisation is to make the regulatory requirements of different jurisdictions more similar, if not identical. Regulatory regimes can differ in numerous aspects, and at least three main types of harmonisation may be usefully distinguished (Leebron, 1996):

- *Specific rules or standards could be harmonised*. These rules prescribe the desired characteristics of the outputs of production processes, institutions, or transactions could be harmonised. For example, emission limits for polluting factories located in different countries may be made more similar. We may call this substantive, or output-, harmonisation since the goal is to reduce pre-existing differences in certain characteristics of the relevant outputs.
- *Regulatory harmonisation may relate to certain governmental policy objectives*. For example, the central banks of the G7 countries attempt to keep inflation within agreed limits – or to general policy principles such as the OECD's polluter-pays principle, or the precautionary principle advocated by the European Commission.
- *Harmonisation of institutional structures, procedures or methodologies is often sought*. The kind of harmonisation which interests us here. Thus, some of the provisions of the North American Free Trade Agreement (NAFTA; the reference here is to the NAFTA "side agreement" on the environment) require that certain procedures for enforcement of domestic laws, including appellate review, be harmonised.

Procedural harmonisation usually serves to reinforce other types of harmonisation. Thus, if the aim is to harmonise decisional outcomes, both substantive criteria and decisional processes are implicated. *Rules, policies, and principles will generally not be truly harmonised unless the procedures and institutions for implementing them are made more similarly effective,* and doing so may mean making them more similar. There are, however, situations where procedural harmonisation is not meant to reinforce other types of harmonisation, but is the only type which is politically, economically, or technically

feasible, which different countries have too different standards and too different levels of domestic protection. Another important example of procedural harmonisation is provided by the WTO Agreement on Sanitary and Phytosanitary Measures (SPMs).[3] Harmonisation is discussed in Article 3 of the Agreement, which refers to international standards.[4] This article is noteworthy in several respects. Nothing substantive is said about the level of the international standards, not even of a qualitative nature. By contrast, the approach of the WTO SPMs Agreement is purely procedural. The requirement that a country provide "scientific justification" if it wishes to adopt a higher level of protection than what is provided by international standards, goes in the same procedural direction: given the uncertainty surrounding the scientific basis of risk regulation, "scientific justification" can only mean that the relevant arguments should satisfy generally accepted rules of scientific methodology.[5]

It seems clear that in an area as politically sensitive as the protection of health and life, and where at the same time regulators face great scientific uncertainty, the only way to promote international regulatory co-operation is through *the harmonisation of procedures*. This, at any rate, is how progress has been achieved in the international harmonisation of testing procedures for new medical drugs – the so-called ICH process – in which the European Agency for the Evaluation of Medicinal Products (EMEA) has played a leading role (Majone, 2002).

3.4. The core concepts of risk analysis and management: risk, uncertainty, and probability

Risk is defined as the probability of an unfavourable event multiplied by the severity of harm, if the event occurs. The connection between risk and probability is clear: risk is simply an *expected* loss, which can be calculated once we know the probability distribution of all possible events. Given this definition of risk, it is clear that probability and utility (or loss = negative utility) are the key concepts of risk regulation.

These two concepts are so intimately related that the modern view of probability was developed in an attempt to understand the logic of decision making in the face of incomplete knowledge. According to this view an individual, when faced with the necessity of making a decision that may have different consequences depending on events about which she has incomplete knowledge, can express her preferences and uncertainties in a way consistent with some basic principles of rational behaviour.

It can then be deduced that the individual has a "utility function" – which measures the value to her of each course of action when each of the uncertain possibilities is assumed to be the true one – and a "subjective probability distribution", which expresses quantitatively her beliefs about the uncertain events. The individual's optimal decision is the one that maximises expected utility (or minimises expected loss) with respect to this probability distribution.

A basic, if often unrecognised, reason for the inability of the advocates of *ad hoc* decision criteria, such as the precautionary principle, to deal consistently with risk and scientific uncertainty is an outdated understanding of the very notion of probability. The modern view of probability as expressing the strength of our knowledge or beliefs, is much broader than the old ("objective") view of probability, which only applies to phenomena or experiments that can be indefinitely repeated under essentially the same conditions. But each political, managerial, or regulatory decision is essentially unique – it can never be repeated under the same conditions – and hence may be analysed only by means of the subjective notion of probability.

From this viewpoint, "objective" probabilities represent only a special case, but as in all good generalisations in science, the same principles ("axioms") apply to both kinds of probability. What is really important about subjective probabilities is the procedure (known as Bayes theorem) by which they can be revised in the light of new information. Hence "subjective" in this context, is not at all equivalent to "arbitrary". Both subjective probabilities and utilities are derived according to precisely defined rules that guarantee their internal consistency (see Annex 3.A1), and also learning – in the sense of transforming "prior" into "posterior" probabilities in the light of new evidence – follows a well-defined procedure, as just noted.

The *consistency* argument is essentially one that hinges on how separate assessments (of probabilities and utilities) are going to fit together and make a consistent whole. It should be clearly understood that the *rule of maximisation of expected utility* (or minimisation of expected loss) does not guarantee better outcomes than other decision rules – including decisions made in purely intuitive fashion. It does, however, guarantee consistency *in decision making*, and no other known decision rule can claim the same.

Consistency is important also from a practical point of view: it facilitates communication among experts, between experts and policy makers, and with the general public; *it also facilitates accountability* by showing how to break down the whole decision problem into separate but coherent components. Moreover, the method provides a way of consistently updating one's beliefs in light of new information. Such a formalised approach to decision making may even facilitate risk taking. For instance, if managers are evaluated exclusively on outcomes, they will naturally be reluctant to engage themselves in very risky undertakings. A more sophisticated method of evaluation, which in addition to results also includes the quality of the decision process, can reduce the cost of failure by distinguishing between foresight and outcomes due to chance (Williamson, 1975). Similarly, risk regulators would have less incentives to take refuge in safety factors and other *ad hoc* methods of dealing with uncertainty if they knew that their decisions are going to be evaluated according to more sophisticated procedural standards than the ones currently used.

What about *uncertainty*? In an otherwise remarkable book published in 1921, the American economist Frank Knight asserted that "a *measurable* uncertainty, or 'risk' proper, is so far different from an *unmeasurable* one that it is not in effect an uncertainty at all".[6] In other words, we should talk about *risk* only *when the events are uncertain but their probabilities are known*, reserving the term "*uncertainty*" *for the case where the probabilities are unknown*. Knight attached great theoretical importance to this distinction – which is still used by some risk analysts – but contemporary probability theory no longer views the two classes of events as different in kind. Probabilities may be known more or less precisely, they may be more or less subjective, but it is logically difficult to give precise meaning to the statement that certain probabilities are completely unknown. For instance, if we insist that we are "completely ignorant" as to which of the possible events $E_1, \ldots, E_n$ will occur, it is hard to escape the conclusion that they are all equally likely to occur. But this implies that the probabilities are in fact known, and that $p(E_j) = 1/n$ for all j: the so-called uniform distribution, well known to first-year students of probability and statistics! From a practical point of view it should also be noted that for some decision problems, it is not necessary to know the entire probability distribution of events: more aggregate information may be sufficient to find a sensible solution. Thus, even though toxicologists may be unable to make exact quantitative statements about the low-dose risk of particular substances, they can often rank the risks of various substances at currently experienced doses. For example,

they might say that a lifetime exposure to x part per million (ppm) of substance A presents in their judgment a larger risk of cancer to a worker than a lifetime exposure to y ppm of substance B. It is not necessary to evaluate precisely the risks posed by both substances in order to have a reasonable basis for a *comparative risk assessment* (Graham *et al.*, 1988).

3.5. Decision rules when deciding under uncertainty

The only consistent rule when deciding under uncertainty is *to choose the alternative which minimises the expected loss* (or maximises the expected utility) of the decision maker. Any other decision rule – and in particular any rule which does not take into account both the losses and the probabilities of *all* possible events – can lead to inconsistent decisions. One such potentially inconsistent decision rule is the *minimax*, which formalises the worst-case approach often used in risk analysis and risk management: The minimax decision rule uses losses but not probabilities, either denying the existence of the latter, or claiming that the method is to be used when they are "unknown" (and perhaps unknowable, as Frank Knight would have it) (see Box 3.3). This particular decision rule makes sense in special situations, such as zero-sum games where the uncertainty is "strategic", *i.e.* part of the strategy of a rational opponent, but not in the general case. A formal proof that the rule can produce inconsistent decisions is beyond the scope of the present discussion.[7]

Box 3.3. **Concrete examples**

The basic problem may be understood with the help of simple examples. Consider first the following decision problem, where the entries in the 2x2 table indicate losses, *e.g.* extra deaths due to exposure to a toxic substance:

EX1	E_1	E_2	**EX2**	E_1	E_2
A_1	10	0	A_1	1.1	0
A_2	1	1	A_2	1	1

In example 1 (EX1), following the minimax rule, for each row (*i.e.* each alternative) we select the maximum loss (10 for A_1 and 1 for A_2), and choose that alternative having the minimum of these values. This is A_2 with value 1. Hence the minimax rule says: always choose A_2. The principle of minimum expected loss would assign probabilities p_1 and p_2 to the uncertain events E_1 and E_2, and choose A_2 if $1 < 10p_1$, *i.e.* $p_1 > 1/10$, otherwise A_1 should be selected. To see which of the two rules is more reasonable, suppose that p_1 is quite small (say, $p_1 = 0.001$ or 0.0001) so that $10p_1$ is much less than 1. The minimax rule would still choose A_2, even though it is almost sure that no extra deaths would occur if A_1 is chosen.

The conclusion is even more striking in a second example (EX 2), where only the loss corresponding to the pair (A_1, E_1) has been changed: The minimax rule would still choose A2, even though the expected loss for A1 is much smaller for all values of p1 less than, say, 0.8.

In short, *the problem with the minimax rule is that it does not take into account all the information available to the decision maker*, by considering only the worst possible case and disregarding probabilities. *The advantage of the expected-loss (or expected-utility) rule is that it takes account of both losses/utilities and probabilities.*

As just noted, the minimax rule is unsatisfactory because it takes into account only the consequences, ignoring their probabilities. *Equally unsatisfactory are decision rules based only on probabilities.* An example of a probability-only approach is the risk-classification method already mentioned in Section 3.2. The method, which has been proposed by some toxicologists, in particular for dealing with food safety, consists in classifying risks into high, moderate, and low risk categories. For example, based on linear extrapolation from animal experiments, a risk higher than 1 in a 100 should be banned, a risk lower than 1 in 100 000 should be regarded as trivial (*de minimis* rule), while a risk between these two levels should be subject to some form of regulation.

This approach is problematic for two main reasons (Williamson, 1981):

- First, a classification based strictly on probabilities implicitly assumes that losses are constant both within and across risk categories. Since risk is defined as an expected loss, to omit the loss in the calculations is equivalent to assuming that it is constant for all items. If the loss is not constant, however, the method could lead to the banning of items that produce trivial losses and to the consumption of items that result in significant losses.
- A second problematic aspect of the method is that it ignores benefits. Again, ignoring benefits would be acceptable only if all benefits were identical, but this is certainly not true in general. Thus, a medical drug that has a high probability of producing severe side effects, but which is also life-saving, would presumably be considered by both patients and doctors to pose an acceptable risk (recall the case of the saccharin ban).
- A third aspect is that the risk-classification method tends to generate a false sense of security, and to favour a rigid bureaucratic approach to risk regulation. It is similar here to the use of safety factors.

The great advantage of the decision-theoretic approach consists in forcing the risk regulator to analyse all the relevant dimensions of the decision problem. This holistic approach differs markedly from the *ad hoc* methods discussed above. It then shows how the different pieces can be put together in a consistent way. The method openly acknowledges that most risk assessments are subjective, but it also provides a way of consistently revising and updating such assessments in light of new information. The fact that the assessments are basically subjective, increases the importance of coherence – all parts of the decision making process must fit together in a consistent and transparent manner.

However, the approach has been criticised for being normative rather than positive or descriptive. For instance, it is said that laboratory experiments, as well as casual observation, prove that people do not choose under uncertainty, nor update their beliefs, in the manner prescribed by the theory (see Section 3.10). However, this criticism overlooks the complex interdependence between normative and positive viewpoints in social life. Grammar, logic, arithmetic, and legal codes are all examples of normative systems that are often violated in practice, but are not discarded as a consequence – society could not function without them. What is true is that social practice, including policy making, is guided by norms, which in turn develop under the influence of social practice. For example, normative principles of decision making have been quite influential in directing the attention of American courts and policy makers to the importance of opportunity costs and the rational setting of regulatory priorities. In turn, this learning process has changed the practice of the regulatory agencies (see Section 3.8).

A very important function of normative models is to provide standards by which old practices and new proposals may be assessed. Thus, anybody familiar with the decision-theoretic approach will immediately see that the Precautionary Principle (PP), like the minimax decision rule, tends to focus the attention of regulators on some particular events and corresponding losses, rather than on the entire range of possibilities. As a consequence, regulators will base their determinations on worst cases, rather than on the weighted average (expected value) of all potential losses and benefits. To mention only one example taken from an official document, it has been argued that in examining the benefits and costs of different alternatives "[a] comparison must be made between the *most likely* positive and negative consequences of the envisaged actions and those of inaction…" (Commission of the European Communities, 2000, p. 19; emphasis added). In fact, we know that rational decision making under uncertainty requires consideration of *all* consequences, not just the most (or, for that matter, least) likely ones.

In recent years the PP has been debated intensely, not only in Europe but also internationally. It has even been suggested that it should be granted the status of a key tenet of international economic law – even though the real meaning and implications of the PP are far from being clear. Hence it seems appropriate to devote two sections of the present chapter to a critical analysis of the principle.

3.6. The precautionary approach: an idea in search of a definition

This section will offer a critical attempt of the precautionary principle, as an ill-defined principle, that may lead to attempts to control poorly understood, low-level risks, using up resources that in many cases could be directed more effectively towards the reduction of well-known, large-scale risks. Therefore, the use of the precautionary principle entails significant opportunity costs, which ought to be considered, as part of full impact assessment under uncertainty. A rational allocation of resources and consistency in policy making requires identifying which risks to regulate, and when to regulate them. Precautionary measures – taken on an *ad hoc* basis, often in response to political pressures – tend to distort priorities and compromise the consistency of regulatory policies.

The precautionary principle is an idea (perhaps a state of mind) rather than a clearly defined concept, much less a decision rule or a guide to consistent policy making. In fact, there are logical reasons for its intrinsic vagueness. Not surprisingly, an authoritative and generally accepted definition is nowhere to be found. The principle is of German origin (*Vorsorge Prinzip*) and has been used in that country since the 1980s in order to justify a number of important developments in environmental law. However, an eminent legal scholar has distinguished no fewer than 11 different meanings assigned to the PP within German policy discourse (Rehbinder, 1991).

The German approach was taken up by other senior decision makers in Europe, including the drafters of the European Community's Fourth Environmental Action Programme who thus sought to develop an approach to environmental policy that was preventive rather than reactive. In the Treaty establishing the European Community (EC Treaty, 1997) the principle is mentioned only in the title on the environment: Article 174(2) provides that Community environmental policy "shall be based on the precautionary principle and on the principles that preventive action should be taken, that environmental damage should as a priority be rectified at the source and that the polluter should pay". No definition of the precautionary principle is offered in this article or anywhere else in the

Treaty. In spite of this, some legal scholars argue that the principle applies beyond EC environmental policy. The reason given is that Article 6 EC provides that the environmental protection requirements be integrated into the definition and implementation of Community policies and activities referred to in Article 3 EC – in practice, all policies, activities and measures undertaken at EU level. Insofar as the PP is one of the core principles of EC environmental policy, it is concluded that it should be integrated, as appropriate, into other Community policies. European institutions have proceeded on this assumption.

The WTO Agreement on sanitary and phytosanitary measures has already been mentioned in Section 3.3. There is an indirect reference to a precautionary approach (again undefined) in Article 5(7) of this Agreement. WTO member states are allowed to take measures unsupported by a risk assessment when the relevant scientific evidence is insufficient, *but only provisionally*.

Perhaps the best known statement of the precautionary approach is provided by Principle 15 of the declaration of the 1992 UN Conference on Environment and Development (Rio Declaration):

> In order to protect the environment, the precautionary approach shall be widely used by States according to their capabilities. Where there are threats of serious and irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.

It should be noted that apparently similar statements of the principle may conceal quite different approaches. Even when such statements refer more or less explicitly to a situation where the probability and extent of damage are said to be poorly understood, and thus to justify precaution, they often differ in the conditions which precautionary measures should satisfy. Thus, according to the SPS Agreement, such measures must be provisional, but some European governments chose to interpret this condition not in terms of clock time, but of the time necessary to achieve a sufficient level of scientific certainty – a very flexible standard, given the pervasive, and often irreducible, uncertainty of regulatory science!

The same governments claim to support Principle 15 of the Rio Declaration, even though the conditions envisaged by the declaration – a threat of serious and irreversible damage, measures must be cost-effective – are considerably stricter than the ones these same governments advocate. Even within the European Union interpretations of the principle vary considerably. Thus, a general inference from major decisions of the European Court of Justice (ECJ) appears to be that in cases of scientific uncertainty member states have considerable discretion in deciding to err on the side of caution. However, they must adduce evidence of specific, concrete risk and not merely of potential risks based on a general precautionary approach. In the well known *German Beer* case (Case 178/84, 1987), for instance, the ECJ refused to allow a ban on additives in beer, based on a generic principle of precaution or prevention. The national authorities, the Court said, must come up with more scientific evidence than a mere reference to the potential risks posed by the ingestion of additives in general. On the other hand, according to the European Commission's *Communication on the Precautionary Principle* of the year 2000 a precautionary measure may be justified if there are reasonable grounds for concern that the potentially dangerous effects on human, animal, or plant health may be inconsistent with the chosen level of protection – a more flexible standard than the one used by the ECJ in *German Beer* and in other cases. In the famous dispute about hormones in beef, the EU found itself in

the same position *vis-à-vis* the WTO bodies that various member states have found themselves in *vis-à-vis* the EU: the Union was sanctioned for introducing a public health and consumer protection measure which was not sufficiently supported by scientific evidence or risk analysis.

In sum, *the PP is invoked by the member states of the EU against the European institutions as a sword*; at the same time, these same institutions use the principle at the international level as a shield to justify measures that are viewed as thinly disguised forms of protectionism by the EU's trading partners (De Bùrca and Scott, 2000; Scott and Vos, 2002). This dual use of the PP – as a sword and as a shield – is made possible by the profound ambiguity of the principle. The consequences of this ambiguity are particularly serious if the precautionary approach – however defined – is considered, not as an exceptional measure, but as a guide in preparing proposals for legislation, or even as a "full-fledged and general principle of international law".

The attempt to control poorly understood, low-level risks necessarily uses up resources that in many cases could be directed more effectively towards the reduction of well-known, large-scale risks. Unfortunately, the opportunity costs of precautionary measures are seldom, if ever, considered. Hence one of the unanticipated consequences of the advocacy of the PP is to raise the issue of a rational setting of regulatory priorities (see also Section 3.8). Since resources are always limited it is impossible to control all actual and potential risks. Even if a society is willing to pay a higher cost to protect an interest, such as the environment or health, to which it attaches a priority, it is still the case that some environmental or risk regulations might be too expensive. Therefore, a rational decision needs to assess both the costs and the benefits of dealing with risks, as well as the need to prioritise public policy efforts.

More generally, the PP appears to be seriously flawed as an aid to rational decision making under uncertainty. The critique of the minimax rule presented in Section 3.5, applies *a fortiori* to the PP, which does not even have the advantage of being a clear-cut decision rule. Like the minimax rule, the PP tends to focus the attention of regulators on some particular events and corresponding losses, rather than on the entire range of possibilities. As a consequence, regulators will base their determinations on worst cases, rather than on the weighted average of all potential losses and benefits. *The most basic conceptual flaw, however, is the artificial distinction between situations where the level of scientific information is sufficient to permit a formal risk assessment, and those where "scientific information is insufficient, inconclusive or uncertain"*. In reality, these are two points on a knowledge-ignorance continuum rather than two qualitatively distinct situations. The same logic which leads to the rejection of Knight's distinction between risk and uncertainty also applies here. As we repeatedly stressed, by its very nature regulatory science deals with uncertainties. Recall that for most toxic substances it is still unknown whether the relevant model for standard setting is a threshold or a linear one. Most scientists today favour the latter model, but this only complicates the regulator's problem since it is unclear where a standard should be set above the zero level. Moreover, the continuous progress of technology produces increasingly precise measurements of toxicity (*e.g.* parts per billion or even per trillion) so that the search for safety becomes ever more elusive.

In sum, regulatory problems are not solved but only complicated by appealing to different logics of decision making, according to the available level of information. Especially in risk regulation, the normal state of affairs is neither scientific certainty nor

complete ignorance. For this reason a sensible principle of decision making is one that uses all the available information, weighted by its reliability in terms of subjective probabilities, instead of privileging some particular risk.

3.7. The precautionary principle: policy implications

The previous section identified and discussed some major conceptual flaws of the precautionary principle. This principle violates basic principles of the logic of decision making under uncertainty; it disregards the opportunity cost of precautionary measures; it fails to take the potential benefits, as well as the potential losses, into consideration; not least, it greatly complicates the already difficult problem of setting rational regulatory priorities.

The current section (see also Box 3.4) will discuss the policy implications of the PP:

- Potentially negative consequences for scientific research and technological development, or for product innovation.
- Recurrent temptations to use the principle as a protectionist device.
- Perverse distributional consequences of some precautionary measures.

Box 3.4. **The policy principle through concrete examples**

The Rio Declaration

Principle 15 of the above-mentioned Rio Declaration provides a good example of an unobjectionable, but also unhelpful, interpretation of the precautionary approach. It is certainly correct to say that "lack of full scientific certainty" should not be used as an excuse for regulatory inertia; but since risk regulators seldom, if ever, can rely on scientific certainty, the statement does not provide any useful guidance.

The EC Communication on the PP

Much more worrisome is the claim that the PP entails the principle of *reversal of the burden of proof*, according to which it is up to the developer of a new product or process to prove that the product or process poses no health or environmental risk. Thus, according to the European Commission's Communication on the PP: "Community rules … enshrine the principle of prior approval (positive list) before the placing on the market of certain products, such as drugs, pesticides or food additives. This is one way of applying the precautionary principle … In this case the legislator, by way of precaution, has clearly reversed the burden of proof by requiring that the substances be deemed hazardous until proven otherwise." It is important to note that reliance on the principle of reversal of the burden of proof is not an exclusive feature of Community legislation.

It is difficult, if not actually impossible, to apply the PP in a consistent way as illustrated through the EU example. In conformity with the reversal-of-the-burden-of-proof interpretation of the principle, Article 3.1 of the 1997 EC "Novel Food" Regulation (Regulation 258/97) states that genetically modified food can be authorised only if "it does not present a danger to the consumer". Since no such proof is, strictly speaking, possible, acceptance of this interpretation is equivalent to advocating *a zero-risk approach* which would effectively stop scientific and technical innovation. But here the European policy makers are caught in a serious dilemma: on the one hand, they have officially espoused the PP, in the hope of enhancing their regulatory credibility and political legitimacy in the eyes of a sceptical public opinion; on the other hand, they want to increase the international competitiveness of Europe's biotech industries. Biotechnology is one of the priorities of the EU's sixth research framework program, and significant budgetary resources have been allocated to this area of research. The European Commission has sought a way out of the dilemma of precaution *versus* innovation by softening the rigorous standard of the Novel Food Regulation. A new regulation lowers the threshold by stating that genetically modified food may be authorised if it does not present an *unacceptable* risk for human health or the environment. Moreover, traces of unauthorised GMOs are now acceptable, under certain conditions, whereas previously they were not allowed to circulate in the market under any condition (Majone 2005).

Box 3.4. **The policy principle through concrete examples** *(cont.)*

The shift from "no risk" to "acceptable risk" represents a significant weakening of the precautionary philosophy in the direction of a more reasonable "balancing approach" which takes the potential benefits, as well as the risks, of a new technology into account (see Section 3.9). In sum, the principle of reversal of the burden of proof, if consistently applied, would lead to a prohibition of potentially beneficial activities, including scientific research and technological innovation.

The case of the US Clean Air Act

The case of the US Clean Air Act Amendments provides further evidence of this danger. The US Clean Air Act distinguishes two types of outdoor pollutants: those for which there is clear evidence of harm, and everything else lumped under the label of hazardous air pollutants (HAP). Before 1990, HAP regulation was a two-step process (Goldstein and Carruth, 2003). First, the US Environmental Protection Agency (EPA) determined that a compound was likely to be hazardous at ambient levels. Once this determination was made and survived a rigorous hearing process, the second step was to choose which emission sources of this pollutant were to be regulated, using a variety of criteria which included risk reduction and abatement costs. Impatience with this careful process, which had succeeded in regulating only a handful of pollutants, led to the 1990 Amendments. Although these amendments of the Clean Air Act made no explicit reference to the PP, they are perfectly compatible with it. In essence, the new HAP provisions switched the burden of proof to industry. If before 1990 the EPA had to show that a compound required regulation, now it is up to industry to show that a compound on the list of some 185 compounds specified by Congress is harmless – a hopeless task. Moreover, Congress required that maximum available control technology (MACT) be installed on all sources, regardless of toxicity. At the same time risk assessment, which used to play a primary role under the old procedure, has been significantly downgraded since 1990. One casualty of the new approach has been research into the health effects of HAPs. EPA's budget for such studies has decreased, while industry has no incentive to invest resources in the impossible task of proving that a chemical is harmless. As a consequence, some *American experts warn that the precautionary approach enshrined in the HAPs amendments may induce a shift from compounds for which there is ample evidence of apparent lack of toxicity at ambient levels, to compounds for which there is little toxicological information and thus a greater likelihood of unwanted health or environmental consequences* (Goldstein and Carruth, 2003; Goldstein, 2004).

The controversy over the use of growth hormones in cattle raising

Equally serious are the potential consequences of relying on the PP, rather than on methodologically defensible risk assessments, in international economic relations. The standard example here is the controversy over the use of growth hormones in cattle raising, which for years has opposed the European Union to some of its major trading partners. In 1997 the US and Canada filed complaints with the WTO against the European ban of meat products containing growth hormones, submitting that this measure violates the Sanitary and Phytosanitary (SPS) Agreement. As we saw, this Agreement allows WTO members to adopt health standards that are stricter than international standards, provided the stricter standards are supported by risk assessment. Unfortunately, the risk assessment conducted by the Community's scientific experts had not established any significant health risk the (Majone, 2005, pp. 126-128). Hence the Commission was forced to meet the WTO challenge with various *ad hoc* arguments. In particular, it pointed to various incidents since the early 1980s, when hormones that entered the European food market had allegedly made European consumers wary of beef. The Commission concluded that a ban of beef containing growth hormones, even if it did not pose a demonstrable health risk, was necessary to restore consumer confidence.

The WTO's Dispute Resolution Panel did not accept this argument, and decided against the EC. The Panel raised three objections: first, more permissive international standards existed for five of the hormones; second, the EC measure was not based on a risk assessment, as required by Article 5(1) of the SPS Agreement; finally, the EC policy was not consistent, hence in violation of the no-discrimination requirement of Article 5(5). The Appellate Body agreed with the panel that the EC had failed to base its

Box 3.4. **The policy principle through concrete examples** *(cont.)*

measure on a risk assessment and decided against the EC essentially for two reasons: because the scientific evidence of harm produced by the Commission was not "sufficiently specific to the case at hand"; and, second, because "theoretical uncertainty" arising because "science can never provide absolute certainty that a given substance will never have adverse health effects" is not the kind of risk to be assessed under Article 5(1) of the SPS Agreement. A key finding that persuaded the Appellate Body was that the carcinogenic risk from banned hormone-treated beef was no greater than the carcinogenic risk from antibiotic treated pork, grown in Europe, which was not banned. This finding seemed to support the contention of the United States and Canada that the EC ban was in fact a disguised restriction on trade aimed at reducing beef surpluses in the EC member states.

One of the objectives of the Commission Communication on the Precautionary Principle of 2 February 2000 was to respond to the objections raised by the WTO bodies, and to the accusations of its trading partners. Hence the exhortations – presumably directed to the member states – to "avoid unwarranted recourse to the precautionary principle as a disguised form of protection" (p. 3); the insistence that "the precautionary principle can under no circumstances be used to justify the adoption of arbitrary decisions" (p. 13); the warning that "reliance on the precautionary principle is no excuse for derogating from the general principles of risk management" (p. 18). This document also insists that the envisioned use of the PP "far from being a way of evading obligations arising from the WTO Agreements" in fact complies with these obligations. Unfortunately, this is not the opinion still prevailing in the WTO.

It has already been noted that under the WTO SPS Agreement, if a health measure has a scientific basis, there is little other countries can do to challenge this. The Beef Hormones case proves this *a contrario*, and also confirms what was already pointed out in Section 3.3, namely that the approach of the WTO dispute resolution bodies to questions of scientific uncertainty is procedural or methodological – requiring a risk assessment meeting internationally recognised scientific standards – rather than substantive.

The case of Asbestos

The *Asbestos Case*, in which the dispute-resolution bodies of WTO upheld the position of France and the European Community, proves that a ban supported by a competent risk assessment will be upheld, not only under the SPS Agreement, but even under the old GATT rules. In 1996 France adopted a decree banning, with few exceptions, the importation of asbestos and asbestos-containing products, for the stated purpose of halting the spread of asbestos-related death and disease. As an exporter of chrysotile asbestos Canada challenged the French ban, invoking, *inter alia*, Article III(4) of the General Agreement on Tariffs and Trade (GATT, the precursor of WTO) which prohibits discrimination against "like products" of another GATT member. Canada argued that chrysotile asbestos and cellulose and other substitute fibers (which were not banned) constitute "like products" within the meaning of Article III(4). Therefore banning one and not the others was a violation of the antidiscrimination rule. In defense of the French position, the European Community responded that the ban was not discriminatory because, due to the significant difference in health risk, chrysotile asbestos and the substitute fibers were not really "like products". At any rate, even if the French ban violated the antidiscrimination rule, it was still permissible under Article XX(b) of the GATT, which allows derogations from GATT obligations where "necessary to protect human… life or health". According to the EC experts, the scientific literature establishing the adverse health effects of asbestos was applicable to chrysotile asbestos; in fact, chrysotile asbestos was a known carcinogen. To Canada's argument that there is no detectable risk from modern chrysotile cement products since the fibers are bound in a compact matrix, the EC replied that cement-bound products often had to be cut during construction or repair, thus freeing fibers and creating inhalation exposures.

In reaching its decision the WTO *Asbestos* Panel made clear that in situations where scientists disagree, it is not the Panel's role to decide which among competing scientific views is the correct one. Rather, its task is to determine whether there is sufficient analysis and scientific evidence to justify a reasonable public health official in adopting a particular measure for the protection of public health (Carruth and

Box 3.4. **The policy principle through concrete examples** *(cont.)*

Goldstein 2004). After reviewing the scientific data presented by the parties and the input from its appointed experts, the Panel found that there was sufficient evidence that chrysotile asbestos is a carcinogen that causes both mesothelioma and lung cancer. Moreover, there is no known threshold below which chrysotile has been shown not to be carcinogenic, and in the absence of data the appropriate approach to extrapolating risk from high doses is a linear, no-threshold dose-response curve (see Section 3.1). The panel was also convinced by the argument of the EC experts that there is inhalation exposure to chrysotile asbestos fibers even with modern cement-bound products, because those products often have to be cut during construction, or for maintenance, repairs, or remodelling. The Panel concluded that the French ban qualified for the exception under Article XX(b) as legitimate health measure. Comparing the beef hormones and the asbestos cases, the crucial difference was the procedural requirement of a risk analysis meeting international standards of quality.

The case of the Aflatoxines and distributional consequences

Finally, let us consider some of the distributional implications which a systematic use of the PP may entail; specifically, the impact of precautionary health standards on the welfare of developing countries. The European Commission's Communication on the PP maintains that in considering the positive and negative consequences of alternative risk strategies, one should take into consideration "*the overall cost to the Community*, both in the long- and short-term" (Commission, 2000, p. 19; emphasis added). Such strict focus on Community's interest could perhaps be justified if the cost of precautionary measures was felt only by exporters in rich countries, but what if the cost is borne by very poor countries? World Bank economists have estimated the impact on some of the poorest African countries of precautionary standards for aflatoxins proposed by the European Commission in 1997. Aflatoxins are a group of related toxic compounds that contaminate certain foods and have been associated with acute liver cancer in humans. Aflatoxin B_1 – the most common and toxic of these compounds – is generally present in corn and corn products, and various types of nuts. The proposed Community standards were significantly more stringent than those adopted by the US, Canada, and Australia, and also stricter than the international standards established by the FAO/WHO Codex Alimentarius Commission. Brazil, Bolivia, India, Mexico, Uruguay, Australia, Argentina, Pakistan, and other countries, in opposing the proposed measures, demanded to know in detail which risk assessments the EC had used in setting the new standards. As a consequence of consultations with the trading partners about these concerns, the Commission relaxed the standard for cereals, dried foods, and nuts. Even after this relaxation, however, aflatoxin standards for products intended for direct human consumption remain quite stringent: 4 parts per billion (ppb), and 2 ppb for B_1 aflatoxin, against an overall Codex standard of approximately 9 ppb.

Using trade and regulatory survey data for the member states of the EU and nine African countries between 1989 and 1998, the World Bank economists estimated that the new standards would decrease African exports of cereals, dried fruits, and nuts to the EU by 64%, relative to regulation set at the international standards (Otsuki *et al.*, 2000). The total loss of export revenue for the nine African countries amounted to USD 400 million under EC standards, compared to a gain of USD 670 million if standards were adopted according to Codex guidelines. Were these costs, imposed on some of the poorest countries in the world, justified by the health benefits to Europeans? According to studies conducted by the Joint Expert Committee on Food Additives of the Food and Agriculture Organisation and World Health Organisation, the Community standard of 2 ppb for B_1 aflatoxin would reduce deaths from liver cancer by 1.4 deaths per billion, *i.e.by less than one death per year in the EU*. For the purpose of this calculation the Community standard was again compared to a standard that follows the international (Codex) guideline of 9 ppb. *Since about 33 000 people die from liver cancer every year in the EU, one can see that the health gain promised by the precautionary standard was indeed minuscule, certainly out of proportion to the cost imposed on the countries of Sub-Saharan Africa.*

The discussion is complicated by the ambiguity and vague definition of the PP. The meanings attached to the PP, and *a fortiori* to a more generic precautionary approach, vary so widely – from the obvious to the obnoxious – that any critique is bound to be inappropriate for at least some of the possible variants of the concept. For this reason the following analysis will focus on official documents, specific decisions, and actual or proposed policies, rather than on general considerations.

These examples complete our analysis of the precautionary principle. The overall assessment is negative. The PP is too ill-defined to serve as a general principle of international economic law, as some had hoped, while any known attempt to give it a precise meaning turns out to be either logically flawed or trite. This lack of a reasonably precise definition invites abuses, and breeds policy incoherence. Even the apparently innocuous statement that lack of scientific certainty does not justify regulatory inertia, reveals a poor understanding of the nature of science in general, and of regulatory science in particular. If science grows through a series of conjectures and refutations, to use Karl Popper's well-known characterisation, then it follows that scientific certainty can never be reached. What is objective in science is the process (the method) rather than the output – the knowledge, which is always conjectural and hence ultimately probabilistic. This is the reason why learning is so important, in science but also in the analysis and management of risk.

3.8. The lessons for risk analysis and management

This section will discuss the lessons the area of risk regulation and management, in a broader, but less rigorous, sense than that of formal decision theory. One of the key elements of the present chapter is that the theory of decision making under uncertainty, as sketched in Section 3.5 and in the annex, provides the appropriate conceptual framework for thinking about uncertain events and their consequences, and thus also for thinking about risk. One limitation of this theory, however, is that it has been developed for structuring the choice problems of an individual decision maker – it does not provide unambiguous advice for group decisions when the members of the group, *e.g.* different stakeholders, have different attitudes toward risk. But even in this situation the methodology can help, without providing formal solutions.

As already noted, the process of breaking down the decision problem into its main components – feasible alternatives, uncertain events, consequences, numerical measures of probabilities and utilities/losses – helps to identify the actual sources of disagreement, and thus facilitates interpersonal communication and the emergence of a common position.

Moreover, the theory shows how to assess the value of additional information, and how the new information is to be processed in order to update probabilities in a consistent manner. This means that the pooling of information available to the different stakeholders may serve as a device for bringing their probability assessments into reasonable agreement. Even more is true: it has been shown (*Blackwell-Dubins Theorem*) that with increasing information the probability assessments of different individuals tend to converge, provided the initial assessments are not directly opposite ("mutually orthogonal").

However, the fundamental conclusion of the discussion in Section 3.5 – that ideas should not be considered in isolation, but should be related to other relevant ideas to see how they fit together in a coherent manner – must always be kept in mind, for the broad analysis of risk regulation. To a large extent, improving the practice of risk management depends on learning this lesson.

The trends towards greater consistency in decision making in the United States

This will be illustrated by the slow but steady improvement in the conceptual foundations of risk regulation in the United States. It is convenient to trace this development through a sequence of four regulatory principles: prohibitions; lowest feasible risk; elimination of significant risk; balancing the costs and benefits of risk reduction. Regulatory practice in the US has not moved along this sequence in a continuous, linear fashion. For example, in the previous section we saw how the 1990 Amendments of the Clean Air Act introduced a principle of reversal of the burden of proof which, from our perspective, represents a regressive move. In spite of this and other lapses, however, a trend is clearly discernible in the direction of a broader inclusion of relevant factors, and of greater consistency in putting together the various elements of the regulatory problem in a consistent regulatory management system.

Prohibitions

Bans represent one of the earliest and least sophisticated approaches to risk regulation. To say this is not to deny that in some cases an outright ban may be the most appropriate regulatory response. For example, the ban on the use of freon in refrigeration was a cost-effective way of reducing chlorofluorocarbon emissions. Generally speaking, however, the appropriateness of such radical measures has to be proved rather than simply assumed. One of the best-known illustrations of the problems raised by an apparently clear-cut prohibition is provided by the already mentioned Delaney clause (see Box 3.1). For nearly twenty years this clause had little influence on FDA's actions, since only very few additives had been shown to cause cancer in animal experiments. On March 9, 1977, however, the FDA announced its intention to ban the use of saccharin because of a recent Canadian study showing that this artificial sweetener (in doses equivalent to 800 cans of diet soft drinks a day!) induced cancer in test animals. At the time no other non-nutritive sweetener was approved for use in the United States. Hence the FDA announcement threatened the marketing of all artificially sweetened foods and beverages and, consequently, precipitated intensive public controversy, see the introductory section.

Responding to these concerns, Congress, through the Department of Health and Human Services, commissioned two studies by the National Academy of Sciences, one to assess the scientific evidence concerning saccharin's safety; the other to evaluate the law's current food safety standards and suggest alternative approaches. The Academy's assessment of the scientific evidence confirmed that saccharin was a carcinogen in laboratory animals, although a weak one. It found no reliable evidence that saccharin caused cancer in humans, but it stressed that epidemiological methods were not capable of detecting increases in the incidence of bladder cancer of the magnitude the animal data suggested saccharin could cause. The second Academy study found that the standards for regulating food additives were inadequate. One proposal was to amend the law to allow FDA to rank additives in three risk categories: those so serious as to merit prohibition; those so trivial as to warrant no regulatory action; and those whose acceptability should depend on an assessment of benefits and on the availability of alternatives (see Section 3.5). The proposals did not lead to any radical amendment of the legislation, but the FDA found other means to avoid a ban if a food additive presented only slight risks, or offered substantial benefits.

In retrospect, we can see that the drafters of the Delaney clause believed that only a few additives caused cancer, but that they were extremely dangerous. By the 1980s it was clear that many substances are carcinogenic, but many of them create exceptionally minor

risks. The new information severely undermined the assumptions of the clause, suggesting that it may well cause more deaths than it prevents. This is because vastly improved detection techniques prevent basically safe, but weakly carcinogenic, substances from coming on the market, whereas cruder and older technology used to test previously authorised substances allowed them to be approved. The result is less rather than more safety (Sunstein, 1990).

Least feasible risk

According to this principle, human exposure to health risks should be reduced to the lowest possible level. This is a sort of second-best rule. The first-best regulatory policy would be one that ensures a risk-free working and living environment, but because of technical and economic constraints a risk-free environment is unattainable; hence the need of a second-best rule. Thus, Section 6(b)(5) of the 1970 US Occupational Safety and Health Act directs the Occupational Safety and Health Administration (OSHA), in regulating worker exposure to toxic substances, to set standards that "most adequately assure, *to the extent feasible*,… that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard… for the period of his working life" (emphasis added). Trade union representatives claimed that this instruction obliged OSHA to mandate the use of whatever available technology an industry could afford without bankrupting itself. Justice Brennan of the US. Supreme Court expressed a similar view: "Congress itself defined the basic relationship between costs and benefits, by placing the 'benefits' of worker health above all other considerations save those making attainment of the 'benefit' unachievable" (cited in Graham *et al*., 1988, p. 97). The meaning of "feasibility" is crucial in the present context. A body of analysis and case law has thus emerged to clarify this term.

According to some court decisions, a standard may be considered technologically feasible even if no existing devices would allow industry to comply with the standard, as long as there is evidence that companies "acting vigorously and in good faith" can develop the technology. This "technology forcing" approach implies that regulatory agencies are not limited to set standards based on existing devices, but may require improvements in existing technology, or even the development of new technology. This may be quite expensive, so the issue of technical feasibility is inseparable from the issue of economic feasibility. It is clear that risk managers estimate the costs of proposed standards, but it is less clear which criteria they use to judge whether a given standard is "affordable". At least as far as the Occupational Safety and Health Act is concerned, American courts have ruled that an expensive standard is not necessarily economically infeasible. Although some firms may find safety standards particularly expensive or even financially prohibitive, courts have not excused individual firms from such standards. As one court put it in a 1978 case: "It would appear to be consistent with the purposes of the (OSH) Act to envisage the economic demise of an employer who has lagged behind the industry in protecting the health and safety of employees and is consequentially financially unable to comply with new standards as quickly as other employers" (cited in Graham *et al*., 1988, p. 99). Thus, economic feasibility has been interpreted quite strictly: a standard is to be considered "infeasible" only if it would cripple or bankrupt an entire industry, rather than some technologically backward firms.

It is clear that the least-feasible-risk approach is far from any sort of balancing of marginal costs and benefits. In fact, marginal considerations are rejected on the ground that the two sides of the basic relationship are incommensurable. As the above-mentioned

opinion of Justice Brennan makes clear, health benefits have to be considered "above all other considerations". Even if one accepts this value judgment, however, serious conceptual problems remain. First, the approach fails to consider possible alternatives to standards, such as information disclosure or greater reliance on liability rules. It also omits any consideration of probabilities of possible events, so that standards are set without any knowledge of the expected number of deaths or accidents prevented. Second, setting standards strictly is a significant cause of the slow pace of the standard-setting process. This means that relatively few standards can be set, so that many hazards remain unregulated; hence, *over-regulation leads to under-regulation* (Mendeloff, 1988). Third, the emphasis on industry viability means that very dangerous occupations in marginally profitable industries may be unregulated, while other jobs may be made so safe at such high cost that employment levels and wages shrink – another way in which over-regulation may lead to under-regulation. Finally by ignoring one of the key lessons of economics and policy analysis – that decisions should be based on marginal costs and benefits – the approach wastes resources that could have been used to control more risks.

The significant-risk doctrine

In *American Petroleum Institute v. OSHA* (1978), the Fifth Circuit Court of Appeals invalidated a regulation which reduced the occupational exposure to benzene, a carcinogen, from 10 ppm to 1 ppm. The court found that the competent regulatory agency, the Occupational Safety and Health Administration (OSHA), had not shown that the new exposure limit was "reasonably necessary and appropriate to provide safe or healthful employment" as required by the relevant statute. Specifically, the court argued that OSHA had failed to provide substantial evidence that the benefits to be achieved by the stricter standard bore a reasonable relationship to the costs it imposed. The court added: "This does not mean that OSHA must wait until deaths occur as a result of exposure levels below 10 ppm before it may validly promulgate a standard reducing the permissible exposure limit. Nevertheless, OSHA must have some factual basis for an estimate of expected benefits before it can determine that a one-half billion dollar standard is reasonably necessary" (cited in Mendeloff, 1988, pp. 116-17).

What the court required was some sort of quantification of benefits as a necessary step to carry out a benefit-cost test of the new standard. Without a quantification of risk, and hence of the expected number of lives saved by the regulation, it is clearly impossible to weigh the benefits against the costs. OSHA, unlike other American agencies involved in risk regulation, had always maintained that quantitative risk analysis is meaningless. Hence, the agency's leaders decided to appeal the Fifth Circuit Court's decision. In *Industrial Union Department (AFL-CIO) v. American Petroleum Institute* (1980), the US Supreme Court upheld the Fifth Circuit's decision. Justice Powell noted that "a standard-setting process that ignored economic considerations would result in a serious misallocation of resources and a lower effective level of safety than could be achieved under standards set with reference to the comparative benefits available at a lower cost" (cited in Mashaw *et al.*, 1998, p. 815). Expressing the view of a four-judge plurality (in a separate opinion, Justice Rehnquist provided the fifth vote for overturning the standard) Justice Stevens explicitly rejected the precautionary, lowest-feasible-risk approach followed by the agency: "We think it is clear that the statute was not designed to require employers to provide absolute risk-free workplaces whenever it is technologically feasible to do so, so long as the cost is not great enough to destroy an entire industry. Rather, both the language and

structure of the Act, as well as its legislative history, indicate that it was intended to require the elimination, as far as feasible, of *significant* risks of harm" (cited in Graham *et al.*, 1988, p. 100; emphasis added).

Thus was born the significant-risk doctrine, a crucial step in the process of learning how to deal with societal risks in a rational manner. Justice Stevens insisted that "safe" is not the same as risk-free, pointing to a variety of risks in daily life – ranging from driving a car to "breathing city air" – that people find acceptable. Hence, before taking any decision, the relevant risk must be quantified sufficiently to enable the agency to characterise it as significant "in an understandable way". In fact, OSHA was not required to support its finding that a significant risk exists with anything approaching "scientific certainty". So long as the determination is supported by a body of reputable scientific thought (again, a procedural standard), the agency is free to use conservative assumptions in interpreting the data, risking error on the side of over-protection. From the government's generic carcinogen policy the agency had concluded that in the absence of definitive proof of a safe level, it must be assumed that *any* level above zero presents *some* increased risk of cancer. But, as the justices pointed out: "In view of the fact that there are literally thousands of substances used in the workplace that have been identified as carcinogens or suspect carcinogens, the Government's theory would give OSHA power to impose enormous costs that might produce little, if any, discernible benefit" (cited in Mashaw *et al.*, 1998, p. 813). The great merit of the significant-risk doctrine is to have raised the crucial issue of regulatory priorities. Most risks are regulated in response to petitions or pressures from labour unions, public-health groups, environmentalists, and other political activists, with little analysis by the agency of other possible regulatory targets. Given that resources are always limited, the real (opportunity) cost of a regulation is the number of lives that could be saved by using the same resources to control other, more significant, risks. By requiring the agency to show significant risk as a prelude to standard setting, the justices were insisting on some analysis in priority setting: regulatory priorities should be directed toward the most important risks – which are not necessarily those that are politically most salient.

The significant-risk doctrine places a higher analytical burden on regulators than the lowest-feasible-risk approach, or the precautionary principle. Not all potential risks are treated equally; only those substances shown to pose a significant risk of cancer will be regulated, focusing limited regulatory resources on the most important health risks. In addition, the doctrine, without requiring a formal analysis of benefits and costs, does place a constraint on the stringency of standards. If exposure to a carcinogen is reduced to the point that the residual risk is insignificant, then no further tightening of the standard is appropriate. *Industrial Union Department (AFL-CIO) v. American Petroleum Institute* is a landmark case also from the point of view of the methodology of risk analysis. The US Supreme Court not only confirmed the legitimacy of quantitative risk assessment; it effectively made reliance on the methodology obligatory for all American agencies engaged in risk regulation. In most subsequent disputes over regulatory decisions to protect human health, the question has not been whether a risk assessment was required but whether the assessment offered by the agency was plausible. This historical background probably explains American advocacy of science-based risk assessment at the international level, as well as that country's opposition to the precautionary principle advocated by the EU. Today, risk assessment is also the standard by which trade-restricting risk regulations are evaluated as necessary and compatible with the rule of the WTO, see Sections 3.3 and 3.7.

Balancing costs and benefits

Until the 1970s judicial review was the only effective control on the quality of the decision making process of US regulatory agencies. Congress can, of course, pass legislation requiring that an agency take a particular type of action. However, congressional oversight is output- rather than process-oriented. At any rate, in the US as in all other OECD countries, routine regulatory measures seldom receive legislative scrutiny. What is most important, there is no need for congressional approval for a regulatory agency to take action, provided that it can survive judicial review. By contrast, the courts have been important agents of policy learning, as we just saw in the *Benzene* case. Nevertheless, judicial oversight, too, suffers from serious shortcomings. First, it is only exercised *ex post* – though it should be noted that a judicial doctrine like the significant-risk doctrine, will influence a stream of future agency decisions. Also, the principle of separation of powers prevents any sustained interaction between courts and agencies before proceedings are formally initiated. Again, there is a serious mismatch between the leisurely time of judicial decision making and the hectic pace of agency rule-making, while heavy reliance on judicial review creates, according to some observers, an adversarial atmosphere which does not always facilitate the achievement of regulatory objectives.

From the point of view of policy learning, the most serious limitation of judicial review, however, is the unpredictability of court decisions. In the *Benzene* case, for example, the Supreme Court criticised the logic of the least-feasible-risk decision rule, and effectively mandated the use of quantitative risk assessment, while taking no position on the issue whether an agency should undertake a formal cost-benefit analysis (CBA) to justify its decisions. More precisely, the question that was not answered in this case was: is the use of CBA by OSHA required, permitted, or outlawed? At any rate, Justice Stevens' opinion, strongly suggests that the plurality shared the belief that the benzene standard imposed high costs with limited benefits. But only a year later the Court – in the *Cotton-Dust* case (*American Textile Mfrs. v. Donovan*, 1981) – held explicitly that OSHA standards need not show a positive cost-benefit ratio; they must only be shown to be technologically achievable and "affordable". Clearly, unpredictable court decisions do not help systematic policy learning. The decision on the cotton-dust standard seemed to interrupt an ongoing learning process, and for this reason it has been severely criticised by students of the regulatory process. No judicial decision, however, could conceal the growing economic impact of risk regulation.

With the great expansion of environmental, health, and risk regulation in the 1970s, the need to calculate more precisely the benefits and costs of the proliferating regulations became increasingly evident. Important steps to improve the quality of federal regulation were taken under President Carter, when the notion of a "regulatory budget" – the attempt to assess an acceptable level of regulatory costs for the entire economy – was first introduced. The oversight mechanism was perfected in the late 1980s, during the second term of the Reagan administration. The Office of Management and Budget (OMB), in the president's executive office, was given responsibility for setting the budgets of all regulatory agencies, and for monitoring the rulemaking process. Instead of simply imposing a cost-effectiveness requirement, as previous presidents had done, Reagan moved to a full-fledged cost-benefit test with his Executive Order 12 291 of 1981:

- Regulatory action is not to be undertaken unless the potential benefits to society outweigh the potential costs.

- Among alternative approaches to any given regulatory objective, the alternative involving the least net cost to society has to be chosen.
- Finally, agencies are required to set regulatory priorities with the aim of maximising the aggregate net benefits, taking into account the condition of the particular industries affected by regulations, the condition of the national economy, and other regulatory measures contemplated for the future.

As a result of this and subsequent reforms, the quality of rulemaking has improved significantly over the last two decades. The usefulness of the regulatory oversight process designed by the Reagan administration explains why subsequent administrations, democratic as well as republican, have continued to use it in a form that has not substantially changed from the original model. In the meantime also Congress was undergoing a learning process, resulting in a better appreciation of the opportunity costs of risk regulation. In 1995, new regulatory legislation was passed, whose net effect was to strengthen the test that must be passed by new regulations. The key congressional concerns were that regulations be based on an accurate and comprehensive assessment of the risks involved, rather than on worst-case scenarios, and that regulatory agencies proceed with regulations only if the benefits exceed the costs (Viscusi *et al*., 1995).

This brief survey of policy and institutional developments in the United States reveals a steady improvement in the understanding of the various dimensions of risk regulation – scientific, economic, legal, and political – and of the methodologies for fitting together these partial analyses in a coherent manner. The progress from the early reliance on outright bans or simple "feasibility" tests to the applications of key principles of decision theory not only to agency rule-making but also to the enabling legislation, is an outstanding, and in many respects unique, example of policy learning. This was also linked to the development of a proper regulatory impact analysis management system.

Compared with these developments, risk regulation in many other OECD countries, is still at a rather early stage. Indeed, some recent episodes, such as the strenuous advocacy of the precautionary principle, suggest an unwillingness to learn from international experience. As illustrated above, policy learning in the United States has been greatly facilitated by the interaction among different, partly co-operating, partly competing institutions. A more detailed study would have revealed also the importance of a style of policy discourse that puts a high premium on reliable quantitative information and on analytic sophistication.

3.9. Institutional implications: avoiding separating risk assessment and risk management

This section will show that, while a conceptual distinction can be made in risk regulation between risk assessment and risk regulation, the analytical distinction should not imply the need for an institutional separation.

Risk assessment is the process used to describe and estimate the likelihood of adverse health or environmental effects. *Risk management* is the process of analysing, selecting implementing and evaluating actions to reduce risk – has become standard in discussions of risk regulation. The distinction is clear, and useful for some purposes. Thus, the four main steps of risk assessment – *hazard identification, dose-response assessment, exposure assessment*, and *risk characterisation* – involve processes that are conceptually distinct from those used in risk management.

The error is to derive from such analytic distinctions the need or at least the usefulness of an *institutional separation* of risk management from risk assessment. Such institutional separation has been tried in several countries, usually with disappointing results. For example, the 1970 US. Occupational Safety and Health Act created the National Institute for Occupational Safety and Health (NIOSH), directing it to perform research and risk assessments for the newly established regulatory agency, the Occupational Safety and Health Administration (OSHA). While NIOSH is an independent agency within the Department of Health and Human Services, OSHA has been placed within the Department of Labor – an institutional design largely dictated by political reasons. This organisational separation, however, yielded functional separation to only a limited extent. On the one hand, NIOSH's "criteria documents" not only provided risk assessments, but also recommended occupational standards. On the other, OSHA tended to take on more of the risk assessment function itself. NIOSH continued to assist OSHA in the preparation of risk assessments, but gradually OSHA asserted control over the entire standard-setting process. As the author of a detailed case study concludes: "despite its separation from OSHA, or indeed perhaps because of it, NIOSH's criteria documents were often found to be deficient as bases for issuing standards. OSHA regulators found them to be little beyond compendium summaries of the literature, with little effort to evaluate the quality of relevant studies or to resolve scientific disputes. The lesson appears to be that such complete organisational separation of functions is counterproductive" (Greenwood, 1984, p. 118).

Complete organisational separation of risk assessment and risk management has been tried also in other jurisdictions, notably in the European Union. Thus, in the case of the European Food Safety Authority (EFSA) – established in 2002 and based in Parma, Italy – the tension between the desire to improve the credibility of EU regulation by appealing to independent scientific expertise, and the European Commission's refusal to delegate rulemaking powers to the agency, has been temporarily resolved by the expedient of separating institutionally risk assessment (the task assigned to the Authority) and risk management (which remains the responsibility of the Commission). There are already some indications that also in this case the organisational and geographical separation of risk analysis and risk management is complicating rather than facilitating the overall regulatory task.

The institutional separation of risk assessment and risk management is counterproductive because while the two functions are conceptually distinct, they are closely intertwined in practice. Thus, the setting of rational regulatory priorities entails scientific, economic, and political judgements that are not easily separable. Again, under conditions of scientific uncertainty the determinations of the risk analysts can effectively pre-empt the decisions of the risk managers. It is often impossible to know whether a dose-response function follows a linear or a non-linear (threshold) model, yet the analysts' choice of one or the other model is crucially important for the determination of the acceptable level of safety. Also the ubiquitous use of "safety factors" (see first section) blurs the distinction between the assessment and the management aspects of risk regulation. Even though it is easy to prove that such factors lack a logically defensible basis, both risk analysts and risk managers will continue to use them, at least in the foreseeable future, because they seem to provide some protection against "Type II" errors – accepting the hypothesis that a product or process is safe when it is not. In this connection it is useful to recall an observation made earlier (see Section 3.4) to the effect that a more sophisticated method of evaluating decision makers – a method which in addition to

results also includes the quality of the decision process – can reduce the cost of failure by distinguishing between foresight and outcomes due to chance. It follows that risk regulators would have less incentives to take refuge in safety factors and other *ad hoc* methods of dealing with uncertainty if they knew that their determinations are evaluated according to standards capable of distinguishing between procedural and substantive rationality.

In sum, if risk assessment and risk management are not separable in practice, if all risk determinations necessarily include a host of subjective judgments, then it follows that accountability and efficiency are best achieved when somebody – typically the head of an expert agency – takes responsibility for the entire process. Regulatory mistakes are always possible, and in such cases it is important for the credibility of the risk regulators that the lines of accountability be unambiguously defined. The institutional, as distinct from the mere functional, separation of risk analysis and risk management certainly does not help in this respect.

3.10. Differences in risk perceptions and in regulatory regimes

The issue of the appropriate standards of accountability is related to another problem facing risk regulators in all countries. The problem is the huge gap which often separates the public's risk perceptions from the assessments of the experts. Studies by Paul Slovic, Baruch Fischoff and other cognitive psychologists have demonstrated that there is a tendency to overestimate events associated with lower-probability events such as botulism and floods, and to underestimate the risks associated with higher-probability events, such as the risk of being killed in a car accident, or risks of cancer, heart disease and stroke. Also risks associated with toxic waste dumps and nuclear power appear near the bottom of most experts' lists, while in many countries they appear near the top of the public's list of concerns.

Notoriously, risk perceptions can vary greatly even among neighbouring countries: cyclamates are permitted and saccharin is banned in Canada, while cyclamates are banned and saccharin was effectively permitted in the USA until acceptable substitutes were available. During the BSE ("mad cow" disease) crisis the European Union imposed a ban on exports of beef from the United Kingdom, while the product was permitted for sale within the UK. Other well-known examples of international differences in risk regulation regimes have been mentioned in preceding sections: the EU's precautionary ban on imports of milk and beef containing growth hormones – products that are consumed daily by millions of Americans and Canadians; and the ban by France and other EU countries on the importation of chrysotile asbestos from Canada – which most experts believe to be virtually harmless if left in place. At least, in cases directly affecting international trade, the differences are openly debated in the WTO, in international standards organisations, and in other international fora; and it often happens that within particular risk domains, such as chemicals and air and sea transport, there is a strong international exchange of knowledge and views.

Paradoxically, there seems to be very little cross-domain exchange within countries. The result, it has been observed, is a policy and intellectual "archipelago" of risk domains isolated from one another, with very different policy stances across the various domains. For some hazards, governments adopt heavy-duty, anticipative, and intrusive regulatory arrangements… For other hazards, such as smoking, much lighter and more reactive approaches are adopted (Hood *et al.*, 2001, pp. 6-7). Such within-country differences in regulatory regimes are due to a variety of historical, cultural, and institutional factors:

among others, differences in regulatory philosophies, in standard-setting practices, or in organisational setups – as when one agency monopolises an entire risk domain, while in others the domain is divided up among a multiplicity of public and private players.

The risk from overestimation of low-probability events: Distorting the public policy agenda and the public policy responses

Now, these conflicts in risk perceptions and in regulatory regimes raise some of the most intractable problems of risk regulation. In particular, the overestimation of low-probability events has substantial implications for public policy. Scientific uncertainties and worst-case scenarios produce public pressure which, in turn, may encourage legislators to closely supervise agencies by encouraging strong action in respect to those substances or activities that catch the public eye.

The result is random agenda setting. An important policy question, therefore, is how governments should respond, if at all, to public (mis)perceptions of risk. According to many advocates of the precautionary principle, and many of those who would like to see democracy at work at all levels and in all areas of policy making, public perceptions of risk should be considered together with "harder" scientific and economic data.

On the other hand, Justice Stephen Breyer of the United States Supreme Court has argued that not every risk-related matter "need become a public issue. A depoliticised regulatory process might produce better results, hence increased confidence, leading to more favourable public and Congressional reactions" (Breyer, 1993, pp. 55-56). Even assuming that public perceptions should be taken into account by risk managers, the crucial, but unanswered, question is which weight should be attached to such social data relative to scientific, technical, and economic data. Some fundamentalists go as far as suggesting that regulatory priorities should follow public perceptions of risk. But there seems to be an odd asymmetry in such an extreme position. If the general public underestimates a certain risk, one presumably would not expect the government to remain idle and let citizens incur risk unknowingly. But if other risks are overestimated, why should the government be guided or influenced by biased perceptions, rather than by the best available estimates of the true risk levels?

Be that as it may, biased public perceptions create what Justice Breyer has called a "vicious circle" – public perceptions influence Congress, Congress (in particular, through media reports of its activities) helps to shape public perceptions, and both influence the response of regulatory agencies, distorting regulatory priorities. He suggests breaking this vicious circle by institutional changes, such as creating a mission-oriented, independent agency commanding significant prestige and authority. This superagency would have "the mission of building an improved, coherent risk-regulating system adaptable for use in several different risk-related programs; the mission of helping to create priorities within as well as among programs; and the mission of comparing programs to determine how better to allocate resources to reduce risks" (Breyer, 1993, p. 60). Breyer envisages a centralised administrative group that "could usefully try to make explicit, and more uniform, controversial assumptions that agencies now, implicitly and often inconsistently, use in reaching their decisions". This group could also help develop models that aim to achieve higher quality analysis and better results, and "might create a 'risk agenda' that helps to prioritise different programs, and different activities within programs, and that looks for tradeoffs among programs that will lead overall to improved health or safety" (*ibid*., pp. 65-67). This centralised, elite group of experts would not directly regulate, but presumably accomplish its ambitious tasks primarily by argument and

persuasion. It is, however, hard to see how such a group, with no rulemaking power and thus taking no responsibility for the final regulatory outcomes, could acquire sufficient prestige and legitimacy to change public perceptions and reform the decision making processes of existing agencies.

A detailed analysis of Justice Breyer's proposal is beyond the scope of the present chapter, but the two key issues he raises – what to do about public misperceptions of certain risks; and how to achieve a more coherent approach to risk regulation across programs and agencies – deserve some additional comments. Biased public perceptions would be irrelevant if risk regulation could be taken out of politics. A depoliticised regulatory process is indeed the basic rationale for delegating rulemaking powers to independent agencies, but in a democracy depoliticisation can only be carried so far, especially in sensitive areas like health and environmental risk.

Addressing political tradeoffs

We are faced with a real dilemma: on the one hand, risk regulation, like any other public policy, should be responsive to the preferences of the citizens; on the other hand, the regulator's task is to issue regulations that are needed to control the "real" risk levels, as indicated by the best available scientific evidence, not to respond to biased perceptions. Even less is it the regulator's responsibility to balance conflicting societal values, such as safety and economic efficiency, or a precautionary approach and the rate of technological innovation. Such balancing is, or should be, the exclusive responsibility of electorally accountable policy makers. Hence, the dilemma can be resolved only by acknowledging that both the regulator and the elected politician have important, but distinct, roles to play in risk regulation. The electorally accountable policy maker should have the right to override an agency's decision if s/he is convinced that societal welfare is thereby promoted. But such interventions into the regulatory process ought to be completely transparent, and follow well-defined and publicly known procedures. Generally speaking, overriding agency decisions should be neither too easy – for in this case agency independence would be an empty concept – nor too difficult – so that basic principles of democratic accountability may not be sacrificed in favour of narrow regulatory principles. An example taken from the area of antitrust regulation may help to clarify this important point.

Suppose an antitrust regulator has disapproved a merger because it violates the competition rules she is supposed to enforce. The government, on the other hand, thinks that in this particular case competition principles are too narrow from the point of view of aggregate welfare, and that the merger should be approved in the interest of the national economy. Here we have a clear situation of conflict of values which, as we said, can only be resolved by electorally accountable policy makers. From the democratic point of view, therefore, the government is justified if it decides to overrule the regulator, as long as it follows certain strict procedures and assumes full responsibility for its decision. In Germany, for example, the procedures which the government must follow when it wishes to overrule a decision of the antitrust regulator (the Federal Cartel Office) are such that they entail high political costs and make the interference plain for all to see. If the Cartel Office refuses to authorise a merger on the grounds that the merger is likely to lead to the creation or strengthening of a dominant position, the interested firms may apply to the Economics Minister for an authorisation. The Minister will evaluate both the advantages and disadvantages of the merger. This evaluation is based on the judgment of the Cartel Office, set against the advantages for the entire economy. In addition, the minister must

obtain the opinion of another independent body, the Monopoly Commission. Because of these strict procedural requirements – which are meant to make it politically costly for the Minister to interfere in the decisions of the Cartel Office for party-political reasons – the Minister has overridden the Cartel Office only on rare occasions.

It is submitted that this example provides a relevant model also for risk regulation. In particular, the procedural approach exemplified by the German case seems to be more realistic than the depoliticisation proposed by Justice Breyer as a way of breaking the vicious circle created by biased public perceptions of risk. Public education may be another effective way of correcting misperceptions. After all, the case of the saccharin ban, discussed in the introductory section, suggests that people are willing to trade off risks and benefits, at the margin, if provided with sound and credible information. Incidentally, it is even possible that underestimation of risks associated with higher-probability events may be a way for the respondents to include benefits in an implicit risk-benefit analysis of certain products or processes. Thus, the observed underestimation of the risk of being killed in a car accident may simply tell us that people value private transportation so highly that they are willing to run certain risks in order to continue enjoying the benefits of this mode of transportation.

Towards a more coherent approach to risk regulation and management: International co-operation, regulatory impact assessment and education and training

This leads to the second issue: how to achieve a more coherent approach to risk regulation across programs and agencies. Indeed, the fragmentation of risk regulation among a variety of national, supranational, and international agencies, using different criteria and methodologies, and responding to different constituencies, is becoming one of the most serious regulatory problems facing the governments of all OECD countries. At the national level, one possible solution is the establishment of co-ordinating groups or task forces. In the US, the Environmental Protection Agency (EPA) has pioneered this approach, and its experience deserves to be studied carefully.

Another promising approach is to use the framework of regulatory impact assessment by adding a facility responsible for analysing the consistency of risk priorities and actual risk measures, both across and within agencies. Justice Breyer's proposed solution – a mission-oriented, independent superagency commanding significant prestige and authority – is more ambitious. As noted above, however, it remains unclear how this elite organisation could acquire prestige and legitimacy. At any rate, Breyer is aware that his proposal is not entirely new. Aside from more or less convincing European examples, such as the French *Conseil d'État*, he points out that the Executive Branch of the US government already contains groups that seek to harmonise the activities of different agencies. Thus, the Office of Information and Regulatory Affairs (OIRA) within the Office of Management and the Budget (OMB), reviews regulatory agendas and major regulations that the different federal agencies intend to propose. The purpose of the review is precisely to bring about greater coherence within and across agencies, and to enforce a more rational setting of regulatory priorities. However, OIRA is understaffed and its perspective tends to be more economic.

Finally, training and education offer interesting policy options. Education could be the most promising, as well as practical, solution. This refers to the education of risk regulators, who should be required to add to their scientific and technical expertise a solid training in the logic of decision making under uncertainty. Annex 3.A1 discusses the introduction of decision theory in the curriculum of all leading business schools during

the 1960s and 1970s. Major corporations complemented university education by in-house courses, introducing senior managers to the key concepts of probability and utility analysis. For instance, the highly diversified du Pont Company discovered that its executives used different, even inconsistent, criteria when assessing the level of risk and expected profits of proposed investments. An intensive course in decision making under uncertainty, supported by graphical displays of various types of utility functions, reportedly helped to harmonise the decision rules used by du Pont executives. Since the 1970s sophisticated software has been developed allowing to perform sensitivity analysis of complex decision problems under a great variety of probability and utility assumptions. In the age of e-government, the development of analogous technology to support the decisions of risk regulators would be a significant contribution to a policy area of growing significance in all OECD countries.

Conclusion

Absolute safety cannot be a sensible regulatory goal. Uncertainty is irreducible in many cases. A zero-risk approach is untenable practically and conceptually. Regulators must move away from *ad hoc* rules and towards more inclusive principles. This assumes a significant capacity for policy learning, to learn from past mistakes.

There are two key challenges: what to do about public misperceptions of certain risks in governance arrangements which value transparency and participation; and how to achieve a more coherent approach to risk regulation, with what that implies for institutional arrangements and accountability. The fragmentation of risk regulation must be overcome.

People are prepared to trade off risks and benefits as long as both sides of the benefit/cost equation are honestly presented. But popular perceptions may be moving in the direction of a "risk society" where problems of "risk distribution" replace those of income distribution which characterised industrial society. In any case, the public has a tendency to over-estimate lo-probability events. The result is random agenda-setting, leading to over- and under-regulation.

The two steps of risk regulation – analysis and management – although conceptually distinct, are not separable in practice, and hence should not be separated analytically. They are closely intertwined in practice. Regulatory mistakes are always possible. For the credibility of the risk regulators, lines of accountability must be defined unambiguously. The institutional separation of risk analysis and risk management does not help in this respect.

Supporting evidence

If the correctness of the outcome can be determined unambiguously, the manner in which the decision is made is largely immaterial: only results count. By contrast, the key concept in the theory of decision making under uncertainty is consistency, a characteristically procedural notion. The international harmonisation of procedures may be the only way to promote regulatory co-operation in politically sensitive areas which are also areas of great scientific uncertainty. The only consistent rule when deciding under uncertainty is to choose the alternative which minimises the expected loss (or maximises the expected utility), and to take account of the probabilities of all possible events. Decisions based on either consequences or on probabilities are unsatisfactory. In a holistic approach, all the parts of the decision making process must fit together in a consistent and transparent

manner, and be open to revision in the light of new information. decision making should use all available information, weighted by its reliability in terms of subjective probabilities, instead of privileging some particular risk.

The minimax decision rule and precautionary principle instead focus on particular probabilities, and not on a range. The precautionary principle is ill-defined, and may direct resources toward attempts to control poorly understood, low-level risks using resources that could be more effectively directed toward the reduction of well-known, large-scale risks. The precautionary principle is inherently ambiguous, making it ill-suited as a guide in preparing legislation or as a principle in international law. Its most basic flaw is the artificial distinction between situations where the level of scientific information is sufficient to permit a formal risk assessment, and where it is not. In reality these are two points on a knowledge-ignorance continuum, rather than two qualitatively distinct situations. The opportunity costs of precautionary measures are seldom, if ever, considered. They include potentially negative consequences for scientific and technological development or for product innovation, its use as a protectionist device, and perverse distributional consequences.

Improving the practice of risk management depends on the consideration of ideas and information in a consistent manner, not in isolation. This is illustrated by the steady improvement in the conceptual foundations of risk regulation in the United States, where over time efforts have been made to put the various elements of the regulatory problem together in a consistent regulatory management system. The chapter shows this progression from consideration of least feasible risk to that of significant risk as criteria. Policy learning was greatly facilitated by the interaction among different institutions, partly co-operating, partly competing, and by the high premium placed on reliable quantitative information and sophisticated analysis.

Proposals for the future

- Well-defined procedures for electorally accountable policy makers to over-ride an agency's decision if he is convinced that social welfare is thereby promoted.
- Education of the public.
- Consideration of a centralised agency to overcome institutional fragmentation.
- Education of risk regulators, including use of electronic media to help decision makers perform sensitivity analysis of complex decisions under a great variety of probability and utility assumptions.
- International harmonisation of regulatory procedures.

Notes

1. This chapter was written by Giandomenico Majone, Professor of Public Policy, Emeritus, European University Institute, Florence, Italy.
2. For example by Richard Neustadt and Harvey Fineberg in their study "The Swine Flu Affair", published in 1978.
3. This will be further discussed in a later section of the present chapter, in connection with a critical evaluation of the precautionary principle.
4. The article states that: *i)* In order to harmonise SPMs on as wide a basis as possible, member states shall base their measures on international standards, guidelines or recommendations, where they exist; *ii)* SPMs that conform to international standards shall be deemed to be necessary to protect human, animal or plant life or health; *iii)* Member states may, however, introduce or maintain SPMs

which result in a higher level of protection than would be achieved by measures based on the relevant international standards, provided there is "scientific justification" for the stricter measures; *iv)* Member states are required to "play a full part, within the limits of their resources, in the relevant international organisations and their subsidiary bodies", such as the Codex Alimentarius Commission. This WTO SPM Agreement can be compared with the NAFTA agreement on environmental co-operation, which stipulates that "each Party shall ensure that its laws and regulations provide for high levels of environmental protection and shall strive to continue to improve those laws and regulations". The NAFTA agreement recognises "the right of each Party to establish its own levels of domestic environmental protection". Thus, according to a widely accepted interpretation, a member of NAFTA is permitted to set its own levels of protection, as long as those levels are "high" by some more or less objective standard. (This was also the case in Article 95(3) of the European Community Treaty, dealing with the harmonisation of national laws, prescribes: "The Commission, in its proposals… concerning health, safety, environmental protection and consumer protection, will take as a base a high level of protection…").

5. This interpretation seems to be supported by Article 5 of the same WTO Agreement (an article dealing with "Assessment of Risk and Determination of the Appropriate Level of Sanitary and Phytosanitary Protection"), which imposes purely methodological constraints on the freedom of each member state to choose its own levels of safety: risk assessments based on the available scientific evidence and on relevant inspection, sampling, and testing methods; consideration of relevant economic factors and of the relative cost-effectiveness of alternative approaches to limiting risks; consistency in the application of the concept of the appropriate level of protection, and so on.
6. Knight 1971 [1921], p. 20, italics in the original.
7. The interested reader may consult Lindley (1971), pp. 172-177, or any other good book on decision analysis).

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ANNEX 3.A1

Recent Trends in the Theory of Decision Making: Towards Procedural Rationality

During the 1960s and 1970s the theory of decision making under uncertainty became part of the standard curriculum in all leading Business Schools and Economics Departments. Now, pervasive uncertainty has always been the most obvious feature of decision processes in business and in economic policy making. Why did it take so long to develop a general theory of such processes, and what is the contribution of this theory to a more rational approach to real decision problems? The answer to the first part of the question is that no general conceptual approach to decision making under uncertainty was possible until the twin concepts of subjective (or personal) probability and of probabilistic utility were introduced in a clear and logically consistent way, and this did not happen until the late 1940s. Once these concepts were well understood it became possible to develop a theory based on three simple principles. First, the uncertainties present in the situation must be quantified in terms of values called probabilities. Second, the various consequences of the feasible courses of action must be similarly described in terms of utilities. Third, that decision must be taken which is expected, on the basis of the calculated probabilities, to give the greatest utility: any deviation from this rule is liable to lead the decision maker into procedures which are inconsistent.

As for the practical contribution to better decision making in business and in government: the theory allows us to open up the black box inside which the various ingredients of a decision problem are mixed and synthesised. It may be true, as President J.F. Kennedy once observed, that the essence of decision remains impenetrable to the observer, often even to the decider himself. But in a world where transparency and accountability are viewed as necessary conditions of legitimacy, decision makers in business, and even more those in government, are under an obligation to be as explicit as possible about the steps which led them to their final determination. In turn, this requires a conceptual framework within which the different components of the decision problem can be separately analysed, and then put together in a consistent way. Modern decision theory adds to the notion of "substantive rationality" – which applies to situations where uncertainty can be assumed away – that of "procedural rationality", which is especially relevant when uncertainty is too important to be disregarded. Whereas substantive rationality refers to the extent to which the chosen course of action leads to what, *ex post*, appears to be the optimal outcome, procedural rationality deals with how complex policy issues are structured.

A decision problem can be expressed as a list of alternatives and a list of possible events with the corresponding consequences. On the assumption of consistent comparison of events and of consequences, probabilities can be assigned to events, and utilities to consequences. Each alternative can also be assigned a utility, calculated as the expected value of the corresponding consequences. The best alternative is the one with the highest utility. Thus, the key assumption of the theory is that there is only one form of uncertainty and that all uncertainties can be compared. By saying that there is only one kind of uncertainty, and that therefore all uncertainties can be compared, it is meant that if E and F are any two uncertain events then either E is more likely than F, F is more likely than E, or E and F are equally likely. Moreover, if G is a third uncertain event, and if E is more likely than F, and F is more likely than G, then E is more likely than G. The first requirement expresses the *comparability* of any two events; the second expresses a *consistency* in this comparison.

The comparability and consistency requirements are then used to define the probability of any uncertain event E. This can be done in several, but equivalent, ways. For example, the probability of E can be obtained by comparing it with the probability of a point falling at random within a set S contained in the unit square. Because S is a subset of the unit square, its area is a probability, *i.e.* it is a positive number between 0 and 1, which satisfies all the rules of the probability calculus. Now, consistent comparability implies a unique value for the uncertainty of E, *i.e.* the probability of S (its area), is judged to be as likely as the uncertain event E, in the sense that a prize awarded on the basis of E occurring could be replaced by an equal prize dependent on a random point falling within S. The interested reader can find the details in any good textbook on decision theory, such as the one by Dennis Lindley (1971, pp. 18-26). In addition to a numerical measure of probabilities, we need a numerical measure for the consequences of our decisions.

We proceed as follows. Let c_{ij} be the consequence if we choose alternative A_i and event E_j occurs, $i = 1, 2,\ldots n$; $j = 1, 2,\ldots m$. Note that the consequences may be qualitative as well as quantitative. Denote by c and C two consequences such that all possible consequences in the decision problem are better than c and less desirable than C (it can be shown that the precise choice of c and C does not matter, as long as the condition of inclusion is satisfied; thus, we could choose as c the worst possible outcome in the payoff table, and C as the best outcome). Now take any consequence c_{ij} and fix on that. Consider a set S of area u in the unit square (the reason for using "u" will be clear in a moment; also, keep in mind that the area of S is a probability). Suppose that if a random point falls in S, consequence C will occur, while c will occur if the random point falls elsewhere in the unit square. In other words, C occurs with probability u and c with probability 1 – u. We proceed to compare c_{ij} with a "lottery" in which you receive C with probability u and c with probability 1 – u. Thus, if u = 1, "C with probability u" is better than (or at least as good as) c_{ij}, while if u = 0 then "C with probability u" is worse than c_{ij} . Furthermore, the greater the value of u the more desirable the chance consequence "C with probability u" becomes.

Using again the principle of consistent comparisons it can be shown that there exists a unique value of u such that the two consequences, c_{ij} and "C with probability u", are equally desirable in that you would not mind which of the two occurred. The argument consists in changing the value of u, any increase making the "lottery" more desirable, any decrease, less desirable, until "C with probability u" is as desirable as c_{ij}. We indicate this value with u and call it the *utility* of c_{ij}: $u_{ij} = u(c_{ij})$. We repeat the process for each of the

possible consequences in the payoff table, replacing each consequence by its utility. The crucial point to remember is that all these utilities are probabilities and hence obey the rules of the probability calculus.

The final step consists in calculating the (expected) utility of each of the alternatives: $u(A_1)$, $u(A_2)$,… $u(A_n)$. Using the basic rules of probability, it is easy to show that $u(A_i)$ is simply the expected value of the utilities of all the consequences corresponding to A_i: $u(A_i) = u(c_{i1})p_1 + u(c_{i2})p_2 + \ldots u(c_{im})p_m$. A moment's reflection will show that the expected utility of A_i is simply the probability of obtaining C, when this particular alternative is chosen. It follows that the best alternative is the one with the highest utility, being the one which maximises the probability of getting C. This is the principle of maximisation of expected utility, the major result of decision theory. Note that this principle, or decision rule, has nothing to do with the notion of an indefinite repetition of the same decision, as in some interpretations of expected gain in repeated games of chance. The principle follows directly from the rules of probability and hence can be applied to any decision situation, whether repetitive or unique.

One final point. Any decision under uncertainty, even one which does *not* make explicit use of probabilities, in fact implies at least a partial probability assessment. There is nothing mysterious in this statement, which is only a straightforward application of a line of reasoning frequently used also in elementary game theory (see for example Morrow 1994). Suppose a decision maker has to choose between two alternatives with the consequences indicated below:

	E_1	E_2
A_1	10	1
A_2	3	2

Without attempting to estimate the probabilities of the uncertain events E_1 and E_2, but only taking the consequences in the payoff table into account, she chooses alternative A_2. This choice suggests that our decision maker is very risk-averse. In fact, she has used the "maximin" decision rule, according to which one should take the worst consequence for each alternative, and then select the alternative which offers the maximum of these minima; hence the name of the decision rule. Although the maximin does not use probabilities, the choice of A_2 indicates that the decision was taken *as if* the probability of E_1 was less than 1/8. In fact, letting p be the unknown probability of E_1, hence $1 - p$ the probability of E_2, the expected values M of the two alternatives are:

$$M(A_1) = 10p + 1\,(1 - p) = 9p + 1$$

$$M(A_2) = 3p + 2\,(1 - p) = p + 2$$

Thus, our decision maker is indifferent between the two alternatives if $9p + 1 = p + 2$, *i.e.* if $p = 1/8$. Any value less than 1/8 makes A_2 preferable to A_1. Since A_2 was chosen we infer that the decision maker implicitly assumed that the probability of E_1 is less than 1/8, q.e.d.

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Chapter 4

Risk Regulation and Governance Institutions

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This chapter offers a critical overview of the key elements of risk regulation and governance institutions, regarding risks to health, safety, environment, security, finance, and other areas. It emphasises the challenges for risk regulation of increasing interconnectedness in a multi-risk world, including: the need to assess the joint effects of simultaneous exposure to multiple risks; the increasingly rapid spread of risks across networks; and the ubiquitous ancillary impacts of risk regulation such as risk-risk tradeoffs. The chapter advocates: comprehensive regulatory impact assessment of the full portfolio of impacts of risk reduction efforts; both ex ante *(prospective) regulatory impact assessment to inform initial policy decisions, and* ex post *(retrospective) regulatory impact assessment to inform subsequent policy revisions and to improve* ex ante *assessment methodologies; evenhanded use of regulatory analysis both to discourage undesirable policy proposals and to encourage desirable policy proposals; greater use of economic incentive instruments in regulation; and better co-ordination and oversight of risk regulation policies across agencies within each government, and across governments internationally.*

Introduction

This chapter offers a critical overview of the key elements of risk regulation and governance institutions, regarding risks to health, safety, environment, security, finance, and other areas. It puts special emphasis on the implications for risk regulation of increasing interconnectedness, including joint effects of simultaneous exposure to multiple risks; rapid cross-border transmission of risks; ancillary impacts such as risk-risk tradeoffs; analysis of the full portfolio of impacts of risk reduction efforts; *ex ante* and *ex post* policy impact assessment; and co-ordination of risk policies across agencies and governments.

Private institutions manage many risks, but are often not sufficient to deal with large-scale risks. Market failures such as negative externalities may undermine the ability of private actors to manage risk efficiently. Systemic risks may arise from individually rational behaviour. High transaction costs may impede negotiation, such that the potential victims of an externality cannot reach an effective agreement with those responsible. In addition, the protection of public goods such as clean air may be compromised. There may also be government failures, such as when state-run enterprises neglect signals of resource scarcity, officials favour parochial interests (such as industry subgroups) over the public interest, or regulators neglect the negative side effects of their policies (such as new risks). Government is challenged to overcome the fragmentation of risk assessment and management among a mix of public and private organisations, and within government.

The policy cycle for risk regulation calls for several different kinds of expertise, including science, engineering, social science, law and policy. Moving forward, impact assessments should develop the means to forecast the joint effects of simultaneous exposure to multiple risks (which is not the same as the sum of individual effects), and the means to assess the full portfolio of multiple impacts in complex systems. Multiple scenarios may be needed to reflect the mix of variables, potentially weighted by probability judgements.

Benefit/cost analysis is one tool for evaluating risk regulation (and other government policies). It is often used, but is not uniformly required, in the United States and in Europe. It is referenced in different pieces of legislation, some requiring and some prohibiting its use. Benefit-cost analysis may be incomplete, such as where it focuses on precise quantification of one impact (*e.g.* business compliance costs) but neglects attention to other salient impacts (*e.g.* ancillary impacts, both harmful and beneficial). Opposition to using benefit-cost analysis may reflect the perception that its use would undermine health and environmental protection, but sound benefit-cost analysis can also be used to identify and promote desirable new health and environmental protections. The tool should be analytically neutral, and regulatory institutions should apply it even-handedly – to a wider array of policy types, to the full portfolio of impacts, and to promote desirable policies as well as to discourage undesirable policies. Greater use of economic incentive instruments (*e.g.* taxes, tradable allowances, information disclosure) can also help improve policy results.

Ex ante assessment runs the risk of errors in evaluating risks and policy impacts, including both false negatives (when something thought to be an insignificant risk turns out to be a serious risk), and false positives (when something thought to be a serious risk turns out to be of little significance). *Ex post* assessment can help evaluate policies in action, and the assessment methodologies themselves, in light of empirical experience. Both *ex ante* and *ex post* assessment are needed to complete a policy cycle. This should promote transparency through reporting of assumptions and methods and comparisons to alternatives. The emergence of a risk, the actual occurrence of a crisis, the adoption of policies, and the results of these policies should all be monitored and assessed to help adjust and improve policies to reduce overall risk.

Thus, a crucial component of effective risk governance is monitoring performance. Do policies actually work? Do they achieve results? This component is often neglected. At present, essentially all countries do some kind of *ex ante* assessment, but few carry out an *ex post* review. These are essential to improve policies through a strategy of adaptive management, and also to validate and improve the *ex ante* assessment methodologies to better inform future decision making.

The real challenge is institutional, not technical: to extend the coverage of sensible risk assessment and policy analysis (including even handed comprehensive benefit-cost analysis) to a wider range of issues, to apply that information effectively to improve regulatory choices, and to build oversight capacity to monitor the policy cycle and seek improved quality at each step. A regulatory oversight body is a key Centre-of-Government task. Such a unit needs, among other attributes, a clear assignment of responsibility, authority to influence decisions, and capacity to conduct and oversee high-quality assessments both *ex ante* and *ex post*.

4.1. The challenge of risk

Risk is one of the major challenges facing governments today. Societies are shaken by the heavy burden of diseases such as cancer, heart disease, influenza and malaria; by environmental pollution and climate change; by financial crises; and by sudden accidents, storms and terrorist attacks. They are also vexed by hasty and poorly designed policies to address risk. In May 2005, UK Prime Minister Tony Blair delivered a "Speech on Risk and the State", emphasising that risk regulation is absolutely necessary, but criticising overregulation of small risks in the hopeless effort to reduce risks to zero (often as an overreaction to a recent crisis), thus impeding innovation and inducing perverse effects that "do more damage than was done by the problem itself". He advocated a programme of "Better Regulation" based on a "rigorous risk-based approach" that will employ impact assessments and "regulate only after reflection" (Blair, 2005).

In 2005, the OECD adopted Guiding Principles for Regulatory Quality and Performance, including an admonition to governments to "assess risk to the public and to public policy in a changing environment as fully and transparently as possible, thereby contributing to a better understanding of the responsibilities of all stakeholders" (p. 8).[2] OECD has also recently undertaken a major study of future risks (OECD, 2003). This attention to risk represents a major new area for OECD study of regulatory policy, as compared with the 1997 *OECD Principles for Regulatory Reform* which had focused on reform of economic regulation via competition, market openness, and deregulation.

This chapter offers a critical overview of the main issues for policy makers considering risk regulation, and identifies important areas for future improvement. The core theme of this chapter is that *interconnectedness*, in several dimensions, creates new challenges and opportunities for dealing with risk.

Traditionally, risks have been handled one at a time, by a single government agency acting in isolation, and sometimes based on an *ex ante* impact assessment of the chosen risk policy. Many individual risks have thereby been reduced. But increasing interconnectedness poses new demands:

- forecasting the joint effects of simultaneous exposure to multiple risks;
- dealing with the rapid transmission of risks (such as disease, terrorism, pollution, or financial downturn) across countries and continents, through increasing interconnections among ecological, trade, travel, and telecommunications systems;
- assessing policy impacts, both *ex ante* and also *ex post*, with effective institutional oversight;
- analysing the full portfolio of impacts, including ancillary harms (countervailing risks) and ancillary benefits, of any effort to reduce a target risk; and
- co-ordinating risk policies across agencies and across governments of different countries, especially for transboundary and global risks.

At the same time, interconnectedness offers an important opportunity:

- learning from other countries' experiences and thereby borrowing policy ideas, in a process of transnational diffusion of regulatory innovations.

Background

Risk is not, of course, a new subject for regulatory policy. In a general sense, risk assessment (asking what could happen, and how serious it would be) and risk management (asking what should be done about it) have been undertaken by human beings for millennia, and are essential to the survival and prosperity of human societies (Bernstein, 1996). More formally, governments have been enacting systems of risk regulation for at least the last century (for example, many laws and agencies addressing food, drug, and workplace safety risks were adopted in the early 1900s, and major financial risk regulations were adopted following the Depression of the 1930s), and especially since the 1960s and 1970s (when many major environmental laws and agencies were created) and since 2001 (major new security regulations). The "economic regulation" of industries such as transport, telecoms and banking has waned in favour of privatisation and more open competition, while the "social regulation" of health, safety and environmental risks has grown (Horowitz, 1989). Thus, risk regulation is now the major regulatory function in many countries.

Some argue that the main goal of civilisation has shifted from prosperity to risk management (Beck, 1992. Others see prosperity as the best antidote to risk, and see the rise of risk regulation as a costly burden on innovation and progress. An intermediate view is that risk regulation is necessary and desirable to protect societies against risks that private markets do not address adequately, but that it is equally desirable to develop a systematic approach to evaluate and oversee risk regulation in order to ensure that it is effective and efficient and does not yield excessive countervailing risks (Breyer, 1993; Graham and Wiener, 1995; Sunstein, 2002). Risk is generally understood as the combination of the probability and consequences of an adverse outcome. Risk is therefore ubiquitous.

It encompasses both highly publicised exotic events such as pandemic flu, SARS, BSE (mad cow disease), terrorist attacks, financial collapse, and global climate change; and more mundane routine events that generate less publicity but that inflict tragically heavy losses, such as cancer, heart disease, diabetes, malaria, and traffic accidents. The term "risk regulation" is typically used to encompass health, safety and environmental policies, but homeland security, banking, and insurance regulations also address risk and employ methods of risk analysis.

It is commonplace, but arguably incorrect, to assert that risks are more serious today than they were in the past. Overall risks to human health have largely declined over time, and life expectancy at birth has substantially increased (nearly doubling in wealthy countries from about 45 to 80 over the period 1900 to 2000). Increasing wealth has led to longer, healthier lives, reductions in many though not all forms of pollution (the so-called Environmental Kuznets Curve), and increasing attention to environmental conservation. Global famine and strategic nuclear war are of less concern today than a few decades ago (though local famine and war remain serious challenges). Prophecies of doom, from Thomas Malthus two centuries ago to the Limits to Growth models of the 1970s, have turned out to be wrong, largely because they did not take account of the feedbacks, signals of scarcity, and adaptive responses (both by markets and by public institutions) which prevent collapse.

On the other hand, other risks might be increasing even as human health is improving. Current life expectancy estimates do not yet reflect inchoate future health risks. Past increase in human longevity might perhaps be temporary – if, say, infectious bacteria soon become widely resistant to antibiotics, or if current technology is sowing the seeds of an abrupt risk in the future. Or, the advance in human longevity might have come at the cost of reduced vitality of non-human ecosystems (such as through deforestation, over fishing, and climate change). Or very low-probability risks of catastrophic impact might be looming, such as a large asteroid on a collision course with the earth.

And, of course, many people living in poor countries continue to suffer a heavy burden of disease, hunger, armed conflict, and other risks, with life expectancies in those countries shorter by two or even three decades than in wealthy countries. Roughly a billion people lack access to clean drinking water, though this number has been declining. Even if this is a smaller percentage of the world's population than in prior eras, the magnitude of the problem remains grave. Risks to health and environment in poor countries, such as malaria and deforestation, may also contribute to persisting poverty.

Looking ahead

Even if the more optimistic vision is correct – that human longevity and environmental conservation will both continue to increase worldwide (due to future gains in prosperity) – it may nonetheless be true that increasing global *interconnectedness* – through trade, travel, telecommunications (including the internet), transboundary environmental spillover effects, and armed conflict – may make future risks spread more quickly to yield distant or systemic impacts, may complicate regulatory strategies, and may make risks faster to be reported via news media worldwide (in turn influencing public opinion regarding policy responses). For example, increased travel enables both pathogens and terrorists to spread more quickly. Interconnectedness and greater speed of transmission may thus make new risks more difficult to foresee and prevent.

And interconnectedness in a complex multidimensional web of risks also means that risk regulation itself will have complex effects: intervening to regulate one risk will also affect other risks, increasing the potential for unintended side effects (Wiener, 2002). At the same time, interconnections may also foster better solutions: the capacity of scientific detection and hence advance warning are improving, and greater information sharing among experts and governments helps them to respond to new risks more rapidly and effectively. Interconnectedness offers the opportunity for experience and learning about risks and policy options to be shared across countries, in an adaptive process of borrowing or diffusion (Wiener, 2001).

Decreasing human health risks may not portend a decreasing public interest in risk regulation. Over the past several decades, public demand for risk regulation appears to have risen even as health risks have declined. This is not as paradoxical as it might at first seem. Although there are declining marginal returns to reducing ever-smaller risks, three factors support an increasing taste for risk prevention: wealth, aging, and science. First, rising wealth (over time and across countries) implies declining preoccupation with basic survival needs and hence rising concern about the environment and about more remote and more distant risks. Countries appear to devote greater resources to controlling pollution as they grow wealthier. Second, greater longevity – a result of declining risk – implies rising concern about risks that might occur later in life (in one's 80s or 90s, at an advanced age that one could not have counted on reaching when life expectancy was, say, 45). Thus an aging population may care more about the risks of latent illnesses caused by exposure to toxic substances, and about harms to one's great-grandchildren caused by long-term climate change. Third, improvement in scientific methods enables detection of new risks and of risks at ever-smaller levels of exposure. Our very success in reducing risks thus can yield increasing demand for action against remaining risks.

But taking action is not simple. Like choosing medical therapies, designing successful risk regulation is a complex and challenging task (Wiener, 1998). Diagnosing a risk does not by itself indicate which is the right remedy. The wrong remedy could be ineffective, or costly, or counterproductive. Interconnectedness only complicates this challenge. The questions remain: Does risk regulation work? When, where, and how well, with what consequences? Which approaches, tools, and institutional structures yield the best results?

4.2. Institutions to assess and manage risk

The basic social institutions for assessing and managing risks are typically private: individuals, families, firms, markets, and civil society organisations. These private actors share overlapping membership, and they number in the billions. Most choices about risks – anticipating risks, setting priorities, undertaking preventive measures, and dealing with crises – are made by these private actors. For example, most decisions about risks to the next generation (children) are made by parents, along with the physicians, teachers, and caregivers they choose. Most interpersonal risks, to which one or more persons are exposed as the result of others' actions, are handled by self-help (avoidance behaviour), negotiation, and insurance. Indeed the insurance industry, including both first-party (*e.g.* health) and third-party (liability) insurance, is one of the most important institutions to assess and manage risks.

But private institutions are generally not sufficient to deal with larger-scale risks. First, market failures may undermine the ability of private actors to manage risk efficiently. Firms and other actors may treat risks that they impose on others as "externalities",

i.e. outside of the factors that they take into account in their decision making, and therefore generate more risk than is socially desirable (Pigou, 1932). For example, a firm that emits pollution may ignore the cost of that pollution to others in society, and therefore produce too much pollution (and too much of the firm's products). Second, high "transaction costs" may impede negotiation between the emitters and receptors, so that private institutions have no effective way to internalise the externality (Coarse, 1960); for example, there may be so many potential victims of an externality, or so many possible sources, or such difficulties in finding and monitoring these sources, that the costs of reaching an effective private bargain exceed the gains from of doing so. Third, a related market failure is that protection of "public goods" such as clean air or biodiversity may go underprovided because the benefits, once provided, will be widely shared (non-excludable) and hence each person has an incentive to let others bear the cost of conserving the resource (*i.e.* to "free ride"), resulting in general underinvestment in the shared objective.[3] Fourth, information about risks may itself be a public good, so that each individual under-invests in learning about the risks he or she may face. Individuals may make heuristic errors about risks based on incomplete information and analysis, such as focusing on "available" visible recent events rather than on the likelihood of future events.

In addition to these market failures, private efforts to address risks may be hampered by government failures (Wolf, 1988). State-run enterprises may be slow to respond to signals of scarcity (*i.e.* may excessively extract and exploit resources), and may be heavy polluters because they focus on production goals and neglect externalities. State-run mines, factories and forests are notorious for pollution and clear cutting. Government subsidies to private actors may perpetuate or exacerbate harmful activities such as over fishing and deforestation. Government-erected barriers to trade and market access may shield dirty industries from competition. Government regulations may themselves be adopted to favour or protect one segment of industry against another (so-called "rent-seeking" or "predation by regulation").

Where private institutions are inadequate to deal with risks, there is a *prima facie* case for a public role in risk assessment and management. (It is only a *prima facie* case because the public role can also impose costs or generate new risks, which must be weighed against the reduction in the target risk.) Governments can and do address risks in numerous ways,[4] including public sector provision of:

- information generation such as scientific research and meteorology;
- infrastructure construction such as seawalls, levees, and warning signals;
- crisis response such as disaster relief, fighting forest fires, rescuing victims or reconstructing damaged homes;
- public defence and security agencies such as the military and the intelligence community;
- social insurance such as pensions, medical care, deposit insurance, and flood insurance;
- regulation such as health and safety standards, pollution controls, aviation security rules, and bank capital reserve requirements; and
- civil tort liability.

Regulation is an *ex ante*, prospective strategy to limit the likelihood or severity of future risks, such as by requiring pre-market screening of new drugs or chemicals, requiring installation of pollution control technology, imposing quantity limits on pollutant

emissions, taxing emissions, or requiring public disclosure of emissions. Civil tort liability is an *ex post*, retrospective strategy to provide compensation for harm, and also thereby to provide deterrence signals that will also influence *ex ante* behaviour.

Regulatory "governance" may imply a wider array of actors than government alone. Governance is often taken to include the roles of nongovernmental organisations in civil society, and perhaps in business as well (Renn, 2005, p. 22). Thus governance includes public-private partnerships to advance public objectives. At the same time, "governance" can also refer to the mode or approach of governing. In this sense, "regulatory governance" means the overall approach to regulating, including the structure of government, interaction between government and nongovernmental entities, policy analysis tools, and policies adopted. The structure of government includes at least two major dimensions:

- a vertical dimension across hierarchical levels of government (international, national, state/province, and local) (and also hierarchies within each level of government, such as executive authority over regulatory agencies), raising questions of federalism, subsidiarity, oversight and pre-emption; and
- a horizontal dimension across government bodies (across agencies with different topical missions, across branches of government such as executive and legislative, and across jurisdictions affected by transboundary or spillover effects), raising questions of co-ordination, competition, co-operation and free riding.

In this institutional context, fragmentation of regulatory bodies is common, and interconnectedness of risks poses a real challenge to policy responses. Fragmentation is the logical result of turf-claiming and specialisation in governance: dividing up problems into pieces to be addressed by different entities. Such specialisation can be desirable, but it can also yield problems when issues are interconnected. Actions by one government entity can impose spillover effects on others – that is, they can yield "regulatory externalities". Fragmented institutions have difficulty dealing with interconnected risks: multiple simultaneous risks, risks that are transmitted across or cause impacts in multiple domains, and policies that reduce one risk but increase other risks in other domains. Some version of co-ordination or integration is needed. But some degree of specialisation is inevitable because a monolithic government entity could not handle all issues at once (and would raise other concerns about concentration of power). Meanwhile, the interconnections across government entities – such as through transnational networks of official and nongovernmental experts – can foster learning and borrowing of innovative approaches that help address risks more successfully.

4.3. Risk regulation through the policy cycle

Although methods vary across countries, across agencies, over time, and depending on the particular risk being addressed, many governments generally follow (or at least espouse) a "policy cycle" regarding risk.[5] This policy cycle typically involves six major steps or components:

- Forecasting ("risk assessment").
- Prevention ("risk management").
- Oversight ("regulatory review").
- Implementation (including Enforcement).

- Coping (Adaptation, Remediation, Crisis Response/Disaster Relief, and Compensation, if Prevention fails and a risk comes to pass).
- Evaluation.

There can be opportunities for public input throughout the cycle.

These several components of the policy cycle invoke different kinds of expertise. Risk analysis is inescapably multidisciplinary, drawing on expertise in toxicology, epidemiology, hydrology, biology, chemistry, physics, engineering, statistics, economics, finance, decision science, psychology, brain science, communications, political science, public policy, philosophy, ethics, law, and other disciplines.

Compared to alternative regulatory approaches, risk-based regulation may require more information in order to make decisions, but may also thereby achieve better decisions. Risk-based regulation sets standards aimed at reducing risk, understood to mean the combination of probability and consequence of adverse outcomes, and also typically (though not necessarily) involves consideration of the benefits and costs of policy options. Statutory language directing agencies to employ risk-based regulation include phrases such as "prevent unreasonable risk" (weighing all risks, benefits and costs) and "reduce overall risk" (weighing all risks). The phrase "as low as reasonably practicable" has been interpreted to require reductions so long as cost is not in gross disproportion to benefit. Statutory phrases such as "protect public health" or "minimise threat" have been interpreted to call for standards to reduce risk to some tolerable or insignificant level, although often without consideration of cost (leaving it unclear where the regulator should stop regulating).[6]

Alternatives to a risk-based approach, by contrast, typically base decisions on less information and on a less complete assessment of their consequences. Such alternatives include:

- Hazard-based regulation (a ban or limit based on a possible harm having been identified, without respect to dose or actual exposure – thus neglecting Paracelsus' adage that "the dose makes the poison" – and without respect to benefits or costs).
- Strong versions of the Precautionary Principle (prohibiting activities if there is a chance of serious risk) – unless the PP is revised to include proportionality or benefit-cost analysis.
- Command-and-control "best technology" requirements, or "as low as feasible" requirements (without respect to risks or benefits; usually limited by cost).
- Deregulation or non-regulation (to reduce costs, but without respect to benefits).
- Trade measures (protectionism) via risk regulation.

Forecasting – risk assessment

In principle, risk regulation begins with some forecast of potential future risk. In practice, regulation may react to a recent crisis event. In either case, risk-based regulation attempts to forecast the future likelihood of adverse consequences, through an initial component usually called "risk assessment". The particular inquiry will differ based on the type of risk. One widely applied form of risk assessment is Environmental Impact Assessment (EIA) (Sand, 1990; Wiener, 2001, Wiener, noting transnational borrowing of EIA requirements). In chemicals regulation, a four-part approach to risk assessment has been developed: Hazard Identification, Dose-Response assessment, Exposure assessment, and Risk Characterisation. This approach gained widespread use in the United States following the US Supreme Court's decision in the *Benzene* case in 1980,[7] in which the Court held that

the regulatory agency must demonstrate "significant risk" before it could regulate. This decision turned on the particular wording of the relevant statute, but it quickly became the impetus for widespread use of quantitative risk assessment across US agencies. This trend was redoubled when the National Academy of Sciences published its "Redbook"[8] in 1983, detailing methods to yield consistency across agencies, and to keep risk assessment a scientific endeavour distinct from risk management. The US approach has been viewed as exceptional, but has also been borrowed in Japan and some European countries.[9]

In the EU, the move toward quantitative risk assessment has been more recent, driven in part by WTO decisions under the Agreement on Sanitary and Phytosanitary Standards (SPS), which requires a scientific risk assessment to support international trade restrictions. The European Commission has espoused scientific risk assessment as a predicate to any invocation of the precautionary principle (Commission of the European Communities, 2000), and the European Court of Justice held, in a case on mad cow disease (BSE) quite reminiscent of *Benzene*, that Member State governments may not invoke precaution to regulate risks that the European Commission has deemed insignificant.[10] Still, major risk regulations within the EU sometimes do without risk assessment methods, as in the recent *Pfizer* and *Alpharma* cases regarding antibiotics in animal feed,[11] in which the court held that a ban could proceed without a risk assessment and even when the relevant scientific advisory committee had recommended against a ban or had not been consulted. The court ruled in the *Pfizer* case, paragraphs 139 and 142-144:

> … a risk assessment cannot be required to provide the Community institutions with conclusive scientific evidence of the reality of the risk and the seriousness of the potential adverse effects were that risk to become a reality… [But] a preventive measure cannot properly be based on a purely hypothetical approach to the risk, founded on mere conjecture which has not been scientifically verified … a preventive measure may be taken only if the risk, although the reality and extent thereof have not been "fully demonstrated by conclusive scientific evidence", appears nevertheless to be adequately backed up by the scientific data available at the time when the measure was taken.

This statement is confusing. The court appears to misunderstand the purpose of a risk assessment, which is never to provide "conclusive scientific evidence" (which is unattainable) but rather to provide a forecast of inevitably uncertain future risks. The court holds that basing decisions on "a purely hypothetical approach" or "mere conjecture" is inadequate, but that a risk assessment is not required, thus leaving it unclear what the court means by its alternative of "adequately backed up by the scientific data" – an invitation to further litigation.

Risk assessment has been criticised for both overstating and understating risks. Overstatement (false positives) arguably results from the use of conservative default assumptions used to fill data gaps, such as the use of a linear low-dose extrapolation with no thresholds or hormesis, the use of the most sensitive test species, identifying any observed effect as adverse, making animal-to-human extrapolations without accounting for mechanistic differences ("modes of action"), using the maximum exposed individual (MEI) as a hypothetical exposure assumption (*e.g.* dirt-eating children on highway median strips). Risk assessors are driven to supply some assumptions by the high cost of animal bioassays (necessitating smaller samples and higher doses), and by a science policy choice to err on the side of caution – even though over regulating based on conservative risk assessments may itself yield countervailing risks.[12]

Understatement (false negatives) arguably results from neglecting risks until they reach a crisis; studying one-risk-at-a-time instead of assessing the joint effects of the multi-risk "soup" of simultaneous exposures (although some simultaneous exposures could exacerbate each other while others offset each other); inattention to sensitive subgroups, *e.g.* children; and inattention to very low-probability high-consequence (extreme/catastrophic) risks.[13]

To address many of these problems, US EPA has adopted cancer risk assessment guidelines,[14] which require greater use of evidence before resorting to conservative default assumptions, greater attention to modes of action, and more attention to children and other susceptible subgroups. And US OMB issued a proposed Bulletin on Risk Assessment in 2006,[15] seeking to ensure greater transparency and realism, use of central estimates, and consistent criteria for identifying adverse effects (this Bulletin was later criticised, revised and re-issued as a memorandum). In addition, although few statutes specify the criteria for scientific risk assessment (Stansell *et al.*, 2005) courts have begun to apply general statutory edicts to use the "best available science" to require agencies to conduct high-quality risk assessments.[16]

Meanwhile, public perceptions of risk may differ from experts' risk assessments. The public may overreact to some risks because of perceptions of dread (unfamiliar, mysterious or sinister risks) and the availability heuristic (recent crisis events), while the public may under-react to other risks (*e.g.* routine risks even if of great magnitude, and very rare extreme event risks which do not offer available recent crises). Public input may improve some policies, but may distort others. But experts may be susceptible to their own heuristic errors. The result of both public heuristics and the errors in expert risk assessments may be a pattern of simultaneous paranoia about some risks and neglect of others (Breyer, 1993; Wiener, 1997).

Risk assessment is also difficult because different risks pose different forecasting problems. Actuarial risks, which have been occurring in large numbers, such as traffic accidents, can be forecast using historical data. Still, past may not be prologue; past patterns may not predict future patterns (*e.g.* if weather conditions, driver characteristics or vehicle technologies change). Risk assessment always involves uncertainty, even for routine well-observed risks: there is no such thing as a "certain" risk. But it can be more difficult to forecast risks with little historical data. Latent risks in which cause and effect are separated by many years may be difficult to foresee. Low-probability extreme events may only occur once in a long time (*e.g.* an asteroid collision). Strategic agents such as terrorists or pathogens may strike or spread suddenly, and may react or evolve to evade preventive measures.

Interconnectedness exacerbates these challenges. Government agencies and scientists typically assess the risk of one chemical or technology at a time.[17] For the most part, agencies regulate one risk at a time (Davies, 1999). Yet the real world is one of interconnection and complexity, in which people and ecosystems are exposed to multiple risks at the same time. Naturalist John Muir famously remarked in 1869 that "when we try to pick out anything by itself, we find it hitched to everything else in the universe".[18] The modern science of ecotoxicology is moving to formalise that insight in models of simultaneous "multiple stressors".[19] Modern legal scholars see the same thing: "It only takes a moment's reflection to see that multiple-risk situations are quite common."[20] "Most of today's environmental law

violates basic principles of ecology. Nature teaches the connectedness of all activities, but most current-generation law regulates pollutants separately with little consideration of ecosystems as a whole" (Elliot, 1997).

Recognition of interconnectedness suggests at least three innovations in risk assessment. First, risk assessors should develop the means to forecast the joint effects of simultaneous exposure to multiple risks. The joint effect may be synergistic (supralinear), linear (additive), or offsetting (subtractive), but the key point is that it is the joint effect rather than the sum of the individual effects that must be forecast. Second, risk assessment needs to account for rapid propagation vectors. Increasing interconnections may accelerate the transmission of risks (such as disease or terrorism) across countries and continents, through increasingly dense networks among ecological, trade, travel, and telecommunications systems (including the internet). Third, rather than simply extrapolating single variables (such as exposure to a chemical), risk assessors need to develop multiple scenarios incorporating the mix of multiple variables affecting risk, potentially weighted by probability judgments.[21] OMB Circular A-4 (Sept. 2003) now requires a formal probabilistic analysis of scenarios for policies with impacts exceeding USD 1 billion.

In addition to the three points just noted, options for improving risk assessment also include:

- Strengthening capacity through increased staff expertise and resources.
- Greater accuracy through more reliance on data and on realistic assumptions and methods. In toxicology, increased testing of human cell clusters (high-throughput toxicity pathway testing) as a complement to traditional animal bioassays.
- Greater transparency through reporting of assumptions and methods and comparison to alternatives.
- Assessment of strategic actors, such as terrorists and pathogens, using game theory.
- Assessment of low-probability extreme events.
- Assessment of the joint effect of multiple risks in concert.
- Attention to interconnected transmission networks or vectors which may foster the rapid propagation of risks.
- Greater use of multiple scenarios for forecasting.
- Conducting an OECD survey of risk assessment methods and innovations across member states.
- Developing OECD guidelines on risk assessment to improve accuracy, consistency and transparency across member states.

Prevention – risk management

After forecasting a risk, decision makers must decide what to do about it. This is the task of risk management.[22] In risk-based regulation, this task is conducted by comparing the consequences of policy alternatives (including the alternative of no action). To compare alternatives, some method of weighing their consequences is needed. Making regulatory choices without considering the consequences (as advocated by some critics of benefit-cost analysis) does not make the consequences disappear, but instead invites undesirable unintended consequences.

Risk management asks at least two question: How much prevention is warranted? And, how to accomplish this prevention? The first question addresses the optimal level of regulatory protection, while the second addresses instrument choice.

How much

The standard approach to assessing "How much" is to compare benefits to costs. Reduction of the target risk (forecast using risk assessment) is the primary benefit. In the United States, every President since Jimmy Carter has required some form of benefit-cost analysis (BCA) of new agency regulations. President Carter issued Executive Order (EO) 12 044 in 1978, requiring economic analysis of regulations. In 1980, President Carter signed legislation creating the Office of Information and Regulatory Affairs (OIRA) within the White House Office of Management and Budget (OMB). President Reagan issued EO 12 291 in 1981, requiring regulations to yield benefits that "outweigh" their costs, with a goal of maximising net benefits, and established OMB/OIRA as the White House office with the authority to oversee such regulatory impact analyses (RIAs). President Clinton issued EO 12 866[23] in 1993, reconfirming the bipartisan commitment to BCA, while also replacing the word "outweigh" with "justify" (a less quantitative term, embracing a broad public judgment about the policy's merits), adding emphasis on qualitative and distributional impacts, adding an instruction to evaluate the countervailing health and environmental risks induced by regulation of a target risk (risk-risk tradeoffs), and adding new procedures for transparency. The subsequent administration of President Bush retained the Clinton EO; it issued more "return" letters (saying "No" to deficient regulations), and also innovated the new device of the "Prompt letters" (using BCA to say "Yes" to desirable regulations, such as rules requiring trans-fat labels on food and electronic defibrillators in the workplace). OMB/OIRA also issued new RIA Guidelines[24] calling for more use of cost-effectiveness analysis, lower discount rates (3% as well as 7%), risk-risk tradeoff analysis, and probabilistic scenarios if impacts exceed USD 1 billion.

In light of this bipartisan consensus among US Presidents for the last three decades, requiring agencies to use BCA for risk management, one prominent author has heralded the era of the "cost-benefit state".[25] But BCA is still not applied to all risk policies in the US. US federal agencies appear to quantify some benefits or costs most of the time, but to quantify and monetise both benefits and costs only about half the time.[26] One reason for this incomplete use of BCA is that federal statutes enacted by Congress sometime prohibit BCA in agency regulation (and the Presidential EOs do not countermand this prohibition). Congress often requires agencies to use BCA, as in the CPSA (1972) (consumer products), FIFRA (1975) (pesticides), TSCA Section 6 (1977) (toxic substances), and UMRA (1995) ("unfunded mandates" on states, businesses). Sometimes Congress permits BCA without requiring its use in decision making, *e.g.* in OSHAct 3(8) (1972) (workplace hazards other than toxics), CWA Section 304 (1977) (water pollution technology standards), and SDWA (1996 amendments) (drinking water contaminants). But some Congressional statutes prohibit agencies' use of BCA in regulation, such as CAA Section 109 (1970) (national ambient air quality standards), OSHAct Section 6(b)(5) (1972) (workplace toxics), ESA Section 7 (1973) (endangered species), RCRA Section 3004m (1984) (hazardous waste treatment standards), and CERCLA Section 121 (1986) (hazardous waste cleanup standards).

Moreover, BCA is not required for Congressional legislation (although UMRA, 1995, encourages it), nor for international treaties, nor for public works projects such as highways, dams and national forest logging (despite the early history of BCA as developed

to evaluate dams in the 1940s, the language in NFMA Section 6(k) requiring economic suitability for timber cutting, and the early effort to require BCA via environmental impact assessments under NEPA in Judge Skelley Wright's opinion in Calvert Cliffs, 1971), nor for military and counterterrorism operations (despite the early history of BCA and systems analysis being brought to the Department of Defence by Secretary McNamara's "Whiz Kids" in the 1960s).[27]

In the European Union, BCA is increasingly required, even if still less often practiced than in the USA. The Proportionality Principle, a general principle of European law, has been held to imply some version of BCA (as noted in the *Pfizer* opinion cited above, paras. 410-411, although that opinion later remarked in para. 456 that "health must take precedence over economic considerations"). The Nice Treaty of the EU provided in Article 174(3) that an accounting of "the potential benefits and costs of action or lack of action" must be undertaken in environmental policy – just after Article 174(2) espoused for the precautionary principle. The European Commission's Communication on the Precautionary Principle of Feb. 2000 (cited above) requires precautionary regulations to be *proportional* to the chosen level of protection, *non-discriminatory* in their application, *consistent* with similar measures already taken, *based on an examination of the potential benefits and costs* of action or lack of action (including, where appropriate and feasible, an economic cost/benefit analysis), *subject to review*, in the light of new scientific data, and *capable of assigning responsibility for producing the scientific evidence* necessary for a more comprehensive risk assessment. In effect, the Communication reclaims the PP as part of decision analysis.

Most recently, the new "Better Regulation" initiative has launched Impact Assessment Guidelines.[28] Of the 70 Extended IAs conducted by the European Commission during 2003-05, though, fewer than 40% quantified and monetised either benefits or costs, and only 17% compared net benefits (Renda, 2006, p. 63). Several member states, including notably the UK and the Netherlands, have adopted strong Better Regulation programmes with RIA procedures.[29] But much of these national Better Regulation initiatives (both in the EU and at the member state level) appear to focus on administrative costs ("cutting red tape") rather than on maximising net benefits to society. Outright prohibitions on BCA do not seem prevalent in European Union law, although such prohibitions may exist in some member states' laws.

Different technical parameters in BCA may yield different policy choices across governments, even if the use of these analytic tools were otherwise the same. For example, the valuation of morbidity and mortality may differ across agencies and across country governments. Apparently the US EPA currently uses a value of a statistical life (VSL) of USD 6 million, whereas the EU's DG Environment uses only USD 1.2 million (both USD, for air pollution).[30] (VSL also differs across US agencies.[31]) Such variations may not be sensible unless the VSL actually relates to differences in public valuations or to the particular risk being evaluated. Another important factor is the discount rate on future impacts (*e.g.* 7% or 3%), which may vary across country governments or agencies.

Interconnectedness again poses an important challenge to risk governance. In theory, BCA embraces all effects. But in practice, BCA is often limited to looking only at the reduction in the target risk (TR) and comparing it to industry's compliance costs. The problem is that ancillary impacts such as risk-risk tradeoffs are thereby neglected. The focus on TR omits countervailing/ancillary effects. And the focus on industry compliance cost favours options with low-cost substitutes, but these substitutes can pose their own

risks. The solution to this problem is to move toward a full portfolio analysis ("treat the whole patient") that interprets Maximise net benefits (max(B-C)) more broadly, to maximise overall risk reduction (including Countervailing Risks and Ancillary Benefits), less overall social costs: Max(ΔTR – ΔCR + ΔAB – C).[32] Thus, risk-risk tradeoff analysis needs to be made an explicit part of BCA (or conducted on its own where BCA is prohibited or otherwise not used). Fragmentation into specialised agencies with narrow missions exacerbates the inattention to risk-risk tradeoffs, by causing spillover effects into the domains of other agencies (*e.g.* the EPA asbestos ban yielding weaker brake linings and hence increased highway accidents, or EPA limits on air toxics emissions yielding increased exposures to workers inside factories). It is worth noting that OMB/OIRA's Circular A-4 (2003) (cited above) contained narrative instructions to perform risk-risk tradeoff analysis, but the table it attached as a scorecard to guide agency calculations did not contain a line on which risk-risk impacts (countervailing or ancillary effects) were to be entered.[33]

BCA is sometimes criticised as biased against health and environmental protection, on the view that costs are overstated by industry *ex ante*, and benefits are understated because they are difficult to quantify. Retrospective analyses of a variety of policies (though not a representative sample) does not support this concern; both benefits and costs appear to be overstated *ex ante* (OMB, 2005; Harrington *et al.*, 2000). Recall as well (from Section 3.1 above) the debate over whether risk assessment, which figures importantly in the calculation of policy benefits, may tend to overstate risks (and hence benefits). And critics of contingent valuation (used to value non-market assets such as ecosystems) contend that it overstates benefits.

Moreover, even if BCA does yield biased estimates, critics of BCA need to offer an alternative method of decision making that produces socially desirable results. If BCA is seen as an un-empathetic form of "cool analysis", one option is to employ a "warm analysis" that compares pros and cons in a structured decision framework but without insisting on strictly quantified and monetised impacts. This is the "prudential algebra" recommended by Benjamin Franklin, in a letter to Joseph Priestley in 1772:

> In the Affair of so much Importance to you, wherein you ask my Advice, I cannot for want of sufficient Premises, advise you *what* to determine, but if you please I will tell you *how*. When those difficult Cases occur, they are difficult, chiefly because while we have them under Consideration, all the Reasons *pro* and *con* are not present to the Mind at the same time; but sometimes one Set present themselves, and at other times another, the first being out of Sight… To get over this, my Way is, to divide half a Sheet of Paper by a Line into two Columns; writing over the one Pro, and over the other Con. Then during three or four Days Consideration, I put down under the different heads short Hints of the different Motives, that at different Times occur to me, *for* or *against* the Measure. When I have thus got them all together in one View, I endeavour to estimate their respective Weights… and thus proceeding I find at length where the Balance lies… And, tho' the Weight of Reasons cannot be taken with the Precision of Algebraic Quantities, yet, when each is thus considered, separately and comparatively, and the whole lies before me, I think I can judge better, and am less liable to make a rash Step; and in fact I have found great Advantage from this kind of Equation, in what may be called *Moral or Prudential Algebra*.[34]

Similarly, John Maynard Keynes remarked that he would "rather be roughly right than precisely wrong".[35] This tradeoff between accuracy and precision suggests that on standard BCA criteria, it would do more to improve policy decisions to get the full set of consequences before the decision maker, than to invest in precisely quantifying only a few of those consequences while neglecting others.[36]

The real concern about BCA may be institutional rather than technical. That is, the frequent institutional bent toward using BCA to stop costly health and environmental regulations poses BCA as antiregulatory, whereas the tool could be understood as neutral if it were applied to a wider array of decisions, to the full portfolio of impacts, and to promote desirable policies as well as to discourage undesirable policies. Greater use of "Prompt" letters (using BCA to promote desirable new risk regulation), and extension of BCA to a wider array of risk policies such as dams, forest clearing, guns, and counterterrorism (as discussed above), would make it more even-handed and would apply it as well to promote health, safety and environmental protection.

In addition, important factors such as distributional equity (fairness) may need to be included in the analysis, and may be difficult to quantify or aggregate with benefits and costs. The specific references to distributional equity in EO 12866, and the term "justify", were added to ensure consideration of these effects.

How to

Regulatory intervention options are numerous. They can be interposed at various points in the sequence from production to outcomes: inputs (materials, fuels), technologies (production methods/processes), activity levels (production level, driving speed), outputs (emissions, disposal, products), ambient levels (concentrations of pollutants), exposure levels, risk levels, injuries, and remediation. The regulator has a choice of regulatory instruments to deploy through these steps of the production sequence:

- Conduct standards, *e.g.*:
  - Requirements or prohibitions on materials inputs or fuels.
  - Requirements or prohibitions on technologies or designs (*e.g.* "best technology").
  - Requirements or prohibitions on outputs, such as product take-backs or waste disposal methods.
  - Negligence-based tort liability.
- Price instruments, *e.g.*:
  - Taxes, fees.
  - Subsidies for abatement.
  - Strict tort liability.
- Quantity instruments, *e.g.*:
  - Emissions limits.
  - Other performance standards.
  - Tradable allowances (marketable permits, cap-and-trade).
- Information instruments, *e.g.*:
  - Requirements to disclose materials, ingredients, emissions.
  - Labelling.
  - Assessment or planning requirements.

- Hybrid instruments, *e.g.*:
  - Tradable allowances with a price ceiling ("safety valve").
  - Deposit-refund, assurance bonding (price linked to conduct).

Self-regulation by industry standards (*e.g.* ISO codes) can similarly choose among these steps and instruments. A combined approach uses industry codes subject to government oversight to achieve promised performance, as in the approach of Dutch environmental covenants and Project XL in the United States (setting broad performance standards with subsequent monitoring of results, while leaving industry the choice of methods).

The more *ex ante* (prospectively) the policy is interposed in the production sequence, the more preventive or precautionary it can be, but the less information the regulator has about actual cause-and-effect and eventual harm.[37] Hence earlier interventions run the risk of false positives – crying wolf, such as regulating a product that turns out to be low risk, or incarcerating an innocent person. They may also reduce the ability of the instrument to encourage cost-effective behaviour at subsequent steps in the production cycle.

The more *ex post* (retrospectively) the policy is interposed, the more information about actual harm the regulator has, but the more such harm must be tolerated and compensated, or deterred *ex ante* by the threat of the *ex post* remedy. Hence later interventions run the risk of false negatives – waiting too long, such as not regulating a product that turns out to be high risk, or not apprehending a dangerous felon – especially if the harm is irreversible, or more irreversible (more costly to repair) than prevention costs would have been.[38]

Options for improving risk management include:

- Strengthening capacity through staff expertise and resources.
- Requiring Impact Assessments that are based on structured decision analysis, addressing the full portfolio of important consequences, including risk-risk tradeoff analysis (evaluation of ancillary impacts, both harmful and beneficial).
- Applying Impact Assessment and BCA more even-handedly to a wider array of types of policies.
- Appling Impact Assessment and BCA even-handedly to promote desirable policies as well as to discourage undesirable policies.
- Greater transparency through reporting of assumptions and methods and comparison to alternatives.
- Greater use of economic incentive instruments, such as taxes, tradable allowances, and information disclosure.
- Conducting an OECD survey of risk management methods and innovations across member states, including the types of analysis employed and the technical assumptions within such analyses.
- Developing OECD guidelines on risk management to improve societal wellbeing, consistency and transparency across member states.

Oversight – regulatory review

A serious 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. Justinian asked "Quis custodiet ipsos custodies", and the question remains

urgent today. As noted above, in the US, EO 12291 and EO 12866 established OMB/OIRA as the White House office, reporting to the President, with the authority and responsibility (and capacity: a staff of experts in economics and now in sciences as well) to oversee risk regulation. Other countries have also developed versions of oversight, including the European Commission's Impact Assessment Board, the UK Better Regulation Executive, the Canadian Privy Council overseeing lifecycle assessments, the Australian Productivity Commission, an independent body in the Netherlands, and others.

Such oversight is particularly needed in a world of interconnections. Risk regulations adopted by one agency may induce countervailing risks in other agencies' domains, requiring some co-ordination and oversight to manage these tradeoffs and if possible overcome them through innovative policies that reduce multiple risks in concert. In addition, the rapid propagation of risks through complex networks may warrant co-ordinated strategies among multiple agencies.

Ideally, the oversight body would review integrated Impact Assessments (IAs) that address all relevant issues. One concern is the tendency to proliferate splintered narrow IA requirements, such as separate IAs for Administrative Costs, Federalism, Energy, Environment, Sustainability, Competitiveness, Children, Small Businesses, etc. An integrated approach to the full portfolio of impacts and societal net benefits should be the real objective.

A second concern is the question of who will serve the oversight role in important institutions. A central oversight office offers a powerful, politically accountable, expert body to review all agencies' regulations. A lateral approach, with one agency reviewing IAs by other agencies, potentially pits factional interests against each other (business *versus* environment) and loses the opportunity to have the oversight body reflect and be accountable to the shared interests of the institution through its presidency. Thus, regulatory oversight should be a key task for centres-of-government. The central oversight body needs the:

- Responsibility: to think through, assess, analyse.
- Authority: to influence decisions, discourage undesirable policies (return), and promote desirable policies (prompt).
- Capacity: to review – the staff and skills (including but not limited to economics, sciences, and law).

In addition, oversight should conduct both *ex ante* and *ex post* analyses, as discussed further under the section "Evaluation and updating" below.

Judicial review of agency action is also available in some countries (especially in the US and increasingly also in the EU), as is legislative review (such as under the US Congressional Review Act). But these reviews serve legal and political functions; they typically lack the expert capacity of executive branch oversight by professional risk analysts. Indeed, effective executive branch oversight can help obviate the resort to judicial and legislative review.

Implementation (including enforcement)

Effective risk regulation needs implementation and enforcement. This is true of economic incentive instruments (such as allowance trading) as well as of traditional regulation. Institutions for this component vary widely across countries. But this (very large) topic goes too far afield to address in detail in the present chapter.

Coping – Adaptation, remediation, crisis response/disaster relief, compensation

Some measures will be needed to cope: to respond to the manifestation of a risk, if prevention fails and the risk occurs (*e.g.* hurricane, disease outbreak, terrorist attack), or if residual risks occur after preventive efforts have been made, or if serious side effects (countervailing risks) arise (*e.g.* children being killed by airbags, or counterterrorism yielding blowback). Coping with disasters is not the focus of this chapter. But the occurrence of the crisis, or just the lower-level emergence of the risk or countervailing risks, should be used as feedback to help adjust and improve the policy to reduce overall risk (*e.g.* the development of "smart airbags"). Note also that disaster relief poses a possible "moral hazard" problem: relief may constitute subsidised or underpriced insurance, which encourages people and firms to incur greater risk in the future. Such perverse incentives may arise from taxpayer-financed protection, insurance, relief and rebuilding (*e.g.* rebuilding in the flood plain, or new risk-taking by banks after a financial downturn and government bailouts).

Evaluation and updating

A crucial component of effective risk governance is monitoring performance. Do policies actually work? Do they achieve results? This component is often neglected, perhaps because agencies have scarce resources which they prefer to devote to new initiatives. There is a crucial need for *ex post* evaluation. At present, essentially all countries do some kind of *ex ante* assessment (through IA), but few conduct *ex post* review.

The question is how accurate are the *ex ante* IA estimates. As noted above, initial retrospective studies by OMB and by Harrington *et al.* (OMB, 2005; Harrington *et al.*, 2000) find both over- and under-estimates in the *ex ante* analyses. *Ex post* analyses are needed in order to improve policies as they evolve ("adaptive management"), and to validate and improve the *ex ante* methodologies for subsequent decision making.

Ex post validation effort should be done:

- As a representative sample rather than a convenience sample.
- Quantifying the degree of error rather than just the fact of over/under estimation.
- As a routine required step for every major rule.
- Taking account of ancillary impacts (countervailing risks and ancillary benefits).

4.4. The challenge of interconnectedness

As discussed above, traditionally risks have been handled one at a time, by a single government agency acting in isolation, and sometimes based on an *ex ante* impact assessment of the chosen risk policy. Many individual risks have thereby been reduced. But increasing interconnectedness poses new demands:

- forecasting the joint effects of simultaneous exposure to multiple risks;
- dealing with the rapid transmission of risks (such as disease, terrorism or financial downturn) across countries and continents, through increasing interconnections among ecological, trade, travel, and telecommunications systems;
- assessing policy impacts, both *ex ante* and also *ex post*, with effective institutional oversight;
- analysing the full portfolio effects, including ancillary impacts (countervailing risks and ancillary benefits), of any effort to reduce a target risk; and
- co-ordinating risk policies across agencies and across governments of different countries, especially for transboundary and global risks.

At the same time, interconnectedness offers an important opportunity:

- Learning from other countries' experiences and thereby borrowing policy ideas, in a process of transnational diffusion of regulatory innovations.

Much current debate over risk regulation concerns conflicts over individual specific risks such as climate change (the Kyoto Protocol), genetically modified (GM) foods, chemicals (the new REACH policy), and counterterrorism (including the war in Iraq). But beyond these specific visible examples, the larger context is characterised by general transatlantic parity in overall governance of risk, and a need for increasing co-ordination on interconnected systems.

Some argue that Europe is now "ahead" in risk regulation, perhaps as the result of underlying culture – European risk-aversion *versus* American risk-taking – or, by contrast, as the result of a reversal in position from greater US precaution in the 1970s to greater European precaution today. The reversal hypothesis highlights the slowdown in new law making in the US. Congress, and the accretion of EU regulatory institutions, since 1990.

But this evidence of greater European precaution, drawn from a few visible policies, is not the whole story. Other cases point in the opposite direction, of greater relative US precaution. For example, the US began phasing out CFCs a decade before Europe, and years before observations confirmed the theoretical link to ozone depletion. The US also phased out lead in gasoline before Europe did. Precaution is espoused in key US statutes, including the Clean Air Act and the Endangered Species Act. The US adopted earlier and more stringent restrictions on fine particulate matter and diesel emissions, in both the Clinton and Bush administrations. In response to the European epidemic of mad cow disease (BSE), the US has banned British beef since 1989, whereas the EU did not do so until 1996 and then removed that ban three years later. Further, in 1999 and 2001 the US FDA adopted "Precautionary Measures" banning blood donations by people who have spent a few months in Britain or a few years in Europe since 1980 – earlier and far stricter than in Europe, despite little evidence of BSE transmission via blood, and despite the countervailing risk of hospital blood shortages.

Thus the cases point both ways. But even these competing cases are not an adequate basis for overall comparisons. Selective examples cannot support broad conclusions about the general pattern. Hasty comparisons are vulnerable to the heuristic errors of disproportionate attention to recent, highly visible events, and exaggerated distinctions between groups that are actually similar.

To overcome these limitations, a multi-year study of a broadly representative sample identified the 2 878 risks mentioned in the relevant literature in the US and Europe from 1970-2004. From this universe, the study selected a random sample of 100 risks and scored the relative precaution in US and European regulations for each over the past 35 years (Hammitt *et al.*, 2005). It found less than a 6% difference in average relative precaution over the period. Neither the cultural hypothesis nor the reversal hypothesis was supported by the data.

The real pattern, then, is not precaution as a principle, it is precautionary particularity. The broader analysis reveals that the US and Europe exhibit general transatlantic parity, punctuated by divergences on a few specific risks, with each side acting more aggressively in some cases. The interesting question is not who is "ahead", but why the US and EU sometimes select such different worries.

Risk regulation is a multifaceted terrain on which no single race is being run. Rather than debating who is ahead, we should be learning from policy experimentation, evaluation, and borrowing. We should be identifying *better* laws, not just more laws. Instead of a race to the top, the United States and the EU should be developing a transatlantic policy laboratory to innovate and compare policy approaches.

Recognition of interconnectedness in risks requires a whole-of-government approach to link and co-ordinate among diverse sectors where interdependent risks may arise or impose consequences. It requires assessment of rapid propagation via linked networks, and of the joint effects of multiple exposures to different risks at the same time. And it requires analysis of the full portfolio effects of policy proposals, in order to weigh risk-risk tradeoffs and to adopt comprehensive policies that reduce multiple risks in concert. Efforts toward comprehensive regulation include the multi-gas approach in the climate treaties, and Integrated Pollution Control in the UK and elsewhere. The importance of interconnected risks and risk-risk tradeoffs underscores the need for co-ordinated, central oversight of diverse risk policies, and for *ex post* review of the actual effects of regulation – "evidence-based regulation", based on outcomes research (as in medicine).

Interconnectedness also offers the opportunity for learning, borrowing, and hybridisation, in a process of "diffusion of innovations".[39] Good policies can spread across countries (even without a crisis event in each country). Numerous examples have occurred in risk regulation, including environmental impact assessment, BCA, precaution, emissions allowance trading, environmental covenants, and others (Wiener, 2001, 2003). A key mechanism of such borrowing is the role of epistemic communities of experts who transcend national boundaries and engage in reflective comparative study. Thus the OECD can help facilitate constructive borrowing via sharing ideas across countries, exchange of visiting experts, and comparative studies of policies in practice.

Conclusion

How best to improve risk governance? This chapter has argued that increasing interconnectedness across risks, sectors, and countries will require new approaches and emphases. In particular:

- forecasting the joint effects of simultaneous exposure to multiple risks;
- dealing with the rapid transmission of risks (such as disease, pollution, terrorism or financial downturn) across countries and continents, through increasing interconnections among ecological, trade, travel, and telecommunications/internet systems;
- assessing policy impacts both *ex ante* and also *ex post*;
- effective centralised and expert oversight institutions;
- analysing the full portfolio effects, including ancillary impacts (countervailing risks and ancillary benefits), of any effort to reduce a target risk; and
- co-ordinating risk policies across agencies and across governments of different countries, especially for transboundary and global risks.

At the same time, interconnectedness offers an important opportunity to learn from other countries' experiences and thereby borrow policy ideas, in a process of transnational diffusion of regulatory innovations.

Oversight institutions require:

- Responsibility – to forecast and to assess policy options; to think through decisions, to improve social wellbeing.
- Authority – to regulate risks effectively and efficiently; to discourage undesirable policies and to promote desirable policies, through a central oversight body that can evaluate and influence decisions.
- Accountability: for decisions, reasons, transparency, performance/results.
- Capacity – staff and skills to conduct high-quality analyses and decisions.

Notes

1. This chapter was prepared by Jonathan B. Wiener, Perkins Professor of Law and of Environmental and Public Policy, Duke University.
2. The 2005 Guidelines also advocate the use of *ex ante* and *ex post* analyses of regulatory impacts (pp. 3-4), and urge that a "good regulation" is one whose benefits justify its costs (including economic, environmental and social effects), p. 3.
3. On the general problem of free riding impeding the collective provision of public goods, see Mancur (1965).
4. For an overview (emphasising fiscal policies), see Moss (2002).
5. For examples, see Graham (2005).
6. The science of health effects is necessary but not sufficient to set regulatory standards; policy analysis is also needed, incorporating valuations of health effects and of the costs, countervailing risks and other sacrifices involved in reducing those health effects. See Gary E. Marchant, Cary Coglianese, Jonathan B. Wiener *et al.*, "Principled Standard-Setting Requires Consideration of More than Science", Brief 00-02, AEI-Brookings Joint Center on Regulatory Studies (September 2000) (Brief Amici Curiae to the US Supreme Court in Browner v. American Trucking Assns.), available at *www.aei-brookings.org/publications/abstract.php?pid=91*.
7. Industrial Union Dept., AFL-CIO v. American Petroleum Institute, 448 US 607 (1980).
8. NAS/NRC, *Risk Assessment in the Federal Government: Managing the Process* (1983).
9. See Sheila Jasanoff (1986) (US approach to quantitative risk assessment is exceptional); Lofstedt (2000) (Japan and others have borrowed US approach).
10. Case 1/00, Commission of the European Communities v. French Republic (Failure of a Member State to fulfill its obligations – Refusal to end the ban on British beef and veal), 2001 E.C.R. I-09989 (European Court of Justice, 2001).
11. Case T-13/99, Pfizer Animal Health SA v. Council, 2002 WL 31337 (European Court of First Instance, 11 September 2002); Case T-70/99, Alpharma Inc. v. Council, 2002 WL 31338 (European Court of First Instance, 11 September 2002).
12. For both sides of this debate, see National Research Council, Science and Judgment in Risk Assessment (National Academy Press, 1994).
13. On false negatives, see European Environment Agency (2001). On extreme event risks, see Richard A. Posner, 2005.
14. US Environmental Protection Agency (2005). Guidelines for Carcinogen Risk Assessment. EP/630/P--03/0001F, *www.epa.gov/cancerguidelines*.
15. US OMB, Proposed Bulletin on Risk Assessment, 9 January 2006, available at *www.whitehouse.gov/omb/inforeg/infopoltech.html#iq*.
16. *E.g.* Chlorine Chemistry Council v. EPA, 206 F.3d 1286 (DC Cir. 2000) (vacating goal for maximum level of chloroform because agency set goal based on linear low-dose extrapolation when it had just found that a threshold model was superior). See also Leather Industries v. EPA, 40 F.3d 392 (DC Cir. 1994). (remanding standard for selenium content in sewage sludge because the exposure assumption – children eating sludge on highway median strips – was not credible).

17. International Life Sciences Institute (ILSI), A Framework for Cumulative Risk Assessment, ILSI Risk Science Institute Workshop Report 5 (1999), available at *http://rsi.ilsi.org/file/rsiframrpt.pdf* (visited 10 September 2003) ("Traditionally, these risk assessments have been conducted on individual chemicals medium by medium; however, humans are exposed to multiple chemicals by multiple routes concurrently in daily life").

18. John Muir, *My First Summer in the Sierra 110* (1988) (journal entry for 27 July 1869).

19. See Nico M. Van Straalen, *Ecotoxicology Becomes Stress Ecology*, Envtl. Sci. and Tech. 325A (1 September 2003); J.A. Foran and S.A. Ferenc (eds.), *Multiple Stressors in Ecological Risk and Impact Assessment* [Society of Environmental Toxicology and Chemistry (SETAC) Press, 1999]; S.A. Ferenc and J.A. Foran (eds.), *Multiple Stressors in Ecological Risk and Impact Assessment: Approach to Risk Estimation* (SETAC Press, Pensacola, FL, 2000).

20. Mark Grady, Book Review, Discontinuities and Information Burdens, reviewing William Landes and Richard Posner, *The Economic Structure of Tort Law* (1987), 56 Geo. Wash. L. Rev. 658, 664 (1988).

21. Herman Kahn and Anthony Wiener, *The Year 2000: A Framework for Speculation* (1967); Bertrand de Jouvenel, L'Art de la Conjecture (1964). Stephen Schneider, *Can We Estimate The Likelihood of Climatic Changes At 2100?,* An Editorial Comment, Climatic Change, 52, pp. 441-451 (2002) (criticising single-scenario forecasts and calling for probability-weighted portfolios of scenarios).

22. Separating risk assessment and risk management makes sense conceptually, but not necessarily organisationally. It is often better to have risk assessors and risk managers in the same agency, where they can be responsive to each other in an iterative conversation. This is especially true under conditions of interconnectedness, where risk managers will need to go back to risk assessors to seek forecasts of the countervailing and ancillary risks of their policy options.

23. Executive Order 12866, "Regulatory Planning and Review", 4 October 1993, available at *www.whitehouse.gov/omb/inforeg/eo12866.pdf*.

24. OMB/OIRA, Circular A-4, "Regulatory Analysis", 17 September 2003, available at *www.whitehouse.gov/omb/circulars/a004/a-4.pdf*.

25. Cass R. Sunstein, *The Cost-Benefit State* (Chicago: American Bar Association, 2002).

26. Hahn and Muething, 55 Admin. L. Rev. 608-42 (2003).

27. Analysis of counterterrorism policies (both domestic homeland security and external intelligence and military operations) is particularly urgent, because effective counterterrorism is essential but counterproductive policies can do serious damage to national security as well as to human life. See Barbara Tuchman, The March of Folly (1984). Yet these policies are difficult to analyse because information may be classified, because terrorists are strategic agents who respond to preventive measures hence requiring dynamic game theory models, and because some consequences may be hard to quantify (*e.g.* loss of privacy and freedom). In a recent article, we argue that little serious *ex ante* analysis was done of the Iraq invasion, with the result that serious countervailing risks were neglected, including collateral damage (civilian deaths), blowback, bog-down, distraction, and theft; and we advocate subjecting counterterrorism policies to a joint OIRA-NSC oversight process using analytic tools of BCA and risk-risk tradeoff analysis. See Jessica Stern and Jonathan B. Wiener, Precaution Against Terrorism, J. Risk Research (forthcoming 2006) and in Paul Bracken *et al.* (eds.), Managing Strategic Surprise (Cambridge Univ. Press, forthcoming 2006).

28. See Andrea Renda, *Impact Assessment in the EU* (Brussels: Center for European Policy Studies, 2006); Lucas Bergkamp, European Community Law for the New Economy (Intersentia, 2004), p. 169.

29. For more on RIAs in a variety of countries, see OECD, RIA Inventory (2003).

30. There is survey evidence indicating that VSL differs across country populations, *e.g.* Viscusi and Aldy, 27 J. Risk and Uncertainty 5, 27 (2003); Cass R. Sunstein, Valuing Life: A Plea for Disaggregation, 54 Duke L.J. 385, 415 (2004) (citing studies from USD 0.2 m to USD 19.9 m).

31. Sunstein, 54 Duke L.J. 385, 396-98 (2004) (USD 1.6 m to USD 6.5 m); Lisa Robinson, paper for National Academy of Sciences/Institute of Medicine, Current Federal Agency Practices for Valuing the Impact of Regulations on Health and Safety (2004) (USD 1 m-USD 8 m).

32. See Graham Wiener (1995), supra; Wiener, *Iatrogenic Risks* (1998), supra.

33. Other approaches do not achieve this full portfolio analysis. For example, "income-risk" ("health-health") analysis translates costs into risk units by estimating the amount of household income reduction (due to regulatory cost) associated with a death (due to reduced household expenditures on health). This in effect "riskizes" costs, instead of the standard practice of "monetising" health risks, to achieve a common numeraire; but it does not address the risk-risk phenomena of CR

or AB, which are additional effects apart from regulatory costs. "Precaution" typically looks only at ΔTR and ignores CR and C (although the European Commission's Communication calls for attention to C). A focus on "Administrative Costs" ("red tape") is only a subset of C, and reducing Administrative Costs could increase social costs, for example if a good BCA would necessitate some administrative costs, or if requiring industry to do more paperwork for information disclosure would save lives.

34. Benjamin Franklin, "Letter to Joseph Priestley", London, 19 September 1772, in Benjamin Franklin: Representative Selections, with Introduction, Bibliography and Notes, Frank Luther Mott and Chester E. Jorgenson; New York: American Book Company, 1936, pp. 348-349.

35. See also Cass R. Sunstein, *Cognition and Cost-Benefit Analysis*, in Mathew Adler and Eric Posner (eds.), *Cost-Benefit Analysis* (2001), also in 29 *Journal of Legal Studies* 1059 (2000).

36. This point is akin to the question of how much analysis is optimal. Better analysis yields fewer policy errors, but also incurs costs in money and time (delay). So one must compare the Value of Information (VOI) *versus* the Cost of Information. The EU therefore calls for "proportionate analysis", see EU Impact Assessment Guidelines (2005), p. 8; Andrea Renda, *Impact Assessment in the EU* (2006), p. 92.

37. *Ex ante* regulation is ordinarily based on forecasts of subsequent results (with and without the policy), such as future emissions, ambient levels, exposures, risk, and harm. Each of these forecasts of future variables is uncertain.

38. Even *ex post* liability often requires a forecast of subsequent harm, *e.g.* liability for natural resource damages after an oil spill, when the harm will persist for decades (compared to a counterfactual forecast of what the site would have been like absent the oil spill).

39. See Everett Rogers, *Diffusion of Innovations* (Free Press, 5th ed. 2003).

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Chapter 5

Management-based Regulation: Implications for Public Policy

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A common set of challenges faced by regulators is to achieve public risk management objectives at lower cost, often by giving greater flexibility to the private sector without sacrificing public health and welfare. In addition to improving existing regulation, challenges increasingly arise from new kinds of risks that seem to evade resolution through traditional forms of regulation. A potentially promising regulatory solution – management-based regulation – may help regulators better address both existing risks and new ones. The underlying concept is to deploy regulatory authority in a way that leverages the private sector's knowledge about its particular circumstances and engages firms in developing their own internal procedures and monitoring practices that respond to risks. This flexibility also raises the question of whether this regulatory strategy can actually deliver value to society. Empirical evidence indicates that management-based regulations can lead firms to make risk-related behavioural changes and induce positive behavioural change within industry. The purpose of this chapter is to explain where management-based regulation fits within government's overall policy toolkit and examine the conditions under which management-based regulation is both a viable and superior policy strategy.

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Introduction

Regulators around the world face major challenges associated with risk management (OECD, 2006) and regulatory reform (OECD, 2005; OECD, 1997). One common set of challenges arises when trying to achieve public risk management objectives at lower cost, often by giving greater flexibility to the private sector without sacrificing public health and welfare. In addition to improving existing regulation, challenges increasingly arise from new kinds of risks that seem to evade resolution through traditional forms of regulation. The purpose of this chapter is to analyse a potentially promising regulatory solution – management-based regulation – that may help regulators better address both existing risks and new ones.

In different jurisdictions and across various policy areas, management-based regulation goes by other names, including process regulation, systems-based regulation, safety-case regulation, and enforced self-regulation. Whatever it is called, the underlying concept is to deploy regulatory authority in a way that leverages the private sector's knowledge about its particular circumstances and engages firms in developing their own internal procedures and monitoring practices that respond to risks. Under management-based regulation, firms are not mandated to adopt specific risk protection technologies or practices, nor even necessarily to achieve specific limits on levels of risk or other measures of performance. Rather, firms are mandated to study their operations comprehensively and develop their own management strategies suited to the risks they identify in their operations.

Management-based regulation is increasingly used around the world to address risks as varied as environmental pollution, workplace hazards, food contamination, and terrorism (Coglianese and Lazer, 2003). Part of the attraction to management-based regulation is that it holds a number of potential advantages over traditional forms of regulation. By charging firms with responsibility for developing their own responses to public problems, management-based regulation takes advantage of firms' superior knowledge about the risks they generate and the potential methods of reducing those risks. As such, the means firms adopt in response to management-based mandates should presumably be less costly and more effective than means selected by a central government regulator. Firms may also be more likely under management-based regulation to innovate and seek out better solutions over time. Furthermore, since firms' managers make the key decisions in designing management systems, they may also be more likely to comply with their own rules and procedures than they would with ones imposed on them by government regulators.

On the other hand, the flexibility inherent in management-based regulation raises the question of whether this regulatory strategy can actually deliver value to society. Some might well worry that firms will easily game a management-based regulatory system, going through the motions of planning and filing required reports but not really doing anything to reduce underlying risks. Even if firms do reduce risks after a management-based regulation is adopted, perhaps they do so for reasons other than the imposition of management-based rules, such as to reduce costs or decrease liability risks.

After all, if a particular management-based regulation were to give firms complete flexibility to decide how to address the risks they create, then it presumably would have no independent affect whatsoever on firm behaviour.

Yet empirical evidence indicates that management-based regulations can lead firms to make risk-related behavioural changes (Bennear, 2007). This evidence, combined with the increasing use of management-based regulation, provides reason to consider management-based regulation as part of a larger "better regulation" strategy and as a potentially cost-effective approach to addressing risk regulatory problems. The purpose of this chapter is to explain what management-based regulation is, when to use it, how it should be implemented, and how it can achieve risk management goals. In the sections to follow, this chapter will explain where management-based regulation fits within government's overall policy toolkit and examine the conditions under which management-based regulation is both a viable and superior policy strategy. Reviewing the existing empirical evidence on the effects of management-based regulation, the chapter provides an account of why management-based regulation can succeed and merits consideration as a potential regulatory option when addressing risk problems. The chapter considers design characteristics that will likely affect management-based regulation's ultimate impact and addresses the challenges of estimating and assessing these impacts *ex ante* using benefit-cost analysis. Finally, the chapter concludes by discussing implications management-based regulation holds for the role of government as risk regulator.

5.1. Management-based regulation in the regulatory toolkit

Regulatory approaches vary greatly. Meeting the challenge to make regulation better requires, as a first step, understanding the differences among regulatory tools and then applying the appropriate mix of tools that will achieve the best results under the relevant circumstances. For many years, regulatory officials and analysts have faced varied but usually overlapping taxonomies of regulatory tools, which has sometimes clouded rather than advanced the clarity needed for regulatory analysis. For example, Richards (2000) summarises over a dozen different taxonomies of regulatory tools, each containing over about six or seven different labels used to describe discrete policy instruments in just one field of regulation. Although the array of instruments available to any decision maker may seem large, regulatory tools all share a common characteristic. By definition, all regulatory tools consist of a rule or rule-like statement having normative force and being backed up with some at least probable consequences. Despite this common characteristic, the myriad regulatory tools available to regulators vary in important ways along distinct dimensions. To understand how management-based regulation differs from other regulatory strategies, it helps to clarify the distinct aspects of regulatory tools and how they make up the regulatory toolkit.

Four dimensions of regulatory tools

Regulatory tools all share in common the following four major dimensions: regulator, target, command, and consequences. Each of these is briefly defined below in order to set the stage for understanding what makes management-based regulation distinctive.

- *Regulator.* The entity that creates the rule and dispenses the consequences is the regulator – typically a legislature or governmental agency. In principle, though, the regulator could also sometimes consist of a nongovernmental standard-setting body, non-profit organisation, industry trade association, or even business firms themselves – forms of what is commonly considered self-regulation (Sinclair, 1997).

- *Target*. The regulated entity is the individual or organisation to which the rule applies and upon whom or which the consequences can be imposed if the rule is not followed. However, the target – or frame of reference – of the regulation can be smaller or larger. For example, if an air pollution regulation prohibits industrial facilities from emitting pollution from any smokestack above a specified level, the target is the individual smokestack even though the facility (or its corporate parent) will suffer the consequences if the smokestack's levels exceed those in the regulation.
- *Command*. A rule directed at a target can specify means or ends. It can direct the target to engage in (or avoid) a specific action designed to advance the regulatory goal, such as a command to install ventilation systems or provide employees with protective equipment would aim to protect worker health and safety. It can direct the target to achieve (or avoid) a specified outcome related to the regulatory goal, such as a rule stating that workplaces shall not have levels of contaminants in the air exceeding a specified concentration level. A further elaboration on commands is provided in the next sub-section.
- *Consequences*. The normative force of a rule is reinforced with consequences. Negative consequences take the form of penalties such as fines or loss of a licence for a regulated entity's failure to comply with the rule. But consequences can also be positive, such as when subsidies, product approvals, regulatory exemptions, or other "rewards" are provided whenever the predicate conditions in a rule (or set of rules) are met.

Four types of regulatory commands

Of these four dimensions, the one central to management-based regulation is the *command*. This is because management-based regulation can be imposed by any type of regulator on any type of target, and it can be reinforced by a host of different kinds of consequences. What distinguishes management-based regulation from other types of regulation is the nature of what it obligates regulated entities to do.

As noted above, there are really only two basic types of commands available to regulators: means and ends. Means regulation mandates the use of technologies or behaviours; regulators tell targets to adopt a particular means, such as install a certain type of pollution control technology, maintain specified types of records, or ensure employees wash their hands or wear safety equipment, to give just a few examples. Alternatively, regulation can mandate the achievement or avoidance of ends; in other words, regulators direct targets to achieve or avoid certain outcomes, such as to keep concentrations of air pollutants below certain levels, ensure new drugs prove to be safe and effective, or avoid causing accidents (Coglianese *et al.*, 2003).

Both of these two types of commands can be distinguished along another dimension having to do with the scope of the command's focus: macro *versus* micro. In other words, both *means* and *ends* embedded in regulation can be either *specific* or *general*. As such, regulatory commands can be classified in four categories, as shown in Table 5.1. When regulation is focused at the micro-level, it requires either the adoption of specific means (such as with equipment standards) or the attainment of concrete outcomes that are proxies for the outcome of ultimate concern to the regulator (such as product testing standards). When regulation is focused at the macro-level, it requires either the adoption of very general means (such as to conduct planning or set up a management system), or the achievement (or avoidance) of the outcome of ultimate concern to the regulator (such as general duty clauses that direct employers to protect workers from harm but do not specify how to do so).

Table 5.1. **Typology of regulatory commands**

	Means	Ends
Macro	**Management-based** *Also sometimes referred to as:* Process or systems regulation; safety case regulation; risk-management requirements; enforced self-regulation; meta regulation. *Examples:* HAACP food safety regulations; workplace process safety; pollution prevention planning.	**Meta-performance** *Also sometimes referred to as:* *Ex post* liability; general duty clause. *Examples:* Tort liability for harm; compensatory and punitive damages for spills/accidents.
Micro	**Means-based** *Also sometimes referred to as:* Design standards; specification standards; technology-based regulation; command and control regulation. *Examples:* Safety equipment requirements; mandated use of pollution control devices.	**Performance-based** *Also sometimes referred to as:* Outcome-based regulation; market-based regulation (when non-uniform performance is permitted, such as with emissions trading). *Examples:* Effluent concentration standards; product testing protocols.

Management-based regulation, then, requires regulated entities to adopt only the most general type of means. Usually these means are defined in terms of internal planning and management practices that are to be aimed at achieving some improvement in achieving the social objectives underlying that regulation. Importantly, with a pure management-based regulation, the desired improvement in social objectives is not what the regulation mandates; if it did mandate achievement of the objective, that particular mandate would be either a performance-based or meta-performance standard. Instead, regulated firms subject to management-based regulation are expected to produce plans or adopt management systems that comply with criteria stated by the regulator, such as to identify hazards, develop a options for risk mitigation, establish procedures for monitoring and correcting problems, train employees in these procedures, and develop measures for evaluating and continuously improving the firm's management with respect to the stated social objective. Firms are sometimes expected to obtain approval or certification by government regulators or third-party auditors of their management practices and their compliance with their internally generated plans and procedures.

Examples of existing applications of management-based regulation

Regulators around the world have adopted management-based regulation in numerous regulatory settings. Often this regulation imposes on firms the obligation to "Plan-Do-Act-Check" with respect to addressing a public regulatory problem. Management-based regulation often requires firms begin by conducting an internal risk analysis. Then firms are expected to identify and evaluate various risk management options; implement some of the effective options; establish procedures, training, documentation, and monitoring functions; and engage in auditing and on-going efforts to improve the firms' management. Three examples illustrate this approach:

Industrial safety

Management-based regulation has been used to address mine safety in Queensland (Gunningham, 2006), rail safety in the United Kingdom (Hutter, 2001), and workplace safety throughout Europe, Canada, Australia, and the United States (Bluff, 2003). For example,

following the 1984 chemical faculty catastrophe in Bhopal, India, environmental and OSHA regulators in the United States adopted management-based regulation for what they called, respectively, "risk management planning" and "process safety management".

US OSHA and EPA regulations require firms to implement a multi-step management practice to assess risks of chemical accidents, develop procedures designed to reduce those risks, and take actions to ensure that procedures are carried out in practice. Firms must begin by conducting a "process hazard analysis" to identify what could potentially go wrong in their facilities' processes and what steps must be in place to prevent such accidents from occurring. Firms must rank their different processes according to factors such as how many workers could potentially be affected and the operating history of the process, including any previous incidents involving the process.

Firms must next identify both actual and potential interventions to reduce hazards associated with each process, including control technologies, monitoring devices, early warning systems, training, or safety equipment. Based on this analysis, firms must develop written operating procedures both for normal operating conditions and emergency situations. These procedures must be made available to employees who work with the chemical processes. In addition, firms must continuously review these procedures and update them as necessary to reflect process changes, new technologies, or new knowledge.

Firms are required to certify their operating procedures on an annual basis and to provide for compliance audits every three years. By tracking process and incident data in a systematic way through process safety management, firms are supposed to make modifications that can improve worker safety over time (Coglianese and Lazer, 2003; Chinander *et al.*, 1998; Kunreuther *et al.*, 2002).

Pollution prevention

For many years, conventional forms of environmental regulation have aimed to get firms to control their air and water emissions. In the United States, a number of states have gone further to impose requirements on firms to manage their operations in such a way as to achieve reductions in the use of the substances that cause polluting emissions. Rather than mandating pollution control, these pollution prevention regulations require businesses to engage in a management process aimed at preventing pollution from occurring in the first place.

The Massachusetts Toxic Use Reduction Act (TURA) represents one such effort at management-based regulation designed to promote pollution prevention rather than just pollution control. Under TURA, firms that use large quantities of toxic chemicals must analyse their use and flow of chemicals throughout their facilities, develop plans to reduce their use and emissions of toxic chemicals, and submit reports of their planning to state environmental agencies (Karkkainen, 2001). The state also requires that a state-authorised "pollution prevention planner" certify each plan as having met the law's criteria.

Interestingly, although firms are required to go through the planning process and develop a system for reducing the use and emissions of toxic substances, TURA does not require firms to comply with their own plans (Coglianese and Lazer, 2003). It is just a planning law. Since TURA was enacted in 1990, about a dozen other states have adopted similar pollution prevention planning laws (Bennear, 2006).

Food safety

The most prominent and globally extensive example of a management-based regulation is the food safety regulatory regime called HACCP – an acronym that stands for Hazards Analysis and Critical Control Points (Ropkins and Beck, 2000). HACCP requires firms to evaluate, monitor, and control potential dangers in the food-handling process. Under HACCP, firms must identify the potential hazards associated with all stages of food processing and assess the risks of these hazards occurring. Food processors are expected to use a flow chart to aid them in analysing the risks at every stage of production after the food enters the plant in question.

HACCP next requires firms to identify the best methods for addressing food safety hazards. The firm must identify all "critical control points" (CCPs), or points in the production process at which hazards can likely be eliminated, minimised, or reduced to an acceptable level. For each CCP, the firm must establish a minimum value at which the point must be controlled in order to eliminate or minimise the hazard. Having developed a methodology for dealing with hazards, the firm is required to ensure that it complies with that methodology. The firm must list the procedures that will be used to verify that each CCP does not exceed its critical limit, and must determine and indicate how frequently each procedure will be performed.

Each firm's HACCP plan should also indicate the actions the firm proposes to use to correct its operating procedures if a CCP is discovered to have exceeded its limit. As part of its corrective action, the firm must ensure that the cause of the deviation is identified and eliminated, that the CCP is "under control" after the corrective action is taken, that steps are taken to prevent recurrence, and that products adulterated by the deviation are not placed on the market. The firm is also expected to develop a methodology for monitoring and evaluating the effectiveness of its HACCP plan. Furthermore, in order to permit effective self-evaluation and government oversight, HACCP imposes extensive record-keeping requirements on firms (Coglianese and Lazer, 2003; Bennear, 2007).

Many countries have adopted HACCP as part of their domestic regulations (Lazer, 2001). In 1997, the Codex Alimentarius adopted HACCP standards and the European Commission subsequently required all member states to implement HACCP legislation by 2006. The European Commission has recognised that one of the advantages of HACCP is that it is "flexible by its very nature, being based on a limited set of principles and procedures supporting the objective of food safety, without compelling food businesses to comply with rules or to implement procedures which are not relevant or adapted to the specific context for their activity" (EC, 2005).

Summary

As these examples suggest, management-based regulation has already been used by regulators in advanced economies around the globe. These examples may also suggest certain similarities to other regulatory strategies. For example, management-based regulation would appear to be like self-regulation in that firms respond to management-based regulation by creating their own internal systems of "regulation". Moreover, like self-regulation, management-based regulation gives firms much flexibility to select the most cost-effective and innovative strategies for risk reduction (Unnevehr and Jensen, 1999). But unlike self-regulation, management-based regulation can be – and is – government-imposed regulation. It is not voluntary, but instead imposes actual legal obligations on firms to engage

in analysis, planning, and management practices. For this reason, scholars have sometimes called it "mandated self-regulation" (Bardach and Kagan, 1982; Rees, 1988) or "enforced self-regulation" (Braithwaite, 1982) to distinguish it from pure self-regulation.

Management-based regulation is also sometimes said to be "performance-based" (DHS, 007a; Chinander *et al.*, 1998). Indeed, it *is* performance-based in the sense that the required planning and management practices are supposed to aim to achieve a certain type of outcomes, such as reducing the use of toxic chemicals or preventing industrial accidents. Like performance-based regulation, and especially meta-performance standards, management-based regulation also gives much flexibility and discretion to firms themselves. But unlike performance-based regulation, which imposes an obligation to attain or avoid a certain *outcome* (Coglianese *et al.*, 2003), management-based regulation requires only that firms engage in certain *management practices* that are designed to achieve (or avoid) the outcome. The achievement or avoidance of the outcome is *not* what is mandatory under a pure management-based regulation; the establishment of management practices is.

Finally, management-based regulation should be distinguished from regulation that compels information disclosure. To be clear, management-based regulation often requires firms to collect and maintain considerable amounts of information. After all, the gathering of information is usually a first step in effective management. Yet management-based regulation is distinct from the most common kinds of information disclosure regulation (Sunstein, 1999; Karkkainen, 2001). The most common forms of information disclosure regulation are actually means-based regulation since the regulator commands the form of information dissemination (such as with labelling standards). Information disclosure could be performance-based if the mandate is output-oriented (such as to achieve a goal of a certain level of disclosure or knowledge by others). Only when the purpose of information collection and disclosure is to inform and affect management or planning decisions would it be proper to consider information disclosure a type of management-based regulation. While most instances of management-based regulation will necessarily have some time of informational component, management-based regulation typically requires firms to do much more than simply generate and disclose information – namely, it requires them to develop internal plans and procedures based on the information they gather.

5.2. Conditions for the use of management-based regulation

As noted at the outset of this chapter, management-based regulation holds advantages over traditional regulation, such as in providing firms flexibility to adopt more cost-effective solutions. However, this does not mean that it should be used to address every regulatory problem. After all, management-based regulation also holds potential disadvantages. The flexibility it gives to regulated firms may be used to the advantage of the firms more than to benefit the broader public. It may also be difficult for government or third-party auditors to determine whether management plans that look thorough and effective on paper are actually making a significant different in practice. Thus, in deciding whether to use management-based regulation, a regulator must compare this regulatory tool with its alternatives. Management-based regulation, like any regulatory option, should be selected only when it can be expected to lead to superior results, based on stated criteria, when compared with other available options.

The first question to ask, then, when considering management-based regulation is whether there is a need for regulation at all. The prevailing assumption is that competitive markets prove highly successful for producing and allocating society's resources, but that

conditions for socially optimal free market transactions do not always obtain (Stokey *et al.*, 1980; Viscusi *et al.*, 2005). Regulation is therefore generally justified when the market fails for reasons of externalities, information asymmetry, market power, or when other problems such as distributional inequities arise (OMB, 2003).

Assuming a need for regulation, how should a regulator choose between means-based, performance-based, or management-based regulation? The choice in any particular regulatory setting will depend on the circumstances and of course should be preceded by a regulatory impact analysis of each regulatory option (a topic addressed in more detail later in this chapter). That said, several general observations can be made at this point about the choice between three major categories of regulatory tools.

Means-based regulation will often provide reasonable certainty of effectiveness in addressing the regulatory problem, since the regulator will usually only mandate those means that have been shown to work in the past. Means-based regulation may also be easier for government to assess compliance, since presumably all an inspector needs to do is observe whether the specified means are in use. However, as already suggested, means-based regulation can be a blunt tool, sometimes requiring more costly behaviour for individual firms and discouraging innovation and the search for better or more cost-effective solutions. In some cases, the means that work well at some regulated firms may not work at all at other firms, given the particular circumstances of their operations. One size may simply not fit all.

In contrast to means standards, performance standards focus attention on desired outcomes and give firms flexibility to find less costly or better solutions. Rather than picking one means and requiring it for everyone, firms can choose how to address a problem as long as they meet the specified outcome. Furthermore, if performance standards are non-uniform, such as with market instruments like emissions trading, firms gain even greater flexibility. Non-uniform performance standards can yield still greater cost-effectiveness by allowing some firms to perform worse provided others perform better, as long as average performance meets the regulatory objective. Of course, making performance standards work depends on being able to measure and monitor firms' performance (Stavins, 1998). As noted at the outset of this chapter, though, sometimes it is difficult to operationalise the desired outcome into an enforceable regulatory standard, or sometimes it is prohibitively costly for the regulator to monitor outcomes.

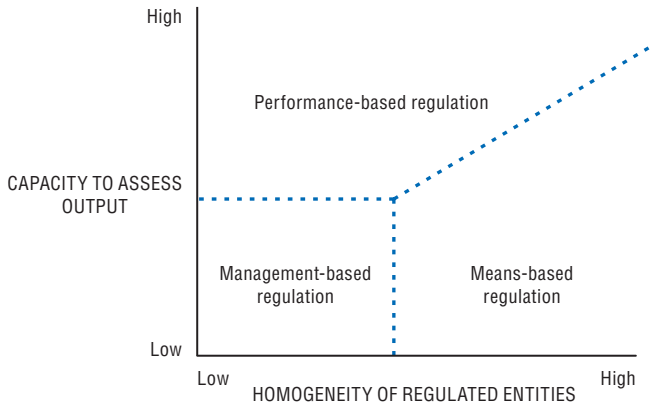
In a world with no administrative or transaction costs, governments could craft optimal regulatory instruments of any type. They could create infinitely specified and adaptable means standards that fit each firm's operations perfectly. For example, if a particular pollution control technology works well for all but a few firms, an environmental regulator would be able easily to identify those few firms and issue alternative means standards applicable to them. Or if the regulator chose a performance-based approach, they could create optimally calibrated performance standards that were fully monitored. But the reality is that regulators do face significant transaction costs in selecting and implementing regulatory standards. They can neither adapt means standards to every firm's circumstances nor costlessly monitor every possible measure of performance. As such, administrative costs to the regulator become a key consideration in choosing among regulatory instruments.

It follows that these administrative costs can be expected to vary depending on at least two general factors that bear on the choice of management-based regulation and its alternatives: *i)* the ease of assessing outputs; and *ii)* the degree of heterogeneity in

regulated firms. If government possesses an ability to assess social outputs cheaply and accurately, then performance standards are a viable (and presumably desirable) regulatory standard. If the regulated sector is homogeneous (*i.e.* most firms have similar operations that remain stable over time), then means standards are likely to be viable; a one-size-fits-all standard works well, obviously, when one size truly does fit all.

As Figure 5.1 shows, if regulatory problems can be arrayed on two axises, depending on the capacity of the regulator to assess outputs and the heterogeneity of the regulated community, the conditions favouring performance-based and means-based regulation are fairly clear. But what is the regulator to do when performance is hard to measure and firms are heterogeneous?

Figure 5.1. **Conditions for use of means-based, performance-based, and management-based regulation**



Consider, for the sake of illustration, three emerging risk regulation issues facing many economies around the world:

- *Nanotechnology.* One of the fastest growing areas of technological development holds both enormous potential for improving consumer products and medicines but also some potential – often yet unknown – for health and safety risks. Nanoparticles' size means that they may more easily lodge in the lungs, penetrate the skin, and even possibly pass through the blood-brain barrier.
- *Import safety.* Recent incidents of tainted consumer imports, ranging from pet food to toothpaste to children's toys, have highlighted the risks from global trade. In an increasingly globalised economy, import countries face an increasing challenge of ensuring that products not directly covered by their own consumer product rules and regulatory oversight will still be safe.
- *Security of hazardous facilities.* Terrorist attacks of chemical plants, nuclear facilities, petroleum refineries, and other industrial operations threaten more than the destruction of these facilities. They also pose grave risks of broad-scale public harm, throughout the surrounding community and even possibly region.

These three examples share two characteristics that make them difficult to address by traditional regulatory instruments. First, they are problems where it is difficult to prescribe a one-size-fits-all solution. Nanoparticles are incredible diverse and their properties vary considerably from one compound to another. Imports are also highly varied and they are

continually changing due to market demand and technological innovation. Industrial operations pose highly varied security risks depending on their location and type of process. As a result of the heterogeneity in these areas, imposing traditional regulatory specifications is difficult, if not impossible for a government regulator. When there is no common solution for all firms, imposing specific requirements will lead to costly, ineffectual, or even at times counterproductive results.

Second, all three problems are ones where it is difficult to specify desired outcomes in regulatory standards. In each, the regulator is unable to monitor or measure risk adequately in order to require that firms keep risks below some specified level. In the case of nanotechnology, the health risks are largely unknown at this time, but the properties of nanoparticles and their size make it plausible that at least some of these new materials will pose public health risks. In contrast, the risks associated with product imports may be better known (*e.g.* lead paint on toys, contaminated toothpaste) – but it is much harder to monitor the risks created by imports, given the vast number of different products and the large volume of imports received by developed economies. With respect to security risks t industrial operations, the consequences will be easy to spot only once it is too late – so while some kind of preventative regulation is needed, it is hard to measure risk when it is ultimately generated by creative agents who can deliberately seek to identify and exploit weaknesses in any firm's security.

Challenges like these defy the conditions where traditional regulatory tools will work. They would meet the conditions where regulators could consider management-based regulation to be a viable regulatory option, because they present problems for which regulators would face substantial difficulty measuring outputs and where the regulated firms or their processes are much too heterogeneous to make it feasible to mandate specific means.

The same is true for the examples of management-based regulation described in the previous section of this chapter: namely, HACCP, chemical accident avoidance planning, and pollution prevention. For obvious reasons, no simple laboratory test of any kind can measure the (generally low) risks of chemical accidents, making performance standards infeasible. In the food area, the traditional methods of sensory monitoring for contamination (such as the so-called "poke and sniff" method) are often unable to detect the presence of pathogens, and lab results from advanced microbial testing can sometimes take too long to generate before perishable products must be shipped out into the supply chain (National Academy of Sciences, 1998). Moreover, the large number of firms covered by all three examples of regulations suggests that that the regulated population is highly heterogeneous. The US Food and Drug Administration once noted, for example, that even in the relatively narrow fruit juice manufacturing sector "no two processors use the same source of incoming materials or the same processing technique, or manufacture in identical facilities" (FDA, 2001). Even more extensive variation in operating conditions can be found across the firms addressed by chemical accident prevention and pollution prevention regulations.

Management-based regulation is worth considering any time the government confronts hard-to-assess risks generated by many diverse firms. Inevitably the firms and their managers will tend to have better information about the risks associated with their operations and the possible ways to reduce or manage those risks cost-effectively (Coglianese *et al.*, 2004). Management-based regulation recognises and seeks to leverage

industry's informational advantages. Unlike traditional forms of government regulation that treat the regulated firm as something of a "black box" – with the regulator not particularly caring what goes on inside companies as long as they used the prescribed means or achieve the outcomes desired by the regulator – management-based regulation explicitly seeks to shape the actual operations of a firm, imposing requirements for systematic planning with respect to public risks and the adoption of internal procedures, training, and management practices.

5.3. Does management-based regulation work – and why?

Can management-based regulation actually work? At least at first glance, a sceptical response to this question might appear warranted. After all, by definition management-based regulation does not require that regulated entities actually make any improvements in their outcomes. Instead it requires them to engage in analysis, planning, and the creation of internal processes. And sometimes, as with the pollution prevention planning laws in various states in the US, management-based regulation does not even require firms to implement their plans. As such, some observers might view with suspicion the flexibility management-based regulation gives to firms to select their own means of fixing the regulatory problem. That discretion could be used by firms to game regulators, perhaps simply by making it look like the firms are managing their operations responsibly by creating documents and procedures that look good on paper but do not reflect the reality of the firms' day-to-day operations.

These are not unreasonable concerns. Ultimately, though, the question of whether management-based regulation works is an empirical one. So far, data on the use of management-based regulation suggests that it can indeed make a difference, at least in some cases. If we look at the three areas where management-based regulation has been used in the United States, there is evidence suggesting it can indeed be effective in addressing important regulatory problems. For example, foodborne illnesses from E. coli O157:H7, a serious pathogen that prompted the mandating of HACCP in the beef industry, have decreased 42% in the United States following HACCP's introduction (CDC, 2006). Insurance claims in chemical industry declined by 40% in the decade after the introduction of federal risk management planning requirements (Coglianese and Lazer, 2003). In the state of Massachusetts – the first state to adopt mandatory pollution prevention planning laws – the use of toxic chemicals declined by 41% in the decade following the law's adoption, with a decline of 88% in the emissions of toxic chemicals (Coglianese and Nash, 2004).

These data need to be approached with some caution, though. In the area of food safety, despite the decline in foodborne illnesses related to E. coli and other pathogens in the US, illnesses related to a small number of other foodborne pathogens have actually increased (CDC, 2006). In addition, other factors unrelated to the introduction of management-based regulation may explain at least some of the changes in reported outcomes, whether for the worse or the better. For example, foodborne illnesses constitute a broad proxy for the impact of HACCP in reducing pathogens during the processing of food. Illnesses can be caused by the spread of pathogens in the handling or preparing food – not just the processing of food in plants covered by the HACCP regulation. Changes in these other pathways leading to the ultimate outcome (illness) could well mask the true effects associated with HACCP in addressing pathogen introduction during the processing of food. Illnesses could rise even if HACCP resulted in pathogen reductions in food processing, and they could drop even if HACCP caused no change in pathogen reductions in food processing.

In addition to confounding effects from other contributing causes, the introduction of management-based regulation does not always occur in isolation of other regulatory changes. For example, the reported declines in toxic emissions in Massachusetts might have been affected by changes in conventional regulations, such as the new performance-based hazardous air pollutant requirements adopted by the federal government around the same time as the passage of the TURA law. The likelihood that broader legal factors explain some of the decline in toxic chemicals is suggested by the fact that overall toxic emissions declined 46% across the United States during the same period (Coglianese and Nash, 2004). Moreover, compared with neighboring states in New England, where toxic emissions also declined an average of 87% during the same period (Coglianese and Nash, 2004), the 88% decline in toxic emissions in Massachusetts does not look nearly as striking (Karkkainen, 2001). The declines reported during the same period in New Hampshire (93%), Connecticut (92%), and Rhode Island (91%) were somewhat larger than experienced in Massachusetts, even though none of these other states had adopted a management-based pollution prevention law (Coglianese and Nash, 2004).

Given the potential for confounding effects, it is necessary to turn to statistical analysis to untangle the precise effects of management-based regulation. Bennear (2007) has tested the effects of the pollution prevention planning laws using longitudinal data on toxic emissions from more than 30 000 facilities throughout the United States, both from the fourteen states that had adopted pollution prevention planning laws similar to TURA as well as those that had not. These laws, recall, only require that firms plan – not necessarily that they implement their plans. Using a differences-in-differences statistical strategy, Bennear compared the trends in toxic emissions across both the "experimental" group of states with management-based regulation and the "control" group of states without management-based regulation. Emissions declined everywhere, but to determine whether changes came about due to the introduction of management-based regulation, Bennear analysed how the trends in management-based regulation states fared against other states, when controlling for a variety of other factors correlated with toxic emissions. She found that the presence of a management-based regulation in the jurisdiction within which facilities were located was associated with about a 30% decrease in toxic emissions – over and above what otherwise would have occurred in the absence of the management-based law. Bennear's (2007) study is the strongest evidence that management-based laws like TURA can contribute positively to their intended results.

This research isolating positive effects of management-based regulation raises the question of how exactly it is that management-based regulation works. If laws like TURA only require firms to engage in planning but do not even require them to follow their internal plans, it may be wondered why firms would ever invest in the additional costs that would be involved in implementing their plans. Is positive social change in the wake of management-based regulation consistent with rational economic behaviour?

It has sometimes been argued that, even in the absence of regulation, socially responsible behaviour yields bottom line results for businesses (Porter and van de Linde, 1995) – what has come to be known as "win-win theory". For example, Reinhardt (2000) shows that making investments in social goals can advance a company's profits if doing so enables the company to lower production costs, differentiate its products from competitors, or manage liability risks better. Yet despite these reasons for businesses to act in socially responsible ways, the continued need for regulation would indicate that firms do not find

enough private benefits to act in ways that are privately costly but socially optimal. As Palmer *et al.* (1995) caution, if there was money simply lying on the floor in terms of profits from corporate responsibility, companies would have picked it up already.

The scholarly debate over win-win theory is relevant to management-based regulation. Although management-based regulation compels firms to engage in planning, it still gives firms considerable discretion to decide what these plans should contain. In the exercise of this discretion, firms may simply engage in the required planning instead of actually undertaking the costly, follow-through action needed to implement their plans and achieve improvements in the outcomes addressed by the regulation. The evidence of the positive effects of management-based regulation suggests that firms do indeed respond to management-based regulation by making at least some investments that they otherwise would not make. Yet these effects cannot stem from win-win theory by itself. After all, if there were private gains to be had from the investments taken after the introduction of management-based regulation, would not firms already have reaped these gains even without the imposition of management-based regulation? Three complementary accounts explain why management-based regulation can be expected to work, even when regulation simply mandates that firms engage in planning and analysis.

The first explanation might be called a theory of "sunk search costs". This account, like win-win theory, recognises that firms can reap private rewards from investing in actions that deliver positive social outcomes. But it also recognises that firms face costs associated with identifying socially beneficial actions that also yield private actions. In other words, to extend Palmer *et al.*'s analogy, firms do not find money simply lying on the floor waiting to be picked up by taking socially responsible action. Rather, such money lies hidden underneath the floor tiles and behind the shop equipment – if only they can find it. Since finding cost savings and competitive advantages from socially responsible behaviour is costly, rational firms will only expend the necessary search costs when the expected net benefits exceed the search costs. Since firms have not found these cost savings yet, they may well view the expected net benefits as small, discounted by a low probability estimate of finding anything. If nothing else, firms' managers may "expect there would be more value in devoting their management resources to some other area" (Bennear, 2006). For this reason, firms might be said to be rationally ignorant of potential win-win opportunities. However, when a management-based regulation mandates firms to engage in planning and analysis, firms must engage in search costs that they otherwise would have avoided. Search costs become sunk costs to the firm, and any cost-saving or profit-enhancing actions firms identify along the way of complying with management-based regulation will be adopted as long as they prove net beneficial.

A second explanatory account focuses on the complementarity between planning and the achievement of social goals. Bennear (2006) argues that for mandated management activities to deliver social benefits, there must be a direct connection between the mandated activities and the desired social outcomes. This complementarity is most readily apparent with problems that arise due to poor management. Accidents in chemical plants, for example, could be expected to occur more frequently in facilities with poor oversight and co-ordination. At the limit, entirely untrained workers who mix chemicals on their own accord, without supervision, would clearly be expected to be more likely to cause an accident. To the extent that there are management-based *problems*, then management-based regulation is clearly complementary. For these types of problems,

management-based regulation would yield results if firms are not already engaging in a socially optimal level or quality of analysis, planning, and other management activities. In other words, the lack of good planning is itself a type of market failure.

Finally, management-based regulation may work because of a background threat of liability under a meta-performance standard (such as tort liability) or other regulatory threats (such as the risk of increased regulatory scrutiny under other laws). If firms face the risk of liability if they discover problems but do nothing to solve them, then once problems are discovered in response to a management-based mandate, firms have a background incentive to take action to solve them. On this account, it is not solely the management-based regulation that operates to induce firms to make costly investments that follow-on management-based regulation, but the interaction between such regulatory commands and other legal norms.

At present, researchers have yet to distinguish which of the three accounts best explains the impact of management-based regulation. It remains possible that a combination of some or all of the three explanations could be operating at the same time. However, the existence of these reasons for expecting management-based regulation to work combined with the available data showing that management-based regulation can indeed work, suggests that management-based regulation should be considered a viable option when regulators consider options for addressing public risks.

That said, it is one thing for a regulatory tool to achieve improvements in the near term, shortly following its introduction. It is another for that tool to sustain long term and continual improvements over time. Since sometimes management-based regulations explicitly seek to encourage businesses to make continuous improvements in their facilities' operations, it is worth asking whether a management-based approach can continue to encourage firms to make investments over time. Interestingly, Bennear (2006) tested for the effects of management-based regulation on facilities over time. The most statistically significant effects (at the 5% level) occurred within two to four years after the imposition of a planning mandate. However, the statistical significance dropped for years five and six (10% level). After year six years, mandatory planning requirements showed no statistically significant effect on toxic emissions.

These declines in statistical significance could simply result from the decrease in the number of states with older management-based regulations related to pollution planning – making statistical analysis difficult due to the small sample size. But it could also indicate that management-based mandates yield diminishing effects over time. According to interviews reported by Coglianese and Nash (2004), facility managers in one state with toxic planning laws generally indicated that they achieved most gains from the required management exercises in the first few years after passage of the management-based regulation. There is reason to wonder, then, whether some businesses tend to view required planning, over time, as little more than a paperwork exercise. After managers identify and respond to the low hanging fruit soon after the introduction of management-based regulation, they may be able to find fewer opportunities (or fewer low-cost opportunities) to make further improvements. This remains an important consideration for both researchers and policy makers.

5.4. Designing effective management-based regulation

Even though research shows that management-based regulation can yield positive social benefits, this does not mean that all types of planning requirements will be equally successful. Policy makers need to consider how best to design management-based regulation. As with other regulatory instruments, the effectiveness of management-based regulation almost certainly depends on how they are designed and used. Management-based regulations vary in terms of at least four major characteristics, each of which may affect the ultimate impact that the regulation achieves.

The first characteristic centres on the nature of the mandate. Management-based regulation can require planning only or it can require planning plus implementation of firms' plans. As noted, the pollution prevention laws studied by Bennear (2007) only required that firms engage in planning, not that they implement their plans. In contrast, HACCP requires that firms not only engage in hazard analysis and internal planning, but that they adhere to the plans and procedures developed under HACCP. Regulatory decision makers should consider the incentive effects that each option may have. "Planning only" requirements can work when firms will find it cost-effective to implement their plans once they have sunk costs into planning. But if firms have no other incentive to implement their plans, either because they are unlikely either to find win-win gains or face background liability, then requiring implementation should be considered because otherwise planning would be an empty gesture. However, regulators also need to be cognizant of the impact an implementation mandate may have on the quality and rigor of the planning firms engage in. If firms know they will be required to implement the plans they develop under a management-based regulation, they may develop plans that identify fewer problems or that only consider the least costly (and perhaps least effective) solutions. In deciding whether to require implementation, then, regulators need to consider whether they have the governmental resources to review the adequacy of firms' internal management plans and monitor firms' diligence in implementing them.

The second characteristic focuses on how prescriptive management directives should be. Some management-based regulations impose only broad standards for planning, while others are quite detailed. Under the Massachusetts Toxic Use Reduction Act, for example, plans must simply contain "a comprehensive economic and technical evaluation of appropriate technologies, procedures and training programmes for potentially achieving toxics use reduction". In contrast, the US Environmental Protection Agency's chemical risk management regulations call for firms plans to address:

- initial start-up;
- normal operations;
- temporary operations;
- emergency shutdown and operations;
- normal shutdown;
- start-up following a normal or emergency shutdown or a major change that requires a hazard review;
- consequences of deviations and steps required to correct or avoid deviations; and
- equipment inspections.

The degree of specificity selected will likely depend in part on the degree to which the regulator already understands the important parameters in managing certain kinds of problems.

A third characteristic centres on whether firms should be required to submit their plans for prior approval from regulators. Actual management-based regulations vary on this dimension in several ways. For example, in Canada the government must review in advance all HACCP food safety plans submitted by seafood processors and must give approval before firms can proceed to implement their food processing. In the United States, chemical companies must submit their risk management plans to the government in advance, but the government does not need to approve them. Finally, some management-based regulations (such as the US Food and Drug Administration's HACCP rules) simply require firms to keep their management plans on file and make them available on request to government inspectors. The regulator's capacity to review firms' plans in advance is likely to affect which of these options gets selected.

A final characteristic of management-based regulation focuses on their associated paperwork and auditing requirements. When management-based regulation is needed to get firms to plan and act to reduce risks, this means that firms' incentives are not aligned to conduct such planning and action on their own, and hence some firms in such situations have incentives to try to resist complying with the letter and spirit of the management-based requirements imposed on them. Some firms can be expected to devote as little effort as possible to their planning and to create plans that simply try to minimise their private implementation costs. When management-based regulation requires both planning and implementation, firms may have the incentive to cut corners on implementation. Regulators therefore need to be able to assess whether firms' planning has been adequate and monitor whether firms are following their plans. The way regulators do this is by imposing suitably detailed record-keeping requirements and instituting inspections or third party audits. Many management-based regulations are enforced by documentation reviews. For example, HACCP includes requirements that food processors regularly check temperatures and the cleanliness of surfaces that come in contact with food – and that they keep meticulous records of both temperatures and surface cleanings.

Management-based regulations vary in terms of the frequency of inspections, from continuous inspections for certain firms in the food industry to annual (or even less frequent) visits for other firms. In addition, under some management-based regulations, third parties are given responsibility for auditing compliance, which may reduce government inspection costs. Massachusetts' TURA, for example, requires that each facility have a certified "pollution prevention planner" review their plans for compliance with the planning criteria in the law. Such third party auditing is also increasingly part of private management-based codes, such as ISO 14000 (Prakash and Potoski, 2006). Whether the auditors are third parties or employed by the government, they nevertheless face common and significant challenges in overseeing management-based regulation. Even when the law contains highly specific planning criteria, what constitute "good" management effort may still be at least somewhat open-ended or case specific, especially since ultimately management-based regulation gives firms discretion in deciding how to address their own risks.

In addition to the characteristics of management-based regulation, an additional design issue is whether other regulatory instruments should be combined with management-based regulation. For analytic purposes in this chapter, management-based regulation has been

treated in isolation – but in practice, it can be combined with some limited forms of means-based or performance-based regulation. For example, even though food processors are now subject to HACCP requirements, they can (and are) still subject to other regulatory commands, such as that they use specific means such as refrigeration or that food handlers wash their hands. When regulators can be confident that a particular means – such as refrigeration and hand-washing – works effectively across all regulated firms to address part of a regulatory problem, or when they know that a particular method of measuring performance can partially addresses a regulatory problem, then it will be appropriate to combine these limited means or performance standards with management-based regulation.

Management-based regulation is sometimes combined with performance measurement, even though the performance measures do not form the basis of the regulation's command. For example, in the area of food safety, the US Department of Agriculture has combined its HACCP requirements with requirements that firms sample products and test for levels of E. coli and salmonella (USDA, 1996). These performance requirements are inadequate by themselves as a basis for the regulatory command, since testing regimens necessarily rely on a relatively small number of samples and since perishable food products must be shipped into distribution before testing results can be confirmed. For reasons like these, regulators often cannot rely on performance measures as the obligatory command in a regulation. Yet even in such circumstances, a performance testing regimen can still be used to aid firms and regulators in assessing the quality and efficacy of firms' management plans and implementation. Regulators can also use such "backdrop" performance measures as a way of determining which firms' plans and record-keeping to scrutinise more closely.

5.5. Regulatory impact analysis and management-based regulation

In choosing between different design characteristics of management-based regulation – and even in deciding whether to use at all – regulators should engage in the same kind of regulatory impact analysis needed for any sound regulatory decision (OECD, 2005). Regulators need to gather discrete information about the nature of the specific problem management-based regulation would address, as well as the estimated costs and benefits of different solutions to that problem, including management-based regulation and its alternatives. In conducting a regulatory impact analysis of management-based regulation, analysts confront many of the same challenges that arise with analysing any proposed regulation, such as quantifying and monetising the anticipated benefits and costs of the regulation (Hahn and Dudley, 2007) and assessing the uncertainties associated with different choices (Jaffe and Stavins, 2007).

The very flexibility inherent in management-based regulation does present some qualitatively distinct challenges for regulatory analysis. Since different firms can be expected to plan for and implement different techniques and technologies, there will be varying costs and benefits associated with each of these approaches. The US Department of Homeland Security (DHS) recognised this challenge when it recently imposed management-based antiterrorism standards on the chemical industry:

> As this regulation is not a "command and control" regulation, owners and/or operators will have considerable flexibility in how they choose to comply with its requirements.[M]any facility owners and/or operators will choose such measures as building fences, enhancing perimeter lighting, and hiring additional security guards in order to comply with the risk-based performance standards.

> We expect that chemical facility owners and/or operators will take full advantage of the flexibility that these risk-based performance standards will provide and will conduct facility-specific and company-specific analyses to determine the most cost-effective method to comply with the requirements of this interim final regulation. However, because process changes are so facility- and business-specific, DHS has no way of estimating how many facilities may ultimately implement such measures for the purpose of estimating compliance costs (DHS, 2007a).

Ideally, the regulatory analyst would want to know which methods which firms will use, and what level of effectiveness these various methods will have in terms of delivering social benefits and at what cost. However, since management-based regulation will tend to be used in situations where the regulated industry is highly heterogeneous, it will be quite difficult to assess these costs and benefits a high level of precision, since what firms will do will vary.

Still, regulators can and must make estimates – even if they are sometimes "simply [the government's] best guess based on currently available information", as the DHS acknowledged in issuing its recent antiterrorism rule (DHS, 2007a). If nothing else, it should be possible to place upper bounds on the predicted costs and benefits of management-based regulation. The cost of a management-based regulation should not be expected ever to exceed the product of the number of regulated firms and the marginal cost of the most expensive intervention possible.

Since all proposed regulations in the US expected to have an annual impact of USD 100 million on the economy must undergo careful economic analysis by the implementing agency and a review of that analysis by the White House Office of Management and Budget (OMB) (Graham, 2007), management-based regulations that meet this threshold have been subjected to extensive benefit-cost analysis and provide instructive examples of some of the distinctive analytical challenges associated with management-based regulation can be addressed.

For example, in the 1990s, the US Occupational Safety and Health Administration (OSHA) developed a major regulatory proposal to address muscular-skeletal disorders (MSDs) caused by repetitive motions in the workplace. OSHA's "ergonomics rule" required employers that had workers experiencing MSDs to create ergonomics management programmes within their workplace. The rule was a classic management-based regulation in that it required employers:

> … to implement a programme that includes the elements of any sound safety and health (ergonomics) programme. These include management leadership and employee participation, job hazard analysis to identify musculoskeletal hazards, the implementation of controls to reduce the hazards identified, training for employees and their supervisors or team leaders in jobs that have MSD hazards, management of musculoskeletal disorders when they occur, and regular evaluation of the programme to ensure that it is functioning as intended (OSHA, 2000a, Fed Register No. 65:68762-68763).

OSHA touted the flexibility the rule provided because it "requires employers to establish a basic framework with widely agreed-upon elements but leaves employers free to provide many of the establishment-specific details" (OSHA, 2000b). The ergonomics rule would protect millions of workers across all industries in the United States. OSHA reported that in 1996 about 625 000 workers experienced MSDs significant enough to lose one or more workdays (OSHA, 2000a). In some industries, workers faced an 80% probability over their career of losing time at work due to a work-related MSD injury (OSHA, 2000a).

Matching the significance of the workplace MSD problem itself were the challenges facing the regulatory analysts. The resulting regulatory impact analysis for the ergonomics rule ran over 700 pages in length – since the rule covered every sector of the economy. Overall, OSHA predicted that "employers will be required to fix almost 7 million jobs in the first year the standard is in place, and a diminishing number every year thereafter" (OSHA, 2000a). Based on an effectiveness analysis in OSHA's risk assessment, the agency estimated that employer fixes would reduce musculoskeletal injuries by 50% annually. The agency then used standard techniques to monetise the benefits of the avoided injuries, yielding an estimated annual benefit of USD 9.1 billion (OSHA, 2000a).

In terms of assessing costs, OSHA distinguished between programmatic costs (administrative, training, paperwork, etc.) and the costs of controlling jobs posing unacceptable MSD risks. To estimate these costs, OSHA studied workplaces that had voluntarily installed ergonomics programmes similar to those called for in the management-based regulation. The agency also "relied on responses to a 1993 ergonomics survey [...] of thousands of general industry employers to estimate the extent to which establishments within the scope of the standard already have implemented ergonomics programmes involving the control of jobs" (OSHA, 2000b). For each provision in the management-based rule, OSHA estimated the number of hours associated with paperwork burdens or the amount of costs needed to comply. For example, the agency estimated that per job it would take one hour of managerial time to engage in a hazard analysis of its MSD risks, and 2-16 hours of employee time and 2-32 hours of managerial time per job to evaluate and implement job controls (OSHA, 2000b). Overall, OSHA estimated that nationwide the rule would impose USD 8.4 billion annually in costs to society and to employers, of which USD 2.2 billion annually were programmatic costs (OSHA, 2000b).

The US Department of Homeland Security (DHS) made similar use of estimates in developing its recent management-based antiterrorism security rule for chemical facilities. That rule, promulgated in 2007, requires covered firms to develop vulnerability assessments and security plans, and to submit both the assessments and the plans to DHS for approval. DHS also required regular auditing by the firms in consultation with DHS, and clarified that DHS would assume a strong inspection authority to assess firms' implementation of their plans. Of course, some firms already had security measures in place, so DHS was careful to note that its estimates were only "intended to represent the marginal cost incurred by owner and/or operators as a result of the [agency's] rule" (DHS, 2007a). These marginal costs included the costs of security measures and equipment, such as fencing and lighting, as well as labour costs associated with security guards, training, and auditing. DHS also estimated the costs of developing and preparing the security plan required under the regulation, including the costs associated with "the expertise of various technical staff which may include engineers, EHS professionals, management, in some cases, lawyers and others" (DHS, 2007b). The agency grouped facilities into different categories and estimated the likely cost for a "model" facility in each category. DHS then multiplied the model facility cost estimate times the number of regulated facilities in each category (a total of about 5 000 facilities), and then summed to reach an estimate of USD 3.6 billion in total costs over a three-year period (DHS, 2007a). About 60% of these costs were for equipment (such as fencing, lighting, locks, and electronic surveillance equipment) and another 30% for security guards and officers (DHS, 2007b). DHS estimated that the costs for preparing the required vulnerability assessment and security plan amounted to only about 3% of the total costs (DHS, 2007b).

As both the ergonomics and chemical security rules illustrate, the cost estimates for major management-based regulations can be significant. They include the costs of planning and, when firms are required to carry out those plans, the implementation costs as well. The planning costs include paperwork burdens on firms, since management-based regulation calls for firms to engage in planning activities (such as hazards and risk analysis) as well as to document their findings and report on their implementation of their management programmes. In an era when regulators around the world are seeking to simplify reporting requirements and lower the administrative costs associated with regulatory compliance (OECD, 2007), the administrative burdens associated with management-based regulation undoubtedly will spark close attention. In the United States, agencies are required under the Paperwork Reduction Act to estimate both the hour burden on regulated entities and their costs of processing the required paperwork. The DHS estimated the paperwork burdens on the private sector from its chemical facility security planning rule to be about USD 110 million over a three year period (DHS, 2007a), while OSHA estimated the annual paperwork costs associated with its ergonomics rule at USD 61 million (OSHA, 2007a).

Although the paperwork burdens of management-based regulation may appear substantial considered all on their own, they may from another vantage point be fully justified. At least in the OSHA and DHS rules, paperwork burdens amounted to only a small fraction of the total costs associated with the rules. Even though they may seem considerable, paperwork costs can be justified if they, plus any implementation costs, are still smaller than the benefits the regulation delivers. Furthermore, it should be kept in mind that if management-based regulation enables firms to implement more effective or cost-effective regulatory measures, any increase in paperwork costs management-based regulation creates will probably be more than offset by implementation cost-savings or an increase in benefits due to the more effective solutions adopted by firms. In its regulatory impact analysis of the chemical security rule, DHS explained that it had adopted a management-based approach for precisely this reason:

> [W]e believe for this rulemaking that any design standard would have been inherently higher cost and lower benefit. The inherent vulnerability of each facility to a terrorist incident is a function of their unique public health and safety risk, economic impact, and the mission critical aspects of the given chemicals and the Threshold Quantities (TQ) of the chemicals the facility processes. Any reasonable design standard the Department would have considered would have likely included provisions not useful for some facilities, and would have likely not included other provisions essential to reducing the risk in other facilities. On the other hand, if a design standard were proscriptive enough to include all of the essential provisions for every facility, it would have likely been much higher cost than this rulemaking (DHS, 2007b).

In the final analysis, paperwork burdens – however substantial they may seem – should be considered as part of an overall assessment of the regulatory impacts of management-based regulation and its alternatives.

5.6. Implementing management-based regulation: a changing government role?

For the same reasons that management-based regulation can be an attractive regulatory alternative – namely, heterogeneous businesses where performance measurement is costly or problematic – the role the government plays as a regulator and inspector may change

under management-based regimes. Instead of inspectors who assess whether one-size-fits-all means are in place at a facility, management-based inspectors have to make highly context specific judgments about management issues. The array of firms covered by management-based regulation will likely employ many different combinations of technologies and processes, and as a result these firms will possess the advantage over government in terms of the knowledge of how these processes could go wrong and how they can be fixed. Firms' managers are likely to understand their own processes in ways that allow them to foresee risks that a regulator would otherwise miss, as well as to anticipate and identify changes in operating conditions that may affect the underlying problem of concern to the regulator.

A critical question for management-based regulation, then, is how regulators can overcome their informational disadvantage to ensure that firms are planning effectively and implementing those plans if required. The tools available to regulators include audits and inspections (Power, 1997). For example, HACCP regulations grant inspectors access to firms' records, analyses, plans, and internal testing results. In addition, on-site inspectors can observe processes during site visits. But do regulators have the capacity to evaluate planning and implementation?

The experience with HACCP implementation in the United States highlights the need, at a minimum, for regulators to have sufficient resources to inspect and audit regulated facilities on a frequent basis (GAO, 2001, p. 17). But even inspections cannot easily reveal whether the firm carries out its plan when an inspector is not there. Instead, inspectors must rely on the firm's records of what occurred, raising the question of whether firms will maintain an accurate record of their actions under incriminating circumstances (Lassiter, 1997, pp. 444-456). Even if firms are not outright untruthful, they may conclude that they would do themselves little good by including in the plan any hazards that government inspectors are unlikely to spot on their own, particularly if these cannot be remedied cheaply. Since management-based regulatory strategies are designed to incorporate a firm's specialised expertise in its product and processes into its safety practices, the very instances in which a firm's expertise would help it to identify hidden hazards may well be some of the same ones in which the firm has the opportunity and incentive to keep its hazards hidden.

In this way, management-based regulation requires a very different profile of governmental capacities than other types of regulation. The very challenges that can make management-based regulation attractive over other regulatory options can also present challenges in government's enforcement role, as there is the inevitable question of how to determine what constitutes sufficiently good management. Ultimately, it is wise to be aware that the nature of the government regulator's role can shift with management-based regulation. Instead of conducting performance tests or observing whether firms have installed proper equipment, inspectors under management-based regulation need to assess the adequacy of a firm's planning and the documentation of its implementation. This can amount to a considerable new burden on certain regulatory agencies, which will need adequate resources to meet the challenges.

Conclusion

Management-based regulation has recently emerged as a regulatory strategy of interest to both researchers and regulators, as it appears likely to be an appropriate instrument for an important, and possibly growing, set of regulatory problems. In a

growing number of important policy areas – from food safety to domestic security – regulators around the world are turning to management-based regulation as a solution for otherwise vexing public problems.

As this chapter has shown, management-based regulation may work well where other regulatory approaches fail, particularly under circumstances of highly heterogeneous regulated firms and in the face of the regulator's inability to assess easily or effectively firms' true performance. Management-based regulation also promises important advantages over conventional regulatory tools. Because it gives firms flexibility to find their own ways to reduce or mitigate risks, management-based regulation may lead to better and less costly solutions to regulatory problems. Empirical research is beginning to show that management-based regulation can induce positive behavioural change within industry.

But management-based regulation is certainly no panacea. How it is designed and implemented will undoubtedly affect its ultimate effectiveness in practice. The same flexibility that generates its advantages also presents its potential sources of policy failure. To prevent shirking by regulated firms, regulators need to design management-based regulation carefully, paying attention to factors such as the degree of specificity in planning criteria and the resources needed to monitor and enforce compliance with management mandates.

Ultimately, determining whether to adopt management-based regulation in the face of any specific set of public risks will call for the same kind of regulatory analysis that should under-gird any regulatory decision making. Regulatory officials should consider not just the costs of the required planning, but also the costs and the benefits of the means firms are likely to adopt to implement their plans. Although there are reasonable concerns about the burdens management-based regulation places on industry in terms of preparing plans and filing reports, these planning and paperwork requirements can be justified in areas where the private sector undersupplies effective risk management practices from the standpoint of overall social welfare.

To understand better when and how to use management-based regulation, additional *ex post* evaluations will be needed. There remains a need for further empirical research on the impacts of management-based regulation, both to learn whether they are achieving meaningful benefits as well as whether their costs turn out as projected. Even though existing research shows that management-based regulation can prove successful under circumstances, clearly an additional open question remains whether such positive effects can be sustained over time – or whether the effects of management-based regulation wear off after the low-hanging fruit has been picked. Finally, management-based regulation poses new challenges for governmental authorities, so additional research is needed to illuminate ways for regulatory personnel to make the transition to what appears increasingly to be a more management-focused regulatory environment.

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Chapter 6

Risk-based Regulation: Choices, Practices and Lessons Being Learnt

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This chapter identifies key aspects of the risk-based frameworks of eleven regulators in four countries across four sectors: environment, food safety, financial markets and health and safety. Risk-based frameworks contain real choices as to the types and levels of risk the regulator is prepared to tolerate. Risk-based regulation therefore requires regulators to take risks. In practice the risk-based frameworks themselves have risks and a regulator's risk tolerance is ultimately driven by the political context. The chapter explores how these are addressed. Section 6.1 of this chapter defines risk-based regulation, explores the motivations for its adoption, sets out the main elements of risk-based frameworks, and provides some examples. Section 6.2 explores key questions that arise in practice with respect to each of these elements. Section 6.3 examines some of the main issues and challenges which have arisen in implementation. Finally, Section 6.4 discusses the evaluation of risk-based frameworks and identifies lessons learned.

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Introduction

Risk-based frameworks are increasingly becoming seen as a necessary attribute of "better regulation". Risk-based frameworks enable regulators to channel their resources to those issues which pose the greatest risk to the achievement of their objectives. In their narrowest form, risk-based frameworks are used to allocate inspection resources. However for an increasing number of regulators, risk-based frameworks are being developed to help them structure choices across a range of different types of intervention activities, including education and advice.

Risk-based frameworks appear technical and mundane, but they contain real choices about what matters to that regulatory agency and what does not. The fundamental question in any risk-based regulatory regime is what types and levels of risk is the regulator prepared to tolerate. Regulators do not often articulate what their risk appetite is in public, or even private. Setting that risk tolerance can be an extremely challenging task. Better regulation enthusiasts usually emphasise the positive aspect of risk-based frameworks – that they require regulators to focus on their priorities. But risk-based regulation is a zero-sum game. Resources which are spent in one area are not spent somewhere else. The flip side of focusing on priorities is that regulators have to identify which risks or levels of risk they are *not* prepared to devote the bulk of their resources to preventing.

In making that determination, regulators are bound to make an error. Risk-based regulation therefore requires regulators to take risks. Regulators, and their political supervisors, have choice. Should they err on the side of assuming a firm does pose a risk when it does not (in statistical terms, a Type II error), or err on the side of assuming that a firm does not pose a risk when in fact it does (a Type I error). These choices have always been made implicitly within regulatory bodies. In risk-based systems, they are rendered explicit. The consequences are significant. If regulators err on the side of assuming firms are risky when they are safe, they run the risk of being accused of over-regulation, and of stifling business and innovation. If they err on the side of assuming firms' activities are safe when they are risky, they run the risk of failure. That failure, as the financial crisis demonstrates, can be far reaching.

In practice, a regulator's risk tolerance is ultimately driven by the political context. All regulators face political risk, the risk that what they consider to be an acceptable level of risk will be higher than that tolerated by politicians, the media and the public. For regulators, minimising political risk is often the overriding concern. The higher the political salience of a sector or risk, the less will be the regulators' tolerance of failure in that particular area. The political context is often fickle, however; issues that were not salient suddenly become so, and *vice versa*. This has consequences for the allocation of resources, which may not always go where the risk model says they should.

Risk-based frameworks also have other risks, notably model risk, that the model does not capture all the relevant risks, and implementation risk, that it is inadequately implemented. This chapter explores how these are addressed.

Aims and scope of the research

The purpose this chapter is to consider the development and role of risk-based approaches to regulation and to identify policy recommendations that can have broader application for risk-based regulatory strategies. The chapter identifies key aspects of the risk-based frameworks of eleven regulators in four countries across four sectors: environment, food safety, financial services and health and safety (see Annex 6.A1 for details). This chapter does not attempt to provide a systematic overview of the state of risk-based regulation in each of these areas, nor does it attempt to set out detailed comparisons. Instead, the chapter focuses on some of the key policy issues in the design and implementation of risk-based frameworks that have arisen in these areas. It looks at how regulators have addressed these issues by comparing the choices they have made in the design and operation of their frameworks. It also explores the different challenges involved in "doing" risk-based regulation and the experiences that regulators have had with its implementation. Throughout, this chapter is concerned with drawing out some of the lessons that can be learnt through examining these frameworks, with a view to informing policy recommendations for the development of risk-based frameworks by other regulators.

Outline of the chapter

The chapter is divided into four main sections. Section 6.1 defines risk-based regulation, explores the motivations for its adoption, sets out the main elements of risk-based frameworks, and provides some examples. Section 6.2 explores the issues that regulators have found arise in the design of risk-based frameworks. Section 6.3 examines some of the main issues which have arisen in implementation. Section 6.4 discusses the evaluation of risk-based frameworks and identifies key challenges and lessons learnt.

6.1. What is risk-based regulation?

Risk-based regulation is a relative newcomer to the lexicon of regulation. It can be used to refer to anything from a loose agglomeration of approaches expressed in terms of risk, to highly structured and systematised decision making frameworks (see also Hutter, 2005). It is usually given one of three broad meanings. The first refers to the regulation of risks to society: risks to health, safety, the environment, or less usually, financial well-being. In this respect, "risk-based" regulation has long been used by regulators and legislators to determine whether or not an activity should be regulated, or what level of preventive measures firms or others should take.

The second meaning, which is particular to banking and insurance regulation, is a far more specific one: it is the use of firms' own internal risk models to determine the amount of capital banks should set aside. This model of "risk-based regulation" is entrenched in the Basle II capital adequacy rules, and enacted in the EU by the Capital Requirements Directive.

The third meaning of risk-based regulation is that on which this chapter focuses. It refers to the use of systematised frameworks of inspection or supervision which are primarily designed to manage regulatory or institutional risk: risks to the agency itself that it will not achieve its objectives. In this third sense, risk-based regulation involves the development of decision-making frameworks and procedures to prioritise regulatory activities and deploy resources, principally relating to inspection and enforcement, based on an assessment of the risks that regulated firms pose to the regulator's objectives.

In risk-based approaches, the focus is not on the potential risks that individuals or the market economy may face from the actions of firms *per se*, but on the risks the regulator faces in failing to achieve its objectives. The objectives of the regulator are translated into a rubric of risk, and their focus becomes the attainment of those objectives. Risk-based regulation thus requires regulators to explicitly define their regulatory objectives, and to translate their statutory mandates into operational objectives. Whether or not the regulator translates the objectives in a way which is supported by the wider polity remains an open question, however. It may be that there is congruence between the two, but this cannot always be assumed. In practice, there is often a misalignment, and regulators are driven by changes in the political and social context to address risks that they might otherwise have regarded as low priority.

It is fair to ask to what extent is the current flurry to develop "risk-based" approaches simply the dressing up of old systems and processes in new, more fashionable clothes? In Meyer and Rowan's familiar argument, organisations adopt structures and follow procedures not just, or not even, to achieve goals, but to gain legitimacy in the widest sense (Meyer and Rowan, 1977). The rhetoric of "risk management" and "risk-based" approaches combines a sense of strategy and control in a way which is politically compelling; moreover, framing one's actions as "risk-based" is, in the current climate, a useful legitimating device. But the framing of the regulatory task in terms of risk has the potential to have more than a rhetorical effect: it imports particular conceptions of the problem at hand, and leads to the framing of a solution in a particular way. Most notably, "risk-based regulation" introduces a matrix of assessments which focuses not, or not only, on economic costs and benefits, but on uncertainties, impacts and probabilities (Black, 2005a).

Risk-based frameworks contain real choices about what matters to that regulatory agency and what does not. For they require regulators to identify what risks or levels of risk it is *not* prepared to devote the bulk of its resources to preventing. We are familiar in debates on societal risk regulation of the choice between Type I and Type II errors: of erring on the side of caution (assuming something is risky when it is not) or erring on the side of risk (assuming that something is safe when it is not) (Schrader-Frechette, 1991). The debate usually operates at the level of deciding whether an activity should be regulated or not: in writing rules or setting standards, should regulators err on the side of protecting consumers (making Type I errors) or favouring producers (making Type II errors). However, regulators also face the same choices in their own organisational decisions of what level of attention to give to any one firm. The consequences are significant. If they err on the side of assuming firms are risky when they are safe, they run the risk of being accused of over-regulation, and of stifling business and innovation. If they err on the side of assuming firms are safe when they are risky, they run the risk of failure. The experience of the UK FSA in it supervision of Northern Rock, and indeed the credit crisis more broadly, is an excellent example (FSA, 2008). The FSA assumed the bank's business model was safer than it was; but intervention any earlier would have created political resistance on the grounds that they were interfering in a highly profitable business.

The key motivations for adopting risk-based approaches

There has been a significant increase in the use of risk-based frameworks for inspection and supervision in a range of countries and across a number of sectors, by both state and non-state regulators (see Black, 2005a; 2005b; Hutter, 2005; IOPS, 2007; Brunner *et al.*, 2008; Rothstein *et al.*, 2006).

Although the precise reasons for each regulator to adopt a risk-based approach are obviously unique, both the research done for this study and the findings of other studies suggests that there is a common core of motivations (Black, 2005b; IOPS, 2007; Hutter and Lloyd Bostock, 2008; Rothstein *et al.*, 2006). These are broadly functional, organisational, environmental (in the broadest sense), political and legal.

First, regulators have turned to risk-based frameworks in an attempt to improve the way in which they perform their functions. They have adopted risk-based frameworks in an attempt to facilitate the effective deployment of scarce resources and to improve compliance within those firms which posed the highest risk to consumers or the regulators' own objectives. Risk-based frameworks are also adopted to improve consistency in supervisors' assessments of firms, to enable regulators with broad remits to compare risks across a widely varying regulated population within a common framework. More broadly, risk-based frameworks are being adopted part of a more general desire by regulators to become more "risk aware" and less rule-driven in their activities.

Second, risk-based frameworks have been adopted to address a range of internal organisational concerns. In particular, they have been introduced to provide a common framework for assessing risks across a wide regulatory remit, and to deal with mergers of regulatory bodies. They have also been seen as a way in which to improve internal management controls over supervisors or inspectors. In federated structures, where the regulatory regime is split between central government and local authorities or municipalities, risk-based frameworks are also used to provide a framework for central government control. An example here are the risk-based frameworks for inspection issued by the UK Food Standards Agency with which local authorities in England and Wales have to comply.

Third, risk-based frameworks have been adopted in response to changes in the market and business environment. For example, banking regulators started developing risk-based systems in tandem with an increasing preoccupation within banks in using risk-based assessments for their own internal purposes. Food regulators in the US point to the introduction of HACCP as facilitating the introduction of a risk-based inspection system (FSIS, 2007).

Fourth, the political context can be highly significant. Risk-based frameworks have been adopted in response to previous regulatory failures, and to provide a political defence to charges of either over- or under-regulation by politicians, consumers, the media or others (Black, 2005a; 2005b). More generally, having a risk-based framework has increasingly become a badge of legitimacy for a regulator. Risk-based systems are a key part of the "better regulation" framework, and as such are a core attribute that regulators need to possess.

Finally, as risk-based regulation becomes seen as a functionally efficient tool for improving better regulation, politicians and others are increasingly requiring regulators to adopt such frameworks by law. In the area of food safety, for example, EC regulations require that inspections be carried out on a "risk basis" (EC 882/2004). In the UK, regulators are now subject to new statutory duties of "better regulation" set out in the Compliance Code. These include the requirement to adopt a risk-based approach to inspection (DBERR, 2007).

The main elements of risk-based approaches to regulation

The frameworks vary considerably in their complexity. However all have a common starting point, and four common core elements.

The key element of risk-based frameworks for allocating resources is that the starting point is risks not rules. Risk-based frameworks require regulators to begin by identifying the risks that it is seeking to manage, not the rules it has to enforce. Regulators are usually over-burdened by rules. They cannot enforce every one of these rules in every firm at every point in time. Selections have to be made. These selections have always been made, but risk-based frameworks both render the fact of selection explicit, and provide a framework of analysis in which they can be made.

The frameworks themselves have four core elements. First, they require a determination by the organisation of its own risk appetite – what type of risks is it prepared to tolerate and at what level. This can be an extremely challenging task for a regulator. In practice, a regulator's risk tolerance is often ultimately driven by political considerations. All regulators face political risk, the risk that what they consider to be an acceptable level of risk will be higher than that tolerated by politicians, the media and the public. Political risk is in practice a critical element in any risk-based system, as discussed below.

Second, risk-based frameworks involve an assessment of the hazard or adverse event, and the likelihood of it occurring. Terminology varies: food and environmental regulators tend to talk in terms of hazards and risks; financial regulators talk in terms of impact and probability. Two broad categories of risk are identified: the inherent risks arising from the nature of the business's activities, and in environmental regulation, its location; and management and control risks, including compliance record. These assessments may be highly quantitative, or be mainly qualitative. The methods by which management and control risks are combined with or offset against inherent risk scores varies, but broadly speaking management and controls can either exacerbate the inherent risk or mitigate it.

Third, regulators assign scores and/or ranks to firms or activities on the basis of these assessments. These may be broadly framed into three categories or traffic lights, or there may be a more granular scoring system, with five or more categories.

Fourth, risk-based frameworks provide a means of linking the organisation and of supervisory, inspection and often enforcement resources to the risk scores assigned to individual firms or system-wide issues. In practice, resources do not always follow the risks in the way that the framework would suggest, however, as discussed further below.

The tables below briefly summarise some of the risk-based frameworks in the different sectors covered by this research. All the risk-based systems investigated are outlined in Annex 6.A3.

Table 6.1. **Financial services: comparison of the risk-based frameworks of FSA, APRA and DNB**

Organisation Element	FSA: Arrow (Advanced Regulatory Risk Operating Framework)	APRA: PAIRS (Probability and Impact Rating System)	DNB: FIRM (Financial Institutions Risk Analysis Method)
Date first introduced	2001 (Arrow 1); 2006 (Arrow 2).	2002.	2006-07.
Outline of risk assessment framework	Risk = impact of risk × probability of risk occurring.	Assess inherent risk and management and control to derive net risk. Then consider capital support to determine overall risk of failure.	Inherent risk minus management and control = net risk. Net risk minus capital support = overall risk of failure.
Risk scoring and categorisation	Four × four matrix. Impact L, ML, MH, H. Probability L, ML, MH, H. On site risk assessment and relationship management for firms of ML impact and above.	Individual risk assessments prepared for all licensed entities. Two stage categorisation: ● Impact analysis based on asset size. ● Probability analysis based on scoring between 0-4 of key risk categories.	All institutions have individual risk analysis. Traffic light system (red for the highest risk; orange for medium risks; green for low risks).

Table 6.1. **Financial services: comparison of the risk-based frameworks of FSA, APRA and DNB** *(cont.)*

Organisation Element	FSA: Arrow (Advanced Regulatory Risk Operating Framework)	APRA: PAIRS (Probability and Impact Rating System)	DNB: FIRM (Financial Institutions Risk Analysis Method)
Risk identification – categories of firm specific risks	53 risk elements which are consolidated into 10 risk groups: ● Environmental. ● Customers, products and markets. ● Business processes. ● Prudential (credit, market, operational, insurance and liquidity). ● Customers, products and markets controls. ● Financial and operating controls. ● Prudential controls. ● Control functions (internal audit, enterprise-wide risk management and compliance). ● Management, governance and culture. ● Capital and liquidity.	● Board. ● Management. ● Risk governance. ● Strategy and planning.[1] ● Credit risk.[1] ● Market and Investment risk.[1] ● Insurance risk.[1] ● Operational risk.[1] ● Liquidity risk.[1] ● Capital support.	Inherent risks: ● Financial risks. ● Liquidity risks. ● Insurance risks. ● Operational risks. ● Integrity risks. ● Strategic risks. ● Governance risks.
Risk assessment against regulatory objectives	Each risk assessed against each of seven "risks to objectives" (RTOs) derived from its 4 statutory objectives (customer protection, market confidence, reducing financial crime and promoting public understanding): ● Financial failure. ● Misconduct/mismanagement. ● Consumer understanding. ● Fraud/dishonesty. ● Market abuse. ● Money laundering. ● Market quality.	Assessed against single objective: ● Financial failure.	Assessed against single objective: ● Financial failure.
Regulatory response	Risk mitigation programme.	SOARS (Supervisory Oversight and Response System) linked to PAIRS risk assessment.	Specified supervisory menus linked to risk score.

1. Assess both inherent risk and management and control for each category.

Table 6.2. **Environment: comparison of the risk-based frameworks of EA, EPA and IGAOT**

Organisation Element	Environment Agency (England and Wales)	Irish Environmental Protection Agency	Portuguese IGAOT
Date first introduced	2002, latest version 2008.	2007-08.	2009-
Outline of risk assessment framework	Probability and hazard analysis with respect to each attribute.	Probability and hazard analysis with respect to each attribute.	Probability and hazard analysis with respect to each attribute.
Risk scoring and categorisation	Individual detailed Opra analysis for bespoke permits only scores.	Individual assessment for all licensed activities/installations. 3 grade scoring system A (high) – C (low); each grade subdivided (A1-3; B1-3; C1-2).	Individual assessment for all IPPC (integrated pollution and prevention control legislation) activities/installations. 3 grade scoring system: (high, medium, low).
Risk identification – risk attributes	5 risk groups: ● Complexity ● Emissions and inputs ● Location ● Operator Performance ● Compliance rating using compliance classification scheme.	5 risk groups: ● Complexity. ● Emissions and inputs. ● Location. ● Operator management. ● Enforcement record.	5 risk groups: ● Complexity. ● Emissions and inputs. ● Location. ● Attitude of operator to the environment and sustainability of the attitude ● Compliance behaviour.
Risk assessment against regulatory objectives	Used with respect to emissions and waste management; anticipated for water quality discharge consent regime in 2009-10.	Used with respect to emissions, waste management and discharges into water/sewers.	Planned introduction in 2009 to emissions, waste management and discharges into water/sewers.
Regulatory response	Supervisory discretion.	Supervisory discretion.	Supervisory discretion.

Table 6.3. **Food: comparisons of the risk-based frameworks of the UK Food Standard Agency and the Food Safety Authority of Ireland**

Organisation Element	Food Standards Agency (England)	Food Safety Authority of Ireland
Date first introduced	1995, latest version 2008.	2000, latest version 2006.
Outline of Risk Assessment Framework	Hazard and impact analysis of activities.	Hazard and impact analysis of businesses.
Risk scoring and categorisation	5 categories A (high) – E (low).	3 categories (high-low).
Risk Identification/Risk attributes	Food hygiene: ● Potential hazard (type of food and method of handling; method of processing; number of consumers at risk). ● Level of current compliance. ● Confidence in management/control procedures. ● Specific risk assessment of potential contamination by specified micro-organisms.	Pre-populated score sheet scoring types of businesses. Businesses not listed to be assessed on basis of analogy with existing categories; and in addition: ● consumer profile; ● scale of the operation; ● type of food; ● nature of handling/processing; ● structure and layout of premises; and ● control systems.
Risk assessment against regulatory objectives	Food safety and public confidence.	Food safety and hygiene.
Regulatory response	Intervention scheme linked to risk levels; minimum levels of interventions (not limited to inspections).	Minimum levels of inspection set for each risk category.

Table 6.4. **Health and safety: the UK Health and Safety Executive's Field Operations Directorate framework for non-hazardous activities**

Organisation Element	Health and safety executive
Date first introduced	1990s; latest version 2008
Outline of Risk Assessment Framework	Analysis of risk, probability and nature of harm
Risk scoring and categorisation	Gap: Gap between level of risk firm is at and where it should be if in compliance. 4 categories of risk gap: extreme, substantial, moderate and negligible; 6 point rating scale for individual risk elements.
Risk identification/Risk attributes	Risk elements: ● consequences; ● likelihood; and ● extent. Categories: ● Safety. ● Health. ● Welfare. ● Competence and attitude of management.
Risk assessment against regulatory objectives	Health, safety and welfare.
Regulatory response	Supervisory discretion in line with enforcement management model.

6.2. Designing risk-based frameworks

The development of risk-based frameworks follows the pattern of many innovations (Black, Lodge and Thatcher, 2005). There have been a few "early adopters", and over recent years the number of regulators adopting some kind of risk-based approach has steadily increased. The later adopters have been directly or indirectly helped by the "early adopters". Regulators have communicated the detail of their frameworks and their experiences to other regulators through transnational networks, such as IMPEL in the environmental context, or by bilateral interchanges (see also Black, 2005b). Models of risk-based systems are thus spread across regulators, and modified each time. For example the Australian Prudential Regulation Authority's (APRA's) risk-based model has been adopted in modified form in a number of different countries. Regulators often "mix" models – so the Portuguese environment regulator, IGAOT, used a mixture of the Irish Environmental Protection Agency's framework, with that of the Dutch environmental regulator, VROM. The Irish EPA's framework itself drew on that of the Environment Agency

for England and Wales, and its food hygiene framework draws on that of the Food Standards Agency's Code of Practice for England.

Despite these patterns of learning, no two risk-based systems are identical in their form, and often differ significantly in their operation, even if in form they may have strong similarities. Some of these differences stem from their widely differing remits, and their location within governments. But others reflect strategic choices. As a result, the differences can be revealing. Risk-based frameworks are not neutral, technical instruments. Each aspect of a risk-based framework involves a complex set of choices. They require decisions by the regulator as to what level of risk or failure it is prepared to accept; what risks it will identify as requiring attention; what indicators and methods it will use to assess those risks, and how it will deal with the majority of firms that fall into the "low risk" categories. This section considers each of these choices in turn.

Risk tolerance

The fundamental question in any risk-based regulatory regime is how much risk is the regulator prepared to tolerate. Regulators do not often articulate what their risk appetite is in public, or even private. Those that have stated their risk tolerances publicly differ significantly between sectors. The financial regulators adopt, in theory, a non-zero failure policy, following the FSA's statement of this position (FSA, *Reasonable Expectations*). In the paper *Reasonable Expectations* the FSA noted there was a gap between public expectations of what regulators should or should not be able to achieve, and what "reasonable" expectations should be (FSA, 2003). The paper made it clear that "non-zero failure" meant that the regulator would not, and should not be expected to, prevent every "negative event": every financial failure of a firm, every incidence of non-compliance, every incidence of market failure, and that public and political expectations of what regulation can achieve should be modified in accordingly.

In food regulation, in contrast, the policy with respect to food additives and residues of pesticides and veterinary drugs is one of "notional zero-failure", although for contamination by micro-organisms, however, food regulators tend to adopt a standard of "as low as reasonably practicable". As a review of food regulatory systems observed, however, given the difficulties in obtaining reliable data and the public expectation that food should pose no risk, targets are usually defined in relative terms (a reduction of 25% over 2 years) rather than absolute terms (Slorach, 2008). Health and safety regulation in the UK also provides for a residual level of risk to remain, even when there has been full compliance with the rules. The requirement is that health and safety be assured "so far as is reasonably practicable".

Whatever their policy, and whatever their legislative framework, risk-based regulation requires regulators to take risks. This is extremely challenging for a regulatory organisation. They have to choose which risks or levels of risk are they *not* prepared to devote the bulk of their resources to preventing. As noted above, they have a further choice. In making that determination, should they err on the side of assuming a firm does pose a risk when it does not (in statistical terms, a Type II error), or err on the side of assuming that a firm does not pose a risk when in fact it does (a Type I error). These choices have always been made implicitly within regulatory bodies. In risk-based systems, they are rendered explicit.

In practice, the political context is determinative. The higher the political salience of a sector or risk, the less will be the regulators' tolerance of failure in that particular area. Indeed, several regulators deliberately calibrate their risk models in terms of their ability to maintain public confidence in themselves and in the sector they are regulating

(see Section 6.3 below). The political context is often fickle, however; issues that were not salient suddenly become so, and *vice versa*. This has consequences for the allocation of resources, which may not always go where the risk model says they should. Rather they go to the area which is most politically sensitive. As the current credit crisis illustrates, even a non-zero failure policy can be abandoned when the political, and systemic, stakes are too high.

Risk identification

Which risks?

The foundation of any risk-based approach is the risks on which it focuses. There is a multitude of risks on which regulators can focus, and regulators have to be selective. Clearly, in addressing model risk, the risk that the risk-based framework does not focus on the relevant risks, regulators have to choose these risks carefully. Regulators have taken different approaches to identifying and selecting these risks.

The starting point is usually the regulators' statutory objectives. The UK Financial Services Authority, for example, has framed the groups of risks on which it focuses as "risks to objectives". Lack of clear statutory objectives can thus be a hurdle to formulating RBFs. In the UK, the previous regime for pensions' regulation was hindered, amongst other things, by a lack of clear statutory objectives. Changing the legislation to introduce clear objectives thus facilitated the development of The Pension Regulator's (TPR's) risk-based approach.

A highly complex legislative framework can also be a hindrance. Regulators are often charged with implementing a significant number of individual pieces of legislation. The Netherlands environmental regulator, VROM, for example, is charged with over 270 specific legislative tasks. A key stage in developing its risk-based framework was therefore synthesising these into four different types of impacts of the activities which they were charged with regulating: health, sustainability, safety and social elements. Over time they have further refined their work into four work programmes: water, soil, safety and air quality, and now examine each type of impact with respect to each work programme.

Other legal duties can be also be relevant for identifying risks. The environmental regulators in the UK, Ireland and Portugal include those emissions to air and discharges to water and sewers which they are required to report to the European Environment Agency. They are required to collect this information, and so it makes sense to include it in their risk-based frameworks.

Public perceptions and expectations of the regulator can also be important. The Food Standards Agency in England and the UK Health and Safety Executive, for example, take into account the perception of public attitudes to risk in identifying which risks they should focus on, as well as their statutory objectives. In Ireland, the Irish EPA has included odour as a risk on which it should focus, as this gives rise to considerable complaints and can be resource intensive to deal with.

Risk-based frameworks can become highly complex as the number of risks on which they focus increases. The risk-based frameworks in use vary considerably in their degree of complexity. Those with simpler systems are often regulators who are just drawing up their risk-based systems, such as IGAOT, and/or whose regulated population is engaged in less complex or hazardous activities, such as the Irish EPA.

Finally, the amount of data that the regulator currently has can have a significant bearing on which risks they focus on. Regulators can only identify risks that they already know about. There is more over the danger that regulators only identify risks that they are confident they can manage, and leave other risks out of consideration. There was a

suggestion from some regulators that limitations on the data that the regulator currently had or thought that it could collect restricted the risks which it included in its risk-based framework. In some respects this makes sense: there is little point in the regulator trying to manage risks when it does not have the information on which to assess them. However, an incomplete set of risks does enhance model risk – the risk that the model itself is flawed. This will be returned to below in Section 6.3.

To address the problems caused by not having the right type of information, others who are just beginning to implement risk-based systems have deliberately designed the system in such a way that it maximises the amount of data they will receive. The UK's Office of Fair Trading (OFT), for example, wanted a risk-based system that would achieve three aims: it would enable the OFT to gain more information on the firms that had licences; it would achieve consumer protection objectives by weeding out those who already had consumer credit licences but did not really need them; and it would emphasise areas that the OFT already knew were high risk, notably debt management and debt guidance. The OFT has thus designed a system which requires licence applicants to give a significant amount of information, on the basis this will give it the data which it needs in order to refine its risk-based system in the future.

Risk indicators

Having identified the risks, regulators have to determine what the risk indicators should be. Risk indicators are those activities or events that are likely to result in the risk crystallising. Risk crystallisation occurs when the adverse event that the regulator was trying to prevent in fact happens; that there is a discharge, accident, food contamination, or financial failure, for example.

With respect to the processes for identifying risk indicators, the interviews revealed that some regulators use external consultants and those who were able to draw on others' frameworks had borrowed heavily from them. All the regulators interviewed, however, held intensive internal discussions as to what the relevant risk indicators were. These discussions drew on the knowledge of inspectors and supervisors as to the causes of previous failures or accidents. Tacit knowledge across the organisation as to what the warning signs were of impending failures was pulled together and then transformed into explicit risk indicators against which risk, in particular probability, would be assessed. In nearly all cases, the risk indicators derived from this process of internal discussion and distillation were judged by those developing and implementing the framework to have been more valuable than those proposed by external consultants.

Balance between objective and subjective indicators and assessments

The choice of risks and risk indicators is subjective, but the frameworks vary considerably in the extent to which the indicators they use can be assessed objectively or subjectively. The indicators used by the environmental and food regulators, for example, tend to be objective, quantitative measures. For the environmental regulators, complexity of the site is based on the types of activities carried out. The activities are defined objectively and grades defined based on judgements as to their significance, or legislative requirements. They are assessed with respect to indicators specifying the types of activities conducted, the capacity for production (not actual production), and/or the area over which the activity occurs. Thus, one of the indicators of complexity for the Irish EPA is the:

a) Production of non-ferrous crude metals from ore, concentrates or secondary raw materials by metallurgical, chemical or electrolytic processes.

b) Smelting, including the alloyage, of non-ferrous metals, including recovered products (refining, foundry casting, etc.) with a melting capacity exceeding 4 tons per day for lead and cadmium or 20 tons per day for all other metals: score is the mid-range grade G3 (POE, 3.4.1).

Emissions and discharges are assessed as capacity for emissions of particular substances measured by number of kilograms per year.

Quality of management is assessed on a yes/no basis. So in the Irish EPA framework, a low grading is given if the site has an approved environmental management system in place, a training plan and an environmental committee that meets regularly, combined with a low number of incidents reported. Enforcement history is quantified. A total score is given for the number of complaints received about the facility by the EPA, non-compliance notifications issued by it, the number of section notices issued and the number of convictions, all in the last year.

Other regulators include indicators which are assessed more subjectively. For the financial regulators, assessment of management, governance and culture, of control functions, and risks arising from dealing with customers are assessed on a qualitative, not a quantitative basis, as are risks to the firm from the external market environment. In the UK Food Standards Agency's framework, the assessments of hazard are based on the type of food, the nature of the handling, the type of processing methods used and the number of consumers at risk. Each is defined briefly, and the assessment criteria are deliberately framed in broad terms to encourage environmental health officers to develop and use their own professional judgement. Confidence in management and controls is defined in terms of the business's compliance record, and the likelihood of this being maintained at current levels, but again no quantitative inputs are used. The UK Health and Safety Executive also uses qualitative assessments of risks to health, safety and welfare and of management and controls in its risk-based framework for non-hazardous activities.

One mode of assessment is not necessarily better than another, and certain risks can be more easily assessed using quantifiable methods than another. However, the extent to which the risk-based framework uses qualitative assessments or relies almost entirely on quantitative assessments does have significant implications for the management, organisation and governance of the risk assessment process. This will be returned to in Section 6.3 below.

Risk assessment

Impact and probability

One of the critical issues in the design of a risk-based system is the relative role played by assessments of probability and impact or hazard. A bias towards impact means that regulatory attention is focused more on activities or events which have a relatively high impact but low probability; a bias towards probability means the regulator focuses more on high probability but relatively low impact events or activities. The regulators take quite different approaches to how they assess impact, the relative weights given to impact and probability, and the relationship between them. The choice is a political one, and the difference can be significant.

Impact measures. Impact is usually an assessment of the impact on the beneficiaries of regulation, broadly defined: the environment or consumers. So environmental regulators look at the maximum capacity of an installation to pollute, or discharge waste. Financial

regulators look at the size of the firm or fund as a proxy for impact measures. In the context of food regulation, proxies are the number of consumers and their nature (for example children or the elderly).

An approach used by several regulators with a high number of regulated firms is to use impact measures to divide the regulated population into risk groups in order to determine the depth and complexity of the risk assessment that will be applied to them. This approach is used by the Environment Agency in England and Wales, and financial and pension regulators in the UK, the Netherlands and Australia. Often, the initial categorisation is used to determine which groups will be subject to a risk assessment at all, and which will not. The group of firms that is subject to a risk assessment is then further subdivided into two groups – those who receive a simplified assessment, and those that receive a full assessment.

For example, under the new environmental permitting regime, the Environment Agency is moving to a system which divides licence holders into three groups or tiers. Tier 1 licences are for low impact activities, such as carrying household waste or fishing. Licence holders are simply required to pay for a licence, and there is a minimal level of random inspection carried out, principally for the purposes of protecting the integrity of the licence regime. Tier 2 licences are standardised permits and licences to which general binding rules apply. A simplified version of the risk framework, "Standardised Opra" applies to these sites. They are given a standard baseline score for four of the Opra risk attributes for each sector. That score is modified at a site level by the site's compliance score. The full Opra risk assessment applies only to Tier 3 licence holders. These are the more complex sites which are given bespoke permits, and the full, individualised version of Opra applies.

APRA uses a similar basis to categorise the pension funds which it supervises, with the smaller funds subject to a simplified version of its risk-based system. The UK Financial Services Authority has three versions of its risk-based framework. It has a "small firms" model which applies to low impact firms; these are not subject to individual risk assessments. Most of those in the medium-low impact categories are subject to ARROW light, which is a reduced scope risk assessment which focuses on core areas and sectorally important issues only. Medium high and high impact firms are subject to the full ARROW process, as are medium-low impact firms with a high probability (FSA, 2006).

Impact measures can also be designed or adjusted for more political ends, and to address political risk. This can be done explicitly, as in VROM's framework. Here "social impacts" are a separate category of impact, and are essentially there to capture issues which have current political and media salience. The UK Pensions Regulator also explicitly takes account of political risk in determining its impact measures for its higher risk firms. It defines impact of pension funds initially in terms of the number of members This gives two groups, those with over 1 000 members (1 600 schemes) and those with less than 1 000 members (83 000 schemes). The latter are a low priority, and regulatory action is focused mainly on education and guidance of trustees and members. The largest schemes are divided again into two groups: the 150-300 firms which pose the highest risk, and the next 300-1 600 schemes. High risk is defined in two ways: first, in terms of the number of members; second, in terms of the impact on the regulators' own reputation and future effectiveness. In other words, risks are identified the basis that if TPR did not pick these up it would be seen as a failure and the public would lose confidence in the pensions system

as a result (TPR, 2006). The regulators' political risk is thus clearly incorporated into the impact measure. Political impact can also be incorporated less explicitly. When Arrow 1 was first introduced, the FSA's impact measures for credit unions were deliberately inflated as the regulator wanted to ensure that they were given more regulatory attention than the scoring system would otherwise have permitted (Black, 2005a).

Others, notably the Food Standards Agency and the Health and Safety Executive, do not undertake this initial categorisation by impact. Moreover, impact measures focus on the scale of the harm, not its nature. There are some frameworks which include an assessment of the nature of the harm as well as its impact. The UK Food Standards Agency's framework, for example, includes both the nature of the micro-organisms that are present in the food and the number of people likely to consume the food. The Health and Safety Executive also combine consideration of the nature of the harm, the probability of it occurring and the number of people likely to be affected in their framework.

Focusing on the nature of harm can move impact measures away from an aggregate measure (how many, how much in total across an area/population) to a focus on individual impacts. The UK Office of Fair Trading focuses more on the nature of the impact on individuals than on the number of individuals that would be affected in its risk-based framework. Thus it identifies home debt collection as high risk, partly because it affects a significant number of those taking out consumer credit, but also because the nature of poor practices in home debt collection often involves violence and intimidation. Consumers are thus particularly vulnerable in these circumstances, even though the aggregate impact might not be great. Secured sub-prime lending is rated as high risk on similar grounds: that mis-selling of secured sub-prime lending will lead to default, which has a significant impact on the consumer. Indeed this example illustrates very well the difference between the financial and, to an extent, the environmental regulators' systemic approach to risk categorisation, and the individualised-consumer focus of the OFT's framework.

Relative weights and relationship of impact and probability. Impact measures are thus often used to determine when a full risk assessment should occur. Within that risk assessment process, probability and impact have different roles and are combined in different ways. They are also differently classified. The environmental regulators classify the inherent risks of a site as hazards, and compliance and management practices as probability. The financial regulators see the equivalent attributes in financial firms or pension funds (nature of the business, relationship with consumers) as an aspect of probability, along with management practices and compliance record.

The Environment Agency has three risk attributes/indicators relate to hazard or impact: these are complexity, location, and capacity for emissions. These are all inherent risks arising from the nature and location of the site itself and are mainly impact measures (amount of capacity to pollute). The probability element is the management and compliance aspects, which is assessed with respect to the site as a whole, not individual risk attributes. Other environmental regulators adopt a matrix-like approach, and assess inherent risk and management and controls with respect to each individual risk. IGAOT, for example, assesses each risk criteria on a matrix of probability and impact.

Regulators also differ as to whether the relationship between probability and impact is calculated on the basis of aggregation or multiplication. The Health and Safety Executive adopts an aggregative approach, as does the Irish EPA. In contrast, the Environment Agency is planning to move away from an aggregative approach to a multiplicative approach in

which inherent risk will be multiplied by compliance risk. It is consulting on proposals in which compliance risk will be expressed as a percentage above or below a baseline of 100%. So a better than average compliance score would multiply the aggregate of the scores for the other attributes by 95%, for example; a worse than average compliance score would multiply the score from the other risk attributes by up to 300% (EA, 2008). IGAOT also adopt a multiplicative approach, using compliance scores as the proxy for probability. In IGAOT's framework, the score for compliance history is a multiplicative criteria applied to the scores for the other six risk attributes.

An alternative to the additive or multiplicative approach is the "net risk" approach. This is used by APRA and DNB. APRA assesses the inherent risk and management and control for key risk categories and then considers the capital support available to determine the overall risk of institutional failure. The overall risk of failure is combined with the impact of failure to determine the supervisory attention index. APRA has in the past assessed management and control on a global basis across the firm as a whole. It is has now moved to a system in which each risk is measured on a "net" basis. In other words, it has started to assess the quality of management and control with respect to each risk category (*e.g.* liquidity risk, operational risk, etc.), rather than provide a global assessment of management and controls across the whole firm. This enables it to have a more granular assessment (APRA, 2008). DNB use the formula of inherent risk minus management and control risk gives net risk. The net risk figure is then multiplied by the impact figure to give a risk rating. The Financial Services Authority also assesses management and control with respect to each risk area on a net risk basis (FSA, 2006).

Weighting

A second important aspect of the design of the framework is the weighting assigned to different scores. Weighting plays a key role in all the risk-based frameworks examined, with the exception of the HSE, who have moved away from weighting scores. Weighting reveals much about a regulator's assessments of what is important, their view of risk and their risk appetite. However, it is also susceptible, like other aspects of risk-based frameworks, to "gaming" by inspectors. A number of regulators have had experience of inspectors "reverse engineering" their scores so that they obtain the risk ranking which they think is appropriate, and not that which is given by "the system". Using supervisors' less structured assessments as a general check on the accuracy of the risk model can be helpful, but reverse engineering can defeat the purpose of having the risk-based system and distort the resource allocation decisions.

Weighting can be done for a number of reasons. At base, risk attributes are weighted so that the final score enables supervisors to devote resources where those designing the framework think they will most be needed. IGAOT, for example, gives additional weight to new installations so that they become a high priority to be inspected. In the Irish EPA framework, certain activities are automatically be assigned a high enforcement category, for example incineration on land or at sea. In addition, a conviction in the last twelve months will raise the grade to one category higher than it would otherwise have been. Negative weights can also be applied to bring scores down. So where the licensed activity has not yet commenced then it is scored one category lower than it would otherwise have been (Irish EPA, 2006).

The research shows that there are other reasons for weighting. Three examples are: incentivising management; structuring supervisors' risk assessments; and structuring charges.

Weighting can be used to incentivise firms to improve their compliance. Many of the risk indicators in any framework relate to the inherent risk of the firm's activities, or, in the environmental context, its location. These are fixed, in the sense that the scores given to them will not vary between poor and well managed firms. Some regulators in the UK, notably the Environment Agency and the Health and Safety Executive, have been criticised for not rewarding well-managed firms sufficiently (NAO, 2008 overview). One approach to how this can be done is through the weighting given to internal management and compliance in calculating the risk scores. For example, in order to incentivise firms to improve their internal controls, IGAOT has deliberately assigned additional weight to firms' internal compliance so that changes in this score will have a significant impact on the score as a whole.

Weighting is also used to "correct" or structure the risk assessments of supervisors. This is particularly relevant where the assessments are qualitative. Regulators who are into the third or fourth version of their risk frameworks have progressively refined their use of weighting to take into account supervisors' behaviour in assessing risk. APRA, for example, used to give supervisors the average scores in each peer group for the different risk categories against which supervisors could compare the particular firm or fund they were assessing. However it found that supervisors were gravitating towards the peer group average in giving their scores. So instead APRA has introduced a significance weight reference points (APRA, 2008). The reference points represent the "typical" significance weights of an entity within a given peer group and are derived according to the importance of the PAIRS category to the overall business profile of the entity (APRA, 2008). The significance weight reference points are set centrally within APRA and applied to each risk category across each peer group. This enables the central risk team within APRA to ensure consistency and also to be able to calibrate the weights more easily depending on changes in the external environment. The reference points are reviewed annually or when significant events occur in the interim that would alter the risk profile of institutions within a given peer group. APRA is currently undergoing a review of the reference points with liquidity risk being given a higher weighting than in the past, for example, due to the extreme conditions in the financial markets. APRA is currently conducting further research into supervisor's behaviour to understand further what affects the supervisors' assessments of risk to see if further modifications need to be made.

Weighting is an important instrument for senior management to structure assessments being made by individual supervisors in the UK Financial Services Authority's model as well. Senior management, or the central risk team, can modify the weights assigned in the ARROW II risk model to emphasise or deemphasise the risk from certain sectors (for example sales of certain retail products), or from certain risk groups within the model (for example business risk, control risk, liquidity risk). Weighting is in turn explicitly linked to risk appetite – what level of risk the regulator decides it is prepared to accept in any one area (FSA, 2006, p. 15).

Finally, where the risk scores are linked to a charging scheme, weighting is also affected not just by risk levels but by a prior assessment by those designing the scheme of the baseline resources that are needed to supervise the organisation due to its inherent

nature. Quite simply, large, complex businesses or installations take longer to look at, so more weight is given to business complexity to ensure the charges are set at an appropriately high level.

Integrating "horizon" scanning and generic, industry wide risk assessments into the firm-specific assessment

A third key issue in the design of risk-based frameworks is the extent to which the risk assessment of individual firms or sites takes into account more generic risks arising from changes in the environment in which the firm is operating. These are particularly relevant for financial firms, whose risk profile can be significantly affected by the market environment. All the financial regulators try to identify and capture these risks, and to bring both strategic and firm-specific risks within a single risk assessment framework. TPR does this through its intelligence gathering and triage process, for example. TPR has a single data base with all the information about a fund on it. This includes fund specific information derived from returns; corporate reports; media reports; and issues in the external environment that it thinks could affect pension funding. It uses this data to derive the risk scores for the high impact funds.

Ensuring that firm specific assessments take into account these more generic risks can be difficult to achieve, however, if the regulator relies on the judgement of the supervisor alone. Both APRA and FSA have found this. The evidence as to the FSA's supervision of Northern Rock illustrated the difficulties (FSA, 2008). The answer that both have gravitated towards is again to adjust the parameters of the risk model centrally, either through adjusting weightings or pre-populating the inspectors score sheets, or both.

What to do about low risk firms – dealing with the "bulge"

For most regulators, the bulk of their regulated population fall into the low risk category. These can easily become "forgotten offenders": firms who offend but which the regulatory framework overlooks. The issue the regulator faces is what level of resources to apply to them. It obviously has to be less than it applies to high risk firms, but how low should it go? How can it identify when regulatory action is needed early enough to make interventions that could prevent the risk occurring, and how can they inform firms of the need to comply and incentivise them to do so?

Most regulators deal with this problem in one or more of three ways: information campaigns, random inspections and/or themed inspections, including sampling.

The first strategy is to use information campaigns to inform small firms of the regulatory requirements. Inspections can serve a useful function by informing firms of their obligations, particularly small and medium enterprises which typically are in the regulators' low risk categories. If inspections cease or are severely reduced for these firms, this source of information obviously disappears. To compensate, information campaigns are being increasingly used to varying degrees by many of the regulators who have risk-based frameworks. A report by the UK's NAO found that "[c]ampaigning activity plays a key role in risk-based systems of regulation in reaching low-risk businesses who might not otherwise come into contact with the regulator" (NAO, 2008f).

The HSE is at the forefront of this approach in the UK. The HSE faces significant resource constraints, and simply does not have the personnel to inspect the bulk of its regulated population on a regular basis. A firm will on average be inspected once every

14.5 years (House of Commons, 2007). In addressing this problem, it has shifted from an approach based mainly on risk, which produces a huge number of firms with similar risk profiles, to one based on achievability: what is the most effective type of intervention that it can do with respect to different types of firms, other than an inspection. It has been working on a system of "segmenting" its regulated population, in much the same way as advertisers segment their target audiences. It has been developing a number of different ways to inform and influence small and medium sized businesses in particular. In order to try to reach agricultural workers, a very difficult sector to influence, it has started going to agricultural shows, farmers' markets, and targeting information to farmers' wives. It even used the BBC radio programme, The Archers, to publicise the dangers of tractors through a storyline about a tractor fatality. To target construction workers, it is using radio and TV campaigns, celebrity endorsement, and shock campaigns. It has also co-operated with hire shops and builders merchants who have run schemes for builders to hand in old equipment and replace it with new at a substantially reduced price (financed by the shops).

However, regulators can be dissuaded from strategies of education and advice by the evaluation criteria used to audit their activities. In the food sector, EU regulations stipulate what is an accepted "official control" for the purposes of auditing food inspection authorities. These do not include offering education and advice (EC 882/2004). However, the Food Standards Agency, following research which showed the effectiveness of such strategies (Fairman and Yapp, 2005), has relaxed its own criteria for auditing local authorities to include education and advice in the intervention strategies that it will "count" in assessing their enforcement activities (Food SA, 2008).

The second strategy is to have random inspections. The reasoning is that these can be an effective way to detect some non-compliance, and if accompanied by well publicised enforcement action, can act as an effective deterrent. Moreover, as many regulators indicated, having an active enforcement policy even for low risk breaches is important as it protects the integrity of the regulatory regime. Regulatory regimes can quickly lose their credibility for regulated firms and the public if there is no monitoring or enforcement of them at all. Again, however, regulators may be restricted by their legislative and/or audit frameworks from using random inspections. The Compliance Code, for example, discourages their use, a potentially significant limitation for risk-based approaches, given the wide coverage of the Code.

The third strategy is to have themed inspections, though again regulators may be restricted from using these as the basis of rating firms. Again in the food sector, for example, partial audits or inspections (such as themed inspections) have only recently been included as one of the "official controls" that the EU will recognise as constituting inspection and enforcement activity. For others, themed inspections have been an increasingly used approach. Regulators identify particular themes or issues that they want to focus on, and inspect firm's activities in those areas alone. The choice of which firms to inspect within the theme may be random or based on a prior risk assessment.

The challenge with themed inspections is to balance attention to thematic risks with attention to firm-specific risks. The HSE moved to a topic based approach to inspections from 2002, as part of its "revitalising health and safety" approach and then its Fit 3 programme (HSE, 2004). The NAO report, conducted late in the transition, found that questions arose within the HSE as to what inspectors should do about risks that they saw during an inspection but which were not part of the "topic pack" that they were using to

assess the generic risks. As a result, there was an under-utilisation of firm specific information, resulting in the risk of making many visits to firms which fall into high risk categories for many different generic risks (although this risk was minimised by pragmatic local judgements). Moreover, inspectors felt unable to use their discretion and judgement (NAO, 2008d). Clearer communications within the HSE have since gone some way to alleviating this problem.

6.3. Risk assessment in practice

The previous section illustrated some of the key policy choices facing regulators when designing their risk-based systems, and illustrated some of the different ways in which regulators are addressing these issues. However, a risk-based framework is in practice only as good, or poor, as its implementation. All risk-based frameworks face implementation risk: the risk that they will be inadequately implemented, including the risk of "model induced myopia" – that inspectors do not look beyond the model itself. The research found that regulators faced challenges with respect to three main aspects of implementation: collecting and managing the data in order to identify and assess risks; the performance of the risk assessment process, and the design and operation of the internal systems of governance over the risk-based approach within the regulatory organisation itself.

Collecting and managing data

Data is critical to the design and operation of risk-based frameworks, and can pose a significant problem. Many of the regulators examined here, and evidence from other reports on risk-based systems, emphasise the difficulties that arise because of data (*e.g.* DNB, 2006, p. 56; IOPS, 2007; NAO, 2008f).

Regulators usually have too little of the information they need, and too much of the information that they do not. If they have too little data, they obviously need to collect more. However data is highly resource intensive to collect both from firms and from elsewhere. As we have seen, risk-based systems usually incorporate information about matters outside the individual firm, for example on the geology, flora and fauna and social geography of the location; or on the conditions in the markets or particular economic sectors. Even if this and other relevant data is held somewhere in government, it is often dispersed across different governmental bodies or between central and local government officials. This can pose problems of co-ordination and delay. For example, the UK OFT has found that in developing its ability to target higher risk activities such as mass-marketed scams, it has to co-ordinate with local trading standards officers. However the lack of an integrated management system for sharing intelligence, the uncertain status of the OFT as leader of the project, and difficulties in funding a regional intelligence network have all posed obstacles (NAO, 2008e).

There is a significant difference between regulators who operate through a licensing regime, such as environmental and financial regulators, and those who do not, such as food and occupational health and safety regulators examined here. Those who operate a licensing or even notification regime have at least some way of knowing who their regulated population is and through the licensing process they have a means of obtaining information from those firms (although difficulties remain in identifying those who operate illegally without a licence, and their information gathering powers may be truncated even with respect to licensees). Most licensing regulators use the introduction of a risk-based approach as an opportunity to reform their licensing process in order to get

the information it needs about its regulated population. Some are also using the new data requirements to filter out the industry. In the UK, the OFT has enhanced the data requirements of firms for consumer credit licences to require them to give sufficient information to demonstrate competence and the adequacy of their internal management. It has found that many small operators who do not really need a licence do not want to go through that process, and so they are not applying. Others are being forced to think about their business in a different way.

In contrast, those regulators who regulate across industries in regulatory regimes where industries do not require a licence face particular problems in getting information as there is no licence process to alert them to who is doing what. The UK HSE, for example, is aware of its own tendency just to focus on the largest firms as these the most visible, although it is taking steps to use a wider range of information sources (NAO, 2008f).

On the other hand, it is easy for regulators to be swamped with data, and as a result to become locked in an endless task of processing rather than evaluating the information that comes in. The UK Pension Regulator's (TPR's) predecessor, the Occupational Pensions Regulatory Agency, for example, received 56 000 notifications in 5 years. TPR still gets around 2 500 notifications and queries per month, ranging from notifications of trustee details to information on major corporate transactions. It has a two level filtering system to prioritise them. Customer support deals with the most straightforward inquiries and notifications of minor breaches. More serious issues are sent to "triage" for analysis. Triage usually reduces the number down to about 100 high risk issues which then become cases. Cases are then directed to specialist practice teams depending on the issues they raise: corporate risk governance; scheme specific funding; and pensions administration and governance (NAO, 2007; TPR, 2006, 2008).

As a result of problems in getting the right type of data initially, regulators often design their initial risk-based systems on the basis of the information they have already got or can easily and quickly acquire, rather than on the basis of the information that they need. Indeed, regulators may explicitly design the first version of their risk-based system in such as way to generate as much data as possible, with a view to refining the framework further once it has sufficient information on which to make a more informed risk assessment. Later versions of the risk-based regime can then reduce the information requirements for low risk firms once the regulator has sufficient data to identify them.

For all regulators using risk-based systems, the IT system is a critical instrument for data management. The IT system which processes the inputs of the risk-based framework is used to collate data and to organise it. Nevertheless, a common criticism of regulators, including those with risk-based frameworks, is that they fail to make full use of the information that they have (*e.g.* NAO, 2008f). This links in part to the question of how to integrate "horizon scanning" or broadly contextual information into firm specific risk assessments. Moreover, knowing what information to seek, and managing it, is critical to knowing what new risks may be relevant, and thus to the continual modification of the risk-based framework.

Performing risk assessments

In talking about assessment, it is important to distinguish between the collection of information with regard to the risk indicators, and then the assessment at to what risk category should be assigned based on that information. Two key differences between

risk-based frameworks is who collects the information for the risk indicators, and the extent to which individual supervisors or others have discretion in determining which risk categorisation should be applied given the information gathered. Risk assessments are inherently judgemental processes. Regulators vary in the extent to which they try to "design judgement out" of their frameworks, or, if they cannot design it out, structure how it is used. There is also a close relationship between the allocation of responsibility for gathering information for each risk indicator and the degree to which the risk scores are automatically assigned.

There are four different ways in which information for the risk indicators is collected: by the firm, a contracted third party, a municipal or state government, or the regulator itself.

In environmental regulation in the UK and Ireland, the firm itself provides the information with respect to each risk indicator. In environmental regulation in Portugal, it is intended that a contracted third party obtain the information. In food safety regulation in the UK and waste management regulation in Ireland, local governments perform the assessment. For all the financial regulators, the regulator's own supervisors perform the assessments.

In the environmental frameworks in Ireland, the UK and Portugal, the indicators are objective measurements or "yes/no" answers, for example, does the firm have a management system which is externally accredited. A risk score is assigned in the framework to each measurement (*e.g.* > 10 tpa is low risk, 10-25 tpa is medium risk; < 25 tpa is high risk). There is thus very little scope for judgement in assigning the risk score. Judgement, of course, is exercised by those designing the framework, for example to determine whether emissions over 25 tpa should be high risk, or whether that figure should be higher or lower. But at the level of making individual assessments, judgement is designed out of the assessment process as much as possible.

This design is deliberately to enable the firm to complete the assessment and to ensure consistency of responses. It does not, of course, ensure accuracy of responses. The Environment Agency validates the responses through inspections. Baseline inspections for those subject to the individualised risk assessment process occur annually (recall that only the highest risk installations are subject to the bespoke risk assessment); for those in the higher risk groups, they occur more frequently as determined by the Opra score. The Irish EPA validates the responses from the operators through a desk-based assessment of the returns submitted. The Portuguese environmental regulator, IGAOT, in contrast, will contract out the task of completing the risk indicator forms to third parties, to ensure from the outset that the information it has is valid.

The rationale for self-completion by firms of the risk indicators form is based on pragmatic and strategic considerations. Pragmatically, firms have the information and so it makes sense that they should complete the forms. Strategically, the regulators argue that the process of completing the forms means that the firms start to recognise their own risks, to see their operations from the regulators' point of view, facilitates "buy-in" from the industry, and reduces the potential for disputes over the categorisation. Even if the regulator raises the categorisation when they verify it, experience suggests that the number of disputes is reduced.

The collection of information for the risk indicators and the assignment of risk scores are more closely combined in the risk frameworks of the financial regulators, and this two-stage process is often collapsed into one. In many areas of assessment, the range of variables is so great that the framework cannot envisage all of them and assign a risk score in advance

to each, or at least not without becoming overwhelmingly complex. Many of the assessments are therefore subjective, and not based wholly on quantitative measures or yes/no answers. The translation from the information that the supervisor collects into a risk score is thus a matter of judgement. This type of risk-based framework poses quite different issues. Self-completion by firms would be a more significant step, for regulators would not only be relying on firms to give accurate responses, but to give responses which involve qualitative assessments. The arguments for self-assessment may still apply, but the level of judgement involves means that regulators are likely to be less comfortable with self assessments without far more extensive validation than regulators in the environmental sector requires, given the scope for inconsistency in assessments that would arise.

Finally, the risk assessments may be performed by local authorities or municipal governments under the guidance or direction of a central state regulator. This is the model used in the UK's food safety regulatory regime. The UK Food Standards Agency's Code of Practice sets out the risk framework, the minimum levels of inspections for each risk category, and the parameters of the compliance or interventions policy. It has no powers however to determine what level of resources that local authorities should spend on food inspections, though it does have powers to take over their responsibilities if it considers that they are being inadequately performed. `

Internal governance of the risk-based system

There is a close relationship between the organisation of the risk assessment process, in particular the degree to which completing the assessment relies on individual discretion, and the organisational structures for governance of the risk-based framework within the regulator. In the environmental regulators examined, inspectors have limited discretion for assigning the risk score (though as we will see below, they still have discretion as to how to respond to individual risk scores). These regulators need a process to validate individual, firm level information and to review and periodically recalibrate the risk framework. However there is therefore less need for an internal governance process to ensure consistency or accuracy of their judgements. There is a need to ensure that when inspectors validate firms' own assessments that they look at the appropriate things and have the technical ability to assess the firm, but the main challenge of consistency comes with respect to supervisory response, not the risk assessment *per se*.

In contrast, in those risk-based frameworks in which supervisors have a considerable degree of discretion in assigning risk scores, regulators have to ensure that supervisors are consistent and accurate in the scores that they give. For these regulators, internal risk governance processes are central, and the introduction of a risk-based framework often entails wide-ranging and on-going changes in the regulators' internal organisational structures. Both APRA and FSA, for example, are on their third or fourth model of internal governance.

Risk-based frameworks that are based on supervisory judgement have three main challenges: how to ensure the quality of supervisors' assessments; how to ensure consistency; and finding the balance between central control and supervisory discretion in assigning risk scores.

Quality of assessments

There are three key issues with respect to quality: training; integrating contextual risk analysis into firm level risk analysis; and understanding supervisors' behaviour in making their judgements.

All regulators who have risk-based systems emphasise the need for training. However, training has to be not just in mechanics of the assessment, but in the whole philosophy of risk-based regulation. The most common mistake that early adopters of risk-based frameworks said that they had made was that they assumed that supervisors would know what a risk-based assessment was, and that therefore they simply needed to be trained in the IT, in how to fill in the assessment spreadsheets. What they found was that supervisors were not really aware of the distinction between a compliance based approach and a risk-based approach to supervision. This problem is not confined to risk-based frameworks which are based on supervisory judgements, and environmental regulators reported the same problem. In those with frameworks based on structured risk classifications, *e.g.* the environmental and food regulators, this issue it manifested itself at the stage of deciding what enforcement action to take; in supervisory judgement frameworks, it manifested itself at the level of assessment as well.

Regulators have different expectations as to the training that their inspectors or supervisors have to undertake. In the health and safety context, for example, the HSE requires inspectors to undergo a two year training programme, take a formal qualification, have ongoing assessments by the peer group and specialist training inspectors. The HSE also provides extensive internal guidance on the objectives and rationales of the inspection with respect to each topic, with examples of the types of responses and interventions they should make, and what is good and bad practice for inspectors. In addition, its Enforcement Management Module provides guidance on risk assessments and on the appropriate responses inspectors should make.

The second issue is integrating contextual risk analysis into the firm level risk analysis. As noted above, market context can have significant effects on the risk profile of individual firms in the financial sector in particular. All the financial regulators examined here have specialists responsible for performing this analysis, usually in a specific division within the regulator. However, as the FSA's experience of supervising Northern Rock illustrated, it can be difficult to ensure that supervisors integrate that risk analysis into their firm-level assessments (FSA, 2008).

The third issue is understanding supervisors' own behaviour in performing the risk analysis. Risk assessments are inherently judgemental, but are critical to the regulators' understanding of its regulated population and to how it responds. Regulators therefore need to understand how supervisors behave when making those judgements. Regulators who are into their second or third generation of risk-based frameworks are developing an awareness of how they need to structure the assessments to adjust for supervisors' behaviour.

APRA, for example, used to give supervisors the average scores in an industry for the different risk categories; however it found that supervisors were gravitating towards the industry average. So instead APRA moved to a significance weight score. APRA has always weighted the different capital support categories; it now weights the different PAIRS categories. Significance weights are derived according to the importance of the PAIRS category to the overall business profile of the entity (APRA, 2008). The significance weight score is set centrally within APRA and is applied to each net risk category. This enables the central risk team within APRA to ensure consistency and also to be able to calibrate the risk scores more easily depending on changes in the external environment. Liquidity is currently being given a much higher weighting than in the past, for example, due to the

extreme conditions in the financial markets. APRA is currently conducting further research into supervisor's behaviour to understand further what affects the supervisors' assessments of risk to see if further modifications need to be made.

Others have also begun to incorporate an understanding of how supervisors assess risk in its risk model. Through its validation processes one regulator discovered that supervisors would over-estimate the quality of management and controls to a relatively high degree, around 30%, and moreover that this over-estimation was consistent across supervisors. Helped by the consistency of the judgements, the regulator is able to adjust the basis of the calculations of the risk scores to take this over-estimation into account.

Further, some in some areas is can be difficult to identify the difference between a risk and a control. The financial regulators are finding this, perhaps particularly at this time: that supervisors may assess certain features of the firm's risk management strategy to be controls, the risk division see them as risks. For example, the structure of control systems can themselves be risks if they structure incentives in a particular way or if they cannot counteract the incentives structured by the systems for awarding pay and bonuses

Current events in the market raise fundamental questions as to when a control becomes itself a risk, and indeed the moral hazard created by the control structure itself.

Consistency

Consistency is closely associated with quality. All regulators with these frameworks found that the internal governance structures were a key issue in ensuring consistency of assessments across a large number of supervisors, and that it was not easy to get these right. In addition to training, key issues were ensuring that internal comparisons and validations were made of supervisors' assessments.

Again, regulators have experimented with different structures. APRA began with PAIRS panels. These were panels of senior management, and they would go through two or three risk assessments in depth with the supervisors, challenging them to ensure accuracy and consistency in assessments across the organisation. However, experience showed this was a relatively cumbersome process in practice, and so APRA has moved to PAIRS forums. This is a more group wide approach to the benchmarking process. The forum is comprised of senior management, other supervisors and the appropriate risk specialist. Around 10 entities are randomly picked from each group of institutions and considered. The forum discusses with the supervisors how they arrived at their scores in order to check for outliers and discus the criteria that supervisors are assessing against. The forum does not have the power to change the rating; APRA considers it important that the final decision lies with the supervisors, though supervisors are likely to change the score if it has been successfully challenged in the forum.

Issues of consistency vary with the number of supervisors involved. The UK Pensions Regulator has only 20-30 people performing assessments, and does not conduct inspections; its problem instead is filtering information that comes in. It has "triage" system and Tasking Co-ordinator Group meeting which decides whether to intervene in a particular case. If it does decide to intervene then set up a taskforce with a case manager, lawyer, actuary, and sector specialist business analyst. Criteria for intervention are set out in TPR's "business rules". These determine how certain types of information are dealt with. An example is the business rule on scheme recovery. Pension schemes that are in deficit must submit a recovery plan to TPR. The plan details how the deficit will be recovered and

over what time period. TPR has created a set of trigger points that indicate when further action should be taken. The business rules are used by the staff to guide their analysis of the deficit recovery plan (NAO, 2007).

A key issue is how to ensure consistency of risk assessments and an "all round view" of risks without creating overly cumbersome committee/panel structures and paralysing the organisation in procedures. Some find that the obstacles to getting information in on all the different risks from a wide number of inspectors or inspectorates, each of which is looking at a particular part, is simply so challenging that it is rarely done. For those that do try to establish a system wide view as part of their standard operations, it is easy for internal structures to proliferate. One regulator reported that the internal assessment system at one point consisted of fourteen committees at four different levels. This clearly affects the speed and responsiveness of the regulator, something which is particularly relevant where external market conditions are highly relevant for risk assessment and where these changing rapidly. It is hard to have a "real time" risk analysis if everyone in the organisation has to have a view. As one regulator said, the central risk unit could do the evaluation but that would not be seen as valid, as it had not been validated by all the different units within the regulator. There is thus a tradeoff between ensuring accuracy, consistency, and "buy in" from across the regulator with speed and responsiveness.

Balance between central control and supervisory discretion

Within all the regulators, there is a separate set of officials responsible for the design and ongoing maintenance of the risk-based system. This unit evaluates the framework, and sets the risk parameters on which the gradings are based. The relationship of this unit with the rest of the regulatory organisation varies. It may be focused specifically on risk analysis, or have a wider role. APRA, for example, recently established a Supervisory Framework team, which is a single team across APRA dealing with all the different industries, and which is responsible not only for the maintenance and development of the risk framework, but monitoring supervisory activity across the whole of APRA, training supervisors and producing guidance for them.

One of the issues that regulators have found is how to balance control by the centre over the risk assessments with local discretion. The degree of central control exercised over the risk assessments of supervisors varies considerably (see also IOPS, 2007).

Risk-based systems, as we have seen, can potentially place heavy reliance on the exercise of discretion and judgement by supervisors and inspectors to ensure that risks have been properly identified, to assess them and to assess whether the preventive measures taken are adequate to control the risk. On the other hand, they remove the discretion of who to visit and when; and perhaps what to look for. Inspectors can then feel devalued. For those regulators who use the self-assessment process, inspectors lose their role to categorise firms. So an inspector might have thought that X was a "good company" but it comes out as high risk, and so the inspectors' assessment is displaced. That kind of personal judgement gets removed from the assessment. This is a significant shift in practice and culture. When risk-assessment frameworks were just being introduced, many inspectors found this hard to accept. Ultimately the central risk teams have found they have to allow inspectors to make representations against a risk score, but in practice few categorisations have been changed because, if they differ from an inspectors' own past experience of a firm, they need a very good reason to have it changed.

Much depends on the internal culture within the organisation. In some regulators, contrary to the example above, the inspector or supervisor can be seen as "king" within the organisation, and as knowing the firm better than anyone else. This can make it very hard for central risk unit to get organisation to move to a "portfolio" approach rather than one led by individual risk assessments, or indeed to get supervisors to change their assessments. It can make for internal battles, as it is hard for supervisors to accept that "their" firms are not as significant for the regulatory organisation, and thus as deserving as resources, as someone else's.

Some regulators allow senior management in different areas to customise the model and adjust the weightings and aggregations of risk scores in their industry areas. Regulators have found that this has helped to engage managers; as one member of a risk team commented, "they can play with it". However it had the effect that the risk scores went up, as everyone thinks their area is more risky than anyone else's. Central risk units then find themselves having to "rebase" the scores to scale them down, and readjust them between divisions in line with its own evaluations to ensure that resource allocation was not distorted.

One technique used by a number of regulators is to "pre-populate" the risk scores. In environmental risk-based systems in the UK, Ireland and Portugal, for example, all the scores are automatically assigned by the framework. In those systems which rely more on supervisory judgement, pre-population has also developed as a technique to ensure some central control over risk weightings. For those who were the "early adopters" of risk-based systems, pre-population developed over time, and so now tends to be characteristic of a second or third generation risk model. Those introducing them now and learning from this experience have benefited from this learning to introduce the technique straightaway. Pre-population can be an extremely useful way in which the centre can structure the judgement of supervisors. Indeed, some financial regulators have found that the only way to ensure that supervisors capture the external risks which it sees as relevant to a firm, for example, is to pre-populate the risk scores.

What do regulators use their risk-based frameworks for?

Allocating resources

One of the purposes of a risk-based framework is to facilitate the efficient and effective allocation of resources. Its presumed role in achieving this purpose is the reason why the UK central government is requiring all regulators to adopt risk-based systems. It is also the reason why the European Commission is incentivising regulators to adopt it in the environmental sector.

Three main questions arise: to what extent do resources follow risks in practice; do regulators in fact have the resources to inspect all the firms that score as "high risk" on their risk scorecards, and what other uses do regulators make of their risk-based frameworks?

Mobility of resources – do they shift and are they adequate to cover all the "high risk" firms? One of the main reasons that risk-based systems are advocated as part of the "better regulation" drive is that they are meant to be a tool for efficient resource allocation. Regulators agree that broadly speaking resources do shift between the main risk categories, but that it is harder to get resources to shift in lines with more fine grained changes in risk assessments.

As explained above, regulators frequently divide their regulated population on the basis of broad impact measures. These do broadly determine resource allocation. So in environmental regulation in England and Wales, a Tier 1 firm receives a tiny proportion of the attention of a Tier 3 firm, for example. This categorisation often determines when the bespoke risk assessments that we are discussing here are done. Difficulties arise in determining which firms within this category, or possibly two highest categories (depending on how many categories there are) require the most resources. Many regulators find that in practice it is hard to ensure that resources shift in accordance with the risk assessments within these higher risk bands, for a number of reasons.

First, risk-based regulation means not doing something; it is hard for regulators to decide what not to do. Once the lowest risk firms have been discounted, as it were, it is difficult for all risks within the higher risk bands not to seem equally as important. Moreover, it is hard for the organisation as a whole to adopt a "portfolio" approach to managing its most significant risks, and to see beyond an individual firm, or firms in a particular sector. One regulator has introduced a two stage process to determining resource allocation with its very senior management and Board. It asks those at the top of the organisation to set a particular *quantum* of risk and resource allocation – to adopt a baseline of say 100, and then rank firms above or below that baseline. But as one pointed out, "it's a zero sum game, and [top management] find that hard to understand, that if we put resources here that means they're not available somewhere else".

Second, there may be reasons for resources not to be determined by the score in particular instances. The Environment Agency is clear that a firm's Opra score is a guide to resource allocation, but only that. Ultimately decisions on resource allocation are made at the regional level, and various factors can modify the resource allocation decisions suggested by the Opra score. So a site will have higher priority than the Opra score would suggest if, for example, the installation or site has been given a lot of improvement conditions, if it is new to the sector, and if it is a contentious site, one that gives rise to a significant number of local objections, a point discussed further below.

Third, there simply may not be enough resources to monitor all the high risk firms in a way that the system might envisage. This may be because the risk scoring is not sufficiently fine grained, but it may also be that there the regulator is simply under resourced. As one regulator commented: "It's very hard to match complexity of the legislation to the risks and then to capacity – it's not one on one… we have more high risks than we have capacity". Those who are just introducing their risk-based systems recognise that they will have to feel their way, to some extent, on the issue of resource allocation. IGAOT, for example, intends to inspect its high risk sites annually; its medium risk ones every two years, and to use random inspections for its low risk firms unless there have been complaints. But it recognises it will have to see what the scores come out as before it can make a final decision. The Irish EPA is in a similar situation. In practice, there may be too many high risk firms for either regulator to perform their desired level of inspections given their current resources.

The HSE in particular has found that in recent years it has had to divert an increasing proportion of its inspectors' time to investigating accidents, rather than performing preventative work such as inspections (NAO, 2008). It is under a mandatory obligation to investigate all major injuries and fatalities. The time taken by this activity has increased partly because of the complexity of the issues, partly because of greater concern by families

of the deceased, and partly because firms are more likely to challenge formal enforcement action than they were in the past. The result has been that fewer resources are available for inspection, even of the higher risk businesses, than there have been previously.

It is hard to know whether this is a problem, however. As many regulators observed, it is difficult to establish what the right number of inspections is for the regulator to be able to say with any confidence what the level of compliance is in a particular area of activity, and to be able to improve it.

Moreover, inspections are performed to achieve a number of objectives: to meet legal requirements; to identify breaches and apply sanctions; to monitor compliance levels and target problem areas; to help businesses comply with the regulations; to prevent major incidents and (critically) to maintain confidence of stakeholders (*e.g.* NAO report, p. 17). Risk-based approaches conflict with the achievement of some of these goals. In particular, helping businesses comply and maintaining confidence of stakeholders require higher levels of inspection that risk-based systems would normally allocate. Yet these goals still need to be achieved. A key issue and point on which regulators often differ between themselves, and with politicians and other stakeholders, is the extent to which inspections should continue to play a valuable role in their attainment.

What ultimately drives resource allocation, however, is the political context and the risk to the regulators' own reputation. As noted above, some regulators routinely factor in public perceptions and the risk of damage to their own reputation in allocating their inspection resources, others do so implicitly. The UK Food Standards Agency, the HSE and the Environment Agency deliberately take into account public perceptions in allocating inspection resources and believe they would be heavily criticised if they cut back inspection activity. This has a significant bearing on the allocation of their resources. The HSE and Environment Agency believe that after their preventative work, the public expectation is that they will investigate and prosecute companies in the wake of accidents or pollution incidents. As noted above, HSE spends over half its front line regulatory resources on accident investigations (NAO overview, p. 17). The UK Pensions Regulator clearly states that firms in the intensive monitoring are those that pose highest risk to objectives, risk is also defined as "risk being that we may be perceived as not making a difference" (TPR, 2006, p. 50).

There are some firms or risks that in political terms a regulator simply cannot leave alone, regardless of the probability. As one commented, "events force you up the probability curve". The higher the political salience, the lower the probability level at which the regulator will intervene. Political risk here is critical in determining a regulators' risk appetite and its risk tolerance, and thus the allocation of regulatory resources; regardless of what the impact and probability studies would otherwise say.

Other uses of risk-based frameworks. Allocation of inspection resources is only one use of a risk-based framework. Regulators also use the frameworks for a number of immediate purposes, as well as to achieve the broader motivations indicated above. Principal other uses are:

- to set fees and charges;
- to provide information for reporting purposes, particularly in the environmental context;
- to gather information on the regulated population; and
- as part of broader strategy and objective of improving management engagement and compliance performance.

The use of the framework to set charges is common amongst the environmental regulators. However, this does mean that much of the risk grading is attributable to fixed attributes of the site, notably its scale and complexity. This is because complex sites take longer to inspect, and so consume more inspection resources. The risk score therefore has to be high for such sites to enable the charges to be recouped. The extent to which the charging structure drives or influences the framework does depend on whether charges are applied on a cost-recovery basis or not. The Environment Agency has to apply charges on this basis, and this has raised a number of issues which potentially cut across the pursuit of a risk-based approach. In particular, inspectors feel that they have to spend longer on such firms as those firms have paid more (NAO, 2008a). The annual enforcement charges assigned by the Irish EPA to the operators take into account the enforcement category arrived at through completion and validation of the methodology. In general, the higher the enforcement/risk category, the greater the annual enforcement charge which the operator has to pay the Irish EPA.

The frameworks are also used by many of the regulators as part of a broader strategy to engage management. This is rationale is particularly evident in those frameworks using self assessment, such as the environmental frameworks and the UK Office of Fair Trading's new approach to licensing. Through the self assessment process the regulator is attempting to ensure firms engage with the regulation and moreover see their operations from the regulators' perspective. It can also be a way of handling the inheritance of a regulator from a previous regulatory regime. In the case of the UK Office of Fair Trading, the previous routine approach to licensing for consumer credit meant that firms simply applied for as broad a license as possible, and the regulator had little idea of what areas they in fact were operating in. The OFT thus has 156 000 current licence holders. Asking them for information in detail in the application process is a relatively efficient way of getting information on their business (subject to validation) and prompting them to reduce the number of different types of consumer credit business for which they apply for a licence.

Performing inspections in risk-based frameworks

One of the most significant challenges for regulators moving to risk-based systems is changing the culture and skills of inspectors. All regulators examined whose risk-based systems have been running for some years have found that it takes at least two years for inspectors to move towards a risk-based approach to inspection. And as the FSA's experience with the supervision of Northern Rock illustrates, it can take far longer.

Four key issues emerged from the research with respect to inspections: the training and re-skilling of inspectors; how to avoid false positives; how to balance a focus on outcomes with a focus on compliance; and how to manage risk-based inspection systems in a federated inspection structure.

Training and re-skilling of inspectors

Risk-based frameworks have significant implications for inspectors and the inspection function. The shift to a risk-based approach often requires a fundamental change in culture, a different analytical approach, a different understanding of the role of inspectors and supervisory staff, and a new skill set. All the regulators examined here, and those examined by others, have found that this is a key challenge in introducing a risk-based system (IPOS, 2007; NAO, 2008f, p. 17).

A shift to risk-based inspections is particularly challenging where the organisations involved in inspection previously had a long practice of routine processing of information or routine inspection processes. These changes can prompt hostility to the risk-based regime from some inspectors. As noted above, by its very nature, risk-based frameworks significantly curtail the scope for inspectors' discretion in determining how to plan inspections, who to inspect, and what to inspect for. It can also be difficult for inspectors to accept that they no longer need to spend too long on particular firms, as it calls into question the validity and usefulness of the way they have performed their roles previously.

Often regulators find that in order to begin to change the inspection culture there has to be a shake out of the current supervisory staff, and new people hired or brought in on secondment. However, even in those regulators who have operated a risk-based framework for some years, firms complain that inspectors are insufficiently skilled and knowledgeable to make risk-based judgements, and that they still have a "tick box" mindset (NAO, 2008a, p. 31).

Many of the regulators who have had risk-based frameworks for some time admit that in hindsight they spent too little time on training inspectors, and/or that the training they did was focused on the wrong things. Frequently, training was given on the IT system and on how to fill in the risk assessment forms. However, what was neglected at first was training in the whole philosophy of risk-based regulation. As one regulator commented, "we thought they would just get it, just understand what risk-based meant, but they didn't".

Avoiding false positives and false negatives

One of the problems that regulators with some years' experience of risk-based frameworks have found is that the system can return false positives or negatives, depending on how it is designed. Where a supervisor or inspector is not sure of how to grade a particular risk, in some systems they can leave this blank. If the IT system underlying the framework automatically defaults to a low risk score, the result can be a lot of false positives. It may be that the score was left blank because it was low risk, but it may also have been left blank because the supervisor or inspector did not look at the issue or did not understand it.

Regulators have met this problem in different ways. The Dutch and Portuguese environment regulators' frameworks cannot be left blank, so one of the appointed solutions is to fill a medium score to those criteria for which there is no available information, to avoid giving weight on high or low priority which could lead to false. The UK Financial Services Authority's revised framework, Arrow 2, requires supervisors to enter a judgement to avoid leaving "dark holes" where the risk score does not properly reflect risk because of an under estimation by supervisors or because it is simply out of date, though as Northern Rock illustrated these "dark holes" still exist.

None of the regulators examined has a system in which the person doing the assessment is required to state their confidence level, however. In contrast, the peer review process for some research councils requires referees to state how expert they are in the particular research area and how confident they are about the rating they give. Some regulators are thinking of introducing such a system, although there are issues as to whether inspectors or supervisors will in fact admit to lack of confidence.

How to balance focus on outcomes with focus on compliance

The shift from a compliance approach to a risk-based approach can also be problematic because of the legal framework in which regulators have to operate. Regulators are often charged with implementing an existing set of legal requirements which are not outcome focused, and which they are unable to change. It may well be that breach of a particular requirement does not affect the risk or outcome. The fact that there is a disparity suggests the rule should be re-written if not removed, but often it is not within the regulator's power to make these changes. In the EU context, it can often require a change in EU legislation. Leaving a number of breaches unsanctioned can reduce the credibility of the regulatory regime as a whole, however. For this reason, inspectors can resist the move to a more risk-based approach.

Federated inspection systems

Federated inspection systems pose particular problems. The extent to which the central or federal regulator, or regulator operating at the level of central government in non-federal systems, can influence what happens at a local level varies with the constitutional and political context of each country. Co-ordination problems are clearly enhanced where the central regulator can exert little control. However, even in systems where the central regulator does have powers over the inspection processes of local or regional authorities, there can be problems with the co-ordination of inspections and consistency in risk assessments. For example, in the UK, in food regulation there have been problems of "join up" between local authorities and the central agency. The Agency sets its own priorities for food safety, but as these are not legal obligations, they are not reflected in the Code of Practice. The result is that inspections and the regulatory priorities are not integrated. Similar problems can arise across regulators with a large number of regionally dispersed inspectors (see *e.g.* NAO, 2008d).

Compliance/enforcement policies and risk-based frameworks

How closely the regulators' risk assessments are linked into a particular enforcement approach is a significant point of variation between the different risk-based frameworks. Many regulators have enforcement policies or compliance strategies. These may categorise firms on the basis of their attitude to compliance, as in the case of the Environment Agency and HSE, for example. The enforcement strategies may themselves be risk-based in that they incorporate an assessment of the likelihood of success of formal enforcement action, such as that of VROM or the Financial Services Authority. Often, however, there is no direct link between the risk category of a firm and the enforcement strategy that the regulator will adopt. Notable exceptions are APRA, DNB, and VROM.

APRA, whose model was followed by DNB, integrates its risk assessment framework to the type of supervisory response it will take. It uses PAIRS to determine a firm's risk level. PAIRS is integrated with SOARS – the Supervisory Oversight Assessment Framework. The development of both PAIRS and SOARS was shaped by the failure of the insurance firm, HIH. This event had revealed both the weaknesses in APRA's existing risk-based frameworks for assessing financial institutions and the absence of an effective culture or practices of supervision and intervention. SOARS was devised to address that failure, and is deliberately intended to create a more pre-emptive and effective supervisory intervention culture within APRA, and to improve consistency in its supervisory interventions (Black, 2006).

SOARS has two components: a supervisory attention index and a supervisory stance. The supervisory attention index computed as the geometric average of the probability (risk) index and the impact index. Although supervisors have discretion as to exactly which intervention and enforcement tools they use, the SOARS index sets the amount of supervisory resources each institution is likely to require, and the supervisory stance that is to be adopted in terms of its relative intrusiveness, intensity and directiveness.

Table 6.5. **The SOARS grid**[1]

		PAIRS Probability rating				
		Low		Medium	High	Extreme
PAIRS impact rating	Extreme	Normal	Oversight	Mandated improvement	Restructure	Restructure
	High	Normal	Oversight	Oversight	Mandated improvement	Restructure
	Medium	Normal	Normal	Oversight	Mandated improvement	Restructure
	Low	Normal	Normal	Oversight	Mandated improvement	Restructure

1. The grid is published widely in APRA documents. See for example, APRA's Risk Rating of Superannuation Funds (Insight, May 2004); APRA, *Annual Report*, 2003.

The intervention settings for the supervisory attention index and the supervisory stance are set by APRA's senior executive and Members. They are currently torqued towards earlier and more interventionist action for larger firms, again a direct consequence of HIH.

In its initial form, APRA's SOARS framework set the level of supervisory resources and supervisory approach, but left the choice of individual intervention plans to the supervisors. APRA has also begun to give the same attention to the supervisory responses adopted with respect to individual firms within each category as it has to risk assessments. The discussions of the PAIRS forums have begun to integrate discussion of the risk assessments with discussions of what the supervisory response should be. APRA is also establishing SOARS panels to establish the same level of scrutiny over the supervisory approach being adopted as they currently have over the risk assessment.

VROM also integrates risk assessment with supervisory response. It has integrated inspection and enforcement teams, which includes members who are specialists on the effectiveness of different intervention strategies. The intervention strategy is linked to the level of risk (VROM, 2004). When an organisation is ranked as red, which is high risk, then a more severe approach is taken. They have intervention specialists and members of the prosecution authorities within the project teams (soil, water, air quality and safety), who work with the inspectors and other team members to explore what would be the best type of intervention to make. VROM have a well articulated Compliance Strategy. This seeks to combine a "task-oriented track", which focuses on the rules to be enforced, and a "problem orientated track", which focuses on the problems to be addressed. High priority is given in enforcement to breaches of rules which pose a high risk and with respect to which there is a high-non-compliance rate. Medium priority is given to areas with respect to which there is low non-compliance but which are high risk, and to which there is high non-compliance but they are low risk. Using the media to draw attention to issues and non-compliance is a key part of the enforcement strategy for medium risk occurrences. Low priority is given to enforcing a rule if there is low non-compliance and it is low risk. The form that the enforcement action takes then varies with an assessment of how enforceable the rule is, the firm's motivation for non-compliance, how it is likely to respond to intervention, and whether a broader approach to tackling the problem is required. VROM uses the "table of 11" used by the Dutch Ministry of Justice as a framework for determining what intervention to take.

Table 6.6. **Dutch Table of 11**

Aspects of spontaneous compliance	1. Knowledge of the regulations. 2. Cost/benefit ratio. 3. Degree of acceptance. 4. Loyalty and obedience. 5. Informal monitoring.
Aspects of monitoring	6. Informal report probability. 7. Monitoring probability. 8. Detection probability.
Aspects of sanctions	10. Choice of sanctions. 11. Severity of sanctions.

Communication of results

Communication both of the nature of the framework and of the results of the risk assessments poses a number of issues. With regards to the framework, the Irish Environmental Protection Agency, for example, found that describing sites in terms of "risk" caused too much confusion, so it deliberately named its framework an environmental "assessment". With respect to communication of results, confusion can often arise as many regulators have found that firms do not necessarily understand the results of the risk assessment or the implications for their relationship with the regulator. Regulators have found that they need to pay greater attention to this aspect of communication than they at first thought.

Regulators also adopt quite different approaches to whether they communicate individual firm's risk assessments to the public or not. The financial regulators do not publish risk assessments, largely out of concern that they will be misunderstood by the public and damage market confidence. In contrast, the Environment Agency does publish the Opra risk assessments of installations via its websites and through its Spotlight reports.

The issue of whether and how to publish the outcomes of the risk assessments has come into sharp relief in the context of UK food safety regulation. Following the example of the Dutch authorities, many local authorities in the UK have started publishing "scores on the doors" of the food establishments that they inspect. There are now over separate 200 schemes run by local authorities, many of which uses a different scoring system. Many of these incorporate all or aspects of the risk score derived from the inspection process. The Food Standards Agency is currently consulting on developing a single, nationwide framework for "scores on the doors" (Food SA, 2008b). Publishing "scores on the doors" can be a very effective way of harnessing consumer power to reinforce the regulatory process. However, there are concerns that the "scores" can only give a snapshot picture of the state of the establishment at the time of inspection, and moreover that it would not be appropriate to incorporate all aspects of the risk score into the "score on the door" as the two have quite different purposes. The principal argument put forward by regulators in a range of sectors for not publishing scores is that they will be misinterpreted. Risk assessments are internal tools used by regulators for a number of purposes; they are not assessments of the quality or even compliance levels of the firm itself.

6.4. Evaluation of risk-based frameworks

Evaluating the effectiveness of regulation is a significant challenge. In order for their risk-based approaches to be effective, regulators have to know whether they are in fact applying the right level of resources to the right issues. But as noted above, it is hard to

know how many inspections to do when the impact of each one is hard to evaluate (see also NAO, 2008f, p. 17).

Traditionally regulators, and their auditors, have been very good at counting what they have done: number of inspections performed; number of notices issued; number of formal prosecutions taken, conviction rates and levels of fines imposed. What they have been less good at is evaluating the effectiveness of any of this activity. Moreover, focusing on formal enforcement actions alone leaves a significant swathe of regulatory work uncounted. Yet inspections do not have to result in a formal enforcement action in order to be effective. Giving advice and information can be as valuable as issuing a notice, often more so.

Moving away from counting inputs to evaluating outcomes is a task that no regulator feels that it has yet managed to accomplish successfully. Regulators in different sectors to an extent face quite different problems of evaluation. Environmental or health and safety regulators have the advantage of a large database, and an environment which can be measured. It is relatively straightforward to measure pollution levels or discharges into water, or injury and fatality rates, even if it is difficult to establish a causal link between the agency's action and any increase or reduction in those levels. Regulators in the financial sector face a slightly different problem. They often have to measure invisibles: what would have happened had they not intervened, yet it is difficult to assess a counter-factual. All regulators face the difficulty of knowing when to assess, and how to establish the causal relationship between what they find and what they have done.

Regulators are experimenting with different modes of evaluation, nonetheless, and moving towards more outcome orientated evaluations. The UK Food Standards Agency is moving away from performance targets and reporting based on number of inspections and specified forms of intervention to an outcome based policy focusing on compliance rates. The Environment Agency has set targets for improving operators' management systems based on OPRA scores. The HSE, liberated from input and output targets set by its parent Department, has also moved to assessing outcomes measured in terms of reductions in injuries and fatalities.

Other regulators, notably in the financial sector, have introduced attempts to assess their frameworks in a number of other ways. They look at the movement of firms between risk categories; the regulators' response time to market activities, and stress testing. Stress testing and scenario analysis are used to estimate how firms would cope if certain events were to occur. Six months or so later the regulator will look at whether any of those events did happen and will then compare it with what it thought would happen. Such an approach is however only useful if the management of the firm is relatively stable. In the food industry, where management changes are frequent, such techniques are not as helpful, as the management in charge of the firm can have changed completely since the initial scenario analysis was performed.

Evaluation is important, and the methods by which the regulator is itself evaluated can be in tension with the operation of a risk-based framework. Essentially, what is counted is what gets done. If legislators impose tight restrictions on what it is they will count in evaluating the agency, then they can unduly hinder the regulator's activity and potential effectiveness. In the food sector, for example, EC legislation stipulating the types of "controls" that competent authorities must impose to ensure food safety has recognised only inspections, sampling and analysis and verification of written documents (EC Directive 89/397). The definition of "controls" was expanded in 2004 to include "any other activity required to ensure that the

objectives of [the] Regulation are met (EC Regulation 882/2204 Article 10), and indeed requires controls to be risk-based. This expansion in the types of controls permitted under EC law, and thus recognised by the Commission as constituting a valid control in evaluating member states" food safety regimes, has enabled the UK Food Standards Authority to broaden the types of intervention that it will include in its assessment of local authority food regulation. This has in turn facilitated the development of a new, broader focus on strategies for improving compliance, and indeed enabled the Food Standards Agency's own shift to an outcome based mode of evaluation of local authorities' enforcement activities by requiring them to assess improvements in compliance. There are other examples of where changes in modes of evaluation facilitate the development of outcomes-based policies. As noted above, changes in the evaluation targets for the HSE from inputs and outputs to outcomes has enabled it to move to evaluating its own work in terms of outcomes.

Main challenges of risk-based frameworks

Risk-based frameworks pose particular challenges. The research identifies nine challenges which are of key relevance for those seeking to introduce risk-based frameworks.

Combining simplicity with complexity. Many regulators spoke of the challenge of designing a system which is sufficiently complex to be able to capture and assess a wide range of risks at the firm specific and generic level and which can operate across a widely varying regulated population, and yet be simple enough to be understood used on a day to day basis by inspectors and supervisors.

Knowledge and data. Getting the right data, and making better use of the knowledge the agency has is a critical challenge. Data issues arise both with respect to individual firms and the identification and integration of system wide risks and risks in the external environment which can impact on firms.

Ensuring that assessments of firms are forward looking. Risk assessments often only capture the risks apparent today. Some regulators, such as OSFI, include a "direction of travel" indicator in their risk assessment: is the firm likely to improve or deteriorate over the period to the next inspection? However many other regulators do not explicitly require this assessment, and have found that supervisors or inspectors tend to focus on the risks as they appear now, and not on what might happen in the near future. As noted above, it can also be challenging to ensure that supervisors understand the difference between risk and control – that what they see as a control may in fact be a risk.

Going beyond the individual firm in assessing risk. Here there are two challenges. First, it can be difficult to ensure the framework integrates "horizon" scanning and generic, industry wide risk assessments into the firm-specific assessment. Second, where the regulator has a broad remit, it can be challenging to develop a portfolio approach which compares risks across the whole of the regulator's portfolio of regulated firms, rather than one which focuses on individual firms alone. A single data base on which all firms are scored commonly is critical to effective management across a diverse portfolio, but not necessarily sufficient.

Structure and operation of internal risk governance processes. How to balance the need for organisational structures to ensure the accuracy and consistency of assessments with speed and responsiveness. It is challenging to achieve the right balance between having sufficient internal controls and review to ensure consistency and a hugely bureaucratic framework that in effect stymies the process. It is also difficult to find the right balance

between central direction and local flexibility: allowing sufficient flexibility for supervisors and inspectors to exercise their own judgement, whilst ensuring an acceptable level of quality and consistency of judgments.

Changing the culture to embed the risk-based approach across the whole organisation, from the Board down to individual supervisors. Experience of those who have had risk-based systems for many years suggests that it can take over two years for inspectors or supervisors to really change their approaches and come round. It can take the same time or longer for senior management to really understand the implications of the approach. In some organisations, senior management treated the introduction of the risk-based framework as something that the organisation had to have, but which was not central to what the organisation was doing. As a result there can be a disconnect between what the senior management were doing and what staff were doing.

Ensuring internal compliance with the risk-based regime. Culture changes take time, and a regulator can have a good risk-based framework in theory, but it can be poorly implemented. Developing internal assurance systems to ensure that supervisors and their senior managers are implementing the framework can therefore be necessary.

Managing blame. Risk-based regulation requires the organisation to take risks. A key part of changing culture can be the need to manage blame within the organisation when things go wrong, otherwise supervisors will never feel that they can leave apparently "low risk" issues alone. In non-zero failure regimes, it can be a challenge to resolve the tension between an *ex ante* non-zero failure policy and *ex post* tendency to blame for failures. As one regulator commented, non-zero failure all very well as long as it's not your failure. Senior management support and understanding of the implications of adopting a risk-based approach is thus essential.

Making resources follow risks. There are four issues here. First, resources cannot always track risks with any granularity. Whilst risk-based frameworks can help identify "blocks" of firms, regulators find it difficult to know how to manage resources within the "high risk" block, particularly when they do not have the resources to adopt an intense supervisory relationship or high frequency of inspections with respect to all high risk firms. Second, it is difficult to determine what the appropriate level of baseline intervention should be for the low risk firms. Third, in many regulators the inspection cycle is planned a year in advance; there is always then a lag between risk identification and response. Fourth, the emergence of a politically salient issue immediately diverts resources to dealing with that issue, even if it would otherwise count as low risk, and therefore low priority.

Managing political risk. Politics is often a key driver of what the regulator does. Some regulators seek to manage political risk by incorporating it into their frameworks, or by allowing local flexibility in the allocation of resources to accommodate local concerns. Others, such as VROM, manage political risk by negotiating closely with the relevant Minister as to what their priorities will be for the coming year, and gaining explicit Ministerial approval for their approach. For most, however, their carefully crafted risk-based frameworks are abandoned when politics intervenes. Quite simply, there are some issues with respect the regulator, or the political system, cannot be seen to fail; and it is to those issues where resources will ultimately go.

Conclusion

One of the purposes of the research was to identify lessons which can be learnt from those who have embarked on using risk-based frameworks. The main lessons coming from the research that are of relevance to others are the following (see also IOPS, 2007):

Start with risks not rules. The legislative provisions which a regulator has to implement are often complex and over-whelming. A risk-based approach requires regulators to focus on the risks they need to manage, not the rules they have to ensure compliance with.

Ensure the organisation has sufficient powers to implement the approach. Many regulators have been hampered by inadequate legislative regimes. Regulators need powers to collect the relevant data, and to adopt a flexible approach to determining their inspection policies, and to have a sufficiently wide range of intervention powers. Overly prescriptive evaluation and audit regimes can have similar restrictive effects.

Beware of other regulatory or governmental policies which may contradict or hinder the adoption of a risk-based approach. The impacts of different types of evaluation were noted above. Charging regimes which require regulators to recover the cost of inspections can also distort a risk-based approach to inspection planning. A further example of the unintended consequences are the requirements that those tendering for public sector contracts give details of all enforcement actions. This has been one of the factors prompting companies to dispute enforcement actions taken by the HSE, increasing the resources that it has to spend on investigating and prosecuting accidents as opposed to performing inspections.

Designing and implementing a risk-based framework will take time. As many commented "don't expect it to be right first time". As another observed, "just because something goes wrong doesn't mean the whole system is wrong". Risk-based frameworks are often "built in the lab" by specialists and consultants, and need refinement and adjustment when put into practice. Regulators who are embarking on forming risk-based inspections systems can by now benefit from the experience of others. Nevertheless, pilot projects are recommended by the more experienced regulators in order to trial the framework and to gain "buy in" from firms. If developing from scratch, those how have been through the process recommend that frameworks are developed alongside the on-site inspection process to make sure the two systems match up.

Keep it simple to use and be prepared for the need to make continual adjustments. Frameworks have to be dynamic. They therefore have to be flexible and regulators have to continually revise and update the risk-based model in order to prevent it stagnating and becoming out of step. Frameworks have to be simple to ensure that they are understood by inspectors, and therefore appropriately used by them. In evaluating the framework, use feedback from as many different sources as possible: firms, supervisors, other stakeholders along with internal evaluations to enhance and refine the framework.

Don't underestimate the organisational challenges involved. Organisational challenges are significant, both in terms of changes needed to internal organisational structures and to the changes in skills and culture that will be needed; this may require turnover in staff and a hiring of staff with a different skill set from that sought by the organisation in the past. Systems that were not easily accepted were those that were associated with failures or as having come out of failures, or as being associated with one regulator in particular from a previous regulatory regime (where a number had merged to form the new regulator). In contrast, frameworks were more readily accepted in organisations where they marked

a step change in approach as part of an organisation-wide recognition for a need for change. Nonetheless, it can still take a considerable amount of time for supervisors and senior managers to understand the implications and limitations of a risk-based approach.

Think beyond the risk assessment to how the organisation will respond. There need to be people in the risk assessment process who know what to do when something arises, when the risk crystallises. This can require an integration of people with enforcement experience on the inspection and supervisory teams, and/or a closely integrated compliance and enforcement policy.

Think in terms of achievability. Recognise that resources are likely to be inadequate to adopt an intensive inspection policy even for high risks so think in terms of where those inspection resources are likely to make the biggest difference, and explore alternative strategies to inspections for influencing behaviour.

Communication is vital both within the organisation, with politicians, with firms, and with the public as to what the process is, what the risk scores mean, and how the framework may need to be adjusted. In particular, openness with the industry as to the fact that it is being rated, what the rating means, and that the rating they get will have an influence on how the regulator interacts with them is vital.

It is worth doing. It provides an explicit framework for organising the regulators' assessments and responses. As one regulator commented, "[e]veryone is risk-based and it is better to face up to it and discuss it rather than allowing the organisation to muddle on". Risk-based frameworks can produce resource savings, help to set outcomes and provide a framework for analysing problems or new developments. They can also be used to help set objectives within firms by providing them with assessments of how the firm performs relative to others in the sector, and can provide a common language for discussion with firms' senior management.

But don't do it for the wrong reasons. Learn from others, but don't just adopt someone else's model because people say it is the best. As one regulator commented, "make sure it can work for you; don't adopt it hoping it will miraculously produce a huge internal change, as it won't – that change is very hard to achieve". Recognise its limitations; it is only a tool, and at some point regulators have to ask if it is giving a common sense answer. Risk assessments are inherently judgemental and cannot be purely objective and quantitative, even though many expect them to be.

Recognise that risk-based processes require regulators, and politicians, to take risks, and it is never possible to get consensus on when failures are acceptable. As Douglas and Wildavsky so famously observed, we do not know the risks we face, but we must act as if we do (Douglas and Wildavsky, 1982). Regulators do not know where the next big failure will come from, but they must act as if they do. In so doing, they have to decide whether to err on the side of doing something now that does not need to be done, because it turns out there is no risk; or of not doing something now which it turns out later on that should have been done. Risk-based frameworks can provide a framework for the systematic assessment of political choices, but they can never remove them.

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ANNEX 6.A1

Methodology

The research was conducted during a six-week period from mid-September to end-October 2008. The project explored some of the risk-based frameworks used by regulators in the environmental, food and financial services sectors in a number of countries. The purpose of the research was to draw on examples of risk-based frameworks in development and use, not to perform a systematic survey of their state of development. Desk-based research was conducted with respect to food, environmental and financial services regulators in the UK, Ireland, the Netherlands and Australia, and occupational health and safety in the UK and the Netherlands. In addition, interviews were conducted with one or more officials from each of the regulators listed below. Others were contacted, but it was not possible to arrange interviews within the time constraints. All interviews were conducted on a semi-structured basis, using the questionnaire in Annex 6.A2. Interviews lasted between 1-1.5 hours; contemporaneous notes were taken and written up immediately after each interview.

Environment

Environment Agency, UK.

Environmental Protection Agency, Ireland.

IGAOT, Portugal.

VROM, Netherlands.

Financial services

Australian Prudential Regulation Authority, Australia.

Australian Securities and Investments Commission, Australia.

Financial Services Authority, UK.

The Office of Fair Trading, UK.

The Pensions Regulator, UK.

Food

Food Standards Agency, UK.

Health and safety

Health and Safety Executive, UK.

ANNEX 6.A2

Questionnaire Used for Semi-structured Interviews

by
Prof. Julia Black, LSE

Risk-based inspection – issues for discussion

a) Background to the development of the framework:

- *i)* What were the main drivers?
- *ii)* Who or what were the main influencers – other regulators in the same country; same-sector regulators overseas; others?

b) Issues in design:

- *i)* Do probability and impact have equal weighting or is there a bias towards, *e.g.* high impact but low probability events?
- *ii)* How were the "risks" identified?
- *iii)* How were the risk indicators identified? Did you need to obtain additional information from regulated firms, scientists or others before the framework could be designed?
- *iv)* How, if at all, are the different indicators weighted?
- *v)* What were the main difficulties in designing the framework?

c) Issues in implementation:

- *i)* What issues have there been, if any, with respect to data collection in the design and operation of the framework?
- *ii)* What additional training/re-skilling for inspectors has the framework required?
- *iii)* How is consistency between risk assessments by inspectors ensured?
- *iv)* How, if at all, are inspectors challenged internally on their risk assessments?
- *v)* Has there been resistance within the organisation to the implementation of the framework; if so, of what nature?
- *vi)* Has implementation entailed changes in the structure of the organisation; if so what?
- *vii)* How useful is the framework as an internal management tool?
- *viii)* To what extent has it been possible to adapt the allocation of resources so that they are in line with the risk assessments?

ix) What role, if any, do random inspections play in the inspection process?

x) What other issues have arisen in the implementation of the framework?

d) Enforcement:

i) What is the relationship between the framework and the Agency's enforcement policy? For example, will the Agency take stronger action against "high risk" firms than low risk ones?

e) Evaluation:

i) How is the effectiveness of the framework evaluated?

ii) What processes exist for modifying the framework?

f) Lessons for other regulators:

i) What lessons, if any, would you offer to other regulators who may be considering adopting a risk-based framework for supervision?

ANNEX 6.A3

Outline of the Different Risk-based Inspection Systems Included in the Research

Australian Prudential Regulation Authority (Australia)

APRA was formed in 1998. It is responsible for the prudential regulation of deposit taking institutions, general and life insurers, and much of the superannuation (pension) industry, and is responsible for their financial soundness (prudential regulation). Its counterpart, the Australian Securities and Investments Commission, regulates securities business, superannuation funds and insurance, and is responsible largely for regulating the manner in which those firms conduct their business. APRA introduced a risk-based approach to supervision in 1999. A new framework was introduced in 2003-04, the Probability and Impact Rating System (PAIRS) and the Supervisory and Oversight Response System (SOARS). PAIRS has been subsequently refined, the latest refinements being introduced in 2008.

All entities are subject to an individual risk analysis, though larger firms and schemes are assessed more intensively. There is a two stage process: an impact assessment based on size, and a probability assessment based on scoring of 0-4 of key risk categories. The framework comprises an assessment of inherent risk and the quality of management and control to derive a net risk score. Net risk is then considered against overall capital support to derive the Overall Risk of Failure. This overall risk score is translated into a probability index rating.

Unusually, all the scoring is based on fourth power averaging. Scores are assigned from 0-4, and there is then a non-linear relationship between the score and the probability indices. The probability of failure increases exponentially through the risk scores, and the probability index runs from 1 to 256. A rating of two, for example, carries sixteen times the risk of a one rating. Once a probability figure is obtained, the figures are assigned to one of five risk categories: low, low medium, high medium, high and extreme.

SOARS has two components: the supervisory attention index and the supervisory stance. The geometric average of the probability rating and the impact index rating determine the supervisory attention index rating, which is intended to set the level of resources to be applied the financial institution. The descriptive probability and impact assessments frame the supervisory stance, that is the actions the supervisor should take with respect to that institution in terms of the relative intrusiveness, intensity and directiveness: how “insistent” or “negotiative” they should be in their attitudes towards it.

De Nederlandsche Bank (DNB) (Netherlands)

DNB is the Dutch Central Bank, and is also responsible for the prudential supervision of deposit institutions, insurance companies and pension funds. It introduced its Financial Institutions Risk Management framework (FIRM) in 2006-07. FIRM was developed drawing on experiences in particular of the Financial Services Authority in the UK and APRA. It draws most closely on APRA's model. FIRM is complemented by an assessment of the risks faced by firms from the external market environment.

Under the framework, all institutions are assessed. Supervisors assess the inherent risk of the business. The categories of inherent risk are:

- Financial risks.
- Liquidity risks.
- Insurance risks.
- Operational risks.
- Integrity risks.
- Strategic risks.

The inherent risk score is set against the assessment of the quality of the firm's management and controls to derive a net risk score. The net risk score is then set against an assessment of available capital to arrive at an overall risk of failure score. Scoring is expressed in a traffic light system: red for high risk; green for low risk.

Similarly to the APRA framework, Specialist Supervisory Menus are linked to each risk score.

Environment Agency (England and Wales)

The Environment Agency for England and Wales is responsible for monitoring emissions to air and water and waste management. Its policy with regard to inspections is comprised of a number of elements:

- Compliance assessment methodology, for inspectors.
- Compliance classification scheme – this categorises non-compliance events on the basis of their potential or actual severity.
- Operational Risk Appraisal system (Opra) – this was introduced in 2002 for application to emissions to air; it has recently been revised and extended to waste management (April 2008), consequent on the merging of waste management licences and pollution permit and control permits into Environmental Permits. The Environment Agency is planning to extend Opra to emissions to water in 2008-09.
- Compliance assessment plans – the plans set out national, sector and site-specific objectives together with the resource allocation for each generic compliance activity (including inspections).

The Environment Agency also has a Compliance Enforcement Model which describes the compliance attitude of firms (top performers; generally compliant; generally non-compliant and criminals), and indicates the overall level of regulatory effort required and the Agency's approach.

Opra is a risk screening methodology based on assessments of five risk attributes (EA, 2008):

- Complexity:
  - Potential for significant releases to one or more media.
  - Use of one or several interconnected but distinct processes.
  - Potential for accidental emissions.
  - Inventory of potentially hazardous materials.
  - Size relative to its sector and other criteria mentioned here.
  - Whether significant regulatory effort is required to assess and maintain compliance and to maintain public confidence.
- Emissions and inputs:
  - The type and quantity of the substance in question.
  - The media into which the release takes place (*e.g.* air, water, land).
  - The input of waste into an operation.
  - The relative impact of substances on media.
- Location:
  - Proximity and nature of human habitation.
  - Proximity to sites designated under wildlife, countryside or habitats location.
  - Sensitivity of receiving waters.
  - Potential for direct release to waters and presence of control measures.
  - Potential for and consequences of flooding.
  - Inclusion within an air quality management zone.
- Operator performance/management systems:
  - Presence or absence of management systems or recognised procedures covering areas such as operation and maintenance; competence and training; emergency planning; monitoring, auditing and evaluation.
  - Compliance record.
- Compliance rating (using compliance classification scheme).

Firms are asked to complete the assessment questionnaires with respect to each of their sites or facilities. Complexity is determined by a "look up" table which assigns risk bands to particular types of activity. The answers given in the assessments are assigned risk bands from A-E, with A as requiring minimal intervention and E the highest level of intervention. Each of the lettered bands can be translated into a risk score. These are aggregated to give an Opra banded profile or risk score. The profile or score is used to determine the risk posed by the facility and to set associated fees and charges.

Financial Services Authority (UK)

The FSA initial version of their current risk-based framework, Arrow I, in 2001. This was revised in 2006. The current risk-based framework is known as Arrow II (FSA, 2006).

Arrow II is designed to identify the main risks to FSA's objectives as they arise, measure the importance of those risks, mitigate them where their size justifies it, and monitor and report on progress. Firms are initially put into one of four categories based on

impact. Low impact firms are assessed under the "small firms" model. They are monitored on the basis of returns and are dealt with through a contact centre. Medium-low impact firms (other than those with high probability) are assessed under "Arrow-light". Medium high and high impact firms, and medium low impact firms with high probability, are subject to the Arrow Firm Risk Assessment Process.

Individual risk assessments involve an assessment of probability for individual issues and for the firm as a whole. The model has vertical and horizontal dimensions. On the vertical dimension, in assessing probability, FSA assesses the gross risk inherent in the business and then the adequacy of controls addressing that particular risk. There are ten 10 high-level business and control "risk groups" which are further divided into risk elements.

Business risks are grouped into three categories:

- customers, products and markets;
- business processes; and
- prudential risks.

Control risks are categorised into three categories:

- customer, product and market controls;
- financial and operating controls;
- prudential risk controls.

To these assessments are added assessments of oversight and governance, the secondary and pervasive controls in the firm, and other mitigants, namely the amount of excess capital and liquidity that can be used to absorb risks. Running across these assessments at the horizontal level are assessments of environmental risk, control functions and management, governance and culture.

Supervisory response is linked to the risk category in that all high impact firms have a relationship manager. However, for those high impact firms that were assessed under Arrow to be high risk, there was no specific set of supervisory measures that should be taken. Following the FSA's internal audit of its handling of Northern Rock (FSA, 2008), a new supervisory response of "heightened supervision" has been introduce for those high impact firms that are assessed to be high risk on the ARROW model.

Food Standards Agency (England)

The Food Standards Agency is a non-ministerial department with responsibility for issuing codes of practice concerning the execution and enforcement of the food safety legislation by food authorities (local authorities). Local authorities are required by law to have regard to the Code in discharging their responsibilities. The Food Standards Agency is empowered, after consulting the Secretary of State, to give a food authority a direction requiring them to take specified steps in order to comply with the Code. The latest version of the Code was published in April 2008 (Food SA, 2008).

Food inspectors are required to determine the food hygiene intervention frequencies of food establishments using the risk criteria in the Code. Following recent changes in European legislation an "intervention" is now regarded by the Food Standards Authority as being broader than an inspection, and including other types of activities such as partial audits. At the European level, regulators are required to have official controls to ensure compliance. These include monitoring, surveillance, verification, audit, inspection and

sampling analysis. In addition the Food Standards Agency will allow local authorities to include all other activities which are effective in supporting food businesses to achieve compliance with food law, such as the provision of targeted education and advice, or information and intelligence gathering.

The Code of Practice sets out a risk-based scoring system for food hygiene and for food standards. The food hygiene system has three elements:

- The potential hazard:
  - Type of food and method of handling.
  - Method of processing.
  - Consumers at risk – based on number and vulnerability.
- Level of current compliance.
- Confidence in the management/control procedures.
- Additional score where there is a risk of contamination from Clostridium botulinum micro-organism and any other micro-organism which is pathogenic to humans.

The scores translate into 5 risk bands, A-E, with A as the highest. Minimum intervention frequencies are set for each band, ranging from at least every 6 months for Band A to at least once every 3 years for Band E.

The food standards intervention rating scheme is based on the same principles. Its elements are:

- The potential risk:
  - Risks to consumers and/or other businesses.
  - Extent to which the activities of the business affect any hazard.
  - Ease of compliance – *i.e.* volume and complexity of relevant food standards law to which the firm is subject.
  - Consumers at risk.
- Level of current compliance.
- Confidence in management/control systems.

Again the scores are translated into risk bands, here A-C with A as the highest. Minimum intervention frequencies are set for each frequency, ranging from at least every 12 months for Band A to once every 5 years for Band C.

Food Safety Authority of Ireland

The Food Safety Authority of Ireland introduced its risk-based code of practice for inspections in 2006. The framework focuses on the types of different food establishments, following the categories required for annual statistical returns to the European Commission. These are:

- Primary producers.
- Manufacturers and packers.
- Distributors and transporters.
- Retailers (retail trade).
- Service sector (restaurants, canteens, caterers and public houses).
- Manufacturers selling primarily to the final consumer.

Within these producer groups, different types of producers are categorised as high, medium or low risk depending on the risks that their activities pose to consumers. The frequency of inspections is linked to the risk category. Those in the highest risk category must be inspected is one full inspection and two surveillance inspections every year; those in the lowest must receive one full inspection a year. Inspection frequencies may be reduced by a stipulated amount if there is a good compliance record and the firm has complied with all requirements relating to Hazard and Critical Control Points analysis and training.

Health and Safety Executive (Field Operations Division) (UK)

The Health and Safety Executive is responsible for monitoring compliance with the health and safety legislation, together with local authorities, and for investigating accidents at work. It is also responsible for monitoring hazardous activities including nuclear installations and hazardous chemical plants. The research here focused on its occupational health and safety remit relating to non-hazardous activities, which is run by its Field Operations Division. It is responsible for monitoring compliance in approximately 2 million business premises in the UK.

The HSE has an extensive body of data on work-related fatalities, injuries and ill health which it uses to develop indicators of the industries and activities which pose the greatest risk. It has used this data to build a strategic programme of interventions, known as Fit 3: Fit for Work, Fit for Life; Fit for Tomorrow. As part of this strategy it has introduced a topic based inspection system, focusing on the most common types of risks, such as "slips and trips", falls from height, stress or workplace transport. The Fit 3 topic packs provide a framework for conducting inspections and assessing firms.

The risk-based assessment has four elements:

- Competence and attitude of management.
- Safety compliance and actual risk.
- Health compliance and actual risk.
- Welfare compliance gap.

The number of inspections has steadily declined from 70 000 in 2002-03 to 35 000 in 2006-07. The HSE has been progressively moving to other types of intervention strategies, notably targeted information campaigns using a variety of delivery mechanisms.

IGAOT (Portugal)

The Portuguese environment regulator, IGAOT, is introducing a risk-based system in 2009. The system was developed in conjunction with IMPEL, the European Network for the Implementation and Enforcement of Environmental Law. It was based on IMPEL's guidance for environmental inspections, *Doing the Right Things*, and was influenced by the frameworks used by the environmental regulators in Ireland and the Netherlands.

All sites with an integrated pollution control licence will be assessed under the framework. The framework will thus apply to emissions, waste management and discharges into water/sewers.

There are 5 risk groups:

- Complexity.
- Emissions and inputs.

- Location.
- Attitude of operator to the environment and sustainability of the attitude.
- Compliance behaviour.

Compliance behaviour is given additional weight in arriving at the overall risk score. There are three scores, high, medium and low. It is envisaged that most resources will be focused on the high risk entities.

Office of Environmental Enforcement of the Environmental Protection Agency (EPA) (Ireland)

The EPA introduced its risk-based framework, the Environment-Based Assessment Tool in 2007 (EPA, 2007). It was developed drawing on frameworks used in Norway, the Netherlands, England and Wales, and Scotland. The Environment Agency of England and Wales' model was used as the basis for the EPA's framework.

The framework allocates an enforcement priority to licensed facilities on the basis of 5 risk elements:

- Complexity.
- Location.
- Emissions.
- Operator management.
- Enforcement record.

There are three broad enforcement categories, high (A), medium (B) and low (C). These are further subdivided thus: A1-A3; B1-B3; and C1-C2. An enforcement category is derived for each risk element; these are then combined to give an overall enforcement category. The EPA will use the categorisation to determine its inspection priorities and its enforcement approach.

The framework operates together with the Environmental Liability Risk Assessment, to be performed by all licensed facilities on an annual basis, and used in conjunction with the enforcement category to determine the EPA's response.

Office of Fair Trading (UK)

The Office of Fair Trading is responsible, amongst other, for the regulation of consumer credit. Those engaging in consumer credit business in the UK require a licence. There are currently over 240 000 licence holders. The OFT has recently been given new powers under the Consumer Credit Act 2006 to carry out fitness and competence checks of licence holders. It has also received powers and responsibilities under the Act to supervise approximately 22 000 credit institutions. It is intending on contracting out some of this work to Trading Standards offices, which are funded by and accountable to local authorities. The OFT is introducing a risk-based system to the monitoring of consumer credit licences in 2008-09.

The 2006 Act introduced a new competence requirement for consumer credit licence holders. Credit competence is defined by the OFT to mean whether the licence holder can demonstrate that he/she or those employed by them have adequate knowledge and experience to carry on credit business concerned, and whether the applicant or licence holder has established or maintained management and financial systems which would

enable it to meet its obligations to customers, and to comply with the legislation and generally accepted business practices. The intention is that the OFT will be able to refuse a licence or licence renewal application on the grounds of lack of competence alone.

It will inspect only high risk activities. The primary factors which affect the level of risk to consumers are the transparency of the market and the consumer's ability to shop around. Based on these principles, the OFT divides activities into three risk categories.

High risk Category A – high risk activity where problems and solutions are well documented and understood; full Credit Competence Plan and on-site visit usually required:

- 3rd party debt collection.
- Debt counselling.
- Debt adjusting.
- Credit information services.

High RISK Category B – high risk activities where there is a potential for serious consumer detriment but the issues are less clear cut. Credit Risk Profile Form and on-site visit sometimes required:

- Lending/broking – secured sub prime.
- Lending/broking – at home.
- Debt administration – secured sub prime.
- Credit reference agencies.

Low Risk category: all activities other than the above on the basis that the risks are considered to be lower and can be dealt with adequately *ex post* or through different means than inspections.

The Pensions Regulator (UK)

The Pensions Regulator was established in 2004 and is responsible for the supervision of work-based pension schemes in the UK, with a focus on employers and trustees. It is not responsible for regulated the financial services providers related to such schemes; that is the responsibility of the UK Financial Services Authority. Its objectives are to protect the funds in pension schemes, to reduce the risk of situations that may lead to compensation being payable from the Pension Protection Fund and to promote and improve understanding of good administration of work based pension schemes.

Its risk-based approach has two dimensions: level of risk and scheme size. Schemes are considered small if they have less than 1 000 participating members. Risk is defined as the negative impact of the failure of a scheme on the member and the market.

The Pensions Regulator has an intervention matrix which comprises four scenarios of three different levels of risk intensity.

- High risk, large scheme: Active intervention; high intensity intervention.
- High risk, small scheme: Intelligence based action; medium intensity intervention.
- Low risk, large scheme: Proactive monitoring; medium intensity intervention.
- Low risk, small scheme: Focus on education and support; low intensity intervention.

The regulator adopts a "triage" approach to organise its workflow and identify the appropriate supervisory response. As information comes in, it is initially handled by customer support. That unit refers more complicated or serious matters to the triage unit.

Triage then assesses the risk and then forwards the issue to one of the three supervisory groups: scheme specific funding, corporate risk management, or pension administration and governance, depending on the issue.

VROM (Netherlands Ministry of Housing, Spatial Planning and the Environment Inspectorate)

The VROM inspectorate is responsible for enforcing some of the rules that still fall under the responsibility of the Minister; it also oversees performance of the municipal and provincial authorities in implementing and enforcing the legal requirements. It mainly focuses on the transportation of environmentally hazardous materials into, out of and within the Netherlands.

VROM organise its activities under its Compliance Strategy, introduced in 2004 (VROM, 2004). The Compliance Strategy is based on seven principles:

- Risk assessments.
- Non-compliance rate.
- Determination of priorities.
- Reasons for non-compliance.
- Smart enforcement.
- Co-operation.
- Feedback.

The Strategy translates these principles into two "tracks". These are the "task orientated track" and the "problem-orientated track".

The "task orientated track": inside – out comprises six assessments:

- What rules must be enforced?
- Are the rules enforceable, executable and fraud resistant?
- What are the risks of not enforcing the rules?
- What is the scale of the non-compliance rate and what is the reason for it?
- What is an appropriate intervention?
- What has been learned and who should be informed about it?

The problem-orientated track (outside-in) comprises a further six assessments:

- What risks exist for the sustainable environment?
- What causes the problem and who is involved?
- What mix of intervention is needed and how will it be organised?
- Is work taking place according to a plan and will the goal be achieved?
- What has been learned and who should be informed about it?
- How will the achieved results be maintained?

Based on the "task orientated track" the VROM inspectorate can prioritise its tasks and concentrate on high risks and high non-compliance rates. The "problem-orientated track" is used to focus attention on which societal problems require attention and how they should be addressed. Some of the VROM inspectorate work is thus determined by the public (VROM, 2004).

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Chapter 7

Why Governments Need Guidelines for Risk Assessment and Management

by
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Regulation can be a key tool to help governments manage risks. The financial crisis has reinforced concern that governments have not done enough to integrate risk management into the design and management of regulations and the functions of regulatory bodies. Formal guidelines for risk prioritisation, assessment, management, and communication may help governments cope with this regulatory governance gap. Themes that should be addressed in such guidelines include optimal risk taking, processes for preparing formal risk assessment reports, the analytic treatment of scientific uncertainty about risk, ranking risks and risk-reduction opportunities, precaution and the value of information, ancillary risks and benefits, transparency of governmental procedures, cross-department co-ordination, public/stakeholder participation and capacity building. The governments of Canada, the USA and the UK as well as the European Commission have already moved in this direction with formal policy statements on risk.

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Introduction

One of the most essential tasks of government is to manage risk on behalf of the public, where risk is simply the chance of an adverse outcome. The "adverse outcome" may concern financial well being, human health, safety, environmental quality or even national security. Of particular concern are new, emerging risks that are unfamiliar to governments (OECD, 2003).

Managing risk is as difficult as it is essential. Indeed, there is a large body of scholarly literature suggesting that people (as individuals or businesses) and their governments do not assess or manage risk with a high degree of competence (Baron, 1998; Thaler and Sunstein, 2008). Risks are both over-regulated and under-regulated, reflecting a public syndrome of paranoia and neglect (Viscusi, 1998). Even the technical task of assessing risk, a key input to risk management, is plagued by complexities such as fundamental scientific uncertainty about whether a risk exists and, if so, its likelihood and severity, and wide variations in the vulnerability of different individuals, households, communities, regions and ecosystems.

In fact, the policy makers who assess and manage risk often do not realise they are doing so. They think they are regulating financial markets, or overseeing the safety of new drugs and medical devices, or crafting policies to reduce automotive air pollution, or negotiating international agreements to slow the pace of climate change. Yet specialists who are trained in risk analysis and decision theory see a commonality to these diverse substantive challenges.

The common challenge is to manage risk wisely in settings where risks are often poorly identified and quantified, where enlightened value judgments about optimal risk taking are disputed, and where well-intentioned policies aimed at curbing one risk may inadvertently create other risks (McDaniels and Small, 2004). And since knowledge about risks changes over time, often slowly but sometimes rapidly, a common challenge is to make wise decisions in a dynamic context where flexibility is needed to account for new information.

A small but growing number of governments are issuing formal policy statements and guidelines about risk. It is difficult to pinpoint when governments began to move in this direction but much activity has occurred since 2000. For example, the European Commission issued in 2000 an official "communication" on the role of precaution in risk management in the face of considerable international criticism of how Brussels was handling risk issues (EC, 2000). In November 2002 the UK government under Tony Blair went much further and issued an extensive policy report on how the capacity of government to respond to risks should be enhanced (UK Government, 2002). In September 2004 an external advisory committee to the Government of Canada issued a report on "smart regulation" that dedicated an entire chapter to the special challenges of risk management (Canadian Government, 2004). This report went further than a 2001 report of the Canadian government that offered principles of a precautionary approach to

risk regulation (Canadian Government, 2001). And in 2007 the US Government issued updated "principles of risk analysis" for use by all federal departments and agencies after backing away from a much more detailed draft technical bulletin on risk assessment (US Government, 2007).

It may be useful for governments around the world to develop, debate, adopt and implement official guidelines in this area. The potential benefits of formal guidelines include improved protection of the public from risk, lower costs of risk-management measures, and increased public confidence in government's capability to manage risk.

The guidelines should not be highly prescriptive or detailed because the nature of risks vary enormously and the proper management strategies will vary tremendously depending on case-specific circumstances. This chapter only tries to identify what guidelines should cover and gives some general directions about policy, but does not propose specific language for guidelines. Scholars of risk assessment and management have accumulated a sufficient knowledge base to support a series of non-obvious and non-trivial guidelines (Haimes, 1998; Paustenbach, 2002; Renn, 2008). Nevertheless, there are areas of controversy. Indeed, some well-considered guidelines may fly in the face of the basic instincts of politicians and the staffs that advise them on these issues.

7.1. Zero risk is not an option: toward an optimal portfolio of risks

The goal of risk management is not zero risk but an optimal portfolio of risks.

Regulators often tackle risks with "tunnel vision" that leads to zero-risk thinking. For example, when it is revealed that a risk (*e.g.* the fatal side effect of a drug) has been suppressed, ignored or poorly managed, politicians may overreact by seeking to eliminate the drug. In some cases this reaction may be appropriate. But the literature on risk management suggests that reducing a "target risk" to zero is rarely the optimal result since the quest for zero risk may be fruitless, may be too expensive, may discourage valuable innovation, may create other risks, or may simply divert the policy maker's attention and resources from the management of more serious risks (Viscusi, 1998).

The proper framing of the regulator's dilemma is to achieve an optimal portfolio of risks. Multiple risks are almost always at issue because: *i)* there is a priority setting question as to which risks should be of concern to policy makers; and *ii)* efforts to reduce a "target" risk frequently create "countervailing" risks. Zero risk is an unattainable goal and, even if it is attainable with respect to one risk, numerous risks would remain.

The word "optimal" is so demanding that it may seem to be an impossible aspiration for governments. But even a less demanding standard such as a "sensible" portfolio of risks, one derived from "satisficing" behaviour (where governments seek satisfactory instead of optimal outcomes), is likely to eschew "zero risk" in favour of a balanced approach to addressing the multiple risks that governments face (Sunstein, 2002).

In settings where technological innovation is at stake, a quest for zero risk is particularly inappropriate. If societies are to reap the benefits of new technologies in diverse fields such as nanotechnology, green chemistry, and renewable energy, a certain amount of risk will have to be incurred. After all, a posture of zero risk would never have permitted electricity, the internal combustion engine, pharmaceuticals, plastics, the Internet or the cell phone.

7.2. Making risk assessment formal and explicit

Before a potential risk is managed by government, it is useful for policy makers to be informed by a formal assessment of the risk prepared by technical specialists making use of the best available evidence.

When policy makers are confronted with a possible risk, the natural tendency is to act immediately (even hastily) to prevent, reduce or mitigate the risk. Urgent action to prevent an imminent hazard is on occasion appropriate. But management of risk prior to a formal assessment of the risk is an invitation to problems.

The question of how much priority should be assigned to a potential risk is difficult to determine if a risk assessment is not undertaken. Governments have a tendency to succumb to the "risk of the month" syndrome, where governmental activity is driven by media reports and pressures from stakeholders (Renn, 2008). Sometimes it is valuable for governments to engage in formal risk-ranking exercises where agency staff, independent scientists, and stakeholders are asked to compare and rank diverse risks as an input to priority setting (Davies, 1996). Moreover, a sensible management strategy can be tailored to the nature and seriousness of the risk only if the risk has been assessed. When reducing a risk is costly, it is useful for managers to appreciate how bad the risk is likely to be, and the marginal benefits of risk reduction can be considered only if a risk assessment has been prepared.

An official risk assessment report examines the weight of the evidence as to whether a risk exists and often provides a quantitative indication of the probability of various outcomes, including a characterisation of the severity of the various outcomes (Wilson and Crouch, 2001). Responsible staff in governments have resources available to assist in the risk assessment process. There are superb textbooks and consultants on risk assessment as well as technical guidelines that have been issued in specialised fields (*e.g.* chemical and radiation risk assessment, natural hazards assessment and modelling of infectious diseases). Special tools are available to assess low-probability, high-consequence threats such as nuclear reactor accidents, explosions, and terrorist attacks.

A risk assessment report is not complete if it does not consider the potential impacts on disadvantaged populations (*e.g.* the poor), vulnerable subgroups (*e.g.* children) and highly sensitive species and ecosystems. Policy makers need to consider these impacts both for the purpose of designing efficient risk management measures and for considering fairness in risk management.

When a possible risk is quite serious and politically sensitive, it is often appropriate to insist that a draft risk assessment report be subject to independent peer review by qualified experts outside of government. The comments of the peer reviewers, and the government's responses to those reviews, should generally be made available to the public, after the final risk assessment report is completed and released to the public. The United States government, for example, has issued general guidelines on when and how agencies should conduct peer review of scientific and technical reports such as risk assessments (Government of USA, 2004).

7.3. Consideration of full distribution of outcomes, and of controversies on evidence

When an uncertain risk is assessed, policy makers should not rely entirely on the worst-case or most optimistic estimates of risk. They should also consider the entire probability distribution of outcomes, including key summary statistics.

When a new technology is considered, the associated risks to public health may not be known with certainty. If a risk assessment is commissioned, the analysts will need guidance from policy makers on what information about the uncertainty is desired. A worst-case estimate of possible risk is often useful because it bounds the downside losses for society. The most optimistic estimate of risk is also potentially useful (*e.g.* a technology may be judged to be too risky even under the most optimistic estimates of risk). The flaw in presenting only the worst-case and most-optimistic estimates of risk is that these estimates are the least likely to be correct and, for that reason, are not very informative (Sunstein, 2007).

A full probability distribution of the possible outcomes is the most informative, though policy makers may need assistance in the proper interpretation of a probability distribution. A few key summary statistics are often worth special attention. The modal estimate of risk – the "most likely" estimate of risk – provides some intuitive balance to the worst-case and best-case estimates, though decision theory does not recommend complete reliance on the modal estimate. When the policy maker takes a "risk-neutral" posture toward management of risk, the "expected value" of the probability distribution is considered the most relevant summary statistic (Viscusi, 1998). For low-probability, high-consequence threats, the policy maker's "certainty equivalent" may be a more relevant summary statistic than the expected value because the certainty equivalent allows the policy maker to introduce a degree of risk aversion (Clemen, 1996). However, a risk assessor cannot obtain the certainty equivalent without close collaboration with the policy maker, including an elicitation of the utility function of the policy maker. For a variety of practical reasons, it may not be feasible to ascertain the relevant utility function. In these settings, the assessor might be asked to report the full probability distribution of risk as well as several summary statistics.

When two or more relevant studies appear to reach conflicting or inconsistent conclusions, risk assessors need to consider how to combine the information or how to determine which study is most appropriate for use in risk assessment. In some cases, where a small sample size is a limitation of the available studies, a formal "meta-analysis" that combines the results from small studies may be informative. Even if a meta-analysis is pursued, risk assessments need to give careful consideration to the quality of the various studies and the competence of the investigative teams.

When scientists disagree about key aspects of risk assessment (which is not uncommon), there will be no unique probability distribution of risk. But a risk assessment can still be informative. If there are two primary schools of thought in the scientific community, two probability distributions can be presented, each representing one of the schools of thought. If one school of thought is more dominant than another, a majority and minority distribution can be presented. For complex risk assessments that require inputs from multiple fields of science (*e.g.* global climate change or chemical risk assessment), tools exist to subdivide the risk assessment into components (*e.g.* toxicology and epidemiology), thereby allowing experts on different components to conduct their work separately. The re-aggregation of component assessments needs to be done carefully to fairly represent the overall degree of precision in the resulting estimates of risk (Morgan and Henrion, 1990).

There are situations where quantitative risk assessment is impossible or too speculative to be useful or credible. At the turn of the 20th century, a distinction was drawn between conditions of "risk", where probabilities of adverse events are known or ascertainable based

on actuarial data, and conditions of "uncertainty", where probabilities of adverse events are unknown. Due to progress in the decision sciences, this distinction is no longer meaningful. With the emergence of Bayesian statistics and modern decision theory, which treat strength of belief as an indication of probability, it is feasible to generate probabilities for uncertain events (Clemen, 1996). Using the techniques of subjective probability elicitation (which include tools to "calibrate" and "validate" the subjective judgments of experts), it is now feasible to apply probabilities to events that previously would have been considered too uncertain to characterise quantitatively (Morgan and Henrion, 1990). Thus, many risk assessments at nuclear power plants are now based on subjective probabilities from qualified scientists and engineers as well as formal probabilities based on actuarial data. Tools also exist to weight the judgments of various experts based on their performance as experts or their reputations among qualified peers.

When risk assessments are performed, it is crucial for analysts to account for extreme possibilities, even though they may seem unlikely. It is the unexpected combination of several seemingly unlikely events that often produces the most serious (even catastrophic) outcomes that impact financial markets, public health or the environment. If risk assessors do not even consider the improbable, we cannot expect policy makers to consider precautionary risk management strategies (Sunstein, 2007). The recent financial meltdown was, *ex ante*, considered impossible or highly improbable by many of the most respected economists and financial analysts, presumably because experts relied on models and modes of thinking that did not account for certain combinations of extreme possibilities.

7.4. Addressing gaps in knowledge

When considering a possible risk that is poorly understood, a key question is whether to take protective action promptly, before additional knowledge is obtained, or whether to gather additional information about the risk before deciding whether or how to take protective action.

One of the most challenging aspects of risk assessment and management occurs when there are clear gaps in scientific knowledge relevant to the completion of the assessment. In some cases, the gaps can be filled with plausible assumptions or judgmental probabilities that are supplied by relevant experts in the field. But the resulting risk assessment may seem quite fragile, or it may not be credible to key stakeholders and policy makers.

A tool called "value of information" (VOI) analysis can be employed to determine what type of precautionary response is appropriate. VOI is a form of decision analysis or benefit-cost analysis that treats "additional data collection" prior to making a decision as a formal decision alternative (Clemen, 1996). The costs of "additional data collection" include not only the financial costs of collecting and analysing data but also the human health or environmental damages that may result from the delay of protective actions.

The benefits of "additional data collection" are treated probabilistically because the results of the data collection are not known until the data are actually collected. (In effect, a "prior" probability distribution is used to characterise what the additional data collection is likely to discover). The benefits of the additional data are derived from a decision-tree format where the policy maker makes more informed decisions after the data collection than would be made without the data. In the final stages of the analysis, the benefits and costs of additional data collection are compared with the benefits and costs of taking one or more immediate protective actions.

Even if VOI analysis is not conducted formally, analysts and policy makers may work together to determine which research gaps are most important, and how long it might take to close those gaps with targeted research programmes. In complex cases, it may be appropriate for risk assessors and policy makers to gather this information from scientific advisory committees.

Sometimes the phrase "precautionary principle" is used to describe how a policy maker might think through the dilemma just discussed (Tickner, 2003). While the precautionary principle does not have a rigorous definition in modern decision theory and is often criticised for ambiguity, the European Commission – in its February 2000 "Communication" on precaution – includes additional scientific research or data collection as one of the possible policies arising from an application of the precautionary principle (European Commission, 2000).

7.5. Weighing costs and benefits of risk management

A crucial yet challenging task for policy makers is to weigh the benefits of risk management (direct and ancillary) against the costs and unintended risks.

When a risk management measure is considered, it is important for policy makers to consider the benefits from reducing the target risk but also any "ancillary" benefits to society that may emerge from the same action (Revesz and Livermore, 2008). For example, some measures to slow the pace of global climate change (*e.g.* building nuclear instead of coal-fired power plants) may also result in a reduction of conventional air pollutants linked to smog and soot. Both the direct and ancillary benefits of risk management need to be considered.

The "costs" of a risk management measure include not only the monetary costs of labour and capital associated with a safer or cleaner technology but also any unintended risks to public health, safety and the environment (Graham and Wiener, 1995). For example, the growth in bio-fuel use throughout the world may have energy security benefits but it appears that large-scale bio-fuel production may also create unintended environmental and resource impacts (*e.g.* water shortages, higher food prices and land-use impacts) that need to be considered.

Policy makers must recognise that the staff members and scientific advisors who are knowledgeable about the target risk of concern may not be knowledgeable about ancillary benefits, costs, or unintended risks. For high-stakes decisions, it may be appropriate for policy makers to assemble multiple teams of experts to work on different aspects of a complex risk management problem. The US Government provides formal guidance to analysts and policy makers about how benefits and costs should be identified, quantified and weighted (US Government, 2003).

7.6. Transparent decisions, based on consultation

The analytic results used to inform risk-management decisions should be transparent, replicable, and subject to public comment and revision prior to their final use by policy makers.

The process of risk analysis and management will be error-prone and mistrusted if it is not transparent. Data and models used by assessors and policy makers should, whenever feasible, be replicable by qualified experts in the field. Before an analytic document is used by policy makers, it should be subjected to a period of public comment and revision. Stakeholders are often particularly effective in discovering errors, submitting overlooked data, and pinpointing ambiguities in the work of agency analysts (Renn, 2008).

No agency analyst is perfect. Indeed, agency analysts need to be protected by open review processes that ensure that analytic results are valid and properly explained before they are used by policy makers.

7.7. A whole-of-government approach

When managing risks of interest to more than one department of government, it is essential for governments to devise mechanisms for participation by multiple departments, including procedures for co-ordination and dispute resolution.

Emerging risk issues are often of interest to more than one department in a national government. Climate change may be of concern to energy departments as well as environmental ministries. A food safety scare may draw the attention of agriculture departments as well as regulatory agencies responsible for food safety. And many national governments have multiple departments engaged in the regulation of different financial sectors of the economy.

In order to ensure informed and co-ordinated management of risk, the leadership of national governments need to put into place procedures to ensure that information and views are elicited from all affected departments. When departments suggest different policies (which is quite common on risk issues), a central unit in national governments needs to take responsibility for dispute resolution and co-ordination of all resulting policies. Although the need for cross-department co-ordination is evident in many policy arenas, the challenge is more complex on risk issues because of the wide range of scientific disciplines and departmental constituencies that may be involved.

7.8. Open government builds trust

In order to justify and sustain public trust in the management of risk, national governments need to develop a climate of openness and transparency about risk prioritisation, assessment, management and communication.

If the public does not trust government to manage risk, then the policies of government cannot possibly work. For example, early in the 20th century the US Government attempted to prohibit alcohol without building public trust and confidence in the initiative. Due to public opposition, the US prohibition on alcohol was reversed. More recently, many national governments are considering a revival of their nuclear power industries in order to address the challenge of global climate change. However, previous governmental efforts to promote nuclear energy were plagued by allegations of secrecy, selective consultation with interest groups, and a lack of openness to new information and the opinions of stakeholders and the public.

One of the central findings of the risk communication literature (Lofstedt, 2005; Renn, 2008) is that government managers of risk must establish and sustain public trust in order to execute their responsibilities effectively. In order to earn trust, governments must develop climates of openness that instil confidence in the stakeholders who are potentially impacted by risk-management decisions. At a minimum, this climate of openness needs to include public access to key data and reports that are used to inform and justify decisions. In some cases, openness entails release of information about the activities of government officials such as where they obtained key information and which stakeholders were consulted on a specific matter. In the United States, for example, the Office of Management

and Budget each day discloses on its website which departmental regulations are being reviewed and which stakeholders have met with OMB professionals about those rules (Graham, 2008).

7.9. Stakeholder participation, especially to cope with innovation

In order to ensure public trust in how governments handle complex, sensitive risk issues, governments need to go beyond risk-analytic efforts and include well-designed deliberative exercises that entail broad stakeholder and public participation.

If lack of scientific and technical information was the only cause of poor management of risk, then the remedies for government would reside primarily in the acquisition of more authoritative information about risk. However, the problems in risk management are deep and varied.

Sometimes the challenge of risk management arises because a new technology poses risks for one group of citizens yet benefits others. Nanotechnology may assist in the production of new medicines for patients and new batteries for plug-in hybrid cars. Yet nanotechnology may also pose health risks for workers or even unexpected risks to ecosystems. How risks and benefits are distributed in a society are issues of fairness and ethics that cannot be fully resolved even with the best scientific information.

Moreover, when scientific data about risk and benefit are highly uncertain (which is common), policy disagreements will arise about how the scientific uncertainty should be resolved and which parties should bear the burdens of uncertainty or the costs of resolving uncertainty. Should industrial chemicals in widespread use be prohibited until they are proven safe or should they be allowed until government departments can provide that their continued use is safe? Answers to these "burden of proof" questions are matters of law and policy as much as they are matters of sound science.

Given the deep and varied nature of risk management controversies, governments need to be adept at devising and implementing deliberative strategies that ensure meaningful participation by stakeholders and the public. The precise deliberative approach may vary enormously from case to case. In some cases a public hearing about the safety of a food additive may be adequate to ensure that all concerned stakeholders have an opportunity to express their views. When a local community is selected for siting of radioactive or chemical wastes, more elaborate mechanisms for community participation are likely to be required. In some cases, formal procedures of mediation and negotiation may be helpful as governments decide how to manage risks. The key point is that good management requires deliberation as well as scientific analysis (National Research Council, 1996; Renn, 2008).

7.10. Improving the capacities of governments for the systematic assessment, management, and communication of risk

One of the central themes of the UK Government's risk policy is the need for a significant improvement in the capacity of government to handle risks, particularly emerging risks that are scientifically uncertain, economically significant, and politically sensitive. The dimensions of effective capacity are numerous and merit a separate report but a few key aspects of capacity are noted here.

The research arms of national governments and international agencies need to consider larger investments in research and development to provide better knowledge of risks, including ways to manage them and communicate about them. In addition,

government officials responsible for risk management – both new recruits and veterans – require training in the modern tools of risk assessment, management and communication. They also need to learn the lessons of case studies in the historical efforts of governments to respond to risk. Few training materials are available that draw together the valuable case studies from successes and failures around the world.

In order to improve governmental capacity, it is appropriate to look to relevant professional societies (*e.g.* the Society for Risk Analysis), university-based centres and programmes, international organisations (*e.g.* OECD and the World Bank), and think tanks (*e.g.* the International Risk and Governance Council in Geneva and Resources for the Future in Washington DC). But until governments recognise risk as a priority concern, it is unlikely that professional societies, universities and other organisations will respond with appropriate vigour. Stakeholders from industry, labour and NGOs can play a useful role by urging national governments to develop more systematic policies and guidelines for the management of risk.

Conclusion

Guidelines for risk management, especially when regulations are chosen as the policy instrument most likely to meet policy objectives efficiently and effectively, have to be broad enough to cope with risks in sectors as varied as food safety, transport, health, environment, energy and financial services. They would contribute to the broader change in the administrative culture of governments.

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RISK AND REGULATORY POLICY

IMPROVING THE GOVERNANCE OF RISK

We expect governments to protect citizens from the adverse consequences of hazardous events. At the same time it is not possible or necessarily in the best interest of citizens for all risks to be removed. A risk-based approach to the design and implementation of regulation can help to ensure that regulatory approaches are efficient, effective and account for risk/risk tradeoffs across policy objectives. Risk-based approaches to the design of regulation and compliance strategies can improve the welfare of citizens by providing better protection, more efficient government services and reduced costs for business. Across the OECD there is great potential to improve the operation of risk policy as few governments have taken steps to develop a coherent risk governance policy for managing regulation.

This publication presents recent OECD research and analysis on risk and regulatory policy. The chapters discuss core challenges today. They offer measures for developing, or improving, coherent risk governance policies. Topics include: challenges in designing regulatory policy frameworks to manage risks; different cultural and legal dimensions of risk regulatory concepts across OECD; analytical models and principles for decision making in uncertain situations; key elements of risk regulation and governance institutions; the use of management-based regulation to help firms make risk-related behavioural changes; an analysis of the risk-based frameworks of regulators in five OECD countries (Australia, Ireland, Netherlands, Portugal, United Kingdom) and across four sectors: environment, food safety, financial markets and health and safety; and the elements for designing formal guidelines for risk prioritisation, assessment, management and communication.

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