

Science and the politics of openness

Here be monsters

Edited by Brigitte Nerlich, Sarah Hartley, Sujatha Raman and Alexander Smith

Manchester University Press

Copyright © Manchester University Press 2018

While copyright in the volume as a whole is vested in Manchester University Press, copyright in individual chapters belongs to their respective authors, and no chapter may be reproduced wholly or in part without the express permission in writing of both author and publisher.

Published by Manchester University Press Altrincham Street, Manchester M1 7JA

www.manchesteruniversitypress.co.uk

British Library Cataloguing-in-Publication Data A catalogue record for this book is available from the British Library

ISBN 978 1 5261 0646 9 hardback ISBN 978 1 5261 0647 6 open access

First published 2018

This electronic version has been made freely available under a Creative Commons (CC-BY-NC-ND) licence. A copy of the licence can be viewed at https://creativecommons.org/licenses/by-nc-nd/3.0/

The publisher has no responsibility for the persistence or accuracy of URLs for any external or third-party internet websites referred to in this book, and does not guarantee that any content on such websites is, or will remain, accurate or appropriate.

Typeset by Toppan Best-set Premedia Limited

Contents

_1st	of figures and tables	page viii
List	of contributors	ix
Sara C o o	roduction – Brigitte Nerlich, Sujatha Raman, ah Hartley, Alexander Thomas T. Smith da: reflections on the politics of openness in a	1
iew	world order - Alexander Thomas T. Smith	12
	Part I Transparency	
1	Transparency – Benjamin Worthy	23
2	Open access: the beast that no-one could – or should control? – Stephen Curry	33
3	Assuaging fears of monstrousness: UK and Swiss initiatives to open up animal laboratory research – Carmen M. McLeod	55
4	What counts as evidence in adjudicating asylum claims? Locating the monsters in the machine: an investigation of faith-based claims – Roda Madziva and Vivien Lowndes	75
	Part II Responsibility	
5	Responsibility – Barbara Prainsack and Sabina Leonelli	97

vi	Contents

6	Leviathan and the hybrid network: Future Earth, co-production and the experimental life of a global institution – Eleanor Hadley Kershaw	107	
7	'Opening up' energy transitions research for development – Alison Mohr	131	
8	Monstrous regiment versus Monsters Inc.: competing imaginaries of science and social order in responsible (research and) innovation – Stevienna de Saille and Paul Martin	148	
	Part III Expertise		
9	Expertise – Mark B. Brown	169	
10	Disentangling risk assessment: new roles for experts and publics – Sarah Hartley and Adam Kokotovich	176	
11	Monstrous materialities: ash dieback and plant biosecurity in Britain – Judith Tsouvalis	195	
12	An Inconvenient Truth: a social representation of scientific expertise – Warren Pearce and Brigitte Nerlich	212	
13	'Science Matters' and the public interest: the role of minority engagement – Sujatha Raman, Pru Hobson-West, Mimi E. Lam and Kate Millar	230	
	Part IV Faith		
14	Faith – Chris Toumey	253	
15	Re-examining 'creationist' monsters in the uncharted waters of social studies of science and religion – Fern Elsdon-Baker	259	
16	Playing God: religious influences on the depictions of science in mainstream movies – David A. Kirby and Amy C. Chambers	278	

Contents	vii	
Afterword: monstrous markets – neo-liberalism, populism and the demise of the public university		
– John Holmwood and Jan Balon	303	
Epilogue: publics, hybrids, transparency, monsters and the	2	
changing landscape around science - Stephen Turner	322	
Index	333	

Disentangling risk assessment: new roles for experts and publics

Sarah Hartley, Adam Kokotovich

Risk assessment is an important stage of risk governance, alongside risk characterisation, risk evaluation and risk management. A burgeoning literature on public involvement in risk governance and sciencebased policymaking more broadly has developed in response to tensions in governing environmental risk, particularly the environmental risks posed by emerging technologies (Irwin, 2014; Levidow, 2007; Renn and Schweizer, 2009; Rothstein, 2013; Wynne, 2006). However, there is relatively little investigation of public involvement in the specific stage of risk assessment, despite increased demands for such involvement (Borrás et al., 2007; Hartley, 2016; Millstone, 2009; Shepherd, 2008). European and North American regulatory agencies have a statutory obligation to involve the public in risk governance, and in recent years many have opened up the traditionally scientific domain of risk assessment to public input through online consultations. In addition, international bodies have created opportunities to engage a broader range of experts and stakeholders. However, there is evidence that regulatory agencies and international organisations are not meeting their statutory obligations, falling short of their own guidelines in practice (Dreyer and Renn, 2014; Hartley, 2016; Herwig, 2014).

We argue that public involvement in risk assessment is not reaching its full potential owing to a considerable lack of clarity in the literature and in practice about which publics should be involved in risk assessment and at what point they should be involved. Much of the risk-governance literature examining public involvement fails to disentangle adequately the process of risk assessment when examining questions

about who to involve, when to involve them, and why. Risk assessment is not a single stage of risk governance that can simply be made participatory; rather, it is a process with different components that need to be considered individually when determining how and why to open risk assessment to publics. Furthermore, for the potential of public involvement to be fully realised, a particular understanding of risk assessment is necessary – one that is detailed and that recognises inherent value judgements. Conflating the different aspects of risk assessment and the different types of participation makes opening risk assessment to publics seem unreasonable and risks the legitimacy of regulatory agencies.

We draw on the theoretical, prescriptive and empirical literature to disentangle risk assessment for governing human health and environmental risks of emerging technologies. This disentanglement begins with an examination of values in risk assessment and restates the case for public involvement when value choices are to be made. First, we argue that effective and legitimate public involvement is dependent upon the degree to which value judgements are acknowledged in the different components of risk assessment. Second, we explore variations in the prescription literatures of the National Research Council (NRC) in the USA, and the international organisation the Codex Alimentarius Commission (CAC, or 'Codex'). Third, we examine the way in which risk assessment is disentangled in practice through the case study of the European Food Safety Authority (EFSA). Finally, we draw on these findings to reassemble public involvement in risk assessment, making clear who should be involved, where and, importantly, why.

Disentangling values and risk assessment: the need for public involvement

Risk governance involves a number of stages, and a plethora of different models exist. The delineation of the various stages depends upon the degree to which the 'scientific' stage can be separated from the 'policy' stage. In general terms, these models do separate the scientific stage (risk assessment) from the policy stage (risk management). However, there is considerable evidence to suggest these stages are not separated in practice (Millstone, 2009). Much of the risk-governance literature that addresses public involvement fails to disentangle risk assessment

from risk management adequately; for example, Renn and Schweizer (2009) suggest there is a default assumption that public involvement should occur in risk management. Kaliarnta et al. (2014) examine stakeholder involvement in risk governance but focus on questions concerning who should participate and why, how much they should participate, and what the participation should address, but they do not tease apart the stages of assessment and management to ask where public involvement should take place.

Where the literature has distinguished the stages of risk governance to examine where public involvement might be best utilised, risk assessment remains an epistemic stage that is seen as insulated from values - with consequences for how public involvement is envisioned in risk assessment. For example, Dreyer and Renn (2014) lay out four stages in risk governance -framing (design discourse), appraisal (epistemic discourse), evaluation (reflective discourse) and management (practical discourse). While they argue that publics can make a contribution to the epistemic discourse, this discourse does not involve the discussion of value choices, which are dealt with in the evaluation and management stages. Therefore, publics, who are often asked to comment on published risk-assessment documents in online consultations, are restricted in terms of the types of input they are able to provide during consultation. Consequently, the value choices inherent in risk assessment are not open to public scrutiny and publics are able to comment only on the scientific aspects of risk assessment, and only on scientific terms.

A key aspect of whether and how to involve publics in risk assessment is based on how we understand the role of values within risk assessment. First, and at the broadest level, choosing to use risk assessment to inform decision making is itself a value-based decision. To frame an issue in terms of risk and risk assessment will privilege certain actors and marginalise other possible ways of understanding that issue (Jasanoff, 1999). Second, if risk assessment itself is understood as an objective scientific process external to value judgements, there is little role for public involvement other than, perhaps, for expert stakeholders to ensure the science is completed correctly (Jasanoff, 1987). Once the role of values in risk assessment is acknowledged and reflected upon, the need for public involvement is strengthened.

There is an extensive body of literature that demonstrates the relevance of values throughout the risk-assessment process (Kokotovich,

2014; Meghani, 2009). Challenging the notion that values can be confined to risk management, this scholarship explores how normative values influence all aspects of risk assessment. This work shows that such judgements have consequences and thus need to be taken seriously, including by opening them to reflection and public involvement. Here we identify and review the value-based nature of three key components of risk assessment: the guidelines that shape risk assessment, the conduct of risk assessment and the science used in risk assessment.

Risk-assessment guidelines

Guidelines establish the steps to follow when conducting a risk assessment and provide assistance both to applicants preparing risk assessments and to risk assessors conducting them. Thus, they incorporate value judgements about the scope of future risk assessments, including what falls inside the scope of risk assessment; what counts as evidence, how much evidence is needed and how it should be interpreted; and how uncertainty should be addressed. There is a growing realisation of the importance of guidelines. Kokotovich (2014), for example, studied two competing sets of guidelines for assessing the risks to non-target organisms from insect-resistant genetically modified plants, and found their divergent foundational value judgements resulted in recommending different processes for risk assessment, and different potential outcomes. These judgements involved the adequacy of substantial equivalence testing and what species needed to be tested, together with the (un)importance of assessing indirect effects, and they resulted in the guidelines calling for different kinds of scientific studies to be completed to inform the risk assessment. Millstone et al. (2008) show that differences in guidelines account for transatlantic trade conflicts such as those that arose over beef hormones, recombinant bovine somatotrophin and genetically modified maize.

Conducting risk assessment: problem formulation, analysis and risk characterisation

Conducting risk assessment is a process that includes problem formulation, exposure and effects analysis, and the characterisation of risk. Many of the decisions in risk assessment that are acknowledged as value based and that have been opened to public involvement occur

in the formulation of the problem (Environmental Protection Agency, 1998; Nelson et al., 2007). Problem formulation is the initial step of the risk assessment that determines the assessment endpoints, the conceptual model linking the stressors to the assessment endpoints, and an analysis plan. This step is widely seen as the place where values most explicitly enter the risk-assessment process. Authors such as Thompson (2003) and Jensen et al. (2003) have revealed how decisions taken in problem formulation, such as identifying the specific hazard to be assessed and determining the time and spatial scale, are value based. These decisions alter the scope of the risk assessment in ways that can influence the ultimate characterisation of the risk. Problem formulation is where values and public involvement are often acknowledged and allowed, and this is also where they are classically confined. Similar to the distinction between risk assessment and risk management within the classical notion of risk governance, problem formulation sets up a dichotomy between science and values. In this understanding, values exist in the formulation of the problem, while the scientific analysis phase remains free from values. Problem formulation does, however, stand apart from the rest of risk assessment owing to the type of value judgements that need to be made. Many of these judgements involve explicit value-based, non-technical judgements that do not require technical expertise from contributors.

While the discussion of values in conducting risk assessment normally begins and ends with problem formulation, the analysis and risk-characterisation steps also contain value judgements. For example, identifying and synthesising relevant scientific studies and addressing uncertainty all involve value judgements that can influence the overall assessment of risk (Meyer, 2011; Winickoff et al., 2005). The differences in how these value judgements are addressed contribute to the reason why different regulatory bodies can arrive at differing assessments of risk (Wickson and Wynne, 2012). The value judgements in these steps require a greater degree of technical expertise than those at the stage of problem formulation.

Scientific studies used in risk assessments

This component of risk assessment is rarely considered distinctly. However, the scientific studies used in a risk assessment are also influenced by value judgements and therefore should not escape scrutiny (Elliott, 2012; Holifield, 2009). Scientific studies influence the ultimate characterisation of risk, yet they themselves can be influenced by the different parts of a risk assessment. Both the development of riskassessment guidelines and the conducting of a risk assessment involve value choices over what scientific studies are relevant (Kokotovich, 2014). Risk-assessment guidelines can influence how scientific studies are completed by, for example, calling for the use of surrogate species or local species in laboratory testing (Hilbeck et al., 2011). There can also be value judgements in the design and conduct of scientific studies that go beyond those stipulated in risk-assessment guidelines and the conduct of a risk assessment. Scientific studies used in a risk assessment depend on the often subtle value judgements that inform them (Elliott, 2012; Holifield, 2009). Elliot calls attention to the notion of 'selective ignorance, or the 'wide range of often subtle research choices or "value judgements" that lead to the collection of some forms of knowledge rather than others' (2012: 331), claiming these judgements will influence what knowledge is available to inform decision making or, in our case, risk assessment.

The existence of value judgements in these three components of risk assessment draws attention to the actors making those value judgements. Who is making them and who should do so? The recognition of these value choices has fuelled the call for democratic accountability and public involvement in risk assessment, which has traditionally been seen as an expert domain (Hartley, 2016).

Prescribing the treatment of values and publics in risk assessment

In reviewing key examples of the existing prescriptive risk-assessment literature, specifically documents from the NRC and Codex, we show how values are acknowledged and public involvement is proposed by the organisations that prescribe risk assessment (NRC, 1983; Stern and Fineberg, 1996). In comparing the 1983 and 1996 NRC reports, we argue that it is the 1983 report that acknowledges the role of values in risk assessment in a more detailed, nuanced and potentially productive way. This is true even though it calls for a separation of risk assessment and risk management, and the 1996 report calls for broader

public involvement in risk governance and for an integration of assessment and management.

The NRC is part of the National Academies of Science, a private, non-profit, self-perpetuating society of distinguished scholars engaged in scientific and engineering research. It advises the US Federal Government on scientific and technical matters and has published several prominent reports on risk assessment (NRC, 1983, 2009; Stern and Fineberg, 1996). These NRC reports have influenced regulatory risk assessment in the USA and internationally (Suter, 2008), and they show how values and the role of public involvement are acknowledged in risk assessment.

Risk Assessment in the Federal Government: Managing the Process was one of the first major reports on risk assessment. This report has become known as the 'Red Book' because of its red cover. It supported the clear separation of risk assessment from risk management to help establish the credibility of risk assessment (NRC, 1983), but, at the same time, recognised the value judgements that are entangled in risk assessment. For example, the NRC states:

If risk assessment as practiced by the regulatory agencies were pure science, perhaps an organizational separation [between risk assessment and risk management] could effectively sharpen the distinction between science and policy in risk assessment and regulatory decision-making. However, many of the analytic choices made throughout the risk assessment process require individual judgments that are based on both scientific and policy considerations. (NRC, 1983: 143)

The NRC refers to value judgements as policy judgements, and introduces the concept of risk-assessment policy to refer to them in conducting risk assessments. The value judgements inherent in risk assessment are seen as being different in character from the value judgements that exist in risk-management decisions. Making a clear distinction between the types of value choices present in risk assessment and risk management, the NRC describes how to distinguish between scientific and value judgements in risk assessment, which it notes is a difficult task. It recommends the development of guidelines, which it defines as 'the principles followed by risk assessors in interpreting and reaching judgments based on scientific data' (NRC, 1983: 51). These guidelines help the risk assessor in conducting future risk

assessments and are similar to the risk-assessment guidelines that we describe above. However, there is no mention of the scientific studies used in a risk assessment or the values-based nature of the research.

In this 1983 report the NRC argues that value judgements in risk assessment are best made by risk assessors and there is no suggested role for public involvement, even though the report recognises the implications of such judgements. However, the NRC recommends the involvement of experts from a wide range of scientific disciplines in the development of guidelines. Overall, then, this report provides an understanding of risk assessment in which the role of values in risk assessment is acknowledged. These judgements are to be addressed by expert risk assessors who will follow risk-assessment guidelines that have been developed by a broad range of experts in advance of an individual risk assessment.

In 1996 the NRC published the report Understanding Risk: Informing Decisions in a Democratic Society, which proposes an analyticdeliberative approach to risk governance, one where 'deliberation frames analysis [and] analysis informs deliberation' throughout the entire risk-governance process (Stern and Fineberg, 1996: 6). In contrast to its 1983 report, the NRC extends its thinking about the role of values in risk governance and the way in which they should be dealt with. It proposes broad involvement in risk governance by experts, decision makers, and interested and affected parties. Yet the distinction between analysis and deliberation makes clear the separation between analysis, an epistemic stage that is the domain of experts, and deliberation, which can be opened up to non-experts. Analysis uses rigorous, replicable methods developed by experts to arrive at answers to factual questions. Deliberation includes value-based decisions with a focus on how issues are framed and what questions need to be answered. It uses processes such as discussion, reflection and persuasion to communicate, raise and collectively consider issues, increase understanding and arrive at substantive decisions (Stern and Fineberg, 1996: 20).

Interested and affected parties can influence what analysis is called for, but they play less of a role in actually influencing that science and the risk-assessment process. Their direct involvement may be possible when they have specialised or local knowledge that can help inform the analysis. While they are not brought explicitly into the analysis, they are seen as having a role in at least checking it:

Participation is important to help ask the right questions of the science, check the plausibility of assumptions, and ensure that any synthesis is both balanced and informative. The more likely it is that the science will be criticized on the basis of its underlying assumptions or alleged omissions, the more important participation is likely to be in a risk decision process. (Stern and Fineberg, 1996: 132)

This approach points to the values-based nature of such judgements, while not explicitly calling for participation in the development of risk-assessment guidelines or in the conduct of a risk assessment where the assumptions and synthesis are determined. Overall, this report takes a bird's-eye view of risk governance without the nuanced attempt to disentangle the process of risk assessment that the 1983 report contained. Rather, it proposes the conceptual separation of the analytical stage of governance from its deliberative stage. Therefore, risk assessment has become a single stage in an approach to risk governance which is free of values and the domain of expert risk assessors. Public involvement is confined to risk management.

Codex is an international organisation established in 1963 by the Food and Agriculture Organization and the World Health Organization (WHO) to develop harmonised science-based international food standards and risk-assessment procedures in order to protect consumer health and ensure fair international trade (Büthe and Harris, 2011). It is a heavily expert-led organisation and exclusively science based, although this reliance on science and scientific experts to the exclusion of non-scientific factors, alternative experts and mechanisms for public involvement has been strongly criticised (Foster, 2008; Herwig, 2014; Peel, 2010).

Codex constitutes the next phase of thinking about risk assessment, developing the concept of 'risk-assessment policy' which is similar to the risk-assessment guidelines that we described above. According to Codex, risk-assessment policy establishes the risk-assessment framework, and is defined as 'documented guidelines on the choice of options and associated judgments for their application at appropriate decision points in the risk assessment such that the scientific integrity of the process in maintained' (CAC, 2013: 114). These judgements include decisions about the scope of future risk assessments, the type and amount of evidence needed, the interpretation of the evidence, and the treatment of uncertainty. The concept departs from the NRC's

reports by stipulating that it is the responsibility of risk managers, not risk assessors, to develop a risk-assessment policy in consultation with all interested parties (CAC, 2013). In 2007, Codex committed its 186 members (including the EU and the USA) to develop explicit risk-assessment policies through the formal adoption of the *Working Principles for Risk Analysis for Food Safety for Application by Governments* (CAC, 2007).

Similar to the NRC in its 1996 report, Codex acknowledges the value judgements in risk-assessment guidelines, yet it maintains the clear distinction between risk assessment and risk management. Risk-assessment guidelines have been carved off from risk assessment and placed under the risk-management phase of risk governance. However, the more nuanced discussion about value judgements in risk assessment present in the NRC's 1983 report has been pushed aside in favour of a clear and convenient separation between facts and values. Risk assessment is now seen to be an exclusively science-based and objective exercise to be conducted by risk assessors (Herwig, 2014). Risk management is the stage of risk governance where values are acknowledged and where the public should be involved. Next, we explore these prescriptions and the tensions that arise in the practical application of guidelines through a case study.

The treatment of values and publics in risk assessment in practice

The EFSA provides a useful case study to examine the way in which risk assessors disentangle risk assessment and involve the public in practice. The EFSA gives independent scientific advice to the European Commission (EC) on matters related to food safety, and has responsibility for risk assessment. Risk assessment is defined in the EFSA's founding regulation as 'a scientifically based process consisting of four steps: hazard identification, hazard characterization, exposure assessment and risk characterization' (EC, 2002: 11). The EFSA develops guidance documents, which are risk-assessment guidelines establishing the principles, procedures and approaches in risk assessment as well as specifying data requirements and the handling of uncertainty (Hartley, 2016; Vos and Wendler, 2006). Applicants conduct risk assessment in line with the EFSA's guidance documents and then the EFSA reviews

the applications and publishes a scientific opinion (the output of an individual risk assessment). It is then the task of the EC and member states (risk managers) to make the decision on whether to approve the product or process under scrutiny.

The EFSA relies heavily on independent external scientific experts in the development of its scientific outputs. These experts sit on standing panels and are called upon to sit on ad hoc working groups. In addition, the EFSA has a statutory obligation to engage with publics (EC, 2002: Article 42). To meet this obligation, the EFSA holds public consultations on its scientific outputs, particularly its guidance documents and scientific opinions. Public involvement is guided by an internal policy. The EFSA's approach to public consultations on scientific outputs defines publics as 'the non-institutional stakeholders, which include academics, NGOs, industry and all other potentially interested and affected parties' (EFSA, n.d.: 3). The EFSA's motivation for public consultation in risk assessment is driven by the goals of both transparency and scientific excellence. Public consultations open up the EFSA's processes and decisions to public scrutiny and they also allow external input from publics to enhance the scientific quality of the risk assessment by ensuring clarity and completeness (EFSA, n.d.: 3). The EFSA's policy on consultations allows it to launch a public consultation at three stages: (1) at the start, to define the scope and major principles; (2) at a preliminary stage, to seek information, data, views and sources available on a specific topic; and (3) at the end, to ensure the clarity, completeness and soundness of the draft scientific output (EFSA, n.d.). However, the EFSA has yet to hold a consultation at the first stage to define the scope of a risk assessment. In practice, publics are typically given two months to comment on a draft scientific output (developed by experts) through the EFSA's website (Hartley, 2016).

The EFSA does not acknowledge that value judgements are made in the development of its guidance documents or scientific opinions (Klintman and Kronsell, 2010). Independent experts on the EFSA's Genetically Modified Organisms (GMO) panel have made it clear that they do not acknowledge or engage in the matter of implicit values, instead insisting that the EFSA's risk assessment is a scientific process and value judgements occur at the risk-management stage of risk governance and are the responsibility of the EC and member states (Perry et al., 2012; Wickson and Wynne, 2012). Further, the

EFSA officials and scientific panels do not recognise that guidance documents are risk-assessment policies, as defined by Codex, or that it is the EC's responsibility to develop them (Hartley, 2016). Guidance documents are treated as scientific outputs free of value judgements. However, despite the legal distinction between risk assessment and risk management and the EFSA's insistence that risk assessment is value free, in practice the distinction is blurred (Tai, 2010).

The institutional denial of value judgements in risk assessment has significant implications for the EFSA's public consultations. First, it means that the EFSA's public consultations are 'science based' and publics are allowed only to provide comments related to the science of risk assessment. For example, when the EFSA consulted the public in the development of its guidance documents on the environmental risk assessment of genetically modified animals in 2013, it informed potential participants: 'The EFSA GMO Panel considered all scientifically relevant comments from the public when finalising the present document. [It] did not consider issues related to risk management (e.g. traceability, labelling, coexistence). Ethical and socio-economic issues are also outside the remit of the EFSA GMO Panel' (EFSA, 2013: 6). However, guidance documents are risk-assessment policies and the EU's commitment to Codex rules requires the EC to develop them. Hartley (2016) has described these guidance documents as policies masquerading as science.

The second implication of the institutional denial of values in risk assessment is that it reinforces the authority of experts, and publics have minimal opportunity for influence through the consultation. Hartley (2016) argues that the public consultations have a minimal impact on the EFSA's scientific outputs owing to the expert-led nature of the process and the unjustified restrictions placed on public involvement. Gaskell et al. (2007) characterise the EFSA's public consultation approach as a 'sound science' type of public dialogue, where the EFSA listens to the public only in terms of its own expert definition of the problem and the possible solutions. Although the EFSA makes public the results of the consultation exercises and its response, which shows how the results of the consultation exercise are used, publics' views are heard only in so far as publics talk in terms of the EFSA's scientific remit.

Overall, the EFSA has responsibility for developing risk-assessment guidelines, conducting risk assessment and determining the scientific studies used in a risk assessment in the EU's broader risk-governance framework. Each of these components of risk assessment is seen to be epistemic and is conducted by the EFSA's independent experts. Publics are involved as a means to improve the quality of the science and to make the process of risk assessment transparent. However, in practice, the institutional denial of values in risk assessment means that it is independent experts who determine the values-based decisions, and these experts are not democratically accountable. Public involvement is restricted to matters of science and the value judgements made by experts are hidden from public scrutiny.

New roles for public involvement in risk assessment

The academic literature presents compelling evidence of the existence of values in risk assessment and makes a convincing case that risk assessment has different component parts and should not be considered a homogeneous stage in risk governance. The prescriptive literature of the NRC and Codex demonstrate the difficulty in disentangling risk assessment in practice, showing that since the late 1980s there has been a growing reluctance to take a nuanced approach to addressing values used in risk assessment. Ironically, this closing down of values has been happening at the same time that risk assessment has been opened up to publics. At present, there is no harmonised approach to acknowledging or handling values in risk assessment, or to thinking about how risk assessment should be disentangled. The case of the EFSA reveals that the values in risk assessment are denied in practice and that the different component parts (risk-assessment guidelines, conducting of risk assessment and scientific studies used within a risk assessment) are seen as a single stage of risk governance. This practice of risk assessment has serious implications for public involvement.

The lack of clarity about which publics should be involved in risk assessment and at what point they should be involved means that public engagement in risk assessment is not reaching its full potential. To address this lack of clarity, we have disentangled risk assessment into three components: (1) risk-assessment guidelines, (2) conducting risk assessment and (3) scientific studies used in a risk assessment. Table 10.1 outlines these risk-assessment components. The types of

Table 10.1 A framework for public involvement in risk assessment

Risk-assessment components Risk-assessment guidelines		Task at hand Establishing the risk-assessment framework	Type of public to be involved Broad range of alternative experts and publics
	Analysis and characterisation of risk	Exposure and effects analysis, including selecting and synthesising relevant studies	Alternative experts
Scientific studies for risk assessment		Designing and conducting scientific studies which are drawn upon during risk assessments	Alternative experts

publics to engage with risk assessment will depend upon the component of risk assessment.

We make a practical distinction for the purposes of this argument between alternative experts and general publics, recognising that this distinction may be a false distinction at times. Alternative experts need to be sought out by risk assessors for their expert knowledge, which expands the existing range of expertise. These experts will be able to address the epistemic questions raised in risk assessment and may come from a broader range of academic disciplines, including the natural, engineering and social sciences. Alternative experts may also come from sector-specific policy communities outside the academy such as civil society, policymakers and government risk assessors. Alternative experts may be brought into existing committees, working groups and panels and work alongside risk assessors. On their part,

general publics will be self-selected in open and transparent engagement mechanisms in order to allow stakeholder groups and individuals access to information and provide them with the opportunity to contribute to values-based questions. General publics cannot be restricted to answering epistemic questions.

Mirroring developments in the public-engagement literature, there is increasing recognition in the risk-assessment literature of the role of public involvement in contributing substantively to risk assessment and providing transparency (Klintman and Kronsell, 2010). Indeed, the EFSA makes it clear that its public consultations are designed to satisfy both these goals. Therefore, the goal of public involvement in risk assessment is democratic and epistemic legitimacy. However, because the judgements in risk assessment are both science- and values-based in nature, epistemic legitimacy requires democratic legitimacy. There is a need, then, to involve the appropriate publics in the specific component being addressed. Because of the types of value judgements that exist in the development of risk-assessment guidelines and in the problem-formulation stage of risk assessment, including those that do not involve technical expertise, public involvement needs to include both alternative experts and publics more broadly. During the analysis and characterisation of risk and for scientific studies, it is important to open up to alternative experts who hold enough expertise to reflect substantively on the relevant values-based questions.

Conclusion

Peel (2010) suggests one of the crucial issues facing risk assessment and governance is related to the way in which facts and values are addressed: '[It 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' (Peel, 2010: 10). We argue that in order to satisfy epistemic and democratic legitimacy, the different features of risk assessment must be disentangled to lay bare the various component parts, and that different publics need to be involved depending on the types of questions asked in each component.

This chapter highlights the tensions between evidence, prescription and practice in risk assessment which complicate efforts to involve publics. However, public involvement in risk assessment presents a significant opportunity to debate the value judgements that exist in the various components of risk assessment. Indeed, it is precisely these implicit value judgements that present the strongest argument for public involvement (Finardi et al., 2012). In contrast, denying that values exist in risk assessment, relying on a narrow range of expertise and limiting public input to epistemic matters imposes a certain set of values made by a narrow range of experts that are insulated from public scrutiny and debate. This institutional denial of the implicit values in risk assessment results in public frustration and lack of trust in regulatory authorities (Hartley, 2016; Wynne, 2006).

References

- Borrás, S., Koutalakis, C., and Wendler, F. (2007). European agencies and input legitimacy: EFSA, EMeA and EPO in the post-delegation phase. *Journal of European Integration*, 29(5), 583–600.
- Büthe, T., and Harris, N. (2011). Codex Alimentarius Commission. In T. Hale and D. Held (eds), *Handbook of Transnational Governance: Institutions and Innovations* (pp. 219–228). Cambridge, MA: Polity Press.
- CAC (2007). Working Principles for Risk Analysis for Food Safety for Application by Governments. CAC/GL 62-2007. Rome: Food and Agriculture Organization (FAO).
- CAC (2013). *Procedural Manual of the Codex Alimentarius Commission*, 21st edition. Joint FAO/WHO Food Standards Programme. Rome: FAO.
- Dreyer, M., and Renn, O. (2014). EFSA stakeholder and public involvement policy and practice: A risk governance perspective. In A. Alemanno and S. Gabbi (eds), *New Directions in EU Food Law and Policy: Ten Years of European Food Safety Authority*. Farnham: Ashgate.
- EC (2002). Regulation (EC) No 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. *Official Journal of the European Communities*, 45(L 31), 1–24.
- EFSA (2013). Guidance on the Environmental Risk Assessment of Genetically Modified Animals. Scientific Opinion. Parma, Italy: EFSA.
- EFSA (n.d.). EFSA's Approach on Public Consultations on Scientific Outputs. Parma, Italy: EFSA.

- Elliott, K. C. (2012). Selective ignorance and agricultural research. *Science, Technology, and Human Values*, 38(3), 328–350.
- Environmental Protection Agency (EPA) (1998). Guidelines for Ecological Risk Assessment. Washington, DC: EPA.
- Finardi, C., Pellegrini, G., and Rowe, G. (2012). Food safety issues: From enlightened elitism towards deliberative democracy? Food Policy, 37, 427–438.
- Foster, C. E. (2008). Public opinion and the interpretation of the World Trade Organisation's agreement on sanitary and phytosanitary measures, *Journal of International Economic Law*, 11(2), 427–458.
- Gaskell, G., Kronberger, N., Fischler, C., Hampel, J., and Lassen, J. (2007). Consumer Perceptions of Food Products from Cloned Animals. A Social Scientific Perspective. Parma, Italy: EFSA.
- Hartley, S. (2016). Policy masquerading as science: An examination of non-state actor involvement in risk assessment policy for genetically modified animals in the EU. *Journal of European Public Policy*, 23(2), 276–295.
- Herwig, A. (2014). Health risks, experts and decision-making within the SPS Agreement and the Codex Alimentarius. In M. Ambrus, K. Arts, E. Hey and H. Raulus (eds), *The Role of 'Experts' in International and European Decision-making Processes: Advisors, Decision-Makers or Irrelevant Actors* (pp. 194–215). Cambridge: Cambridge University Press.
- Hilbeck, A., Meier, M., Römbke, J., Jänsch, S., Teichmann, H., and Tappeser, B. (2011). Environmental risk assessment of genetically modified plants: Concepts and controversies. *Environmental Sciences Europe*, 23(13), 1–12.
- Holifield, R. (2009). How to speak for aquifers and people at the same time: Environmental justice and counter-network formation at a hazardous waste site. *Geoforum*, 40(3), 363–372.
- Irwin, A. (2014). From deficit to democracy (re-visited). Public Understanding of Science, 23(1), 71–76.
- Jasanoff, S. (1987). EPA's regulation of daminozide: Unscrambling the messages of risk. *Science, Technology, and Human Values*, 12(3–4), 116–124.
- Jasanoff, S. (1999). The songlines of risk. *Environmental Values*, 8, 135–152.
 Jensen, K. K., Gamborg, C., Madsen, K. H., Jorgensen, R. B., von Krauss, M. K., Folker, A. P., and Sandoe, P. (2003). Making the EU 'risk window' transparent: The normative foundations of the environmental risk assessment of GMOs. *Environmental Biosafety Research*, 2(3), 161–171.
- Kaliarnta, S., Hage, M., and Roeser, S. (2014). Involving stakeholders in risk governance: The importance of expertise, trust and moral emotions. In M. B. A. van Asselt, M. Everson and E. Vos (eds), *Trade, Health and the Environment: The European Union Put to the Test* (pp. 235–253). Abingdon: Routledge.

- Klintman, M., and Kronsell, A. (2010). Challenges to legitimacy in food safety governance? The case of the EFSA. *European Integration*, 32(3), 309–327.
- Kokotovich, A. (2014). Delimiting the study of risk: Exploring values and judgments in conflicting GMO ecological risk assessment guidelines. In *Contesting Risk: Science, Governance and the Future of Plant Genetic Engineering* (pp. 13–67). PhD thesis, University of Minnesota.
- Levidow, L. (2007). European public participation as risk governance: Enhancing democratic accountability for agbiotech policy? *East Asian Science, Technology and Society*, 1(1), 19–51.
- Meghani, Z. (2009). The US' Food and Drug Administration, normativity of risk assessment, GMOs, and American democracy. *Journal of Agricultural and Environmental Ethics*, 22(2), 125–139.
- Meyer, H. (2011). Systemic risks of genetically modified crops: The need for new approaches to risk assessment. *Environmental Sciences Europe*, 23(7), 1–11.
- Millstone, E. (2009). Science, risk and governance: Radical rhetorics and the realities of reform in food safety governance. *Research Policy*, 38, 624–636.
- Millstone, E., van Zwanenberg, P., Levidow, L., Spök, A., Hirakawa, H., and Matsuo, M. (2008). *Risk-Assessment Policies: Differences across Jurisdictions*. Brussels: EC Joint Research Centre.
- Nelson, K. C., Basiao, Z., Cooper, A. M., Dey, M., Fonticiella, D., Hernandez, M. L., Kunawasen, S., et al. (2007). Problem formulation and options assessment: Science-guided deliberation in environmental risk assessment of transgenic fish. In A. Kapuscinski, K. Hayes, S. Li and G. Dana (eds), Environmental Risk Assessment of Genetically Modified Organisms, vol. 3, Methodologies for Transgenic Fish (pp. 29–60). Cambridge, MA: Centre for Agriculture and Biosciences International.
- NRC (1983). *Risk Assessment in the Federal Government: Managing the Process.* Washington, DC: National Academies Press.
- NRC (2009). Science and Decisions: Advancing Risk Assessment. Washington, DC: National Academies Press.
- Peel, J. (2010). *Science and Risk Regulation in International Law*. Cambridge: Cambridge University Press.
- Perry, J. N., Arpaia, S., Bartsch, D., Kiss, J., Messéan, A., Nuti, M., Sweet, J. B., et al. (2012). Response to 'the anglerfish deception'. *EMBO Reports*, 13, 481–482.
- Renn, O., and Schweizer, P.-J. (2009). Inclusive risk governance: Concepts and application to environmental policy making. *Environmental Policy and Governance*, 19(3), 174–185.
- Rothstein, H. (2013). Domesticating participation: Participation and the institutional rationalities of science-based policy-making in the UK Food Standards Agency. *Journal of Risk Research*, 16(6), 771–790.

- Shepherd, R. (2008). Involving the public and stakeholders in the evaluation of food risks. *Trends in Food Science and Technology*, 19(5), 234–239.
- Stern, P. C., and Fineberg, H. V. (1996). *Understanding Risk: Informing Decisions in a Democratic Society*. Washington, DC: National Academies Press.
- Suter, G. W., II. (2008). Ecological risk assessment in the United States Environmental Protection Agency: An historical overview. *Integrated Environmental Assessment and Management*, 4(3), 285–289.
- Tai, S. (2010). Comparing approaches towards governing scientific advisory bodies on food safety in the United States and the European Union. Wisconsin Law Review, 2010, 627–671.
- Thompson, P. B. (2003). Value judgments and risk comparisons: The case of genetically engineered crops. *Plant Physiology*, 132, 10–16.
- Vos, E., and Wendler, F. (2006). Food safety regulation at the EU level. In E. Vos and F. Wendler (eds), *Food Safety Regulation in Europe: A Comparative Institutional Analysis* (pp. 65–138). Antwerp and Oxford: Intersentia.
- Wickson, F., and Wynne, B. (2012). The anglerfish deception. *EMBO Reports*, 13(2), 100–105.
- Winickoff, D., Jasanoff, S., Busch, L., and Grove-White, R. (2005). Adjudicating the GM food wars: Science, risk, and democracy in world trade law. *Yale Journal of International Law*, 30, 81–123.
- Wynne, B. (2006). Public engagement as a means of restoring public trust in science: Hitting the notes, but missing the music? *Public Health Genomics*, 9(3), 211–220.