1 Introduction: science and risk regulation in international law

Introduction

Environmental and health risks are today a subject of great debate and concern in many countries, as well as at the global level. Risks of climate change, ozone depletion, the spread of disease and loss of species, among many others, have become central issues of policy and legal development preoccupying national governments and international organisations. The language of 'risk' is used in discussing these issues because, in many cases, available information is inadequate or incomplete.[1] Enough is known to suspect or predict that a threat exists, but the full outcomes for human health and the environment, including for future generations, may not be well understood. This uncertainty, together with the complexity of the ecological systems and processes at issue, encourages a proliferation of plausible perspectives on risk problems and the best way to manage them.[2] In this context, the regulatory and adjudicative systems of international law may be turned to as a forum for mediating between different risk perspectives and, indeed, for determining whether risks exist that should be the subject of legal intervention.

Where international legal disputes arise over the nature and extent of health and environmental risks – such as the 2006 World Trade Organization (WTO) dispute involving genetically modified organisms (GMOs) – typically an enormous amount of scientific material is

[1] The term 'risk' here is used in the sense of unknown dangers rather than in the more limited sense characteristic of scientific risk assessment exercises. As to the latter, see further Chapter 3.

[2] John Dryzek, *The Politics of the Earth: Environmental Discourses*, 2nd edn, (New York: Oxford University Press, 2005), p. 9.

gathered in order to substantiate (and contest) risk claims.[3] In the *GMO* case, for instance, the WTO panel involved consulted six independent experts on scientific and technical matters, who produced reports running to hundreds of pages. The parties to the dispute then hired their own scientists to digest and review the reports of the panel's independent experts, as well as the analyses of those reports produced by the opposing sides' experts. The result was reams of technical data and expert opinion regarding the health and environmental risks of GMOs intended to inform the legal findings made by the three non-scientifically trained members of the WTO panel.[4]

From the perspective of international law, the *GMO* case raises many important issues about the interaction of trade rules with health and environmental regulation.[5] One of the most critical questions posed by the dispute, and others like it, concerns the role of science in the evolving international legal system governing risk regulation. Given the uncertainties surrounding many risks and the multitude of different perspectives on health and environmental issues, we may ask whether it should be primarily to science that international law and decision-makers turn in understanding and managing such issues. Alternatively, if a broader information base for international risk regulation is seen to be appropriate (or at least in those risk situations where uncertainties abound or there is intense socio-political debate over potential harms), what additional sources should be consulted, and how might such views be integrated with scientific inputs?

These are the questions at the heart of this book, which addresses the role of science in risk regulation, and in the development and application of relevant areas of international law, such as international trade law. The book brings to this task an interdisciplinary perspective and analytical approach that allow a more comprehensive treatment of the

[3] See *European Communities – Measures Affecting the Approval and Marketing of Biotech Products*, Reports of the Panel, WTO Docs WT/DS291/R, WT/DS292/R, WT/DS293/R, 29 September 2006 (*GMO* case), [7.39], Annexes H–J.

[4] The members of the WTO panel in the *GMO* case were Christian Häberli (Head of International Affairs at the Swiss Federal Office for Agriculture), Mohan Kumar (India's Deputy High Commissioner in the Diplomatic Mission in Sri Lanka) and Akio Shimizu (Professor in Law at Waseda University, Tokyo, Japan).

[5] A comprehensive analysis of these issues is beyond the scope of this book. For a useful overview of the principal questions in the dispute see Simon Lested, 'International Decisions: European Communities – Measures Affecting the Approval and Marketing of Biotech Products. WT/DS291/R, WT/DS292/R, & WT/DS293/R', Am. J. Int'l L., 101 (2007), 453.

ways that scientific evidence and risk regulatory processes are, and might be, addressed in international law. The analysis reveals that the question of science's role in international risk regulation is one that has deep interconnections with a number of pivotal issues in current international legal scholarship and practice. These include debates over the legitimacy of international law, calls for greater democratic input into global governance, the desirability or otherwise of reducing fragmentation in international law, and the role of particular international institutions, such as the WTO, in shaping normative understandings and processes adopted in international law. While the book does not seek to deal definitively with all such issues, it situates the field of science and global risk regulation against this backdrop and demonstrates how the questions raised in the risk regulatory arena may illuminate broader discussions in the general field of international law.

Science-based regulation of global risks

As the *GMO* case illustrates, science increasingly occupies a central place in the risk decision-making processes of international organisations, such as the organs of the WTO dispute settlement system. In this respect, the WTO regime, established in 1995, appears to have played an important role through agreements such as the Sanitary and Phytosanitary Measures Agreement (SPS Agreement). This Agreement explicitly requires WTO members to ensure that national trade measures taken to protect human, animal or plant life or health have a basis in scientific evidence and risk assessment.[6] In the event that a dispute arises over trade-restrictive sanitary or phytosanitary (SPS) measures adopted by any member, the matter may be brought before the WTO dispute settlement system where decision-makers (with the help of experts)[7] review the scientific justification for the measures.

The SPS Agreement and disputes under it are of relatively recent origin, but the trend in international law towards science-based regulation of risk has its source in developments that go back over a century. These lie in the evolution of global legal rules in tandem with a culture of scientific rationality, and the emergence of future harms, in addition to

[6] Agreement on the Application of Sanitary and Phytosanitary Measures, Marrakesh, 15 April 1994, in force 1 January 1995, 1867 UNTS 493, Articles 2.2 and 5.1.

[7] Article 11.2 of the SPS Agreement directs panels, in disputes involving scientific or technical issues, to seek advice from experts chosen by the panel in consultation with the parties to the dispute.

present dangers, as a preoccupation of industrialised societies around the globe. In recent times rules developed at the international level are seen to have become more pervasive in their influence over nation states and the decisions governments take regarding the identification of, and response to, risks to the health of their populations and the environment. Together these factors – the growing importance of scientific knowledge to international regulatory processes and the transition to greater governance over risk issues exercised by international legal rules – have combined to position science at the heart of global debates and decision-making on matters of health and environmental concern.

Yet, at the same time as science has achieved such prominence in international risk regulation, there has been an improved understanding of its potential limitations to provide complete and accurate information about the threats posed by human activities to health and the environment, especially over the longer term.[8] In many fields scientific knowledge has developed to the point where certain risks are accepted to exist (for example, the risk of developing cancer as a result of exposure to asbestos fibres).[9] In other cases scientists are able to specify the possible adverse consequences of an activity with reasonable confidence, but recognise that the odds of occurrence of these events remain uncertain (for example, in respect of projections of the degree of future global warming and associated sea level rise).[10] Equally, though, there are many areas of science, particularly in the field of the environment, where there are significant unknowns – 'we don't know what we don't know'.[11] Greater understanding of the scope for scientific uncertainty in predicting threats of damage has led to the development of the precautionary principle in international law, which some see as a necessary counterweight to the proliferation of more narrowly science-based decision-making processes of expert risk assessment.[12]

[8] European Environment Agency, *Late Lessons from Early Warnings: the Precautionary Principle 1896–2000* (Luxembourg: European Union, 2001).

[9] General acceptance of the health risks posed by asbestos was evident in the rulings of the WTO Appellate Body in its decision in *European Communities – Measures Affecting Asbestos and Asbestos-Containing Products*, Report of the WTO Appellate Body, WT/DS135/AB/R, 12 March 2001.

[10] See Intergovernmental Panel on Climate Change, *Climate Change 2007: The Physical Science Basis – Summary for Policy-makers* (Geneva: IPCC, 2007), pp. 12–17.

[11] Brian Wynne, 'Uncertainty and Environmental Learning: Reconceiving Science and Policy in the Preventative Paradigm', *Global Environmental Change*, 2(2) (1992), 114.

[12] Andy Stirling and David Gee, 'Science, Precaution and Practice', *Public Health Reports*, 117(6) (2002), 525–6.

Undoubtedly there will be those who deplore the rise of science-based risk regulation as a triumph of neo-liberal conceptions of risk on the international stage or the technologising of global society.[13] Such concerns, however, have not prevented rapid growth in globally oriented, science-based decision-making processes that often give scientific forms of knowledge a key – if not privileged – place in risk regulation. International legal development of this kind makes pertinent the issue of whether it is appropriate for science to play such a central role in global legal structures dealing with the regulation of risk. This is particularly so in light of acknowledgement of the many uncertainties and limitations in scientific knowledge regarding risks, especially where complex human–environmental interactions or poorly understood ecosystems are at issue.

Rise of science in international risk governance

The first three chapters of the book address the questions of how and why science is becoming a fundamental organising principle in international legal regimes concerned with risk, particularly in the areas of health and environmental protection.

Chapter 2 traces the way in which questions of risk to human health and the environment – traditionally a matter over which national governments enjoyed virtually unlimited regulatory control – are now subject to substantial constraints dictated by global legal rules or other supranational regulations. Such rules and regulations are often to be found in governance arrangements of an administrative character, which operate at a level below the legislative processes of intergovernmental negotiation and agreement.[14] The far-reaching effects of rules generated by such structures of 'global governance',[15] and their remoteness from democratic mechanisms operating in many nation

[13] See, e.g., Daniel Kleinman and Abby Kinchy, 'Against the Neoliberal Steamroller? The Biosafety Protocol and the Social Regulation of Agricultural Biotechnologies', *Agriculture and Human Values*, 24(2) (2007), 195.

[14] Peter Lindseth, 'Democratic Legitimacy and the Administrative Character of Supranationalism: The Example of the European Community', Columbia L. Rev., 99 (1999), 632.

[15] The term 'governance' is used to signify the authoritative effects of these rules that yet do not originate from a particular government or governments. 'Global' is preferred to 'international' since many forms of governance originate from sources that are not strictly inter-national (in the sense of being collective decisions of national governments) but are rather supranational or trans-national in character.

states, have given rise to questions over their legitimacy. In the area of risk regulation, this has prompted governments and international organisations to turn to expertise as one possible means for legitimating the increasing reach of global rules into the daily lives of individuals, communities and businesses.

Chapter 3 investigates, in more detail, the concept of risk that has emerged as a central concern of regulation in the (world) 'risk society'.[16] The chapter explores how the determination of risks to health and the environment has come to be heavily reliant on science. This has led to the proliferation of procedures for science-based decision-making and risk assessment in international legal instruments, which in turn seek to provide legitimacy for the increasing transfer of decisions on risk issues from the national to the international level.

The chapter also discusses changes in international law's relationship with science over time as other disciplines, such as the social sciences, have brought to light the potential limitations of scientific knowledge as a reliable basis for predicting future risks. Such insights have exposed the inherently fuzzy boundaries between science and values and, indeed, the difficulty of drawing any firm line between the two in the context of regulating uncertain, complex risks.[17]

The permeability of the science/values boundary in risk regulation is the starting point for the analysis in Chapter 4 of the principal competing paradigms of risk regulation that have emerged in contemporary international law. These are encapsulated in the notion of sound science and the international legal principle known as the precautionary principle. Whereas proponents of sound science emphasise the importance of empirical, field-tested or peer-reviewed studies as a prerequisite for risk regulation, precautionary approaches advocate for action to address threats even in circumstances where the potential for harm is not well established by the available scientific evidence. These two regulatory paradigms are increasingly being brought into contact and conflict in diverse international settings, with indications that some of the potential breadth and flexibility of precautionary approaches are

[16] Ulrich Beck, *Risk Society: Towards a New Modernity* (London: SAGE Publications, 1992).

[17] While the book uses 'science' and 'values' (or 'politics') as key terms in the discussion, it is recognised that these refer to fluid, and eminently contestable, categories. Nevertheless, the distinction between science and values, albeit unfixed and permeable, serves a useful purpose in international risk regulation; namely that the form of knowledge that is generally labelled 'science' organises information in a useful way for the regulatory task of making decisions on health and environmental risk.

being eroded as a result.[18] This is particularly so in the key area of international trade law where precautionary approaches must navigate the widely held perception that the precautionary principle is often mere rhetoric masking protectionist motives.[19]

Science-based risk regulation in practice: the SPS Agreement

The emphasis on (sound) science-based regulation of risk in international law can be problematic where it overestimates the extent to which scientific evidence provides universally accepted, universally valid, guidance for risk policy. Elevating science to a privileged position in international risk regulation may often downplay the necessary role of non-scientific considerations in producing social – and also scientific – consensus on the importance of the risks posed by a given activity, especially in the face of unknowns.

This is well illustrated by science-based risk determination under the WTO SPS Agreement, which is the subject of a detailed case study in Chapter 5. The SPS Agreement is often put forward as a leading example of the adoption of a sound science decision-making model in international law.[20] It has been the forum for the adjudication of several interstate disputes, including that over GMOs. It has also been the focus of political discussion in the SPS Committee, a body 'which self-consciously aim[s] to bring together networks of like-minded regulators to discuss and elaborate norms of behaviour of particular relevance to the trade regime'.[21]

Applying the interdisciplinary understanding of science and risk regulation developed in the previous chapters, Chapter 5 analyses the approach which regulators and decision-makers have taken to the role of scientific evidence and risk assessment under the WTO SPS Agreement. This analysis is undertaken both in respect of the political

[18] John Applegate, 'The Taming of the Precautionary Principle', William & Mary Envtl L. & Policy Review, 27 (2002), 13.

[19] Sabrina Shaw and Risa Schwartz, *UNU-IAS Report: Trading Precaution – The Precautionary Principle and the WTO* (Tokyo: Institute of Advanced Studies, United Nations University, 2005).

[20] Warren H. Maruyama, 'A New Pillar of the WTO: Sound Science', *International Lawyer*, 32 (1998), 651.

[21] Andrew Lang, 'Some Sociological Perspectives on International Institutions and the Trading System', in Colin B. Picker, Isabella D. Burn and Douglas W. Arner (eds.), *International Economic Law: The State and Future of the Discipline*, (Portland: Hart Publishing, 2008), p. 79.

forum of the SPS Committee, and in the adjudicative arena of dispute settlement. In the latter area there has been an emphasis on the need for positive scientific evidence in order to establish risks justifying the introduction of trade measures (although the decision of the WTO Appellate Body in *Hormones II* suggests the pendulum may be swinging back towards a position that is more deferential to risk analysis undertaken by national authorities).[22] This approach effectively precludes reference to other, non-scientific considerations or values (such as those underlying policy decisions, consumer preferences, intuitive judgments, and ethical or socio-economic concerns) as a basis for risk regulation.

In a fragmented international legal environment, the relative institutional strength of the international trade rules and their associated dispute settlement procedures gives added importance to the treatment afforded scientific risk assessment in SPS law. There is thus the potential for the narrower approach to science-based decision-making that has been characteristic of the SPS area to exercise significant influence over the way in which science is used in other international legal fora concerned with risk regulation.

Alternatives to sound science in international risk regulation

The trend of strictly science-based decision-making emerging in SPS law illustrates the limitations of a one-dimensional over-reliance on sound science by global risk governance structures such as the WTO. Given the realities of international risk regulation as a value-laden process characterised by numerous contingencies, a broader approach would seem to be warranted. Yet this raises vexed questions as to available and reliable alternatives that might be looked to as the basis for international risk regulation. The discussion in Chapter 5 of the WTO Appellate Body's procedurally focused approach in the SPS case, *Hormones II*, provides an evaluation of one such alternative that purports to avoid searching international review of the science underlying particular risk regulatory measures.

Chapter 6 examines several other international legal contexts in which the role of science in risk regulation has emerged as a key issue. These include the settlement of health and environmental disputes

[22] United States – Continued Suspension of Obligations in the EC-Hormones Dispute, Report of the WTO Appellate Body, WT/DS320/AB/R, 16 October 2008 (Hormones II).

under the WTO's General Agreement on Tariffs and Trade;[23] consensus-seeking processes of the international organisation charged with developing global food safety standards, the Codex Alimentarius Commission; negotiations for the Cartagena Biosafety Protocol governing the transboundary movement of GMOs, which purports to adopt a precautionary approach;[24] and the operation of scientific assessment processes under multilateral environmental agreements, such as the convention regulating persistent organic pollutants,[25] and the international climate change regime.[26] These sites of international risk decision-making illustrate a variety of models for the use of science in global risk regulation. There is hence the potential for cross-institutional learning whereby elements of particular models could be incorporated into other international risk regulatory processes.

Another rich source of experience with science and risk regulation lies in the domestic systems established in many industrialised countries to assess and manage health and environmental risks. For instance, the United States of America (USA) has well-developed structures for the formulation and judicial review of risk regulatory measures on a range of health and environmental topics, which have been highly influential in the design of similar systems around the globe.[27] For those who look to domestic models as a guide for the appropriate role of science in international risk regulation, a common theme is the need for values and public views to inform determinations made about risk. A further, nascent thread of the literature looks at how democratic values (rather than domestic models of democracy) can be translated into a realisable institutional form for the purpose of

[23] General Agreement on Tariffs and Trade, Marrakesh, 15 April 1994, in force 1 January 1995, 55 UNTS 194, 1867 UNTS 187.

[24] Cartagena Protocol on Biosafety to the Convention on Biological Diversity, Montreal, 29 January 2000, in force 11 September 2003, 2226 UNTS 208.

[25] Convention on Persistent Organic Pollutants, Stockholm, 23 May 2001, in force 17 May 2004, (2001) 40 ILM 532.

[26] Two treaties currently make up this regime: the United Nations Framework Convention on Climate Change, Rio de Janeiro, 9 May 1992, in force 24 March 1994, 1771 UNTS 164 and the Kyoto Protocol to the United Nations Framework Convention on Climate Change, Kyoto, 11 December 1997, in force 16 February 2005, 2303 UNTS 148. The latter is supplemented by a detailed set of rules agreed by the parties known as the Marrakesh Accords: see Report of the Conference of the Parties on its Seventh Session, held at Marrakesh from 29 October to 10 November 2001, FCCC/CP/2001/13/Add.2. The Kyoto Protocol expires at the end of 2012 and international negotiations are underway with the aim of agreeing on post-2012 arrangements.

[27] See generally, Sheila Jasanoff, *Designs on Nature: Science and Democracy in Europe and the United States* (Princeton University Press, 2005).

designing or reforming global governance systems.[28] Chapter 7 critically reviews the potential for so-called 'democratisation' of global risk regulation through deference to national risk decision-making or the institution of transparency and participatory mechanisms that permit international decision-makers to take account of non-scientific inputs, alongside science. As in Chapter 5, the focus is upon science-based processes of review under the WTO SPS Agreement that have been the subject of a significant number of reform proposals in the international legal literature.

To the extent that such proposals allow for a more comprehensive appraisal of uncertainty concerns and conflicting values in processes of risk evaluation, they represent a means of reintroducing socio-political dimensions of risk lost where there is an insistence on narrowly science-focused assessments. Nonetheless, a continual obstacle that must be confronted in any attempt to translate accountability processes to the global level is the lack of conventional modes of democratic representation and underdeveloped structures for public participation in international law. This may not necessarily be a reason to abandon efforts for greater democratisation of international risk regulation (an outcome which could leave in place equally flawed, narrowly science-focused processes). However, it highlights the difficult trade-offs involved in seeking a broader basis for global risk governance: enhanced legitimacy may only come at the expense of decreasing the technical credibility of an assessment, at least for some audiences.[29]

What role for science in international risk regulation?

Emerging as a crucial issue for global risk regulation and governance is not whether science *or* values should triumph, but rather how scientific *and* non-scientific inputs might be blended in risk assessment in different settings to ensure a broadly acceptable balance of credibility and legitimacy concerns. In approaching this task an important prerequisite is a realistic understanding of the capacities of science to support risk assessment, as well as of those of international legal and governance structures to accommodate non-scientific inputs in a fair

[28] See, e.g., Gráinne de Búrca, 'Developing Democracy Beyond the State', Colum. J. Transnat'l L., 46 (2008), 221.

[29] Ronald B. Mitchell, William C. Clark and David W. Cash, 'Information and Influence', in Ronald B. Mitchell *et al.* (eds.), *Global Environmental Assessments: Information and Influence* (Cambridge, MA: MIT Press, 2006), p. 309.