*Chapter 2*

# Risk Regulatory Concepts and the Law

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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.

## *Bibliography*

**Books, articles and other sources**

Ackerman, B. and L. Heinzerling (2004), *Priceless: On Knowing the Price of Everything and the Value of Nothing*, The New Press, New York.

The National Forum for Risk Management in the Public Sector (ALARM) (2007), *Benchmarking Risk Management*, ALARM, Sidmouth.

Applegate, J. (1995), "A Beginning Not an End in Itself: The Role of Risk Assessment in Environmental Decision Making", *University of Cincinnati Law Review*, Vol. 63, pp. 1 643-1 678.

Audit Commission (2001), *Worth the Risk?*, UK Government, London.

Auditor General Victoria (2004), *Managing Risk across the Public Sector*, Victorian Auditor-General's Office, Melbourne.

Australian Prudential Regulation Authority (2000), "2000 Annual Report Supervision and Enforcement", Australian Government.

Baldwin, R. (2005), "Is Better Regulation Smarter Regulation?", *Public Law*, pp. 485-511.

Baldwin, R. and J. Black (2008), "Really Responsive Regulation", *Modern Law Review*, Vol. 71, pp. 59-94.

Bammer, G. and M. Smithson (eds.), *Uncertainty and Risk: MultiDisciplinary Perspectives*, Earthscan, London.

Barret, P. (2005), *Future Challenges for Risk Management in the Australian Public Sector*, National Audit Office, Canberra.

Bazelon, D. (1977), "Coping with Technology through the Legal Process", *Cornell Law Review*, Vol. 62, pp. 817-832.

Bazelon, D. (1981), "Science and Uncertainty: A Jurist's View", *Harvard Environmental Law Review*, Vol. 5, pp. 209-215.

Bernstein, P. (1996), *Against the Gods: The Remarkable Story of Risk*, John Wiley and Sons, New York.

Better Regulation Commission (2008), *Public Risk: The Next Frontier for Better Regulation*, January.

Better Regulation Commission (2006), *Risk, Responsibility and Regulation – Whose Risk Is It Anyway?*, October.

Black, J. (2005), "The Emergence of Risk-based Regulation and the New Public Risk Management in the United Kingdom", *Public Law*, pp. 512-548.

Carnegie Commission on Science Technology and Government (1993), *Risk and the Environment: Improving Regulatory Decision Making*, New York.

Cass, D. (2005), *The Constitutionalisation of the World Trade Organisation: Legitimacy, Democracy and Community in the International Trading System*, Oxford University Press, Oxford.

Clear, T. and E. Cadora (2001), "Risk and Correctional Justice", in Stenson, K. and R. Sullivan (eds.), *Crime, Risk and Justice: The Politics of Crime Control in Liberal Democracies*, Willan Publishing, Cullompton.

Codex Alimentarius Commission (2004), *Report of the Twentieth Session of the Codex Committee on General Principles*, ALINORM 04/27/33A, Paris, 3-7 May.

Commission of the European Communities (2000a), *Communication from the Commission on the Precautionary Principle*, COM(2000)1/final.

Commission of the European Communities (2000b), *White Paper on Food Safety*, COM(1999)719/final.

Committee to Review the OMB Risk Assessment Bulletin – National Research Council (2007), *Scientific Review of the Proposed Risk Assessment Bulletin from the Office of Management and Budget*, National Academy of Sciences, Washington DC.

Cook, B. (1996), *Bureaucracy and Self Government: Reconsidering the Role of Public Administration in American Government*, Johns Hopkins University Press, Baltimore.

Covello, V. and J. Mumpower (1985), "Risk Analysis and Risk Management: An Historical Perspective", *Risk Analysis*, Vol. 5, pp. 103-120.

Cranor, C. (2006), *Toxic Torts: Science, Law and the Possibility of Justice*, Cambridge University Press, Cambridge.

Davies, A. (2001), *Accountability: A Public Law Analysis of Government by Contract*, Oxford University Press, Oxford.

Deighton-Smith, R. (2006), "Determinants of Quality in Regulatory Impact Analysis", OECD, Group on Regulatory Policy, SG/GRP(2006)3, Paris.

Deighton-Smith, R. (2007), "Methodological Frameworks for Regulatory Impact Analysis: Valuation, Risk and Cost-Benefit Analysis", OECD, Group on Regulatory Policy, SG/GRP(2007)6, Paris.

Department for the Environment Food and Rural Affairs (2006), *Defra Circular 01/2006: Environmental Protection Act 1990: Part 2A – Contaminated Land*, Department for the Environment Food and Rural Affairs, London.

Department for the Environment Food and Rural Affairs (July 2008), *Guidance on the Legal Definition of Contaminated Land*, Department for the Environment Food and Rural Affairs, London.

Department of Health – National Mental Health Risk Management Programme (2007), *Best Practice in Managing Risk*, Department of Health, London, June.

Deville, A. and R. Harding (1997), *Applying the Precautionary Principle*, Federation Press, Sydney.

Dorf, M. and C. Sabel (1998), "A Constitution of Democratic Experimentalism", *Columbia Law Review*, Vol. 98, p. 267.

Douglas, M. and A. Wildasky (1982), *Risk and Culture*, University Of California Press, Berkeley.

Dovers, S. and J. Handmer (1999), "Ignorance, Sustainability and the Precautionary Principle", in Harding, R. and E. Fisher (eds.), *Perspectives on the Precautionary Principle*, Federation Press, Sydney.

Edmond, G. (2008), "Secrets of the 'Hot Tub': Expert Witnesses, Concurrent Evidence and Judge-led Law Reform in Australia", *Civil Justice Quarterly*, Vol. 27, pp. 51-82.

Elliott, D. (1992), "Reinventing Rulemaking", *Duke Law Journal*, Vol. 41, pp. 1490-1496.

Elliott, D., A. Raul, R. Pierce, T. McGarity and W. Wagner (2001), "Science, Agencies and the Courts: Is Three a Crowd?", *Environmental Law Reporter*, Vol. 31, 10 125.

Environment Agency (2005), *A 21st Century Approach to Regulation: Delivering for the Environment*, Environment Agency, Bristol.

Erikson, K. (1994), *A New Species of Trouble: The Human Experience of Modern Disasters*, WW Norton and Co., New York.

Feeley, M. and J. Simon (1994), "Actuarial Justice: The New Criminal Law", in Nelken, D. (ed.), *The Futures of Criminology*, Sage Publications, London.

Financial Services Authority (2006), *The FSA's Risk-Based Approach*, Financial Services Authority, London.

Fisher, E. (1997), "The Risks of Quantifying Justice: The Use of the Substantial Evidence Test in Judicial Review of OSHA Rule-Making", in Baldwin, R. (ed.), *Law and Uncertainty, Risks and Legal Processes*, Kluwer Law International, The Hague.

Fisher, E. (2000a), "Drowning by Numbers: Standard Setting in Risk Regulation and the Pursuit of Accountable Public Administration", *Oxford Journal of Legal Studies*, Vol. 20, pp. 109-130.

Fisher, E. (2000b), "Passive Smoking and Active Courts: The Nature and Role of Risk Regulators in the US and the UK", *Journal of Environmental Law*, Vol. 12, p. 83.

Fisher, E. (2001), "Is the Precautionary Principle Justiciable?", *Journal of Environmental Law*, Vol. 13, pp. 317-334.

Fisher, E. (2002), "Precaution, Precaution Everywhere: Developing a 'Common Understanding' of the Precautionary Principle in the European Community", *Maastricht Journal of European and Comparative Law*, Vol. 9, pp. 7-28.

Fisher, E. (2003a), "General Conclusions: Risk and the Challenges for Administrative Law", *Review of European Public Law*, Vol. 15, pp. 707-729.

Fisher, E. (2003b), "The Rise of the Risk Commonwealth and the Challenge for Administrative Law", *Public Law*, pp. 455-478.

Fisher, E. (2004), "The European Union in the Age of Accountability", *Oxford Journal of Legal Studies*, Vol. 24, pp. 495-515.

Fisher, E. (2005), "Precaution, Law and Principles of Good Administration", *Water Science and Technology*, Vol. 52, pp. 19-24.

Fisher, E. (2006), "Risk and Environmental Law: A Beginner's Guide", in Richardson, B. and S. Wood (eds.), *Environmental Law for Sustainability*, Hart Publishing, Oxford.

Fisher, E. (2007), *Risk Regulation and Administrative Constitutionalism*, Hart Publishing, Oxford.

Fisher, E. (2008), "Administrative Law, Pluralism and the Legal Construction of Merits Review in Australian Environmental Courts and Tribunals", in Pearson, L. and C. Harlow (eds.), *Administrative Law in a Changing State: Essays in Honour of Mark Aronson*, Hart Publishing, Oxford.

Fisher, E. and R. Harding (2006), "The Precautionary Principle and Administrative Constitutionalism: The Development of Frameworks for Applying the Precautionary Principle", in Fisher, E., J. Jones and R. von Schomberg (eds.), *Implementing the Precautionary Principle: Perspectives and Prospects*, Edward Elgar, Cheltenham.

Food Standards Agency (2000), *Statement of General Objectives and Practices, Putting the Consumer First*, October.

Freedland, M. (1998), "Public Law and Private Finance – Placing the Private Finance Initiative in a Public Law Frame", *Public Law*, 288.

Furedi, F. (1997), *Culture of Fear: Risk Taking and the Morality of Low Expectation*, Cassell, London.

Garland, D. (2001), *The Culture of Control: Crime and Social Order in Contemporary Society*, Oxford University Press, Oxford.

Gill, T. (2007), *No Fear: Growing up in a Risk Adverse Society*, Calouste Gulbenkian Foundation, London.

Godard, O. (2006), "The Precautionary Principle and Catastrophism on Tenterhooks: Lessons from Constitutional Reform in France", in Fisher, E., J. Jones and R. von Schomberg (eds.), *Applying the Precautionary Principle: Perspectives and Prospects*, Edward Elgar, Cheltenham.

Goold, B. and L. Zedner (eds.), *Crime and Security*, Ashgate, Aldershot.

Graham, J. (1996), "Making Sense of Risk: An Agenda for Congress", in Hahn, R. (ed.), *Risks, Costs, and Lives Saved*, Oxford University Press, New York.

Hampton, P. (2005), *Reducing Administrative Burdens: Effective Inspection and Enforcement*, HM Treasury, London.

Harlow, C. and R. Rawlings (2009), *Law and Administration*, 3rd ed., Cambridge University Press, Cambridge.

Harremoës, P., D. Gee, M. MacGarvin, A. Stirling, J. Keys, B. Wynne and S. Guedes Vaz (eds.), *The Precautionary Principle in the Twentieth Century: Late Lessons From Early Warnings*, Earthscan Publications, London.

Harris, R. and S. Milkis (1989), *The Politics of Regulatory Change: A Tale of Two Agencies*, Oxford University Press, New York.

Hawkins, K. (2002), *Law as Last Resort: Prosecution decision making in a Regulatory Agency*, Oxford University Press, Oxford.

Health and Safety Executive (1999), *Reducing Risks, Protecting People*, Health and Safety Executive, London.

Heyvaert, V. (2006), "Facing the Consequences of the Precautionary Principle in European Community Law", *European Law Review*, Vol. 31, pp. 185-206.

HM Government (2006), *Countering International Terrorism: The United Kingdom's Strategy*, Cm 6 888, July, London.

HM Treasury (2001), *Management of Risk: A Strategic Overview*, London.

HM Treasury (2003), *The Green Book: Appraisal and Evaluation in Central Government*, TSO, London.

HM Treasury (2004), *The Orange Book: Management of Risk – Principles and Concepts*, HM Treasury, London.

HM Treasury (2006a), *Thinking About Risk: Managing Your Risk Appetite – A Practitioner's Guide*, HM Treasury, November, London.

HM Treasury (2006b), *Thinking About Risk: Managing Your Risk Appetite – Good Practice Examples*, HM Treasury, November, London.

Holder, J. (2005), *Environmental Assessment: The Regulation of decision making*, Oxford University Press, Oxford.

Hood, C. (2002), "Managing Risk and Managing Blame: A Political Science Perspective", in Weale, A. (ed.), *Risk, Democratic Citizenship and Public Policy*, Oxford University Press, Oxford.

Hood, C., H. Rothstein and R. Baldwin (2001), *The Government of Risk: Understanding Risk Regulation Regimes*, Oxford University Press, Oxford.

Hutter, B. (2005), "The Attractions of Risk-Based Regulation: Accounting for the Emergency of Risk Ideas in Regulation", *ESRC Centre for Analysis of Risk and Regulation Discussion Paper*, No. 33.

Inquiry into BSE and vCJD in the United Kingdom (2000), *The BSE Inquiry Report*, HMSO, London.

Jaeger, C., O. Renn, E. Rosa and T. Webler (2001), *Risk, Uncertainty, and Rational Action*, Earthscan, London.

Jaffe, L. (1965), *Judicial Control of Administrative Action*, Little, Brown and Co., Boston.

James, P. (1997), *Food Standards Agency: An Interim Proposal*.

Jones, J. (2007), "Regulatory Design for Scientific Uncertainty: Acknowledging the Diversity of Approaches in Environmental Regulation and Public Administration", *Journal of Environmental Law*, Vol. 19, pp. 347-365.

Jowell, J. (2000), "Of Vires or Vacuums: The Constitutional Context of Judicial Review", in Forsyth, C. (ed.), *Judicial Review and the Constitution*, Hart Publishing, Oxford.

Kagan, R. (2003), *Adversarial Legalism: The American Way of Law*, Harvard University Press, Cambridge.

Knight, F. (1964), *Risk, Uncertainty, and Profit*, Century Press, New York.

KPMG (1999), *Annotated Bibliography for the Study on: Best Practices in Risk Management: Private and Public Sectors Internationally*, Treasury Board of Canada, Ottowa.

Law Commission of Canada (2006), *In Search of Security: The Future of Policing in Canada*, Law Commission of Canada, Ottowa.

Leventhal, H. (1974), "Environmental Decision Making and the Role of the Courts", *University of Pennsylvania Law Review*, Vol. 122, pp. 509-555.

Lowi, T. (1979), *The End of Liberalism: The Second Republic of the United States*, 2nd ed., WW Norton and Co., New York.

Majone, G. (2005), *Dilemmas of European Integration: The Ambiguities and Pitfalls of Integration by Stealth*, Oxford University Press, Oxford.

Mashaw, J. (1997), *Greed, Chaos and Governance: Using Public Choice to Improve Public Law*, Yale University Press, New Haven.

McDonald, M. (2000), "Accountability, Anthropology, and the European Commission", in Strathern, M. (ed.), *Audit Cultures: Anthropological Studies in Accountability, Ethics and the Academy*, Routledge, London.

McGarity, T. (1991), *Reinventing Rationality: The Role of Regulatory Analysis in the Federal Bureaucracy*, Cambridge University Press, Cambridge.

McGarity, T. (2004), "Our Science is Sound Science and Their Science is Junk Science: Science-Based Strategies For Avoiding Accountability and Responsibility for Risk-Producing Products and Activities", *University of Kansas Law Review*, Vol. 52, pp. 897-937.

McGarity, T. and W. Wagner (2003), "Legal Aspects of the Regulatory Use of Environmental Modeling", *Environmental Law Reporter*, Vol. 33, 10751.

McGarity, T., S. Shapiro and D. Bollier (2004), *Sophisticated Sabotage: The Intellectual Games Used to Subvert Responsible Regulation*, Environmental Law Institute, Washington DC.

Michaels, D. (2008), *Doubt Is Their Product: How Industry's Assault on Science Threatens Your Health*, Oxford University Press, New York.

National Probation Service (2004), *Risk Management Policy and Strategy: A Guide for Probation Areas and NPD*, Home Office, London.

National Research Council (1983), *Risk Assessment in the Federal Government: Managing the Process*, National Academy Press, Washington DC.

National Research Council (1994), *Science and Judgement in Risk Assessment*, National Academy Press, Washington DC.

National Research Council (1996), *Understanding Risk: Informing Decisions in a Democratic Society*, National Academy Press, Washington DC.

National Research Council (2007), *Models in Environmental Regulatory Decision Making*, National Academies Press, Washington DC.

Nelken, D. (2004), "Using the Concept of Legal Culture", *Australian Journal of Legal Philosophy*, Vol. 29, pp. 1-26.

Normanton, E. (1966), *The Accountability and Audit of Governments: A Comparative Study*, Manchester University Press, Manchester.

O'Malley, P. (2004), *Risk, Uncertainty and Government*, Glasshouse Press, London.

OECD (2006), "Risk and Regulation: Issues for Discussion", Working Party on Regulatory Management and Reform, GOV/PGC/REG(2006)1, Paris.

OECD (2008), *Public-Private Partnerships: In Pursuit of Risk Sharing and Value For Money*, OECD Publishing, Paris.

Office of Fair Trading (2007), *Statement of Consumer Protection Enforcement Principles*, UK Government, November.

Office of Gene Technology Regulator (2005), *Risk Analysis Framework*, Australian Government, Canberra.

Peel, J. (2005), *The Precautionary Principle in Practice: Environmental decision making and Scientific Uncertainty*, Federation Press, Sydney.

Perrow, C. (1984), *Normal Accidents: Living With High Risk Technologies*, Basic Books, New York.

Pierce, R. (1997), "Judicial Review of Agency Actions in a Period of Diminishing Resources", *Administrative Law Review*, Vol. 49, pp. 61-94.

Policy Foresight Programme (2008), *A New Look at the Interaction of Scientific Models and policy making: Record of the Workshop*, James Martin 21st Century School, University of Oxford, Oxford.

Porter, T. (1995), *Trust in Numbers: The Pursuit of Objectivity in Science and Public Life*, Princeton University Press, Princeton.

Power, M. (1997), *The Audit Society: Rituals of Verification*, Oxford University Press, Oxford.

Power, M. (2007), *Organised Uncertainty: Designing A World of Risk Management*, Oxford University Press, Oxford.

President's Commission on the Accident at Three Mile Island (1980), *Final Report*, Government Printing Office, Washington DC.

Presidential/Congressional Commission on Risk Assessment and Risk Management (1997), *Framework for Environmental Health Risk Management – Volume One*, Washington DC.

Rayner, S. and R. Cantor (1987), "How Fair is Safe Enough?: The Cultural Approach to Societal Technology Choice", *Risk Analysis*, Vol. 7, p. 39.

Regulatory Impact Unit (2003), *Better Policy Making: A Guide to Regulatory Impact Assessment*, Cabinet Office, London.

Renn, O., A. Klinke, C. Losert, A. Stirling, P. van Zwanenberg, Muller-Herold, Morosini and E. Fisher (2003), *The Application of the Precautionary Principle in the European Union: Regulatory Strategies and Research Needs to Compose and Specify a European Policy on the Application of the Precautionary Principle (PrecauPri)*, Centre for Technology Assessment, Stuttgart.

Resource Safety (2005), *Resources Safety's Enforcement and Prosecution policy*, Department of Consumer and Employment Protection, Government of Western Australia, Perth.

Revesz, R. and M. Livermore (2008), *Retaking Rationality: How Cost-Benefit Analysis Can Better Protect the Environment and Our Health*, Oxford University Press, New York.

Rhomberg, L. (1997), *A Survey of Methods for Chemical Risk Assessment Among Federal Regulatory Agencies*, National Commission for Risk Assessment and Management, Washington DC.

Rosen, R. (2003), "Risk Management and Corporate Governance: The Case of Enron", *Connecticut Law Review,* Vol. 18, p. 1157.

Royal Commission on Environmental Pollution (1998), *Setting Environmental Standards, 21st Report*, HMSO, London.

Royal Society (1992), *Risk, Analysis, Perception and Management*, London.

Scalia, A. and F. Goodman (1973), "Procedural Aspects of the Consumer Product Safety Act", *University of California Law Review*, Vol. 20, pp. 899-982.

Schultz Bressman, L. and M. Vandenburgh (2006), "Inside the Administrative State: A Critical Look at the Practice of Presidential Control", *Michigan Law Review*, Vol. 105, p. 47.

Science Advisory Board (1990), *Reducing Risk: Setting Priorities and Strategies for Environmental Protection*, US Environmental Protection Agency, Washington DC.

Scotford, E. (2007), "Trash or Treasure: Policy Tensions in EC Waste Regulation", *Journal of Environmental Law*, Vol. 19, pp. 367-388.

Scotford, E. (2008), "Mapping the Article 174(2) EC Case Law: A First Step to Analysing Community Environmental Law Principles", *Yearbook of European Environmental Law*, Vol. 8.

Scott, C. (2000), "Accountability in the Regulatory State", *Journal of Law and Society*, Vol. 27, pp. 38-60.

Shrader-Frechette, K. (1993), *Burying Uncertainty: Risk and the Case against the Geological Disposal of Nuclear Waste*, University of California Press, Berkeley.

Stirling, A., O. Renn and P. van Zwanenberg (2006), "A Framework for the Precautionary Governance of Food Safety: Integrating Science and Participation in the Social Appraisal of Risk", in Fisher, E., J. Jones and R. von Schomberg (eds.), *Implementing the Precautionary Principle: Perspectives and Prospects*, Edward Elgar, Cheltenham.

Sunstein, C. (2002a), *The Cost Benefit State: The Future of Regulatory Protection*, American Bar Association, Washington DC.

Sunstein, C. (2002b), *Risk and Reason: Safety, Law and the Environment*, Cambridge University Press, Cambridge.

The Strategy Unit of the Cabinet Office (2002), *Risk: Improving Government's Capability to Handle Risk and Uncertainty, Full Report: A Source Document*, HMSO, London.

Treasury Board of Canada (1999), *Best Practices in Risk Management-Coordinated Conclusions from PMN and KPMG*, Treasury Board of Canada, Ottowa.

Treasury Board of Canada (2001), *Integrated Risk Management Framework*.

Treasury Board of Canada Secretariat (2003), *Management Accountability Framework*, Treasury Board of Canada, Ottowa.

Treasury Solicitor (2006), *Judge Over Your Shoulder*, 4th ed., Government Legal Service, London.

Tribe, L. (1973), "Technology Assessment and the Fourth Discontinuity: The Limits of Instrumental Rationality", *Southern California Law Review*, Vol. 46, pp. 616-660.

Tridimas, T. (2006), *The General Principles of European Community Law*, 2nd ed., Oxford University Press, Oxford.

UK Government (1998), *The Food Standards Agency: A Force for Change*, Cm 3830, HMSO, London.

Wagner, W. (1995), "The Science Charade in Toxic Risk Regulation", *Columbia Law Review*, Vol. 95, pp. 1613-1720.

Werhan, K. (1996), "Delegalising Administrative Law", *University of Illinois Law Review*, p. 423.

Wiener, J. (2006), "Risk and Regulation: Issues for Discussion, Annex 2. Risk and Regulatory Governance", OECD, Working Party on Regulatory Management and Reform, GOV/PGC/REG(2006)1/ANN2, Paris.

Williams, S. (1976), "Hybrid Rulemaking" Under the APA: "A Legal and Empirical Analysis", *University of Chicago Law Review*, Vol. 42, pp. 401-456.

Zedner, L. (1995), "Comparative Research in Criminal Justice", in Noaks, L., M. Levi and M. Maguire (eds.), *Contemporary Issues in Criminology*, University of Wales Press, Cardiff.

**Cases**

***Australia***

*BGP Properties Pty Limited v. Lake Macquarie City Council* (2004), NSWLEC 399.

*Commonwealth v. Tasmania* ("Tasmanian Dam Case") (1983), 158 CLR 1.

*Friends of Hinchinbrook Society Inc v. Minister for the Environment* (1997), 142 ALR 632.

*Gray v. Minister for Planning* (2006), NSWLEC 720.

*Minister for Aboriginal Affairs v. Peko-Wallsend Ltd.* (1986), 162 CLR 24.

*Murphyores Incorporated Pty Ltd. v. The Commonwealth* (1976), 136 CLR 1.

*Re Minister for Immigration and Multicultural and Indigenous Affairs: Ex parte Applicant* S 20/2002 v. (2003), 198 ALR 59.

***European Community cases***

Case 9/56, *Meroni v. ECSC High Authority* [1957-8] ECR 133.

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.

Case C-321/95 P, *Stichting Greenpeace Council v. Commission* (1998), ECR I-1651.

Case C-180/96, *United Kingdom v. Commission* (1998), ECR I-2265.

Case C-6/99, *Association Greenpeace France v. Ministère de l'Agriculture et de la Pêche* (2000), ECR I-1651.

Case T-13/99, *Pfizer Animal Health SA v. Council* (2002), ECR II-3305.

Case C-1/00, *Commission v. France* (2001), ECR I-9989.

Case C-24/00, *Commission v. France* (2004), ECR I-1277.

Case T-366/03, *Land Oberosterreich v. Commission* (2005), ECR II-4005.

Case C-439/05, *Land Oberosterreich v. Commission of the European Communities* (2007), 3 CMLR 52.

Case C-14/06 and C-295/06, *Parliament and Kingdom of Denmark v. Commission of the European Communities*, 1 April 2008.

Case T397/06, *Dow AgroSciences Ltd. v. European Food Safety Authority*, 17 June 2008.

***United Kingdom***

*Associated Provincial Picture Houses Ltd. v. Wednesbury Corporation* (1948), 1 KB 223.

*Gateshead Metropolitan Borough Council v. Secretary of State for the Environment* (1995), Env LR 37.

*Harris v. First Secretary of State* (2007), EWHC 1847 (Admin).

*Newport Borough Council v. Secretary of State for Wales* (1998), Env LR 174.

*Padfield v. Minister of Agriculture Fisheries and Food* (1968), AC 997.

*R (Price) v. Governor HMP Kirkham* (2004), EWHC 461 (Admin).

*R v. Chief Constable of Sussex ex parte International Trader's Ferry* (1998), 2 AC 418.

*R v. Secretary of State for Health ex parte Eastside Cheese Company* (1999), 3 CMLR 123.

*R v. Secretary of State for the Home Department Ex p. Pierson* (1998), AC 539.

*R v. Secretary of State for the Home Department Ex p. Venables* (1998), AC 407.

*R v. Secretary of State for Trade and Industry ex parte Duddridge* (1995), Env LR 151.

*R v. Tanridge District Council, ex parte al Fayed* (1999), 1 PLR 104.

*Ridge v. Baldwin* (1964), AC 41.

*T Mobile (UK) Ltd. v. First Secretary of State* (2005), Env LR 18.

***United States***

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

*AFL-CIO v. OSHA* 965 F 2d 962 (11th Cir. 1992).

*Alabama Power Co. v. OSHA* 89 F 3d 740 (11th Cir. 1996).

*American Dental Association v. Martin* 984 F 2d 823 (7th Cir. 1993).

*American Iron and Steel Institute v. OSHA* 939 F 2d 975 (DC Cir. 1991).

*American Textile Manufacturers v. Donovan* 452 US 488 (1981).

*Brown and Williamson Tobacco Corporation v. FDA* 153 F 3d 155 (4th Cir. 1998).

*Chevron USA Inc v. NRDC* 467 US 837 (1984).

*Competitive Enterprise Institute v. NHTSA* 45 F 3d 481 (DC Cir. 1995).

*Competitive Enterprise Institute v. NHTSA* 956 F 2d 321 (DC Cir. 1992).

*Corrosion Proof Fittings v. EPA* 947 F 2d 1201 (5th Cir. 1991).

*Coyn Beahm Inc v. FDA* 966 F Supp 1374 (MDNC 1997).

*Ethyl Corp v. EPA* 541 F2d 1 (DC Cir. 1976).

*FDA v. Brown and Williamson Tobacco Corporation* 529 US 120 (2000).

*Federal Power Commission v. Hope Natural Gas Co.* 320 US 591 (1944).

*Flue-Cured Tobacco Co-op v. EPA* 4 F Supp 2d 435 (MD NC, 1998).

*Greater Boston Television Corp v. FCC* 444 F 2d 841 (DC Cir. 1970).

*Industrial Union Dept AFL-CIO v. American Petroleum Institute* 448 US 607 (1980).

*Industrial Union Dept, AFL-CIO v. Hodgson* 499 F 2d 467 (DC Cir. 1974).

*International Harvester v. Ruckelshaus* 478 F 2d 615 (DC Cir. 1973).

*International Union, UAW v. OSHA* 938 F 2d 1310 (DC Cir. 1991).

*Motor Vehicles Manufacturers Association v. State Farm Mutual Automobile Insurance Company* 463 US 29 (1983).

*Natural Resources Defense Council v. Nuclear Regulatory Commission* 547 F 2d 633 (DC Cir. 1976).

*Portland Cement Association v. Ruckelshaus* 486 F 2d 375 (DC Cir. 1973).

*Small Refiner Lead Phase Down Taskforce v. EPA* 705 F 2d 506 (DC Cir. 1983).

*United Steelworkers of America v. Marshall* 647 F 2d 1189 (DC Cir. 1980).

*Walter Holm and Co. v. Hardin* 449 F 2d 1009 (DC Cir. 1971).

*Whitman v. American Trucking Associations* 531 US 457 (2001).