

**BEYOND RHETORIC:**

**CLOSING THE GAP BETWEEN POLICY AND  
PRACTICE IN THE EU'S REGULATION OF RISKY  
TECHNOLOGIES**

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I, Olivia Alice Hamlyn, confirm that the work presented in this thesis is my own. Where information has been derived from other sources, I confirm that this has been indicated in the thesis.

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## ABSTRACT

Several decades of research in the social sciences, particularly science and technology studies, have demonstrated both the political and controversial nature of technological innovation and the limitations of regulating its implications solely by reference to scientific assessments of its risks. This has led to calls for greater socio-technical integration in regulatory decision-making in recognition of the values, commitments and concerns underpinning both risk assessment and societal attitudes to risk. Much EU policy on regulating risk technologies acknowledges these findings and commits to enhancing socio-technical integration in its decision-making, often through enhanced public participation and debate. Much EU law, however, remains committed to a model of regulation based on scientific risk assessment resulting in a gap between EU policy and practice. This thesis investigates reasons for the persistence of this gap.

Taking pesticides and synthetic biology as example technologies and examining their associated governance discourses (sustainability and responsible research and innovation, respectively) this thesis explores the opportunities provided for enhancing socio-technical integration in the regulation of those technologies. It focuses on the ways in which the legal and policy frameworks of both operate to deprive those two discourses of their potential and thereby contribute to maintaining the policy-practice gap. It derives further insights into the persistence of the policy-practice gap by looking beyond those specific technologies to the EU internal market, the WTO regime and wider EU policy on innovation. It argues firstly that science is frequently attributed priority of agency in determining the existence of a problem warranting the law's response, excluding other perspectives. It argues secondly, that the weight of EU policy commitment to economic competitiveness, technological progress and commercialisable innovation to realise its future visions fundamentally undermines its commitment to, and ability to achieve, enhanced socio-technical integration. The policy-practice gap remains.

99,972 words

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## ACRONYMS

5EAP	Fifth Environmental Action Programme
6EAP	Sixth Environmental Action Programme
7EAP	Seventh Environmental Action Programme
AB	Appellate Body
AG	Advocate General
ALOP	appropriate level of protection
BSE	bovine spongiform encephalitis
CETA	Comprehensive Economic and Trade Agreement
CFC	chlorofluorocarbon
CJEU	Court of Justice of the European Union
CUD	Contained Use Directive
DDT	dichlorodiphenyltrichloroethane
DNA	deoxyribonucleic acid
DRD	Deliberate Release Directive
ECHA	European Chemicals Agency
ECJ	European Court of Justice
EFSA	European Food Safety Authority
EGE	European Group on Ethics in Science and New Technologies
ERA	environmental risk assessment
ETP	European Technology Platform
EU	European Union
FP7	Seventh Framework Programme for Research and Technological Development
GATT	General Agreement on Tariffs and Trade
GFL	General Food Law
GM	genetic modification/genetically modified
GMO	genetically modified organism
IPM	integrated pest management
KBBE	knowledge-based bioeconomy
KBE	knowledge-based economy
MEE	measures having equivalent effect to a quantitative restriction
NAP	national action plan
NGO	non-governmental organisation
NRC	National Research Council
NPR-PPM	non-product-related process and production method
OECD	Organisation for Economic Co-operation and Development
PES	public engagement with science

PM	particulate matter
PPM	process and production method
PPPR	Plant Protection Product Regulation
PUS	public understanding of science
rDNA	recombinant DNA
REACH	Regulation, Evaluation, Authorisation of Chemicals
RNA	ribonucleic acid
RRI	responsible research and innovation
SO	synthetic organism
SPS	sanitary and phytosanitary
SPSA	Agreement on the Application of Sanitary and Phytosanitary Measures
SRA	strategic research and innovation agenda
STS	Science and Technology Studies
SUD	Sustainable Use Directive
SVHC	Substance of very high concern
TBTA	Agreement on Technical Barriers to Trade
TEU	Treaty on the European Union
TFEU	Treaty on the Functioning of the European Union
TTIP	Transatlantic Trade and Investment Partnership
WTO	World Trade Organisation

## Chapter One – Introduction

### 1. Introduction

Technology is controversial. Its ambiguity inheres in its very etymological root: ‘*techne*’, signifying art or skill, but also cunning.<sup>1</sup> Ancient suspicion of *techne* presaged many contemporary concerns; unpredictable consequences, uncontrollability, the potential destruction invited by increasing technological domination of nature and even the dangers of mistaking good judgment for technical knowledge.<sup>2</sup> Though technology evolved, those themes persist.

Equally controversial is whether, and how, the law should respond to socio-technical change.<sup>3</sup> These are vast, infinitely complex and politically charged questions, for all technologies differ, as do the societies in which they exist. Protecting human health and the environment is an important reason for regulating but there are others.

Research by the social sciences, particularly science and technology studies (STS) into the nature of risk, technology and science, including regulatory science, over the past five decades, has significantly enhanced our understanding of societal attitudes to the risks and implications of technological innovation and the limitations of basing regulation on risk alone. Anticipating Chapter Two, briefly the arguments are that risk assessment offers a reductive and incomplete foundation on which to regulate a particular technology, despite its frequent employment to that end. This is firstly because it generally provides a simple, probabilistic picture of the risks to health and to the environment posed by the technology in question. This fails to incorporate the multifarious considerations and values constituting broader, societal attitudes to risk and technologies and the (scientific) uncertainty which inevitably stems from the interaction of a technology with highly complex

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<sup>1</sup> Henry G Liddell (ed), *An Intermediate Greek-English Lexicon* (Clarendon Press 1889) 804.

<sup>2</sup> David E Tabachnick, ‘Techne, Technology and Tragedy’ (2004) 7 *Techné: Research in Philosophy and Technology*.

<sup>3</sup> On some potential guiding principles, see Lyria Bennett Moses, ‘Regulating in the Face of Sociotechnical Change’ in Roger Brownsword, Eloise Scotford and Karen Yeung (eds), *The Oxford Handbook of the Law and Regulation of Technology* (OUP 2016).

(eco)systems.<sup>4</sup> It is secondly because, contrary to frequent claims to objectivity, risk assessment is coloured by the commitments, values and assumptions of those conducting it, such that the results of risk assessment cannot genuinely be credited with this quality.<sup>5</sup> Furthermore, this model of regulation has been criticised for forcing all concerns relating to a technology through the validating filter of risk,<sup>6</sup> when they might be better expressed otherwise. If a concern cannot be expressed in terms of safety or risk, it may be ignored. Any expression of broader considerations and values in decision-making tends to be shunted into overtly political discussions regarding risk management in accordance with the rubric of ‘facts first, values second’.

This risk-centric paradigm means firstly, that the commitments, values and assumptions underpinning risk assessment remain unexamined; and secondly, that despite the existence of other valid reasons for regulating a technology which cannot be elucidated by risk assessment, such reasons rarely constitute the primary (or indeed, any) basis for regulating a technology.

The norms that derive from this social science research tend towards increasing ‘socio-technical integration’ in the governance of technology, spurred too by an acknowledgement of the valuable knowledge which non-expert ‘publics’ could contribute.<sup>7</sup> That is, informing regulatory decision-making with a broader range of information than scientific data produced by risk assessment, founding decisions on values beyond safety or environmental protection and opening up the commitments, values and assumptions underpinning risk assessment to examination. In other words, regulation of ‘risky technologies’ should not proceed

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<sup>4</sup> For example in relation to agricultural biotechnology in the UK, Matthew Kearnes and others, ‘From Bio to Nano: Learning Lessons from the UK Agricultural Biotechnology Controversy’ (2006) 15 *Science as Culture* 291, 296–297.

<sup>5</sup> Royal Society, *Risk: Analysis, Perception and Management* (Royal Society 1992) 97.

<sup>6</sup> EGSG, *Taking European Knowledge Society Seriously* (EUR-OP 2007) 10–11, ch 3.

<sup>7</sup> Jack Stilgoe, Alan Irwin and Kevin Jones, *The Received Wisdom: Opening up Expert Advice* (Demos 2006) 31–33, 43.

solely on the basis of managing and reducing the risks to safety that such technologies pose, albeit that these risks may often seem most urgent.

Rhetorically, the EU broadly recognises and accepts these norms and the overall thrust of this social science research.<sup>8</sup> Increasing public participation or engagement, in particular, is frequently invoked in aid of opening up governance of science and technology.<sup>9</sup> As Chapters Two to Five indicate, attempts to enhance participation in decision-making have often constituted the core of the EU's response to this research.<sup>10</sup> Much of the argument in this thesis adopts the basic position that participation, *if genuine and conducted well*, can aid decision-making and it is on such EU initiatives that much of the following analysis focuses.

However, Sheila Jasanoff observes: 'All the empirical observations about the constructedness, context-dependency, and incompleteness of regulatory science and its consequent function as a political force, have left curiously untouched the discourse of good science that still permeates Western practices of governance'.<sup>11</sup> That the EU simultaneously remains stubbornly dedicated to privileging risk assessment in its regulation of risky technologies has been extensively and eloquently established elsewhere, particularly by Maria Lee. Indeed, it is Lee's arguments and observations<sup>12</sup> that there exists an unacceptable gap between what the EU says and what it does in relation to the regulation of risky technologies, which prompted the line of enquiry pursued in this thesis.

It is, I argue, important to close the gap between policy and practice for the following reasons. Firstly, for the political integrity of the EU. If the EU claims non-

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<sup>8</sup> Maria Lee, 'Risk and beyond: EU Regulation of Nanotechnology' (2010) 35 *European Law Review* 799, 820.

<sup>9</sup> Andy Stirling, "'Opening Up" and "Closing Down": Power, Participation, and Pluralism in the Social Appraisal of Technology' (2008) 33 *Science, Technology & Human Values* 262, 263–264.

<sup>10</sup> EGSG (n 6) 33; Žaneta Ozoliņa and others, *Global Governance of Science* (EUR-OP 2009) 26–28.

<sup>11</sup> Sheila Jasanoff, *Designs on Nature: Science and Democracy in Europe and the United States* (Princeton UP 2007) 231.

<sup>12</sup> In particular, Lee, 'Risk and beyond' (n 8); Maria Lee, 'Beyond Safety? The Broadening Scope of Risk Regulation' (2009) 62 *Current Legal Problems* 242.

safety values are important and that it will regulate on the basis of such values, it should do so. Secondly, to respond to the valid concerns of citizens by basing decisions on as much information about the technology as possible, from as many different perspectives as possible. Thirdly, better and more acceptable decisions may result from the genuine appreciation, for example through deliberation or participation,<sup>13</sup> of more and different knowledge and perspectives.

To summarise, the thesis works from three foundations. Firstly, that EU regulation of technologies which pose risks to the environment and human health, needs to be: a) founded on a range of considerations beyond ensuring safety; and b) informed by broader information than scientific data produced by risk assessment. Secondly, EU policy accepts, at least rhetorically, the need for a broad evidence base. Thirdly, despite this acceptance, the EU paradigm of risk regulation still emphasises risk as a decision-making technique and thereby prioritises protection of health and the environment to the near exclusion of all other values and aims. This gap between policy and practice, should be closed. This thesis investigates why the policy-practice gap persists.

Each stage of this argument is dealt with more fully in subsequent chapters, as set out in section 7. Before that, however, these observations and underlying concepts require some preliminary context and explanation. Section 2 considers what I mean by 'risky technologies'. Section 3 discusses the place of science and technology in the thesis and what it means to assess and regulate technology on the basis of risk. Section 4 firstly introduces two specific technologies which I discuss throughout the thesis. Secondly, it provides support for the third foundation, above, demonstrating that the EU's reliance on risk in decision-making extends beyond these two technologies and pervades its regulation of risky technologies generally. Sections 5 and 6 discuss methodology and the scope of the thesis respectively and section 7 sets out its structure.

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<sup>13</sup> Daniel J Fiorino, 'Citizen Participation and Environmental Risk: A Survey of Institutional Mechanisms' (1990) 15 *Science, Technology, & Human Values* 226, 228. See also Chapter Three.

## 2. 'Risky technology'

It is hardly necessary to state that there are many different kinds of technology. Some, incorporeal financial technologies, others material devices. Some living, others non-living. Some visible to the naked eye, some too minute for human perception. While the same sorts of concerns can surface across many technologies, this thesis focuses on a sub-group of technologies which exemplify a specific set of concerns. These are technologies which pose risks to the environment and human health, including for example, genetically modified organisms (GMOs), nanotechnology, chemicals, pesticides, synthetic biology, genome editing, fracking and nuclear energy. I refer to them, for brevity's sake, as 'risky technologies'. While we may be preoccupied with privacy in relation to smart meters, for example, or ethics in stem cell research, the most obvious concern with risky technologies is their capacity to alter and damage the environment and health often in unpredictable and unintended ways. We have, by now, sufficient experience of comparable technologies, for example CFCs and the pesticide DDT, and the almost predictable pattern of unintended damage,<sup>14</sup> to countenance the likelihood of variations on this theme with each new technology, and indeed mature technologies (see Chapter Four). While the overall theme is predictable,<sup>15</sup> the individual variations are not and may be exacerbated by interaction between complex technologies and the equally complex and unpredictable socio-economic sphere.<sup>16</sup> Environmental problems in particular are characteristically 'messy' and often subject to profound scientific uncertainty<sup>17</sup> which, as discussed in Chapter Two, significantly complicates decision-making.

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<sup>14</sup> For example, EEA, *Late Lessons from Early Warnings: Science, Precaution, Innovation* (EUR-OP 2013).

<sup>15</sup> Jenny Steele, *Risks and Legal Theory* (Hart 2004) 31.

<sup>16</sup> Tomas Hellström, 'Systemic Innovation and Risk: Technology Assessment and the Challenge of Responsible Innovation' (2003) 25 *Technology in Society* 369.

<sup>17</sup> Elizabeth Fisher, 'Risk and Environmental Law: A Beginner's Guide' in Benjamin Richardson and Stepan Wood (eds), *Environmental Law for Sustainability: A Reader* (Hart 2006) 99.

However, beyond the show-stopping question of potential harm, the same risky technologies raise questions of economic costs, distribution and certainty of risks and benefits,<sup>18</sup> ethics and whether in general a technology helps create a desirable society, to name but a very few. Notwithstanding this variety of questions and impacts, regulatory decision-making in the EU (and elsewhere)<sup>19</sup> remains concentrated on ascertaining the risks to safety and then managing those risks, as argued immediately below and throughout the thesis. This emphasis on risks and pursuit of safety forms one half of an asymmetrical understanding of, and response to, risky technologies which will also be touched upon throughout the thesis. It is based on an assumption that any negative impacts will manifest themselves solely in safety terms. This is seen, for example, in the acceptance that the main worries about pesticides are their impacts on health and the environment, discussed in Chapter Four. By contrast, it is assumed (as highlighted in Section II and Chapter Eight) that any non-safety impacts will be solely beneficial, such as economic growth and competitiveness, job creation or other kinds of social progress. Indeed, science and technology have long been presented as guaranteeing democracy, freedom and social justice.<sup>20</sup> This understanding of risky technologies is highly disputable, as argued in Chapter Two and illustrated by the discussions in Section II.

### 3. Science, technology and risk regulation

Science appears in this thesis in two guises. Its first guise is as pure scientific research, disclosing facts about the natural world and delivering innovation. Some caution is required regarding this conception of science. The terms ‘pure science’ or ‘basic science’ are used to describe the fundamental, curiosity-driven scientific research conducted to enlarge human understanding of nature, whose primary goal is not necessarily innovation or application. For example, research into planetary atmospheres or the study of fundamental particles at CERN. The rhetorical concept of a ‘linear model of innovation’ casts technological innovation and diffusion as

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<sup>18</sup> Lee, ‘Risk and beyond’ (n 8) 801–803.

<sup>19</sup> Stilgoe, Irwin and Jones (n 7) 37–39; Lee, ‘Beyond Safety?’ (n 12) 253–260.

<sup>20</sup> Langdon Winner, ‘Do Artifacts Have Politics?’ (1980) 109 *Daedalus* 121, 121.

issuing from basic, via applied, science.<sup>21</sup> Blue skies to blu-ray is an intuitive and attractively simplified account of where technologies come from. It is of course hard to generalise either way,<sup>22</sup> but research indicates that technological innovation is not necessarily applied science nor the inevitable result of pure scientific research,<sup>23</sup> developed in a rational and orderly manner towards a pre-determined, precise goal.<sup>24</sup>

The distinction is blurred and the kinds of risky technologies to which this thesis is relevant are sometimes closely linked to scientific research. For example, biotechnology originated in research into recombinant DNA,<sup>25</sup> and the recent discovery of CRISPR/Cas9, a new method of genome editing, arose directly out of fundamental research into bacterial immune systems.<sup>26</sup> Thus, it is often difficult and perhaps futile to distinguish between pure science and applied science and technology. Pure scientific research itself raises questions, regarding *inter alia*, its purpose, direction, speed, the motivations of those who conduct it<sup>27</sup> and whether we should act early while control is still relatively easy.<sup>28</sup> Frustration at the limitations of *post hoc*, risk-based regulation have prompted innovation governance initiatives to respond to some of these concerns,<sup>29</sup> marking a shift

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<sup>21</sup> Benoît Godin, 'The Linear Model of Innovation: The Historical Construction of an Analytical Framework' (2006) 31 *Science, Technology, & Human Values* 639.

<sup>22</sup> See discussion of the three technologies in Wiebe E Bijker, *Of Bicycles, Bakelites, and Bulbs: Toward a Theory of Sociotechnical Change* (MIT Press 1995).

<sup>23</sup> Sergio Sismondo, *An Introduction to Science and Technology Studies* (2nd ed, Wiley-Blackwell 2010) 93–94.

<sup>24</sup> Eugene S Ferguson, 'Toward a Discipline of the History of Technology' (1974) 15 *Technology and Culture* 13, 19.

<sup>25</sup> Sheila Jasanoff, "'Let Them Eat Cake": GM Foods and the Democratic Imagination' in Melissa Leach, Ian Scoones and Brian Wynne (eds), *Science and Citizens: Globalization and the Challenge of Engagement* (Zed Books 2005) 188–189.

<sup>26</sup> Colin Barras, 'Right on Target: New Era of Fast Genetic Engineering' [2014] *New Scientist* <<https://www.newscientist.com/article/mg22129530.900-right-on-target-new-era-of-fast-genetic-engineering/>> accessed 26 June 2017 accessed 12 July 2015.

<sup>27</sup> Phil Macnaghten and Jason Chilvers, 'The Future of Science Governance: Publics, Policies, Practices' (2014) 32 *Environment and Planning C: Government and Policy* 530, 534–537.

<sup>28</sup> David Collingridge, *The Social Control of Technology* (Frances Pinter 1980) 17–20.

<sup>29</sup> Jack Stilgoe, Richard Owen and Phil Macnaghten, 'Developing a Framework for Responsible Innovation' (2013) 42 *Research Policy* 1568, 1569.

‘upstream’ of the discourse on socio-technical integration, discussed further in Chapters Three and Five.

Science’s second guise is as assessor and producer of information regarding the health and environmental risks created by technologies, for the purpose of regulation.<sup>30</sup> It is the use of such ‘regulatory science’<sup>31</sup> or ‘science for governance’ and specifically risk assessment, its potential, limitations and problems, which is the main focus of this thesis. The origins and practice of risk assessment are discussed further in Chapter Two. However, a word is due here on the EU’s approach to risk in general in order to highlight the assumptions about science, expertise and public attitudes, which pervade the EU’s approach to regulating risky technologies, and which the subsequent analysis rejects.

In its Communication on the Precautionary Principle, the European Commission declares that ensuring ‘proportionate, non-discriminatory, transparent and coherent’ decisions requires a structured decision-making process.<sup>32</sup> It derives this structure from that proposed to guarantee ‘objective’ decision-making by the US National Research Council, in its 1983 ‘Red Book’.<sup>33</sup> This structure (including ‘risk communication’), which the EU refers to as ‘risk analysis’, separates the objective, scientific, fact-gathering exercise of risk assessment, from the subsequent, political, value-based exercise of risk management during which decisions regarding the regulation of the risks identified by risk assessment are taken.<sup>34</sup> This is partly a response to the inadequacies identified in the Commission’s handling of the BSE crisis in the late 1990s in which expert scientific advice was found to have been excessively influenced by politics, specifically British political interests.<sup>35</sup> The creation of the independent and expert European Food Safety Authority (EFSA) by

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<sup>30</sup> For a discussion of the difference between risk as an object of regulation and risk as a decision-making technique, see Steele (n 15) 3–7.

<sup>31</sup> On the differences between regulatory and research science, see Sheila Jasanoff, *The Fifth Branch: Science Advisers as Policymakers* (Harvard UP 1990) 76–79.

<sup>32</sup> Commission, ‘Communication on the Precautionary Principle COM(2000) 1 Final’ 8.

<sup>33</sup> Fisher, ‘Risk and Environmental Law’ (n 17) 105.

<sup>34</sup> *ibid.*

<sup>35</sup> Maria Lee, *EU Regulation of GMOs: Law and Decision Making for a New Technology* (Edward Elgar 2008) 6.

the General Food Regulation (GFL),<sup>36</sup> for example, aimed to separate science from politics and thereby regain legitimacy in risk regulation for the Commission.<sup>37</sup>

Given the damage done by the BSE crisis and the strength of the criticisms regarding the mixing of science and politics,<sup>38</sup> it is easy to understand the EU's dedication to an institutional separation between expert advice and political deliberation as a means to guard against bias in decision-making and ensure political responsibility.<sup>39</sup> Expert knowledge and advice is crucial to decision-making concerning risky technologies<sup>40</sup> and neither scientists nor politicians should step beyond the limits of their respective roles. However, evidence does not speak for itself<sup>41</sup> and may not necessarily translate easily into policy; evidence-based policy often creates further difficult questions about the purpose, type or quality of the evidence provided and may overlook uncertainties.<sup>42</sup> Finally, more knowledge or information may aggravate, rather than resolve, political conflict<sup>43</sup> or de-legitimise political institutions as decision-makers.<sup>44</sup> Scientific advice, however, resists challenge due to its expert authority and apparent impartiality, objectivity, certainty and

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<sup>36</sup> European Parliament and Council Regulation (EC) No 178/2002 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 [2002] OJ L31/1.

<sup>37</sup> Lee, *EU Regulation of GMOs* (n 35) 4–6.

<sup>38</sup> *ibid* 5.

<sup>39</sup> *ibid* 41–42.

<sup>40</sup> Jasanoff, *The Fifth Branch* (n 31) 1.

<sup>41</sup> Stilgoe, Irwin and Jones (n 7) 50, 72.

<sup>42</sup> *ibid* 23–24.

<sup>43</sup> Daniel Sarewitz, 'How Science Makes Environmental Controversies Worse' (2004) 7 *Environmental Science & Policy* 385.

<sup>44</sup> Maria Weimer, 'Risk Regulation, GMO's, and the Challenges to Deliberation in EU Governance - Politicization and Scientification as Co-Producing Trends' (SSRN 2014) 40–41 <[https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2400553](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2400553)> accessed 26 June 2017 and references therein.

independence,<sup>45</sup> and regimes of measurement and assessment may be held in place by political, cultural and economic stays.<sup>46</sup>

Furthermore, dogmatic adherence to this separation between risk assessment and risk management institutionalises a set of artificial dichotomies and perpetuates assumptions, unsupportable in light of the STS insights, discussed in Chapter Two. This division is the clearest expression of an ideological commitment to an overarching dichotomy between objectivity and subjectivity – facts and values<sup>47</sup> - enhanced procedurally by the norm that scientific risk assessment precedes political discussion and risk management. It further reflects another broad distinction between ‘science’ and ‘society’ to which are attributed, respectively, objectivity and rationality, or subjectivity and sometimes irrationality,<sup>48</sup> which disintegrate under closer scrutiny but which persist, as touched upon throughout the thesis.

This overarching dichotomy has been a defining feature of risk discourses and still is, albeit with some modifications, despite challenges from social science research. For example, questioning the implicit claims of objectivity, Mary Douglas and Aaron Wildavsky argue that it is made into ‘an absolute value for all discourse’, that it excludes subjectivity and that the objectivity of a judgment or report does not guarantee that it is right; intelligence and experience are also required in determining the relevant facts.<sup>49</sup> However, they continue, ‘objectivity comes to mean some final truth about physical nature’.<sup>50</sup> Further challenges have targeted

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<sup>45</sup> Stilgoe, Irwin and Jones (n 7) 57; though a decline in science may be detectable in contemporary mass democratic politics, Yaron Ezrahi, ‘Science and Political Imagination in Contemporary Democracies’ in Sheila Jasanoff (ed), *States of Knowledge: The Co-production of Science and Social Order* (Routledge 2010).

<sup>46</sup> Andrew Barry, ‘The Anti-Political Economy’ in Andrew Barry and Don Slater (eds), *The Technological Economy* (Routledge 2005) 91–92.

<sup>47</sup> For example, EGSG (n 6) 77–78.

<sup>48</sup> Alan Irwin, ‘STS Perspectives on Scientific Governance’ in Edward J Hackett and others (eds), *The Handbook of Science and Technology Studies* (MIT Press 2008) 590; Brian Wynne, ‘Creating Public Alienation: Expert Cultures of Risk and Ethics on GMOs’ (2001) 10 *Science as Culture* 445, 455.

<sup>49</sup> Mary Douglas and Aaron Wildavsky, *Risk and Culture: An Essay on the Selection of Technical and Environmental Dangers* (UC Press 1982) 72.

<sup>50</sup> *ibid.*

the assumed objectivity of risk assessment itself and the distinction between that and risk management alleging that it is in fact impossible to separate science and politics; decisions may take a scientific form but still be based on political concerns and present varying answers depending on context.<sup>51</sup> Furthermore, the fact/value divide is permeable: “the facts’ are less self-evident than they sometimes appear, and values are not an illegitimate intruder in ‘objective’ decision-making”.<sup>52</sup> Another facet is the expanding boundary around matters deemed to be ‘factual’: the Expert Group on Science and Governance (EGSG) notes that ‘the avowed societal benefits of GM crops’ have been described by scientists as being a scientific fact.<sup>53</sup> This is interpreted as science replacing moral judgment through its invocation as public authority and an example of the normative prescription with which ‘innocent factual’ learning is imbued,<sup>54</sup> an act of depoliticising goalpost-movement which shuts out debate.

#### 4. The primacy of risk in EU regulation of risky technologies: pesticides, synthetic biology and beyond

My argument that risk and safety concerns dominate EU regulation of risky technologies, though there exist other valid reasons to regulate, is largely presented in Section II with a discussion of two example technologies. However, a brief introduction to these technologies is warranted here as they permeate the entire thesis.

##### 4.1 *Meeting the technologies*

In 2009, the EU introduced a new Directive designed to achieve the sustainable use of pesticides (the Sustainable Use Directive, or SUD).<sup>55</sup> Pesticide use is complex, encompassing a diverse range of social, ethical, economic, environmental, health-related and scientific questions and impacts, discussed further in Chapter Four.

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<sup>51</sup> Maria Lee, *EU Environmental Law, Governance and Decision-Making* (2nd ed, Hart 2014) 43.

<sup>52</sup> *ibid* 38.

<sup>53</sup> EGSG (n 6) 67.

<sup>54</sup> *ibid*.

<sup>55</sup> European Parliament and Council Directive 2009/128/EC establishing a framework for Community action to achieve the sustainable use of pesticides [2009] OJ L309/71.

Sustainability is equally complex, demanding the consideration of, amongst other things, the social, economic and environmental, as discussed in Chapter Three. As such, legislation built on the principles of sustainability could provide a powerful and sophisticated framework through which to consider, and respond to, the multiple concerns pesticide use raises. The regulation of pesticides was chosen, therefore, for the opportunity to examine the EU's current approach to sustainability and the potential it provides to increase socio-technical integration in the regulation of a risky technology, a question not previously addressed. Despite its significant potential, risk and safety concerns still dominate the legislation: I argue in Chapter Four that the SUD essentially eschews an interpretation of sustainable use informed by the richness of the sustainability discourse in favour, primarily, of an unambitious understanding of 'sustainable use' as 'risk reduction' and efficiency.

Synthetic biology is an emerging biotechnology. Its great potential is a central theme of EU policy and its alleged promises include speeding up and simplifying processes for producing useful products, improving efficiency and vastly reducing both costs<sup>56</sup> and the uncertainty of traditional biotechnology.<sup>57</sup> It also raises numerous social, economic, ethical, environmental and health-related concerns as well as being characterised by significant uncertainty as to its implications, both beneficial and harmful. Synthetic biology, as argued in Chapter Five, exhibits a fresh enthusiasm for openness and EU policy itself promotes responsible research and innovation (RRI) as a governance framework for synthetic biology. This framework, as discussed in Chapter Three, aims specifically to enhance socio-technical integration in policy- and decision-making. The regime regulating GMOs applies to synthetic biology and has been extensively researched. Indeed, this research has played a significant role in establishing and criticising the primacy of risk in EU

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<sup>56</sup> Commission, *Synthetic Biology: Applying Engineering to Biology* (EUR-OP 2005).

<sup>57</sup> Bernd Giese and others, 'Promising Applications of Synthetic Biology - and How to Avoid Their Potential Pitfalls' in Joachim Boldt (ed), *Synthetic Biology: Metaphors, Worldviews, Ethics, and Law* (Springer VS 2016) 196.

regulation of risky technologies.<sup>58</sup> The growing prominence of RRI represented an opportunity to test the current regulatory regime, in light of a different technology, against recent EU initiatives to enhance socio-technical integration. However, I argue in Chapter Five that the continued dominance of risk undermines realisation of these new initiatives.

#### 4.2 *The broader context*

The features identified in relation to these two examples are part of a larger trend in EU regulation of risky technologies. A survey of all such EU legislation is impossible and unnecessary here. I therefore review academic comment on two other areas of regulation which are not considered subsequently in this thesis but which epitomise the EU's overall approach: chemicals and nanotechnology. It would be, of course, overly simplistic to claim that the EU always and only considers risks to human health and the environment when regulating risky technologies and one should perhaps refrain from asserting that EU governance of biotechnology, for example, is entirely technocratic.<sup>59</sup> A more nuanced picture than sole reliance on risk assessment emerges. This is acknowledged in the literature<sup>60</sup> and instances where other concerns can be considered will be highlighted, particularly in Chapters Four to Seven as well as briefly below. However, safety remains the primary concern in regulation<sup>61</sup> and the use of technical or scientific criteria to define risks (including uncertain risks) remains the primary decision-making tool.<sup>62</sup>

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<sup>58</sup> Lee, *EU Regulation of GMOs* (n 35) ch 3.

<sup>59</sup> Christine Landfried, 'The European Regulation of Biotechnology by Polycratic Governance' in Christian Joerges and Ellen Vos (eds), *EU Committees: Social Regulation, Law and Politics* (Hart 1999); Lee, *EU Regulation of GMOs* (n 35) 103.

<sup>60</sup> For example, in regulation of GMOs, Lee, *EU Regulation of GMOs* (n 35) 80ff; and chemicals, Joanne Scott, 'REACH: Combining Harmonization and Dynamism in the Regulation of Chemicals' in Joanne Scott (ed), *Environmental Protection: European Law and Governance* (OUP 2009).

<sup>61</sup> Lee, 'Risk and beyond' (n 8) 799.

<sup>62</sup> Michelle Everson and Ellen Vos, 'The Scientification of Politics and the Politicisation of Science', *Uncertain Risks Regulated* (Routledge-Cavendish 2009) 3–4.

#### 4.2.1 Chemicals

Chemicals in the EU are governed by the REACH Regulation.<sup>63</sup> Briefly, REACH requires manufacturers or importers seeking market access and which produce or import over one tonne of a chemical per year to apply for registration of that chemical.<sup>64</sup> Where a substance is deemed to be ‘of very high concern’ (SVHC), that substance requires authorisation<sup>65</sup> according to various criteria, including that the risks it poses to human health and the environment are ‘adequately controlled’.<sup>66</sup>

REACH contains a number of positive features from the point of view integrating non-safety values into decision-making. There is scope under REACH, despite the predominantly expert-driven and risk-centric tone of the authorisation process, for the integration of existing risk management information into the science-based risk assessment process, thereby influencing the final risk characterisation<sup>67</sup> and eroding the fact/value dichotomy in some small but arguably important way. However, perhaps the most significant evidence of an effort to move beyond safety and risk assessment is the ability, under Article 60(4), where adequate control is not possible, to authorise a SVHC where the socio-economic benefits of authorisation outweigh the risks to human health and the environment and no suitable alternatives are available. Furthermore, in assessing the availability of alternatives, the Commission, under Article 60(5), is required to consider ‘all relevant aspects’ and ‘the technical and economic feasibility of alternatives’. As Joanne Scott observes, ‘the conditions for authorization are anything but scientific’ and require ‘wide judgment... in balancing costs and benefits’.<sup>68</sup>

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<sup>63</sup> European Parliament and Council Regulation 1907/2006/EC concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) [2006] OJ L33/1.

<sup>64</sup> Art. 6(1) REACH.

<sup>65</sup> Art. 30(2) REACH.

<sup>66</sup> Art. 60(2) REACH.

<sup>67</sup> V Heyvaert, ‘The EU Chemicals Policy: Towards Inclusive Governance?’ in Ellen Vos (ed), *European Risk Governance: Its Science, Its Inclusiveness and Its Effectiveness* (CONNEX 2008) 199–200.

<sup>68</sup> Scott, ‘REACH: Combining Harmonization and Dynamism’ (n 60) 77. Also, Heyvaert (n 67) 200; Lee, ‘Risk and beyond’ (n 8) 812.

However, Article 60(4) only applies to a sub-set of high risk substances.<sup>69</sup> Where a suitable alternative is available, there is no scope to consider the social benefits of either that or the SVHC, which may be a particular problem for nanosubstances subject to REACH.<sup>70</sup> Furthermore, there are concerns the socio-economic analysis will simply allow industry ‘to mitigate any unfavourable indications in the risk assessment’ given the commercial orientation of the concerns emphasised.<sup>71</sup> There is no scope for socio-economic considerations to prevent marketing, and the equivalent provision in relation to the availability of substitutes also works to permit a SVCH.<sup>72</sup> This illustrates the asymmetry mentioned in section 2, leaving intact, as opposed to challenging, the hegemony of risk and suggesting a predisposition towards particular economic interests.<sup>73</sup> Restrictions may be imposed where there is an unacceptable risk to human health or the environment, taking into account the socio-economic impact of the restriction,<sup>74</sup> but ‘the implication seems to be that this is another hurdle to be crossed to impose a restriction rather than a reason for a restriction’.<sup>75</sup>

Other, more general criticisms highlight the overall paucity of opportunities for non-safety concerns to influence decision-making under REACH. Although the consultation leading to REACH has received (qualified) praise for its breadth and inclusivity,<sup>76</sup> REACH itself has been criticised for its poor public participation provisions<sup>77</sup> and for the limited range of actors that can prompt change under REACH by submitting information dossiers.<sup>78</sup> Provision for public participation does not guarantee expression of non-safety concerns or that scientific expertise will be

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<sup>69</sup> Scott, ‘REACH: Combining Harmonization and Dynamism’ (n 60) 79.

<sup>70</sup> RG Lee and S Vaughan, ‘REACHing Down: Nanomaterials and Chemical Safety in the European Union’ (2010) 2 *Law, Innovation and Technology* 193, 214–215.

<sup>71</sup> Heyvaert (n 67) 210–211.

<sup>72</sup> Lee, ‘Risk and beyond’ (n 8) 812.

<sup>73</sup> Maria Lee, ‘The Legal Institutionalisation of Public Participation in the EU Governance of Technology’ (SSRN 2014) 12–13 <[https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=908644](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=908644)> accessed 26 June 2017.

<sup>74</sup> Art. 68(1) REACH.

<sup>75</sup> Lee, ‘Risk and beyond’ (n 8) 812.

<sup>76</sup> Heyvaert (n 67) 197–198, 211–212.

<sup>77</sup> *ibid* 205–206.

<sup>78</sup> Scott, ‘REACH: Combining Harmonization and Dynamism’ (n 60) 75.

challenged by other public forms of knowledge but, without it, any chance for such contributions is absent. Broad conclusions are that there is very little scope for socio-technical integration in the control process. Overall, REACH is 'framed around narrow human health and environmental protection concerns as grounds for limiting availability of chemicals'.<sup>79</sup>

#### 4.2.2 *Nanotechnology*

Nanotechnology is not regulated by its own dedicated regime, but by a sprawling web of regulations covering chemicals, food and cosmetics. Nanomaterials are regulated by REACH and so the criticisms above apply, alongside criticisms specific to its application to nanotechnology.<sup>80</sup> Elen Stokes argues that the wholesale application of existing regulatory regimes, here REACH and EU consumer protection law, designed without nanotechnology in mind, imposes an inappropriate scope and set of assumptions on nanomaterials which prevent scrutiny of the aims and values underlying (or which should underlie) its regulation.<sup>81</sup> In addition, she notes criticism by the European Parliament of the reluctance, in consumer protection legislation, to consider concerns other than risks to safety and the promotion of the internal market over other socio-economic and environmental objectives.<sup>82</sup>

In her wide-ranging studies of regulation relevant to nanotechnology, Lee considers the extent to which, in addition to REACH, the Cosmetics Regulation<sup>83</sup> and the GFL regulate on the basis of social and ethical concerns 'beyond risk'.<sup>84</sup> Her observations are summarised below.

With respect to the GFL, perhaps its most significant feature is the recognition that 'scientific risk assessment alone cannot, in some cases, provide all the information on which a risk management decision should be based' and that 'other factors

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<sup>79</sup> Lee, 'Risk and beyond' (n 8) 813.

<sup>80</sup> For example, Lee and Vaughan (n 70); Elen Stokes, 'Regulating Nanotechnologies: Sizing up the Options' (2009) 29 *Legal Studies* 281, 286–289.

<sup>81</sup> Elen Stokes, 'Nanotechnology and the Products of Inherited Regulation' (2012) 39 *Journal of Law and Society* 93. This idea is explored further in Chapter Five.

<sup>82</sup> *ibid* 106–107.

<sup>83</sup> Regulation 1223/2009 on cosmetic products (recast) [2009] OJ L342/59.

<sup>84</sup> Lee, 'Risk and beyond' (n 8); Lee, 'Beyond Safety?' (n 12).

relevant to the matter under consideration should legitimately be taken into account'.<sup>85</sup> This works alongside the requirement, in Article 6(3), that risk management decisions take into account, alongside the results of the risk assessment and the opinion of EFSA, 'other factors legitimate to the matter under consideration'. Other legitimate factors hold great potential, for example enabling 'the regulator to take account of, and explain a decision by reference to, the likely impacts of corporate control and industrialization of the food industry', 'the scale of uncertainty and ignorance'<sup>86</sup> or even the outcomes of innovation governance activities (see Chapter Five).

However, the legal context ultimately 'limits the scope of 'other legitimate factors'' and otherwise 'constrains the openness of policy-making and legislation,<sup>87</sup> due to the following factors. The GFL aims to ensure the effective functioning of the internal market and the protection of human health; exercising power for other purposes would be unlawful.<sup>88</sup> The GFL also seeks to protect consumers which could provide a chink through which the ray of other concerns could shine. However, the consumer interests listed in Article 8 GFL are narrow, and relate mainly to deceiving or misleading the consumer and the adulteration of food. In general, the GFL prioritises human health and, even though food regulation achieves a degree of openness with its reference to other legitimate factors, 'there are enormous legal incentives to frame decisions in terms of safety assessments'.<sup>89</sup> Amongst these legal incentives too are the EU's approach to the precautionary principle which conceives uncertainty narrowly and privileges scientific and technical information,<sup>90</sup> and EU case law, which also incentivises 'the explanation

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<sup>85</sup> Recital 88 GFL. Lee, 'Beyond Safety?' (n 12) 263.

<sup>86</sup> *ibid* 264.

<sup>87</sup> *ibid* 268.

<sup>88</sup> *ibid* 265.

<sup>89</sup> Lee, 'Risk and beyond' (n 8) 816–817.

<sup>90</sup> See also, Naomi Salmon, 'What's Cooking? From GM Food to Nanofood: Regulating Risk and Trade in Europe' (2009) 11 *Environmental L Rev* 97.

of decisions by reference to (perhaps minority) scientific evidence',<sup>91</sup> discussed further in Chapter Six.

Turning briefly to the Cosmetics Regulation, Lee identifies an acceptance that more flexibility may be required to deal with uncertainty surrounding nanomaterials.<sup>92</sup> She also praises the regulation for its obligation to indicate ingredients which are nanomaterials, enabling consumers to 'make judgments on ethical and social issues as well as issues of personal risk' thereby taking a 'step towards addressing ethical and social commitments in the regulation of nanotechnology'.<sup>93</sup> However, labelling may struggle to fulfil its various policy goals for various reasons including a lack of information supporting consumer choice and low consumer awareness.<sup>94</sup> Furthermore, it is not possible to label for purposes other than safety and individual consumer choice, of course, cannot 'respond fully to the collective ethical issues around nanotechnology'.<sup>95</sup> Stokes argues that without engagement or further information, the label 'nano' alone 'does little to enable consumers meaningfully to differentiate between nano and non-nano products, whether on the grounds of risk, uncertainty or any other social or ethical repercussions'; it does however, enable their commercialisation and normalisation through trade on the regular market.<sup>96</sup> On the regulation of nanotechnology in general: '[t]he regulation leaves little if any space for consideration of... broader social and ethical issues...'.<sup>97</sup>

Scientifically-defined safety appears to be the dominant value, operating in support of narrow economic (primarily commercial/market) values, by minimising the restriction of economic or commercial activity by regulation to that necessary to ensure safety and environmental protection. However, there remains reason for optimism that non-safety values may compete with such narrow economic values

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<sup>91</sup> Lee, *EU Regulation of GMOs* (n 35) 87–88.

<sup>92</sup> Lee, 'Risk and beyond' (n 8) 814.

<sup>93</sup> *ibid.*

<sup>94</sup> In relation to labelling nano foods, Elen Stokes, 'You Are What You Eat: Market Citizens and the Right to Know about Nano Foods' (2011) 2 *Journal of Human Rights and the Environment* 178.

<sup>95</sup> Lee, 'Risk and beyond' (n 8) 814–815.

<sup>96</sup> Stokes, 'Nanotechnology' (n 81) 111.

<sup>97</sup> Lee, 'Risk and beyond' (n 8) 807.

and even that non-safety values may influence risk assessment. The internal market is still the EU's core project<sup>98</sup> but the EU does explicitly espouse other, non-market policy goals which project beyond the arguable minimalism of health and environmental protection. Article 2 TFEU mentions *inter alia*, democracy, equality, pluralism, non-discrimination and justice. Article 3(3) TEU commits the EU to working for 'the sustainable development of Europe based on balanced economic growth and price stability, a highly competitive social market economy, aiming at full employment and social progress'. Other social aims expressed here include combating 'social exclusion and discrimination, and [promoting] social justice and protection, equality between women and men, solidarity between generations and protection of the rights of the child'.

The crucial point is that these admittedly broad-brush and vague aims indicate, at minimum, the existence of a space, sanctioned at the highest political and legal level, in which the acknowledgement, discussion and pursuit of non-safety and non-economic policy goals is entirely valid. Perhaps even required.

## 5. Methodology

This thesis sits within the field of environmental law scholarship. It therefore encountered several of the methodological challenges faced by environmental law scholars, particularly the difficulty of identifying a single, appropriate methodology.<sup>99</sup> The primary challenge has been the interdisciplinary nature of the subject.<sup>100</sup> Though legal scholarship, this thesis is interdisciplinary in that I have drawn on knowledge and conceptualisations from disciplines outside legal academia,<sup>101</sup> primarily the social sciences. Environmental law also transcends

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<sup>98</sup> Jukka Snell, 'The Internal Market and the Philosophies of Market Integration' in Catherine Barnard and Steve Peers (eds), *European Union Law* (OUP 2014).

<sup>99</sup> Elizabeth Fisher and others, 'Maturity and Methodology: Starting a Debate about Environmental Law Scholarship' (2009) 21 *Journal of Environmental Law* 213.

<sup>100</sup> *ibid* 231–235.

<sup>101</sup> Ole W Pedersen, 'The Limits of Interdisciplinarity and the Practice of Environmental Law Scholarship' (2014) 26 *Journal of Environmental Law* 423, 242–245 and references therein.

traditional legal disciplinary boundaries<sup>102</sup> and I have, accordingly, drawn on other legal sub-disciplines, such as administrative law and trade law.

I approached the question at the heart of this thesis – why does the policy-practice gap persist? – in two stages. Firstly, I sought to understand the nature of the gap; evidence of its existence, where it has been articulated and the scholarly basis for its articulation. This enquiry entailed textual analysis of EU policy ambitions for the governance and regulation of risky technologies. It also required engagement with legal, and other, scholarship on the primacy of risk in EU regulation of risky technologies. Finally, though the thesis does not aim to contribute to STS research, it required interactional expertise<sup>103</sup> in STS, acquired through extensive reading in this field.

STS concerns the relationship between society, science and technology. It is, itself, profoundly interdisciplinary, encompassing sociology, history, philosophy, politics, law, economics and anthropology.<sup>104</sup> Space prevents a full exposition of its precepts. In brief, however, much STS scholarship takes a social constructivist<sup>105</sup> approach to science and technology which rejects a model of science as provider of privileged methods which translate nature into knowledge.<sup>106</sup> Rather, it sees scientific knowledge and technological artefacts as socially constructed.<sup>107</sup> It thus, more or less, rejects realist arguments that ‘truths are more dependent upon the natural world than upon the people who articulate them’<sup>108</sup> and looks to the social realm to account for scientific knowledge or facts.<sup>109</sup> Likewise, it rejects a

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<sup>102</sup> Fisher and others (n 99) 230.

<sup>103</sup> *ibid* 232; HM Collins and Robert Evans, ‘The Third Wave of Science Studies: Studies of Expertise and Experience’ (2002) 32 *Social Studies of Science* 235, 254–256.

<sup>104</sup> Sheila Jasanoff, ‘The Idiom of Co-Production’ in Sheila Jasanoff (ed), *States of Knowledge: The Co-production of Science and Social Order* (Routledge 2010) 2.

<sup>105</sup> The term ‘social constructionist’ is also used. The concept in itself is problematic for STS, Sheila Jasanoff, ‘Ordering Knowledge, Ordering Society’ in Sheila Jasanoff (ed), *States of Knowledge: The Co-production of Science and Social Order* (Routledge 2010) 19–20.

<sup>106</sup> Jasanoff, ‘The Idiom of Co-Production’ (n 104) 3.

<sup>107</sup> Sismondo (n 23) 11.

<sup>108</sup> *ibid* 58.

<sup>109</sup> For example, David Bloor, ‘The Strengths of the Strong Programme’ (1981) 11 *Philosophy of the Social Sciences* 199.

technological determinist account of history, according to which technological change drives social change.<sup>110</sup> In co-productionist terms, knowledge and artefacts both arise from, and constitute, society; natural and social orders are produced in conjunction.<sup>111</sup> These notions underpin much STS scholarship.

This thesis however, mines a much more specific seam of STS scholarship concerning public attitudes to risk, which criticises an (over-)emphasis on scientific assessments of risk in the governance of technologies. While this literature may be less esoteric and more practice-orientated than that just mentioned, its theoretical, constructivist foundations are clear and crucial to my argument, particularly the connection between a rejection of technological determinism and a faith in the ability of public engagement to influence technological trajectories. Together they form the framework I adopt to explain and understand concepts central to this thesis (science, scientific knowledge, technology, risk, public attitudes etc.) and which I use to criticise the EU's attempts (or lack thereof) to respond meaningfully to the findings of STS scholarship in its regulation of risky technologies.

The second stage of my analysis sought to answer the question posed by this thesis by employing three different analytical angles. Firstly, I selected, as examples, two technologies and their surrounding policy and regulatory frameworks to enable concrete examination of the gap and reasons for its persistence. These technologies were chosen for the reasons described in section 4.1 and offer helpful insights into the gap's persistence in the different, but complementary, conclusions drawn.

I approached the analysis of each technology as follows. Initially, drawing on (non-legal/STS) scholarship, policy (including documents produced or commissioned by EU institutions, such as Commission communications or agency opinions) and other grey literature, I sought to understand the technologies themselves and associated risks and concerns. Next, I engaged in doctrinal analysis of the relevant law. This, partly descriptive work, consisted primarily of analysis of legislation in light of the

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<sup>110</sup> Jasanoff, 'Ordering Knowledge' (n 105) 16.

<sup>111</sup> Jasanoff, 'The Idiom of Co-Production' (n 104) 2–3; Jasanoff, 'Ordering Knowledge' (n 105).

EU's policy ambitions in order to measure the capacity of the legislation to implement those ambitions. Finally, I re-contextualised the regulation of each technology in a broader policy framework and, drawing on both policy and academic literature, identified reasons, within the specific policy areas, for the gap.

Technologies are traded. I therefore chose, as my second angle, both EU internal market law and WTO law. This involved doctrinal analysis of primary legal sources: relevant treaty provisions and case law. The method of analysis applied to both regulation and trade law constituted problem-based doctrinal analysis in that it analysed, synthesised, interpreted and evaluated a body of primary legal material in terms of its application to existing and hypothetical problems of controlling technological innovation.<sup>112</sup> It adopted, in addition, an 'external approach' to such analysis. This concerns the study of law in practice – in a social, economic and political context – and sees legal systems as partly determined by external forces.<sup>113</sup> As such, the analysis was strongly informed by STS literature and my own research into pesticides and synthetic biology regulation.

Reasons for the gap remaining evaporate at the boundaries of neither technology-specific regulation nor trading regimes; these too sit in context. Maintaining the external approach, for my third angle therefore, I chose the realm of ideas. To keep this, potentially limitless, enquiry manageable, I restricted my starting point to EU innovation policy ambitions. Drawing on STS and political science, I used the concepts of imaginaries and master narratives to understand the power of these policy ambitions and the role such ideational factors play in maintaining the gap.

Structurally, the first stage corresponds roughly to Section I and the second stage to Sections II and III. However, both stages of the enquiry informed each other and the analysis contained in Sections II and III corroborates the arguments in Section I.

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<sup>112</sup> Terry Hutchinson and Nigel Duncan, 'Defining and Describing What We Do: Doctrinal Legal Research' (2012) 17 *Deakin Law Review* 83, 101–106, 110–113.

<sup>113</sup> JC McCrudden, 'Legal Research and the Social Sciences' (2006) 122 *The Law Quarterly Review* 632, 633–634, 636–641.

My argument is not simply that the law should ‘solve’ a particular societal problem.<sup>114</sup> It is rather that the law, as currently constituted, undermines the EU’s own ambitions to solve a problem it has acknowledged. I make the assumption that the law can contribute to fulfilling these ambitions and in this sense view the law instrumentally. However, my argument and criticism of the current law is strongly normative and points towards change, though no explicit recommendations are made. Due to the significant STS influence permeating my doctrinal analysis and pervasive reference to the policy context, though not empirical, the thesis can be described as a socio-legal<sup>115</sup> endeavour.

## 6. Scope

Due to limitations of space, this thesis cannot, of course, present a comprehensive discussion of every area of potential interest and relevance to its main subject matter. Firstly, I concentrate my criticisms of the use of regulatory science in decision-making on scientific risk assessment. However, I am aware of the existence of other reductive decision-making techniques, such as cost-benefit analysis (CBA), which may also play a role in regulating technology. Risk assessment and CBA are closely related and exhibit similar difficulties associated with the privileging of technical expertise in decision-making.<sup>116</sup> However, this thesis is specifically concerned with the kinds of considerations (other than science-backed safety concerns) which decision-makers may take into account when regulating risky technologies and the degree to which regulatory science itself may be opened up to other values, perspectives and framings as opposed to balancing costs and benefits. Furthermore, risk is the primary decision-making technique for the two technologies I discuss in detail in this thesis. For these reasons, I have restricted the decision-making techniques examined to risk assessment.

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<sup>114</sup> Rob van Gestel and Hans-Wolfgang Micklitz, ‘Why Methods Matter in European Legal Scholarship’ (2014) 20 *European Law Journal* 292, 301.

<sup>115</sup> McCrudden (n 113) 637–638.

<sup>116</sup> Lee, *EU Environmental Law* (n 51) 29–38.

Secondly, both technologies have agricultural applications. I acknowledge their connections with agriculture, particularly in Chapter Four. However, I have refrained from engaging in-depth with the EU's legal and policy framework on agriculture, primarily due to its sheer size and complexity. I chose these technologies as illustrative examples for reasons other than their connection to agriculture, as described in section 4.1. Furthermore, pesticides, and particularly the 2009 regulatory regime, are currently under-examined, representing an opportunity to initiate discussions in this field.

Thirdly, the SUD has a twin: the Plant Protection Product Regulation (PPPR).<sup>117</sup> I decline to discuss the latter. The relationship between the two instruments is undoubtedly a matter worthy of further research, not least into the extent to which the PPPR may support or undermine achievement of sustainable pesticide use. However, breadth would have sacrificed depth in that a single chapter could not deliver an analysis of both instruments and sustainability in satisfactory detail.

Fourthly, I occasionally allude to the place and importance of intellectual property in relation to technological innovation, particularly biotechnology. Indeed, the growth of this field has been partly attributed to the landmark US case of *Diamond v Chakrabarty*<sup>118</sup> which provided that living organisms could be patented.<sup>119</sup> Arguments for strong IP protection are central to the knowledge-based economy discussed in Chapter Eight and IP protection forms part, increasingly perhaps, of the political economy of technoscience.<sup>120</sup> Patent law also provides, controversially,<sup>121</sup> another forum for political contestation over the rights and wrongs of biotechnology.<sup>122</sup> However, other than brief mentions, particularly in Chapters Three and Five, I have not engaged further with this field. My intention is to

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<sup>117</sup> European Parliament and Council Regulation 1107/2009/EC concerning the placing of plant protection products on the market [2009] OJ L309/1.

<sup>118</sup> *Diamond v Chakrabarty* 447 US 202, 100 S Ct 2204.

<sup>119</sup> For discussion, see Jasanoff, *Designs on Nature* (n 11) ch 8.

<sup>120</sup> R Lave, P Mirowski and S Randalls, 'Introduction: STS and Neoliberal Science' (2010) 40 *Social Studies of Science* 659.

<sup>121</sup> Julia Black, 'Regulation as Facilitation: Negotiating the Genetic Revolution' (1998) 61 *The Modern Law Review* 621, 644–650.

<sup>122</sup> Lee, *EU Regulation of GMOs* (n 35) ch 5.

maintain a strict focus on regulation which governs the authorisation and use of technologies as this is where the policy-practice gap I am interested in lies. It would be a different and ambitious thesis indeed which sought to encompass other forums for decision-making.

Finally, as discussed, much of the analysis in this thesis is influenced by elements of social constructivist thinking, specifically in relation to technology,<sup>123</sup> and the sociology of scientific knowledge.<sup>124</sup> Indeed, this thinking is fundamental to my final argument in Chapter Nine that we have a choice with respect to the kinds of technology we, as a society, develop<sup>125</sup> and the shape of the markets we allow to distribute them.<sup>126</sup> These are questions whose inherently political nature perhaps appears denied by much of the policy examined in Chapter Eight but which contribute to inspiring calls for participation in decision-making.<sup>127</sup> However, I include no discrete analysis of social constructivism or the sociology of scientific knowledge *per se*. Many of their precepts, as elucidated by STS, already form the well-established foundations of scholarship on risk regulation to which this thesis contributes. They find implicit acceptance in the vast majority of such scholarship cited hereafter which consistently highlights the need to acknowledge the ‘social constructedness’ of the regulatory science employed to aid governance of technology. Given this context, a general exposition of social constructivist thought is not vital to the following discussion.

The law and policy is up to date as at 31 December 2016, although some later developments are included.

## 7. The structure of this thesis

The arguments of this thesis, as indicated above, rest on three foundations. Section 4 above, established the third foundation. Chapter Two discusses the

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<sup>123</sup> For example, Bijker (n 22).

<sup>124</sup> For example, *ibid* 75–76, 270.

<sup>125</sup> *ibid* 280.

<sup>126</sup> For a discussion of three different models, see Snell (n 98).

<sup>127</sup> Bijker (n 22) 281.

arguments behind the normative claims in the first foundation. It reviews STS (and related) literature which criticises risk assessment as a regulatory tool, contextualised in the broader relationship between science and society both in general, and more specifically, in relation to risk. The review examines the appeal of risk-based governance methods and gives an account of the now (academically) uncontroversial conclusion that risk assessment is not necessarily the value-free and objective endeavour it has been touted as.<sup>128</sup> It identifies the importance of values both in assessing risk and in governing technologies. This forms a basis for picking out certain problems and problematic assumptions embedded in the current paradigm of risk governance in the EU, for example the narrowness of risk assessment as a decision-making tool and the tendency to reduce all concerns about a technology to questions of safety resolvable by science,<sup>129</sup> often combined with a lack of acknowledgment of the diversity of values and concerns which constitute individual or societal attitudes to risk. This chapter does not aim to break new ground but rather provides context and acts as a springboard into the analysis and arguments contained in the rest of the thesis.

Chapter Three establishes the second foundation, i.e. that EU policy relating to the governance of risky technologies displays a commitment to socio-technical integration. It does so through a survey of European policy, specifically concerning pesticide use and synthetic biology. It also considers European innovation policy more broadly, highlighting the relevance of innovation governance for downstream risk regulation. In relation to synthetic biology, it focuses on the EU's adoption of 'Responsible Research and Innovation' (RRI) as a governance framework for synthetic biology.<sup>130</sup> It argues that this approach demonstrates a general commitment to opening up a range of synthetic biology-specific concerns to early and ongoing public debate and greater socio-technical integration. In relation to pesticides, it argues that a commitment to exploring both the social and economic

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<sup>128</sup> Royal Society (n 5) 97.

<sup>129</sup> EGSG (n 6) 31.

<sup>130</sup> DG SANCO, 'Synthetic Biology: From Science to Governance' (2010) 15; ERASynBio, 'Next Steps for European Synthetic Biology: A Strategic Vision from ERASynBio' (2014).

dimensions in the broadest terms, as well as the environmental dimension of the technology, is implicit in the EU's employment of the language of sustainability in the relevant policy and legislation.

Section II comprises Chapters Four and Five which discuss pesticide use and synthetic biology regulation respectively. Together, they bolster the third foundation of this thesis and identify some technology-specific reasons for the persistence of the policy-practice gap.

Chapter Four provides an in-depth examination of one of the primary pieces of legislation regulating pesticides in the European Union: the SUD. It discusses the various problems and concerns related to pesticide use. It recalls the argument in Chapter Three that employment of the language of 'sustainability' implies that the elements commonly associated with sustainability will influence the regulation of pesticides under this Directive. Finally, it examines the detail of the SUD in light of the foregoing discussions. It argues that while there is some flexibility and potential for consideration of broader issues, the unambitious approach taken, which equates sustainable use with risk reduction and efficiency, overall limits potential for the substance of decision-making under this directive to reflect the various elements of sustainability and therefore represents a failure by the EU to close, or even narrow, the policy-practice gap. It attributes this failure to, amongst other things, the narrowness of the consultation process leading to the SUD and the EU's current overall lack of ambition for sustainable development.

Chapter Five reviews the current regulatory regime governing synthetic biology and, with reference to the EU's policy ambitions discussed in Chapter Three, assesses the potential of the regime to meet those ambitions. The chapter focuses on opportunities for public and other stakeholder participation as the main legislative instrument capable of implementing the principles of RRI, in addition to other opportunities for values other than safety to influence decision-making processes. I argue that the legislation examined cannot implement the EU's policy ambitions, primarily due to the weakness of its provision for participation. Returning to policy, I argue that overall confusion as to the goals of participation in the governance of synthetic biology renders it unlikely that legislation will be

amended to reflect increased ambition. That confusion, I argue, is exacerbated by the fact that discussion relating to the governance and regulation of synthetic biology is conditioned by its inheritance of a regime designed for a different technology<sup>131</sup> which further restricts opportunities to enhance socio-technical integration.

Section III comprises Chapters Six, Seven and Eight, which present an analysis of reasons for the persistence of the policy-practice gap from the angles of trade law and the ideational context.

Chapter Six tackles the EU internal market and focuses on opportunities in internal market law for Member States to regulate on the basis of a range of social values and uncertainty through analysis of Articles 36 and 114 TFEU, the mandatory requirements<sup>132</sup> and the precautionary principle. It considers the degree to which these provisions restrict or support socio-technical integration. It argues that when adjudicating a Member State's justification for maintaining a trade-restrictive measure, the EU Courts tend to grant scientific or technical expertise priority of agency in determining whether a problem justifying regulation actually exists. This approach pre-empts the use of other forms of (non-scientific) evidence and reasoning as to the existence of a problem, inhibiting fulfilment of the EU's policy commitments discussed in Chapter Three and reinforcing the policy-practice gap.

Chapter Seven considers the World Trade Organisation rules within which EU risk regulation regimes operate. Focusing on the General Agreement on Tariffs and Trade (GATT), the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPSA), the Technical Barriers to Trade Agreement (TBTA) and associated case law it performs a similar analysis to that in the previous chapter. It examines, in particular, scope to restrict trade in risky technologies for reasons other than

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<sup>131</sup> Elen Stokes, 'Recombinant Regulation: EU Executive Power and Expertise in Responding to Synthetic Biology' in A De Ruijter and M Weimer (eds), *Regulating Risks in the European Union: The Co-Production of Expert and Executive Power* (Hart forthcoming) (manuscript on file with author).

<sup>132</sup> Case 120/78 *Rewe-Zentral AG v Bundesmonopolverwaltung für Branntwein (Cassis de Dijon)* [1979] ECR 649.

safety, such as public morals or on the basis of scientific evidence inflected by the culture, values and concerns of the regulating Member. I argue that, while the GATT and TBTA recognise a broad range of justifications for national regulation, their availability may still be restricted. With respect to the SPSA, there is little scope for the EU to justify its regulation on the basis of risk assessment as defined by its own values and concerns. I argue that in these ways, the interpretation of these agreements contributes to constraining the EU's own progress towards closing the policy-practice gap.

Chapter Eight examines reasons, outside the realm of regulation and trade law, for the difficulty in closing the policy-practice gap. I focus almost exclusively on analysing EU policy on innovation, governance and the regulation of technology in order to describe the ideational context for the EU's approach to regulating risky technologies. I save the analysis of the relationship between this context and the law examined in the rest of the thesis for Chapter Nine. I use this policy analysis to construct a picture of the EU's ambitions by identifying various imaginaries and master narratives which permeate EU policy. I argue that the EU is committed to the idea that its future survival and success depend upon economic competitiveness and growth which in turn are contingent upon science and technological innovation and a well-functioning internal market. Furthermore, this commitment is reinforced by the depoliticising effect of these imaginaries and narratives and their potential to shut down wider democratic debate on, for example, what the future of Europe should be and the direction research and innovation should take.<sup>133</sup> Instead, a narrow debate about safety in relation to specific technologies<sup>134</sup> occurs in which regulatory science is granted priority of agency in identifying which implications of technological innovation warrant a regulatory response. Implicit in these arguments is the contention that while EU policy presents its vision as the only option for its future, the direction it pursues is still very much a matter of choice.

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<sup>133</sup> EGSG (n 6) 76.

<sup>134</sup> Kearnes and others (n 4) 302.

Chapter Nine attempts to demonstrate the manifestation of the EU's commitments discussed in Chapter Eight in the fine detail of the policy and legislation explored in Chapters Three to Five. I argue it is these commitments to which we may, at least partially, ascribe the lack of ambition in these fields and locate the source of obstacles to greater socio-technical integration, deriving therefrom an explanation for the persistence of the policy-practice gap. With respect to pesticides, I link the EU's overarching commitment to the reconciliation of environmental and social/economic goals through innovation-aided resource efficiency, discussed in Chapter Eight, with its equation of sustainability with risk reduction and efficiency identified in the policy and regulation of pesticide use. With respect to synthetic biology, I link the EU's commitment to an imaginary of governable emergence of innovation and search for consensus, discussed in Chapter Eight, with the priority of agency granted to science to define problems worth regulating and the narrow provision for, and expectations of, public participation established in the policy and legislation. I also highlight broader themes and patterns pervading EU policy on innovation, governance and technology which contribute to maintaining the policy-practice gap. Much of the analysis throughout the thesis, particularly Chapter Eight, shows or implies the difficulty of taking substantive steps towards realising the EU's commitment to increasing socio-technical integration due to, for example, the longevity, appeal and resilience of its commitment to innovation and its commercialisation as guarantor of future well-being. However, this chapter concludes by highlighting the potential for change enlivened by an inextinguishable flame of choice.

SECTION I – TALKING THE TALK: EUROPEAN POLICY ON GOVERNING  
'RISKY TECHNOLOGIES'

## Chapter Two – Setting the scene: insights into risk regulation from science and technology studies

### 1. Introduction

In the preceding chapter, I set out my overarching argument that there is typically a gap between the EU's policy and practice in its regulation of risky technologies. In that chapter, I argued that the EU's approach to regulating risky technologies is primarily based on risk assessment. This chapter discusses the critical light shed on risk as a regulatory tool and on the risk assessment exercise itself, by social science research, particularly STS. It gives an account of the scholarly basis for, and content of, the position I contend EU *policy* on risky technologies has accepted but which its practice does not implement. The chapter is structured as follows. Section 2 concentrates on risk and risk assessment. It discusses the origins and development of these concepts and their popularity through an account of their perceived benefits and advantages for regulation.

Section 3 presents a summary of the criticisms of risk assessment resulting from social scientific research over the last few decades. Firstly, it discusses the formation of public attitudes to science and technology, demonstrating the vast range of public concerns and values typically ignored by the reductive pictures of risks obtainable from scientific risk assessment. Secondly, it scrutinises claims that risk assessment provides an objective, neutral and therefore rational representation of reality. Thirdly, it discusses the inability of risk assessment to deal with the uncertainty and unpredictability endemic in the interactions between technology and the social world<sup>135</sup> and environment.<sup>136</sup> Finally, it looks outside assessing physical risks to questions of trust in matters of science and technology governance which indicate the need not only to improve and broaden our understanding of risk, but also to pay attention to the relationships between publics and institutions.

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<sup>135</sup> Brian Wynne, 'Uncertainty and Environmental Learning: Reconceiving Science and Policy in the Preventive Paradigm' (1992) 2 *Global Environmental Change* 111.

<sup>136</sup> Fisher, 'Risk and Environmental Law' (n 17) 99.

Section 4 contains a brief account of changes which have occurred in response to the criticisms in section 3. It charts developments in the relationship between science and society in preparation for discussion of European policy on these matters in Chapter Three. Section 5 concludes.

## 2. Risk assessment

### 2.1 *The meaning and growth of risk and risk assessment*

The definition of 'risk' is not, in itself, straightforward or uncontroversial. Ten different formal definitions of 'risk' have been identified.<sup>137</sup> With regard to environmental risks, risk can be defined as the probability of an identified hazard occurring<sup>138</sup> and 'hazard' as 'the situation that in particular circumstances could lead to harm or damage'.<sup>139</sup> Likewise, there is no monolithic understanding of risk assessment. Techniques of risk assessment have developed differently for different risks.<sup>140</sup> It is defined in many different ways depending on context, not just scientific but institutional and socio-political too.<sup>141</sup> Risk assessment here means a scientific, probabilistic analysis, which in the EU, is divided into four stages:<sup>142</sup> (1) hazard identification, defined as 'identifying the biological, chemical or physical agents that may have adverse effects'; (2) hazard characterisation, defined as determining 'the nature and severity of the adverse effects' of those agents; (3) appraisal of exposure, defined as evaluating the probability of exposure to the agent of the relevant population or the environment; and (4) risk characterisation, defined as

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<sup>137</sup> Royal Society (n 5) 94.

<sup>138</sup> For example Henry Rothstein, Michael Huber and George Gaskell, 'A Theory of Risk Colonization: The Spiralling Regulatory Logics of Societal and Institutional Risk' (2006) 35 *Economy and Society* 91, 106.

<sup>139</sup> Royal Society (n 5) 3.

<sup>140</sup> Fisher, 'Risk and Environmental Law' (n 17) 109.

<sup>141</sup> *ibid* 97, 109–110, 114.

<sup>142</sup> For a brief description of how an environmental risk assessment might be conducted, see Peter Calow, 'Environmental Risk Assessment and Management: The Whats, Whys and Hows?' in Peter Calow (ed), *Handbook of Environmental Risk Assessment and Management* (Blackwell Science 1998) 2–4.

estimating the probability, frequency and severity 'of the known or potential adverse environmental or health effects liable to occur'.<sup>143</sup>

The popularity of risk-based governance can be traced to the Victorian predilection for measurement and quantification, which returned, post-World War II, as renewed enthusiasm for rationality and measurement,<sup>144</sup> perhaps reflecting the increasing authority of quantification and measurement in the West over the last two centuries.<sup>145</sup> Probabilistic risk assessment techniques themselves have their origins in various different industries, including finance and insurance and engineering, in assessments of risk and safety problems arising out of for example, mercantile shipping, or the design and control of chemical or nuclear plants.<sup>146</sup> These were regarded, at least initially, as well defined and well bounded human activities and therefore amenable to scientific analyses of risk.<sup>147</sup> Such quantification exercises were also extended, in the USA, to new problems; assessing the risk of cancer from increasing environmental pollution, or ecosystem disruptions.<sup>148</sup>

Risk assessment came to be specifically encouraged in US agencies in the second half of the 20<sup>th</sup> century as a way of making decision-making 'more objective and 'rational' and therefore more accountable and effective', in a society increasingly concerned with over-regulation.<sup>149</sup> At the end of the 1970s, a US Supreme Court

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<sup>143</sup> Commission, 'Communication on the Precautionary Principle' (n 32) 14, 29.

<sup>144</sup> Rothstein, Huber and Gaskell (n 138) 94.

<sup>145</sup> Theodore M Porter, *Trust in Numbers: The Pursuit of Objectivity in Science and Public Life* (Princeton UP 1995) 74.

<sup>146</sup> Brian Wynne, 'Risk as Globalizing "Democratic" Discourse? Framing Subjects and Citizens' in Melissa Leach, Ian Scoones and Brian Wynne (eds), *Science and Citizens: Globalization and the Challenge of Engagement* (Zed Books 2005) 70–71; Wynne, 'Uncertainty and Environmental Learning' (n 135) 113; Rothstein, Huber and Gaskell (n 138) 98–99; Fisher, 'Risk and Environmental Law' (n 17) 109.

<sup>147</sup> Wynne, 'Uncertainty and Environmental Learning' (n 135) 113.

<sup>148</sup> Sheila Jasanoff, 'The Practices of Objectivity in Regulatory Science' in Charles Camic, Neil Gross and Michèle Lamont (eds), *Social Knowledge in the Making* (University of Chicago Press 2011) 317; Jasanoff, *Designs on Nature* (n 11) 265.

<sup>149</sup> Fisher, 'Risk and Environmental Law' (n 17) 104; Jasanoff, 'Practices of Objectivity' (n 148) 317.

decision made risk central to regulation.<sup>150</sup> The growing scientific ‘look’ of risk assessment was subsequently promoted in the US National Research Council’s (NRC) 1983 ‘Red Book’. This report concluded that there should be a clear conceptual distinction, in regulatory decision-making, between scientific risk assessment, which would disclose objective ‘facts’ regarding risks, and ‘political’ risk management, during which expression of values would be appropriate in deciding whether or not to accept a risk and how that risk might be managed. That distinction, it was believed, would guarantee the objectivity of decision-making.<sup>151</sup> The NRC’s statement of the role of risk assessment in environmental regulation came to be authoritative<sup>152</sup> and is reflected in the Commission’s risk assessment structure, described above.<sup>153</sup> More generally, the dichotomies established then, between facts and values, subjectivity and objectivity and risk assessment and risk management persist in the European model of risk regulation, as discussed in Chapter One.

## 2.2 *The appeal of numbers*

The above brief history of the development of risk assessment already hints at some of the reasons behind its appeal. Firstly, it was promoted for its perceived ability to legitimise new US regulatory agencies, for example the Environmental Protection Agency. This perceived ability may also appeal to the European political institutions,<sup>154</sup> as may quantification generally for its ability to create a unified environment out of disparate cultures with ‘systematic and rational methods’.<sup>155</sup> Framing actions and decisions as ‘risk-based’ is a useful method of gaining

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<sup>150</sup> Fisher, ‘Risk and Environmental Law’ (n 17) 105.

<sup>151</sup> Jasanoff, *Designs on Nature* (n 11) 265–266; Fisher, ‘Risk and Environmental Law’ (n 17) 105; Royal Society (n 5) 5.

<sup>152</sup> Fisher, ‘Risk and Environmental Law’ (n 17) 105.

<sup>153</sup> *ibid* 121.

<sup>154</sup> Lee, *EU Environmental Law* (n 51) 54; Fisher, ‘Risk and Environmental Law’ (n 17) 107.

<sup>155</sup> Porter (n 145) 77. For an account of this phenomenon and resistance to it within the EU, see Claire Waterton and Brian Wynne, ‘Knowledge and Political Order in the European Environment Agency’ in Sheila Jasanoff (ed), *States of Knowledge: The Co-production of Science and Social Order* (Routledge 2010).

legitimacy for a regulatory actor by creating a ‘sense of strategy and control’<sup>156</sup> and for ‘...rationalizing the practical limits of what regulation can achieve and rendering given degrees of regulatory failure acceptable’.<sup>157</sup> Thus it can also be seen as a response to demands for accountability and justification in political and regulatory decision-making, and the result of increasing public, executive, judicial and public scrutiny of such decisions.<sup>158</sup> Set against the political extremes of the 20<sup>th</sup> Century, objective public knowledge was regarded as the best protection against arbitrary political power.<sup>159</sup> Furthermore, risk, by transforming decision-making into a probabilistic assessment of success and failure, compensates for the uncertainties which result from our inevitably limited knowledge. Risk-based regulation can allocate blame and set out those risks which it is reasonable to require an agency to prevent.<sup>160</sup> Risk assessment may be used in conjunction with, or alongside, other regulatory tools based on technical expertise such as CBA.

Secondly, its legitimising power stems from the understanding of risk assessment as provider of ‘objective facts’,<sup>161</sup> a perception itself inherited from an understanding of science generally as disinterested discloser of trustworthy, neutral and universal knowledge about nature.<sup>162</sup> These ‘facts’ are valued as a ‘common metric by which competing social goods... can be compared in an apparently simple and objective way’.<sup>163</sup> Numbers and the neutral language of risk assessment can speak across different viewpoints and cultural contexts and provide a ‘universal justification of action’.<sup>164</sup> The appearance of mirroring reality places authority founded on ‘objective facts’ beyond contestation,<sup>165</sup> and gives the

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<sup>156</sup> Julia Black, ‘The Emergence of Risk-Based Regulation and the New Public Risk Management in the United Kingdom’ [2005] Public Law 512, 519.

<sup>157</sup> Rothstein, Huber and Gaskell (n 138) 100.

<sup>158</sup> Black (n 156) 522.

<sup>159</sup> Ezrahi (n 45) 273.

<sup>160</sup> Black (n 156) 522.

<sup>161</sup> Jasanoff, ‘Practices of Objectivity’ (n 148) 317–319.

<sup>162</sup> Sismondo (n 23) 58; Porter (n 145) 218–219.

<sup>163</sup> Lee, *EU Environmental Law* (n 51) 37.

<sup>164</sup> *ibid* 54.

<sup>165</sup> Jasanoff, ‘Practices of Objectivity’ (n 148) 335.

impression of reliability.<sup>166</sup> It may also contribute to stabilising policy-relevant knowledge;<sup>167</sup> indeed objectivity has been closely associated with the ability to reach consensus.<sup>168</sup> Basing decisions on risk may be intended to generate public trust in a governmental authority and its decisions: '[p]olicymakers earn our trust through demonstrations of epistemic virtue, which include... the capacity to produce and act on objective knowledge'.<sup>169</sup>

Much of the appeal is based on the assumption that factual evidence has normative force.<sup>170</sup> In extreme cases, it may,<sup>171</sup> but subjective value judgments must complement and interpret 'objective' science.<sup>172</sup> Furthermore, talking 'objective' numbers and 'facts', allows decision-makers to avoid talking a 'more politically contentious and difficult ethical language'.<sup>173</sup> Likewise, a reliance on neutral technical expert advice has the attraction of relieving governments of the responsibility to make difficult political decisions.<sup>174</sup> Finally, objectivity, with its promise of impartiality and freedom from bias, may appeal in its potential to help decision-makers appear 'fair and impersonal',<sup>175</sup> protecting against 'charges of arbitrariness or self-interest'.<sup>176</sup> It is thus vital to governmental power,<sup>177</sup> especially perhaps in liberal democracies, committed to value-neutrality.<sup>178</sup> According to Sheila Jasanoff, '[o]bjectivity... allows governing bodies to claim the cognitive high ground, a place from which they can be seen to be acting for the benefit of all, without bowing to any particular interests or knowledge claims'.<sup>179</sup> The appearance

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<sup>166</sup> Jasanoff, *Designs on Nature* (n 11) 265.

<sup>167</sup> Jasanoff, 'Practices of Objectivity' (n 148) 308.

<sup>168</sup> Porter (n 145) 3.

<sup>169</sup> Jasanoff, 'Practices of Objectivity' (n 148) 335.

<sup>170</sup> EGSG (n 6) 64.

<sup>171</sup> Lee, *EU Environmental Law* (n 51) 37.

<sup>172</sup> Andy Stirling, 'Opening Up the Politics of Knowledge and Power in Bioscience' (2012) 10 *PLOS Biology* 1, 3.

<sup>173</sup> Lee, *EU Environmental Law* (n 51) 56.

<sup>174</sup> Kearnes and others (n 4) 297; Stilgoe, Irwin and Jones (n 7) 17, 72 and references therein.

<sup>175</sup> Porter (n 145) 8.

<sup>176</sup> Jasanoff, 'Practices of Objectivity' (n 148) 308.

<sup>177</sup> *ibid.*

<sup>178</sup> Andrew Dobson, *Citizenship and the Environment* (OUP 2003) 142.

<sup>179</sup> Jasanoff, *Designs on Nature* (n 11) 264–265.

of risk assessment in trade law may be attributed to this perception, found in the commitment that requiring state action to be founded on scientific risk assessment will prevent discriminatory and arbitrary behaviour,<sup>180</sup> alongside its promise of creating universal standards and *their* role in building markets.<sup>181</sup>

Thirdly, the above claims to objectivity, truth, universality and neutrality establish risk assessment as the basis for a 'rational' and unemotional response to an uncertain future. Indeed '[t]here can be no higher form of rationality than acting on the strength of objective knowledge'.<sup>182</sup> Viewing hazards in terms of risks can hold out the attractive 'promise that the challenges and complexities of regulation can be rationalised, ordered, managed, and controlled'.<sup>183</sup> If we cannot know the risks we face and yet must act as if we do,<sup>184</sup> science-driven risk assessment would appear to grant us that ability.

Finally, as stated above, one of the causes of an increasing reliance on risk as basis for regulation was concern about over-regulation and a conviction that regulatory costs should be balanced against benefits to health and the environment.<sup>185</sup> Furthermore, risk, in its ability to set clear limits on the circumstances in which regulation is and is not appropriate, may appeal as a spur for regulation consistent with deregulatory agendas<sup>186</sup> and is therefore popular with certain economic interests, examined further in Chapter Eight.

### 3. The limits of risk

The traditional understandings of the capabilities and reach of rational science and risk assessment presented above have, over the last few decades, been subject to

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<sup>180</sup> Fisher, 'Risk and Environmental Law' (n 17) 108; Warren H Maruyama, 'A New Pillar of the WTO: Sound Science' (1998) 32 *The International Lawyer* 651.

<sup>181</sup> Porter (n 145) 23.

<sup>182</sup> Jasanoff, 'Practices of Objectivity' (n 148) 335.

<sup>183</sup> Black (n 156) 542.

<sup>184</sup> Douglas and Wildavsky (n 49) 1.

<sup>185</sup> Jasanoff, 'Practices of Objectivity' (n 148) 317.

<sup>186</sup> Fisher, 'Risk and Environmental Law' (n 17) 108.

challenge and scrutiny. This has significantly enhanced our comprehension of risk, risk assessment and its limitations. This section focuses on these insights.

### 3.1 *Public attitudes to risks*

The branch of social science discussed here challenges the notion that an expression of risk as a simple probability grants a rational and sufficient basis for regulation. The assumption of rationality based on objective, scientific information denies the possibility of valid disagreement. It leads directly to taking public disagreement with the level of risk deemed acceptable by experts, or public assumption of risks with statistically higher chances of injury or death, as evidence of irrationality, based on subjective bias, emotion and a misperception of the probabilities involved.<sup>187</sup> A distinction, discussed further in section 3.2, is drawn between ‘real’ risk as understood by scientist risk assessors, due to their objective scientific knowledge, and ‘perceived’ risk held by the public as a result of their misunderstanding and ignorance of the scientific content of risk knowledge.<sup>188</sup>

This characterisation of the public as ignorant has been labelled the ‘deficit’ model of the public understanding of science. Or, more specifically, the ‘cognitive deficit’ model, to distinguish it from later iterations of the same idea, discussed below. Public opposition to scientific development which runs counter to assertions of safety as calculated by risk assessment is deemed to be a wholesale rejection of science,<sup>189</sup> again, due to the public’s ignorance, further corroborated by the consistently low levels of public scientific literacy observed since the 1970s.<sup>190</sup> Public concerns about the limits of our knowledge (discussed below), for example, have been likened by institutional science, to the ‘imaginings of some fevered brow’, implying the irrationality of seeking to acknowledge such matters as

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<sup>187</sup> KS Shrader-Frechette, *Risk and Rationality: Philosophical Foundations for Populist Reforms* (UC Press 1991) 98.

<sup>188</sup> Brian Wynne, ‘Public Engagement as a Means of Restoring Public Trust in Science - Hitting the Notes, but Missing the Music?’ (2006) 9 *Community Genetics* 211, 214.

<sup>189</sup> *ibid.*

<sup>190</sup> Jane Gregory and Steve Miller, *Science in Public: Communication, Culture, and Credibility* (Basic Books 1998) 88–89.

relevant.<sup>191</sup> Such opposition has led to a further characterisation of the public as a threat to innovation-based progress, as discussed in Chapters Five and Eight.<sup>192</sup>

The cure for public ignorance, irrationality and mistrust was education, to engender trust, a proper, rational understanding of risk and thereby replace opposition with support.<sup>193</sup> Thus, as a response to the ‘legitimation vacuum which threatened the wellbeing and social standing of science’,<sup>194</sup> in the mid-1980s, the Public Understanding of Science (PUS) movement was born.<sup>195</sup> The movement was based on several further assumptions. It was assumed, for example, that experts were grounded in reality while public discourses were ‘essentially groundless and emotionally-based only’ and ‘intellectually unreal’.<sup>196</sup> In addition to the need to address the public’s scientific illiteracy<sup>197</sup> and mistrust, it was assumed that the public’s ignorant rejection of science was the result of the failure of scientists to communicate well with the public.<sup>198</sup> Scientific illiteracy was also conceived of as a moral problem; people incapable of understanding the world would be unable to act rationally in it.<sup>199</sup> The approach taken by the PUS movement to address these concerns, was therefore one of one-way transmission of knowledge to a passive public.<sup>200</sup>

However, while it is admitted that there is public ignorance of science,<sup>201</sup> the deficit and PUS models have been profoundly criticised. Social scientists have argued that

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<sup>191</sup> Brian Wynne, ‘Risk and Environment as Legitimatory Discourses of Technology: Reflexivity Inside Out?’ (2002) 50 *Current Sociology* 459, 469.

<sup>192</sup> EGSG (n 6) 26.

<sup>193</sup> *ibid* 54.

<sup>194</sup> B Wynne, ‘Public Understanding of Science Research: New Horizons or Hall of Mirrors?’ (1992) 1 *Public Understanding of Science* 37, 38.

<sup>195</sup> *ibid*.

<sup>196</sup> Wynne, ‘Creating Public Alienation’ (n 48) 451–452.

<sup>197</sup> EGSG (n 6) 54.

<sup>198</sup> Wynne, ‘Public Engagement’ (n 188) 215.

<sup>199</sup> Sismondo (n 23) 174. This may sound patronising but it is a genuine concern with, for example, quantum computing, which is almost impossible to explain in layman’s terms, Sciencewise-ERC, ‘Public Attitudes to Quantum Technology’ (2014) 4 although it is not characterised here as problem of being unable to act rationally.

<sup>200</sup> EGSG (n 6) 54.

<sup>201</sup> Wynne, ‘Public Engagement’ (n 188) 213.

ignorance neither explains nor correlates with public responses to science and technology.<sup>202</sup> Nor does it explain why the same scientific facts and technological artefacts provoke different public responses.<sup>203</sup> It is argued that the deficit model ‘fails to appreciate the contextual nature of knowing’<sup>204</sup> and privileges public knowledge of facts ‘over more complex frames of meaning’.<sup>205</sup> Moreover, it makes little sense, in highly technologised contemporary societies, flatly to dismiss public responses as ‘anti-technology’.<sup>206</sup>

The study of public attitudes to risk has seen the development of various strands of research which combine to challenge and demonstrate the PUS model’s lack of explanatory power.<sup>207</sup> For example, the ‘cultural theory’ of risk selection argues that risks are selected for attention by different people in keeping with the forms of social organisation they prefer to belong to and which confirm their way of life.<sup>208</sup> According to this analysis, attitudes to risk are based on cultural biases, there can be no single metric for risk assessment and even the concept of ‘risk’ is variable.<sup>209</sup>

Another approach, the psychometric tradition, used revealed preferences to examine judgments of acceptable risk. This method relies on observing the risks people actually take by focusing on the economic costs people pay for, against the benefits they receive from, a given activity.<sup>210</sup> Later studies using psychometric

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<sup>202</sup> *ibid*; Rob Hagendijk and Alan Irwin, ‘Public Deliberation and Governance: Engaging with Science and Technology in Contemporary Europe’ (2006) 44 *Minerva* 167, 168; Jasanoff, *Designs on Nature* (n 11) 250.

<sup>203</sup> Jasanoff, *Designs on Nature* (n 11) 270.

<sup>204</sup> Sismondo (n 23) 175.

<sup>205</sup> Jasanoff, *Designs on Nature* (n 11) 270.

<sup>206</sup> Ulrike Felt, ‘Keeping Technologies Out: Sociotechnical Imaginaries and the Formation of Austria’s Technopolitical Identity’ in Sheila Jasanoff and Sang-Hyun Kim (eds), *Dreamscapes of Modernity: Sociotechnical Imaginaries and the Fabrication of Power* (University of Chicago Press 2015) 121.

<sup>207</sup> For a more detailed account of these, see Brian Wynne, ‘Understanding Public Risk Perception’ in A Saltelli, DA Stanners and M D’Alessandro (eds), *Risk Analysis in Nuclear Waste Management* (Kluwer Academic Publishers 1989).

<sup>208</sup> Douglas and Wildavsky (n 49) 9.

<sup>209</sup> Royal Society (n 5) 113.

<sup>210</sup> Douglas and Wildavsky (n 49) 68.

surveys, employed expressed preferences,<sup>211</sup> which involve asking people directly about their preferences in relation to various risk/benefit trade-offs.<sup>212</sup>

Each of these methods comes with its own imperfections and assumptions,<sup>213</sup> like risk assessment itself. However, they and others have added valuable colour and depth to our understanding of the considerations people take into account when judging acceptable risk. Firstly, when considering risks, people look both at the probability of a hazard occurring and at its possible consequences. For example, the catastrophic consequences of a severe nuclear reactor accident may weigh more heavily on people's minds than the extreme unlikelihood of it ever happening. Risk assessment reaches its limits on such questions and normative judgment is crucial. While a high likelihood of one death and a low likelihood of 10,000 deaths are numerically similar, the social and ethical consequences of each are very different.<sup>214</sup>

Secondly, the overall purpose of the underlying research or controversy over the claimed benefits of a technology, for example whether GM crops will increase yields or reduce pesticide use, will influence attitudes to risk. The risks of a given technology, to some, may not seem to be worth its alleged benefits.<sup>215</sup> In the biosciences for example, along with safety,<sup>216</sup> a primary public consideration appears to be 'whether there is a sense of genuine social benefit from publicly funded science' and 'where the social benefit was high, the public were prepared to accept higher trade-offs'.<sup>217</sup> Purposes of research also appear to be related, in public discourses, to the unpredictability of technologies and their impacts, for

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<sup>211</sup> See Silvio O Funtowicz and Jerome R Ravetz, 'Three Types of Risk Assessment and the Emergence of Post-Normal Science' in Sheldon Krinsky and Dominic Golding (eds), *Social Theories of Risk* (Praeger 1992).

<sup>212</sup> *ibid* 118.

<sup>213</sup> Shrader-Frechette (n 187) 61–62; Douglas and Wildavsky (n 49) 68–69, 71; Wynne, 'Understanding Public Risk Perception' (n 207).

<sup>214</sup> Lee, *EU Environmental Law* (n 51) 36; Shrader-Frechette (n 187) 94.

<sup>215</sup> Shrader-Frechette (n 187) 93.

<sup>216</sup> Science and Technology Select Committee, 'Science and Society' (House of Lords 2000) para 2.13.

<sup>217</sup> Macnaghten and Chilvers (n 27) 537.

example in terms of controllability and irreversibility.<sup>218</sup> Uncertainty is discussed in greater detail in section 3.3. However, people are not hereby necessarily demanding complete control. It is rather the case that uncertainty will more likely be tolerated 'if the purposes driving research and innovation are sound' but not necessarily where they are unsound, unaccountable or unclear.<sup>219</sup> Furthermore, the unfamiliarity of a risk may lower public tolerance and may even reflect concern over reckless pursuit of technical change in situations of scientific uncertainty.<sup>220</sup>

Thirdly, public attitudes to risk are influenced by concerns regarding to whom the risks and benefits accrue.<sup>221</sup> It is a common adage that taking some risk is a necessary condition for progress.<sup>222</sup> However, there is a sense that large, multinational corporations receive the benefits of new scientific research while the risks are socialised.<sup>223</sup> Beyond this instrumental approach to risks and benefits, principles themselves matter. Where equitable distribution of risks and benefits throughout society is considered desirable, differential impacts may increase risk aversion,<sup>224</sup> as may the principle that the more vulnerable members of society should be protected from risks.<sup>225</sup>

Fourthly, such questions about distribution, and indeed about safety in general,<sup>226</sup> are broadly speaking, ethical. The biosciences in particular have prompted wide-ranging ethical (and religious/spiritual) debate concerning, for example, human control of and interference with nature, where the distinction between 'natural' and 'unnatural' lies, what it means to be human<sup>227</sup> and human dignity.<sup>228</sup>

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<sup>218</sup> *ibid* 536.

<sup>219</sup> Wynne, 'Creating Public Alienation' (n 48) 466.

<sup>220</sup> Wynne, 'Understanding Public Risk Perception' (n 207) 10.

<sup>221</sup> In relation to nanotechnology for example, see Macnaghten and Chilvers (n 27) 537.

<sup>222</sup> See for example, Sir Aaron Klug's evidence in Science and Technology Select Committee (n 216) para 4.3.

<sup>223</sup> *ibid* 2.44.

<sup>224</sup> Shrader-Frechette (n 187) 20.

<sup>225</sup> Lee, 'Beyond Safety?' (n 12) 247.

<sup>226</sup> Lee, *EU Regulation of GMOs* (n 35) 34.

<sup>227</sup> *ibid* 34–38; Jasanoff, *Designs on Nature* (n 11) ch 7.

<sup>228</sup> For example, Dieter Birnbacher, 'Human Cloning and Human Dignity' (2005) 10 *Reproductive BioMedicine Online* 50.

Finally, though it may be difficult to distinguish between voluntary and involuntary risks,<sup>229</sup> there is evidence that attitudes to risk vary where risks are perceived to be imposed by others rather than voluntarily assumed. People tend to demand higher levels of safety and certainty where risks are imposed involuntarily,<sup>230</sup> for example a nuclear power station, than for voluntary risks, like dangerous sports. Obtaining consent to a risk does not necessarily address this problem. Those most able to give genuine, informed consent are likely to be educated, well-informed people who, being better-off, would be less willing to grant consent, while those most likely to consent to a risk, for example for financial betterment by accepting a risky job, are those who are least able to give it, likely due to poor education and financial insecurity.<sup>231</sup> Thus, attitudes to risk may depend on the social situation of the individual concerned.

The main achievement of these lines of research is the recognition that ‘the public’s viewpoint must be considered not as error but an essential datum’.<sup>232</sup> Our traditional model of rationality, based on facts and probabilities, provides only a partial explanation of how rational humans make decisions; the kind of brain required by this model is one that ‘would have to know and *understand* everything, completely and at once’.<sup>233</sup> Civic epistemology criticises the PUS model’s construction of the public as either knowing or not knowing<sup>234</sup> by asking how knowledge comes to be seen as reliable in political settings. People evaluate scientific knowledge by evaluating different things, such as the institutions and scientists presenting it. Public attitudes to risk are not simply about factual knowledge. There are different types of expertise,<sup>235</sup> as seen most famously in Brian Wynne’s analysis of the interactions between Cumbrian sheep farmers and

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<sup>229</sup> Douglas and Wildavsky (n 49) 17.

<sup>230</sup> Science and Technology Select Committee (n 216) para 2.58.

<sup>231</sup> Shrader-Frechette (n 187) 72–73.

<sup>232</sup> Royal Society (n 5) 91.

<sup>233</sup> Peter L Bernstein, *Against the Gods: The Remarkable Story of Risk* (Wiley 1998) 265, 284 quoting Daniel Kahneman.

<sup>234</sup> Jasanoff, *Designs on Nature* (n 11) 253.

<sup>235</sup> Sismondo (n 23) 175; Steven Yearley, ‘Computer Models and the Public’s Understanding of Science: A Case-Study Analysis’ (1999) 29 *Social Studies of Science* 845, 846–847.

scientists post-Chernobyl and their respective types of specialist knowledge.<sup>236</sup> Furthermore, attitudes are 'conditioned by different rationalities and knowledges from those of experts'.<sup>237</sup> Civic epistemology argues against the reductionist assumption that societal knowledge is the sum of a population's understanding of scientific facts and rejects the ignorant and illiterate publics presented by the deficit model. Instead, it presents humans as knowledgeable agents able to know things in common and who share approaches to sense-making to create public knowledge by appraising knowledge claims 'according to culturally sanctioned criteria of competence, virtue, and reasoning'.<sup>238</sup>

Risk assessment need not be quantitative and indeed, can be qualitative,<sup>239</sup> perhaps incorporating a more explicit element of judgment. However, juxtaposed against the diversity of meanings and attitudes described above, the paradigm of risk assessment is ill-equipped to reflect the nuanced value-judgments of publics in response to the multiple technological risks they frequently face. All these considerations are relevant to determining 'acceptable risk' when it comes to regulating technologies,<sup>240</sup> and not just to managing risks. However, the appeal of risk has encouraged the expression of non-risk considerations as concerns about safety for humans or the environment,<sup>241</sup> on the assumption that the 'real' issues are about risk and therefore any other public concerns must be too.<sup>242</sup> This has the effect of obscuring the types of considerations behind public attitudes to technologies and their risks,<sup>243</sup> of which lack of official acknowledgement leads to an intensifying of such concerns.<sup>244</sup> As Wynne puts in: '[t]he full range of moral and

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<sup>236</sup> Brian Wynne, 'Misunderstood Misunderstanding: Social Identities and Public Uptake of Science' (1992) 1 *Public Understanding of Science* 281.

<sup>237</sup> Jasanoff, *Designs on Nature* (n 11) 254.

<sup>238</sup> *ibid* 270–271.

<sup>239</sup> Lee, *EU Environmental Law* (n 51) 30.

<sup>240</sup> Science and Technology Select Committee (n 216) para 2.47.

<sup>241</sup> *ibid* 2.50; J Petts, 'Barriers to Participation and Deliberation in Risk Decisions: Evidence Form Waste Management' (2004) 7 *Journal of Risk Research* 115, 121.

<sup>242</sup> EGSG (n 6) 31.

<sup>243</sup> *ibid*.

<sup>244</sup> Kearnes and others (n 4) 296.

social issues at stake is *not* adequately described by leaving the ‘factual’ science realm as if it is a separate black box from the normative’.<sup>245</sup>

### 3.2 *Objectivity and neutrality*

The problematic nature of understanding risk assessment as provider of objective and authoritative ‘facts’ is implicit in the above discussion of the complex concerns which make up public attitudes to risk. The conceptualisation, in the PUS model, of the relationship between ‘the public’ and ‘scientists’, reinforced dichotomies between subjectivity and objectivity and the public as consumers of innovation on one side and innovators and science on the other. It was not considered that the public might have a role in ‘defining the public interest or social benefit in technoscientific domains’ and scientists, while claiming to be objective, did not separate their own commitments, such as their technological, policy and social choices, from the ‘science’ they practised and advised on,<sup>246</sup> although, as we shall see in Chapter Three, the former at least is now subject to challenge.

The ideal of factual, objective risk assessment and the reification of ‘risk’ as an object itself amenable to scientific enquiry without being constructed,<sup>247</sup> have also come under specific challenge. As a result, the separation between ‘objective’ risk and subjective ‘perceived’ risk is no longer a mainstream position. It is now generally acknowledged that all scientific risk assessment is conditional, predicated upon myriad assumptions and value judgments<sup>248</sup> which combine to undermine its claims to objectively disclose a risk.<sup>249</sup>

Risk assessors, in identifying a risk, employ a process of ‘framing’ in order to select and characterise a problem.<sup>250</sup> This process is informed by their own assumptions,

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<sup>245</sup> Wynne, ‘Uncertainty and Environmental Learning’ (n 135) 125.

<sup>246</sup> EGSG (n 6) 54.

<sup>247</sup> *ibid* 31.

<sup>248</sup> Wynne, ‘Uncertainty and Environmental Learning’ (n 135) 116; Royal Society (n 5) 97.

<sup>249</sup> Royal Society (n 5) 89, 97.

<sup>250</sup> David Winickoff and others, ‘Adjudicating the GM Food Wars: Science, Risk, and Democracy in World Trade Law’ (2005) 30 *Yale Journal of International Law* 81, 94.

commitments, values, priorities and knowledge,<sup>251</sup> which may not reflect those of society. Frames are ‘principles of selection, emphasis, and presentation composed of little tacit theories about what exists, what happens, and what matters’.<sup>252</sup> Framing excludes or includes questions, such as different types of scientific uncertainty, depending on their perceived relevance, comprehensibility and controllability.<sup>253</sup> It may also involving choosing between ‘conflicting scientific criteria of valid knowledge (for example, precision, or comprehensiveness, or realism).<sup>254</sup> Likewise, basing problem identification on mortality, morbidity or economic consequences may influence assessments of risk.<sup>255</sup> And, with respect to new technologies particularly, the relevant expertise may not always be clear.<sup>256</sup> Wynne’s example regarding the risk assessment of herbicide 2,4,5-T in which it was assumed that the herbicide would be applied under strictly controlled conditions, illustrates the type of assumptions made in a risk assessment.<sup>257</sup> More recently, the discovery that lab rats and mice react differently depending on the gender of the researcher in behavioural experiments<sup>258</sup> may indicate the existence of previously unexamined assumptions about gender in research. The framing of a problem may also directly influence the quality of proposed solutions and, in cases of uncertainty, is likely to create chronic disagreement.<sup>259</sup> Ultimately, techniques such as risk assessment tend only to be capable of responding to ‘lessons compatible with their initial assumptions’.<sup>260</sup>

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<sup>251</sup> See examples in Brian Wynne, ‘Frameworks of Rationality in Risk Management: Towards the Testing of Naive Sociology’ in Jennifer Brown (ed), *Environmental Threats: Perception, Analysis and Management* (Belhaven 1989).

<sup>252</sup> Winickoff and others (n 250) 94 and references therein.

<sup>253</sup> *ibid.*

<sup>254</sup> EGSG (n 6) 34.

<sup>255</sup> Winickoff and others (n 250) 95 and references therein.

<sup>256</sup> Stilgoe, Irwin and Jones (n 7) 22.

<sup>257</sup> B Wynne, ‘Risk and Social Learning: Reification to Engagement’ in Sheldon Krinsky and Dominic Golding (eds), *Social Theories of Risk* (Praeger 1992).

<sup>258</sup> Bob Holmes, ‘Scent of a Man: Male Sweat Stresses out Lab Mice’ [2014] *New Scientist* <[www.newscientist.com/article/dn25483-scent-of-a-man-male-sweat-stresses-out-lab-mice.html#.VUe0npNGxZY](http://www.newscientist.com/article/dn25483-scent-of-a-man-male-sweat-stresses-out-lab-mice.html#.VUe0npNGxZY)> accessed 4 May 2015.

<sup>259</sup> Sheila Jasanoff, ‘Technologies of Humility: Citizen Participation in Governing Science’ (2003) 41 *Minerva* 223, 240–241.

<sup>260</sup> *ibid* 239.

Furthermore, due to incomplete and imprecise information at every stage of risk assessment, risk assessors are required to make methodological value judgments in order to interpret the data at hand.<sup>261</sup> These judgments include, for example, 'which data to select...; how to choose statistical tests...; how to select sample size'.<sup>262</sup> Since risk assessments necessarily depend on such judgments, they are often subjective<sup>263</sup> and contingent.<sup>264</sup> Individual scientists may evaluate data differently and advise policy-makers on the basis of their own 'epistemic, theoretical and methodological commitments', while these commitments and professional judgments are concealed in the 'natural' discourse of science and quantification,<sup>265</sup> demonstrating the '*fundamentally* negotiable definition of the boundary between science and policy'.<sup>266</sup> This framing of the results of risk assessments may have significant policy implications or elicit vastly different public reactions.<sup>267</sup> A scientist might also choose to examine particular areas which will support the desired conclusions.<sup>268</sup>

Finally, the presence of the market in science and technology, as providers of economic 'goods' (as discussed in Chapter Eight) may undermine the ideal of science's adherence to the Mertonian<sup>269</sup> norm of disinterestedness, with further implications for its objective and neutral status.<sup>270</sup> Claims of the societal benefits of GM crops being asserted as scientific facts,<sup>271</sup> for example, illustrate the infiltration of normative judgments into science, and perhaps echo idealised images of science

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<sup>261</sup> Shrader-Frechette (n 187) 62.

<sup>262</sup> *ibid* 57.

<sup>263</sup> Royal Society (n 5) 89.

<sup>264</sup> Jasanoff, 'Practices of Objectivity' (n 148) 308; as is pure science, Sismondo (n 23) ch 6.

<sup>265</sup> Wynne, 'Uncertainty and Environmental Learning' (n 135) 125; Jasanoff, 'Practices of Objectivity' (n 148) 313.

<sup>266</sup> Wynne, 'Uncertainty and Environmental Learning' (n 135) 125; Sheila Jasanoff, 'Contested Boundaries in Policy-Relevant Science' (1987) 17 *Social Studies of Science* 195.

<sup>267</sup> National Research Council, *Understanding Risk: Informing Decisions in a Democratic Society* (National Academy Press 1996) 56–61.

<sup>268</sup> Douglas and Wildavsky (n 49) 60–61.

<sup>269</sup> See Sismondo (n 23) ch 3.

<sup>270</sup> Jasanoff, *Designs on Nature* (n 11) 226.

<sup>271</sup> EGSG (n 6) 67.

as inherently socially beneficent.<sup>272</sup> However, while the ‘science’ contained implicit value commitments, the focus on educating the public in risk science, excluded the possibility of wider political discussions of other considerations.

Given the many considerations that contribute to the formation of an understanding of a risk, risk is not in fact a simple object, amenable to understanding through scientific study but is itself, constructed.<sup>273</sup> However, the persistent ideal of risk as a scientific object contributes to the exclusion of other social, ethical and political dimensions in the debate over acceptable risk which therefore become more ‘intractable’,<sup>274</sup> while the dismissal of the public as irrational becomes ‘provocative and self-defeating’.<sup>275</sup>

It is not denied that experts are vital to decision-making in modern societies.<sup>276</sup> We should want experts to be ‘final arbiters on everything in their domains’,<sup>277</sup> but not necessarily on ‘good judgment’ in general<sup>278</sup> since decisions on risk acceptability ultimately ‘require judgments beyond the scope of science’.<sup>279</sup> We should recognise the caveats elaborated by the social sciences, including the porous boundaries between facts and values and between risk assessment and risk management and that even ‘objective’ expert knowledge is embedded in assumptions about the real world.<sup>280</sup> It is ‘impossible to disentangle social values and worldviews from the process of identifying, estimating and evaluating risks’.<sup>281</sup>

### 3.3 *Uncertainty confounds*

While science is often seen as conqueror of ignorance and uncertainty,<sup>282</sup> incomplete knowledge is pervasive in many areas of scientific endeavour, especially

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<sup>272</sup> For example, CP Snow, *The Two Cultures* (CUP 1993). See also Chapter Eight.

<sup>273</sup> Royal Society (n 5) 7; Douglas and Wildavsky (n 49) 73.

<sup>274</sup> EGSG (n 6) 31.

<sup>275</sup> Wynne, ‘Understanding Public Risk Perception’ (n 207) 19.

<sup>276</sup> Jasanoff, *Designs on Nature* (n 11) 267.

<sup>277</sup> Sismondo (n 23) 179, citing Collins and Evans (n 103).

<sup>278</sup> Lee, *EU Environmental Law* (n 51) 28.

<sup>279</sup> Royal Society (n 5) 62.

<sup>280</sup> Wynne, ‘Frameworks of Rationality’ (n 251) 44.

<sup>281</sup> Royal Society (n 5) 136–137.

<sup>282</sup> Funtowicz and Ravetz (n 211) 255.

environmental science,<sup>283</sup> diagnosed by some (along with disputed values, high stakes and urgency) as characteristic of ‘post-normal science’.<sup>284</sup> I use Wynne’s scheme of uncertainty<sup>285</sup> to describe the various challenges risk assessment faces here. According to Wynne, the term ‘risk’ strictly applies to a situation in which the odds of harm are known. Uncertainty applies where the ‘types and scales of possible harms’ are known, but not their probabilities. ‘Risk assessment’ does not apply here.<sup>286</sup> Next, ignorance, characterised by our incomplete knowledge of the possible harms. These are ‘unknown unknowns’; for example, we did not consider the relevance of the ozone layer during the development and use of CFCs but much later became aware of the damage caused.<sup>287</sup> Ignorance is, of course, endemic to scientific knowledge. However, it is only problematic, according to Wynne, when scientific knowledge is institutionalised in policy-making without acknowledging its inevitable presence.<sup>288</sup>

Wynne’s final category of uncertainty is indeterminacy, which is characterised by the openness and reflexive changeability of the social, technological and natural systems in which we operate. We can never comprehensively measure an open system<sup>289</sup> and any attempt to perform a risk assessment will be based on assumptions about the behaviour of its various participants. Indeterminacy underlies scientific knowledge even if ‘uncertainty’ is actually small, and in fact all types of uncertainty are overlaid on each other, increasing as social commitments based on current knowledge increase.<sup>290</sup> This open-endedness is found in both in both ecosystems and social systems. In the latter, for example, it is impossible to predict how individual actors will behave, for example farm workers’ behaviour

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<sup>283</sup> Science and Technology Select Committee (n 216) para 4.1.

<sup>284</sup> Funtowicz and Ravetz (n 211).

<sup>285</sup> Wynne, ‘Uncertainty and Environmental Learning’ (n 135).

<sup>286</sup> EGSG (n 6) 36.

<sup>287</sup> Lee, *EU Environmental Law* (n 51) 32.

<sup>288</sup> Wynne, ‘Uncertainty and Environmental Learning’ (n 135) 115.

<sup>289</sup> Lee, *EU Environmental Law* (n 51) 33.

<sup>290</sup> Wynne, ‘Uncertainty and Environmental Learning’ (n 135) 116.

when applying pesticides.<sup>291</sup> It is therefore difficult, in this situation, to establish lines of causation between decisions and consequences.<sup>292</sup>

Where ignorance comes to light, the response tends to focus on improving the scientific model to generate more knowledge for policy. Recalling risk assessment's origins in analysing well-defined systems, this reductive approach 'tends to treat all uncertainties as if they were due to incomplete definition of an essentially determinate cause-effect system', when in fact risk assessment is now being applied to unpredictable and complex systems, where even identifying the target systems to protect and assess is challenging.<sup>293</sup> The consequence of this, and the assumptions made in such assessments, is to misrepresent and hide ignorance and indeterminacies in risk systems, generating an illusion of control.<sup>294</sup> This 'distorts public debate and understanding of the proper relationship between expert knowledge and public value-choices' in regulating technologies.<sup>295</sup> While uncertainty implies that more knowledge is needed, indeterminacy suggests contingent social behaviour should be included in assessment frameworks.<sup>296</sup> Furthermore, both ignorance and indeterminacy should be treated 'as potential sources of risk in themselves' and embraced 'in broader debate about the implications of societal commitments'.<sup>297</sup>

Even established scientific knowledge is contingent,<sup>298</sup> resting on the particular conditions in which it became 'knowledge'. When it is transferred, to a different context where different variables obtain, it may no longer hold true.<sup>299</sup> Thus, despite extensive testing of products before commercialisation, newly-marketed

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<sup>291</sup> Wynne, 'Risk and Social Learning' (n 257).

<sup>292</sup> Wynne, 'Uncertainty and Environmental Learning' (n 135) 116–117.

<sup>293</sup> Calow (n 142) 2.

<sup>294</sup> Wynne, 'Uncertainty and Environmental Learning' (n 135) 123; DA Schon, 'The Fear of Innovation' in Barry Barnes and David Edge (eds), *Science in Context: Readings in the Sociology of Science* (Open UP 1982) 298–299.

<sup>295</sup> Wynne, 'Uncertainty and Environmental Learning' (n 135) 116, 119.

<sup>296</sup> *ibid* 118–119.

<sup>297</sup> *ibid* 123.

<sup>298</sup> EGSG (n 6) 68.

<sup>299</sup> For example, the behaviour of radiocaesium in different soils, Wynne, 'Uncertainty and Environmental Learning' (n 135).

innovations will always meet novel conditions to which pre-market testing is not entirely applicable.<sup>300</sup> In other words, what is presented as an established fact, for example, the safety of a product, is contingent on what tests have been conducted. Contingencies have typically been misrepresented as residual uncertainties which will be conquered by further research and experimentation, when more research may in fact reveal more ignorance.<sup>301</sup> Indeed, the best foundation for policy that science can provide is a 'robust consensus', not proof.<sup>302</sup> This situation is further exacerbated by the current speed of innovation, often outstripping ethical and regulatory oversight,<sup>303</sup> in which society finds that it is, itself, the laboratory; a fact often left unacknowledged.<sup>304</sup>

Governance processes based on risk assessment have often failed to predict subsequent, significant impacts of innovation.<sup>305</sup> Ultimately, the potential for risk assessment to enable us to act as if we know the risks and to exert a degree of control, ceases to be so convincing. This danger is inherent in the model: the rigidity found in the detailed rules of risk-based frameworks ends up restricting the scope for a regulatory response to 'an unpredicted and unpredictable future'.<sup>306</sup> Even the desire for control and 'zero uncertainty' may in itself be based on a false assumption that this is what the public demands yet cannot understand science's inability to provide.<sup>307</sup> In fact, publics understand uncertainty and 'recognise a more radical uncertainty (indeed indeterminacy) than that admitted by science'.<sup>308</sup> The exaggeration of control by experts has significant negative implications for trust

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<sup>300</sup> EGSG (n 6) 68.

<sup>301</sup> Douglas and Wildavsky (n 49) 63–64.

<sup>302</sup> Naomi Oreskes, 'Science and Public Policy: What's Proof Got to Do with It?' (2004) 7 *Environmental Science & Policy* 369, 369–370.

<sup>303</sup> Macnaghten and Chilvers (n 27) 536.

<sup>304</sup> Douglas and Wildavsky (n 49) 63–64.

<sup>305</sup> Stilgoe, Owen and Macnaghten (n 29) 1569, 1570 who use the 2008 financial crisis as an example.

<sup>306</sup> Black (n 156) 521; Michael Power, *The Risk Management of Everything: Rethinking the Politics of Uncertainty* (Demos 2004) 59.

<sup>307</sup> Wynne, 'Creating Public Alienation' (n 48) 476–478.

<sup>308</sup> Science and Technology Select Committee (n 216) 2.56; Wynne, 'Creating Public Alienation' (n 48) 477.

between publics and scientific and policy institutions, discussed below, and uncertainty may be ‘manipulated politically, to accelerate or defer initiatives’.<sup>309</sup>

The above ‘uncertainties’ do not fit comfortably into traditional risk assessment and as such, tend to be excluded from discussion. For example, in the EU and the WTO (discussed further in Chapters Six and Seven), hypothetical risk may not form the basis of a regulatory decision, nor may regulation seek ‘zero risk’,<sup>310</sup> despite the clear case for acknowledging uncertainty in decision-making. Uncertainty is also relevant to other questions. In relation to the ‘acceptability’ of hypothetical risk, ‘ignorance may be more salient if the contested activity raises ethical concerns, or has doubtful social benefits’.<sup>311</sup> Likewise, uncertainty ‘may be compounded by issues of ethics, economics, social implications and public acceptability’,<sup>312</sup> and suggests a need for public engagement and deliberation on those very questions.<sup>313</sup>

### 3.4 Risk and trust

The lines of research detailed in section 3.1, especially psychometric research, showed that scientists had reduced salient dimensions of ‘risk’ to a narrow object of research which did not reflect the more complex public definitions of risk. The value of this research is not doubted. However, these insights still left intact the assumption that all public concerns were related to the inherent properties of the risk.<sup>314</sup> Public scepticism towards risky technologies does not derive simply from their risks but also reflects judgments about the science and policy institutions controlling the risks and crucially, the reliability of their track record.<sup>315</sup> These judgments are both ethical and intellectual and may concern, for example, institutional denial of the limitations of scientific knowledge, a sense of the available science as being ‘captured’ by commercial or political interests and a

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<sup>309</sup> Funtowicz and Ravetz (n 211) 264.

<sup>310</sup> Lee, *EU Environmental Law* (n 51) 8–9, 32.

<sup>311</sup> *ibid* 32.

<sup>312</sup> Science and Technology Select Committee (n 216) para 1.5.

<sup>313</sup> Waterton and Wynne (n 155) 96, 100 and references therein; Stirling, ‘Opening Up the Politics of Knowledge’ (n 172).

<sup>314</sup> Wynne, ‘Creating Public Alienation’ (n 48) 454.

<sup>315</sup> Wynne, ‘Understanding Public Risk Perception’ (n 207) 7, 11, 18–19.

greater need for public accountability and debate over driving purposes and forces,<sup>316</sup> some of which do also exacerbate risk aversion. Wynne further attributes public scepticism to a rejection of expert discourses of control and knowledge, which ignores the findings described in section 3.1 and which continue to construct the public as emotional and intellectually-vacuous, concerned only with statistical risk.<sup>317</sup>

Public attitudes to risky technologies are therefore not solely composed of nuanced personal understandings of physical risk. They involve general matters of trust between publics and institutions,<sup>318</sup> understandings of the social processes involved in risk management, for example, the degree of organised safety, or level of personal control,<sup>319</sup> or confidence in the risk assessment procedures.<sup>320</sup> Trust is two-fold and involves public concerns that the responsible institutions act in the public interest and in accordance with the best possible technical and safety practices.<sup>321</sup> Thus mistrust of institutions, combined with an unavoidable dependence on the same institutions,<sup>322</sup> contributes to the formation of public responses to (risky) technologies.

These insights further undermine the artificial separation between facts and values, or ethics: public meanings and responses do not fit into these categories and public judgments regarding the matters described above comprise both intellectual and ethical content.<sup>323</sup> These insights also undermine the deficit model,<sup>324</sup> even with sophisticated scientific knowledge, concerns about the responsible institutions would clearly persist. This could also be seen as part of the morphing relationship between the public and authority (in this instance, scientists) wherein it is normal for assertions of authority to be questioned. Indeed, such critical questioning may

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<sup>316</sup> Wynne, 'Creating Public Alienation' (n 48) 475–476.

<sup>317</sup> *ibid* 445, 447.

<sup>318</sup> Yearley (n 235) 847.

<sup>319</sup> Royal Society (n 5) 109, 123.

<sup>320</sup> Douglas and Wildavsky (n 49) 89.

<sup>321</sup> Royal Society (n 5) 123.

<sup>322</sup> EGSG (n 6) 54.

<sup>323</sup> Wynne, 'Creating Public Alienation' (n 48) 447.

<sup>324</sup> EGSG (n 6) 54.

even be an indication of a ‘more informed and scientifically literate citizenry’.<sup>325</sup> On the question of independence, public opinion surveys have shown that people regard the perceived source of, or source of funding behind, scientific research as important.<sup>326</sup> As Sir Aaron Klug observed, ‘it is probably futile to argue that a scientist can interact with a commercial company without becoming an implicit advocate for the company’.<sup>327</sup> This being the case, it may be hard for people to retain the belief that the public interest is always being protected.

### 3.5 *Summary*

The above insights and arguments combine to form a powerful case for relieving risk assessment of its burden as ascendant source of knowledge in regulatory decision-making. The information it provides is vital, as is expert knowledge, but its deficiencies beyond probabilistic analysis are apparent and undermine many of its assumed attributes. It is not sensitive to public methods of rationalising risks and cannot necessarily lay claim to providing an authoritative characterisation of the risk faced, though it may be an authoritative expression of a particular perspective on risk. The presence of assumptions and value judgments in expert risk assessment suggests its results may not be unqualifiedly ‘objective’, which further weakens its ability to provide institutional accountability and support ‘rational’ decisions. These two observations would also seem to suggest the need for elision between the matters deemed appropriate for discussion during risk assessment and management. It struggles to cope with uncertainty, with implications for its adequacy as a foundation for future control of the implications of a technology. Finally, public attitudes towards technologies may not stem from their attitudes to physical risks but instead reflect their confidence in the institutions charged with controlling those risks, which risk assessment, by definition, also cannot read.

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<sup>325</sup> Sir Robert May’s evidence, Science and Technology Select Committee (n 216) para 2.43.

<sup>326</sup> *ibid* 4.20.

<sup>327</sup> *ibid* 4.24.

#### 4. The impact of social science research

##### 4.1 *The institutional response*

Many suggestions for addressing some of the problems identified above through broadening considerations in regulatory decision-making beyond risk involve promoting some kind of wider public deliberation in which different opinions, values, frames of meaning etc. can be aired and where expert assumptions may be challenged. The growth of this approach, often referred to as the Public Understanding of Science movement (though without the pejorative associations mentioned above), demonstrates a recognition that citizens can contribute worthwhile and relevant insights which may, though not necessarily,<sup>328</sup> improve a decision.<sup>329</sup>

Scholarship on deliberation is vast and the arguments for it are impossible to condense here but the following key ideas are briefly noted. As a theory of democracy, it is concerned primarily with the legitimacy and justification of political authority,<sup>330</sup> thought to be enhanced by the participation of those affected by a decision.<sup>331</sup> Multiple models of 'deliberative democracy' have been proposed.<sup>332</sup> These differ in significant ways but all adhere to the basic belief that participants can change their preferences and values through reasoned argument designed to persuade one another, ultimately reaching a collective decision.<sup>333</sup> Deliberation may foster the exchange of ideas,<sup>334</sup> challenge political priorities<sup>335</sup> and make public

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<sup>328</sup> Jasanoff, 'Technologies of Humility' (n 259) 237–238.

<sup>329</sup> Sismondo (n 23) 184.

<sup>330</sup> Jenny Steele, 'Participation and Deliberation in Environmental Law: Exploring a Problem-solving Approach' (2001) 21 *Oxford Journal of Legal Studies* 415, 416–417.

<sup>331</sup> John Dryzek, *Deliberative Democracy and beyond: Liberals, Critics, Contestations* (OUP 2000) 1.

<sup>332</sup> For a discussion of two of these, see Dryzek (n 331).

<sup>333</sup> *ibid* 10, 31; Jon Elster, 'Introduction' in Jon Elster (ed), *Deliberative Democracy* (CUP 1998); Steele (n 330) 428.

<sup>334</sup> James Meadowcroft, 'Participation and Sustainable Development: Modes of Citizen, Community and Organizational Involvement' in William Lafferty (ed), *Governance for Sustainable Development: The Challenge of Adapting Form to Function* (Edward Elgar 2004) 166–167.

<sup>335</sup> Michael Jacobs, 'Sustainable Development as a Contested Concept' in Andrew Dobson (ed), *Fairness and Futurity* (OUP 1999) 44.

policy responsive to public opinion through communication between the public sphere and the state.<sup>336</sup> There are various rationales for deliberation. Firstly, ‘procedural’, which argues that the procedures of deliberation are intrinsically good in terms of, for example, promoting a sense of ownership over resulting decisions and therefore more successful implementation,<sup>337</sup> benefiting participants morally and intellectually<sup>338</sup> and enhancing public-spirited attitudes and tolerance between groups.<sup>339</sup> Secondly, ‘substantive’, which argues that deliberation can lead to better decisions<sup>340</sup> and improved policy.<sup>341</sup> Finally, ‘instrumental’, which argues that it can foster trust in institutions of governance of technological innovation or help manage negative social reactions to a (pre-made) decision,<sup>342</sup> as discussed below.

In the environmental sphere, the substantive rationale resembles arguments for the superior qualities of deliberation to solve complex environmental problems by recognising that in a diverse society, relevant knowledge (especially ‘situated knowledge’), expertise and values are widely distributed. These arguments similarly hold that more inclusive, deliberative decision-making processes, in which citizens’ contributions are valued as resources for problem-solving, could improve the quality of decision-making, the decisions themselves and broaden the range of solutions available.<sup>343</sup> This account further recognises the centrality of values to deliberation and the benefits of incorporating, through deliberation, citizens’

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<sup>336</sup> Dryzek (n 331) 47, 50–55.

<sup>337</sup> Dan Bloomfield and others, ‘Deliberation and Inclusion: Vehicles for Increasing Trust in UK Public Governance?’ (2001) 19 *Environment and Planning C: Government and Policy* 501, 510.

<sup>338</sup> Elster (n 333) 11.

<sup>339</sup> Simone Chambers, ‘Deliberative Democratic Theory’ (2003) 6 *Annual Review of Political Science* 307, 318.

<sup>340</sup> John Parkins and Ross Mitchell, ‘Public Participation as Public Debate: A Deliberative Turn in Natural Resource Management’ (2005) 18 *Society & Natural Resources* 529, 531–533.

<sup>341</sup> Jacobs (n 335) 42.

<sup>342</sup> Andy Stirling, ‘Opening Up or Closing Down? Analysis, Participation and Power in the Social Appraisal of Technology’ in Melissa Leach, Ian Scoones and Brian Wynne (eds), *Science and Citizens: Globalization and the Challenge of Engagement* (Zed Books 2005) 221–222.

<sup>343</sup> Steele (n 330).

values, in framing policy questions, evaluating risks and benefits and assessing whether any uncertainty is worth tolerating in light of putative benefits.<sup>344</sup>

This idea of broadening involvement is reflected in techniques suggested elsewhere, such as extended peer review, which involves the many stakeholders affected by the relevant science or technology to democratise science.<sup>345</sup> The NRC itself, originator of the almost indelible risk assessment/risk management divide, departed in its 1996 report *Understanding Risk*, from this previous advice and emphasised ‘risk characterisation’, a responsive, analytic-deliberative process that deals with uncertainties in a ‘comprehensible way’.<sup>346</sup>

Although there is evidence that the deficit model of the public understanding of science and the belief that scientific knowledge is objective still persist (discussed further in Chapters Five, Eight and Nine),<sup>347</sup> a change in emphasis in the relationship between science and society has occurred. There was a shift, since the late 1990s from the one-way transmission of scientific information of the PUS movement, to a two-way dialogue, termed Public Engagement with Science (PES), or ‘new scientific governance’.<sup>348</sup> This can be attributed to an acceptance in policy and science circles of the above findings that values are important in regulatory science and should be integrated into decision-making. These developments in public involvement have been tracked at EU level, with the shift from the 2001 ‘Science and Society’ Action Plan<sup>349</sup> to ‘Science in Society’ in 2007 and then to ‘Science with and for Society’ under *Horizon 2020*.<sup>350</sup>

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<sup>344</sup> *ibid* 421–427.

<sup>345</sup> Funtowicz and Ravetz (n 211).

<sup>346</sup> Fisher, ‘Risk and Environmental Law’ (n 17) 111; National Research Council (n 267) paras 36–6.

<sup>347</sup> For example, the analysis of EU Research Commissioner, Potocnik’s speech in EGSG (n 6) 75.

<sup>348</sup> *ibid* 55. See Lord Broers’ final lecture in the Reith Lectures 2005 for an excellent example of the arguments for embracing PES from a science point of view.

<sup>349</sup> Commission, *Science and Society: Action Plan* (EUR-OP 2002).

<sup>350</sup> Commission, ‘Horizon 2020 - The Framework Programme for Research and Innovation COM(2011) 0808 Final’; ‘Research & Innovation: Science With And For Society’ <<http://ec.europa.eu/research/swafs/index.cfm?pg=about>> accessed 5 May 2015; R Owen, P Macnaghten and J Stilgoe, ‘Responsible Research and Innovation: From Science in Society

An early example of this new form of scientific governance is the Royal Commission on Environmental Pollution's 1998 report, *Setting Environmental Standards*.<sup>351</sup> The report emphasises that lay people can contribute to defining environmental problems and that 'people's values' are an integral part of the environmental policy process and should be taken into account 'from the earliest stage'.<sup>352</sup> This new approach was based on openness and transparency and was presented as a means of stemming the decreasing public trust in science and its use in regulation.<sup>353</sup> The assumptions were that mutual education would restore public trust in science,<sup>354</sup> that consensus could be achieved by greater transparency, openness and public consultation and thereby achieve the somewhat instrumental aim (identified above) of diffusing subsequent public opposition to technological innovation.<sup>355</sup>

However, due to various systemic and practical problems, it has been argued that the PES movement has failed to achieve its objectives.<sup>356</sup> Firstly, understanding as to the required extent and timing of engagement is lacking. Engagement events, at least in the UK, have tended to be 'isolated ad hoc events, disconnected from institutional responsibilities and decision-making procedures, which do not themselves change the terms, relationships and cultures of the institutions which make public policy'.<sup>357</sup> They have also been described as 'partial and limited in scope',<sup>358</sup> with mainstream policy still insulated from such engagement attempts.<sup>359</sup> Secondly, while it is acknowledged that concerns about (amongst other things) the purpose, direction and benefits of innovation need to be considered early in the

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to Science for Society, with Society' (2012) 39 *Science and Public Policy* 751, 753 and references therein.

<sup>351</sup> Alan Irwin, 'The Politics of Talk: Coming to Terms with the "New" Scientific Governance' (2006) 36 *Social Studies of Science* 299, 305; Royal Commission on Environmental Pollution, 'Setting Environmental Standards Cm 4053' (1998).

<sup>352</sup> Irwin (n 351) 305.

<sup>353</sup> *ibid.*

<sup>354</sup> Wynne, 'Public Engagement' (n 188) 213.

<sup>355</sup> Irwin (n 351) 299.

<sup>356</sup> Wynne, 'Public Engagement' (n 188) 213.

<sup>357</sup> Science and Technology Select Committee (n 216) para 5.40; Hagendijk and Irwin (n 202) 174.

<sup>358</sup> Hagendijk and Irwin (n 202) 183.

<sup>359</sup> *ibid.* 175.

innovation process ('upstream engagement'),<sup>360</sup> it is doubtful whether true upstream engagement is or will be implemented,<sup>361</sup> although it forms part of the innovation governance activities discussed in Chapter Three. The idea behind upstream engagement is that people's values could influence or change research trajectories.<sup>362</sup> However, it is often presented as a way to address the impacts of technology by shifting downstream questions from their traditional home in risk management discussions, to an earlier point in the research process.<sup>363</sup> The resonance of the upstream/downstream metaphor with the linear model of innovation has been criticised as unhelpful in terms of its ability, genuinely, to open up social appraisal of technologies or to effect a departure from instrumental use of such processes to dissolve public opposition thereby ensuring the smooth commercialisation and distribution of the technology in question.<sup>364</sup> It may also exacerbate social indeterminacy.<sup>365</sup> As currently enacted, then, it may not represent a significant challenge to the science/society divide.<sup>366</sup>

Thirdly, there is the risk that PES exercises are not, or are not perceived to be, genuine. There are doubts as to whether there is real scope for dialogue given that the underlying enthusiasm for a science-led society is still strong,<sup>367</sup> and a sense that PES exercises pursue trust purely instrumentally, to support a pre-determined approach,<sup>368</sup> discussed further in Chapters Five and Eight. In the EU specifically, the Commission's commitment to PES appears to be mainly rhetorical, undermined by the ongoing commitment of EU institutions to reductionist understandings of scientific risk.<sup>369</sup> This could indicate scepticism as to whether government is actually

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<sup>360</sup> James Wilsdon, Brian Wynne and Jack Stilgoe, *The Public Value of Science: Or How to Ensure That Science Really Matters* (Demos 2005) 32–33.

<sup>361</sup> *ibid* 33.

<sup>362</sup> *ibid* 34.

<sup>363</sup> *ibid* 32–33.

<sup>364</sup> Stirling, "Opening Up" and "Closing Down" (n 9) 264.

<sup>365</sup> Wynne, 'Uncertainty and Environmental Learning' (n 135) 123.

<sup>366</sup> Some of these criticisms are picked up again in Chapter Eight.

<sup>367</sup> Irwin (n 351) 316.

<sup>368</sup> J Stilgoe, SJ Lock and J Wilsdon, 'Why Should We Promote Public Engagement with Science?' (2014) 23 *Public Understanding of Science* 4, 6 and references therein.

<sup>369</sup> EGSG (n 6) 36, 41.

listening, perhaps exacerbated by a governmental need to avoid accusations of bias by having PES exercises conducted independently.<sup>370</sup>

Finally, the existence of such a strong link between increased engagement and transparency and increased public confidence in decision-making has been criticised as perhaps creating more criticism and scepticism.<sup>371</sup> Indeed, instead of generating the much-desired consensus, public engagement can uncover areas of dissensus and provoke more questions about trust; a social or political benefit but perhaps an unexpected inconvenience for the funding institutions.<sup>372</sup>

#### 4.2 *Unfinished business*

The above initiatives have not received resounding approval in the social science literature reviewed here. It is acknowledged that PES can be used both to open up and close down discussion over science,<sup>373</sup> with consequences for realising its potential to legitimise and improve decision-making.

Despite the, at least rhetorical, rejection of the cognitive deficit model and efforts to cultivate public trust in science and innovation, new incarnations of the deficit model appear. For example, there is now the perception of a ‘deficit’ of public trust.<sup>374</sup> Arguments that PES has failed to stop the development of public mistrust cite, as a reason for its persistence, the failure of this approach to engender critical and reflexive learning among the scientific institutions involved.<sup>375</sup> Wynne argues that the institutional scientific learning about its culture and assumptions, which was supposed to form half of the two-way process of new scientific governance has failed.<sup>376</sup> The impact of the absence of institutional self-reflection has been the

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<sup>370</sup> Hagendijk and Irwin (n 202) 176.

<sup>371</sup> Irwin (n 351) 314–315.

<sup>372</sup> Stilgoe, Lock and Wilsdon (n 368) 7.

<sup>373</sup> *ibid* 11; Stirling, “‘Opening Up’ and ‘Closing Down’” (n 9).

<sup>374</sup> Irwin (n 351) 303. More recently, the 2011 Public Attitudes to Science study noted an increase in generic trust in scientists and engineers but notes that this could be attributed to an ‘increasingly resigned trust’ where the public feel they have no option but to trust those responsible for governing science, Sarah Castell and others, ‘Public Attitudes to Science 2014’ (Ipsos MORI 2014) URN BIS/14/P111 4, 101, 183.

<sup>375</sup> Wynne, ‘Public Engagement’ (n 188) 212.

<sup>376</sup> *ibid* 213.

maintaining of various assumptions regarding risk, science, expert knowledge and the public and the perpetuation of the dichotomies between facts/values, or rational science/irrational publics, discussed in Chapter Five. For example, embarking on public engagement to regain trust may again be based on dismissing the genuineness of public concerns and defining the problem as 'lack of trust rather than lack of trustworthiness'.<sup>377</sup>

Another incarnation is the 'public deficit of understanding of the scientific process'. This purports to explain public opposition to technological innovation as a desire for science to provide absolute certainty and safety, which, when it becomes apparent that this is asking too much of science, also results in mistrust.<sup>378</sup> As discussed above, however, the public are in fact able to accept, and act under, uncertain conditions. Wynne has described all forms of the deficit model as 'institutional alibis', employed by scientific institutions to avoid taking responsibility for their role in creating the mistrust. It also allows them to avoid engaging in the necessary self-reflection and to continue viewing all public concerns as scientific matters.<sup>379</sup> He argues that the proper description of 'public rejection of science' is 'public rejection of commitments based on value commitments that are misunderstood and misrepresented by scientists and policy experts as if solely scientifically determined'.<sup>380</sup> This lack of self-reflection contributes to public mistrust by denying firstly, the contingencies of scientific knowledge, secondly, the limits of scientific knowledge and its lack of predictive control<sup>381</sup> and thirdly, the fact that scientific methods are as much based on assumptions, biases and preferences as are public attitudes to risk.

Secondly, public dissatisfaction at the reduction of their valid concerns to scientific issues has been cited as a separate cause of public mistrust.<sup>382</sup> While public

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<sup>377</sup> Joanna Goven, 'Dialogue, Governance, and Biotechnology: Acknowledging the Context of the Conversation' (2006) 6 *Integrated Assessment* 99, 107.

<sup>378</sup> Wynne, 'Public Engagement' (n 188) 215.

<sup>379</sup> *ibid* 214, 216.

<sup>380</sup> *ibid* 214.

<sup>381</sup> *ibid* 217.

<sup>382</sup> Science and Technology Select Committee (n 216) para 2.50.

concerns are given short shrift, expert positions have been presented as incontestable, reinforcing the traditional divide between experts and the lay public, and elevating the former relative to the latter.<sup>383</sup> So, it is concluded, public mistrust stems from the behaviour of the institutions responsible for innovation, regulation and engagement and their relationship with the public.<sup>384</sup> Indeed, mistrust may relate not so much to science but rather to its governance.<sup>385</sup>

Thirdly, while research has revealed that one of the key factors in the development of public attitudes to risk is the benefits of the technology in question, it has been argued that 'social benefits are simply assumed by dint of someone's wish to advance a product for approval through the regulatory process'.<sup>386</sup> Thus, highly arguable benefits are excluded from discussion and public trust is damaged through the lack of acknowledgement of the 'provocatively exaggerated role for science as provider of public meaning'.<sup>387</sup>

## 5. Conclusion

The above analysis demonstrates the inadequacy of risk assessment as sole authority and knowledge-provider for regulatory decision-making and the weight of issues risk has inappropriately been required to support. It shows the huge range of other factors and concerns which have a bearing on any regulatory decision regarding technologies. Many considerations have been identified as composing public attitudes to risk and, while this approach has been criticised for reinforcing the notion that the question is always all about risk, these considerations do need to be factored into regulatory decisions. Furthermore, public attitudes and their component concerns may not exist as an isolated object of study but rather as a reaction to institutional behaviour and the characterisation of those same publics and their concerns, which raises deeper questions of trust between actors and the purposes of research. Again, both are matters which are relevant in decision-

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<sup>383</sup> EGSG (n 6) 60.

<sup>384</sup> *ibid.*

<sup>385</sup> Ozoliņa and others (n 10) 27 and references therein.

<sup>386</sup> Wynne, 'Public Engagement' (n 188) 217.

<sup>387</sup> *ibid.*

making and which risk assessment is unable to read. In addition, the criticism of risk assessment in terms of its claimed objectivity and its inability to tackle various types of uncertainty further highlight its limitations.

These are the arguments for reviewing and adapting the way decisions are made in the regulation of technology and which, politically, the EU broadly acknowledges, as discussed in Chapter Three. As argued, progress has been made in recognising and adopting some of the findings of social science. However, clearly more is needed. New developments are afoot, in particular in innovation governance, both academically and at EU level, also discussed further in Chapter Three. These are the arguments too which, despite acknowledgement in policy, play a muted and diminished role (if any) in practice, as I aim to show and analyse in the remainder of this thesis.

## Chapter Three – The EU’s policy commitment

### 1. Introduction

This chapter serves two purposes. Firstly, it sets out the EU’s general intentions to look beyond safety concerns, as established by regulatory science, in governing innovation, science and technology. Section 2 fulfils this purpose and concentrates on the EU’s current policy mission to construct a framework for innovation governance founded on responsibility. This discussion supports a more general appreciation of EU policy ambitions relevant to enhancing socio-technical integration. It also provides context for the more specific policies, examined in the remainder of this chapter, pertaining to the two example technologies explored in this thesis.

The most important purpose of this chapter, then, is to set out and discuss the policy frameworks for the two example technologies and their regulatory regimes examined in Section II. Both frameworks stem from discourses with strong potential for introducing concerns and values, other than those relating to safety, into decision-making which could counter narrow commercial or market values.

In section 3, I examine the EU’s policy ambition to open up research and decision-making relating to synthetic biology. I focus, in particular, on specific initiatives to govern research in accordance with the principles of Responsible Research and Innovation (RRI, sometimes referred to as ‘Responsible Innovation’ or ‘RI’) and its potential to enhance socio-technical integration. I argue that both synthetic biology itself and its policy exhibit an explicit commitment to openness; to other perspectives, participants and collectively defined goals. It is against this commitment that I assess the regulatory regime in Chapter Five.

In section 4, I examine EU policy on the sustainable use of pesticides. I discuss the policy ambition to achieve sustainable use in the context of broader academic and political discourse on sustainability. I argue that this policy ambition and the expectations which the phrase ‘sustainable use’ imports by virtue of the discourse on sustainable development and sustainability indicate genuine potential to

enhance socio-technical integration here. It is against this potential that I assess the regulation of pesticide use in Chapter Four.

For simplicity, I refer throughout the chapter to the ‘EU’ and the ‘Commission’ as originators of the policy discussed, though I acknowledge that neither is monolithic, nor always univocal.

## 2. EU science and innovation policy

### 2.1 *Risk regulation, innovation governance and their relationship*

European policy seeking to better integrate a societal and/or ethical dimension into ‘science’ (in its broadest possible terms) can be dated as far back as 1987 and the Second Framework Programme for Research and Technological Development.<sup>388</sup> Apparently responding to the findings and recommendations of research discussed in Chapter Two, subsequent research policy has increasingly demanded enhanced socio-technical integration.<sup>389</sup>

The tenor and intentions of EU science policy until the present have remained, in many ways, consistent with this original vision to extend the gaze of science, innovation and its governance to ‘non-safety’ concerns, as seen in the new emphasis on shared responsibility and cooperation discernible in EU science policy,<sup>390</sup> discussed below. However, the location has shifted from a focus split between research science and regulatory science to concentration on opening upstream research and innovation systems, as recommended by the hefty 2007 *Taking European Knowledge Society Seriously*,<sup>391</sup> in recognition of the necessity of

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<sup>388</sup> Hannot Rodríguez, Erik Fisher and Daan Schuurbiers, ‘Integrating Science and Society in European Framework Programmes: Trends in Project-Level Solicitations’ (2013) 42 *Research Policy* 1126, 1127.

<sup>389</sup> *ibid* 1127–1128; early examples include: Commission, *Science and Society* (n 349); TRUSTNET 2, ‘Towards Inclusive Risk Governance’ (2004) EUR 21024/1; Commission, ‘Science, Society and the Citizen in Europe’ (2000) Commission Working Document SEC(2000) 1973.

<sup>390</sup> Council Decision establishing the specific programme implementing Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020) [2013] OJ L347/965 pt V (Horizon 2020 - specific programme).

<sup>391</sup> EGSG (n 6).

debating not only the implications of science and innovation but also their processes and trajectories.<sup>392</sup>

There are various reasons for this shift in focus. It is a response to the transformative potential of science and technology which generates and sustains Ulrich Beck's risk society,<sup>393</sup> and the shortcomings of traditional methods of managing risks which have frequently failed to predict such profound impacts,<sup>394</sup> prompting reassessment of 'linear models of science and innovation policy and the social contract for science'.<sup>395</sup> This, it is argued, requires anticipatory governance, including participatory debate on the world we are creating with innovation.<sup>396</sup> It explicitly links risk to responsibility<sup>397</sup> and reimagines responsibility in (environmental) regulation or governance as future-orientated care and 'responsiveness'.<sup>398</sup> This constitutes a shift from mechanisms of retrospective liability and accountability, including risk-based regulation,<sup>399</sup> codes of conduct and ethical review;<sup>400</sup> the traditional framework for ensuring responsibility in scientific research, which struggles to cope with the complexity and uncertainty (in all its forms) of technological innovation risks and environmental problems.<sup>401</sup>

Responsiveness is characterised by openness to the commitments, concerns and perspectives of others and a willingness to rethink one's own,<sup>402</sup> usually precluded

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<sup>392</sup> Ozoliņa and others (n 10) 15.

<sup>393</sup> Ulrich Beck, *Risk Society: Towards a New Modernity* (Sage Publications 1992).

<sup>394</sup> Stilgoe, Owen and Macnaghten (n 29) 1569.

<sup>395</sup> Owen, Macnaghten and Stilgoe (n 350) 751; Richard Owen and others, 'A Framework for Responsible Innovation' in Richard Owen, John Bessant and Maggy Heintz (eds), *Responsible Innovation: Managing the Responsible Emergence of Science and Innovation in Society* (Wiley 2013) 30–31.

<sup>396</sup> Robert G Lee, 'Look at Mother Nature on the Run in the 21st Century: Responsibility, Research and Innovation' (2012) 1 *Transnational Environmental Law* 105, 108–109.

<sup>397</sup> *ibid.*

<sup>398</sup> Stilgoe, Owen and Macnaghten (n 29) 1569.

<sup>399</sup> *ibid* 1569–1570.

<sup>400</sup> Owen and others, 'A Framework for Responsible Innovation' (n 395) 30.

<sup>401</sup> Luigi Pellizzoni, 'Responsibility and Environmental Governance' (2004) 13 *Environmental Politics* 541, 544–557.

<sup>402</sup> *ibid* 557.

by current approaches to governing science and innovation.<sup>403</sup> It is inclusive<sup>404</sup> and, it is argued, better able to accommodate uncertainty and reflection on the purposes and values underlying research and innovation.<sup>405</sup> It recognises further that risk, as originating in technological and social systems,<sup>406</sup> demands responsibility shared among scientists, funders, innovators and others,<sup>407</sup> and that innovation raises questions which are trans-scientific, i.e. they extend beyond issues of risk to fundamental questions about direction, application and control.<sup>408</sup> While responsibility sharing may not remove risk, it may ‘negate extreme opposition to innovation’ and ‘enhance anticipatory governance by conferring greater legitimacy’.<sup>409</sup>

This thesis focuses on the use of regulatory science in decision-making, in other words, ‘downstream’ regulation. However, the growing focus on upstream governance of innovation invites attention for several reasons. Firstly, as discussed, this is now the object of much policy and scholarly energy and optimism. Secondly, as a reaction to the shortcomings of traditional risk regulation, it forms essential context for discussing current approaches to risk regulation in the EU. Thirdly, for this reason, it represents, *in principle*, a commitment to acknowledging these shortcomings and an acceptance of the worth of contributions from sources external to professional scientific communities. Finally, this recognition-in-principle creates a reasonable expectation that it should be reflected in other areas of technology governance and regulation. After all, regulatory science *is* still science

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<sup>403</sup> Owen and others, ‘A Framework for Responsible Innovation’ (n 395) 35. See Chapter Two.

<sup>404</sup> Pellizzoni (n 401) 559.

<sup>405</sup> Stilgoe, Owen and Macnaghten (n 29) 1569.

<sup>406</sup> Hellström (n 16) 369–370.

<sup>407</sup> Stilgoe, Owen and Macnaghten (n 29) 1569; Hellström (n 16) 372; Lee, ‘Look at Mother Nature’ (n 396) 107.

<sup>408</sup> Robert G Lee and Judith Petts, ‘Adaptive Governance for Responsible Innovation’ in Richard Owen, JR Bessant and Maggy Heintz (eds), *Responsible Innovation: Managing the Responsible Emergence of Science and Innovation in Society* (Wiley 2013) 144.

<sup>409</sup> Lee, ‘Look at Mother Nature’ (n 396) 110.

and as such, for example, remains subject to frequent policy calls for ‘ongoing’ engagement<sup>410</sup> or deliberation for their alleged benefits, discussed in Chapter Two.

Policy and scholarship on innovation governance, along with the parade it has spurred of projects, initiatives, codes, guidelines, declarations etc., are rarely explicit about their implications for risk regulation. However, risk regulation is acknowledged to be an important part of responsible innovation, despite its limitations<sup>411</sup> and it is likely that responsible innovation will require the adaptation of downstream regulation.<sup>412</sup> Self-regulation or soft law, for example, may be a good place to start by encouraging anticipation, ‘proactive management of emerging risks’ and flexibility, leading eventually to hard regulation on the basis of the knowledge gained.<sup>413</sup> Indeed, the two may often be interdependent and the latter preferred for its ability to generate stability and certainty in complex and uncertain situations, although the prior existence of hard legislative frameworks may in fact constrain the ability of the former to challenge the regulatory *status quo*.<sup>414</sup>

Innovation governance explicitly assumes responsibility for anticipating and responding to the potential impacts of innovation. That responsibility, currently shouldered by risk regulation, is no lighter a burden when borne upstream. Innovation governance itself has limits relating to, for example, scale, speed of innovation and the timing and purpose of engagement.<sup>415</sup> Ultimately, innovation governance and risk regulation are part of the same continuum. Each diverse opportunity for intervention, equally valuable yet insufficient, requires a bespoke

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<sup>410</sup> For example, Commission, *Life Sciences and Biotechnology - A Strategy for Europe* (EUR-OP 2002) 20 (Life Sciences Strategy); Council of the European Union, ‘Council Conclusions and Roadmap of 26 November 2002 for a Strategy on Life Sciences and Biotechnology (2003/C 39/05)’ para IA (Life Sciences Roadmap). Ozoliņa and others (n 10) 16 and references therein.

<sup>411</sup> Owen and others, ‘A Framework for Responsible Innovation’ (n 395) 32.

<sup>412</sup> Lee and Petts (n 408) 160.

<sup>413</sup> *ibid* 154–155; Lee, ‘Look at Mother Nature’ (n 396) 116.

<sup>414</sup> Elen Stokes, ‘Demand for Command: Responding to Technological Risks and Scientific Uncertainties’ (2013) 21 *Medical Law Review* 11.

<sup>415</sup> Lee and Petts (n 408) 158–160.

governance toolkit ‘responsive to changing societal views and expectations about technologies’.<sup>416</sup>

Various upstream tools now gathered under the banner of innovation governance (for example, constructive and real-time technology assessment<sup>417</sup>) were developed to complement downstream regulation<sup>418</sup> and enable the necessary burden-sharing by coupling, for example, more anticipatory activities such as ‘horizon scanning’ with risk governance mechanisms. Horizon scanning and risk analysis should, ideally, be *inter alia* continuous and framed ‘socially’, for example through stakeholder engagement.<sup>419</sup> Furthermore, wider, soft governance mechanisms work with hard law regulation throughout the innovation process/system.<sup>420</sup> Finally, where the relevant regulation allows ‘other legitimate factors’ to be considered in decision-making,<sup>421</sup> the outcomes of innovation governance activities could be expressed in this context.<sup>422</sup> There seems to be genuine potential, then, for an uninterrupted and coherent flow throughout the innovation-regulation governance ‘stream’; an appropriate response too, to Collingridge’s dilemma of control<sup>423</sup> in which action – neither upstream nor downstream alone – is sufficient to achieve a desirable level of social control.

More pragmatically, while nascent innovation governance and senescent risk governance co-exist (as discussed, in particular, in Chapter Five) they should operate according to a consistent set of principles. This thesis therefore proceeds on the assumption that, as much of the discourse on innovation governance aims

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<sup>416</sup> *ibid* 158.

<sup>417</sup> David H Guston and Daniel Sarewitz, ‘Real-Time Technology Assessment’ (2002) 24 *Technology in Society* 93.

<sup>418</sup> Ozoliņa and others (n 10) 14–15.

<sup>419</sup> Richard Owen and others, ‘Beyond Regulation: Risk Pricing and Responsible Innovation’ (2009) 43 *Environmental Science & Technology* 6902, 6903–6904.

<sup>420</sup> Lee and Petts (n 408) 151.

<sup>421</sup> For example, the PPPR, GFL (n 36) (General Food Law); European Parliament and Council Regulation (EC) 1829/2003 on genetically modified food and feed [2003] OJ L268/1 (Food and Feed Regulation).

<sup>422</sup> For a discussion of ‘other legitimate factors’ in relation to the GFL, see Lee, ‘Beyond Safety?’ (n 12) 263–268; and in relation to the Food and Feed Regulation, see Lee, *EU Regulation of GMOs* (n 35) 83–89. See also Chapter One.

<sup>423</sup> Collingridge (n 28) 17–20.

to reform the relationship between science and society and open up the assumptions and commitments underlying ‘ostensibly ‘neutral’, ‘objective’, scientific activities’,<sup>424</sup> its precepts should apply equally to regulatory science,<sup>425</sup> though the risks associated with technological innovation are by no means its starting point.<sup>426</sup> Crucially, governance upstream should not be used as a distraction from the persistently thorny problems of risk regulation. In other words, we should see a commitment to the principles explored below in downstream regulation, both in recognition of its potential benefits and in the interests of consistency throughout the innovation-governance stream.

## 2.2 *EU policy on innovation, science and society*

Perhaps the most prominent policy commitment is to using science and innovation to tackle grand societal challenges.<sup>427</sup> The EU also commits to pursuing research and innovation in accordance with societal goals and ethical values.<sup>428</sup> The emphasis on tackling grand challenges to justify investment in research and innovation is novel in the EU.<sup>429</sup> It responds to questions often raised, but raised too late, during risk regulation about the purposes of the research, the need for the innovation and its alleged benefits. These questions are likely to influence public tolerance of uncertainty and risk, as discussed in Chapter Two. Indeed, the Commission’s 2000 *Communication on the Precautionary Principle*, recognised this with its reference ‘to the relevance of ‘all pertinent factors’ in situations of scientific uncertainty’ including “‘socio-economic information, technological perspectives”, and perception of risk, efficiency or social acceptability...’.<sup>430</sup>

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<sup>424</sup> Owen and others, ‘A Framework for Responsible Innovation’ (n 395) 28.

<sup>425</sup> EGSG (n 6) 83.

<sup>426</sup> Owen and others, ‘A Framework for Responsible Innovation’ (n 395) 29.

<sup>427</sup> The Lund Declaration, Commission, ‘Horizon 2020’ (n 350) 2, 4; Recital 2 Horizon 2020 - specific programme (n 390). For synthetic biology specifically see ERASynBio (n 130) 8, 12, 16.

<sup>428</sup> Commission, *Life Sciences Strategy* (n 410) 19–20; Commission, *Towards a European Strategy for Nanotechnology* (EUR-OP 2004) 18.

<sup>429</sup> René von Schomberg, ‘A Vision of Responsible Research and Innovation’ in Richard Owen, John Bessant and Maggy Heintz (eds), *Responsible Innovation: Managing the Responsible Emergence of Science and Innovation in Society* (Wiley 2013) 58–59.

<sup>430</sup> Lee, ‘Risk and beyond’ (n 8) 805.

Secondly, the EU commits to espousing openness and inclusion in innovation and science.<sup>431</sup> With respect to innovation, for the EU this means combining ideas and knowledge from different actors to co-create products and find solutions to societal needs, creating shared economic and social values based on a citizen and user-centric approach.<sup>432</sup> This approach, in principle, acknowledges public capacity to define ‘the public interest and social benefit in technoscientific domains’<sup>433</sup> (inching towards unifying science and society previously dichotomised as experts/innovators and consumers of innovation) and the socially-distributed nature of knowledge,<sup>434</sup> a recognition lacking in current models of risk assessment.<sup>435</sup> With respect to science, this includes, for example, making science more responsive to societal and economic expectations,<sup>436</sup> an aim closely linked to targeting grand challenges, and wider circulation of knowledge<sup>437</sup> potentially enhancing societal responses to unexpected turns of events<sup>438</sup> and, perhaps, the opening up of risk assessment.

The EU also commits, via its ‘Science with and for Society’ (SwafS) programme, firstly to broader engagement between the public, policy-makers and scientists, particularly in relation to future and emerging technologies,<sup>439</sup> as a means to ‘anticipate and clarify political, societal and ethical issues’<sup>440</sup> and secondly, to reflection and debate to aid understanding of the place of science and technology in society.<sup>441</sup> Again, this is linked to a desire to involve all sections of society in

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<sup>431</sup> Commission, *Open Innovation, Open Science, Open to the World - a Vision for Europe* (EUR-OP 2016).

<sup>432</sup> *ibid* 14.

<sup>433</sup> EGSG (n 6) 54.

<sup>434</sup> Commission, *Open Innovation* (n 431) 13; EGSG (n 6) 23.

<sup>435</sup> EGSG (n 6) 16.

<sup>436</sup> Commission, *Open Innovation* (n 431) 45.

<sup>437</sup> *ibid* 42.

<sup>438</sup> EGSG (n 6) 82.

<sup>439</sup> Annex I, Part I, para 2.4 Horizon 2020 - specific programme (n 390); Council of the European Union (n 410) para IA.

<sup>440</sup> Charu Wilkinson, Jan Franke and James Stroyan, *Ex-Post Evaluation of Science in Society in FP7: Final Report* (EUR-OP 2016) 12.

<sup>441</sup> *ibid* 13; Commission, ‘Work Programme 2012: Capacities. Part 5: Science in Society’ (2011) C(2011)5023 4.

setting the research agenda.<sup>442</sup> The *Life Sciences Strategy* called for societal scrutiny and open dialogue on research in the life sciences and biotechnology.<sup>443</sup> The EU promises, furthermore, that '[s]afety assessment and the management of overall risks in the deployment of [nanotechnology and biotechnology] will be systematically addressed'.<sup>444</sup> With respect to the implications of these policies specifically for risk assessment, while 'systematically addressed' is vague, overall they do indicate an appetite for opening up the current expert-driven, safety-focused risk assessment to being more sensitive to collaboratively defined risks. The EU also recognises the diversity of ethical acceptability among Member States<sup>445</sup> and confirms the value of dialogue on research ethics.<sup>446</sup> References to ethics abound, particularly to support from the European Group on Ethics,<sup>447</sup> although its influence on the negotiation of legislation or the regulatory process in the context of nanotechnology, at least, appears to have been slight.<sup>448</sup>

These commitments are reinforced, generally, by the diffusion of RRI throughout EU policy.<sup>449</sup> RRI will be discussed in greater detail in relation to synthetic biology. For now, however, it acts to some extent, as an umbrella concept for the policy intentions and mechanisms discussed here, including transformation of institutions on risk (as well as ethics and innovation) from expert-domination to open deliberation.<sup>450</sup>

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<sup>442</sup> Wilkinson, Franke and Stroyan (n 440) 33; Commission, *Towards a European Strategy for Nanotechnology* (n 428) 18.

<sup>443</sup> Commission, *Life Sciences Strategy* (n 410) 18.

<sup>444</sup> Annex I. Part II, para 1 Horizon 2020 - specific programme (n 390).

<sup>445</sup> Council of the European Union (n 410) para IA.

<sup>446</sup> Wilkinson, Franke and Stroyan (n 440) 36–37.

<sup>447</sup> Council of the European Union (n 410) para IA; Commission, 'Nanosciences and Nanotechnologies: An Action Plan for Europe 2005-2009. First Implementation Report 2005-2007 COM(2007) 505 Final' 7; Lee, 'Risk and beyond' (n 8) 820, in relation to nanotechnology.

<sup>448</sup> Lee, 'Risk and beyond' (n 8) 820.

<sup>449</sup> Wilkinson, Franke and Stroyan (n 440) 39–41.

<sup>450</sup> *ibid* 41.

### 2.3 Summary

As discussed in Chapter One, the gap between policy and practice in risk regulation is problematic. While much of the EU's most up-to-date science policy refrains from explicit discussion of its intentions vis-à-vis the *regulation* of emerging technologies, clear and applicable principles emerge. These include openness and inclusion, collaboration and cooperation in defining societal needs, research trajectories and risks, shared responsibility, anticipation and (ideally continuous) deliberation for its ability to enhance the legitimacy of research funding.<sup>451</sup> The emanation of these principles from an area of science policy pertaining to innovation and science-society interactions further upstream and the fact that extraordinary energy and resources are being thrown behind changing innovation systems arguably casts risk regulation as outmoded by comparison, renders the gap more acute, and intensifies the imperative for moulding the contours of risk assessment to fit this new governance jigsaw puzzle. This is all the more so because there are specific commitments to upstream engagement on risks, the outcomes of which should work to (re)shape downstream risk regulation.

## 3. Enhancing socio-technical integration in synthetic biology: EU policy and RRI

### 3.1 *The open ethos of synthetic biology*

Aside from the difference in approach to genetic engineering that characterises synthetic biology (see Chapter Five), the discipline often distinguishes itself by adopting 'openness' as a guiding principle. This openness manifests in two distinct respects; in relation to intellectual property rights and engagement with publics. Briefly, with respect to the former, the difficulties posed to research by the presence of patents are known<sup>452</sup> and various initiatives respond to these

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<sup>451</sup> René von Schomberg, 'Prospects for Technology Assessment in a Framework of Responsible Research and Innovation' in Marc Dusseldorp and Richard Beecroft (eds), *Technikfolgen abschätzen lehren* (VS Verlag für Sozialwissenschaften 2012) 16 <[https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2439112](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2439112)> accessed 25 June 2017.

<sup>452</sup> Nikolai Braun and Keira Havens, '3 Challenges in Plant Synthetic Biology' <<http://blog.addgene.org/3-challenges-in-plant-synthetic-biology>> accessed 30 July 2016; Ewen Mullins, 'A Novel Method for Genetic Transformation of Plant Cells'

difficulties by establishing synthetic biology as an open-source discipline and by fostering an ethos of sharing (of information, knowhow and biological ‘parts’) amongst researchers.<sup>453</sup>

With respect to the latter, for many in the synthetic biology community, a community publicly perceived as inaccessible and aloof,<sup>454</sup> public engagement is the *sine qua non* of continuing research.<sup>455</sup> The BioBricks Foundation, for example pursues a mission to engineer biology in ‘an open and ethical manner to benefit all people and planet’.<sup>456</sup> The iGEM competition too has been at the forefront of the move to embed public engagement in synthetic biology research. Its website declares ‘the field of synthetic biology demands thoughtful public engagement and dialogue, educating while inviting public input to shape the direction of research’. Thus undergraduate teams competing to create biological machines are encouraged to go ‘beyond the bench’ to incorporate ethics, sustainability, social justice and education in their projects.<sup>457</sup>

In the EU, the move to a more open ethos can be seen in the adoption of RRI as a framework for the governance of synthetic biology research. RRI is a specific manifestation of the policy shift described in section 2 and grows out of the fertile

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<[http://www.teagasc.ie/publications/2010/1072/a\\_novel\\_method\\_for\\_genetic\\_transformation\\_of\\_plant\\_cells\\_5630.pdf](http://www.teagasc.ie/publications/2010/1072/a_novel_method_for_genetic_transformation_of_plant_cells_5630.pdf)> accessed 21 September 2015.

<sup>453</sup> Addgene, ‘Addgene - Homepage’ <<https://www.addgene.org/>> accessed 30 July 2016; OpenPlant, ‘Data Sharing’ <<http://openplant.org/research/data-sharing/>> accessed 30 July 2016; OpenWetWare, ‘Main Page - OpenWetWare’ <[http://www.openwetware.org/wiki/Main\\_Page](http://www.openwetware.org/wiki/Main_Page)> accessed 30 July 2016; Bernadette Bensaude Vincent, ‘The Moral Economy of Synthetic Biology’ in Joachim Boldt (ed), *Synthetic Biology: Metaphors, Worldviews, Ethics, and Law* (Springer VS 2016) 90–91.

<sup>454</sup> Macnaghten and Chilvers (n 27) 536.

<sup>455</sup> Lee and Petts (n 408) 149; Colin Macilwain, ‘World View: Talking the Talk’ (2010) 465 *Nature* 867, 867.

<sup>456</sup> ‘About’ (*BioBricks Foundation*) <<http://biobricks.org/about-foundation/>> accessed 30 July 2016.

<sup>457</sup> ‘Human Practices - 2016.igem.org’ <[http://2016.igem.org/Human\\_Practices](http://2016.igem.org/Human_Practices)> accessed 30 July 2016.

STS research of the previous few decades.<sup>458</sup> René von Schomberg proposes the following definition:

*Responsible Research and Innovation is a transparent, interactive process by which societal actors and innovators become mutually responsive to each other with a view to the (ethical) acceptability, sustainability and societal desirability of the innovation process and its marketable products (in order to allow a proper embedding of scientific and technological advances in our society).*<sup>459</sup>

RRI has four dimensions: anticipation, reflexivity, inclusion and responsiveness.<sup>460</sup> Anticipation involves considering ‘contingency, what is known, what is likely, what is plausible and what is possible’ through, *inter alia* upstream engagement.<sup>461</sup> Reflexivity requires actors and institutions to reflect on their ‘own activities, commitments and assumptions, [be] aware of the limits of knowledge and [be] mindful that a particular framing of an issue may not be universally held’.<sup>462</sup> Inclusion, as the term suggests, establishes a place for public engagement, deliberation and dialogue in the governance of innovation.<sup>463</sup> Responsiveness requires that research and innovation ‘change shape or direction in response to stakeholder and public values and changing circumstances’ aided by work in the previous three dimensions<sup>464</sup> and directly challenges the policy discourse which indiscriminately demands more research to spur economic growth.<sup>465</sup> These four dimensions, delineated in scholarship, have metamorphosed, in the EU’s hands, into requiring research and innovation that is: diverse and inclusive; anticipative and reflective; open and transparent; and responsive and adaptive to change.<sup>466</sup>

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<sup>458</sup> Michiel van Oudheusden, ‘Where Are the Politics in Responsible Innovation? European Governance, Technology Assessments, and Beyond’ (2014) 1 *Journal of Responsible Innovation* 67, 71.

<sup>459</sup> von Schomberg (n 451) 9.

<sup>460</sup> Stilgoe, Owen and Macnaghten (n 29).

<sup>461</sup> *ibid* 1570–1571.

<sup>462</sup> *ibid* 1571.

<sup>463</sup> *ibid* 1571–1572.

<sup>464</sup> *ibid* 1572.

<sup>465</sup> *ibid* 1573; von Schomberg (n 429) 58.

<sup>466</sup> ‘About RRI - RRI Tools’ <<http://www.rri-tools.eu/about-rri>> accessed 27 July 2016.

Openness is an emerging feature of RRI<sup>467</sup> and the explicit emphasis again reinforces the European policy goal to open up its science and innovation.

### 3.2 *EU policy on synthetic biology*

RRI has been enthusiastically adopted in EU policy on synthetic biology, most notably its SYNENERGENE project on the governance of synthetic biology, and many of its aims reflect the broad dimensions defined above. Speaking to inclusion, citizens are regarded as ‘co-creators’ of responsible research and innovation in synthetic biology,<sup>468</sup> echoing the EU’s overarching policy goal of open innovation and reflecting the collective nature of both innovation and responsibility.<sup>469</sup> This project also emphasises early and open dialogue, engagement and mutual learning processes with a wide variety of stakeholders,<sup>470</sup> the results of which will be made available to policy makers so that the views of citizens are systematically taken into account.<sup>471</sup> Elsewhere, the need is emphasised for participation at ‘all levels dealing with the planning, implementation, dissemination and use of synthetic biology research’.<sup>472</sup> The benefits of early public engagement are familiar.<sup>473</sup> Specifically, however, inclusion aims to address a persistent sense of powerlessness amongst publics over, for example, which kinds of research receive funding and for whose interests, though it is questionable how much progress intensified institutional efforts to include have made.<sup>474</sup> It should also demand not just involvement of

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<sup>467</sup> Owen, Macnaghten and Stilgoe (n 350) 754.

<sup>468</sup> SYNENERGENE, ‘Objectives’ <<https://www.synenergene.eu/information/objectives>> accessed 29 July 2016.

<sup>469</sup> Owen, Macnaghten and Stilgoe (n 350) 756 and references therein.

<sup>470</sup> SYNENERGENE, ‘Objectives’ (n 468); SYNENERGENE, ‘Responsible Research and Innovation in Synthetic Biology’ <[https://www.synenergene.eu/sites/default/files/uploads/SYNENERGENE-Flyer\\_web2014.pdf](https://www.synenergene.eu/sites/default/files/uploads/SYNENERGENE-Flyer_web2014.pdf)> accessed 29 July 2016.

<sup>471</sup> SYNENERGENE, ‘Objectives’ (n 468); Commission, ‘Work Programme 2012’ (n 441) 9.

<sup>472</sup> ERASynBio, ‘Activity Catalogue for Measures in Public Dialogue’ (2013) Deliverable 2.1 5; supported by EASAC, ‘Synthetic Biology: An Introduction’ (2011) 2.

<sup>473</sup> For example, James Wilsdon and Rebecca Willis, *See-through Science: Why Public Engagement Needs to Move Upstream* (Demos 2004).

<sup>474</sup> Kathy Sykes and Phil Macnaghten, ‘Responsible Innovation - Opening Up Dialogue and Debate’ in Richard Owen, JR Bessant and Maggy Heintz (eds), *Responsible Innovation: Managing the Responsible Emergence of Science and Innovation in Society* (Wiley 2013) 103.

diverse groups but that the topics up for discussion ‘reflect the full range of aspirations and concerns’ held by the participants and the way the dialogue is framed, for example the breadth of questions and range of alternatives.<sup>475</sup>

Demonstrating a commitment to anticipation, SYNENERGENE aims to be strongly future-orientated.<sup>476</sup> It has, for example, collaborated with iGEM by stimulating teams to consider future opportunities for innovation (and their impacts) in the context of societal problems by employing different innovation governance ‘tools’.<sup>477</sup> The value of mechanisms for anticipation lies in their ability to prompt consideration of contingencies, likely, plausible, possible and desirable futures alongside ‘recognition of the complexities and uncertainties of science and society’s co-evolution’.<sup>478</sup> Anticipation also contributes to shaping ‘agendas for socially-robust risk research’<sup>479</sup> and products.<sup>480</sup> Foresight exercises such as technology assessment, particularly if deliberative, could help identify the ‘right impacts’ (or negative impacts)<sup>481</sup> or knowledge gaps or improve the decision-making process<sup>482</sup> in order to ‘reduce the human cost of trial and error’.<sup>483</sup>

Reflexivity appears in the desire to encourage scientists to consider their purposes and motivations as well as alternatives to a synthetic biology approach.<sup>484</sup> Furthermore, it is not just research in which stakeholders participate as co-creators, but in regulatory frameworks themselves in ensuring they are ‘aligned with societal needs and expectations’.<sup>485</sup> This perhaps follows proposals to move towards ‘governing in the public interest’ as an antidote to unreflective use by policy-makers of new science governance procedures for instrumental ends and a recognition that

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<sup>475</sup> *ibid* 96.

<sup>476</sup> SYNENERGENE, ‘Objectives’ (n 468).

<sup>477</sup> Dirk Stemerding, ‘iGEM as Laboratory in Responsible Research and Innovation’ (2015) 2 *Journal of Responsible Innovation* 140.

<sup>478</sup> Stilgoe, Owen and Macnaghten (n 29) 1570–1571 and references therein.

<sup>479</sup> *ibid* 1570.

<sup>480</sup> von Schomberg (n 451) 7.

<sup>481</sup> *ibid* 5, 11.

<sup>482</sup> *ibid* 7.

<sup>483</sup> *ibid* 11.

<sup>484</sup> ERASynBio (n 130) 16.

<sup>485</sup> Commission, ‘Work Programme 2012’ (n 441) 9.

public concerns often relate to how science is governed as opposed, simply, to individual technologies *per se*.<sup>486</sup> Public engagement may be fruitful in engendering reflexivity throughout the innovation-regulation stream by confronting researchers and policy-makers with alternative value-framings challenging ‘assumptions of scientific amorality and agnosticism’.<sup>487</sup> Alternative methods exist too, for example, the EPSRC’s pilot requirement for ‘risk registers’ in nanoscience funding applications, in which applicants reflect on the wider implications of their research and assess potential risks, and which aim to embed anticipatory and participatory approaches and early adaptive management without squashing research.<sup>488</sup>

The quest for the ‘right impacts’ appears in the desire to foster responsiveness in considering how to shape research and innovation according to societal needs, how to define those needs (recognising that societal challenges, for example may be contested<sup>489</sup>), and how to embed social aims in research.<sup>490</sup> It aims to understand public concerns, is collaborative and seeks to align processes and outputs with the needs, values and expectations of society.<sup>491</sup> Responding to evolving public values or circumstances<sup>492</sup> may occur for example through midstream modulation<sup>493</sup> or checkpoints at each developmental stage of research.<sup>494</sup>

Even without RRI, policy emphasises socio-technical integration throughout synthetic biology research,<sup>495</sup> including downstream where regulation may need to be adapted.<sup>496</sup> Timely and reflexive consideration of the ethical aspects of

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<sup>486</sup> Macnaghten and Chilvers (n 27) 544. Sykes and Macnaghten (n 474) 104.

<sup>487</sup> Stilgoe, Owen and Macnaghten (n 29) 1571.

<sup>488</sup> Richard Owen and Nicola Goldberg, ‘Responsible Innovation: A Pilot Study with the U.K. Engineering and Physical Sciences Research Council’ (2010) 30 *Risk Analysis* 1699.

<sup>489</sup> Stilgoe, Owen and Macnaghten (n 29) 1572.

<sup>490</sup> SYNENERGENE, ‘Objectives’ (n 468).

<sup>491</sup> SYNENERGENE, ‘Responsible Research and Innovation in Synthetic Biology’ (n 470).

<sup>492</sup> Stilgoe, Owen and Macnaghten (n 29) 1572.

<sup>493</sup> E Fisher, RL Mahajan and C Mitcham, ‘Midstream Modulation of Technology: Governance From Within’ (2006) 26 *Bulletin of Science, Technology & Society* 485.

<sup>494</sup> Mark A Bedau and others, ‘Social and Ethical Checkpoints for Bottom-up Synthetic Biology, or Protocells’ (2009) 3 *Systems and Synthetic Biology* 65.

<sup>495</sup> ERASynBio (n 472) 3–4; ERASynBio (n 130) 16, 25; DG SANCO (n 130) 26; EGE, *Opinion on the Ethics of Synthetic Biology* (EUR-OP 2010) 11, 36, 52.

<sup>496</sup> ERASynBio (n 130) 17.

innovation is regarded as beneficial for its capacity to aid ‘value-sensitive’ technological design. Where ethical concerns are raised early enough, they may be incorporated as a design factor, for example in ICT where privacy is becoming a design principle,<sup>497</sup> and prevent expensive rejection of insufficiently value-sensitive technologies.<sup>498</sup> David Guston argues that anticipation should encompass ‘speculative ethics’, that is, enquiring of a particular line of research/innovation ‘*why might it be done*, and if it is to be done, how best to do it’ and creatively contemplating its possible, uncertain futures, *before* its material outputs (and their potential implications) are likely or imminent, in order to focus discussion on responsibility.<sup>499</sup> More profoundly, without broad engagement in speculative ethics, definition of the emergent field may be ceded to an exclusive cadre of established participants whose vision may (wittingly) perpetuate present injustices.<sup>500</sup>

Uncertainty and the place of precaution are also acknowledged.<sup>501</sup> In an RRI context,<sup>502</sup> the precautionary principle can be seen not as dampening innovation but as a goad to action, aiding consideration of alternatives,<sup>503</sup> pursuing new risk research or identifying knowledge gaps.<sup>504</sup> In Chapter Five, I argue that downstream regulation can influence upstream innovation and governance systems. The precautionary principle operating as an incentive to create safe and sustainable

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<sup>497</sup> von Schomberg (n 451) 15–16.

<sup>498</sup> Jeroen van den Hoven, ‘Value Sensitive Design and Responsible Innovation’ in Richard Owen, JR Bessant and Maggy Heintz (eds), *Responsible Innovation: Managing the Responsible Emergence of Science and Innovation in Society* (Wiley 2013).

<sup>499</sup> David H Guston, ‘“Daddy, Can I Have a Puddle Gator?”: Creativity, Anticipation, and Responsible Innovation’ in Richard Owen, JR Bessant and Maggy Heintz (eds), *Responsible Innovation: Managing the Responsible Emergence of Science and Innovation in Society* (Wiley 2013) 114–116.

<sup>500</sup> *ibid* 115.

<sup>501</sup> DG SANCO (n 130) 26; EGE (n 495) 43.

<sup>502</sup> It is acknowledged that the meaning of the precautionary principle is highly contested and that its interpretation and operation vary widely depending on context, E Fisher, ‘Precaution, Precaution Everywhere: Developing a Common Understanding of the Precautionary Principle in the European Community’ (2002) 9 *Maastricht Journal of European and Comparative Law* 7.

<sup>503</sup> von Schomberg (n 429) 63.

<sup>504</sup> *ibid* 67.

products<sup>505</sup> could stand as an example of this effect. Furthermore, anticipatory engagement in the context of uncertain and unpredictable innovation is argued to reframe the ethical model governing innovation from consequentialist to virtue ethics in terms both of the innovator and the values instilled in the innovation, opening up discussion on purposes and space for uncertainty.<sup>506</sup>

#### 4. Enhancing socio-technical integration in pesticide use: EU policy and sustainability<sup>507</sup>

EU policy on regulating pesticides has long been framed in terms of achieving sustainability. The 1993 Fifth Environmental Action Programme (5EAP), the first European sustainable development strategy in all but name,<sup>508</sup> recognised the problems, in terms of cost and pollution, of systematic use of pesticides<sup>509</sup> and sought reduction to the point where none of the processes indispensable for sustainable agriculture and important for nature conservation were affected.<sup>510</sup> Overall, the 5EAP pushed towards an ambitious conception of sustainability which entailed 'continued economic and social development without detriment to the environment', sensitivity to the 'real socio-economic effects and values of consumption and conservation', 'equitable distribution and use of resources' and socio-economic well-being across generations.<sup>511</sup> It acknowledged, furthermore, that political, economic and social trends all contribute to environmental problems

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<sup>505</sup> von Schomberg (n 451) 11.

<sup>506</sup> Owen, Macnaghten and Stilgoe (n 350) 756; Alexei Grinbaum and Christopher Groves, 'What Is "Responsible" about Responsible Innovation? Understanding the Ethical Issues' in Richard Owen, JR Bessant and Maggy Heintz (eds), *Responsible Innovation: Managing the Responsible Emergence of Science and Innovation in Society* (Wiley 2013).

<sup>507</sup> This section draws heavily on research conducted for Olivia Hamlyn, 'Sustainability and the Failure of Ambition in European Pesticides Regulation' (2015) 27 *Journal of Environmental Law* 405.

<sup>508</sup> Marc Pallemarts, 'Developing More Sustainably?' in Andrew Jordan and Camilla Adelle (eds), *Environmental Policy in the EU: Actors, Institutions and Processes* (3rd ed, Routledge 2013) 350.

<sup>509</sup> Commission, 'Towards Sustainability: A European Community Programme of Policy and Action in Relation to the Environment and Sustainable Development' [1993] OJ C138/7 35.

<sup>510</sup> *ibid* 38.

<sup>511</sup> *ibid* 12–13.

and that human values and behaviour are the root cause.<sup>512</sup> The Sixth Environmental Action Programme (6EAP) contained a more reductive vision of the sustainable use of pesticides, confined principally to mitigating the impacts of pesticide use on human health and the environment, though this was expressed as a separate policy goal to generally achieving ‘more sustainable use of pesticides’ which implied something more ambitious, albeit vague.<sup>513</sup>

The 2002 Communication *Towards a Thematic Strategy on the Sustainable Use of Pesticides* reiterated this objective, similarly formulated.<sup>514</sup> The underlying policy goals are primarily safety-orientated,<sup>515</sup> although there is a call to develop ‘a plant protection practise [sic] that fits into the concept of sustainable agriculture including social and economic dimensions’,<sup>516</sup> recognising both the multi-functionality of agriculture<sup>517</sup> and the relevance of factors outside the realm of safety, though in the absence of further detail we are left to speculate what precisely this goal entails. The socio-economic benefits of pesticides and the costs to the environment and human health are rehearsed.<sup>518</sup> These impacts and their asymmetric characterisation (goods are socio-economic; bads are environmental/health-related) are discussed in more detail in Chapter Four. For now however, the point is that, though safety is prime, the non-safety dimension (including the distribution of risks and benefits, the uncertainty haunting

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<sup>512</sup> *ibid* 68.

<sup>513</sup> Art. 7 European Parliament and Council Decision No 1600/2002/EC laying down the Sixth Community Environmental Action Programme [2002] OJ L242/1.

<sup>514</sup> Commission, ‘Towards a Thematic Strategy on the Sustainable Use of Pesticides COM(2002) 349 Final’ 7; Council of the European Union, *Renewed EU Sustainable Development Strategy* (2006) 15; Commission and others, *General Union Environment Action Programme to 2020: Living Well, within the Limits of Our Planet* (EUR-OP 2014) para 54(e).

<sup>515</sup> See also Commission, ‘A Thematic Strategy on the Sustainable Use of Pesticides COM(2006) 372 Final’ 11.

<sup>516</sup> Commission, ‘Towards a Thematic Strategy’ (n 514) 8.

<sup>517</sup> Jules Pretty, ‘Reality Cheques’ in Jules Pretty (ed), *The Earthscan Reader in Sustainable Agriculture* (Earthscan 2005) 51–53.

<sup>518</sup> Commission, ‘Towards a Thematic Strategy’ (n 514) 11–12; Commission, ‘Proposal for a Directive of the European Parliament and of the Council Establishing a Framework for Community Action to Achieve a Sustainable Use of Pesticides COM(2006) 373 Final’ 3.

assessments of pesticide risk<sup>519</sup> and the dependence of agriculture on chemical inputs<sup>520</sup>) is at least recognised. Finally, policy acknowledges the value of broad participation in developing risk/use reduction plans,<sup>521</sup> discussed further in Chapter Four.

Although sometimes in vague terms, then, the multi-dimensionality and social embeddedness of pesticide use is recognised. This is reinforced, to a certain extent, by general EU policy on sustainable development. For example, the 6EAP explicitly acknowledges the relevance of the social and economic alongside the environmental<sup>522</sup> and the value of broad societal participation.<sup>523</sup> Four years later, the Renewed EU Sustainable Development Strategy asserted the importance of solidarity within and between generations, public participation in decision-making, the integration of the three pillars of sustainable development into regulation<sup>524</sup> and of further research into the interplay between social, economic and ecological systems.<sup>525</sup> Similar, if vague, commitments re-emerge in the Commission's latest Communication on sustainable development<sup>526</sup> which seeks to implement the 2030 Agenda for Sustainable Development.<sup>527</sup>

The adoption of sustainable development as an overarching policy goal and the range of concerns addressed in the policy framework leave no doubt that non-safety goals are firmly within the EU's sights. There is more, however. The language

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<sup>519</sup> Commission, 'Towards a Thematic Strategy' (n 514) 14–15.

<sup>520</sup> *ibid* 22. The EESC argues that dependence reduction should be a long-term objective of policy, EESC, 'Opinion of the European Economic and Social Committee on the "Communication from the Commission to the Council, the European Parliament and the European Economic and Social Committee: Towards a Thematic Strategy on the Sustainable Use of Pesticides"' (COM(2002) 349 Final)' para 4.1.

<sup>521</sup> Commission, 'Towards a Thematic Strategy' (n 514) 29; Commission, 'Thematic Strategy' (n 515) 8.

<sup>522</sup> Art. 2(4) second sentence 6EAP.

<sup>523</sup> Arts 3(9), 10(a) and (b) 6EAP.

<sup>524</sup> Council of the European Union (n 514) 4–5.

<sup>525</sup> *ibid* 23.

<sup>526</sup> Commission, 'Next Steps for a Sustainable European Future: European Action for Sustainability COM(2016) 739 Final'.

<sup>527</sup> United Nations, 'Transforming Our World: The 2030 Agenda for Sustainable Development A/RES/70/1' (2015).

of sustainability houses a rich content inherited from the previous several decades of discourse which could form the foundations of a regime in which the myriad concerns raised by pesticide use are considered and addressed. In order to fully realise the potential of sustainability in the regulation of pesticides then, full engagement with this discourse should attend the EU's employment of the language of sustainability in the relevant policy and legislation. It is this potential which the remainder of this section discusses. While there is, of course, much more to sustainability and sustainable development beyond the elements I discuss below,<sup>528</sup> I highlight those which, I argue, demonstrate its usefulness in regulating pesticide use. These are: its three dimensions, its normativity and the centrality of inter- and intra-generational equity. Much of the discourse relating to sustainability uses the terms 'sustainability' and 'sustainable development' interchangeably, or without delineating a boundary between the two.<sup>529</sup> I use the term 'sustainability', but have drawn on literature which employs both terms, in analysing the EU's law and policy on 'sustainable use' of pesticides. Ultimately, the policy develops a decreasingly ambitious concept of sustainability as applied to pesticide use until reaching the vision of sustainable use in the SUD which, as argued in Chapter Four, bears little resemblance to the early policy ambitions<sup>530</sup> and the rich content explored below.

#### 4.1 *The three dimensions*

The overarching draw of sustainability, with respect to the regulation of pesticide use, is its acknowledgement of the relevance of social, economic and environmental dimensions. Sustainability arose in the 1980s to 'dissolve the conflicts between environmental and economic values'<sup>531</sup> and its popularity stems

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<sup>528</sup> For further discussion, see John Dryzek, *The Politics of the Earth: Environmental Discourses* (3rd ed, OUP 2013) ch 7; Andrea Ross, 'Modern Interpretations of Sustainable Development' (2009) 36 *Journal of Law and Society* 32.

<sup>529</sup> For a discussion of the potential difference between the two terms, see Robert Paehlke, 'Sustainability, Sustainable Development, and Values' in John Martin Gillroy and Joe Bowersox (eds), *The Moral Austerity of Environmental Decision Making: Sustainability, Democracy, and Normative Argument in Policy and Law* (Duke UP 2002).

<sup>530</sup> For example in the 5EAP and Commission, 'Towards a Thematic Strategy' (n 514).

<sup>531</sup> Dryzek (n 528) 16.

from its optimistic linking of the environment and development<sup>532</sup> by ‘bundling together environmental, social and economic policy strands’.<sup>533</sup> Much debate over sustainable development has focused on the three ‘mutually reinforcing’ pillars of social well-being, economic growth and environmental protection, whether they are equal or whether one, particularly the environment pillar, enjoys priority.<sup>534</sup> Although there is no overall consensus as to the meaning of sustainable development<sup>535</sup> (or sustainability), the ‘official’ policy view, in the EU and internationally, appears to endorse equality between the pillars,<sup>536</sup> encouraging the balancing and prioritisation of aims, during decision-making, in response to given circumstances. The EU Court of Justice has, to a certain extent, demonstrated willingness to engage in balancing exercises where commercial economic interests are involved. For example, in *First Corporate Shipping*, AG Léger opined that sustainable development did not mean that the environment should always prevail over other interests but rather that interests should be balanced and reconciled.<sup>537</sup> However, consideration of such commercial economic issues does not guarantee

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<sup>532</sup> Klaus Bosselmann, *The Principle of Sustainability: Transforming Law and Governance* (Ashgate 2008) 26.

<sup>533</sup> Mark Stallworthy, *Understanding Environmental Law* (Sweet & Maxwell 2008) 174.

<sup>534</sup> Bosselmann (n 532); Ross (n 528).

<sup>535</sup> Bosselmann (n 532) 23.

<sup>536</sup> United Nations, ‘The Future We Want’ UN doc A/RES/66/288 paras 74, 87; Raymond Cléménçon, ‘Welcome to the Anthropocene: Rio+20 and the Meaning of Sustainable Development’ (2012) 21 *The Journal of Environment & Development* 311, 312; Pallemarts (n 508) 362.

<sup>537</sup> Case C-371/98 *R v Secretary of State for the Environment, Transport and the Regions, ex parte First Corporate Shipping Ltd* [2000] ECR I-9235, Opinion of AG Léger; Lee, *EU Environmental Law* (n 51) 65; Donald McGillivray, ‘Valuing Nature: Economic Value, Conservation Values and Sustainable Development’ (2002) 14 *Journal of Environmental Law* 85 on the use of sustainable development to ‘economise’ environmental problems in *First Corporate Shipping*. See also the Court’s analysis of the provisions of European Parliament and Council Directive 2000/60/EC establishing a framework for Community action in the field of water policy [2000] OJ L327/1 in Case C-43/10 *Nomarchiaki Aftodioikisi Aitolokarnanias and Others v Ypougos Perivallontos, Chorotaxias kai Dimosion ergon and Others* EU:C:2012:560. This involved Greek plans to divert water from one river basin to another to provide drinking water, electricity supply and irrigation. Despite acknowledging the potential harm to the environment of water power and irrigation, AG Kokott held that water power and irrigation could be regarded as sustainable development measures, elevating narrow economic interests over others, Opinion of AG Kokott, EU:C:2011:651; Lee, *EU Environmental Law* (n 51) 66.

that the court will take into account broader economic or distributive issues. Nor does it address the difficulty of calculating the costs of a particular activity. Sustainability's economic dimension should encourage careful and open consideration of the range of costs of pesticide use, acknowledging the inevitable uncertainties. The social dimension of sustainability should likewise encourage consideration of the social implications of pesticide use.<sup>538</sup>

Even if the changing priority, or the equal strength, of the three dimensions, leaves sustainability without a clear direction,<sup>539</sup> this is a question of hierarchy, not a challenge to the fundamental relevance of each dimension. The discussion here does not take a view on this point, but simply highlights the value of sustainability for its treatment of all these dimensions (as opposed to, for example, the environment alone) as relevant in decision-making. Mere relevance of these dimensions may seem to be a normatively weak position if the aim is to *require* technology regulation, often dominated by risk and safety considerations,<sup>540</sup> genuinely to engage with the broader social and economic impacts of the technology in question. Furthermore, from an environmental perspective, sustainability may not necessarily lead to a greener outcome as it can increase the importance of economic considerations relative to environmental considerations.<sup>541</sup> However, decision-making guided by a principle which explicitly treats a broader range of considerations as relevant, and which construes such considerations themselves broadly, would represent progress towards greater socio-technical integration, provided it included, with respect to pesticides, all impacts of use and the social, economic and environmental interests of society.

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<sup>538</sup> The social and economic implications of pesticide use are discussed in Chapter Four.

<sup>539</sup> Ross (n 528) 37.

<sup>540</sup> Lee, 'Beyond Safety?' (n 12) 285.

<sup>541</sup> Lee, *EU Environmental Law* (n 51) 65–66. See also Pallemarts (n 508) 351 on the reference to sustainable development in Art. 11 TFEU. It is also notable that the reference to sustainable development in Art. 3(3) TEU is made in an overtly economic context, Lee, *EU Environmental Law* (n 51) 63.

## 4.2 Sustainability and values

The regulatory pursuit of ‘sustainable use’ immediately raises the question: ‘what is sustainable and how should it be achieved and judged?’ It has been asserted that what is sustainable can be determined and measured scientifically,<sup>542</sup> by establishing ecological limits, thresholds etc., and/or by using economic models which measure growth.<sup>543</sup> This is the approach adopted throughout much of European environmental policy-making. For example, the Seventh Environmental Action Programme (7EAP) aims to be based on scientific knowledge,<sup>544</sup> and the analysis in the Commission’s Impact Assessment of the Thematic Strategy on the Sustainable Use of Pesticides has a strong economic bent.<sup>545</sup> Despite the inclusion of references to citizen involvement in the 7EAP,<sup>546</sup> the need to understand socio-economic and environmental factors and individual and societal behaviour is expressed as a technical exercise of filling a data gap.<sup>547</sup> Full public debate is reserved for the later risk management stage of regulation.<sup>548</sup>

Sustainability is not just a question of science or economics; it is political and value-based.<sup>549</sup> Measuring sustainability has been interpreted as depending on what we think matters. What we think matters is the thing whose value must be maintained.<sup>550</sup> The point is illustrated by Andrew Dobson’s discussion of thresholds, in which he argues that science can identify whether a particular practice will breach a particular threshold, but not whether the element to which the threshold

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<sup>542</sup> See discussion in Dobson (n 178) 143–147.

<sup>543</sup> See Bryan Norton, ‘Sustainability: Descriptive or Performative?’ in John Martin Gillroy and Joe Bowersox (eds), *The Moral Austerity of Environmental Decision Making: Sustainability, Democracy, and Normative Argument in Policy and Law* (Duke UP 2002) 51–53 who also highlights the presence of commitments beneath support for this approach, 57.

<sup>544</sup> Commission and others (n 514) paras 55, 66.

<sup>545</sup> Commission, ‘The Impact Assessment of the Thematic Strategy on the Sustainable Use of Pesticides’ SEC/2006/0894.

<sup>546</sup> Commission and others (n 514) 66–67.

<sup>547</sup> *ibid* 71.

<sup>548</sup> *ibid* 72.

<sup>549</sup> Lee, *EU Environmental Law* (n 51) 57.

<sup>550</sup> Brian Barry, ‘Sustainability and Intergenerational Justice’ in Andrew Dobson (ed), *Fairness and Futurity* (OUP 1999) 101, 105.

applies ‘matters’.<sup>551</sup> The latter judgment is a question of values. In other words, the fruits of scientific research and economic data about growth and welfare levels, though vital, are purely descriptive and cannot resolve fundamental ideological disagreements over what needs to be maintained in order to achieve sustainability.<sup>552</sup> Disagreement is further exacerbated by the presence of uncertainty over, for example, the impacts of human activity<sup>553</sup> or the way natural capital stocks work<sup>554</sup> (if indeed we agree on sustaining natural capital to achieve sustainability), or the behaviour of pesticides. This uncertainty limits the utility of tools such as indicators and technical expertise.

Determining what constitutes ‘sustainable use of pesticides’ must involve scientific expertise for sure, but expertise should be prised open and applied using the tools and principles described in sections 2 and 3. For example, open, early and reflective dialogue between experts, stakeholders and publics, on the meaning of sustainability as applied to pesticide use, the outcomes of which could guide, examine and challenge expert advice or develop indicators, a key tool for implementing and measuring progress under the SUD.<sup>555</sup> Furthermore, decision-making should look beyond establishing numerical values for sustainability, towards the context of, and the range of considerations bearing on, the use of pesticides, to ensure breadth in regulation. This could also be addressed, pre-legislation, through inclusive deliberation, perhaps alongside a report specifically commissioned to examine, for example, distributive socio-economic impacts of pesticides use and the attitudes of different publics to pesticide use and their values. Such initiatives are precisely what I argue the three dimensions of sustainability in decision-making are designed to promote and support.

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<sup>551</sup> Dobson (n 178) 146–148.

<sup>552</sup> Norton (n 543) 57–58.

<sup>553</sup> Lee, *EU Environmental Law* (n 51) 77.

<sup>554</sup> David Pearce and others, *Blueprint 3: Measuring Sustainable Development* (Earthscan Publications 1993) 17.

<sup>555</sup> Art. 15 SUD.

Debate over what matters in relation to pesticide use should include broad political discussion of the level and type of pesticide use which equates to sustainable use and the practices and goals required to achieve it. It should also be acknowledged that values transform over time and legislation should be able to adapt to evolution in the meaning of sustainable use and society's changing values and priorities, not just advances in technology and science. (Indeed, taking a leaf out of the innovation governance book, developments in pesticide technology should adapt too.) Member States and the Commission, for example, could be required to revisit the conclusions of any public dialogue on which the prevailing interpretation of sustainable use was based and assess whether they hold in the light of any changes in attitudes, or developments in pesticide use and its regulation.

#### 4.3 *Inter-generational and intra-generational equity*

The principle of sustainable use has traditionally been associated with conservation of natural resources so as to prolong their exploitation.<sup>556</sup> Applying the term to pesticides then is, in some ways, a paradox. On the one hand, the intention may not be to eke out a scarce resource, nor to ensure that pesticide use can continue forever, especially since the SUD also aims to reduce pesticide use.<sup>557</sup> On the other hand, a non-pesticide-resistant insect population is an important resource to preserve.<sup>558</sup> However, with respect to pesticides generally, the search for sustainability focuses primarily on ensuring that the sustained existence and welfare of everything pesticides touch (people, nature, agriculture, communities, public finances etc.) is not adversely affected.<sup>559</sup>

As discussed above, there is debate over what we should maintain for the purposes of sustainability, fuelled by our ignorance of what future generations will value and

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<sup>556</sup> For more, see Philippe Sands and Jacqueline Peel, *Principles of International Environmental Law* (3rd ed, CUP 2012) 210–213.

<sup>557</sup> Art. 4(1) third sub-paragraph SUD.

<sup>558</sup> Lee, *EU Regulation of GMOs* (n 35) 27.

<sup>559</sup> Compare the policy to achieve sustainable use of phosphorus which seeks, *inter alia*, to preserve a limited resource for future generations and prevent pollution and eutrophication, Commission, 'Consultative Communication on the Sustainable Use of Phosphorus COM(2013) 517 Final'.

indeed the often unknowable impacts of pesticide use. There is a convincing case that equality of opportunities must be maintained such that future generations may live according to their conceptions of 'the good life', by not foreclosing options now.<sup>560</sup> Edith Brown Weiss makes a similar argument<sup>561</sup> and advocates a conception of inter-generational equity based on the conservation of options (the diversity of the resource base), quality (the condition in which the natural and cultural environment is passed on) and access (obliging each generation to ensure equitable access to this legacy).<sup>562</sup> This last principle is important for future intra-generational equity, as preserving options does not necessarily ensure their equitable distribution in the future.<sup>563</sup>

Aspects of pesticide use which raise questions of inter-generational justice include the following. Firstly, the contribution that diversity makes to robustness is key to the principle of conservation of options.<sup>564</sup> Dependence solely on the use of agrochemicals for crop protection, and indeed, the monocultures partly supported by pesticides, may breach this principle. Secondly and closely related, the negative impact on the environment and biodiversity can narrow the resource base, resulting in loss of options, for example for developing new products, maintaining the planet's health and for enabling future generations to address their own problems.<sup>565</sup> Finally, the persistence of pesticide damage shifts the costs of remediation onto future generations, who are unable to reap any associated benefits.<sup>566</sup> There is, moreover, no guarantee that remediation will be cheaper in the future. These are all issues which the requirements of inter-generational equity could address. Indeed, the strong moral undercurrent of inter-generational equity

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<sup>560</sup> Barry (n 550) 104; Dobson (n 178) 162–163.

<sup>561</sup> Edith Brown Weiss, *In Fairness to Future Generations: International Law, Common Patrimony, and Intergenerational Equity* (United Nations University 1989) 38.

<sup>562</sup> *ibid* 38–45.

<sup>563</sup> Barry (n 550) 112.

<sup>564</sup> Brown Weiss (n 561) 40–42.

<sup>565</sup> *ibid* 8–9.

<sup>566</sup> *ibid* 5, 10–11.

could provide an ethical context in which to evaluate the ability of current policies to pursue sustainability.<sup>567</sup>

A more general problem, still relevant to pesticides, is that the lack of representation of future (both younger and unborn) generations in decision-making processes means that ‘potential trade-offs between the preferences of present and future generations are usually ignored’.<sup>568</sup> The particular problems associated with inter-generational equity should find formal expression in the regulation of pesticides. Despite the reference to sustainability, a large part of the SUD’s approach to the regulation of pesticides is risk-based, as discussed in Chapter Four. Technical assessments have little to say about the above, and other ‘justice’-related questions, including inter-generational equity, a position exacerbated by the gaps in our knowledge about the distribution of environmental goods and bads.<sup>569</sup> However, if the question of inter-generational equity becomes the object of genuine attention in pesticide use decision-making, it could challenge our technocratic decision-making procedures, or even our ways of life.<sup>570</sup> Whether this occurs may depend on the openness of any discussion over sustainability under the auspices of the SUD and whether this endows the concept of sustainability with the necessary moral content.

In terms of intra-generational equity, as discussed, the uneven distribution of the costs and benefits of pesticide use among members of the present generation deserves consideration through the social and economic dimensions of sustainability. Furthermore, there exists an essential connection between social justice and the environment,<sup>571</sup> and this underpins more specific environmental

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<sup>567</sup> Celia Campbell-Mohn, ‘Sustainability in the United States: Legal Tools and Initiatives’ in John Martin Gillroy and Joe Bowersox (eds), *The Moral Austerity of Environmental Decision Making: Sustainability, Democracy, and Normative Argument in Policy and Law* (Duke UP 2002) 148.

<sup>568</sup> Brown Weiss (n 561) 5.

<sup>569</sup> Lee, *EU Environmental Law* (n 51) 78–79.

<sup>570</sup> *ibid.*

<sup>571</sup> Joel Kassiola, ‘Why Environmental Thought and Action Must Include Considerations of Social Justice’ in John Martin Gillroy and Joe Bowersox (eds), *The Moral Austerity of*

policy.<sup>572</sup> The Commission does acknowledge the distribution problem but goes no further.<sup>573</sup> The starkest examples are those of local residents bearing the burden of pesticide spraying in the form of air pollution, excessive spraying by one farmer leading to pest resistance which affects neighbouring farmers or crop losses due to pesticides drifting to non-target crops<sup>574</sup> and burdens can be felt far more remotely, by all actors in the food distribution chain.<sup>575</sup>

Pesticides also raise questions of land use. Crop protection activities which, for example, unreasonably exclude members of the public from recreational use or aesthetic enjoyment of land may fall foul of Brown Weiss's principle of conservation of access which grants members of the present generation 'a reasonable, non-discriminatory right of access to the natural and cultural resources of our planet'.<sup>576</sup> On the other hand, if transition to low-pesticide input requires extensification of farming (i.e. reducing inputs, such as agro-chemicals, while increasing the area of land farmed to maintain yields), this too has implications for land allocation.

Finally, pesticide use affects the structure of our agricultural systems. It has supported continuous, simplified, large-scale farming<sup>577</sup> and reduced the need for labour.<sup>578</sup> While the Commission has characterised minimisation of labour input as

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*Environmental Decision Making: Sustainability, Democracy, and Normative Argument in Policy and Law* (Duke UP 2002).

<sup>572</sup> This was also a key tenet of World Commission on Environment and Development, *Our Common Future* (OUP 1987) 2–7.

<sup>573</sup> Commission, 'Towards a Thematic Strategy' (n 514) 14. There is only a cursory acknowledgment of this phenomenon in Commission, 'Impact Assessment' (n 545) 61, 152–153, 181.

<sup>574</sup> David Pimentel and others, 'Assessment of Environmental and Economic Impacts of Pesticide Use' in David Pimentel and Hugh Lehman (eds), *The Pesticide Question: Environmental, Economics and Ethics* (Routledge, Chapman & Hall Inc 1993) 61.

<sup>575</sup> See Pimentel and others (n 574) for more detail.

<sup>576</sup> Brown Weiss (n 561) 43–44.

<sup>577</sup> Frank den Hond, Peter Groenewegen and Nico van Straalen, 'Questions Around the Persistence of the Pesticide Problem' in Frank den Hond, Peter Groenewegen and Nico van Straalen (eds), *Pesticides: Problems, Improvements, Alternatives* (Blackwell 2003) 7.

<sup>578</sup> Jules Pretty, William Vorley and Dennis Keeney, 'Pesticides in World Agriculture: Causes, Consequences and Alternative Courses' in William Vorley and Dennis Keeney (eds), *Bugs in the System: Redesigning the Pesticide Industry for Sustainable Agriculture* (Routledge 1998) 20.

beneficial,<sup>579</sup> it also recognises the importance of employment.<sup>580</sup> Alternative agricultural structures exist. For example, the benefits of organic farming for sustainable development, consumers and social and economic development of rural communities, have been recognised.<sup>581</sup> Sustainability, and the concept of intra-generational equity in particular, could prompt exploration of such alternatives to address some of the concerns related to the distributive impacts of pesticide use.

## 5. Conclusion

The policy areas examined above at a minimum demonstrate an openness towards holistic consideration of all aspects and implications of research and technological innovation. The discourse and policy on innovation governance, and specifically RRI, encompass ambitious elements and great potential for changing the conduct of research and innovation to address some or all of the types of societal concerns expressed in relation to technological innovation<sup>582</sup> and specifically synthetic biology. These developments upstream have the attendant potential both to complement and become mirrored in downstream risk regulation. Likewise, the three elements of sustainability discussed above have the potential to respond to many of the concerns related to pesticide use, if genuinely and carefully implemented in legislation. Either individually or in combination, they could address the distribution of the impacts of pesticide use between and within generations, the diversity of actors involved, the importance of values when determining what counts as 'sustainable' in pesticide use and the distribution of information about pesticide use throughout society. They also highlight a wealth of means, beyond risk assessment, available to appraise this particular technology

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<sup>579</sup> Commission, 'Thematic Strategy' (n 515) 5.

<sup>580</sup> Commission, 'Europe 2020: A Strategy for Smart, Sustainable and Inclusive Growth COM(2010) 2020' 18–19.

<sup>581</sup> Commission and Eurostat, *Sustainable Development in the European Union: 2013 Monitoring Report of the EU Sustainable Development Strategy* (EUR-OP 2013) 96. For a concise discussion the role of agriculture and pesticide use in achieving sustainable development, see Pearce and others (n 554) ch 8.

<sup>582</sup> See Chapter Two and Macnaghten and Chilvers (n 27) 534–538.

(and indeed others). How far these policy ambitions are reproduced in the relevant regulation is the question to which the following two chapters now turn.

## SECTION II – LOCATING THE GAP: TWO ILLUSTRATIVE EXAMPLES

## Chapter Four – European regulation of pesticides: an unambitious approach to sustainability<sup>583</sup>

### 1. Introduction

As discussed in Chapter Three, several decades of scholarship and policy have populated the concept of sustainability with various, now familiar, elements. Even while significant details remain subject to debate, one may see, at minimum, a loose consensus on their relevance to sustainability. That chapter argued furthermore, that when used, for example in legislation or policy, sustainability should raise expectations that these elements will exist and exert influence.

This chapter considers how successfully the Sustainable Use Directive (SUD) incorporates elements of sustainability and uses them to address the complexities of pesticide use, and thus, how successfully it meets expectations associated with sustainability. A wholesale adoption of ‘sustainability’ as a framework on which to hang European regulation of pesticides could provide a real spur for ambitiously opening up decision-making to a broad range of issues and contributions from a variety of sources. It thereby presents an opportunity to depart from the narrow, predominantly risk-based, approach commonly applied to regulation of risky technologies in the EU, discussed in Chapter One, and to enhance socio-technical integration. In terms of the overall thesis, this chapter presents a detailed analysis of one manifestation of the policy-practice gap and reasons for its persistence. It focuses on how decision-making techniques, in this context, exclude consideration of information other than that concerning the risks of pesticide use and values other than ensuring safety and environmental protection despite their relevance, as discussed in Chapter Three.

Pesticides display a constellation of considerations, many, if not all, of which should be visible through the regulator’s telescope. I discuss these in section 2. The SUD is a framework directive, acknowledging the vast diversity of national conditions in the EU with respect to the structure of the agricultural sector, climate, geography

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<sup>583</sup> This chapter draws heavily on research conducted for Hamlyn (n 507).

and existing national legislation.<sup>584</sup> It is the culmination of a long period of development and consultation set in motion in 2002 by the 6EAP<sup>585</sup> and operates alongside the 2009 Plant Protection Product Regulation.<sup>586</sup> In section 3, I evaluate the SUD in light of the key elements of sustainability discussed in Chapter Three. I argue that the label ‘sustainable’ conceals an approach which falls far short of adopting such elements, and consequently realising the potential of sustainability.

In section 4, I offer some explanations for the EU’s lack of ambition in this area. The SUD, I argue, contains a reductive and unimaginative approach to the implementation of sustainable use, which ignores the richness and ambition of the discourse on sustainability and its well-established elements. This potential, I argue further, is overlooked in favour of an approach primarily aimed at achieving ‘efficiency’ by managing and reducing risks to human health and the environment. This safety-orientated approach and its unambitious ethos of ‘doing the *status quo* better’ stifles the potential of sustainability to enhance socio-technical integration in the EU’s regulation of pesticides. Section 5 concludes.

## 2. The pesticide question

Pesticides occupy a unique place in modern society. They are substances,<sup>587</sup> acknowledged to be inherently toxic, that are deliberately released into the environment<sup>588</sup> both in spite of and because of their toxic properties, in pursuit of socio-economic benefits such as crop protection. These benefits also include the

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<sup>584</sup> Commission, ‘Proposal for a Directive of the European Parliament and of the Council Establishing a Framework for Community Action to Achieve a Sustainable Use of Pesticides COM(2006) 373 Final’ (n 518) 9.

<sup>585</sup> 6EAP (n 513). Prior to this launch, the Commission had been collaborating on a project to develop a ‘Framework for the Sustainable Use of Plant Protection Products’ since 1992, <<http://ec.europa.eu/environment/archives/ppps/history.htm>> accessed 30 April 2017.

<sup>586</sup> Plant Protection Product Regulation (n 117).

<sup>587</sup> Pesticides are predominantly chemicals. For discussion of chemicals regulation in general, see Commission, ‘Strategy for a Future Chemicals Policy COM(2001) 88 Final’.

<sup>588</sup> Commission, ‘Towards a Thematic Strategy’ (n 514) 9, 12; Geert de Snoo, ‘Variations in Agricultural Practice and Environmental Care’ in Frank den Hond, Peter Groenewegen and Nico van Straalen (eds), *Pesticides: Problems, Improvements, Alternatives* (Blackwell 2003) 105.

production of high-quality, affordable fruit and vegetables,<sup>589</sup> the reduction of labour (and labour costs) and freedom from dependence on crop rotation.<sup>590</sup> Overall, pesticides ‘make a significant contribution to maintaining world food production’.<sup>591</sup>

Regarding the risks and costs of pesticides, those to the environment and public health are the most immediately obvious. Intensive agriculture, including pesticide use, has led to serious environmental degradation.<sup>592</sup> The potential impacts on human health are well-documented,<sup>593</sup> and include risks of direct exposure of workers, indirect exposure of consumers and bystanders and possible bioaccumulation and persistence, carcinogenicity, mutagenicity and endocrine disruption.<sup>594</sup>

Regulation, for example the landmark<sup>595</sup> adoption of the Plant Protection Product Directive,<sup>596</sup> and improvements in the pesticide products themselves,<sup>597</sup> have improved safety.<sup>598</sup> However, one need only look at events within the last few years

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<sup>589</sup> Commission, ‘Towards a Thematic Strategy’ (n 514) 11.

<sup>590</sup> den Hond, Groenewegen and van Straalen (n 577) 7.

<sup>591</sup> Pimentel and others (n 574) 47.

<sup>592</sup> den Hond, Groenewegen and van Straalen (n 577) 7.

<sup>593</sup> See, for example, British Medical Association, *The Bma Guide to Pesticides, Chemicals, and Health* (Edward Arnold 1992); Stanley Schuman, ‘Risks of Pesticide-Related Health Effects: An Epidemiologic Approach’ in David Pimentel and Hugh Lehman (eds), *The Pesticide Question: Environmental, Economics and Ethics* (Routledge, Chapman & Hall Inc 1993).

<sup>594</sup> Commission, ‘Towards a Thematic Strategy’ (n 514) 12–13.

<sup>595</sup> den Hond, Groenewegen and van Straalen (n 577) 2.

<sup>596</sup> Council Directive 91/414/EEC concerning the placing of plant protection products on the market [1991] OJ L230/1.

<sup>597</sup> den Hond, Groenewegen and van Straalen (n 577) 3.

<sup>598</sup> There are still accounts of adverse effects, Georgina Downs, ‘Pesticides - the Government Must Protect Us!’ [2013] *The Ecologist* <[www.theecologist.org/blogs\\_and\\_comments/commentators/2200835/pesticides\\_the\\_government\\_must\\_protect\\_us.html](http://www.theecologist.org/blogs_and_comments/commentators/2200835/pesticides_the_government_must_protect_us.html)> accessed 30 April 2017.

in relation to neonicotinoids,<sup>599</sup> glyphosate<sup>600</sup> and developments in EU policy relating to endocrine disrupting chemicals<sup>601</sup> to see that the impacts of pesticides are still sources of serious concern. More generally, other problems persist. For example, pesticides and their metabolites are ubiquitous; persistent organochlorines have been found in ecosystems distant from any industrial or agricultural source, raising concerns about their potential ecological effects on pristine ecosystems, and increasing numbers of species are developing resistance.<sup>602</sup> In addition, agricultural produce still contains residues which exceed limit values<sup>603</sup> and pesticides residues in water are a concern.<sup>604</sup>

The largest battleground regarding the pesticide question is the impact on health and the environment. However, these impacts have repercussions beyond purely physical damage. One is the socio-economic costs of the intensive cultivation of a small variety of crops in large monocultures partially facilitated by low-cost pesticides; for example, the growing operating costs for farmers attempting to increase production.<sup>605</sup> At the same time, distribution of the overall costs of pesticide use raises questions of equity.<sup>606</sup> Farmers incur a capital outlay on pesticides, but the environmental and health impacts of use are borne off-site. For

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<sup>599</sup> Romain Loury, 'Neonicotinoids Face Total EU Ban' (*EURACTIV.com*, 28 November 2016) <<http://www.euractiv.com/section/agriculture-food/news/neonicotinoids-face-total-eu-ban/>> accessed 30 April 2017. For background to the concerns related to the effects of neonicotinoids on bees, see EEA (n 14).

<sup>600</sup> Sarantis Michalopoulos, 'Glyphosate Is Not Carcinogenic, EU Agency Says' (*EURACTIV.com*, 15 March 2017) <<http://www.euractiv.com/section/agriculture-food/news/glyphosate-is-not-carcinogenic-eu-agency-says/>> accessed 30 April 2017.

<sup>601</sup> Commission, 'Communication on Endocrine Disruptors and the Draft Commission Acts Setting out Scientific Criteria for Their Determination in the Context of the EU Legislation on Plant Protection Products and Biocidal Products COM(2016) 350 Final'.

<sup>602</sup> den Hond, Groenewegen and van Straalen (n 577) 4–5.

<sup>603</sup> Manuela Olga Pogăcean and Maria Gavrilesu, 'Plant Protection Products and Their Sustainable and Environmentally Friendly Use' (2009) 8 *Environmental Engineering and Management Journal* 607, 624.

<sup>604</sup> Jules Pretty and Hermann Waibel, 'Paying the Price: The Full Cost of Pesticides' in Jules Pretty (ed), *The Pesticide Detox: Towards a More Sustainable Agriculture* (Earthscan 2005) 13.

<sup>605</sup> This trend has been observed across the world, Pretty, Vorley and Keeney (n 578) 20; den Hond, Groenewegen and van Straalen (n 577) 1.

<sup>606</sup> Pimentel and others (n 574) 71; Pretty (n 517) 51; The Commission recognises this, Commission, 'Towards a Thematic Strategy' (n 514) 14.

example, consumers pay costs incurred by water companies to clean water.<sup>607</sup> Workers, bystanders and local residents may also sustain uncompensated damage. This is not just a question of intra-generational equity but also inter-generational equity since pesticides persist long after the associated benefits have been consumed.<sup>608</sup> These distributive questions have an ethical dimension.<sup>609</sup> To take an extreme example, the weight attributed to the various benefits of pesticide use, for example cosmetic appearance, and the various risks, for example loss of human life, requires ethical scrutiny.<sup>610</sup> Likewise the eradication of, for example, entire bird species and bequeathing to future generations an ecologically impoverished world.<sup>611</sup>

In addition, pesticides can be ineffective. For example, modern insecticides must be sprayed repeatedly to maintain control, sometimes leading to resistance and exacerbating a pest problem by killing natural enemies.<sup>612</sup> This leads to inefficiency, reducing the economic return on investment in the pesticide.<sup>613</sup>

A related concern is the level of knowledge and visibility of the costs and benefits of maintaining or reducing pesticide use.<sup>614</sup> There is little data on the health and environmental costs of use on other sectors and interests, although the Commission has conducted an Impact Assessment of the Thematic Strategy on the Sustainable Use of Pesticides.<sup>615</sup> There may be economic benefits to reducing pesticide use, for example, reduced input costs.<sup>616</sup> However, there may also be disadvantages; if food prices increase, the poor will be hit worst<sup>617</sup> and more

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<sup>607</sup> Pretty (n 517) 55.

<sup>608</sup> Brown Weiss (n 561) 5.

<sup>609</sup> Pimentel and others (n 574) 71.

<sup>610</sup> *ibid* 71–72.

<sup>611</sup> Oreskes (n 302) 376.

<sup>612</sup> Gordon Conway, 'The Doubly Green Revolution' in Jules Pretty (ed), *The Earthscan Reader in Sustainable Agriculture* (Earthscan 2005) 115.

<sup>613</sup> Pimentel and others (n 574) 57.

<sup>614</sup> Pretty and Waibel (n 604) 39–42.

<sup>615</sup> Commission, 'Impact Assessment' (n 545).

<sup>616</sup> Pretty and Waibel (n 604) 52.

<sup>617</sup> Frederick Buttel, 'Socioeconomic Impacts and Social Implications of Reducing Pesticide and Agricultural Chemical Use in the United States' in David Pimentel and Hugh Lehman (eds), *The Pesticide Question: Environmental, Economics and Ethics* (Routledge, Chapman &

extensive agriculture may be required,<sup>618</sup> potentially absorbing land previously used for other purposes, such as recreation. Visibility of such costs and benefits is clearly an important concern, not just in terms of economic efficiency, but in terms of building a clear picture of the economic distributional landscape on which to found a fair regulatory regime. The economic context for these trade-offs is the size and importance of the plant protection industry to Europe and the benefits that it brings in terms of, for example, employment.<sup>619</sup> However, the consolidation of the agrochemical industry (including the seed industry) around the turn of the century,<sup>620</sup> partly driven by more stringent regulation and consequent increased R&D costs,<sup>621</sup> may also raise concerns regarding corporate control over food supply.<sup>622</sup> There are also fears that industry may influence regulatory design and guidelines in their favour.<sup>623</sup>

Uncertainty and indeterminacy (using Wynne's taxonomy,<sup>624</sup> as discussed in Chapter Two) characterise the environmental and health impacts (as well as costs) of pesticides. We still have limited knowledge about causal relationships between harmful products and damage to health and the environment,<sup>625</sup> or indirect or cumulative effects on ecosystems. Knowledge of these effects accrues slowly and

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Hall Inc 1993) 170. The discussion here is centred around Europe, but the EU is sensitive towards the implications of its regulation of, for example, residue levels, for international trade in commodities grown using pesticides, Commission, 'Towards a Thematic Strategy' (n 514) 17.

<sup>618</sup> Buttel (n 617) 175.

<sup>619</sup> Pogăcean and Gavrilăscu (n 603) 622; Commission, 'Towards a Thematic Strategy' (n 514) 11.

<sup>620</sup> Pierre-Benoît Joly and Stéphane Lemarié, 'The Technological Trajectories of the Agrochemical Industry: Change and Continuity' (2002) 29 *Science and Public Policy* 259, 259–260 and references therein.

<sup>621</sup> Jos Bijman and Pierre-Benoît Joly, 'Innovation Challenges for the European Agbiotech Industry' 4 *AgBioForum* 4, 8.

<sup>622</sup> As is the case with GM, Lee, *EU Regulation of GMOs* (n 35) 167. Currently expressed concerning the proposed Bayer-Monsanto merger, FoE Europe, 'Marriages Made in Hell – Why Agribusiness Mega-Mergers Must Be Stopped' (2017).

<sup>623</sup> Henry Rothstein and others, 'Regulatory Science, Europeanization, and the Control of Agrochemicals' (1999) 24 *Science, Technology & Human Values* 241, 255–256.

<sup>624</sup> Wynne, 'Uncertainty and Environmental Learning' (n 135).

<sup>625</sup> Jules Pretty, 'Preface' in Jules Pretty (ed), *The Pesticide Detox: Towards a More Sustainable Agriculture* (Earthscan 2005).

can still surprise us.<sup>626</sup> Our ignorance extends further, to the ‘underlying interdependencies, structures and driving forces’<sup>627</sup> which influence pesticide use. Indeterminacy also extends to the social sphere. Decisions regarding pesticide application made by individual farmers and their actual use are absent from *ex ante* evaluation of chemicals at authorisation.<sup>628</sup> As such, there have been calls for better understanding of farmer decision-making and the wide variety of factors that influence it, for the benefit of policy-making and regulation.<sup>629</sup>

The relative maturity of pesticide technology is, in some ways, still important. We are not teetering on the edge of a technological precipice as we are with, for example, synthetic biology or quantum computing. Sheila Jasanoff perhaps encapsulates the state of play with respect to pesticides and their entrenchment in modern societies:

*The argument from political economy suggests how technologies can be made to seem apolitical. Artifacts – social no less than material ones – can become so hardened through design and use that the ways in which they incorporate political choice or economic power cease to be visible... Once a technology has been blackboxed and put to use, it takes unusual convulsions to make the underlying social choices apparent again: like a... powerful lobby of organic food consumers that creates a market for things grown certifiably without the aid of agricultural biotechnology.*<sup>630</sup>

Unlike emerging technologies, pesticides are not disruptive of our current mode of living, but rather constitutive of it, down to our apparent preference for cosmetically perfect produce. It is, for many reasons, extremely difficult to change course, for example away from chemical inputs towards lower input pest control

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<sup>626</sup> Catrin Meir and Stephanie Williamson, ‘Farmer Decision-Making for Ecological Pest Management’ in Jules Pretty (ed), *The Pesticide Detox: Towards a More Sustainable Agriculture* (Earthscan 2005) 15–17.

<sup>627</sup> Peter Groenewegen, Frank den Hond and Nico van Straalen, ‘Integration: Learning to Solve the Pesticide Problem’ in Frank den Hond, Peter Groenewegen and Nico van Straalen (eds), *Pesticides: Problems, Improvements, Alternatives* (Blackwell 2003) 250.

<sup>628</sup> *ibid* 242–243; Wynne, ‘Risk and Social Learning’ (n 257) 284–286.

<sup>629</sup> de Snoo (n 588) 100; Meir and Williamson (n 626) 83–84.

<sup>630</sup> Jasanoff, *Designs on Nature* (n 11) 206–207.

techniques such as integrated pest management (IPM).<sup>631</sup> Protection of human health and the environment are unquestionably important.<sup>632</sup> However, as the foregoing discussion illustrates, these concerns do not form the entire picture with respect to pesticides. According to Jasanoff, ‘the element of choice so often becomes invisible once a technology assumes its working form’.<sup>633</sup> However, even with a well-established technology such as pesticides, we still have a choice.<sup>634</sup> The opportunity to revisit our choices here depends on the ambition with which sustainability is conceived and implemented.

### 3. The Sustainable Use Directive and European policy on sustainable pesticide use

#### 3.1 *The meaning of ‘use’*

Chapter Three demonstrated the potential of sustainability by discussing three of its elements in detail. These were a) sustainability as consisting of three dimensions: the social, economic and environmental; b) the importance of values in defining sustainability; and c) inter- and intra-generational equity. Legislation seeking sustainable use should exhibit at least a commitment to these elements and it is against these elements that I assess the SUD.

Before proceeding to discuss the SUD’s implementation of these elements, the meaning of ‘use’ deserves attention. The Oxford Dictionary of English<sup>635</sup> defines ‘use’ as ‘take, hold, or deploy (something) as a means of accomplishing or achieving something’, with the additional meanings of ‘employ’, ‘exploit’ or ‘consume’. Use is a fundamental human activity and humans achieve and maintain sustenance, shelter, health and well-being, work and enjoyment through using their

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<sup>631</sup> For example, Joly and Lemarié (n 620); Robin Cowan and Philip Gunby, ‘Sprayed to Death: Path Dependence, Lock-in and Pest Control Strategies’ (1996) 106 *The Economic Journal* 521. On the (evolving) role of advertising in obscuring the various negative implications of pesticide use and re-enforcing the *status quo*, see Margaret M Kroma and Cornelia Butler Flora, ‘Greening Pesticides: A Historical Analysis of the Social Construction of Farm Chemical Advertisements’ (2003) 20 *Agriculture and Human Values* 21.

<sup>632</sup> PAN-Europe focuses on health and environmental protection. Also, Paul B Thompson, *The Spirit of the Soil: Agriculture and Environmental Ethics* (Routledge 1995) 32.

<sup>633</sup> Jasanoff, *Designs on Nature* (n 11) 205.

<sup>634</sup> EEA (n 14) 240; Pretty (n 517) 56.

<sup>635</sup> Angus Stevenson (ed), *Oxford Dictionary of English* (3rd ed, OUP 2010).

surroundings. However, our methods of use are not preordained and immutable but reflect the values of the individual users and their societies. As with 'sustainable agriculture',<sup>636</sup> the meaning of 'sustainable use' is not obvious. The meaning attributed to it will shape the ambition of the regime established. For example, use could be exclusive or common, profligate or parsimonious. Ultimately, individuals and societies have a choice about their patterns and objects of use and those choices will have, amongst others, social, economic and environmental consequences.

Traditionally, 'sustainable development' as applied to agriculture has often simply meant 'optimising (or reducing) the use of synthetic pesticides and minimising environmental impact',<sup>637</sup> or increasing 'efficiency'.<sup>638</sup> However, given the multi-functionality of agriculture, the complex drivers of pesticide use,<sup>639</sup> the existence of multiple considerations beyond safety and the thorough embedding of pesticide use in modern society, it may be reasonable to ask: is this a fitting response to the intricacies of pesticide use? Construing the problems of pesticide use as narrow risk problems and considering them in isolation of contiguous policy spheres would surely eviscerate sustainability of much of its content.

My point is that pesticide use has consequences which policy and law, by adopting sustainability as guiding principle, seek to shape. These consequences extend beyond damage to health and the environment. Attaching a narrow risk- or efficiency-based understanding of sustainability to pesticide use fails both to respond to these diverse consequences and reflect what sustainability is and what sustainable use could be.

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<sup>636</sup> Les Levidow, 'Governing Conflicts over Sustainability: Agricultural Biotechnology in Europe' ResearchGate 13 <[https://www.researchgate.net/publication/42791491\\_Governing\\_conflicts\\_over\\_sustainability\\_agricultural\\_biotechnology\\_in\\_Europe](https://www.researchgate.net/publication/42791491_Governing_conflicts_over_sustainability_agricultural_biotechnology_in_Europe)> accessed 23 December 2016.

<sup>637</sup> Susan Carr, 'New Biotechnology, Crop Protection and Sustainable Development' in Frank den Hond, Peter Groenewegen and Nico van Straalen (eds), *Pesticides: Problems, Improvements, Alternatives* (Blackwell 2003) 170.

<sup>638</sup> Pretty, Vorley and Keeney (n 578) 18 and references therein.

<sup>639</sup> Pretty, Vorley and Keeney (n 578).

Turning to the SUD, Article 1 states that the SUD aims ‘...to achieve a sustainable use of pesticides’. Achievement of sustainable pesticide use rests on two sub-aims. Firstly, reducing the risks and impacts of pesticide use on human health and the environment. Secondly, promoting IPM and other alternatives to chemical pesticides. IPM is a pest management technique which uses all plant protection methods to discourage the development of pests, keeping the use of pesticides to ‘levels that are economically and ecologically justified’ and involves minimising disruption of agro-ecosystems and encouragement of natural pest control.<sup>640</sup>

The rest of the SUD provides the legislative armoury to achieve one or both of these sub-aims and includes requirements relating to the training and certification of professional users, distributors and advisors, aerial spraying, reduction of risks in specific protected areas and the adoption of harmonised risk indicators. However, the key mechanism, representing the greatest opportunity to implement the principles of sustainability, is the obligation, in Article 4, on each Member State to produce a National Action Plan (NAP) specifying how it plans to implement the other provisions in the Directive.<sup>641</sup> The NAPs are shared with the Commission and other Member States and must be reviewed every five years.<sup>642</sup>

### 3.2 *Three dimensions*

As discussed above, human health and environmental impacts of pesticide use dominate debate, notwithstanding the clear presence of other issues. The

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<sup>640</sup> Art. 3(6) SUD. For more nuance, see David Dent, *Integrated Pest Management* (Springer Science & Business Media 1995) ch 1. IPM plays a role in promoting the substitution of more harmful practices and pesticides for those less harmful (Art. 14(1) SUD), a principle espoused in the Plant Protection Product Regulation (n 586) (e.g. Art. 50). The simplicity of the principle belies its complexity and difficulty in implementation, as demonstrated by its fraught operation under REACH (n 63). See Christian Schaible and Vito Buonsante, ‘Identifying the Bottlenecks in REACH Implementation: The Role of ECHA in REACH’s Failing Implementation’ (European Environment Bureau and ClientEarth 2012); Ragnar Lofstedt, ‘The Substitution Principle in Chemical Regulation: A Constructive Critique’ (2014) 17 *Journal of Risk Research* 543, 547–549.

<sup>641</sup> All NAPs are available at [http://ec.europa.eu/food/plant/pesticides/sustainable\\_use\\_pesticides/nap\\_en](http://ec.europa.eu/food/plant/pesticides/sustainable_use_pesticides/nap_en) accessed 30 April 2017.

<sup>642</sup> Art. 4(2) SUD.

Commission's Impact Assessment, possibly the most detailed and complex European document on the subject, is perhaps a qualified exception in that it does, sporadically and partially, consider dimensions of pesticide use beyond health and the environment. On the social and economic front it highlights, for example, the costs of damage by pesticides to health and the environment, competition and consumer issues and the economic impact of a ban on industry and jobs.<sup>643</sup> However, it is important to remember that this is an assessment of the impacts of *regulating*, not of pesticide use itself. There is some treatment, in the Impact Assessment, of the *status quo* but the asymmetry of the treatment is clear. On the one hand, social, economic and environmental *benefits* are attributed to pesticide use (and indeed keenly emphasised elsewhere by industry which highlights the economic benefits pesticides produce in terms of food production<sup>644</sup>). On the other hand, the types of risks acknowledged tend to be solely environmental and health-related.<sup>645</sup> This position is reflected in Commission Communications on the subject, *Towards a Thematic Strategy on the Sustainable Use of Pesticides*<sup>646</sup> (*Towards a Thematic Strategy*) and *A Thematic Strategy on the Sustainable Use of Pesticides*<sup>647</sup> (*The Thematic Strategy*), both of which present a rather asymmetrical analysis of the impacts of pesticide use, focusing on the socio-economic benefits and the health- and environment-related harms.

Perhaps understandably, while acknowledging the difficulty of valuing and measuring certain impacts of pesticide use and its regulation,<sup>648</sup> the impacts and benefits of regulation are nonetheless quantified, almost exclusively, in monetary

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<sup>643</sup> Commission, 'Impact Assessment' (n 545) 59–66.

<sup>644</sup> For example, European Crop Protection Association, 'ECPA Position on Proposals for a Quantitative Reduction in the Use of Crop Protection Products' (2002) <[ec.europa.eu/environment/archives/ppps/pdf/ecpareduceuse.pdf](http://ec.europa.eu/environment/archives/ppps/pdf/ecpareduceuse.pdf)> accessed 30 April 2017, 2-3.

<sup>645</sup> Commission, 'Impact Assessment' (n 545) 5-7 and 21-24. There is a brief reference to negative impacts on sustainability of agricultural production and consumer preferences, 59.

<sup>646</sup> Commission, 'Towards a Thematic Strategy' (n 514).

<sup>647</sup> Commission, 'Thematic Strategy' (n 515).

<sup>648</sup> Commission, 'Impact Assessment' (n 545) 56–57.

terms in the Impact Assessment.<sup>649</sup> The overall result is a detailed, but narrow and one-sided, numerical analysis of a complex problem. This selection of numerical values as a focal point over less quantifiable impacts again illustrates a general danger for more nuanced, open socio-economic assessments (of either the baseline or impacts of regulation) to become closed, technical exercises.<sup>650</sup> Furthermore, if beneficial aspects of the *status quo* are characterised as predominantly social or economic and negative aspects as predominantly environmental or health-related,<sup>651</sup> we are left with an unbalanced and flawed basis on which to proceed, in which certain types of values are permanently pitched against each other.<sup>652</sup> If taken seriously, sustainability could address this tendency. It could, for example, explicitly demand a comprehensive analysis of all impacts of pesticide use - beneficial, questionable and harmful - and thereby introduce some symmetry into the analysis of the current baseline (i.e. an analysis of all types of impacts in all dimensions). The same could apply to assessment of the impacts of regulating.

There is no specific requirement, in the SUD, for the three dimensions of sustainability, discussed in Chapter Three, to be considered in relation to the *impacts* of pesticide use, with the aim of fully comprehending the *status quo*. All impacts of use mentioned relate either to health or the environment alone. This

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<sup>649</sup> Commission, 'Impact Assessment' (n 545). The assessment of the impacts of individual potential measures is often expressed in monetary values. For example, analyses of the impacts of certification of new spraying equipment (143-146), enhanced protection of the aquatic environment (151-154) and measures to encourage IPM (164-169) emphasise financial costs and savings. See too, the summary of the overall impact of the recommended measures at 179-184, much of which is also monetary or economic, although impacts which cannot be quantified are acknowledged here, and throughout. While there is some evaluation of impacts in non-monetary terms, this is often also expressed numerically, in terms of jobs lost or created (e.g. 143, 164, 184).

<sup>650</sup> Lee, *EU Environmental Law* (n 51) 220-221.

<sup>651</sup> A bias found elsewhere, for example Commission, 'Thematic Strategy' (n 515).

<sup>652</sup> It is not denied that this is extremely challenging. In relation to REACH, see Lee, *EU Environmental Law* (n 51) 220. Even the wide-ranging set of EU-commissioned studies conducted in the decade leading up to the 2002 Thematic Strategy consultation touched only cursorily on matters beyond risk or those not linked in some respect, to risk, Oppenheimer Wolff & Donnelly, 'Possibilities for Future EU Environmental Policy on Plant Protection Products: Synthesis Report' (European Commission, Netherlands Ministry of Housing, Spatial Planning and the Environment, Netherlands Ministry of Agriculture, Nature Management and Fisheries 1997).

lack is reflected overall in the infrequency in the SUD with which the term ‘sustainable’ appears. ‘Sustainable development’ appears only once,<sup>653</sup> and ‘sustainable use’, substantively only once too.<sup>654</sup> The discussion above argues that consideration of these elements in Commission documents prior to the introduction of the SUD was shallow, and, with no provision in the legislation, it looks unlikely to occur. By contrast, Article 4(1), fourth paragraph requires Member States, during their national planning processes, to consider the ‘health, social, economic and environmental impacts of the measures considered’. While acknowledgement of the relevance of these dimensions is welcome, their consideration is directed towards impacts of *regulation*, rather than actual use, and so not aimed at generating an understanding of the full consequences of pesticide use which could then be fed into decision-making. In this respect, the provision, and its asymmetry, may be likened to the power in REACH, discussed in Chapter One, to authorise substances of very high concern (which might otherwise be restricted) where the ‘socio-economic benefits outweigh the risks to human health or the environment arising from the use of the substance’.<sup>655</sup> Here too, the broader socio-economic impacts of regulating are considered relevant, but acknowledgement of these aspects of the *status quo* is absent. That said, consideration of such issues is not explicitly prohibited by the SUD and so, due to the flexibility of the national planning process (discussed below), could still occur.

Instead of the three dimensions of sustainability, the emphasis in the SUD is clearly on risk reduction and the pursuit thereby of more efficient pesticide use, in line with the traditional application of sustainability to agriculture. After the mention, in Article 1, of the SUD’s aim to achieve a sustainable use of pesticides, elsewhere its purpose, for example in Articles 4 and 15(2)(c), is described as risk (or occasionally dependence or use) reduction. Furthermore, its other provisions, for example on training, inspections, protection of water, storage, do seem primarily

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<sup>653</sup> Recital 23 SUD.

<sup>654</sup> Art. 1 SUD.

<sup>655</sup> Art. 60(4) REACH (n 63). See Lee, *EU Environmental Law* (n 51) 221.

aimed at reducing risks through implementing risk management measures.<sup>656</sup> (Economic and social) questions beyond risk are part of the policy mix but predominantly through myopic acknowledgement of economic and social benefits of pesticide use, isolated from less commercial, distributive questions.<sup>657</sup> Overall, the SUD perhaps reflects this policy imbalance and exhibits a structural favouring of certain economic interests: limiting reasons for regulation to risk may reduce opportunities to introduce restraints on economic activity.

### 3.3 *Sustainability and values*

As discussed, the SUD declares its aim to be the sustainable use of pesticides, to be achieved through the sub-aims of risk and impact reduction and promotion of non-chemical alternatives to pesticides. Despite a lengthy consultation process,<sup>658</sup> this aim appears to have been present since the early 2000s with its appearance, in a slightly different linguistic formulation, in Recital 26 and Article 7(1) 6EAP. These provide for a more sustainable use of pesticides which reduces the risks and impacts of pesticides on human health and the environment. In *Towards a Thematic Strategy*, which initiated public consultation on the sustainable use of pesticides,<sup>659</sup> ‘sustainable use’ is deemed to require the minimisation of hazards and risks to health and the environment from pesticide use,<sup>660</sup> and seems to conform to the traditional understanding of sustainability as applied to agriculture, identified above, in its pursuit of enhanced efficiency of pesticide use. There were major disagreements among the responses, including from stakeholders, individual members of the public, consultants and European institutions, throughout the consultation process. These disagreements centred on whether sustainable use of pesticides could best be achieved by risk reduction (supported by industry)<sup>661</sup> or

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<sup>656</sup> Respectively, Arts 5, 8, 11 and 13 SUD.

<sup>657</sup> For example, Commission, ‘Towards a Thematic Strategy’ (n 514) 11; Commission, ‘Impact Assessment’ (n 545) 21–22.

<sup>658</sup> For a summary of the consultation process, see Commission, ‘Impact Assessment’ (n 545) 16–17.

<sup>659</sup> *ibid* 17.

<sup>660</sup> Commission, ‘Towards a Thematic Strategy’ (n 514) 8.

<sup>661</sup> Similarly in the USA, Pretty, Vorley and Keeney (n 578) 35.

use reduction (supported by NGOs).<sup>662</sup> In my view, neither genuinely reflects the demands of sustainability. However, this was by and large the extent to which the content of ‘sustainable use’ with respect to pesticides was explored. There was little room to articulate and understand the values behind these positions, which may have reflected deeper disagreements and convictions about, for example, the viability of our current agricultural systems.<sup>663</sup> In the end, risk, use and dependence reduction appear in the SUD,<sup>664</sup> continuing and reflecting political disagreements, discussed further in Chapter Nine. This may add flexibility but also perhaps confusion as to the SUD’s direction, although risk reduction does still dominate.

By the time the SUD came into force, the understanding of ‘sustainable use’ as primarily risk reduction had existed for seven years: since the 6EAP and *Towards a Thematic Strategy* in 2002 and the understanding of ‘sustainable use’ assumed therein, as discussed above. The subsequent consultation was narrow and did little to genuinely open up this assumption as to the content of sustainable use to more profound reflection through debate or political definition. As discussed above, ‘use’ is complex and requires normative engagement. Sustainability is normative too and has the potential to incorporate concerns other than safety and environmental protection into how we use resources. However, the lack of opportunity to challenge this assumption and decide collectively whether sustainable use in the context of pesticides should mean primarily risk reduction and efficient use, or something else or something more, already has the potential to impoverish the SUD in terms of its founding principle.

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<sup>662</sup> Documents relating to the consultation are still available on the archived website: DG Environment, ‘Sustainable Use of Pesticides’ <<http://ec.europa.eu/environment/archives/ppps/home.htm>> accessed 30 April 2017.

<sup>663</sup> For example, David Morley and Beth Franklin, ‘Future Searching for New Opportunities Involving the Pesticide Industry and Sustainable Agriculture’ in William Vorley and Dennis Keeney (eds), *Bugs in the System: Redesigning the Pesticide Industry for Sustainable Agriculture* (Routledge 1998) 174.

<sup>664</sup> Art. 4(1) first and third sub-paragraphs SUD.

The Impact Assessment contains tacit value-judgments,<sup>665</sup> but rarely grapples with questions of values or conflicts head-on, preferring expression in numerical and monetary terms. Sustainability could help infuse the narrower, numerical calculations of the Impact Assessment with more openly considered preferences and values by specifically challenging these tacit value-judgments and assumptions or encouraging public involvement.<sup>666</sup> Furthermore, a balanced picture of the impacts of pesticide use, for which I argued above, could generate a more detailed value landscape with the potential to enable a more nuanced discussion of, and response to, conflicts between priorities in the question of what to sustain.

The removal, from broader debate, of the normativity of sustainable use, is reinforced by its absence from Article 4 (on national planning), the SUD's main provision for decision-making and participation. However, Member States are still left with a significant degree of autonomy regarding the content and emphasis of their NAPs. They are directed, in Article 4(1), to focus on various aspects of pesticide use, which seem, at face value, perhaps self-explanatory and uncontroversial. However, these aspects all hinge on significant value judgments. This potential (and arguably, need) for value judgments provides a welcome layer of flexibility which, combined with the requirement to involve the public in the planning process,<sup>667</sup> could enable access to some areas of decision-making typically off-limits. For example, Article 4(1) requires NAPs to contain 'quantitative objectives, targets, measures and timetables to reduce risks and impacts of pesticide use on human health the environment'. Which 'risks and impacts' are not specified, nor are the structure and stringency of the objectives etc. These can be decided politically. There are some suggested 'areas of concern' for the targets to cover but the list is not exhaustive.<sup>668</sup> Again, politics and values can weigh in.

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<sup>665</sup> For example, 'the relative importance of impacts' is identified as a principle of the methodology of the impact assessment without further explanation as to how 'relative importance' will be judged, Commission, 'Impact Assessment' (n 545) 84.

<sup>666</sup> For a discussion of participation and sustainable development see, Meadowcroft (n 334).

<sup>667</sup> Recital 7 and Art. 4(5) SUD.

<sup>668</sup> There is little official guidance to Member States on such aspects of the SUD.

NAPs must include ‘indicators to monitor the use of plant protection products containing active substances of particular concern’.<sup>669</sup> Neither the active substances nor the indicators are specified, leaving it open for the Member States to decide on the basis of public attitudes to the diverse risks associated with pesticides, or other concerns perhaps. Furthermore, Member States are required to establish ‘timetables and targets for the reduction of use..., in particular if the reduction of use constitutes an appropriate means to achieve risk reduction with regard to priority items...’.<sup>670</sup> This provision requires a host of value judgments, relating to the types of timetables and targets, whether use reduction is an appropriate means to achieve risk reduction, and which items should be prioritised. The requirement to ‘take account of the health, social, economic and environmental impacts of the measures envisaged, of specific national, regional and local conditions and all relevant stakeholder groups’<sup>671</sup> is an invitation for a debate over trade-offs, reflecting the priorities and values of the participants. Finally, the requirement<sup>672</sup> that Directive 2003/35/EC providing for public participation in respect of the drawing up of certain plans and programmes relating to the environment<sup>673</sup> is to apply to the ‘preparation and modification’ of NAPs represents an openness to different values and opinions.

If implemented well, this national planning process could prompt honest, challenging and inclusive reflection on the purpose of pesticide policy, the role of pesticides in agriculture and society, and perhaps even the kind of agricultural systems we should be supporting.<sup>674</sup> While ‘sustainable use’ as a normative aim is

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<sup>669</sup> Art. 4(1) second sub-paragraph SUD.

<sup>670</sup> Art. 4(1) third sub-paragraph SUD. These priority items are those, identified by Member States, ‘such as active substances, crops, regions or practices, that require particular attention’, Art. 15(2)(c). Very few have set such targets and timetables, PAN-Europe, ‘Reducing Pesticide Use Across the EU’ (Undated) 8.

<sup>671</sup> Art. 4(1) fourth sub-paragraph SUD.

<sup>672</sup> Art. 4(5) SUD.

<sup>673</sup> [2003] OJ L156/17.

<sup>674</sup> Some argue that ‘some rethinking of what constitutes agriculture’ is required to move away from the current model based on ‘agrochemicals, mechanical and petrochemical energy and genetic modification’, Erick Fernandes, Alice Pell and Norman Uphoff, ‘Rethinking Agriculture for New Opportunities’ in Jules Pretty (ed), *The Earthscan Reader in Sustainable Agriculture* (Earthscan 2005); Thompson (n 632) 32.

not explicitly up for debate, flexibility in relation to national objectives, timetables etc., may allow national assertion of ‘what matters’ through alternative routes. Responsibility therefore shifts to Member States to draw up ambitious NAPs and to the Commission to ensure Member States implement their commitments.<sup>675</sup>

There is also a requirement to establish harmonised risk indicators.<sup>676</sup> This raises three points. Firstly, the requirement to ‘calculate harmonised risk indicators... by using statistical data collected in accordance with<sup>677</sup> the EU’s pesticide statistics regulation<sup>678</sup> (PSR), implies a technical, expert-driven approach, which could close down discussion of broader values or alternative courses of action<sup>679</sup> and may struggle to reflect reality.<sup>680</sup> Secondly, the indicators are harmonised<sup>681</sup> and so may display limited sensitivity towards local conditions or national priorities and values and attitudes towards risks perhaps reflective of a commitment in the EU to the idea of a universal regulatory science.<sup>682</sup> Although Member States are allowed to retain their own national indicators or adopt others in addition to the harmonised ones,<sup>683</sup> the harmonisation here perhaps seems somewhat at odds with the SUD’s accommodation of national diversity. Thirdly, though potentially extremely

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<sup>675</sup> Commission action on the content of NAPs is, as yet, lacking, PAN-Europe, ‘Letter to Commissioner Borg’ (27 March 2014) <[www.pan-europe.info/Campaigns/documents/NAPS/letter%20borg%20-%20SUD%20implementation%20Mar%202014.pdf](http://www.pan-europe.info/Campaigns/documents/NAPS/letter%20borg%20-%20SUD%20implementation%20Mar%202014.pdf)> accessed 30 April 2017.

<sup>676</sup> Art. 15(1) SUD.

<sup>677</sup> Art. 15(2)(a) SUD.

<sup>678</sup> European Parliament and Council Regulation 1185/2009/EC concerning statistics on pesticides [2009] OJ L324/1.

<sup>679</sup> Stirling, “Opening Up” and “Closing Down” (n 9) 279. Although, Recital 12 PSR provides that it should apply without prejudice to European Parliament and Council Directive 2003/4/EC on public access to environmental information [2003] OJ L41/26 and to European Parliament and Council Regulation 1367/2006/EC on the application of the provisions of the Aarhus Convention [2006] OJ L264/13.

<sup>680</sup> Gabriele Sacchetti and others, ‘New Risk Indicator Approach for Operators, Workers, Bystanders and Residents for a Sustainable Use of Plant Protection Products’ (2015) 22 *Environmental Science and Pollution Research* 17586, 17588, 17593.

<sup>681</sup> The exact distribution of labour here is unclear in the SUD but both Member States (Arts 15(1) and 15(2)(a)) and the Commission (Art. 15(4)) appear to be obliged to calculate risk indicators on the basis of data collected by Member States under the PSR.

<sup>682</sup> Rothstein and others (n 623) 252.

<sup>683</sup> Art. 15(1) first sub-paragraph SUD.

valuable,<sup>684</sup> wider civil society involvement in establishing these EU-wide, harmonised indicators is not provided for which again may block ingress of points of view not represented through the narrow expertise required by this activity and limits the potential for non-experts to challenge the judgments applied in this process.<sup>685</sup> The absence in either the legislation or prior consultation process of a mechanism which directly elicits and explores values in relation to pesticide *use* may lead to the articulation of indicators uninformed by values, based on unchallenged expert assumptions. The selection of indicators is an ‘unavoidably value-based activity’ and the reasons for preferring a particular indicator and the availability of alternatives should perhaps be clear.<sup>686</sup> Although Member States are required to take account of social, economic, environmental etc. impacts of *regulating*, this exercise arguably happens both too late (assessment of regulation rather than *status quo*) and at the wrong level (national, rather than European) to inform development of these EU-level indicators.

Finally, while there are provisions enabling amendment and updating of the SUD to reflect scientific and technical progress,<sup>687</sup> there is no scope for updating the Directive to correspond to changing public values or attitudes to pesticide use. The required five-yearly review of NAPs<sup>688</sup> could be used to ensure any such changes are reflected in national policy and the ability of the Commission to propose amendments to the SUD based on Member State reports,<sup>689</sup> could perform a similar function at EU level, but there is no obligation to use these provisions thus.

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<sup>684</sup> PCR Gray and PM Wiedemann, ‘Risk Management and Sustainable Development: Mutual Lessons from Approaches to the Use of Indicators’ (1999) 2 *Journal of Risk Research* 201, 215; Sacchetti and others (n 680) 17587.

<sup>685</sup> No EU-wide indicators have been established yet and the project has been put on hold, Eurostat, ‘Agri-Environmental Indicator - Pesticide Risk - Statistics Explained’ <[http://ec.europa.eu/eurostat/statistics-explained/index.php/Agri-environmental\\_indicator\\_-\\_pesticide\\_risk](http://ec.europa.eu/eurostat/statistics-explained/index.php/Agri-environmental_indicator_-_pesticide_risk)> accessed 30 April 2017 although the EU has developed a software tool, HAIR2014 (Harmonised environmental Indicators for pesticide Risk), for calculating indicators to evaluate performance of, for example, an NAP, <[www.pesticidemodels.eu/haire/home](http://www.pesticidemodels.eu/haire/home)> accessed 30 April 2017.

<sup>686</sup> Gray and Wiedemann (n 684) 213.

<sup>687</sup> For example, Arts 5(3) and 8(7) SUD.

<sup>688</sup> Art. 4(2) second sub-paragraph SUD.

<sup>689</sup> Art. 16 SUD.

### 3.4 Equity

While *Towards a Thematic Strategy* showed some evidence of long-term thinking,<sup>690</sup> and the 7EAP aims at ‘farming with a sense of responsibility for future generations’,<sup>691</sup> broader acknowledgment, in the SUD, of the impacts of pesticide use on future generations, or a moral obligation to bequeath a less toxic planet, are conspicuously absent, although Sweden’s NAP does seek this goal.<sup>692</sup> Room for explicit consideration of ethical questions in general is also absent, as evident from the lack of opportunity in the SUD for a more normative discussion of sustainable use, discussed above. Likewise any opportunity for the present generation to articulate the values they are willing to commit to for future generations,<sup>693</sup> other than reduced risks from pesticide use, is lacking. Furthermore, the SUD does not explicitly foster a long-term view. There are indications that the Directive is intended to regulate for the foreseeable future given the requirements to review NAPs every five years and the Commission’s powers to amend the legislation, going forward. However, this is hardly a bold statement that the SUD is prioritising concern for future generations or using inter-generational equity as a moral guide for developing and implementing measures.

Focusing primarily on risk reduction may maintain equal opportunities across generations, but it means a lot rides on being right about the risks and managing them correctly. If the approach is wanting in any way, it could narrow the resource base for future generations before the mistake is discovered. The fact that the SUD is not firmer in its obligations to reduce dependence on pesticides may also raise concerns for inter-generational equity in terms of bequeathing diverse and robust agricultural systems. There is no explicit<sup>694</sup> requirement in the SUD to consider the

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<sup>690</sup> Commission, ‘Towards a Thematic Strategy’ (n 514) 25, 30, 34. This mainly relates to long-term risks and impacts of pesticides and the need for more research. Long-term planning or regard for the future is lacking.

<sup>691</sup> Commission and others (n 514) para 20.

<sup>692</sup> Ministry for Rural Affairs, ‘National Action Plan for the Sustainable Use of Plant Protection Products for the Period 2013–2017’ (2013) 65–66.

<sup>693</sup> Norton (n 543) 58–59.

<sup>694</sup> One could interpret ‘all relevant stakeholder groups’, Art. 4(1) fourth sub-paragraph SUD, to include future generations.

interests of future generations, for example, in the obligation on Member States to produce NAPs. Notably, despite having had an Ombudsman for Future Generations at the relevant time,<sup>695</sup> Hungary's NAP does not refer to this aim or indicate that its Ombudsman was consulted in the negotiation of its NAP.<sup>696</sup>

In terms of intra-generational equity, as with inter-generational equity, there is no obvious scope to raise ethical questions. Risk reduction may have a social aim insofar as it may minimise the costs of pesticide use inflicted off-field, perhaps supporting a more equitable (re-)distribution of costs. This dimension of the policy is far from explicit, although cross-compliance provisions under the Common Agriculture Policy will apply,<sup>697</sup> which presents a form of financial incentive. Allocation of 'goods' does, however, surface in the SUD's provisions requiring prohibition or minimisation of pesticide use in certain areas, such as parks, recreation and school grounds and playgrounds and in areas protected under EU conservation laws.<sup>698</sup> This provision specifically cordons off land for, amongst other things, recreation and recognises the need to protect the more vulnerable members of society and more sensitive parts of the environment. It thus supports Brown Weiss's principle of conservation of access. In addition, the provisions supporting participation, information and awareness raising, if carried out sensitively, could enhance education, leading to a more knowledgeable and engaged society with benefits for the level and quality of participation and potentially implementation.<sup>699</sup>

PAN-Europe notes the potential of NAPs to stimulate rural employment, for example through organic farming,<sup>700</sup> entailing social benefits. It may be possible to pursue such ends, but it is hardly highlighted in the SUD. As discussed above, in addition to such potential benefits, there are also potential distributional

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<sup>695</sup> Now abolished: <<http://jno.hu/en/>> accessed 6 January 2017.

<sup>696</sup> Ministry of Rural Development, 'National Plant Protection Action Plan' (2012).

<sup>697</sup> Commission, 'CAP Reform – an Explanation of the Main Elements MEMO/13/621' 6.

<sup>698</sup> Art. 12 SUD.

<sup>699</sup> Lee, *EU Environmental Law* (n 51) 178–179.

<sup>700</sup> PAN-Europe, 'NAP Best Practice: Sustainable Use of Pesticides: Implementing a National Action Plan' (Undated) 30.

drawbacks to reduced pesticide use, such as harm to the less well-off by increased food prices. However, beyond the requirement to consider the ‘health, social, economic and environmental impacts of the measures envisaged’,<sup>701</sup> nowhere is this highlighted as a concern. This may hinder progress towards greater sustainability generally as inequality can undermine the mutual trust and willingness to cooperate arguably required for such progress.<sup>702</sup> While there is some flexibility for the consideration or pursuit of a broad range of concerns in the SUD, its primary focus is still safety and environmental protection and depends on the commitment of the individual Member States.

#### 4. Sustainable use and sustainable development in the EU

In sum, there are promising aspects of the SUD, which genuinely do reflect some of the elements of sustainability identified in Chapter Three and which are employed to address some of the concerns raised in section 2. The national planning process constitutes a valuable opportunity for broad involvement in shaping a Member State’s approach to pesticide use and the potential to consider the social, economic and environmental (and other) impacts of pesticide use along with societal values surrounding pesticide use. It also acknowledges the diversity of actors involved in, or affected by, pesticide use. Both of these aspects, however, could be stronger. The importance of the three dimensions to analysing the impacts of pesticide *use* could also be made more explicit, as could the relevance of inter- and intra-generational equity. Both of these are largely implicit, if in existence at all.

I have argued that the overarching goal of the SUD is that of risk reduction in pursuit of greater efficiency of pesticide use. This is a far less ambitious goal than sustainability in its fullest sense, in that it is less about examining and challenging pesticide use in a holistic and inclusive way and more about making the current patterns of use safer, thereby accommodating the *status quo*. The difficulty with

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<sup>701</sup> Art. 4(1) fourth sub-paragraph SUD.

<sup>702</sup> Nicolas Kosoy and others, ‘Pillars for a Flourishing Earth: Planetary Boundaries, Economic Growth Delusion and Green Economy’ (2012) 4 *Current Opinion in Environmental Sustainability* 74, 76.

pursuing risk reduction is that it commits us to an approach to regulation based on technical probabilistic assessments, which is problematic, not least due to uncertainty<sup>703</sup> and the difficulty in determining, or agreeing on, things like acceptable exposure and cumulative effects.<sup>704</sup> Characterising sustainable use as the reduction of risk does not answer any questions; it merely hides one set of unexamined assumptions behind another and avoids one normative judgment by substituting another. It may work, but only perhaps until we develop more sensitive measurement tools. Furthermore, unlike sustainability as characterised in Chapter Three, risk management tends to imply maintenance of the existing state of affairs or practices rather than driving change, providing limited insight into the overall direction technological development should take.<sup>705</sup> Therefore, from a more ambitious point of view, it may not constitute a sufficiently disruptive force to send transformative ripples through the rest of our current crop protection or agricultural systems, by prompting deeper reflection on the desirability of our intensive, monoculture-based farming models which the use of pesticides supports<sup>706</sup> and which are rarely questioned.<sup>707</sup> Nor may it challenge the decision-making *status quo*, which I argue, referring back to Jasanoff's diagnosis in relation to highly socially-embedded technologies, is needed. In essence, it implements the traditional model of sustainable development as applied to agriculture.

This criticism is partly to do with the extent to which we care about language. According to Bob Pepperman Taylor, writing about the tendency of some to reduce sustainability to meaning 'efficiency' (or 'eco-efficiency'<sup>708</sup>), we could apply the

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<sup>703</sup> Richard Owen and others, 'Conclusions: Pollutants, Risk and Society' in Jane A Plant, Nikolaos Voulvoulis and K Vala Ragnarsdottir (eds), *Pollutants, Human Health and the Environment* (Wiley 2011) 322.

<sup>704</sup> PAN-Europe, 'NAP Best Practice' (n 700) 24.

<sup>705</sup> Gray and Wiedemann (n 684) 203.

<sup>706</sup> Pretty, Vorley and Keeney (n 578) 19–21.

<sup>707</sup> Gaëtan Vanloqueren and Philippe V Baret, 'How Agricultural Research Systems Shape a Technological Regime That Develops Genetic Engineering but Locks out Agroecological Innovations' (2009) 38 *Research Policy* 971, 977.

<sup>708</sup> Les Levidow, Kean Birch and Theo Papaioannou, 'EU Agri-Innovation Policy: Two Contending Visions of the Bio-Economy' (2012) 6 *Critical Policy Studies* 40, 49. 'Eco-efficiency' refers to the ability to increase benefits from economic activity while lowering resource use and pollution, Les Levidow and others, 'Eco-Efficiency Improvements in

term 'sustainable' to anything we want to. But, he asks, what would be the benefit of doing this?<sup>709</sup> We already have other words and discourses to describe and explore these concepts; as with efficiency, so with risk reduction and risk management. Applying the title of sustainability to a risk reduction programme adds little. Instead it creates ambiguity<sup>710</sup> and ultimately confines the potential of sustainability to less ambitious purposes. If sustainability is applied to policy and regulation, its integrity should be maintained and its own content respected.

A partial explanation as to why sustainability is so reduced may lie in the current weakness of sustainable development in the EU. The 1993 5EAP<sup>711</sup> was ambitious. For example, the ultimate aim of the 5EAP is proclaimed to be 'transforming the patterns of growth in the Community in such a way as to reach a sustainable development path'.<sup>712</sup> The 6EAP, which represented the basis for the environmental dimension of the European sustainable development strategy, presented a milder approach than its predecessor, commuting the rhetoric of transformation to the softer language of de-linking economic growth from environmental damage.<sup>713</sup> Two European instruments which contribute to the EU's current sustainable development strategy (such as it is) are the 7EAP and *Europe 2020*.<sup>714</sup> The rhetoric of change and transformation does appear in the 7EAP.<sup>715</sup> However, overall transformation is linked to a different object – the 'reductionist'<sup>716</sup> notion of a green economy. This emphasises the narrower question of compatibility between environmental protection and economic growth,<sup>717</sup> arguably prioritising

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Industrial Water-Service Systems: Assessing Options with Stakeholders' (2014) 69 *Water Science & Technology* 2113, 2113.

<sup>709</sup> Bob Pepperman Taylor, 'Comments on Sustainability' in John Martin Gillroy and Joe Bowersox (eds), *The Moral Austerity of Environmental Decision Making: Sustainability, Democracy, and Normative Argument in Policy and Law* (Duke UP 2002) 303–304.

<sup>710</sup> *ibid* 304.

<sup>711</sup> Commission, 'Towards Sustainability' (n 509).

<sup>712</sup> 5EAP (n 711) 24.

<sup>713</sup> Arts 2(1) first sub-paragraph and 8(1) first sub-paragraph 6EAP (n 585).

<sup>714</sup> Commission, 'Europe 2020' (n 580). For a discussion of the two instruments and their relationship see, Lee, *EU Environmental Law* (n 51) 63–79.

<sup>715</sup> For example, Commission and others (n 514) para 43(c).

<sup>716</sup> Pallemmaerts (n 508) 361.

<sup>717</sup> Lee, *EU Environmental Law* (n 51) 70.

the economic over the social and environmental,<sup>718</sup> and the availability of technological solutions for increasing resource efficiency which may paradoxically increase consumption, while ignoring the complex drivers of economic-socio-ecological problems.<sup>719</sup> *Europe 2020*, regarded by the Commission as the main instrument for implementing sustainable development,<sup>720</sup> following Rio+20,<sup>721</sup> similarly advocates an omnipotent ‘resource efficient, sustainable and competitive economy’.<sup>722</sup> Furthermore, running throughout all the above policy there may be seen an emphasis on ‘efficiency’,<sup>723</sup> which may be hard to dislodge given its endurance as a principle of resource management dating back to the early twentieth century conservation movement and association with the growth and development of (some forms of) environmentalism and sustainability.<sup>724</sup> Indeed, an ‘eco-efficiency’ account of sustainability supported claims regarding the environmental safety and other benefits of GM crops, for example in terms of reducing pesticide use, in the face of competing accounts of sustainability emphasising other values.<sup>725</sup>

Overall, the place of sustainable development in EU environmental policy currently seems uncertain.<sup>726</sup> In light of this state of affairs, locating a robust basis for transformation in a particular area of policy may be difficult in practice. Particularly since ‘sustainable development’, due to its vagueness, could easily slip into denoting the *status quo*’s ‘sustained economic growth’.<sup>727</sup> There is little in the EU’s

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<sup>718</sup> On the green economy in the lead up to Rio+20, Karen Morrow, ‘Rio+20, the Green Economy and Re-Orienting Sustainable Development’ (2012) 14 *Environmental Law Review* 279, 288.

<sup>719</sup> Kosoy and others (n 702) 75, 76–77.

<sup>720</sup> Lee, *EU Environmental Law* (n 51) 64.

<sup>721</sup> Commission and others (n 514) para 13.

<sup>722</sup> Commission, ‘Europe 2020’ (n 580) 14.

<sup>723</sup> For example, Commission, ‘Towards Sustainability’ (n 509) 15, 20, 24; 6EAP (n 513) Articles 1(2) fourth sub-paragraph, 5(2)(iv)(a); Commission and others (n 514) 32–45; Commission, ‘Europe 2020’ (n 580) 15–16; Lee, *EU Environmental Law* (n 51) 70–71.

<sup>724</sup> D Torgerson, ‘Strategy and Ideology In Environmentalism: A Decentered Approach To Sustainability’ (1994) 8 *Organization & Environment* 295, 297–298.

<sup>725</sup> Levidow, ‘Governing Conflicts over Sustainability’ (n 636) 6–7.

<sup>726</sup> Pallemmaerts (n 508) 361–362.

<sup>727</sup> Torgerson (n 724) 303–304.

most recent Communication on sustainability<sup>728</sup> to suggest a radically different approach to these matters, despite a vague call to take the three pillars of sustainability into account.<sup>729</sup> The emphasis remains on the preservation of natural capital and resource efficiency both delivered now by a ‘circular economy’ which will stimulate competitiveness and innovation and reconcile economic growth with environmental protection.<sup>730</sup> Innovation appears as unambiguous solver of problems, discussed further in Chapter Eight, rather than as sometime generator of complex and controversial implications which perhaps require a more prudential approach.

Klaus Bosselmann encapsulates sustainable development’s frozen potency in the EU by describing the EU as both model of governance for sustainability, in that it shows states can reorganise their sovereignty, and also a model of failure,<sup>731</sup> arguing that economic growth and competitiveness are still in ascendency.<sup>732</sup> Economic competitiveness (discussed further in Chapter Eight) tends to mean ‘productive efficiency of intensive monoculture’<sup>733</sup> and may therefore conflict with the broader values potentially encompassed by ‘sustainable agriculture’.<sup>734</sup> Sustainability, for all sorts of reasons, may not yet encourage a wide range of considerations and opinions to be aired in decision-making and there often seems to be a sizeable lacuna between potential and reality. This, combined with the recent economic crisis and its consequences,<sup>735</sup> poses a significant challenge to any potential for disrupting the *status quo*. However, a potential is still a potential, even if reality looks unpromising.

Finally, it cannot be said that the SUD offers no opportunities to implement sustainability ambitiously, at least on paper. It depends primarily, however, on the

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<sup>728</sup> Commission, ‘Next Steps for a Sustainable European Future’ (n 526).

<sup>729</sup> *ibid* 18.

<sup>730</sup> *ibid* 2, 5, 8–9.

<sup>731</sup> Bosselmann (n 532) 187–193.

<sup>732</sup> *ibid* 194.

<sup>733</sup> Levidow, ‘Governing Conflicts over Sustainability’ (n 636) 13.

<sup>734</sup> *ibid* 4.

<sup>735</sup> Cléménçon (n 536) 331.

Member State and the contributions of participants during the national planning process. Unfortunately, PAN-Europe diagnoses a generally unambitious approach in most Member State NAPs, out of kilter with what it defines as the SUD's philosophy of going beyond other instruments.<sup>736</sup> The UK NAP, for example, is fairly narrow, with little potential to challenge the *status quo*, focusing on risk reduction, improving agricultural competitiveness and reducing regulatory burdens<sup>737</sup> with no mention of either sustainable development or sustainable agriculture. The Hungarian and Swedish NAPs are more ambitious and encompass a greater range of considerations. The former is fairly holistic, providing detail on measures to support more 'ecological' methods of farming<sup>738</sup> and referring to changes in consumption.<sup>739</sup> The latter refers to Sweden's ambitious aim to achieve a non-toxic environment by 2020. It also links plant protection policy to sustainable rural development<sup>740</sup> and aims to achieve 'cost-effective, environmentally friendly and socially sustainable' plant protection.<sup>741</sup> In sum, commitments to using sustainability to open up decision-making may vary significantly across the EU.

Ultimately, the picture of sustainable use embedded in the rest of the SUD may not support a particularly strong challenge to the European economic order since, outside the NAPs, it does little to open up decision-making or address the pesticide question beyond narrowly conceived issues of protection of human health and the environment. This is partly due to the lack of ambition in implementing sustainability and the elements discussed in Chapter Three. It is also perhaps due to the fact that the question of what 'sustainable pesticide use' actually means and requires was never sufficiently opened up to deliberation. The preconceived notion of sustainable use as risk reduction or increased efficiency and the narrow consultation process left fundamental disagreements unexplored, leading to an

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<sup>736</sup> PAN-Europe, 'Reducing Pesticide Use' (n 670) 8–9.

<sup>737</sup> DEFRA, 'UK National Action Plan for the Sustainable Use of Pesticides (Plant Protection Products)' (2013) 3–4.

<sup>738</sup> Ministry of Rural Development (n 696) 16 and 37.

<sup>739</sup> *ibid* 31.

<sup>740</sup> Ministry for Rural Affairs (n 692) 67.

<sup>741</sup> *ibid* 9.

ambiguous and unambitious piece of legislation. The broader consequences of this are that firstly, there is little chance of systematically addressing all the issues relating to pesticide use, and secondly the scope of decision-making in this field remains restricted, by and large, to safety, environmental protection and risk management.

## 5. Conclusion

Part of the promise of sustainability is that it could provide a means to enhance socio-technical integration by incorporating diverse considerations into decision-making processes, however hard they may be to implement. This promise exists despite disagreements over its internal structure or the correct distribution of weight between its various dimensions. It has the potential to prompt ambitious policy and legislation, by, amongst other things, opening up decision-making to explicit consideration of the future and a wide range of other issues. Realisation of its potential depends on the manner in which it is employed in policy and legislation. Due to its emphasis on risk, the SUD establishes a reductive and unambitious approach to the implementation of sustainable use which fails to realise the potential of sustainability and instead leaves its initial promise rather hollow. It does provide some flexibility for Member States to choose the appropriate level of ambition. This flexibility is a good thing in terms of Member State autonomy and enabling the generation of plans tailored to specific national conditions. However, a more far-sighted impetus from the centre could perhaps have achieved more, given the minimalism of many NAPs. Possible reasons for this lack of ambition at both EU, and national, level include the narrowness of the procedures through which the SUD and NAPs were developed. Finally, the lack of a more ambitious approach may simply be a reflection of the current fragility of sustainable development in the EU.

## Chapter Five – European regulation of synthetic biology: regulating an emerging technology

### 1. Introduction

Chapter Three discussed the open ethos promoted by a significant portion of EU policy towards research into, and governance of, synthetic biology largely under the heading of ‘responsible research and innovation’ (RRI). I argued that the European policy ‘vision’ for participation in relation to synthetic biology espouses, to a great extent, the promise of engagement and mutual learning between scientists and stakeholders, including publics.

This chapter looks beyond that policy to some of the legislation which applies to synthetic biology in the EU. Out of the 39 Directives and Regulations potentially applicable to different synthetic biology applications,<sup>742</sup> I focus on two: the Contained Use Directive (CUD)<sup>743</sup> and the Deliberate Release Directive (DRD),<sup>744</sup> both of which contain authorisation procedures likely to apply (as discussed in section 3) to various types of organisms resulting from synthetic biology research, or substances produced by such organisms. This legislation predates much of the policy discussed in Chapter Three. The question therefore concerns its potential to realise the EU’s rhetorical ‘vision’ for a governance framework for synthetic biology based on the principles of RRI.

Chapter Three makes clear that RRI is more than public engagement. However, due to provisions for public participation presenting most potential, the primary (though not exclusive) focus of my discussion below is on public participation and openness. In this context, ‘governance’ extends beyond regulating the risks associated with an end product to the processes of innovation too.<sup>745</sup> As argued in Chapter Three, the full burden of realising the EU’s ambitions does not therefore

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<sup>742</sup> Annex IV, SCHER, SCENIHR and SCCS, ‘Opinion on Synthetic Biology I: Definition’ (2014).

<sup>743</sup> European Parliament and Council Directive 2009/41/EC on the contained use of genetically modified micro-organisms [2009] OJ L125/50.

<sup>744</sup> European Parliament and Council Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms [2001] OJ L106/1.

<sup>745</sup> Stilgoe, Owen and Macnaghten (n 29) 1570.

rest on these downstream authorisation procedures, though they should support the overall spirit of synthetic biology governance and operate according to consistent principles. While RRI aims at broader opening-up, and creation of a shared sense of responsibility for, innovation trajectories, participation in risk regulation could support and complement RRI by providing an opportunity to reflect on specific material outputs of those trajectories.

Section 2 briefly considers synthetic biology research and the challenge of defining its potential benefits and risks. Section 3 examines application of the DRD and CUD and in particular their potential to facilitate RRI. Section 4 assesses that potential against the ‘vision’ for participation and openness discussed in Chapter Three. I argue that, despite isolated potential, the current regulatory regime is not equipped to implement the policy ambitions discussed in Chapter Three. In section 5, I analyse that deficiency on two fronts. Firstly, I argue that underlying much of the policy and legislation is a drive to enable passage of synthetic biology to the market, suggesting a lack of political will towards opening up, in general, applicable decision-making procedures. Secondly, I argue that the regulatory regime, originally designed for genetically modified organisms, faces the challenges of ‘inherited regulation’.<sup>746</sup> Section 6 concludes.

## 2. Synthetic biology, its promises and risks

Synthetic biology eludes straightforward definition.<sup>747</sup> Essentially it involves the application of engineering principles to biology.<sup>748</sup> It is ‘the rational design and construction of new biological parts, devices and systems with predictable and reliable functional behaviour that do not exist in nature, and the re-design of

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<sup>746</sup> Stokes, ‘Nanotechnology’ (n 81); Elen Stokes and Diana M Bowman, ‘Looking back to the Future of Regulating New Technologies: The Cases of Nanotechnology and Synthetic Biology’ (2012) 2 *European Journal of Risk Regulation* 235; Stokes, ‘Recombinant Regulation’ (n 131).

<sup>747</sup> On different definitions, see Jan C Schmidt, ‘Philosophy of Late-Modern Technology; Towards a Clarification and Classification of Synthetic Biology’ in Joachim Boldt (ed), *Synthetic Biology: Metaphors, Worldviews, Ethics, and Law* (Springer VS 2016) 14–19.

<sup>748</sup> EASAC (ed), *Realising European Potential in Synthetic Biology: Scientific Opportunities and Good Governance* (2010) 5.

existing, natural biological systems for basic research and useful purposes’,<sup>749</sup> for example for social or commercial benefit.<sup>750</sup> Research in the field of synthetic biology is profoundly interdisciplinary<sup>751</sup> and covers a range of approaches, some of which may eventually involve the creation of life from non-living materials.<sup>752</sup>

Much of synthetic biology involves working with nucleic acids, the building blocks of genes, and therefore exhibits strong links with genetic modification (GM), prompting controversy over whether it is in fact a new technology or simply a new label.<sup>753</sup> What distinguishes it then is arguably less its techniques and processes (though developments in techniques increase the extent to which biological systems can be manipulated<sup>754</sup>) but its conceptual framework; its philosophy, assumptions and ambitions, complete with epic narratives about ‘creating life’.<sup>755</sup> With synthetic biology, ‘engineering stops being a metaphor to become a veritable methodology...’ thus, instead of thinking in terms of DNA, RNA and proteins, synthetic biologists think in terms of parts, devices and systems.<sup>756</sup> This constitutes a shift in conceptual framing away from the trial and error of traditional biotechnology towards rational design on the assumption that the component parts employed are predictable.<sup>757</sup> This in turn suggests an ontological blurring between organism and machine (encapsulated in the metaphor ‘living machine’<sup>758</sup>) and perhaps therefore a fading of the distinction from which ethical values are

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<sup>749</sup> Katia Pauwels and others, ‘Synthetic Biology: Latest Developments, Biosafety Considerations and Regulatory Challenges’ (ISP-WIV 2012) D/2012/2505/46 3.

<sup>750</sup> EASAC (n 472) 4.

<sup>751</sup> Commission, *Synthetic Biology* (n 56) 20.

<sup>752</sup> EASAC (n 472) 3.

<sup>753</sup> Joachim Boldt, ‘Swiss Watches, Genetic Machines and Ethics: An Introduction to Synthetic Biology’s Conceptual and Ethical Challenges’ in Joachim Boldt (ed), *Synthetic Biology: Metaphors, Worldviews, Ethics, and Law* (Springer VS 2016) 1.

<sup>754</sup> Harald König and others, ‘Synthetic Biology’s Multiple Dimensions of Benefits and Risks: Implications for Governance and Policies’ in Joachim Boldt (ed), *Synthetic Biology: Metaphors, Worldviews, Ethics, and Law* (Springer VS 2016) 220.

<sup>755</sup> See contributions to Joachim Boldt (ed), *Synthetic Biology: Metaphors, Worldviews, Ethics, and Law* (Springer VS 2016).

<sup>756</sup> ERASynBio (n 130) 2.

<sup>757</sup> Boldt (n 753) 2.

<sup>758</sup> Harald Matern and others, ‘Living Machines. On the Genesis and Systematic Implications of a Leading Metaphor in Synthetic Biology’ in Joachim Boldt (ed), *Synthetic Biology: Metaphors, Worldviews, Ethics, and Law* (Springer VS 2016).

derived.<sup>759</sup> This chapter treats synthetic biology as different to GM and for this reason I use the term ‘synthetic organism’ (SO) to acknowledge that approach, despite the fact that many SOs are technically ‘genetically modified’.

Synthetic biology promises multiple, diverse outputs including biosensors, biomaterials, biofuels, biomedicine, food ingredients and fine chemicals, improving nutrition, healthcare and decontaminating the environment.<sup>760</sup> Specific outputs include artemisinic acid, a precursor to the anti-malarial drug artemisinin, vanillin, fragrances, palm oil, spider silk and biological adhesives. Agricultural applications include modifying plants to photosynthesise and use water and nitrogen more efficiently while increasing yields and reducing CO<sub>2</sub> emissions, to enhance product quality (in terms of flavour, fibre etc.), improve processing characteristics or create *in planta* production of raw materials, for example sugar, cellulose, starch etc.<sup>761</sup>

Much of the field remains at a basic research phase,<sup>762</sup> is contained and mostly involves the use of well-characterised micro-organisms and genetic material, although longer-term developments may result in the production of SOs which fundamentally differ from naturally occurring organisms.<sup>763</sup> It will be some time before an SO will be ready for introduction into the environment, or available as a commercial environmental application.<sup>764</sup> Concerns often relate to the release of poorly characterised and unpredictable new biological machines, their numerous potential hazardous qualities and possible effects on the environment or human

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<sup>759</sup> Oliver Müller, ‘Synthetic Biology: On Epistemological Black Boxes, Human Self-Assurance, and the Hybridity of Practices and Values’ in Joachim Boldt (ed), *Synthetic Biology: Metaphors, Worldviews, Ethics, and Law* (Springer VS 2016) 34.

<sup>760</sup> EASAC (n 748) 7; Commission, *Synthetic Biology* (n 56) 13–17; Pauwels and others (n 749) 9–12.

<sup>761</sup> Johnjoe McFadden, ‘Synthetic Biology: The Best Hope for Mankind’s Future?’ *The Guardian* (29 March 2012) <<https://www.theguardian.com/commentisfree/2012/mar/29/synthetic-biology-best-hope-mankind>> accessed 30 March 2017; Stuart John Dunbar, ‘Synthetic Biology Opportunities in Agriculture’ (Syngenta, 2010) <[rosbnet.org/wiki/images/c/c1/Rosbnet\\_SDunbar.pdf](http://rosbnet.org/wiki/images/c/c1/Rosbnet_SDunbar.pdf)> accessed 30 March 2017.

<sup>762</sup> Giese and others (n 57) 195.

<sup>763</sup> Pauwels and others (n 749) 3.

<sup>764</sup> *ibid.*

health, exacerbated by unpredictable multiplication rates.<sup>765</sup> There is, for example, the potential for horizontal transfer of synthetic genes to other organisms or the colonisation and take-over of natural microbial communities<sup>766</sup> which further challenge risk assessment processes.

These risks exist alongside equally important questions regarding socio-economic and ethical implications, the correct approach to intellectual property rights in the processes and products of synthetic biology and the distribution of risks and benefits. For example, there is concern that mass synthesis of vanillin will put vanilla producers in developing countries out of work.<sup>767</sup> A bioeconomy which increases demand for biomass to process into industrial products could encourage land grab in the search for farmland to meet demand and destroy biodiversity at the expense of local communities.<sup>768</sup> Synthetic biology's promise of speed, efficiency and ease in doing so in particular could exacerbate problems with food security already associated with competition between biofuels and food.<sup>769</sup> The distribution of power between corporations and Western and developing nations is a concern. For example, a shift from cultivated to synthetic artemisinin could, *inter alia*, concentrate power in western pharmaceutical companies by shifting formerly local production westwards,<sup>770</sup> while intellectual property frameworks could prevent developing countries accessing the benefits they produce.<sup>771</sup> The implications of synthetic biology for the relationship between man and nature,<sup>772</sup> or the distinction between man and machine<sup>773</sup> raise ethical concerns. Finally, the inherently

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<sup>765</sup> Giese and others (n 57) 198.

<sup>766</sup> Victor de Lorenzo, 'Environmental Biosafety in the Age of Synthetic Biology: Do We Really Need a Radical New Approach?' (2010) 32 *BioEssays* 926, 927.

<sup>767</sup> FoE, 'Synthetic Biology: GMOs 2.0' (*Friends of the Earth*) 1–2 <[http://webivadownton.s3.amazonaws.com/877/88/b/5292/Issue\\_brief\\_-\\_Synbio\\_GMOs\\_2\\_2015.pdf](http://webivadownton.s3.amazonaws.com/877/88/b/5292/Issue_brief_-_Synbio_GMOs_2_2015.pdf)> accessed 24 September 2015.

<sup>768</sup> ETC Group, 'The New Biomasters: Synthetic Biology and the Next Assault on Biodiversity and Livelihoods' (2010).

<sup>769</sup> ETC Group, 'Extreme Genetic Engineering: An Introduction to Synthetic Biology' (2007) 28–31.

<sup>770</sup> *ibid* 40–42, 52–55.

<sup>771</sup> König and others (n 754) 219 and references therein.

<sup>772</sup> DG SANCO (n 130) 26.

<sup>773</sup> *ibid* 14.

industrial and commercial end of synthetic biology<sup>774</sup> leads to questions about the kind of world we are trying to create, how widely shared visions of the future are and the purpose of this research.<sup>775</sup>

### 3. Uncharted territories: regulating synthetic biology

#### 3.1 *Scope and definition*

While not uncontroversial (as elaborated below), the EU's position appears to be that current EU regulation is capable of assessing and managing the risks of short-term synthetic biology applications and thereby ensuring safety,<sup>776</sup> though in the mid- to long-term this regime will require adaptation.<sup>777</sup> Application of the two instruments examined in this chapter to SOs depends on the definitions contained in the CUD, of 'genetically modified micro-organism' (GMM)<sup>778</sup> and in the DRD, of 'genetically modified organism' (GMO).<sup>779</sup>

Like GM, synthetic biology encompasses a collection of methods for creating synthetic versions of existing materials or re-designed or entirely novel organisms. Synthetic biology currently falls within the definitions because the methods employed and the products of synthetic biology most likely to appear in the shorter term, are not yet too dissimilar to familiar GM techniques.<sup>780</sup> The CUD concerns the use of GMMs in laboratory-based research involving the GM techniques listed in Annex I Part A, including rDNA techniques. Non-food/feed GM products<sup>781</sup> destined for trade on the internal market 'as or in products',<sup>782</sup> e.g. seeds for cultivation,

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<sup>774</sup> *ibid* 5.

<sup>775</sup> E.g. Darren Bhattachary, Juliet Pascall Calitz and Andrew Hunter, 'Synthetic Biology Dialogue' (BBSRC, EPSRC 2010) 7.

<sup>776</sup> Pauwels and others (n 749) 4; Jürgen Robiński, Jürgen Simon and Rainer Paslack, 'Legal Aspects of Synthetic Biology' in Joachim Boldt (ed), *Synthetic Biology: Metaphors, Worldviews, Ethics, and Law* (Springer VS 2016) 127.

<sup>777</sup> König and others (n 754) 225.

<sup>778</sup> Art. 2(a)-(b) CUD.

<sup>779</sup> Art. 2(1)-(2) DRD.

<sup>780</sup> Pauwels and others (n 749) 30.

<sup>781</sup> Products for food/feed use require authorisation under Food and Feed Regulation (n 421). See Lee, *EU Regulation of GMOs* (n 35) 65 on the relationship with the DRD.

<sup>782</sup> Art. 1 DRD.

biosensors or SOs intended for environmental decontamination, require authorisation under the DRD, discussed below.

The definitions of GMM/GMO may not necessarily encompass some longer-term developments in synthetic biology.<sup>783</sup> For example, organisms not capable of self-replication could escape the legislative definitions and fall outside the regulatory regime.<sup>784</sup> The most present implication of this gap relates to risk assessment. Risk assessment under the current regime is partially based on a comparative analysis between the GMO (or SO) and existing non-GM counterparts.<sup>785</sup> The more artificial the organism and the corresponding unavailability of natural comparators, the more difficult it is to characterise risk, and the more unreliable comparative risk assessment becomes.<sup>786</sup> Furthermore, an organism composed of non-natural DNA molecules may not be classified as ‘genetically modified’ and therefore may fall outside the regulation.<sup>787</sup> Indeed, the language of risk assessment developed for genetic engineering may become meaningless with advances in synthetic biology<sup>788</sup> as, for example, concepts of ‘donor’ and ‘acceptor’ organisms become obsolete<sup>789</sup> for some SOs. Even the distinction between ‘contained use’ and ‘deliberate release’ is blurred.<sup>790</sup>

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<sup>783</sup> Pauwels and others (n 749) 20.

<sup>784</sup> Hans-Jörg Buhk, ‘Synthetic Biology and Its Regulation in the European Union’ (2014) 31 *New Biotechnology* 528, 530.

<sup>785</sup> Annex II DRD; Annex II, paragraph 3.3 and Annex III, paragraph 4 CUD; Shlomiya Bar-Yam and others, ‘The Regulation of Synthetic Biology: A Guide to United States and European Union Regulations, Rules and Guidelines’ (2012) *SynBERC and iGEM Version 9.1* 18; Pauwels and others (n 749) 6.

<sup>786</sup> Pauwels and others (n 749) 6, 11–12, 14, 21; JY Zhang, C Marris and N Rose, ‘The Transnational Governance of Synthetic Biology: Scientific Uncertainty, Cross-Borderness and the “art” of Governance’ (2011) *BIOS Working Paper* 8; EGE (n 495) 29.

<sup>787</sup> Pauwels and others (n 749) 31.

<sup>788</sup> Zhang, Marris and Rose (n 786) 8.

<sup>789</sup> Helge Torgersen, ‘Synthetic Biology in Society: Learning from Past Experience?’ (2009) 3 *Systems and Synthetic Biology* 9, 13.

<sup>790</sup> C Marris and C Jefferson, ‘“Workshop on ‘Synthetic Biology: Containment and Release of Engineered Micro-Organisms’: Scoping Report”’ (2013) 19–22.

### 3.2 *The Contained Use Directive*

The CUD provides for the application of containment measures to activities involving GMMs ‘to limit their contact with, and to provide a high level of safety for, the general population and the environment’, with certain limitations and exclusions.<sup>791</sup>

The Directive aims to establish ‘common measures for the contained use of genetically modified micro-organisms with a view to protecting human health and the environment’.<sup>792</sup> These common measures are justified by reference to certain over-arching political motivations. Firstly, the EU’s interest in developing biotechnology for economic gain.<sup>793</sup> Secondly, the likelihood that micro-organisms, once released into the environment, will reproduce and spread across national boundaries,<sup>794</sup> requiring common measures to evaluate and reduce the potential risks of contained use of GMMs<sup>795</sup> to ensure the safe development of biotechnology in the EU. Clearly, the regime’s foundational principles are: facilitating economic progress in Europe and ensuring safety. The EU’s direction, i.e. towards technological progress, is assumed, as discussed below.

Under Article 4, the contained use in question is assessed and classified according to its level of risk and a level of containment is assigned. Containment and other protective measures are selected on the basis of the level identified, taking into account three further considerations. These are: (i) ‘the characteristics of the environment likely to be exposed’, for example the existence of vulnerable biota; (ii) ‘the characteristics of the activity’, for example its scale; and (iii) ‘any non-standard operations’. The legislation anticipates that consideration of these three variables may alter the level of risk identified.<sup>796</sup> This analysis results in assigning the activity in question to a particular risk class.<sup>797</sup> Article 4(4) introduces an

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<sup>791</sup> Art. 2(c) CUD.

<sup>792</sup> Art. 1 CUD.

<sup>793</sup> Recital 4 CUD.

<sup>794</sup> Recital 7 CUD.

<sup>795</sup> Recital 8 CUD.

<sup>796</sup> Annex III, para 7 CUD.

<sup>797</sup> Annex III, para 8 CUD.

element of precaution by providing that where the appropriate risk class is in doubt, ‘the more stringent protective measures shall be applied’ unless agreed with the competent authority that ‘there is sufficient evidence to justify the application of less stringent measures’.

Acknowledging the rapid development in this field of research, measures must be reviewed periodically or, for example, where ‘there is reason to suspect that the assessment is no longer appropriate judged in the light of new scientific or technical knowledge’.<sup>798</sup> Premises in which contained uses occur are licensed according to their risk classification by the national competent authority to which notifications of the contained use are sent.<sup>799</sup> Higher risk contained uses trigger enhanced information obligations in the notification including the purpose and expected results of the contained use.<sup>800</sup> Such uses require the prior consent of the competent authority. There is provision to suspend, terminate or adjust the conditions of the contained use where it poses risks which may have significant consequences.<sup>801</sup>

Article 12 allows Member States, where they consider it appropriate, to provide for public consultation on ‘aspects of the proposed contained use’, subject to the confidentiality provisions in Article 18.

### *3.3 The Deliberate Release Directive*

Article 1 of the DRD states that its purpose is ‘to approximate the laws, regulations and administrative provisions of the Member States and to protect human health and the environment’. This aim is to be accomplished ‘[i]n accordance with the precautionary principle’ and applies to two specific activities: firstly, deliberate release into the environment of GMOs for non-commercial, experimental purposes<sup>802</sup> and, secondly, placing on the market of GMOs. Like the CUD, the

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<sup>798</sup> Art. 5(2) CUD.

<sup>799</sup> Arts 6-10 CUD.

<sup>800</sup> Annex V, Part C CUD.

<sup>801</sup> Art. 11 CUD.

<sup>802</sup> Bar-Yam and others (n 785) 18.

principles underlying the DRD relate to facilitating industrial development and ensuring safety. Living organisms released into the environment may reproduce and cross national borders,<sup>803</sup> implying that this is best dealt with at EU level. Approximation of Member State laws is also required to 'ensure the safe development of industrial products utilising GMOs',<sup>804</sup> emphasising both the economic and safety advantages of harmonised regulation in relation to GMOs.

Part B sets out the procedure for seeking authorisation to deliberately release a GMO into the environment. Notifications are sent to the competent authority of the Member State in which release is intended containing, *inter alia* an environmental risk assessment (ERA).<sup>805</sup> Having considered any observations made by other Member States,<sup>806</sup> the competent authority indicates whether the release may proceed or not.<sup>807</sup> Member States must conduct public consultations on the proposed release over a reasonable time-period 'in order to give the public or groups the opportunity to express an opinion'.<sup>808</sup>

Part C establishes a separate authorisation procedure for placing a GMO 'as or in products' on the market. Under Article 13, a notifier must submit a notification to the competent authority of the Member State in which it intends to market the GMO. The notification must contain *inter alia* information on the diversity of sites in which the GMO is to be used and data from releases carried out for research, an ERA, the conditions for placing it on the market including conditions of use and handling, a proposed period for the consent, a monitoring plan and proposals for labelling and packaging.<sup>809</sup> A summary of the notification must also be included.<sup>810</sup> The Member State must compile an assessment report stating whether or not the

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<sup>803</sup> Recital 4 DRD.

<sup>804</sup> Recital 7 DRD.

<sup>805</sup> Art. 6(2)(b) DRD.

<sup>806</sup> Art. 11 DRD.

<sup>807</sup> Art. 6(5) DRD.

<sup>808</sup> Art. 9 DRD.

<sup>809</sup> Art. 13(2) DRD.

<sup>810</sup> Art. 13(2)(h) DRD.

GMO should be placed on the market.<sup>811</sup> Both this and the summary must be made available to the public which has 30 days to make comments to the Commission.<sup>812</sup>

Following receipt of an assessment report, the Commission and competent authorities may request further information, make comments or present reasoned objections.<sup>813</sup> They may discuss outstanding issues with a view to achieving agreement,<sup>814</sup> failing which, the decision goes to comitology.<sup>815</sup> The Commission must consult EFSA, including at the request of a Member State if there is an objection regarding the risks of GMOs to human health or the environment.<sup>816</sup> There is no obligation to take its opinion into account or make it publicly available. Consultation of an ethics committee is permitted (though Member States retain competence here), the outcome of which must be publicly accessible.<sup>817</sup>

Partly in response to deficiencies in the GMO regulatory framework including chronic deadlock in comitology<sup>818</sup> and to provide Member States with enhanced flexibility to respond to their specific circumstances,<sup>819</sup> Directive 2015/412<sup>820</sup> amended the DRD. It introduced a new Article 26b, governing Member State rights to restrict cultivation. A Member State may, during the authorisation procedure, 'demand that the geographical scope of the... authorisation be adjusted to the effect that all or part of [its] territory... is to be excluded from cultivation'.<sup>821</sup> Alternatively, following authorisation under Part C, Members States may restrict or

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<sup>811</sup> Art. 14 DRD.

<sup>812</sup> Art. 24(1) DRD.

<sup>813</sup> Art. 15(1) DRD.

<sup>814</sup> Art. 15(2) DRD.

<sup>815</sup> Arts 18(1) and 30(2) DRD.

<sup>816</sup> Art. 28 DRD.

<sup>817</sup> Art. 29 DRD.

<sup>818</sup> See, for example, Sara Poli, 'The Reform of the EU Legislation on GMOs: A Journey to an Unknown Destination?' (2015) 6 *European Journal of Risk Regulation* 559; Maria Weimer, 'What Price Flexibility? - The Recent Commission Proposal to Allow for National "Opt-Outs" on GMO Cultivation under the Deliberate Release Directive and the Comitology Reform Post-Lisbon' (2010) 1 *European Journal of Risk Regulation* 345, 346–347.

<sup>819</sup> Recital 6 European Parliament and Council Directive 2015/412 amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory [2015] OJ J68/1.

<sup>820</sup> *ibid.*

<sup>821</sup> Art. 26b(1) DRD.

prohibit the cultivation of a single or group of GMOs in all or part of their territory.<sup>822</sup> Such measures must conform with EU law (most importantly free movement provisions, discussed in Chapter Six), be ‘reasoned, proportional and non-discriminatory... and based on compelling grounds’ for example environmental policy objectives, socio-economic impacts and public policy. Measures must not conflict with the ERA conducted under either the DRD or the Food and Feed Regulation<sup>823</sup>.<sup>824</sup> The opt-out does ‘not affect the free circulation of authorised GMOs as, or in, products’.<sup>825</sup>

#### 4. Reality vs rhetoric: assessing the legislation

##### 4.1 *Upstream potential*

Given that much synthetic biology remains at the research and development stage and that few products of synthetic biology are likely to be ready for deliberate release or marketing in the EU for some time, the legislation currently most pertinent is the CUD. If the principles of RRI are to operate, the CUD would seem to be an appropriate player. It is, however, an instrument of very limited scope. The classification of contained uses is conducted almost entirely through the medium of a tightly drawn scientific risk assessment, making it a narrow, closed and technocratic procedure.

Risk assessment and the licensing of premises are the minimum requirements enabling research to proceed. As discussed in section 2, there may be other research-related concerns. However, there is currently no obvious connection between the regulated contained use and the wider discussions conducted, presumably often simultaneously, under the policy discussed in Chapter Three. Where hard law is concerned only with ensuring safety, it could create a hierarchy of concerns in which safety matters are perhaps the only matters researchers must genuinely heed at that stage, when in fact a little lab-based anticipation of potential

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<sup>822</sup> Art. 26b(3) DRD.

<sup>823</sup> Food and Feed Regulation (n 421).

<sup>824</sup> Art. 26b(3) DRD.

<sup>825</sup> Art. 26b(8) DRD.

consequences and reflection on research aims and endeavours could be salutary. As discussed in Chapter Three, the techniques exist.<sup>826</sup>

Member States are under no obligation to consult the public and where they do, they may select the aspects of the matter on which to focus the consultation. Where concerns are expressed, there is no obligation on the Member State to take the results of the consultation into account in its decision regarding the proposed contained use. This power to consult implies the provision of information but nowhere is this stated explicitly, although it is still subject to a confidentiality exclusion.<sup>827</sup> Clearly, public involvement in decision-making under the CUD was not high on the policy agenda. Inclusion is limited therefore, and with it opportunity to anticipate and reflect.

It could be regarded as inappropriate, at this stage, to have publics 'interfering' with 'contained' research which poses minimal risk and which does not directly and immediately affect them; containing technology can be as much about containing public fear.<sup>828</sup> Indeed, the CUD may well not be the best instrument through which to institute change; tighter or laxer containment measures are not necessarily apt to respond to concerns over socio-economic or ethical implications. However, the consequences of excluding publics or other upstream opportunities to reflect on research are demonstrated by the limitations of downstream participation<sup>829</sup> and the dilemma of control.<sup>830</sup> If the EU is genuine about implementing RRI including upstream public engagement then it is during the stages of research governed by this Directive (and Part B DRD and perhaps earlier) that at least part of that programme should occur. This would provide the best chance of shaping the innovation and research arc, on the assumption that many new products that are

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<sup>826</sup> See also Emma Frow and Jane Calvert, 'Opening up the Future(s) of Synthetic Biology' (2013) 48 *Futures* 32.

<sup>827</sup> Art. 18(1) CUD.

<sup>828</sup> Sheila Jasanoff and Sang-Hyun Kim, 'Containing the Atom: Sociotechnical Imaginaries and Nuclear Power in the United States and South Korea' (2009) 47 *Minerva* 119.

<sup>829</sup> Wilsdon and Willis (n 473) 27.

<sup>830</sup> Collingridge (n 28) 17–20.

destined for commercial release start life in controlled laboratory conditions<sup>831</sup> and that part of the point of anticipation is that it should take place before research materialises in products. It would enhance the consistency of the EU's innovation governance vision and could be supported by a mechanism in the CUD providing for consideration of, for example, outputs of projects like SYNENERGENE during risk assessment. Potentially burdensome but the alternative is futile engagement and isolated research and development processes until commercialisation. In this model, any debate that might have appropriately occurred earlier and might genuinely have helped shape the research, is squeezed into the final authorisation process. At this stage, it is often too late for publics to exert influence or they must compete with the weight of investment in research and development driving towards marketing and generation of a return. Ultimately, the broader participatory ambitions of EU innovation governance policy are unrealised.

#### 4.2 *Downstream influence*

Article 24 DRD enables the public to make comments to the Commission on proposals to place an SO on the market and on the Member State's assessment report. Part of the purpose of public engagement and deliberation is to open up and improve decision-making, as discussed in Chapter Two, and it is promoted as a means to serve democracy.<sup>832</sup> However, that opening-up will not result, automatically, from any mechanism for engagement.<sup>833</sup>

While the lack of opportunities for public involvement was a flaw in the previous regime which the current regime attempted to improve upon,<sup>834</sup> the provisions for consultation remain narrow, restrictive and unambitious. Firstly, the 30-day time limit for responses to applications to place on the market is insufficient for a member of the public to inform themselves, form an opinion and respond,

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<sup>831</sup> Pauwels and others (n 749) 19.

<sup>832</sup> Marko Ahteensuu and Helena Siipi, 'A Critical Assessment of Public Consultations on GMOs in the European Union' (2009) 18 *Environmental Values* 129, 132–134.

<sup>833</sup> Stirling, "Opening Up" and "Closing Down" (n 9).

<sup>834</sup> Patrycja Dąbrowska, 'Civil Society Involvement in the EU Regulations on GMOs: From the Design of a Participatory Garden to Growing Trees of European Public Debate' (2007) 3 *Journal of Civil Society* 287, 287, 294.

especially when compared with the applicant who will have invested huge resources, time and money, in producing the information supporting its application.<sup>835</sup> This is perhaps compounded by the vague<sup>836</sup> information-sharing provisions.<sup>837</sup> Applicants provide the majority of the information required during the authorisation process and, while there are reasonable, resource-related reasons for requiring so,<sup>838</sup> their control over this information raises concerns.<sup>839</sup> The completeness of the information available to the public may be in question, due to confidentiality provisions<sup>840</sup> and perhaps due to the potential for selective reporting of evidence and information.<sup>841</sup> Inadequate information can hinder participation.<sup>842</sup> In terms of quality, publics may be excluded by the technical nature of the information, which may simultaneously be insufficiently detailed for analysis by external experts.<sup>843</sup> Indeed, the structural linking of the legal framework to the ‘state of the art in science and technology’ tends to exclude non-specialist actors.<sup>844</sup>

Secondly, while notification under Part C occurs earlier than under the previous Directive,<sup>845</sup> potentially allowing discussion between Member States ‘before positions are entrenched’,<sup>846</sup> consultation only takes place following the environmental risk assessment (contained in the initial notification)<sup>847</sup> and the Member State assessment report. This structure does not foster an exchange of

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<sup>835</sup> Maria Paola Ferretti, ‘Why Public Participation in Risk Regulation? The Case of Authorizing GMO Products in the European Union’ (2007) 16 *Science as Culture* 377, 389.

<sup>836</sup> Herbert Gottweis, ‘Participation and the New Governance of Life’ (2008) 3 *BioSocieties* 265, 279.

<sup>837</sup> Arts 9(2) and 24 DRD.

<sup>838</sup> Lee, *EU Regulation of GMOs* (n 35) 78.

<sup>839</sup> For example, Jasanoff, ‘Technologies of Humility’ (n 259) 233–234.

<sup>840</sup> Art. 25 DRD. Lee, *EU Regulation of GMOs* (n 35) 78, 82; Ferretti (n 835) 389.

<sup>841</sup> Ferretti (n 835) 385.

<sup>842</sup> Ahteensuu and Siipi (n 832) 139.

<sup>843</sup> Ferretti (n 835) 390.

<sup>844</sup> *ibid* 391; Alfons Bora and Heiko Hausendorf, ‘Participatory Science Governance Revisited: Normative Expectations versus Empirical Evidence’ (2006) 33 *Science and Public Policy* 478.

<sup>845</sup> Council Directive 90/220/EEC on the deliberate release into the environment of genetically modified organisms [1990] OJ L117/15.

<sup>846</sup> Lee, *EU Regulation of GMOs* (n 35) 65–66.

<sup>847</sup> Art. 13(2)(b) DRD.

views on risks between publics and experts<sup>848</sup> so as to reflect the policy ambition expressed for dialogue on risk or the recognition that attitudes to risk vary throughout society and merit expression during expert assessments of risk. Nor do the procedures seem to envisage that participants will change their preferences as a result of engaging in the consultation process as one would hope from genuinely deliberative debate.<sup>849</sup> Instead each presents their case before a final judgment is made by a national or European arbiter.<sup>850</sup> Although there is provision for some exchange of views between Member States on a notification for placing on the market,<sup>851</sup> there is no direct link between the public views and their expression on this level. There is, in addition, no consultation on the Commission's draft authorisation provisions, despite Recital 46 providing that public comments should be taken into account in such measures.

Thirdly, within the consultation procedures themselves, public comments are only permitted on the information contained in the summary of the notification.<sup>852</sup> Ethical or political issues fall outside the scope of the consultation process, raising questions about whether this procedure is fully equipped to capture public concerns.<sup>853</sup> Moreover, engaging the public in decisions where assessments of risk are at issue, should be in explicit recognition of the contingency of expert evaluations of risk and the existence and validity of public evaluations of risk, as discussed in Chapter Two, otherwise much of its potential benefit could be lost. The DRD does recognise the importance of non-technical values, for example in its acknowledgment of the relevance of ethics.<sup>854</sup> However, the overall emphasis on

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<sup>848</sup> Dąbrowska (n 834) 296; Maria Paola Ferretti, 'Participation, Democratic Deficit and Good Regulation: A Case Study of Participatory Strategies in the European Regulation of GMO Products' (2006) ZERP-Diskussionspapier 6/2006 17–18.

<sup>849</sup> Ahteensuu and Siipi (n 832) 132–133.

<sup>850</sup> Ferretti (n 835) 385.

<sup>851</sup> Art. 15(1) DRD.

<sup>852</sup> Art. 24(1) DRD.

<sup>853</sup> Ferretti (n 835) 384–389.

<sup>854</sup> For example, Art. 29, DRD. Maria Lee, 'Public Participation, Procedure, and Democratic Deficit in EC Environmental Law' in Han Somsen (ed), *The Yearbook of European Environmental Law*, vol 3 (OUP 2003) 222.

expert risk assessment and narrowness of the consultation exercise means that concerns not founded on science will probably struggle to be heard.<sup>855</sup>

Fourthly, outcomes of participation exercises at national level under Article 9 are difficult to feed into EU level decision-making, partly due to qualified majority voting during comitology, and may therefore have limited impact.<sup>856</sup> Member States and the Commission are free to take the comments into account if they wish. However, there is no formal requirement that they explain how they have taken any comments into account if they choose to do so.<sup>857</sup> As such, and in the absence of any legal mechanism to challenge a decision if the comments are ignored, neither consultation procedure is likely to have much influence. It is even unclear what should happen to public comments, once made.<sup>858</sup> Ultimately, this weak version of the 'due consideration model'<sup>859</sup> seems unlikely to prompt anything close to the policy ambition to create a dialogue.<sup>860</sup>

Finally, the provisions do not seem intended to implement any particular model of public participation<sup>861</sup> but rather evince a legislative ambivalence to participation.<sup>862</sup> Furthermore, due to the poor information provisions and difficulty for comments to affect decisions, the DRD does little to enhance democracy.<sup>863</sup> These deficiencies and weaknesses appear to stem from the confused motives behind increasing public participation in EC law<sup>864</sup> which include an instrumental desire to overcome public opposition to GMOs and to increase the 'democratic

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<sup>855</sup> Lee, *EU Regulation of GMOs* (n 35) 80; Lee, 'Public Participation' (n 854) 223–224.

<sup>856</sup> Lee, 'Public Participation' (n 854) 214–223; Lee, *EU Regulation of GMOs* (n 35) 82.

<sup>857</sup> Ferretti (n 835) 389.

<sup>858</sup> Dąbrowska (n 834) 296.

<sup>859</sup> *ibid* 295.

<sup>860</sup> Lee, 'Public Participation' (n 854) 222.

<sup>861</sup> Dąbrowska (n 834) 296.

<sup>862</sup> Lee, 'Public Participation' (n 854) 197, 220; Lee, *EU Regulation of GMOs* (n 35) 80.

<sup>863</sup> Ahteensuu and Siipi (n 832) 138–140.

<sup>864</sup> Lee, 'Public Participation' (n 854) 197.

legitimacy' of decisions,<sup>865</sup> and the unambitious, business-as-usual EU policy context for public participation in which the DRD was born.<sup>866</sup>

The pattern of rhetoric in favour of civil society involvement under an EU-wide strategy<sup>867</sup> but minimal provision in regulation, originally in relation to GM, is now repeated with synthetic biology. The difference here is that synthetic biology has been part of huge, technology-specific projects to promote RRI (a large part of which involves public engagement and deliberation) and, as argued in Chapter Three, inclusion and openness seem part of the field's principles and ethos in the way that they never were with GM. However, as the scale of the EU's ambitions and upstream deliberative activity increases, the stasis of the narrow downstream participation provisions widens the gap between policy and practice yet further and decreases the credibility of the EU's grand rhetoric on innovation governance. Deliberation perhaps works best upstream, where more meaningful discussion of the economic, environmental and social impact of proposed initiatives may be easier.<sup>868</sup> However, eventually, a decision is required. It is the narrow and closed nature of risk assessment at this stage and regulatory reliance on it which is of particular concern. While there are limits to the views and concerns that can meaningfully be expressed in relation to a single product pre-marketing, there are also limits upstream, given the level of abstraction and generalisation necessary.<sup>869</sup> Both are necessary and complementary, as argued in Chapter Three. At the very least, there should be a means by which the results of 'innovation governance' activities should feed into authorisation procedures, for, at present, innovation governance and risk regulation seem to operate in isolation of one another. Otherwise, the limitations of risk assessment (as discussed in Chapter Two) persist and the drive to enhance socio-technical integration founders.

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<sup>865</sup> Dąbrowska (n 834) 298; Lee, 'Public Participation' (n 854) 210.

<sup>866</sup> Lee, 'Public Participation' (n 854) 196, 219.

<sup>867</sup> Dąbrowska (n 834) 288f.

<sup>868</sup> Ferretti (n 835) 392.

<sup>869</sup> Lee, 'Public Participation' (n 854) 213; see also Lee and Petts (n 408) 158–160.

This chapter has so far focused on opportunities to enhance socio-technical integration through participation. However, other mechanisms of regulation/governance can contribute and the new Article 26b DRD is perhaps one. The granting of a procedurally flexible, wide competence to Member States to restrict cultivation on numerous grounds without the need for supporting scientific evidence,<sup>870</sup> though limited, is potentially significant both for its recognition of diverse (sub)-national interests and values<sup>871</sup> and as an attempt to embed that political dimension in the regulatory process.<sup>872</sup> Though controversial, the reform should be welcomed as a response to the typically narrow grounds for regulation criticised in Chapters One and Two, especially if it eliminates the need for arguments over safety as proxy for objections based on other values in favour of honest expression of reasons for regulation.

There is still concern, though, that the reform seeks to protect the sanctity of EU risk assessment in decisions regarding placing on the market by arrogating consideration of safety concerns solely to EU level and comitology as separate from, and untainted by, ‘other concerns’, now assigned to Member States.<sup>873</sup> However, these risk assessments have caused much conflict between Member States and EFSA.<sup>874</sup> While Directive 2015/412 recognises the need to improve risk assessment,<sup>875</sup> the approach chosen accepts neither competing national risk assessments nor criticism of EFSA’s risk assessment.<sup>876</sup> Member States may only rely on grounds to regulate ‘impacts which are distinct from and complementary to’ EFSA’s assessment of the risks to health and the environment.<sup>877</sup> According to

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<sup>870</sup> Art. 26b(3) Directive 2015/412 (n 819); Poli (n 818) 563–564.

<sup>871</sup> Maria Lee, ‘GMOs in the Internal Market: New Legislation on National Flexibility’ (2016) 79 *The Modern Law Review* 317, 332.

<sup>872</sup> *ibid* 334–335.

<sup>873</sup> Karolina Zurek, ‘Indicating Reasons for National GM “Opt-Outs”: The Way Forward or a Dead End Street?’ (2011) 2 *European Journal of Risk Regulation* 241, 243; Weimer, ‘What Price Flexibility?’ (n 818) 349; Recital 14, Directive 2015/412 (n 819).

<sup>874</sup> Maria Weimer, ‘Risk Regulation and Deliberation in EU Administrative Governance—GMO Regulation and Its Reform’ (2015) 21 *European Law Journal* 622, 628–629.

<sup>875</sup> Recital 3.

<sup>876</sup> Lee, ‘GMOs in the Internal Market’ (n 871) 328.

<sup>877</sup> Recital 13 Directive 2015/412 (n 819).

Nicolas de Sadeleer, this allows Member States to conduct additional assessments of risks not covered by EFSA's imperfect risk assessments and to regulate in response to potential health and environmental impacts thereby disclosed.<sup>878</sup> However, the boundaries drawn by the legislation between EFSA's science and the science behind national restrictions and their respective protection goals may be hard to maintain<sup>879</sup> and could risk becoming battle lines.

In essence, while the reform could enhance socio-technical integration in some areas of regulation,<sup>880</sup> it ignores that imperative with respect to risk assessment itself, thereby preserving many of its problems, principally the unacknowledged influence of values, commitments and assumptions on purportedly objective assessments and diverse attitudes to biotechnology and its risks among the Member States<sup>881</sup> bound by its conclusions.<sup>882</sup> Largely excluding political, normative debate and other perspectives in favour of a single universal definition of safety here may further strengthen the technocratic nature of the EU's approach to authorisations of GMOs/SOs, entrench artificial dichotomies between facts and values, de-politicise decisions which are profoundly political<sup>883</sup> and ultimately reinforce the gap between policy and practice. Furthermore, given that Article 26b applies only to cultivation, it does little to accommodate diverse national values and

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<sup>878</sup> Nicolas de Sadeleer, 'Marketing and Cultivation of GMOs in the EU: An Uncertain Balance between Centrifugal and Centripetal Forces' (2015) 6 *European Journal of Risk Regulation* 532, 552–553.

<sup>879</sup> *ibid* 553; Weimer, 'Risk Regulation and Deliberation' (n 874) 632.

<sup>880</sup> To be extended if the current proposal succeeds, Commission, 'Proposal for a Regulation Amending Regulation (EC) No 1829/2003 as Regards the Possibility for the Member States to Restrict or Prohibit the Use of Genetically Modified Food and Feed on Their Territory COM(2015) 177 Final'. For discussion, see Poli (n 818) 567–570.

<sup>881</sup> George Gaskell and others, 'Biotechnology and the European Public' (2000) 18 *Nature Biotechnology* 935, 937–938; George Gaskell and others, *Europeans and Biotechnology in 2010: Winds of Change?* (EUR-OP 2010). See also, Chapter Two on diverse public attitudes to risk generally.

<sup>882</sup> Though arguments relating to the acceptability of a risk on the basis of, for example, uncertainty combined with distributional effects, are feasible, Lee, 'GMOs in the Internal Market' (n 871) 328.

<sup>883</sup> *ibid* 333–337; Weimer, 'What Price Flexibility?' (n 818) 352.

interests in the majority of applications not seeking authorisation for cultivation, deadlocked in comitology.<sup>884</sup>

Member States regulating on the grounds contained in Article 26b(3) must ensure their regulation complies with the requirements of internal market law, including proportionality and non-discrimination, and will need to provide supporting evidence in the event of a challenge. The application of internal market law could place significant restraints on this new flexibility,<sup>885</sup> perhaps reasonably so given the potential destabilising risks of multiple opt-outs feared by some.<sup>886</sup> The hope is that the CJEU should respect the spirit of Directive 2015/412 and resist too strict an approach to adjudicating national opt-outs.<sup>887</sup> Likewise, while Member States would likely need to present a more convincing case than Poland,<sup>888</sup> 'diverse evidence should be acceptable'.<sup>889</sup> However, the reform is capable of encouraging equally reductive and expertise-driven methodologies as risk assessment to generate the necessary evidence and the Commission's current indications of acceptable evidence do not suggest opening up decision-making overall.<sup>890</sup>

Regarding the extent to which the reformed DRD could otherwise further RRI, there is cause for moderate optimism. Though applicable post-authorisation rather than during development, the list of 'compelling grounds' in Article 26b(3) clearly responds to a wide range of concerns about the implications of biotechnological

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<sup>884</sup> Maria Lee, 'The Ambiguity of Multi-Level Governance and (De-)Harmonisation in EU Environmental Law' (2013) 15 Cambridge Yearbook of European Legal Studies 357, 373.

<sup>885</sup> On the relationship between Directive 2015/412 and internal market law, see de Sadeleer, 'Marketing and Cultivation of GMOs' (n 878).

<sup>886</sup> Shane H Morris and Charles Spillane, 'EU GM Crop Regulation: A Road to Resolution or a Regulatory Roundabout?' (2010) 1 European Journal of Risk Regulation 359, 365–366; Poli (n 818) 572. So far, 130 demands for geographical restrictions by 19 Member States have been agreed, see <[http://ec.europa.eu/food/plant/gmo/authorisation/cultivation/geographical\\_scope\\_en](http://ec.europa.eu/food/plant/gmo/authorisation/cultivation/geographical_scope_en)> accessed 6 July 2017.

<sup>887</sup> Lee, 'GMOs in the Internal Market' (n 871) 330; Poli (n 818) 571; de Sadeleer, 'Marketing and Cultivation of GMOs' (n 878) 551.

<sup>888</sup> Poli (n 818) 571; Case C-165/08 *Commission v Poland* [2009] ECR I-06843. See Chapter Six.

<sup>889</sup> Lee, 'GMOs in the Internal Market' (n 871) 338.

<sup>890</sup> *ibid* 337–339.

innovation. While Article 26b(3) omits public opposition as a compelling ground and makes no explicit provision for public participation, the Commission does anticipate that Member States will use the reform to respond to its citizens' concerns and increase public involvement in national and regional decision-making.<sup>891</sup> Thus the reform perhaps encourages inclusion and reflexivity and inches towards enhanced responsiveness, at the national level at least. Further encouragement for inclusion and reflexivity may result from the need for Member States to collaborate with industry, each other and the EU institutions during and after authorisation, which could help create space for political debate.<sup>892</sup> However, the fact that these activities take place very 'downstream' could act as a major limit on this potential. These questions, if raised, would arguably be raised too late, though that need not rule out positive effects upstream, discussed below.

Most importantly perhaps, the reform is designed to facilitate authorisation for trade and the 'smooth functioning of the internal market',<sup>893</sup> potentially extinguishing space for deliberation on deeper questions such as the need for the technology and the kind of society they could create, especially where, as seems likely, EFSA's epistemic authority persists.<sup>894</sup> Retaining regulation of placing on the market and import of GMOs at EU level to preserve the internal market<sup>895</sup> suggests the retention too of the DRD's fundamental market logic, guaranteed by EFSA's centralised and less politicised scientific safety assessments.<sup>896</sup> Finally, if Member State regulations breach WTO rules, the opt-outs may be less flexible than they appear.<sup>897</sup>

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<sup>891</sup> Commission, 'Proposal for a Regulation Amending Directive 2001/18/EC as Regards the Possibility for the Member States to Restrict or Prohibit the Cultivation of GMOs in Their Territory COM(2010) 375 Final' 5–6; Lee, 'GMOs in the Internal Market' (n 871) 339.

<sup>892</sup> Lee, 'GMOs in the Internal Market' (n 871) 337.

<sup>893</sup> Recital 8 Directive 2015/412 (n 819).

<sup>894</sup> Weimer, 'Risk Regulation and Deliberation' (n 874).

<sup>895</sup> Recital 6 Directive 2015/412 (n 819).

<sup>896</sup> Gottweis (n 836) 279–280.

<sup>897</sup> Zurek (n 873) 243–244.

## 5. Policy and practice un-synthesised

The provisions examined above are ill-equipped to support the realisation of the EU's broader policy on governance of synthetic biology specifically, or, more generally, its overarching policy on innovation governance discussed in Chapter Three. Clearly, authorisation procedures do not permit the luxury of months' worth of ethical deliberation. Many scientists do not naturally think about the big picture, incentives to do so are absent<sup>898</sup> and ultimately, embedding dialogue into governance is difficult.<sup>899</sup> However, the legislative reticence over information and the limited opportunities for participation again illustrate the gap between these and the open, broad and deliberative ideal envisaged in the adoption of RRI as governance framework for synthetic biology. Moreover, the available procedures do not really enable challenges to the dominance of (probabilistic) risk assessment or the commercial imperative. This section considers the role of policy and the regulatory regime itself in maintaining the gap.

### 5.1 *A closer look at policy*

#### 5.1.1 *Synthesising public acceptance*

To support the EU's vision for RRI and deliberation in the governance of synthetic biology and to reflect the open and inclusive ethos of synthetic biology right up until authorisation decisions, significant changes to the legislation are required. However, sufficient clarity in the political vision or a genuine political will to realise such changes are largely absent. The EU's rhetoric enthusiastically promotes dialogue to open up governance of synthetic biology. However, for all the potential of public engagement to do so by, for example, enabling consideration of broader social values and interests and challenging the dominance of traditional expert analysis in the governance of technology, it may be used instrumentally, reinforcing pre-determined policy commitments, and operate as reductively as expert analysis itself.<sup>900</sup> As argued by Sherry Arnstein, for example, there are many different

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<sup>898</sup> Bhattachary, Pascall Calitz and Hunter (n 775) 48.

<sup>899</sup> Sykes and Macnaghten (n 474) 101.

<sup>900</sup> Stirling, "Opening Up" and "Closing Down" (n 9).

models of participation, offering various levels of citizen control over decision making, many of which are tokenistic.<sup>901</sup> (Upstream) participation may be employed as risk management<sup>902</sup> or in hopes of definitively dispelling controversy,<sup>903</sup> and even the stream metaphor itself suggests unidirectional, deterministic technological progress.<sup>904</sup> As argued below, much of the EU's policy ultimately emphasises such processes of closing down, displaying motivations which confuse or contradict the express purpose of allowing societal concerns and values to shape synthetic biology research and its governance.

Support for participation seems to stem from an instrumental desire to achieve certain ends: primarily overcoming opposition to facilitate the marketing and use of synthetic biology. Chiara Armeni has described two different models of public engagement in the context of technological development.<sup>905</sup> 'Participatory models', on the one hand, are characterised by open debate over multiple available options in which the views and knowledges of publics are both valued and genuinely able to influence decisions. 'Acceptance models', on the other, involve top-down attempts to educate the presumed irrational and ignorant public and persuade it to 'accept' and validate pre-made decisions. Publics defer to experts while their own values and knowledges hold minimal sway. Such models seek to 'enhance social awareness and support to accelerate implementation and facilitate compliance'.<sup>906</sup> An acceptance model dominates EU policy on synthetic biology, according to which the public is brought on board<sup>907</sup> by having its concerns

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<sup>901</sup> Sherry R Arnstein, 'A Ladder Of Citizen Participation' (1969) 35 *Journal of the American Institute of Planners* 216.

<sup>902</sup> Jack Stilgoe, *Nanodialogues: Experiments in Public Engagement with Science* (Demos 2007) 18.

<sup>903</sup> Wilsdon, Wynne and Stilgoe (n 360) 33–34.

<sup>904</sup> Stirling, "'Opening Up" and "Closing Down"' (n 9) 264.

<sup>905</sup> Chiara Armeni, 'Participation in Environmental Decision-Making: Reflecting on Planning and Community Benefits for Major Wind Farms' (2016) 28 *Journal of Environmental Law* 415, 421–423.

<sup>906</sup> *ibid* 416.

<sup>907</sup> For example, EASAC (n 472) 2; DG SANCO (n 130) 7; see also Sacha Loeve, 'Beyond Unity: Nurturing Diversity in Synthetic Biology and Its Publics' in Joachim Boldt (ed), *Synthetic Biology: Metaphors, Worldviews, Ethics, and Law* (Springer VS 2016) 175–177.

identified<sup>908</sup> and addressed/overcome,<sup>909</sup> rather than respected and responded to or treated as a valid challenge to current research trajectories or evaluations of risks.<sup>910</sup> Policy states, for example, that it is important ‘to address ethical and safety concerns, and to address potential or perceived risks of synthetic biology..., so that future development work can be done in conditions of public trust’.<sup>911</sup> The public is encouraged to imagine a world where synthetic biology is commonplace as part of the future ‘bioeconomy’<sup>912</sup> and warned against the stifling consequences of ‘excessive regulation’ for scientific progress.<sup>913</sup> But such models cannot capture all the nuances of concern, intensified by the profound surrounding uncertainty.<sup>914</sup> They can mislead publics over the matters truly open to debate and the degree of public influence in decision-making.<sup>915</sup> Ultimately, they ‘make the normative and substantive justification of the decision inevitably more fragile’.<sup>916</sup>

This desire to persuade is infused with fear, amongst policy-makers and researchers, of, for example, alarmism and inaccuracy in media reporting of synthetic biology and of the resurrection of narratives of technological doom<sup>917</sup> of the kind seen with respect to GM. There is a sense that the grand destiny for synthetic biology to ‘heal us, feed us and fuel us’ risks subversion by ‘public perceptions and fear’, engendering the paradox that public attitudes are getting in the way of public benefits.<sup>918</sup> Formal participation is frequently based on construction of publics and a futile search for a pure, unpartisan public, open to

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<sup>908</sup> For example, EGE (n 495) 55; ERASynBio (n 472) 3.

<sup>909</sup> Claire Marris, ‘The Construction of Imaginaries of the Public as a Threat to Synthetic Biology’ (2015) 24 *Science as Culture* 83, 86.

<sup>910</sup> *ibid* 95.

<sup>911</sup> Commission, *Synthetic Biology* (n 56) 5.

<sup>912</sup> SYNENERGENE, ‘Newsletter 01’ 2  
<<http://www.synenergene.eu/sites/default/files//uploads/SynenergeneNewsletter01-SYNENERGENE-%2520The%2520project%2520in%2520a%2520nutshell%282%29.pdf>>  
accessed 29 September 2015.

<sup>913</sup> EASAC (n 472) 6.

<sup>914</sup> Lee, *EU Regulation of GMOs* (n 35) 80–81.

<sup>915</sup> Armeni (n 905) 423.

<sup>916</sup> *ibid* 416.

<sup>917</sup> DG SANCO (n 130) 24.

<sup>918</sup> Marris (n 909) 84–85 and references therein.

‘rational’ education<sup>919</sup> and adoption of the consensus view. Here, the fear of public fear, or ‘synbiophobia-phobia’,<sup>920</sup> stems from constructions of the publics involved as irrationally fearful and concerned primarily with narrow risks and benefits for their own interests; if they express other concerns, they are off-topic and ‘politically motivated’, and so definitions of publics become self-fulfilling.<sup>921</sup> Such ‘folk theories’ of scientists and technologists often rest on little evidence and instead represent hyper-sensitivity towards any (including projected) opposition which persists despite attempts to explain the new technology.<sup>922</sup>

Thus, the undimnable flame of the deficit model burns, evidenced too by the language of ‘public perceptions’<sup>923</sup> and a desire to exercise control over the debate by controlling the information on which it is based. For example, policy promotes accessible and accurate information about synthetic biology as necessary to inform debate. It cautions that ‘public acceptance... is compromised through perceptions that have little basis in fact’<sup>924</sup> and seeks to help the public ‘realistically assess fears expressed in more sensationalist accounts’,<sup>925</sup> by calling for the presentation of synthetic biology ‘in ways that explain the risks and benefits to ordinary citizens’.<sup>926</sup> It warns against the potential for emotive language to damage ‘calm and rational discussion’.<sup>927</sup> Concerns over creating life are acknowledged but accompanied by an assessment of science outstripping current ethical frameworks and a somewhat patronising call ‘to develop a more sophisticated appreciation of what is meant by

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<sup>919</sup> Gottweis (n 836) 282–283.

<sup>920</sup> Marris (n 909). Similar fears are common among technology developers, Torgersen (n 789) 10.

<sup>921</sup> Marris (n 909) 90–91.

<sup>922</sup> Arie Rip, ‘Folk Theories of Nanotechnologists’ (2006) 15 *Science as Culture* 349. The vast majority of Europeans had not heard of synthetic biology and were found not to be technophobic, according to a 2010 Eurobarometer report, Gaskell and others, *Europeans and Biotechnology in 2010* (n 881) 29–36.

<sup>923</sup> For example, DG SANCO (n 130) 27; Commission, *Synthetic Biology* (n 56) 5; EASAC (n 472) 6.

<sup>924</sup> Commission, *Synthetic Biology: A NEST Pathfinder Initiative* (EUR-OP 2007) 37.

<sup>925</sup> EASAC (n 472) 2.

<sup>926</sup> Commission, *Synthetic Biology: A NEST Pathfinder Initiative* (n 924) 37.

<sup>927</sup> DG SANCO (n 130) 13–14.

'life' than is current in popular discourse'.<sup>928</sup> While public engagement is regarded as useful to ensure publics understand how synthetic biology will provide societal benefits and that potential risks are not exaggerated, there is no recognition that deliberation may aid definition of benefits and risks and no advocacy of debate where people could disagree about what is at stake.<sup>929</sup> This casting of science simultaneously as all-purpose problem solver and provider of all necessary understanding leaves minimal room for public evaluation, reinforcing the deficit model<sup>930</sup> and reducing socio-technical integration. It is this imaginary which is also reinforced by the narrow participation procedures of the DRD, its privileging of technical, over 'other', discourses and difficulties of communication between the different discourses.<sup>931</sup>

The predominantly instrumental rationale permeating much of this policy surfaces too in its focus on 'trusting participants' (here, the public and attempts to secure its trust) rather than 'trustworthy objects', i.e. the qualities of the particular technologies or institutions in question.<sup>932</sup> Inclusiveness and information sharing are highlighted as critical 'as opinions based on misperceptions can undermine trust and hamper innovation', as is dialogue in order to lower uncertainty and secure investments.<sup>933</sup> While trust and accountability are important, this rationale can frame participation 'within the boundaries of established agency practices and policy objectives' inhibiting the influence of diverse knowledges and values on the final decision.<sup>934</sup>

Policy, then, seems to offer a compromise in its emphasis on the pursuit of 'public acceptability' for the applications and risks of synthetic biology,<sup>935</sup> defining success as contingent on the ability of synthetic biology to make products that are needed

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<sup>928</sup> Commission, *Synthetic Biology* (n 56) 19.

<sup>929</sup> Marris (n 909) 85.

<sup>930</sup> G Meyer, 'In Science Communication, Why Does the Idea of a Public Deficit Always Return?' (2016) 25 *Public Understanding of Science* 433.

<sup>931</sup> Lee, 'Public Participation' (n 854) 223; Black (n 121).

<sup>932</sup> Stirling, "'Opening Up" and "Closing Down"' (n 9) 270.

<sup>933</sup> DG SANCO (n 130) 16.

<sup>934</sup> Armeni (n 905) 420.

<sup>935</sup> DG SANCO (n 130) 23.

by, or acceptable to, the public and/or other stakeholders.<sup>936</sup> This approach defines the public firmly as consumers, rather than as citizens capable of expressing themselves other than at the checkout. It also sets up scientific research as ‘an endeavour independent from society producing a stream of bitter pills society might be expected to swallow until point of nonacceptance’.<sup>937</sup> Despite frequent calls to discuss ethical implications, both public acceptance and the success of synthetic biology research is ultimately seen as conditional upon understanding and managing risks<sup>938</sup> due to the misinterpretation of public concerns as desire for more robust risk regulation and consideration of downstream moral and ethical issues.<sup>939</sup>

However, public acceptance is far more complex; it exists on a continuum, is contingent and context-dependent and cannot be reduced to ‘politics’ or nimbyism.<sup>940</sup> It relates to the formation of attitudes to risk and is relevant to the definition and assessment of what is ‘biosafe’ and ‘biosecure’ enough, rather than something to be moulded by expert-defined and -conducted procedures. This blind spot and the absence of any recognition that public concerns vis-à-vis emerging technologies ‘tend to focus on the process of research, rather than the products’<sup>941</sup> speaks to the overall closing down of appraisals of risk itself to other values and other conceptions of risk. Furthermore, if biosafety and biosecurity are already treated in the policy as the main issues it raises doubt as to how much room there is for other concerns expressed by publics and whether engagement will have any significant impact on the content of the debate at all. Ultimately, debate should

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<sup>936</sup> E.g. ERASynBio (n 130) 25.

<sup>937</sup> Torgersen (n 789) 15.

<sup>938</sup> EGE (n 495) 49; EASAC (n 472) 17–18; Commission, *Synthetic Biology: A NEST Pathfinder Initiative* (n 924) 3; Commission, *Synthetic Biology* (n 56) 5.

<sup>939</sup> Marris (n 909) 89.

<sup>940</sup> Amy K Wolfe and others, ‘A Framework for Analyzing Dialogues over the Acceptability of Controversial Technologies’ (2002) 27 *Science, Technology, & Human Values* 134.

<sup>941</sup> Marris (n 909) 89.

extend beyond narrowly defined questions of biosafety and biosecurity typically discussed<sup>942</sup> to the many dimensions encompassed by RRI.<sup>943</sup>

### 5.1.2 Assumed futures

Behind the drive for acceptance lies a cast iron conviction that synthetic biology represents an unmissable opportunity to enhance Europe's competitiveness; '[i]t is obvious that Europe should invest in this area...'.<sup>944</sup> Its beneficial contribution to the future bioeconomy is assumed<sup>945</sup> and its potential to deliver products and solutions more quickly and thus provide an early return on investment is emphasised.<sup>946</sup> The EU wishes to lead in synthetic biology research,<sup>947</sup> illustrating its general desire for any innovation,<sup>948</sup> discussed further in Chapter Eight. The deficient and hostile public,<sup>949</sup> again, is viewed as being in the way.<sup>950</sup> As with GM, this fear of missing out on a great opportunity may explain EU ambivalence towards the messy politics of participation.<sup>951</sup>

In addition, despite the (at least superficial) openness and inclusivity of synthetic biology research and policy, as an engineering discipline, it is still inherently industrial and these two sides to its character may not necessarily co-exist

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<sup>942</sup> ETC Group (n 769) 50.

<sup>943</sup> Brigitte Nerlich, 'Synthetic Biology Markets: Opportunities and Obstacles' <<https://blogs.nottingham.ac.uk/makingsciencepublic/2014/12/31/synthetic-biology-markets-opportunities-and-obstacles/>> accessed 24 September 2015.

<sup>944</sup> Commission, *Synthetic Biology* (n 56) 5.

<sup>945</sup> ERASynBio (n 130) 3, 25; SYNENERGENE, 'Newsletter 01' (n 912) 4; Marris (n 909) 83–84. Jack Stilgoe, 'Don't Shut the Door on the Synthetic Biology Debate' <<http://www.theguardian.com/science/political-science/2014/may/08/dont-shut-the-door-on-the-synthetic-biology-debate>> accessed 24 June 2014.

<sup>946</sup> Commission, *Synthetic Biology* (n 56) 5; ERASynBio (n 130) 4, 15; DG SANCO (n 130) 8, 16.

<sup>947</sup> ERASynBio (n 130) 4, 13; Commission, *Synthetic Biology: A NEST Pathfinder Initiative* (n 924) 7; EASAC (n 748) 2.

<sup>948</sup> von Schomberg (n 429) 54.

<sup>949</sup> EASAC (n 472) 6.

<sup>950</sup> For example, public perceptions are treated as a barrier to funding, Sybille Gaisser and others, 'TESSY Achievements and Future Perspectives in Synthetic Biology' (2008) TESSY Final Report 24 <[http://www.eurosfair.prd.fr/7pc/doc/1245144155\\_tessy\\_final\\_report\\_d5\\_3.pdf](http://www.eurosfair.prd.fr/7pc/doc/1245144155_tessy_final_report_d5_3.pdf)> accessed 25 June 2017.

<sup>951</sup> Lee, *EU Regulation of GMOs* (n 35) 102.

harmoniously. For example, the desire to stimulate commercial investment by providing regulatory certainty<sup>952</sup> or demonstrating proximity of products to the market and their benefit to consumers,<sup>953</sup> or generally to accelerate market-wards<sup>954</sup> so as to, for example, achieve an early return on investment,<sup>955</sup> all represent somewhat conflicting aspirations. There is no mention of public engagement in these contexts and the rhetorical commitments elsewhere, examined in Chapter Three, would seem to be undermined by these directions to speed up achievement of synthetic biology's commercial destiny, especially since the speed and direction of synthetic biology itself is a public concern.<sup>956</sup>

### 5.1.3 *Interrupted flows*

Reference is often made to public dialogue influencing funding and the way science is conducted. For example,<sup>957</sup> funded organisations are encouraged to show they have given due consideration to potential ethical and social issues and environmental and other risks<sup>958</sup> and to make the outcomes of public dialogue available to policy makers, other stakeholders and the public.<sup>959</sup> However, indications that such dialogue should influence regulatory decisions are rare. The enthusiasm for upstream participation found in much of the policy may further exacerbate the gap between policy and regulation, perhaps allowing the EU to point to its energetic upstream dialogue and other RRI activities and deny therefore, the need to revise and open up its downstream authorisation procedures on the basis that all relevant issues have already been resolved.

I argued in Chapter Three that innovation governance and risk regulation are part of the same continuum, that they should operate according to consistent principles and that encouraging the former should not detract attention from opening up the

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<sup>952</sup> DG SANCO (n 130) 22.

<sup>953</sup> *ibid* 7; ERASynBio (n 130) 14 and references therein.

<sup>954</sup> ERASynBio (n 130) 25.

<sup>955</sup> Gaisser and others (n 950) 2.

<sup>956</sup> Sykes and Macnaghten (n 474) 103.

<sup>957</sup> For example, ERASynBio (n 472) 5–6.

<sup>958</sup> ERASynBio (n 130) 26.

<sup>959</sup> 'Synenergene' <<http://www.synenergene.eu/>> accessed 20 November 2014.

latter. They should support and complement one other. However, if the governance of innovation and the authorisation procedures which regulate risk operate in isolation to one another, it will be difficult to verify whether all relevant issues have in fact been resolved. There are significant numbers of potential applicants under this regime. Even with meaningful public dialogue, there is no guarantee that a particular applicant under the DRD or CUD will have engaged in RRI or will have adapted its project to reflect the outcomes such that the relevant SO does not need to undergo further societal scrutiny before authorisation, but just needs confirmation of safety. With no monitoring or reporting requirements on industry on their part in these activities, there is no way, currently, to transmit any of this information, if it exists, to decision-makers.

Essentially, participation in such activities is voluntary and, as such, the absence of sanctions may mean low participation.<sup>960</sup> Furthermore, industry may be deterred from participating if, for example, it perceives any threat to the confidentiality of commercially sensitive information.<sup>961</sup> Ultimately, plans are vague and so far there is little indication that the outcomes of any upstream governance activities are expected, or will be allowed, to reach or influence decision-makers. If this is so, it could undermine realisation of any potential substantive or problem-solving benefits of deliberative activities, discussed in Chapter Two, at this stage of decision-making.

Altogether, the fear amongst policy-makers, the attempted control of debate and the presumption in favour of commercialisation creates the impression that the EU is engaged in selling synthetic biology *to* the public rather than engaging *with* the public. Specifically, its apparent ambitions for strong public participation are tempered significantly by a desire to control the information on which debate is based and the scope of the debate so as not to challenge the direction set out for scientific research or Europe's leadership in that research.<sup>962</sup> Ultimately, this

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<sup>960</sup> Stokes, 'Demand for Command' (n 414) 31–32.

<sup>961</sup> *ibid.*

<sup>962</sup> Irwin (n 351) 316.

suggests that even if there were space for expression of any concerns the public may have during authorisation, they may not necessarily be taken seriously.

## 5.2 *Inherited regulation*

The conflicting aspirations of policy, consequential closing down of debate and separation between innovation governance and regulation identified above are perhaps intensified by the fact that synthetic biology has inherited an old regulatory regime, designed for a different technology. 'Inherited regulation' refers to the idea that a piece of legislation is born out of the values salient at the time it was negotiated and drafted and reflects a contemporaneous set of principles and assumptions. When those old rules are applied to new products, the underlying policies, aims, assumptions and priorities of those rules are transferred to the new product when they may not be appropriate.<sup>963</sup> As such, synthetic biology inherits a framework of regulatory values, goals, intentions, priorities and powers and interpretive practices and in fact the whole broader policy setting,<sup>964</sup> designed to regulate the products of genetic engineering which may struggle to respond to challenges posed by the new technology unanticipated at the time the regulation was drafted.<sup>965</sup>

To contextualise, the EU's core project is the internal market and safeguarding its integrity is paramount.<sup>966</sup> The two prominent narratives running through the Directives examined here reflect the position that '[t]ypically the starting point of regulation is the potential of new technology to open markets and create wealth, and to position jurisdictions as a competitive and dynamic knowledge society'.<sup>967</sup> Public involvement always started from the acceptability of growing GMOs in the EU, subject only to ERA.<sup>968</sup> The EU's policy towards biotechnology at the turn of the

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<sup>963</sup> Stokes, 'Nanotechnology' (n 81).

<sup>964</sup> *ibid* 101.

<sup>965</sup> Stokes and Bowman (n 746) 240.

<sup>966</sup> Sara Poli, 'Overhaul of the European Legislation on GMOs, Genetically Modified Food and Feed: Mission Accomplished - What Now?' (2004) 11 *Maastricht Journal of European and Comparative Law* 13, 19, 40–41.

<sup>967</sup> Stokes and Bowman (n 746) 240.

<sup>968</sup> Lee, 'Public Participation' (n 854) 224.

century, when the DRD was drafted, demonstrates its clear interest in commercialising the products of biotech quickly, improving the situation of European biotechnology research and its concern about global economic competition.<sup>969</sup>

As discussed, some processes and products of synthetic biology research are not covered by the CUD and DRD as they currently stand and the only potential changes to the regulation discussed seriously relate to risk assessment procedures to ensure biosafety. Inquiries into whether existing regulation covers emerging, high risk, technologies focus on health, safety and the environment in order to establish regulatory connection. Regulatory disconnection can occur where ‘the original regulatory purposes no longer provide clear justificatory cover for the uses to which the technology is now put’.<sup>970</sup> This arguably describes the regulation of synthetic biology where connection is established through definitions<sup>971</sup> but where its many potential negative implications derive not from the specifics of synthetic biology but from its global applications,<sup>972</sup> meaning the purpose of the regulation is ill-equipped to respond to the possible consequences.

Treating the application of the old rules to synthetic biology as a technical question of definition bypasses the democratic processes associated with legislating.<sup>973</sup> By contrast, the potential openness and inclusion of synthetic biology, along with its philosophy and assumptions and the socio-economic or ethical concerns highlighted above and perhaps discoverable through RRI, might have indicated that the current regulatory regime was neither adequate nor appropriate. For example, evaluations of the reliability of risk assessment of SOs are liable to vary depending on the evaluator’s level of commitment to synthetic biology’s core assumption of

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<sup>969</sup> Les Levidow, ‘European Public Participation as Risk Governance: Enhancing Democratic Accountability for Agbiotech Policy?’ (2007) 1 *East Asian Science, Technology and Society: an International Journal* 19, 21. See Chapter Eight.

<sup>970</sup> Roger Brownsword and Morag Goodwin, *Law and the Technologies of the Twenty-First Century: Text and Materials* (CUP 2012) 64–65.

<sup>971</sup> Stokes, ‘Recombinant Regulation’ (n 131) 12–23.

<sup>972</sup> König and others (n 754) 221.

<sup>973</sup> Stokes, ‘Recombinant Regulation’ (n 131) 3, 7–12.

predictability.<sup>974</sup> EFSA's uncertainty intolerance already propagates the 'uncertainty paradox',<sup>975</sup> which may become further entrenched if claims to predictability increase demands that science provide certainty on uncertain risks while synthetic biology's increasingly profound manipulation, or even creation, of life perhaps increases uncertainty.

In other words, policy-makers could assume that those other socio-economic or ethical questions, or values, which might actually be different to those associated with genetic engineering, or which have evolved, or intensified,<sup>976</sup> in the 16 years since the DRD was negotiated, had already been dealt with in the negotiation and implementation of that legislation. For example, much of the debate around genetic engineering focused on bioethics. For all the enthusiasm to cover ethics in discussions, in other places, socio-ethical questions involving recombinant DNA are passed over because they are considered to be stable and already settled,<sup>977</sup> despite the profound (and novel) ethical implications of synthetic biology's core metaphor, 'living machines', discussed above and, ironically, despite ongoing controversy surrounding GMOs. Technoscientific development is still viewed as the driver of change indicating the priority of technical questions,<sup>978</sup> despite the argument above that the distinguishing features of synthetic biology are its philosophy, assumptions and ambitions, all of which deserve open scrutiny. The belief that the products of synthetic biology should be regulated by the same regulatory framework as products from other sources<sup>979</sup> further indicates that such socio-ethical discussions are perhaps simultaneously expected to have no impact.

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<sup>974</sup> Boldt (n 753) 7.

<sup>975</sup> Marjolein BA Van Asselt, Ellen Vos and Bram Rooijackers, 'Science, Knowledge and Uncertainty in EU Risk Regulation' in Michelle Everson and Ellen Vos (eds), *Uncertain Risks Regulated* (Routledge-Cavendish 2009).

<sup>976</sup> König and others (n 754) 219.

<sup>977</sup> Stokes, 'Recombinant Regulation' (n 131) 23–26.

<sup>978</sup> *ibid* 25.

<sup>979</sup> EASAC (n 472) 14.

While there are good practical reasons not to re-legislate for every emerging technology,<sup>980</sup> the open ethos of synthetic biology, its promises to address multiple diverse problems and the energy put into its governance – in essence its disruptiveness – should entail review, involving publics, of existing regulatory structures, priorities and definitions of our assumed futures.<sup>981</sup> A similar straight-jacketing of issues within existing structures is also visible in policy. Indeed, while we are sometimes warned that the novelty of synthetic biology represents a significant challenge to regulation, more specific examination of regulation results in arguments that provision is in fact sufficient.<sup>982</sup> Furthermore, there is a tendency to frame problems with synthetic biology to match established policy categories, so that governance involves fitting into readily available solutions, for example, that governance must be based on sound scientific evidence and that ‘other’ concerns can be dealt with separately, downstream.<sup>983</sup>

A presumption that the legislation applies on the basis of technical coverage further undermines ambitious implementation of policy on RRI and participation in two ways. Firstly, the existing regulations condition the terms of the debate, such as it is; synthetic biology is seen through the lens of the DRD and the CUD.<sup>984</sup> This is important because downstream regulation can influence research and innovation upstream,<sup>985</sup> discussed below. Secondly, ‘it makes questioning the desirability of new, innovative products difficult since their introduction into the market becomes an inevitable and incontrovertible consequence of their supposed regulation’, provided the products are ‘safe’.<sup>986</sup> It also prevents an ambitious regulatory shift

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<sup>980</sup> Lyria Bennett Moses, ‘Sui Generis Rules’ in Gary E Marchant, Braden R Allenby and Joseph R Herkert (eds), *The Growing Gap Between Emerging Technologies and Legal-Ethical Oversight*, vol 7 (Springer Netherlands 2011) 83–87.

<sup>981</sup> Diana Bowman, Elen Stokes and Michael Bennett, ‘Anticipating the Societal Challenges of Nanotechnologies’ (2013) 7 *Nanoethics* 1, 4.

<sup>982</sup> Zhang, Marris and Rose (n 786) 7.

<sup>983</sup> *ibid.*

<sup>984</sup> Stokes, ‘Recombinant Regulation’ (n 131) 12.

<sup>985</sup> Joyce Tait, ‘Risk Governance of Synthetic Biology: International Risk Governance Council Project Workshop Presentation’ (University of Edinburgh, 2010) 16. See Chapter Three on the relationship between the upstream and the downstream.

<sup>986</sup> Stokes, ‘Nanotechnology’ (n 81) 95.

commensurate with the alleged disruptive potential of synthetic biology products<sup>987</sup> because of the narrow circularity of current legislation-contingent exercises in defining synthetic biology, and the adaptation and legitimisation of current legislation by understanding synthetic biology ‘as a variant of established practices of biotechnology’.<sup>988</sup> The above observations correlate to a broader trend with synthetic biology as identifier and solver of societal challenges, in which democratic institutions defer to science to define plausible futures and matters warranting societal attention. Science acts; society reacts, and normative, socio-ethical questions ‘are rendered subsidiary to – and are often silenced by – expert assessments of novelty’.<sup>989</sup>

Though not explicitly addressed to developments in synthetic biology specifically, the new Article 26b DRD could help alleviate these deficiencies. Member States have more flexibility to adapt their regulation to such new developments. Their new power could indirectly mandate reflection amongst synthetic biologists, who presumably want their research outcomes authorised, on the processes and trajectories of their research and development, in line with RRI. Directive 2015/412 is clear that national regulation under Article 26b should not prevent biotechnology research but, interestingly, it requires ‘that the activity does not undermine the respect of the grounds on which the restriction or prohibition has been introduced’,<sup>990</sup> perhaps demanding sensitivity amongst researchers towards the national values and concerns motivating the measure. Though Member States’ hard legal rights are limited to regulating cultivation, this provision perhaps enables their exercise to send ripples upstream and percolate more deeply through innovation systems.

More specifically, knowing the range of grounds on which Member States may regulate cultivation, or even the mere fact that such concerns are deemed valid,

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<sup>987</sup> ERASynBio (n 130) 4, 13.

<sup>988</sup> Stokes, ‘Recombinant Regulation’ (n 131) 22.

<sup>989</sup> J Benjamin Hurlbut, ‘Reimagining Responsibility in Synthetic Biology’ (2015) 2 *Journal of Responsible Innovation* 113.

<sup>990</sup> Recital 19 Directive 2015/412 (n 819).

could provide a framework for encouraging RRI. For example, and more specifically, it could encourage upstream anticipation of the plausible and possible directions of synthetic biology, reflection on commitments and the likely concerns of Member States and their citizens, greater willingness to engage with these actors and/or greater responsiveness to the outcomes of that engagement.<sup>991</sup> If an applicant under the DRD has engaged with or responded poorly to public concerns about a modified organism intended for cultivation, perhaps that behaviour can be cited as evidence in support of a restriction on one of the grounds, or a ground itself if the resulting organism falls short of claims and promises made of it upstream. That the list of compelling grounds in Article 26b(3) is open is a further help. One of the most prominent policy commitments discussed in Chapter Three is to use science and technology to tackle grand societal challenges and pursue research and innovation in accordance with societal goals and ethical values. The lack of need for, or social benefit of, a modification is not a compelling ground<sup>992</sup> but nothing prevents Member States from relying on other such justifications.<sup>993</sup> Indeed, given the prominence of the commitment to targeting societal challenges with science and innovation in accordance with societal goals and values, denial of the relevance of a societal need for a technology at this stage would appear irrational and inconsistent. However, the absence of societal need as a compelling ground raises reasonable questions regarding the coherence of the EU's overarching vision for innovation governance/regulation, what the EU thinks RRI, for example, is actually for and whether the policy-practice gap remains as wide as before.

Furthermore, the reform seeks to increase authorisations and 'the role of GMOs in EU agriculture'.<sup>994</sup> In addition, the maintenance of a harmonised authorisation procedure, risk assessment and level of protection facilitates trade within the internal market, benefiting commercial actors.<sup>995</sup> Overall, the commercial

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<sup>991</sup> Stilgoe, Owen and Macnaghten (n 29) 1570–1572.

<sup>992</sup> Lee, 'GMOs in the Internal Market' (n 871) 333.

<sup>993</sup> de Sadeleer, 'Marketing and Cultivation of GMOs' (n 878) 555.

<sup>994</sup> Lee, 'GMOs in the Internal Market' (n 871) 325.

<sup>995</sup> de Sadeleer, 'Marketing and Cultivation of GMOs' (n 878) 541.

imperative stands and the quest for potential to inspire deeper change in synthetic biology research and innovation systems occurs in a reform ultimately designed to facilitate that imperative. This raises questions about how genuinely the EU believes in its own policy ambitions relating to participation at each stage of innovation governance and risk regulation. It also reinforces the impression that no matter how forceful the conclusions coming out of earlier participation exercises are, they are likely to wield little influence in regulatory decision-making or on the values on which regulation itself should be based.

## 6. Conclusion

The policy and legislative matrix in relation to synthetic biology is exquisitely complex. The conflicting sentiments and contradictory aims of policy make it impossible to ascertain, for certain, what the EU's true intentions are. At times policy seems to support ambitiously opening up governance to public values and debate. At other times, instrumental approaches to participation, attempts to control the debate, a focus on public acceptability, the assumption that commercialisation will automatically produce societal benefits and the centripetal force of risk undermine any more ambitious visions for participation expressed elsewhere. The embracing of public engagement by the synthetic biology community is perhaps prompted by synbiophobia-phobia. This is 'a belief system that closes down, rather than opens up, the politics of knowledge and power in technology choice' and which reinforces 'entrenched modes of managing controversy' which postpones conflict until products begin to reach market.<sup>996</sup>

If this is really how the EU views engagement, then it seems unlikely that it would regard any outcomes of participation as requiring change to the legislation, including the participation provisions during authorisation, or as influential in individual authorisation decisions. The legislation, as it currently stands, with its restrictive provisions on participation and narrow authorisation procedures, gives the EU a degree of control, which it seems to be aiming for in its sponsored dialogue

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<sup>996</sup> Marris (n 909) 96; Stirling, 'Opening Up the Politics of Knowledge' (n 172).

exercises, and which it is therefore unlikely, perhaps, to want to relinquish. This structure of the regulation, moreover, fails to strike a reasonable balance between the participatory and industrial aspirations of synthetic biology.

The uncertainty of the EU's policy vision is further exacerbated by the presence and application of a regime designed for a different technology. This creates the impression that the kinds of social, ethical, distributive or other issues relating to synthetic biology, which would be discussed in a broad and open participation exercise, have already been settled, meaning that anything more than the narrowest of participation exercises is otiose. It also provides a restrictive frame for the conduct of any deliberative activities upstream which could stifle any potential challenges to existing regulation.<sup>997</sup> Article 26b may do little to change this.

Ultimately, the regulatory regime is inadequate to support the EU's policy vision for RRI and especially dialogue in synthetic biology and it seems unlikely to be otherwise in the near future, at least. This is not a criticism of the attempts to engage publics, which may be run by individuals who are committed to the ideals of public engagement, nor of attempts to use the outcomes of that engagement to shape research. The problem lies more in the inflexibility of some aspects of the regulatory structure and a political unwillingness to relinquish enough control to enable genuine participation, with the potential to influence decision-making, during all stages of governance and regulation. The unfortunate results are that the promising open ethos of synthetic biology does not reach as far as regulation, that any discussions not related to the adequacy of the regulatory risk assessment procedures appear to be drowned in the flow downstream and that alternative views remain, by and large, silent during a critical decision-making procedure.

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<sup>997</sup> Stokes, 'Demand for Command' (n 414).

SECTION III – NOT WALKING THE WALK: WHY CLOSING THE POLICY-  
PRACTICE GAP IS SO DIFFICULT

## Chapter Six – The role of the EU internal market in maintaining the gap between policy and practice

### 1. Introduction

Science plays a crucial role in establishing the lawfulness of regulation which claims to ensure safety (as opposed to being a cover for protectionism) by showing that there is a risk to human health or the environment, enabling safety or environmental protection to prevail over interests in economic freedom. However, 'safety' is ambiguous and, as discussed in Chapter Two, there are many *non-safety* concerns associated with such technologies which regulatory science cannot explicitly demonstrate. These concerns may still influence societal attitudes to risk or constitute valid, if not necessarily lawful, reasons to regulate a risky technology independent of scientific 'proof' of a risk. This chapter examines the extent to which non-safety concerns as well as diverse understandings of risk or safety can compete with economic interests in the context of the EU's internal market.<sup>998</sup>

Sections I and II examined concerns peculiar to risky technologies; peculiar that is, for the characteristic entanglement of moral, social, economic and environmental/health concerns, which perhaps explain the very existence of the discourse on socio-technical integration in their governance and regulation.<sup>999</sup> All technologies differ in the detail of their implications.<sup>1000</sup> However, regardless of the technology, familiar concerns, which citizens and Member States may wish to address through regulation, are clear. The following would ideally be recognised by internal market law as valid reasons for introducing trade-restrictive measures: concerns over the potential negative impacts of technologies and their uncertain, unknown or indeterminate severity; doubt over an uncertain, perhaps illusory,

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<sup>998</sup> I have avoided casting these as trade and non-trade values in this and the next chapter and recognise that their boundaries may be fluid, Andrew Lang, 'Reflecting on "Linkage": Cognitive and Institutional Change in The International Trading System' (2007) 70 *Modern Law Review* 523.

<sup>999</sup> EGSG (n 6); Owen, Macnaghten and Stilgoe (n 350) 751–752.

<sup>1000</sup> Roger Brownsword, 'So What Does the World Need Now? Reflections on Regulating Technologies' in Roger Brownsword and Karen Yeung (eds), *Regulating Technologies: Legal Futures, Regulatory Frames and Technological Fixes* (Hart 2008) 30.

need for the technology; concerns over consequences for society or the economy beyond those to the environment and/or human health; concerns over the distribution of impacts within and between generations which may be unpredictable and regressive; concerns over ownership structure – who owns the intellectual property rights behind the technology, the openness of the structure and whether it tends towards consolidation or distribution of market power; ethical or religious concerns; the direction and speed of technological innovation; the likelihood of further commoditisation, mechanisation or control of nature; whether a technology undermines human dignity or certain relationships and boundaries, for example that between man and nature or between man and machine, respectively; its tendency to preserve, alter or erode a culture, tradition or social structure; whether it threatens or promotes diversity; its impact on consumers and employment; and its compatibility with a more or less open society, or a centralised or de-centralised style of government.

This chapter considers the role internal market law plays in preventing greater socio-technical integration in the regulation of risky technologies, as committed to in EU policy (see Chapter Three). To that end, it examines the extent to which the above types of concerns could constitute valid reasons to regulate under internal market law. While the EU has increasingly pursued areas of social policy,<sup>1001</sup> the internal market remains its core project.<sup>1002</sup> The fulfilment of certain desirable goals for the EU, including increased growth and economic competitiveness and myriad other consequential social benefits are regarded as contingent upon its completion.<sup>1003</sup> The EU does however, for example through exceptions to free movement discussed below, recognise that certain policy goals may not necessarily be achieved through the elimination of barriers to trade and that some trade-restrictive measures may be necessary to achieve those goals. It is at least arguable, though, whether the fundamental non-negotiability of the EU's economic goals and

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<sup>1001</sup> Catherine Barnard and Steve Peers, 'Introduction' in Catherine Barnard and Steve Peers (eds), *European Union Law* (OUP 2014) 2.

<sup>1002</sup> Snell (n 98) 301.

<sup>1003</sup> See, for example, Commission, 'Europe 2020' (n 580). See also Chapter Eight.

the dominance of risk assessment ultimately provide a structure which can recognise and accommodate non-economic interests,<sup>1004</sup> specifically here the infinitely subtle concerns over risky technologies.

Chapter Two discussed the political incentives for using regulatory science to justify decisions. There may also be significant legal incentives for decision-makers in an EU context to justify decisions to regulate technologies on the basis of a scientifically-diagnosed risk to safety, despite the salience of other concerns.<sup>1005</sup> Furthermore, the predominant vision driving market integration in the EU – i.e. the removal of barriers to free movement and distortions to competition – perhaps tends to favour uniformity in standards protecting consumers and the environment and ‘prizes market efficiency and Europe-wide neutrality of competition above other competing values’<sup>1006</sup> also perhaps placing certain policy goals beyond reach.<sup>1007</sup> To those arguments I add the observation that where a technology could pose risks *inter alia* of harm to the environment or human health, the EU institutions often treat the existence of a problem as an epistemic question, granting science priority of agency in determining whether a problem justifying regulation actually exists.<sup>1008</sup> The effect, I argue, is to pre-empt any alternative lens (for example, moral, distributional etc.) through which to discern and articulate a problem, thereby precluding the application of justifications for measures which ostensibly seek to protect interests other than safety, despite their in-principle availability. I argue, furthermore, that the type of regulatory science required in support of such measures is strictly defined, restricting scope for diverse framings

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<sup>1004</sup> Gareth Davies, ‘Democracy and Legitimacy in the Shadow of Purposive Competence’ (2015) 21 *European Law Journal* 2.

<sup>1005</sup> Lee, ‘Legal Institutionalisation’ (n 73).

<sup>1006</sup> JHH Weiler, ‘The Transformation of Europe’ (1991) 100 *The Yale Law Journal* 2403, 2477–2478.

<sup>1007</sup> Floris de Witte, ‘EU Law, Politics, and the Social Question’ (2013) 14 *German Law Journal* 581, 584.

<sup>1008</sup> See J Benjamin Hurlbut, ‘Remembering the Future: Science, Law, and the Legacy of Asilomar’ in Sheila Jasanoff and Sang-Hyun Kim (eds), *Dreamscapes of Modernity: Sociotechnical Imaginaries and the Fabrication of Power* (University of Chicago Press 2015) on this phenomenon, discussed in greater detail in Chapter Eight.

of even the underlying epistemic question (i.e. whether there is a threat to safety) as influenced by specific values or concerns.

Ultimately, this reinforces the ‘facts-then-values’ order prescribed for decision-making where risky technologies are concerned, as discussed in Chapter Two. Little opportunity remains then, to justify trade-restrictive measures on the basis of *either* values other than the protection of human health and/or the environment independently of a technology’s safety profile, *or* regulatory science conducted according to a frame shaped by such values. In other words (perhaps as an example of the potential of internal market law to depoliticise social questions<sup>1009</sup> such as those raised by risky technology) the arrangement further stifles socio-technical integration.

This has implications for the kind of evidence which may substantiate the need for a trade-restrictive measure. Omnipresent uncertainty over the implications of a technology raises further challenges to providing convincing evidence of a reason to regulate. As the problem of uncertainty pervades the regulation of risky technologies, I begin with a brief discussion of its treatment in the EU. Section 3 considers the justifications available for restricting free movement under Article 36 TFEU and the public interest requirements doctrine.<sup>1010</sup> I argue that while case law indicates that those justifications could cover many of the concerns associated with risky technologies,<sup>1011</sup> they are likely to be unavailable where a risk to human health and/or the environment has not already been scientifically diagnosed. These justifications do not apply where the relevant area of law has been harmonised at EU level.<sup>1012</sup> However, the harmonisation status of an area of law can be unclear<sup>1013</sup> and it is possible that instruments which harmonise the law with respect to environmental/human health protection leave unharmonised concerns other than

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<sup>1009</sup> de Witte (n 1007) 604–605.

<sup>1010</sup> As developed in *Cassis de Dijon* (n 132).

<sup>1011</sup> See, for example Lee, ‘Legal Institutionalisation’ (n 73) 14–16.

<sup>1012</sup> Case C-473/98 *Kemikalieinspektionen v Toolex Alpha AB* [2000] ECR I-05681 [25].

<sup>1013</sup> Lee, *EU Environmental Law* (n 51) 237; JH Jans and Hans Vedder, *European Environmental Law: After Lisbon* (Europa Law 2012) ch 3.

safety.<sup>1014</sup> Furthermore, as discussed in Chapter Five, other concerns have now been de-harmonised under Article 26b DRD.<sup>1015</sup> Section 4 considers the justifications for derogating from harmonised EU measures. In all three areas, I argue that recourse to some form of scientific or technical expertise, reasoning or information pre-empts employment of other, value-driven, forms of reasoned inquiry into the existence of a problem justifying regulation and eliminates opportunity to adduce such evidence. In these ways, the EU's approach to disciplining trade-restrictive measures curtails fulfilment of its commitment to greater socio-technical integration in regulatory decision-making. Section 5 concludes.

## 2. Uncertainty and precaution

As discussed in Sections I and II, technologies, and the systems (natural and social) with which they interact are inherently unpredictable.<sup>1016</sup> In addition to risk and uncertainty, knowledge about their behaviour and impacts on society is characterised by ignorance, indeterminacy and contingency.<sup>1017</sup> Risk assessment is unable to tame this uncertainty. This presents a challenge in terms of assembling evidence to justify a trade-restrictive measure designed to ensure safety, indicating the wisdom of reference to other factors in determining a course of action in situations of uncertainty.<sup>1018</sup>

The precautionary principle<sup>1019</sup> is designed to assist in such situations of uncertainty. Though it may (and perhaps should) operate differently in different contexts within the EU,<sup>1020</sup> that operation has perhaps become more tightly controlled. The EU judiciary has reserved its most intense judicial review for the

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<sup>1014</sup> Lee, *EU Environmental Law* (n 51) 237–238.

<sup>1015</sup> DRD (n 744).

<sup>1016</sup> Fisher, 'Risk and Environmental Law' (n 17) 99; Dryzek (n 528) 9.

<sup>1017</sup> Wynne, 'Uncertainty and Environmental Learning' (n 135). See Chapter Two.

<sup>1018</sup> Elizabeth Fisher, 'Opening Pandora's Box: Contextualising the Precautionary Principle in the European Union' in Michelle Everson and Ellen Vos (eds), *Uncertain Risks Regulated* (Routledge-Cavendish 2009) 24.

<sup>1019</sup> Article 191(2) TFEU.

<sup>1020</sup> Fisher, 'Opening Pandora's Box' (n 1018).

Commission's application of the precautionary principle perhaps in an effort to ensure against arbitrary trade restrictions<sup>1021</sup> which the principle is feared to enable.<sup>1022</sup>

The landmark cases, *Pfizer*<sup>1023</sup> and *Alpharma*,<sup>1024</sup> marked a milestone in the EU's approach to dealing with scientific uncertainty.<sup>1025</sup> Prior to these cases, the Court took a slightly lighter approach to measures designed to deal with uncertainty.<sup>1026</sup> In *Sandoz*, without mentioning the precautionary principle, the Court recognised the uncertainties surrounding consumption of vitamins and held that, in the absence of harmonisation, Member States had discretion to decide their own level of public health protection.<sup>1027</sup> In *Fedesa*, the Court was satisfied that the existence of divergent Member State appraisals regarding the impacts of using certain hormones in meat production leading to different regulation, justified the Council instituting an EU-wide prohibition of five such hormones. In *UK v Commission (BSE)*, new scientific evidence indicating (but not proving) the possibility that BSE was transmissible to humans constituted a sufficient basis for a temporary ban on the transport of bovine animals and derived products from the UK.<sup>1028</sup>

However, since *Pfizer/Alpharma*, precautionary regulation must be based on 'the best scientific information available'<sup>1029</sup> and 'as thorough a scientific risk assessment as possible'<sup>1030</sup> such that the regulator can 'reasonably' conclude there

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<sup>1021</sup> PP Craig, *EU Administrative Law* (OUP 2012) 437–438; perhaps tempered post-*Pfizer*, *ibid* 419.

<sup>1022</sup> Elizabeth Fisher and Ronnie Harding, 'The Precautionary Principle and Administrative Constitutionalism: The Development of Frameworks for Applying the Precautionary Principle' (SSRN 2006) <[https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=908644](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=908644)> accessed 26 June 2017.

<sup>1023</sup> Case T-13/99 *Pfizer Animal Health SA v Council* [2002] ECR II-3305.

<sup>1024</sup> Case T-70/99 *Alpharma v Council* [2002] ECR II-3495.

<sup>1025</sup> Elen Stokes, 'The EC Courts' Contribution to Refining the Parameters of Precaution' (2008) 11 *Journal of Risk Research* 491, 497.

<sup>1026</sup> *ibid* 500–501, 503–504.

<sup>1027</sup> Case 174/82 *Officier van Justitie v Sandoz BV* [1983] ECR 2445 [16–17].

<sup>1028</sup> Case C-180/96 *United Kingdom v Commission (BSE)* [1998] ECR I-2265 [61–62].

<sup>1029</sup> *Alpharma* (n 1024) [171]; *Pfizer* (n 1023) [158].

<sup>1030</sup> *Alpharma* (n 1024) [175]; *Pfizer* (n 1023) [162]. Sometimes the legislative context will extinguish the requirement to perform a risk assessment, Lee, *EU Environmental Law* (n 51);

is a risk of harm, or that preventative measures are required.<sup>1031</sup> In addition, risk assessment must be conducted ‘on the basis of scientific advice founded on the principles of excellence, transparency and independence... to ensure the scientific objectivity of the measures adopted’.<sup>1032</sup> These principles are elaborated in the General Food Law<sup>1033</sup> and the Commission’s White Paper on Food Safety<sup>1034</sup> and aim to raise confidence in the EU’s risk assessment procedures. Transparency, conceived as entailing openness and public consultation,<sup>1035</sup> in particular could suggest potential for socio-technical integration in this context. However, Chapter Five illustrates that we are still far from achieving these goals and ‘scientific objectivity’, as discussed in Chapter Two, is not straightforward. Overall, it is not clear that such measures could diffuse tensions between scientific and lay reason or successfully integrate both in decision-making.<sup>1036</sup>

The cases mark a proceduralisation of precaution<sup>1037</sup> and, in contrast to the pre-*Alpharma/Pfizer* approach, the development of a certain rigour in the Courts in demanding the steps set out be followed. Flexibility is retained in various respects. A public authority can take precautionary measures despite the impossibility of conducting a full scientific risk assessment due to inadequate available scientific data.<sup>1038</sup> Indeed, the ‘cases do not seem to set a particularly high threshold for

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Case C-343/09 *Afton Chemical Limited v Secretary of State for Transport* [2010] ECR I-7027, Opinion of AG Kokott.

<sup>1031</sup> *Pfizer* (n 1023) [393]; Case C-236/01 *Monsanto Agricoltura Italia SpA v Presidenza del Consiglio dei Ministri* [2003] ECR I-8105 [113].

<sup>1032</sup> *Alpharma* (n 1024) [183]; *Pfizer* (n 1023) [172].

<sup>1033</sup> GFL (n 36).

<sup>1034</sup> COM(1999) 719 final.

<sup>1035</sup> Arts 9, 10, 38 GFL.

<sup>1036</sup> Joanne Scott and Ellen Vos, ‘The Juridification of Uncertainty: Observations on the Ambivalence of the Precautionary Principle within the EU and the WTO’ in Christian Joerges and Renaud Dehousse (eds), *Good Governance in Europe’s Integrated Market* (OUP 2002) 282, 284.

<sup>1037</sup> Stokes, ‘The EC Courts’ Contribution’ (n 1025) 492.

<sup>1038</sup> *Alpharma* (n 1024) [173]; *Pfizer* (n 1023) [160]. Elsewhere, the Court has required ‘solid and convincing evidence which, while not resolving the scientific uncertainty, may reasonably raise doubts as to the safety and/or efficacy of the medicinal product’, Cases T-74/00, T-76/00 and T-141/00 *Artegodan v Commission* [2002] ECR II-4945 [192].

legitimate intervention with precautionary measures'.<sup>1039</sup> In addition, EU institutions are not bound by the conclusions of scientific committees<sup>1040</sup> although where they do depart from such advice, they must provide a statement of reasons 'of a scientific level at least commensurate with that of the opinion in question'.<sup>1041</sup> This may form a significant legal incentive to justify decisions with scientific reasons<sup>1042</sup> and perhaps marks a departure from a less constraining test previously indicated by the Commission which would also consider 'for example economic, societal, traditional, ethical or environmental factors, as well as the feasibility of controls'.<sup>1043</sup> EU institutions also have a broad discretion in determining the level of risk deemed unacceptable for society and in establishing the factual basis of its action such that the scope of judicial review is limited,<sup>1044</sup> although its intensity may still vary unpredictably.<sup>1045</sup>

In addition, the General Court held that 'a preventive measure cannot properly be based on a purely hypothetical approach to the risk... which has not been scientifically verified'. Though the 'reality and extent' of the risk need not be fully and conclusively demonstrated, the risk still needed to be 'adequately backed up by the scientific data' at the time the measure was taken. The Court rejects hypothetical risk as a basis for regulating due to the impossibility of proving, scientifically, the existence of 'zero risk'.<sup>1046</sup>

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<sup>1039</sup> Lee, *EU Environmental Law* (n 51) 8; V Heyvaert, 'Facing the Consequences of the Precautionary Principle in EC Law' (2006) 31 *European Law Review* 185.

<sup>1040</sup> *Alpharma* (n 1024) [239].

<sup>1041</sup> *Pfizer* (n 1023) [199]. This requirement was omitted in Case C-77/09 *Gowan Comércio Internacional e Serviços Lda v Ministero della Salute* [2010] ECR I-13533; Lee, *EU Environmental Law* (n 51) 40; Alberto Alemanno, 'Case C-79/09, *Gowan Comércio Internacional E Serviços Lda v. Ministero Della Salute*' (2011) 48 *Common Market Law Review* 1329.

<sup>1042</sup> Lee, 'Legal Institutionalisation' (n 73) 9.

<sup>1043</sup> Damian Chalmers, "'Food for Thought": Reconciling European Risks and Traditional Ways of Life' (2003) 66 *The Modern Law Review* 532, 541.

<sup>1044</sup> *Alpharma* (n 1024) [177–179]; *Pfizer* (n 1023) [166–168].

<sup>1045</sup> Lee, *EU Environmental Law* (n 51) 41.

<sup>1046</sup> *Alpharma* (n 1024) [156–158]; *Pfizer* (n 1023) [143–145].

The Court's approach is reasonable; a fixation in decision-making on hypothetical risk or proof of 'zero risk' would surely lead to stagnation.<sup>1047</sup> And the Court is frequently faced with the delicate task of reconciling discretion with protection against arbitrary decision-making.<sup>1048</sup> However, limiting the application of the precautionary principle to scientific uncertainty, as if uncertainty is amenable to scientific scrutiny,<sup>1049</sup> reinforces an understanding of risk as constituting solely threats to health or environmental concerns by requiring regulation to be justified by scientifically identifiable concerns.<sup>1050</sup> Our ignorance relates to both potential social impacts and health or environmental impacts, the latter being the province of scientific investigation and emphasised by the Courts to the exclusion of the former. A lesser requirement that the *fact* of our ignorance be weighed in the balance could sufficiently acknowledge the question without distorting the entire process.<sup>1051</sup> Indeed, as we become increasingly aware of our own ignorance, not doing so may be culpable.<sup>1052</sup> There is certainly evidence that pursuing technological innovation in ignorance of all its implications can be harmful.<sup>1053</sup> Though we should beware of over comparison,<sup>1054</sup> the mistakes and unintended consequences of the Green Revolution for example, could prove salutary in defining a sensitive approach to certain risks of GM crops,<sup>1055</sup> or agricultural applications of synthetic biology.

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<sup>1047</sup> Theofanis Christoforou, 'The Precautionary Principle and Democratizing Expertise: A European Legal Perspective' (2003) 30 *Science and Public Policy* 205, 208.

<sup>1048</sup> Alemanno (n 1041) 1329; Heyvaert (n 1039) 202.

<sup>1049</sup> Stokes, 'The EC Courts' Contribution' (n 1025) 494; Everson and Vos (n 62) 3–4; Giandomenico Majone, 'What Price Safety? The Precautionary Principle and Its Policy Implications' (2002) 40 *Journal of Common Market Studies* 89, 104.

<sup>1050</sup> Christopher Anderson, 'Contrasting Models of EU Administration in Judicial Review of Risk Regulation' (2014) 51 *Common Market Law Review* 425, 342, 438–439.

<sup>1051</sup> Lee, 'Beyond Safety?' (n 12) 264.

<sup>1052</sup> Steele (n 15) 33.

<sup>1053</sup> EEA (n 14).

<sup>1054</sup> Govindan Parayil, 'Mapping Technological Trajectories of the Green Revolution and the Gene Revolution from Modernization to Globalization' (2003) 32 *Research Policy* 971.

<sup>1055</sup> Collingridge (n 28) 13–14.

The Court's observation, in *Pfizer*, that 'scientific legitimacy is not a sufficient basis for the exercise of public authority',<sup>1056</sup> recognises that regulation can be political<sup>1057</sup> and hence the need for political legitimacy.<sup>1058</sup> However, the Court appears to take political legitimacy for granted<sup>1059</sup> and apparently ignores the fact that even its scientific legitimacy may be deeply contested due to the shortcomings of regulatory science, discussed in Chapter Two. Overall, the general emphasis on scientific evaluation does not indicate an appetite for opening up either risk assessment or the decision-making process as a whole. Indeed, the Court has stated explicitly that the principle that protection of public health takes precedence over economic considerations requires *inter alia* 'taking account exclusively of considerations relating to the protection of public health',<sup>1060</sup> but fails to acknowledge that the need to protect in the first place may be contested.

There is not necessarily a lack of acknowledgement of the *existence* of various shades of uncertainty amongst EU institutions. But, as the cases on precaution arguably demonstrate, it is not unquestionably a lack of *acknowledgement* alone which stifles a response befitting this more accurate understanding of the nature of technology. However, the requirement for a scientific risk assessment even in situations of uncertainty extends the influence of scientific reasoning such that its terms 'are still to be used to guide disputes'<sup>1061</sup> importing a facts-before-values logic. This denies the possibility that uncertainty (including hypothetical risk and past experience) in combination with, for example, consumer concerns or moral objections could form a valid reason for a regulatory measure.<sup>1062</sup> Without science to specify a problem, there seems to be a presumption that other sensibilities have

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<sup>1056</sup> *Pfizer* (n 1023) [201].

<sup>1057</sup> Lee, *EU Environmental Law* (n 51) 44.

<sup>1058</sup> Although the Court perhaps viewed scientific legitimacy as reinforcing political legitimacy, Anderson (n 1050) 441–442 and guarding against arbitrary regulation, *Alpharma* (n 1024) [183]; *Pfizer* (n 1023) [172]; Commission, 'Communication on the Precautionary Principle' (n 32).

<sup>1059</sup> Lee, *EU Environmental Law* (n 51) 44.

<sup>1060</sup> In the context of medicinal products, *Artegodan* (n 1038) [174].

<sup>1061</sup> Chalmers (n 1043) 543.

<sup>1062</sup> See the discussion of the institutionalisation of this order in relation to EFSA in *ibid* 542–543.

no right to take umbrage such as to justify intervention in the market, despite the wisdom of factoring other concerns into decisions in situations of uncertainty.<sup>1063</sup>

### 3. Exceptions to free movement: Article 36 TFEU and public interest requirements

Much of the legislation examined in Section II provides for the positive harmonisation of the areas to which it applies, save for the recently de-harmonised provisions relating to the cultivation of GMOs, discussed in Chapter Five. This section presents a more in-depth discussion of the justifications for restricting free movement so as to achieve policy goals other than safety. Vital though this clearly is, the argument that other interests and concerns can and should also justify regulation of risky technologies is central to this thesis.

#### 3.1 *Justifications for restricting free movement*

Article 34 TFEU provides the primary legislative instrument for creating and maintaining the EU's internal market in relation to goods and prohibits 'Quantitative restrictions and all measures having equivalent effect' (MEE). The ECJ initially interpreted 'MEE' broadly<sup>1064</sup> and subsequently extended the reach of Article 34 yet further to indistinctly applicable national measures.<sup>1065</sup>

The counterbalances to the breadth of Article 34 are found in Article 36 which allows Member States to prohibit or restrict imports (or exports) if 'justified on grounds of public morality, public policy or public security; the protection of health and life of humans, animals or plants...' amongst other things. The Court in *Cassis de Dijon* provided an additional, non-exhaustive list of grounds for maintaining non-discriminatory prohibitions or restrictions, which included, *inter alia*: 'the protection of public health, the fairness of commercial transactions and the defence of the consumer'.<sup>1066</sup> These grounds have been expanded subsequently to

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<sup>1063</sup> Christian Joerges, 'Sound Science in the European and Global Market: Karl Polanyi in Geneva' in Michelle Everson and Ellen Vos (eds), *Uncertain Risks Regulated* (Routledge-Cavendish 2009) 421.

<sup>1064</sup> Case 8/74 *Procureur du Roi v Dassonville* [1974] ECR 837 [5].

<sup>1065</sup> *Cassis de Dijon* (n 132).

<sup>1066</sup> *ibid* [8].

include, for example, fundamental rights, as enshrined in the European Convention on Human Rights or the Charter of Fundamental Rights.<sup>1067</sup>

Case law clearly demonstrates the Court's willingness to accept environmental protection as a justification for restricting free movement,<sup>1068</sup> including a combination of both environmental or human health protection and other factors such as ease of administration of the relevant rules<sup>1069</sup> and the geographical circumstances of a Member State.<sup>1070</sup> In addition, within those broad justifications, the Court has recognised multiple reasons justifying trade restrictions, which do not relate to ensuring safety, many of which could apply, directly or by analogy, to concerns commonly expressed regarding risky technologies, summarised above. With respect to public morality, the ECJ granted a broad discretion to Member States 'to determine in accordance with its own scale of values and in the form selected by it the requirements of public morality in its territory'.<sup>1071</sup> This should encompass moral concerns regarding for example, increased control over nature, the manipulation of life or the relationship between humans and machines.

The protection of young persons,<sup>1072</sup> vulnerable sections of the population and the prevention of potential disruption to certain areas from the establishment of sex shops<sup>1073</sup> were recognised as lawful reasons for restricting trade. Protection of future generations or the cultural or social *status quo* from the potentially

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<sup>1067</sup> Case C-36/02 *Omega* [2004] ECR I-09609; Case C-112/00 *Schmidberger v Austria* [2003] ECR I-5659. For a discussion on balancing these rights see Niamh Nic Shuibhne, 'Margins of Appreciation: National Values, Fundamental Rights and EC Free Movement Law' (2009) 34 *European Law Review* 230.

<sup>1068</sup> See, for example, Case 302/86 *Commission v Denmark* [1988] ECR 4607; Case C-2/90 *Commission v Belgium* [1992] ECR I-4431; Case C-389/98 *Aher-Waggon GmbH v Bundesrepublik Deutschland* [1998] ECR I-4473; Case C-573/12 *Ålands Vindkraft AB v Energimyndigheten* EU:C:2014:2037.

<sup>1069</sup> Case C-110/05 *Commission v Italy* [2009] ECR I-519 [67].

<sup>1070</sup> Case C-142/05 *Åklagaren v Mickelsson and Roos* [2009] ECR I-4273 [34, 36].

<sup>1071</sup> Case 34/79 *R v Henn and Darby* [1979] ECR 3795 [15]. See also Case 121/85 *Conegate Ltd v Commissioners of Customs and Excise* [1986] ECR 1107 [42].

<sup>1072</sup> Case C-244/06 *Dynamic Medien Vertriebs GmbH v Avides Media AG* [2008] ECR I-505, Opinion of AG Mengozzi [78].

<sup>1073</sup> Case C-23/89 *Quietlynn Limited and another v Southend Borough Council* [1990] ECR I-03059, Opinion of AG Lenz [28].

disruptive effects of a technology could therefore plausibly constitute valid reasons. More generally, the Court relied on the requirement under (then) Community law to respect human dignity as justification for a German prohibition on laser games which simulated homicide.<sup>1074</sup> The acceptance of that justification should therefore indicate its applicability to implications for human dignity of technological innovation.

The Court accepted the need to maintain a domestic supply of petroleum products as vital to public security and the existence of a country.<sup>1075</sup> The recognition of this policy goal as a lawful reason to restrict trade, could seem in some senses analogous to a policy goal to protect food supply by, for example, restricting use of pesticides harmful to bees.

Restrictions on lotteries have been upheld on the basis of the protection of consumers and the maintenance of order in society. More detailed justifications included preventing the generation of private profit from the exploitation of addiction<sup>1076</sup> and its damaging individual and social consequences.<sup>1077</sup> Acceptance by the Court of such reasons indicates a sensitivity towards distributive concerns, specifically private benefit and socialisation of risk, a common concern with respect to the distribution of the risks and benefits of technological innovation.

The language of fundamental rights in the context of free movement has been described as ‘highly significant in showing the permeation of trade law by wider values’.<sup>1078</sup> For example, the Court has recognised the maintenance of press diversity (and thereby freedom of expression) through protecting small publishers

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<sup>1074</sup> *Omega* (n 1067). See also Case C-208/09 *Sayn-Wittgenstein* [2010] ECR I-13693 [83–89].

<sup>1075</sup> Case 72/83 *Campus Oil Limited v Minister for Industry and Energy* [1984] ECR 2727 [35]. This case might be decided differently today given the context of the Commission’s current project to build an Energy Union.

<sup>1076</sup> Case C-447 and 448/08 *Sjöberg* [2010] ECR I-6921 [43]; Lee, *EU Environmental Law* (n 51) 239.

<sup>1077</sup> Case C-275/92 *HM Customs and Excise v Gerhart and Joerg Schindler* [1994] ECR I-01039 60.

<sup>1078</sup> Stephen Weatherill, *Cases and Materials on EU Law* (10th edn, OUP 2012) 344.

from damaging competition as lawful reasons for restricting trade.<sup>1079</sup> While not linked to freedom of expression, concern over consolidation of market power and the ownership structure of the relevant commercial entities is often expressed in relation to risky technologies. In the context of free movement of capital, the Court, in *Ospelt*, accepted the social objectives pursued by an Austrian law which regulated transfers of agricultural land. These objectives included: ‘preserving agricultural communities, maintaining a distribution of land ownership which allows the development of viable farms and sympathetic management of green spaces and the countryside as well as encouraging a reasonable use of the available land by resisting pressure on land, and preventing natural disasters...’.<sup>1080</sup> Many of the objectives in *Ospelt* speak to concerns raised in connection with the effect certain risky technologies may have on social structures, for example rural communities, the intensification of agriculture supported by pesticide use and biotechnology and again, the distribution of costs and benefits.

Finally, the Court in *Torfaen*, expressed respect for ‘certain political and economic choices... [and] national or regional socio-cultural characteristics’ by recognising the legitimacy of a Member State wishing to arrange its working hours in accordance with such characteristics.<sup>1081</sup> Again, where a technology threatens to undermine socio-cultural characteristics, as novel food-related technologies may do – in particular given the centrality of food to culture,<sup>1082</sup> arguably a similar level of judicial respect should apply.

The Court has frequently held that Member States enjoy some discretion<sup>1083</sup> when drawing on the above justifications: for example to accommodate their ‘cultural,

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<sup>1079</sup> Case C-368/95 *Vereinigte Familienpress Zeitungsverlags- und vertriebs GmbH v Heinrich Bauer Verlag* [1997] ECR I-368 [18]. See also *Schmidberger* (n 1067).

<sup>1080</sup> Case 452/01 *Ospelt v Schlössle Weissenberg Familienstiftung* [2003] ECR I-9743 [39]; Lee, ‘Legal Institutionalisation’ (n 73) 15.

<sup>1081</sup> Case 145/88 *Torfaen BC v B&Q plc* [1989] ECR 3851 (ECJ) [14].

<sup>1082</sup> Marsha A Echols, *Food Safety and the WTO: The Interplay of Culture, Science and Technology* (Kluwer Law International 2001) ch 2.

<sup>1083</sup> Perhaps too broad, David O’Connor, ‘Limiting Public Morality Exceptions to Free Movement in Europe: Ireland’s Role in a Changing European Union’ (1996) 22 *Brooklyn Journal of International Law* 695, 717–718; Louise Catchpole and Ami Barav, ‘The Public

religious, moral and historic sensitivities’;<sup>1084</sup> or in recognition of the fact that public policy justifications may vary between countries and eras;<sup>1085</sup> or where it is necessary to balance two fundamental rights – that of freedom of expression<sup>1086</sup> or freedom of assembly<sup>1087</sup> on the one hand and on the other, right to free movement.<sup>1088</sup> That discretion and the above acceptance of diverse justifications for trade-restrictive measures are illustrations of the general respect the EU has for national self-determination on the basis of unique ‘ideological, demographic, geographic, historical, religious and cultural idiosyncrasies’, according to which each Member State is ‘always right’.<sup>1089</sup> This is so particularly with respect to so-called ‘morality policy’ which is often characterised by conflict over fundamental first principles, decisions over ‘right’ and ‘wrong’ and lack of consensus.<sup>1090</sup>

There are, however, limits to the Court’s deference, evident in particular in its proportionality analysis, discussed below. With respect to public policy, it does adopt a stricter approach, stating that Article 36 requires ‘a genuine and sufficiently serious threat to a fundamental interest of society’,<sup>1091</sup> though how this would be judged is unclear.<sup>1092</sup> And, where it was required to weigh the right to take collective action and the protection of workers against the right to freedom of

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Morality Exception and the Free Movement of Goods: Justification of a Dual Standard in National Legislation?’ (1980) 7 *Legal Issues of Economic Integration* 1, 16–18.

<sup>1084</sup> *Dynamic Medien* Opinion of AG Mengozzi (n 1072) [83–84, 86]. See also *Schindler* (n 1077) [60–61].

<sup>1085</sup> *Omega* (n 1067) [30–31].

<sup>1086</sup> *Familiapress* (n 1079).

<sup>1087</sup> *Schmidberger* (n 1067).

<sup>1088</sup> *ibid* [81–82].

<sup>1089</sup> Floris de Witte, ‘Sex, Drugs & EU Law: The Recognition of Moral and Ethical Diversity in EU Law’ (2013) 50 *Common Market Law Review* 1545, 1550–1551.

<sup>1090</sup> Christopher Z Mooney, ‘The Politics of Morality Policy: Symposium Editor’s Introduction’ (1999) 27 *Policy Studies Journal* 675, 675; Christoph Knill, ‘The Study of Morality Policy: Analytical Implications from a Public Policy Perspective’ (2013) 20 *Journal of European Public Policy* 309, 309.

<sup>1091</sup> *Omega* (n 1067) [30]; Paul Craig and Gráinne De Búrca, *EU Law: Text, Cases and Materials* (6th edn, OUP 2015) 697.

<sup>1092</sup> Lee, ‘GMOs in the Internal Market’ (n 871) 323.

establishment,<sup>1093</sup> and freedom to provide services<sup>1094</sup> despite acknowledging that the EU had ‘not only an economic but also a social purpose’,<sup>1095</sup> it found for the latter right. For all the Court’s talk of balancing economic and social policy, its approach in fact favours ‘the economic freedoms (Articles 43 and 49) and creates a presumption that the national rule is unlawful’.<sup>1096</sup>

Others have criticised this apparent tendency for social interests to lose out<sup>1097</sup> and it has been argued that the very means of achieving European integration structurally prioritises economic free movement rights over social considerations.<sup>1098</sup> However, *Laval* is typically framed as a conflict between the right of Swedish unions to use collective bargaining and the right of a Latvian company to provide services. The missing players are the Latvian workers’ (Laval’s employees) and their right to exercise freedom of movement to improve their economic and social well-being. While the case has been criticised for being insensitive to certain social rights, the Court’s recognition that the prevention of social dumping could justify a restriction of a fundamental freedom<sup>1099</sup> further hints at an insensitivity towards any distributional (and therefore social) consequences of preventing the exercise of freedom of movement by workers for regions and Member States.<sup>1100</sup> Ultimately, the commercial interests are protected here. The approach perhaps indicates the fragility of non-economic and distributional

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<sup>1093</sup> Case C-438/05 *International Transport Workers’ Federation and Finnish Seamen’s Union v Viking Line* [2007] ECR I-10779.

<sup>1094</sup> Case C-341/05 *Laval v Svenska Byggnadsarbetareförbundet* [2007] ECR I-11767.

<sup>1095</sup> *Viking Line* (n 1093) [79]; *Laval* (n 1094) [105].

<sup>1096</sup> C Barnard, ‘Restricting Restrictions: Lessons for the EU from the US?’ (2009) 68 *Cambridge Law Journal* 575.

<sup>1097</sup> Phil Syrpis and Tonia Novitz, ‘Economic and Social Rights in Conflict: Political and Judicial Approaches to Their Reconciliation’ (2008) 33 *European Law Review* 411; A Davies, ‘One Step Forward, Two Steps Back? The *Viking* and *Laval* Cases in the ECJ’ (2008) 37 *The Industrial Law Journal* 126.

<sup>1098</sup> Fritz W Scharpf, ‘The Asymmetry of European Integration, or Why the EU Cannot Be a “social Market Economy”’ (2010) 8 *Socio-Economic Review* 211.

<sup>1099</sup> *Laval* (n 1094) [103].

<sup>1100</sup> Damjan Kukovec, ‘Law and the Periphery’ (2015) 21 *European Law Journal* 406, 412–415.

concerns as against other, commercial, economic interests which may well extend to the types of concerns triggered by risky technologies.

Finally, in general, exceptions may only be used for non-economic purposes<sup>1101</sup> on the grounds that allowing such arguments opens the door to protectionism.<sup>1102</sup> This norm can pose difficulties for Member States pursuing certain social goals such as redistribution.<sup>1103</sup> Concerns raised in relation to pesticides include the distribution of remediation costs and in relation to GM crops, for example, include threats to existing farming structures from ‘contamination’ or competition from large agribusiness, all of which have more or less obvious economic dimensions.<sup>1104</sup> However, there is flexibility in this general principle.<sup>1105</sup> The Court has also allowed measures pursuing a public health objective which is contingent on achieving an economic objective,<sup>1106</sup> indicating that the mere presence of an economic objective does not necessarily prevent Article 36 from applying.<sup>1107</sup> As such, Member States wishing to protect national agricultural structures, for example, will have to prove their farming systems pursue objectives beyond the economic.<sup>1108</sup>

To summarise, the above cases are evidence of the wide variety of non-safety interests Member States may raise to justify obstacles to intra-EU trade beyond the Treaty’s predetermined policy objectives.<sup>1109</sup> The justifications most salient to this thesis could cover concerns relating to the moral implications of technology, distribution of risks and benefits of technology, potentially both within and

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<sup>1101</sup> Case 35/98 *Staatssecretaris van Financiën v BGM Verkooijen* [2000] ECR I-4071; N Nic Shuibhne and M Maci, ‘Proving Public Interest: The Growing Impact of Evidence in Free Movement Case Law’ (2013) 50 *Common Market Law Review* 965, 997–1004; Niamh Nic Shuibhne, ‘Exceptions to the Free Movement Rules’ in Catherine Barnard and Steve Peers (eds), *European Union Law* (OUP 2014) 486–487; Lee, *EU Environmental Law* (n 51) 240.

<sup>1102</sup> Miguel Poiarés Maduro, ‘Striking the Elusive Balance between Economic Freedom and Social Rights in the EU’ in P Alston (ed), *The EU and Human Rights* (OUP 1999) 452.

<sup>1103</sup> *ibid.*

<sup>1104</sup> Lee, ‘GMOs in the Internal Market’ (n 871) 330.

<sup>1105</sup> Nic Shuibhne (n 1101) 487.

<sup>1106</sup> Case 118/86 *Nertsvoederfabriek* [1987] ECR 3883 15.

<sup>1107</sup> Lee, ‘GMOs in the Internal Market’ (n 871) 330–331; Jans and Vedder (n 1013) 280–282; N de Sadeleer, *EU Environmental Law and the Internal Market* (OUP 2014) 287.

<sup>1108</sup> Lee, *EU Environmental Law* (n 51) 241.

<sup>1109</sup> Nic Shuibhne (n 1101) 497.

between generations, distribution of economic power and the ownership of technologies and the effects of technology on certain, especially agricultural, communities. Few cases, however, have exhibited the combinations of concerns which frequently characterise risky technologies and so their application is perhaps unpredictable.

Societal need for a technology is often considered important.<sup>1110</sup> *Commission v Netherlands* concerned a Dutch requirement that importers demonstrate the existence of a nutritional need to market fortified foodstuffs, in addition to their safety. The Netherlands sought to justify their requirement under Article 36 on grounds of public health. With respect to public health, while the Court's language suggests the primary importance of protecting public health<sup>1111</sup> and that Member States enjoy a breadth of discretion here approaching that for public morality,<sup>1112</sup> that discretion appears restricted by tough evidentiary requirements and intense scrutiny.<sup>1113</sup> In light of the uncertainty surrounding individual and cumulative risks to public health posed by the fortifying nutrient, discretion in accordance with the precautionary principle was permissible, provided it was properly applied. This involved adherence to European norms of risk assessment.<sup>1114</sup>

The case was largely won and lost on the basis of The Netherlands' failure to comply with these requirements.<sup>1115</sup> While the Court conceded that need may be a part of the risk assessment, perhaps recognising its relevance in framing the assessment, it could not be a separate ground on which to prohibit marketing.<sup>1116</sup> The arguments

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<sup>1110</sup> See Chapter Three; Macnaghten and Chilvers (n 27) 535, 540.

<sup>1111</sup> Case C-183/95 *Affish BV v Rijksdienst voor de keuring van Vee en Vlees* [1997] ECR I-04315 [43]. NB the economic considerations here related to the viability of an individual trader, not the internal market, de Sadeleer, *EU Environmental Law and the Internal Market* (n 1107) 293–4.

<sup>1112</sup> Case C-171/07 *Apothekerkammer des Saarlandes* [2009] ECR I-04171 [19]; Nic Shuibhne (n 1101) 476; Case C-41/02 *Commission v Netherlands* [2004] ECR I-11375 [43].

<sup>1113</sup> Nic Shuibhne (n 1101) 285–286.

<sup>1114</sup> *Commission v Netherlands* (n 1112) [49–54].

<sup>1115</sup> *ibid* [67].

<sup>1116</sup> *ibid* [68–69]. See also *Sandoz* (n 1027) [19]. Compare Case C-3/00 *Denmark v Commission* [2003] ECR I-2643 which concerned EU legislation which in fact conditioned approval of food additives on *inter alia* demonstration of a 'technological need'.

over need in this case were another facet of The Netherlands' desire to protect human health. However, the Court's rejection of need as a separate ground for prohibiting a product arguably excludes a valid reason for regulating a technology which in another situation may not be associated with safety but perhaps, for example, expresses doubts over what a technology is actually for.<sup>1117</sup> Such an approach may become increasingly incompatible with the current direction taken by innovation governance which, as discussed in Chapter Three, seeks to guide innovation towards fulfilling societal needs. The Court's approach here neatly illustrates the gap between the EU's policy commitment to greater socio-technical integration and its practice by potentially blunting any teeth the former possessed.

*Commission v Poland*, which concerned a Polish refusal to enter GM seeds in its seed catalogue and a ban on their marketing, naturally exhibited the complex considerations characteristic of risky technologies. Poland argued that, since the DRD 'ignore[d] essential aspects characterising' GMOs (here, ethical and religious concerns), these aspects should be regarded as unharmonised and therefore subject to Articles 34 and 36.<sup>1118</sup> The Court was unconvinced that these concerns were genuinely behind Poland's measures and declined to pass judgment on the point, potentially leaving open the possibility of regulating cultivation on ethical or religious grounds.<sup>1119</sup> However, in assessing the persuasiveness of Poland's arguments, the Court's analysis glanced on both the moral (as per Poland's understanding)<sup>1120</sup> and safety dimensions of GMOs. It found that Poland invoked public morality, not separately, but 'as an aspect of the justification relating to the protection of human health and the environment' and therefore subject to the Directive.<sup>1121</sup>

It is hard to draw any general conclusion from this observation as it hinges so crucially on the Court's assessment of the quality and consistency of Poland's

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<sup>1117</sup> Lee, *EU Regulation of GMOs* (n 35) 34, 39.

<sup>1118</sup> *Commission v Poland* (n 888) [38–39].

<sup>1119</sup> Lee, *EU Environmental Law* (n 51) 240.

<sup>1120</sup> *Commission v Poland* (n 888) [58].

<sup>1121</sup> *ibid* [55].

evidence.<sup>1122</sup> However, a similar mixing of public morality and protection of (animal) health appeared elsewhere. *Compassion in World Farming* concerned a restriction on exports of live calves to prevent their being reared using veal crate systems. The applicants argued that as the relevant Directive had not harmonised questions of public morality or public policy in relation to rearing calves, a Member State could restrict exports under Article 36 on the grounds that the Directive did not adequately protect animal health. As in *Commission v Poland*, the Court found that public morality/policy were not invoked as separate justifications but rather as an aspect of the justification relating to protection of animal health, the subject of the Directive, and were therefore unable to benefit from Article 36.<sup>1123</sup> AG Léger acknowledged the conviction held by various groups in society that the treatment of calves in question was cruel and immoral. However, he still required ‘objective scientific evidence that the rearing system in question causes unreasonable harm to the health or life of animals’,<sup>1124</sup> effectively excluding any explicitly definitive role for public morality in regulation, even though ‘harm’ as a value-judgment<sup>1125</sup> would seem naturally to invite ethical input.

The judicial analysis of public morality (and indeed, need) as an aspect of health and environmental protection on the one hand accepts that values and scientific assessment cannot easily be separated. However, instead of using morality to introduce flexibility, the Court allows safety concerns to subsume, and thereby obscure, that morality aspect.<sup>1126</sup> On the other hand, eliding the two justifications denies the influence values can have on framing risk assessments. The effect of the

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<sup>1122</sup> On consistency, the Court’s analysis appears justified. However, regarding quality, given the lightness of both the evidence presented, and judicial scrutiny, in earlier cases concerning public morality, examined above, Poland’s deficiencies here may be explicable. The poor quality of evidence and lack of guidance are systemic problems in European litigation, Nic Shuibhne and Maci (n 1101).

<sup>1123</sup> Case C-1/96 *Compassion in World Farming* [1998] ECR I-1251 [65–66].

<sup>1124</sup> Case C-1/96 *Compassion in World Farming* [1998] ECR I-1251, Opinion of AG Léger [105–106]. This point was not discussed by the Court.

<sup>1125</sup> House of Commons Science and Technology Committee, ‘Advanced Genetic Techniques for Crop Improvement: Regulation, Risk and Precaution’ (House of Commons 2015) HC328 46.

<sup>1126</sup> Even though more than one ground under Art. 36 can be used to justify the same measure, de Sadeleer, *EU Environmental Law and the Internal Market* (n 1107) 284.

Court's approach in these two cases is to affirm the 'facts-before-values' order by granting regulatory science priority of agency in determining the existence of a problem. In other words, while public morality is not necessarily irrelevant in principle in cases which involve a similar mixture of concerns, its relevance is contingent upon, and subsequent to, diagnosis through a scientific lens of a valid (i.e. safety-related) reason to regulate.

On the basis of these admittedly fragile examples, scientific priority seems incapable of pre-emption by, for example, use of a moral lens to define a problem independently of scientific enquiry. This is despite the fact that first principles are often at stake and that the public morality exception should arguably apply here on the basis that 'Member States are free to restrict the import and marketing of goods wherever this would offend against official scales of values'.<sup>1127</sup> It thus eliminates a valid, separate reason to regulate a technology.

If this interpretation of the Court's approach is correct, while a ban on GMO cultivation to 'protect the viability of family or organic farming' would plausibly constitute a legitimate objective following *Ospelt*,<sup>1128</sup> depending on the framing of this hypothetical claim, the Court may conceivably treat the interest protected as an aspect the justification relating to environmental protection, for example. In which case, the force of the *Ospelt* justification may depend on prior detection through the lens of regulatory science of a threat to the environment. The same may well go for all the justifications recognised in the case law discussed above where the specifics of the case allow judicial perception of the values at stake as contingent on a concern over safety. It will be interesting to watch the Court's approach to any litigation arising out of the newly de-harmonised justifications under Article 26b DRD.

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<sup>1127</sup> *Chalmers* (n 1043) 553; *Conegate* (n 1071).

<sup>1128</sup> Following *Ospelt* (n 1080); Lee, 'Legal Institutionalisation' (n 73) 15.

### 3.2 *Establishing proportionality*

While the Court has indeed accepted as valid a broad range of justifications, a national measure must also be proportionate.<sup>1129</sup> This means firstly that it is appropriate to protect the interest in question (which must genuinely be threatened)<sup>1130</sup> requiring a link between the measure and the objective pursued.<sup>1131</sup> Secondly, it must be limited to what is necessary to achieve its objective,<sup>1132</sup> i.e. it must be the least trade restrictive measure possible.<sup>1133</sup> Member States must produce factual evidence to substantiate their claim. In cases where the justification is public health (and also presumably environmental protection), this will be scientific evidence, even where uncertainty persists in the assessment.<sup>1134</sup> In the context of the free movement of persons in *Commission v Austria*, the Court required numerical figures demonstrating over-subscription to courses in Austrian universities to justify Austria's restriction on access to higher education.<sup>1135</sup> On the whole however, the nature of evidence required to prove a public interest justification is unclear, the ease of 'proving' public interest is open to doubt<sup>1136</sup> and public interest arguments are immensely complex.<sup>1137</sup> This is a problem for all Member States wishing to convince the Court that their measure seeks to protect a genuine interest, particularly perhaps in cases involving risky technologies where concerns reflect such complex, diverse and competing interests.

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<sup>1129</sup> In addition, measures justified under Article 36 must not be a 'means of arbitrary discrimination or a disguised restriction on trade' (Article 36, second sentence). Member States are likely to meet these criteria where the national requirements apply equally to domestic and imported products where the same circumstances prevail. Otherwise, it would indicate that the measure was not in fact inspired by concern to protect the interest in question, Case 50/80 *Bernhard Schloh v Auto Contrôle Technique SPRL* [1986] ECR 1855 [15]. There is not necessarily a sharp division between these requirements and the proportionality principle, Jans and Vedder (n 1013) 274. See also Case 40/82 *Commission v United Kingdom* [1982] ECR 2793.

<sup>1130</sup> Weatherill, *Cases and Materials on EU Law* (n 1078) 308.

<sup>1131</sup> de Sadeleer, *EU Environmental Law and the Internal Market* (n 1107) 309.

<sup>1132</sup> Case C-333/08 *Commission v France* [2010] ECR I-00757.

<sup>1133</sup> *Commission v Denmark* (n 1068) [13].

<sup>1134</sup> See discussion in Craig (n 1021) 619–620; *Commission v Netherlands* (n 1112) [52–67].

<sup>1135</sup> Case C-147/03 *Commission v Austria* [2008] ECR I-05969 [64–65].

<sup>1136</sup> Nic Shuibhne and Maci (n 1101) 966.

<sup>1137</sup> *ibid* 970.

If the Court's approach, identified above, of apparently depriving values other than safety of priority is correct, it may continue to demand solely scientific evidence of a risk as part of its proportionality review. Given that Member States' arguments shape the Court's discussion,<sup>1138</sup> they would first have to disentangle the various interests at stake to demonstrate the priority or independence of their non-safety concerns in order to ensure that discussion focuses on those elements.<sup>1139</sup> If they get that far, it is unclear what evidence they would need to adduce to demonstrate the measure is appropriate and necessary to protect a genuinely threatened interest. In *Commission v Poland*, general statements about religiously- or ethically-inspired public objections to GMOs were insufficient to convince the Court that the interest was threatened and that the contested measure was causally linked to the justification.<sup>1140</sup> Early cases on public morality are unhelpful on this question due to absence of a proportionality review from the judgments,<sup>1141</sup> but other case law perhaps suggests that the Court's language of deference to a Member State's own scale of values<sup>1142</sup> may not translate to proportionality analysis, as discussed below.

That said, in *Omega*, the Court seemed convinced by the national referring court's belief in the correspondence between the contested measure and the level of protection sought on the appropriateness of that measure, without the need for further analysis or reasoning.<sup>1143</sup> In *Ospelt*, the Court's proportionality analysis was limited to a brief consideration of necessity. However, Geelhoed AG's opinion acknowledges that Austria put forward substantial evidence in support of its measure. That evidence explained the measure's objectives, the problems associated with the agricultural and geographic structure of Austria and its

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<sup>1138</sup> *ibid* 979–980.

<sup>1139</sup> It could have been the inconsistency of Poland's justifications which enabled the Court to find the Poland's true concern was safety and morality only a subsidiary aspect. Although its argument that ethical considerations remained unharmonised could constitute an assertion of their priority [50].

<sup>1140</sup> *Nic Shuibhne and Maci* (n 1101) 980–982.

<sup>1141</sup> For example, *Henn and Darby* (n 1071); *Conegate* (n 1071); Case C-23/89 *Quietlynn Limited and another v Southend Borough Council* [1990] ECR I-03059; *Schindler* (n 1077).

<sup>1142</sup> *Henn and Darby* (n 1071) [15].

<sup>1143</sup> *Omega* (n 1067) [39].

population distribution, the dangers of non-intervention and specifically the inability of competition and free trade to achieve the objectives.<sup>1144</sup> While AG Geelhoed was not convinced as to proportionality,<sup>1145</sup> his reasoning did not relate to the insufficiency of the evidence. The case could therefore provide some guidance as to arguments appropriate to justify a restriction on GMO cultivation.

The intensity of the Court's proportionality review has not been consistent. In some sensitive areas, for example gambling, review has been less intense<sup>1146</sup> and has often been sensitive to different national values.<sup>1147</sup> In others, for example *Viking Line* and *Laval*, which involved the extremely sensitive balancing of different values,<sup>1148</sup> the Court presented a narrow reading of proportionality requiring that industrial action be regarded as a last resort. This conclusion appeared to ignore a range of collective social values, supported at the national level and believed to be supported at the EU level.<sup>1149</sup> It perhaps showed that 'recourse to the justification/proportionality formula is insufficiently sensitive to local needs'<sup>1150</sup> and that such balancing exercises cause concerns that 'ultimately the nature and purpose of EC law, and the Court's limited mandate under the Treaty, tends to push economic motivations to the fore, to the detriment of national preferences'.<sup>1151</sup>

Finally, it is unclear whether a third element of proportionality, *stricto sensu*, also operates.<sup>1152</sup> Case law suggests that the Court may consider it as part of the other two elements and will address it where raised by the applicant, though again, the depth of enquiry is variable.<sup>1153</sup> This element directly opposes market and other

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<sup>1144</sup> Case 452/01 *Ospelt v Schlössle Weissenberg Familienstiftung* [2003] ECR I-9743, Opinion of Advocate General Geelhoed [85–91].

<sup>1145</sup> *ibid* [133–157].

<sup>1146</sup> *Nic Shuibhne* (n 1101) 496–497.

<sup>1147</sup> *Craig* (n 1021) 631–634.

<sup>1148</sup> Stephen Weatherill, 'Free Movement of Goods' (2009) 58 *International and Comparative Law Quarterly* 985, 989.

<sup>1149</sup> *Barnard* (n 1096) 599; Lee, 'GMOs in the Internal Market' (n 871) 327.

<sup>1150</sup> *Barnard* (n 1096) 605.

<sup>1151</sup> Weatherill, 'Free Movement of Goods' (n 1148) 989.

<sup>1152</sup> *Jans and Vedder* (n 1013) 285–286; Stephen Weatherill, 'Free Movement of Goods' (2012) 61 *International & Comparative Law Quarterly* 541, 545.

<sup>1153</sup> *Craig* (n 1021) 601–602.

(social or environmental) aims and raises constitutional concerns about the proper division both between the judiciary and the legislature and between the EU and Member States, especially since the Court appears to be imposing its own evaluation of the acceptable level of protection. So, while applicants may struggle to succeed especially where the protected interest is public health,<sup>1154</sup> proportionality *stricto sensu* could require Member States to reduce their level of protection, in spite of the effectiveness of a measure.<sup>1155</sup> This approach undermines the allegedly 'wide' discretion the Court claims to grant to Member States in the fields of environmental and public health protection. If the Court is too willing to substitute its own standard, this not only dismisses the national choice, but also silences the various values (including broader social values and concerns) which contributed to that choice.

More generally, the overall structure of the justifications (that the national measure has already been found unlawful under Article 34,<sup>1156</sup> the burden of proof,<sup>1157</sup> the narrow interpretation of the justifications) perhaps already sets up a (structural) preference for the economic over the social, for example,<sup>1158</sup> and over-prescription of national moral and ethical choices.<sup>1159</sup>

Overall, internal market law recognises diverse reasons other than safety to regulate and these reasons should be available to justify regulations addressing the implications of risky technologies. As Lee argues, the cultivation of GMOs could be regarded an area where 'there are significant moral, religious and cultural differences between the Member States' and one where, now de-harmonised, 'it is for each Member State to determine... in accordance with its own scale of values,

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<sup>1154</sup> *ibid* 603–604.

<sup>1155</sup> de Sadeleer, *EU Environmental Law and the Internal Market* (n 1107) 320. For example, *Commission v Denmark* (n 1068).

<sup>1156</sup> Barnard (n 1096) 601.

<sup>1157</sup> *ibid* 600.

<sup>1158</sup> See, in relation to *Viking Line* and *Laval Nic Shuibhne* (n 1101) 492; C Barnard, 'Social Dumping or Dumping Socialism?' (2008) 67 *The Cambridge Law Journal* 262; Davies, 'Democracy and Legitimacy' (n 1004) 12.

<sup>1159</sup> de Witte (n 1089) 1566–1570.

what is required to protect the interests in question'.<sup>1160</sup> However, the possibility that the Courts will predicate the acceptability of these reasons upon a scientifically demonstrated threat to the environment and/or human health may severely undermine any potential contribution of internal market law to enhanced socio-technical integration. Furthermore, the evidentiary challenges associated with convincing a court that the contested measures genuinely pursue a legitimate objective mean the justifications are perhaps more unreliable than they should be.

#### 4. Member State derogations under Article 114 TFEU

Article 114(1) aims to effect positive integration of the internal market through harmonisation. Article 114(4)-(6) enables Member States to derogate from harmonised EU measures in various circumstances. The European Institutions have, in general, adopted a restrictive approach to Article 114(4)-(6) as exceptions to fundamental Treaty principles.<sup>1161</sup> Such a restrictive approach has significantly circumscribed Member State autonomy. Since both technologies examined in this thesis are the subject of harmonising measures, and for reasons of space, after a brief discussion of Article 114(4), this section will focus on the extent to which the EU's approach to Article 114(5) restricts opportunity to integrate values other than safety into justifications for derogations.

##### 4.1 Article 114(4)

Article 114(4) allows a Member State to derogate from an EU harmonisation measure in order to maintain a national provision already in force at the time that measure was adopted, justified on the basis of 'major needs referred to in Article 36 TFEU, or relating to the protection of the environment or the working environment'.<sup>1162</sup> These grounds *prima facie*, imply a fairly broad range of

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<sup>1160</sup> Case C-447 and 448/08 *Sjöberg* [2010] ECR I-6921 (n 1076) [37]; Lee, *EU Environmental Law* (n 51) 240.

<sup>1161</sup> Craig and De Búrca (n 1091) 619.

<sup>1162</sup> In addition, Article 114(6) requires that derogations under Article 114(4)-(5) must not be 'a means of arbitrary discrimination or a disguised restriction on trade', nor 'constitute an obstacle to the functioning of the internal market.' The Commission has tended to assess the first two conditions on the basis of a proportionality test and an assessment of whether the national provision in question is based on a real concern to achieve a higher level of

justifications for derogation from a harmonisation measure. However, the Article 36 reasons are subject to restrictive interpretation<sup>1163</sup> and 'dependent on a wide discretion of the Community institutions to approve or reject the national measures.'<sup>1164</sup> Member States are therefore unlikely to enjoy a significant degree of flexibility in composing justifications for their national provisions and may face the same problems identified in section 3.1.

In terms, in particular, of its appropriateness to accommodate the idiosyncrasies of regulating emerging technologies, the scope of Article 114(4) and its relationship with Article 114(5) may present problems. This is for two connected reasons relating to timing. Firstly, if the EU moves first in producing a harmonised regulatory regime to deal with a particular emerging technology, a slower moving Member State which objects to the technology on an Article 36 ground will have no measure to maintain and will be unable to introduce a measure to reflect such concerns not addressed by the EU measure due to the narrow grounds for justification under Article 114(5). The second reason relates to a situation where an emerging technology inherits a regulatory regime.<sup>1165</sup> While a Member State may have adopted a more permissive attitude to the technology originally targeted by the regime (for example GMOs), it may not have a similarly permissive attitude to the emerging technology (for example synthetic biology) and may wish to regulate due to changing political attitudes or for any number of reasons specific to that technology not covered by the regulation. However, it would again be too late to do so under Article 114(4) and the grounds would be unavailable under Article 114(5). The justification for the restrictive grounds for derogation in

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protection. The third condition is also construed as requiring an assessment of proportionality, Lee, *EU Environmental Law* (n 51) 230; M Doherty, 'The Application of Article 95(4-6) of the EC Treaty: Is the Emperor Still Unclothed?' (2008) 8 *Yearbook of European Environmental Law* 48, 65; N de Sadeleer, 'Procedures for Derogations from the Principle of Approximation of Laws under Article 95 EC' (2003) 40 *Common Market Law Review* 889, 906.

<sup>1163</sup> de Sadeleer, 'Procedures for Derogations' (n 1162) 896; Craig and De Búrca (n 1091) 696.

<sup>1164</sup> Doherty (n 1162) 49.

<sup>1165</sup> See discussion in Chapter Five and, for example, Stokes, 'Nanotechnology' (n 81).

Article 114(5) is that the EU institutions could take existing national measures into account during harmonisation (as well as a range of competing economic, social, environmental and strategic concerns<sup>1166</sup>) but not those introduced after harmonisation.<sup>1167</sup> This opportunity for evolution is lost where legislation is simply inherited and with it an opportunity for greater socio-technical integration.

#### 4.2 *Article 114(5)*

Article 114(5), which allows Member States to derogate from EU harmonisation measures by introducing new national provisions, requires that such provisions be based on ‘new scientific evidence’, relate to the protection of the environment or the working environment and be ‘on grounds of a problem specific to that Member State’, which arose after adoption of the harmonisation measure from which derogation is sought.<sup>1168</sup> The absence of space for non-safety concerns is evident on the face of the provision and already limits opportunity for greater socio-technical integration. This is further circumscribed by restrictive interpretation by the Court,<sup>1169</sup> particularly of the requirements for new scientific knowledge and a specific problem. Though specificity and novelty have normative dimensions, the Court has drawn on scientific evidence in its analysis with the effect of eliminating other ways of framing these questions.

##### 4.2.1 *Specifying a specific problem*

When judging the existence of a specific problem, perhaps as a further manifestation of an increasing reliance in the EU on technical and scientific criteria to frame risk problems in order to transcend social and cultural differences and sensitivities,<sup>1170</sup> the EU institutions have at times treated specificity as a largely epistemic question answerable by scientific advice provided by EU scientific

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<sup>1166</sup> Doherty (n 1162) 77.

<sup>1167</sup> Case C-512/99 *Germany v Commission* [2003] ECR I-845 [41].

<sup>1168</sup> These conditions are cumulative, *ibid* 81.

<sup>1169</sup> See, for example, Lee, *EU Environmental Law* (n 51) 228–231.

<sup>1170</sup> Everson and Vos (n 62) 3–6.

committees.<sup>1171</sup> Specificity however, is partly normative, as perhaps indicated by the uncertainty in the case law over the test for specificity. Some early cases indicate that whether a specific problem existed in a Member State would be judged on the basis of ‘extent’ as compared with other Member States, for example *Netherlands Creosote II*.<sup>1172</sup> It was unclear what the standard of comparison was there.<sup>1173</sup> The General Court in *Netherlands v Commission*, a case involving Dutch measures to control concentrations of particulate matter (PM), stated that to be a specific problem, the concentrations of PM must be ‘so acute as to distinguish them significantly from those observed in other Member States’<sup>1174</sup> and that specificity depended on the ‘aptness or inaptness of the harmonisation of the applicable Community rules’ to deal with the local difficulties.<sup>1175</sup> These statements provide some guidance, but phrases such as ‘so acute’ and ‘significantly’ still require the exercise of judgment. In many cases, this approach to specificity may not be unduly controversial. However, in cases concerning risky technologies often subject to low certainty and low consensus<sup>1176</sup> and high stakes, it hinders greater socio-technical integration.

In its judgment on Austria’s application to derogate from the DRD, the ECJ denied that the small-structured farming system and substantial proportion of organic farms in Upper Austria which, Austria argued, would be threatened with

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<sup>1171</sup> For example, Commission Decision 1999/836/EC on the national provisions concerning mineral wool notified by Germany derogating from Directive 97/69/EC adapting to technical progress for the 23rd time Council Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances [1999] OJ L329/100; Commission Decision 2012/719/EU on the national provisions notified by the Kingdom of Sweden pursuant to Article 114(5) of the Treaty on the Functioning of the European Union concerning the maximum admissible content of cadmium in fertilisers [2012] OJ L326/19.

<sup>1172</sup> Doherty (n 1162) 59. For example, Commission Decision 2002/59/EC concerning draft national provisions notified by the Kingdom of the Netherlands under Article 95(5) of the EC Treaty on limitations on the marketing and use of creosote-treated wood [2002] OJ L23/37.

<sup>1173</sup> Doherty (n 1162) 59.

<sup>1174</sup> Case T-182/06 *Netherlands v Commission* [2007] ECR II-1983 [53].

<sup>1175</sup> *ibid* [63].

<sup>1176</sup> See Winickoff and others (n 250) 104–106.

contamination by GM crops, constituted a specific problem.<sup>1177</sup> The Commission and the two Courts all found EFSA's scientific evidence, which held that no scientific evidence had been presented which demonstrated 'unusual or unique ecosystems' or the existence of a specific problem, convincing and that risk assessments conducted for 'Austria as a whole or in other similar areas of Europe' would suffice.<sup>1178</sup> It is hard to judge whether Austria's evidence was rejected due to poor quality or because it was not scientific.

When the ECJ separated out the various conditions in Article 114(5), it did not require scientific proof of specificity.<sup>1179</sup> However, regardless of the normative or scientific quality of the grounds raised by the Member State, the Commission worked on the assumption, endorsed by the Courts,<sup>1180</sup> that specificity should be judged scientifically and has tended to defer to the assessment of a scientific committee. But, due to the normative quality of 'specific' as exhibited by the depth of Sharpston AG's engagement with the concept, it is at least arguable. She would locate a specific problem on a scale 'somewhere between one which is unique and one which is common, generalised or widespread'.<sup>1181</sup>

The *physical* individuality of Austrian farms could indeed be established by a comparative study of Austrian against other European farms. But this is surely only half the picture. Firstly, it ignores the relevance of the requirement for a 'problem' which like 'risk', as discussed in Chapter Two, is something which a scientific inquiry may or may not discern depending on how it is framed and interpreted.<sup>1182</sup> Both depend, *inter alia*, on the values constituting the lens through which the 'problem' is observed. Secondly and relatedly, it again asserts science's priority of agency in determining the existence of a problem. GMOs clearly challenged deeply held

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<sup>1177</sup> Cases C-439/05 and C-454/05 *Land Oberösterreich and Austria v Commission* [2007] ECR I-7141.

<sup>1178</sup> *ibid* [63].

<sup>1179</sup> *Germany v Commission* (n 1167) [80].

<sup>1180</sup> *Land Oberösterreich* (n 1177) [61–64].

<sup>1181</sup> Case C-439/05 and C-454/05 *Land Oberösterreich and Austria v Commission* [2007] ECR I-7141, Opinion of AG Sharpston [110].

<sup>1182</sup> Wynne, 'Risk and Social Learning' (n 257).

notions of Austrian identity in the form of a socio-technical imaginary of technological choice.<sup>1183</sup> At the risk of reading too much between the lines, it may have been through the lens of its own identity that Austria perceived a problem, prior to any empirical evaluation of its farming structures or the risks of GMOs. Ecological variation tends to be framed as a technical matter but is in fact inseparable from social and institutional factors.<sup>1184</sup> Austria's farming structures may not have been specific, but Austria's identity and the *value* it placed on their preservation may have been. These three things combined arguably 'constructed' the specific problem, as 'risk', and indeed 'emergency',<sup>1185</sup> are constructed.<sup>1186</sup>

The Court's preference for centrally-produced scientific advice, perhaps as part of a mission to define a single, objective standard for 'safety' thereby enabling trade liberalisation<sup>1187</sup> ignores these kinds of details. This illustrates the familiar tension between relying on the perceived 'objectivity' of scientific evidence in the quest for (and paradoxical loss of) political legitimacy, highlighted in Chapter Two, and adopting the kind of nuanced approach required to integrate concerns other than safety into regulatory science and therefore regulation. Here, the approach to judging the existence of a specific problem simply does not accommodate either the potential concerns of a Member State or the way those concerns might influence its apprehension and evaluation of a problem.<sup>1188</sup> Furthermore, the European denial that a shared 'problem' can be specific leads to the 'absurd result that the more Member States are faced with a given problem after harmonization, the smaller the chance that their individual counter-measures will be authorised'.<sup>1189</sup>

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<sup>1183</sup> Felt (n 206). Discussed further in Chapter Eight.

<sup>1184</sup> Rothstein and others (n 623) 259.

<sup>1185</sup> Jana Sillmann and others, 'Climate Emergencies Do Not Justify Engineering the Climate' 5 *Nature Climate Change* 290.

<sup>1186</sup> See Chapter Two.

<sup>1187</sup> Chalmers (n 1043) 545.

<sup>1188</sup> Similarly true of economic analyses, Davies, 'Democracy and Legitimacy' (n 1004) 18–19.

<sup>1189</sup> H Sevenster, 'The Environmental Guarantee After Amsterdam: Does the Emperor Have New Clothes?', *Yearbook of European Environmental Law* (2000) 302–303.

The question of evidence is again relevant. Austria adduced scientific evidence to support its case and did not raise explicit arguments about its identity and values beyond indicating the importance of organic farming in Upper Austria.<sup>1190</sup> Much of this discussion is clearly speculative. But it is surely not implausible that such values may implicitly have motivated, and perhaps in the future explicitly would motivate, a derogation under Article 114(5). In which case, how would a Member State substantiate an identity, value or, even more esoterically, a socio-technical imaginary? And could (or should?) the review process become subtle enough to countenance the influence these factors may have on the framing of any associated scientific evidence such as to enable the Court to see the problem through the lens of ‘Austrianness’? Scientific evidence may undeniably be a crucial part of identifying the existence of a specific problem. But the incomplete picture it provides and indeed the elusive nature of ‘specificity’, like uncertainty, indicates the relevance of other values.<sup>1191</sup>

#### 4.2.2 *New scientific evidence*

The notifying Member State must also produce new scientific evidence demonstrating the necessity of the derogating national provision. The requirement is restrictive enough on its face, given that it excludes arguments not based on scientific evidence.<sup>1192</sup> The Commission has reinforced this with a willingness ‘to subject the nature and quality of the evidence relied on by the Member States to ‘centralised’ scrutiny’ by relying on EFSA’s assessments of that evidence in its decisions on national derogations.<sup>1193</sup>

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<sup>1190</sup> *Land Oberösterreich* (n 1177) [61].

<sup>1191</sup> *Everson and Vos* (n 62) 4.

<sup>1192</sup> For example, the Commission rejected Poland’s arguments in support of its derogation based on the need to fulfil the expectations of Polish society, the fragmentation of Polish agriculture and the absence of a compensatory regime for losses due to ‘uncontrolled crossing of [GM with conventional] varieties’, Commission Decision 2008/62/EC relating to Articles 111 and 172 of the Polish Draft Act on Genetically Modified Organisms, notified by the Republic of Poland pursuant to Article 95(5) of the EC Treaty as derogations from the provisions of Directive 2001/18/EC [2008] OJ L257/23.

<sup>1193</sup> *Lee, EU Environmental Law* (n 51) 229.

Regarding novelty, successful applications have tended to rely ‘on evidence clearly gathered and published after the harmonization measure’.<sup>1194</sup> This would seem to conform to the Commission’s decision in *Land Oberösterreich*, which followed EFSA’s finding that most of the data presented by Austria were published and available before the DRD was adopted.<sup>1195</sup> This narrow approach to questions of novelty and knowledge evaluation excludes the potential, allowed under Article 114(4) in recognition of the uncertainty inherent in risk assessment, for Member States to rely on ‘divergent assessments’ of risks,<sup>1196</sup> which ‘is a more realistic understanding of what might provoke a change in national policy, and allows greater scope for national diversity’.<sup>1197</sup> Availability of information does not necessarily entail proper evaluation by the legislators,<sup>1198</sup> and even if evidence predated adoption of a harmonisation measure, it may not have been entirely validated.<sup>1199</sup> It also ignores the fact that data can be reassessed and interpreted differently depending on a Member State’s standpoint, which, ‘may constitute new scientific evidence within the meaning of Article [114](5)’.<sup>1200</sup> As such, this narrow approach ‘makes it virtually impossible for Member States to pursue environmental policy through Article [114](5)’.<sup>1201</sup>

Furthermore, the contingency of an opportunity to derogate on ‘new scientific evidence’ again attributes priority of agency to science. This implies that the only property in society capable of change is scientific knowledge. However, the values, habits, behaviours and politics of a society may also evolve and independently result in a different framing of a problem.

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<sup>1194</sup> Doherty (n 1162) 55.

<sup>1195</sup> Commission Decision 2003/653 relating to national provisions on banning the use of genetically modified organisms in the region of Upper Austria notified by the Republic of Austria pursuant to Article 95(5) of the EC Treaty [2003] OJ L230/34.

<sup>1196</sup> Case C-3/00 *Denmark v Commission* [2003] ECR I-2643 [63].

<sup>1197</sup> Lee, *EU Environmental Law* (n 51) 229.

<sup>1198</sup> Doherty (n 1162) 57.

<sup>1199</sup> de Sadeleer, ‘Procedures for Derogations’ (n 1162) 901.

<sup>1200</sup> *Land Oberösterreich*, Opinion of AG Sharpston (n 1181) [124]; Doherty (n 1162) 58.

<sup>1201</sup> Floor M Fleurke, ‘What Use for Article 95(5) EC? An Analysis of *Land Oberösterreich and Republic of Austria v Commission*’ (2008) 20 *Journal of Environmental Law* 267, 269.

The Court has occasionally hinted at an awareness of such evolution. Most generally, the public interest requirements are designed to accommodate policy concerns which have developed since the Treaty of Rome.<sup>1202</sup> It has also recognised, for example, that consumer conceptions may vary between Member States and are likely to evolve over time<sup>1203</sup> as do justifications for recourse to public policy.<sup>1204</sup> ‘The Court’s assessment of the public interest can also evolve over time, in tune with how the premises of public interest evolve too’.<sup>1205</sup> As discussed in Chapter Two, attitudes to risk are conditioned by values and politics. Even if the scientific knowledge behind risk assessments remained static, it may not be enough solely to consider the numbers.<sup>1206</sup> Legislative opportunities to regulate post-authorisation that hinge only on the existence of ‘new scientific information’ ignore the reality that attitudes change too. The Commission’s interpretation of protection of the environment and working environment in *Land Oberösterreich* reflected the narrow approach adopted. It characterised Austria’s concerns regarding coexistence as more of a socio-economic problem.<sup>1207</sup> This separation dismisses the relevance of those concerns as factors which may have influenced the way Austria framed and interpreted its problem and again moves further from the goal of greater socio-technical integration.

The same can perhaps be said of the intense scrutiny of the science presented by Austria to justify its measure. Austria clearly disagreed with the Commission over what constituted ‘new’ scientific evidence,<sup>1208</sup> indicating that novelty itself may not be a straightforward matter, but may instead be a normative question open to

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<sup>1202</sup> Nic Shuibhne (n 1101) 480.

<sup>1203</sup> Case 178/84 *Commission v Germany* [1987] ECR 1227 [32].

<sup>1204</sup> *Omega* (n 1067) [31].

<sup>1205</sup> Nic Shuibhne (n 1101) 481.

<sup>1206</sup> Christoforou (n 1047) 209; Stokes, ‘The EC Courts’ Contribution’ (n 1025) 494.

<sup>1207</sup> Recital 66, Commission Decision 2003/653 relating to national provisions on banning the use of genetically modified organisms in the region of Upper Austria notified by the Republic of Austria pursuant to Article 95(5) of the EC Treaty [2003] OJ L230/34 (n 1195).

<sup>1208</sup> *Land Oberösterreich*, Opinion of AG Sharpston (n 1181) [120–126].

contestation.<sup>1209</sup> In addition, that case reveals a dispute over the appropriate level of safety. Austria felt that the relevant risk assessments were inadequate, not precautionary enough and that the decision at first instance did not comply with the principle of a high level of protection.<sup>1210</sup> The reasoning behind those arguments is not provided but if they were in part fuelled by Austria's deeply held cultural beliefs, it should arguably have been possible for those to be expressed during proceedings, at least as background explanation. Doing so would perhaps represent a small step towards enabling socio-technical integration in regulatory science and risk regulation in terms of retrospective adjudication.

Finally, while there should be monitoring of the quality of national risk assessments, the Commission's assessment should leave room for Member State autonomy, otherwise scrutiny of Member State methodologies may result in the growth of 'an implicit scientific hierarchy'.<sup>1211</sup> One risk assessment methodology is unlikely to disclose all relevant information and relying on it could have a dangerous limiting effect on Europe's ability to uncover and interpret risks. Furthermore, given that risk assessments do involve value judgments, emphasis on conforming to a European methodology excludes the operation of other values in gathering and analysing data, or may in other ways disregard 'ethical and social sensibilities'.<sup>1212</sup>

## 5. Conclusion

There are occasions in internal market law when examples of the concerns summarised in section 1 may be expressed. The Court does recognise the need to adjust the balance between trade and regulation due to distributional or ethical concerns. However, the ability of such concerns to qualify as justifications for

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<sup>1209</sup> True also with respect to technological innovation which is subject to a 'politics of novelty' in the form of disagreements over whether or not, and if so how, it might be novel, Guston (n 499) 112–114.

<sup>1210</sup> *Land Oberösterreich*, Opinion of AG Sharpston (n 1181) [47–49].

<sup>1211</sup> Fleurke (n 1201) 270–271; Doherty (n 1162) 57–58; Lee, *EU Environmental Law* (n 51) 228.

<sup>1212</sup> Everson and Vos (n 62) 5; Michelle Everson and Julia Eisner, *The Making of a European Constitution: Judges and Law beyond Constitutive Power* (Routledge-Cavendish 2007) 208–214.

regulation addressing the implications of risky technologies is very much in doubt. In all three areas examined above, the assumption is that problems requiring regulation will consist of risks to human health and/or the environment. Science is therefore invoked as the appropriate primary arbiter of their existence. The corollary of this approach is that other lenses equally capable of framing and identifying a problem/reason to regulate are denied priority and their inevitable but undetected influence on the scientific assessment invoked is ignored. There is little evidence therefore that the EU's rhetorical commitment to integrating concerns which do not relate to safety as disclosed by scientific inquiry into decision-making has filtered down to fine judicial interpretation of treaty articles.

The discussion above has largely presented non-safety concerns over the implications of risky technologies as additional reasons to regulate. Were they successful, they would constitute additional impediments to free movement. The internal market alongside technological innovation, as discussed in Chapter Eight, form the foundations on which the EU seeks to build its future prosperity. The EU's confidence in science to deliver the goods it anticipates extends to a faith in science to stand in judgment over those technologies.<sup>1213</sup> The two form a consistent ideological outlook. All decisions and judgments involving the delicate balancing of highly sensitive interests create an acute need for decisional legitimacy in which the EU places too much emphasis on scientific and technical criteria in the search for the common among the diverse.<sup>1214</sup>

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<sup>1213</sup> A disposition perhaps embedded in synthetic biology itself, Hurlbut, 'Reimagining Responsibility' (n 989).

<sup>1214</sup> Everson and Vos (n 62) 4 and 6.

## Chapter Seven – The WTO regime and its influence on EU practice

### 1. Introduction

The introduction to Chapter Six observed that science plays a crucial role in establishing a risk and therefore a lawful reason to regulate, allowing interests in health and environmental protection to prevail over economic interests. However, as discussed in Chapter Two, it is unable to evidence broader values which influence societal attitudes to risky technologies and which, I argue, often also constitute valid reasons to regulate a risky technology independent of scientific ‘proof’ of a risk to safety. Mirroring Chapter Six, this chapter concentrates on the extent to which WTO Members may justify national measures on the basis of either concerns and values other than safety, or assessments of risk inflected by such national concerns and values.<sup>1215</sup>

The question at the heart of this chapter then is how much flexibility do the relevant WTO rules grant Members to introduce potentially trade-restrictive regulatory measures (including setting the level of protection) necessary to manage the non-safety implications of technological innovation? The chapter does not aim to present an ideological argument for increased national regulatory autonomy at all costs. Rather, it is founded on the argument that the less flexibility Members enjoy, the less scope is available to the EU to regulate risky technologies on the basis of its citizens’ concerns and values or assessments of risk influenced by such concerns and values. Accordingly, this chapter forms a crucial part of the enquiry into the factors limiting socio-technical integration and maintaining the policy-practice gap in EU decision-making.

The purpose of the WTO trading regime has changed over its lifetime. Post-war, its emphasis was on multilateral trade liberalisation coupled with ensuring domestic stability and a recognition of the legitimacy of government intervention to do so;

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<sup>1215</sup> These are summarised in the introduction to Chapter Six.

an order termed 'embedded liberalism'.<sup>1216</sup> The 1970s onwards saw an increased influence of neoliberal thought and associated push for further liberalisation as a driver of growth and modernisation, removing governmental interference in trade<sup>1217</sup> and a 'technicalisation' of its decision-making procedures.<sup>1218</sup> The amount of freedom accorded to Members to regulate is closely connected to the prevailing model. As eloquently argued by Andrew Lang, global liberal trade can assume different forms and properly considering the social purpose of the WTO is a task worth engaging with.<sup>1219</sup>

This chapter focuses on the three WTO agreements most salient to the technologies examined in this thesis: the General Agreement on Tariffs and Trade 1994 (comprising GATT 1947) (GATT), the Agreement on Technical Barriers to Trade (TBTA) and the Agreement on the Application of Sanitary and Phytosanitary Measures (SPSA). The TBTA disciplines 'technical regulations',<sup>1220</sup> including regulations specifying product characteristics. The GATT and TBTA may apply to the same measure but compliance with the one does not guarantee compliance with the other.<sup>1221</sup> The SPSA disciplines sanitary and phytosanitary (SPS) measures<sup>1222</sup> which are measures designed to protect human, animal or plant life from diseases, pests and food risks. SPSA-compliant measures are presumed to comply with the GATT.<sup>1223</sup> Article 1.5 TBTA excludes SPS measures from its scope. However, where

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<sup>1216</sup> A Lang, 'Reconstructing Embedded Liberalism: John Gerard Ruggie and Constructivist Approaches to the Study of the International Trade Regime' (2006) 9 *Journal of International Economic Law* 81, 85–89.

<sup>1217</sup> Lang, 'Reflecting on "Linkage"' (n 998) 529.

<sup>1218</sup> Robert Howse, 'From Politics to Technocracy-and Back Again: The Fate of the Multilateral Trading Regime' (2002) 96 *The American Journal of International Law* 94; Andrew Lang, *World Trade Law after Neoliberalism: Reimagining the Global Economic Order* (OUP 2011).

<sup>1219</sup> Lang, 'Reconstructing Embedded Liberalism' (n 1216); Lang, 'Reflecting on "Linkage"' (n 998).

<sup>1220</sup> Defined in Annex 1.1, TBTA. See also Appellate Body Report, *EC-Measures Affecting Asbestos and Products Containing Asbestos (EC-Asbestos)* (adopted 12 March 2001) WT/DS135/AB/R [66–70].

<sup>1221</sup> Petros C Mavroidis, 'Driftin' Too far from Shore—why the Test for Compliance with the TBT Agreement Developed by the WTO Appellate Body Is Wrong, and What Should the AB Have Done Instead' (2013) 12 *World Trade Review* 509.

<sup>1222</sup> Defined in Art. 1.1, Annex A(1) SPSA.

<sup>1223</sup> Art. 2.4, SPSA.

a single measure constitutes both an SPS measure and a technical regulation, it may be found in breach in its former capacity but justified in its latter.<sup>1224</sup> With respect to the GATT and TBTA, I consider the scope they provide for Members to justify regulation by reference to reasons other than protection of human health and the environment. Discussion of the SPSA, where the goals of regulation necessarily relate to safety, focuses specifically on the degree of flexibility afforded Members to regulate according to their own evaluation of the SPS risks they face, influenced by factors which, as discussed in Chapter Two, commonly shape attitudes to risk.

The chapter is structured as follows. Section 2 considers the non-discrimination principles contained in each agreement and the question of 'likeness'. Section 3 considers the policy goals recognised under the GATT and TBTA as valid bases for regulation and the deference displayed by a panel/Appellate Body (AB) towards Member justifications of regulatory action on these grounds. Sections 4 and 5 examine the stringency of the additional requirements on Members, relating to the proportionality of their measures and their method of application, respectively. Section 6 presents a self-contained analysis of the SPSA, focusing in particular on the requirement for measures to be based on a risk assessment and scope for precautionary action. Section 7 concludes.

With respect to the GATT and TBTA, I argue that while the vast majority of policy goals pursued by Members are respected, the overall approach to assessing compliance with WTO disciplines restricts Members' ability to realise that apparent flexibility. WTO disciplines operate as a factor therefore in the EU's ability to enhance socio-technical integration in its own decision-making to the extent that unless measures are extremely carefully designed, trade interests will prevail. With respect to the SPSA, I argue that while there is some respect for national regulatory

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<sup>1224</sup> Joanne Scott, *The WTO Agreement on Sanitary and Phytosanitary Measures: A Commentary* (OUP 2007) 19–20, 29–30; on the relationship between the three, see Gabrielle Marceau and Joel P Trachtman, 'A Map of the World Trade Organization Law of Domestic Regulation of Goods: The Technical Barriers to Trade Agreement, the Sanitary and Phytosanitary Measures Agreement, and the General Agreement on Tariffs and Trade' (2014) 48 *Journal of World Trade* 351.

choices, overall, interpretation of its provisions is strict and leaves little room for the EU to regulate in response to nuanced concerns about risky technologies.

A single chapter on a subject of such breadth and complexity necessarily requires the exclusion of certain topics. Firstly, the EU has approved and is negotiating bilateral trade and investment agreements with Canada (CETA) and the USA (TTIP) respectively.<sup>1225</sup> These agreements are controversial<sup>1226</sup> and part of their purpose appears to be shaping future global trade norms according to the preferred model of the parties.<sup>1227</sup> The WTO/GATT contains rules governing its interaction with bilateral/regional trade agreements<sup>1228</sup> but the relationship between the WTO and these new trade agreements is not considered here. However, the point is that the WTO may increasingly compete (or conflict) with other regimes in disciplining international trade<sup>1229</sup> and the EU's regulatory autonomy may be further, or differently, constrained by these new agreements. Secondly, both the TBTA and SPSA contain provisions<sup>1230</sup> encouraging harmonisation by requiring Members to base domestic measures on international standards. Detailed discussion of these provisions is omitted due to space constraints. However, there is debate over whether panel/AB interpretation under the TBTA has transformed non-binding international standards into binding norms of international law,<sup>1231</sup> possibly

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<sup>1225</sup> TTIP negotiations are on hold, TTIP Advisory Group, Meeting Report 9 March 2017, <[http://trade.ec.europa.eu/doclib/docs/2017/april/tradoc\\_155484.pdf](http://trade.ec.europa.eu/doclib/docs/2017/april/tradoc_155484.pdf)> accessed 7 June 2017. CETA is provisionally in force and awaiting ratification by Canada and all EU Member States, having been granted consent by the European Parliament in February 2017, <<http://trade.ec.europa.eu/doclib/press/index.cfm?id=1624>> accessed 7 June 2017.

<sup>1226</sup> Nick Dearden, 'Like TTIP, the Ceta Deal Is a Ticking Time Bomb' (*The Independent*, 31 October 2016) <<http://www.independent.co.uk/voices/justin-trudeau-brussels-eu-ceta-ttip-toxic-deal-wallonia-a7388841.html>> accessed 25 April 2017.

<sup>1227</sup> Trade Justice Movement, 'TTIPing Away the Ladder: How the EU-US Trade Deal Could Undermine the Sustainable Development Goals' (2015) 4–5.

<sup>1228</sup> Simon Lester, Bryan Mercurio and Arwel Davies, *World Trade Law: Texts, Materials and Commentary* (2nd ed, Hart 2012) ch 8.

<sup>1229</sup> For a perspective on how such agreements could affect the WTO, see Gary Clyde Hufbauer and Cathleen Cimino-Isaacs, 'How Will TPP and TTIP Change the WTO System?' (2015) 18 *Journal of International Economic Law* 679.

<sup>1230</sup> Art. 2.4 TBTA and Art. 3.1 SPSA.

<sup>1231</sup> Robert Howse, 'A New Device for Creating International Legal Normativity: The WTO Technical Barriers to Trade Agreement and "international Standards"' in C Joerges and EU

shrinking national autonomy. Thirdly, this thesis is concerned with internal regulatory regimes applicable to particular technologies, as opposed to internal or import-related taxes. This chapter therefore focuses its GATT analysis on discrimination in relation to regulatory measures under Article III:4.<sup>1232</sup> Article I, establishing the most favoured nation principle in the WTO/GATT, covers the same measures as Article III:4, as well as customs duties/tariffs. However, given its less frequent invocation<sup>1233</sup> and the tendency of disputes to concern matters less relevant to this thesis, this provision is also excluded from analysis.<sup>1234</sup>

## 2. Non-discrimination and likeness

Discrimination between 'like products' is prohibited by Articles III:4 GATT and 2.1 TBTA. Discrimination is also relevant under Article 5.5 SPSA, discussed in section 6. Members are entitled to treat different products differently. Whether there has been a breach of such provisions (but notably not Article 2.2 TBTA) therefore depends on an analysis of 'likeness'. While not directly concerned with the reasons Members can cite to justify their measures, a discussion of likeness is relevant as an insight into the level of sensitivity towards the values behind national judgments of difference and the reasons for their measures.

The concept of discrimination was originally closely linked to 'protectionism' thus respecting national regulatory diversity.<sup>1235</sup> The interpretation of discrimination and 'trade barrier' has evolved over the lifetime of the GATT/WTO to become fairly wide, attributable broadly to what has been described as the regime's 'neoliberal

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Petersmann (eds), *Constitutionalism, Multilevel Trade Governance and Social Regulation* (Hart 2006); contrast Scott, *The WTO Agreement* (n 1224) 261–266.

<sup>1232</sup> As opposed to taxation, governed by Article III:2 GATT. Lester, Mercurio and Davies (n 1228) 287.

<sup>1233</sup> *ibid* 311.

<sup>1234</sup> But see Appellate Body Report, *EC-Conditions for the Granting of Tariff Preferences to Developing Countries* (adopted 7 April 2004) WT/DS246/AB/R where the AB's interpretation of 'non discriminatory' left more flexibility for Members to pursue certain policy goals.

<sup>1235</sup> Howse, 'From Politics to Technocracy' (n 1218) 97.

turn'.<sup>1236</sup> This expanding trend<sup>1237</sup> is evident for example, in the growth in influence of *de facto* discrimination,<sup>1238</sup> and a focus on eliminating market distortions, i.e. the effect of a measure, rather than on the intent behind the measure.<sup>1239</sup> This potentially enables increasing intrusion into Members' regulatory choices.<sup>1240</sup> It is also perhaps evident in the evolution of panel/AB approaches to likeness.

Likeness is a controversial,<sup>1241</sup> highly normative and inherently indeterminate<sup>1242</sup> concept and may be interpreted differently depending on the agreement or provision.<sup>1243</sup> A broad definition of likeness 'sometimes leads almost inevitably to a finding of violation'<sup>1244</sup> while a narrow definition renders the non-discrimination principle immensely respectful of regulatory autonomy.<sup>1245</sup> Although so far untested, likeness raises questions over a Member's ability to regulate on the basis of a product's 'profile', for example, whether it is fair trade, organic or made using child labour.<sup>1246</sup>

The analyses of likeness under Articles III:4 GATT and 2.1 TBTA are similar; both essentially requiring the existence of a competitive relationship between the products in question.<sup>1247</sup> In *EC-Asbestos*, the AB specified determination on a case-

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<sup>1236</sup> Lang, *World Trade Law after Neoliberalism* (n 1218).

<sup>1237</sup> From the late 1980s, Robert E Hudec, 'GATT/WTO Constraints on National Regulation: Requiem for an "Aim and Effects" Test' (1998) 32 *The International Lawyer* 619, 622–623.

<sup>1238</sup> For the TBTA, Appellate Body Report, *United States-Measures Affecting the Production and Sale of Clove Cigarettes (US-Cloves)* (adopted 24 April 2012) WT/DS406/AB/R [175]; for the GATT, Appellate Body Report, *Korea-Measures Affecting Imports of Fresh, Chilled and Frozen Beef (Korea-Beef)* (adopted 10 January 2001) WT/DS161/AB/R and WT/DS169/AB/R [147].

<sup>1239</sup> Lang, *World Trade Law after Neoliberalism* (n 1218) 254–257.

<sup>1240</sup> Debra P Steger, 'Afterword: The "trade and ..." Conundrum-a Commentary' (2002) 96 *The American Journal of International Law* 135, 141–142.

<sup>1241</sup> Lester, Mercurio and Davies (n 1228) 316.

<sup>1242</sup> Tomer Broude and Philip I Levy, 'Do You Mind If I Don't Smoke? Products, Purpose and Indeterminacy in *US – Measures Affecting the Production and Sale of Clove Cigarettes*' (2014) 13 *World Trade Review* 357.

<sup>1243</sup> Hudec (n 1237) 625.

<sup>1244</sup> Lester, Mercurio and Davies (n 1228) 305.

<sup>1245</sup> Robert Howse, 'Democracy, Science, and Free Trade: Risk Regulation on Trial at the World Trade Organization' (2000) 98 *Michigan Law Review* 2329, 2332.

<sup>1246</sup> Lester, Mercurio and Davies (n 1228) 316.

<sup>1247</sup> *EC-Asbestos* (AB) (n 1220) [99] with respect to Art. III:4 GATT; *US-Cloves* (AB) (n 1238) [111–112] with respect to Art. 2.1 TBTA.

by-case basis according to criteria which include: the product's end-uses; consumers' tastes and habits; the product's properties, nature and quality and tariff classification.<sup>1248</sup> Previously, approaches to determining likeness under the TBTA were characterised by a struggle between the Article III:4 'economic' or competition-based test<sup>1249</sup> and a regulatory purpose, or 'aims and effects', test.<sup>1250</sup> The latter test was arguably designed to intrude less into domestic policy-making;<sup>1251</sup> products would only be considered like where a protectionist aim and discriminatory effect of the relevant regulatory distinction could be demonstrated. Under that test the relevant question would therefore be whether the Member had a legitimate reason for distinguishing between the products.<sup>1252</sup>

The regulatory purpose approach suggested greater respect for national regulatory autonomy in its ability to balance free trade and other goals.<sup>1253</sup> Its recognition that likeness 'can only ever be evaluated from a particular perspective and for a particular purpose'<sup>1254</sup> is positive, but also arbitrary,<sup>1255</sup> and there are problems, generally, with reviewing intent.<sup>1256</sup> The competition-based approach appeals due to its perceived ability to provide an account of likeness, based on 'objective'/factual or 'technical' economic factors. However, if determinacy is the yardstick of a useful analytical approach, then this test is barely superior, by reason of the subjective assumptions necessary to conduct it (much like risk

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<sup>1248</sup> *EC-Asbestos* (AB) (n 1220) [101].

<sup>1249</sup> Robert Howse and Philip Levy, 'The TBT Panels: *US-Cloves, US-Tuna, US-COOL*' (2013) 12 *World Trade Review* 327, 341; Broude and Levy (n 1242) 367.

<sup>1250</sup> As demonstrated by Broude and Levy (n 1242). See also, generally, Hudec (n 1237).

<sup>1251</sup> Lester, Mercurio and Davies (n 1228) 278; Shi Jingxia, 'Factoring Cultural Element into Deciding the "Likeness" of Cultural Products: A Perspective From the New Haven School' (2012) 20 *Asia Pacific Law Review* 167, 186.

<sup>1252</sup> Lang, *World Trade Law after Neoliberalism* (n 1218) 259–260.

<sup>1253</sup> Steger (n 1240) 143.

<sup>1254</sup> Lang, *World Trade Law after Neoliberalism* (n 1218) 260.

<sup>1255</sup> Howse and Levy (n 1249) 340.

<sup>1256</sup> David M Driesen, 'What Is Free Trade--The Real Issue Lurking behind the Trade and Environment Debate' (2000) 41 *Virginia Journal of International Law* 279, 354; also perhaps, Appellate Body Report, *Chile-Taxes on Alcoholic Beverages* (adopted 12 January 2000) WT/DS87/AB/R and WT/DS110/AB/R [61].

assessment<sup>1257</sup>),<sup>1258</sup> its simplistic nature and the *necessity*, still, of looking at the regulation and product to perform this analysis.<sup>1259</sup> Furthermore, its apparent exclusion of value judgments as to the measure's legitimacy,<sup>1260</sup> suggests the irrelevance of Members' concerns and interests, at least at this stage, though there may be valid reasons for differentiating, for example, the products of synthetic biology, as discussed in Chapter Five.

While broadly rejecting the regulatory purpose test, the AB does attempt to retain some of its flavour by accepting that the regulatory concerns underlying a measure may still play a role in determining likeness,<sup>1261</sup> suggesting, for example, that health risks may be relevant to analysing likeness criteria under Articles III:4 GATT and 2.1 TBTA.<sup>1262</sup> In *EC-Asbestos*, toxicity as a physical characteristic and factor affecting the tastes and habits of consumers was found 'likely to influence the competitive relationship'.<sup>1263</sup> While this slight extra flexibility is welcome for the respect it implies for national regulatory purposes, it is perhaps unclear how much respect it would afford regulation of a product whose risk profile is more controversial than asbestos, as it might be, for example, with certain pesticides,<sup>1264</sup> or where the protected interest is deemed less critical than human health.<sup>1265</sup> Rather, it will likely

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<sup>1257</sup> Or indeed deployment of any technical knowledge over more deliberative decision-making procedures, Lang, *World Trade Law after Neoliberalism* (n 1218) 350. See also Chapter Two.

<sup>1258</sup> Broude and Levy (n 1242) 368–278.

<sup>1259</sup> Alexia Herwig, 'Competition, Not Regulation - or Regulated Competition?: No Regulatory Purpose Test Under the Less Favourable Treatment Standard of GATT Article III:4 Following *EC-Seal Products*' (2015) 6 *European Journal of Risk Regulation* 405, 409–410.

<sup>1260</sup> Lang, *World Trade Law after Neoliberalism* (n 1218) 262; Henrik Horn and Petros C Mavroidis, 'Still Hazy after All These Years: The Interpretation of National Treatment in the GATT/WTO Case-Law on Tax Discrimination' (2004) 15 *European Journal of International Law* 39, 60.

<sup>1261</sup> *US-Cloves* (AB) (n 1238) [117].

<sup>1262</sup> *ibid* [120]; Broude and Levy (n 1242) 383.

<sup>1263</sup> *EC-Asbestos* (AB) (n 1220) [122].

<sup>1264</sup> E.g., the current controversy over the carcinogenicity of glyphosate, EURACTIV.com and AFP, 'UN Panel Now Says Monsanto Weedkiller "unlikely" to Cause Cancer' (*EurActiv.com*, 17 May 2016) <<http://www.euractiv.com/section/agriculture-food/news/un-panel-now-says-monsanto-weedkiller-unlikely-to-cause-cancer/>> accessed 18 June 2016.

<sup>1265</sup> On the implicit arrangement of objectives in hierarchies by panel/AB rulings, see Michael Ming Du, 'Domestic Regulatory Autonomy under the TBT Agreement: From Non-

be subject to an analysis of competitiveness, although this is debated.<sup>1266</sup> On the other hand, the possible influence on consumers' tastes and habits of harmful, physical properties,<sup>1267</sup> the interrelationship of the criteria<sup>1268</sup> and their ability to combine thus may enhance arguments in favour treating products differently.

It is also unclear whether a panel/AB would be persuaded that 'social concerns' rather than harm to health would influence consumer tastes and habits to the same, or significant, degree. For example, in adjudicating a hypothetical ban on products containing synthetic vanillin on grounds of unsustainability (assuming this constituted a legitimate objective under Article 2.2 TBTA),<sup>1269</sup> would a panel accept that unsustainability could influence consumer tastes and habits and hence the competitive relationship between the relevant products? This also raises the question of the role of process and production methods (PPMs) in determining likeness (and indeed whether synthetic biology techniques would qualify as a 'related' or 'non-product-related' (NPR) PPM) as it is these production processes which catalyse the unsustainable effect. The Panel in *US-Tuna II* suggested the need for very strong consumer preferences for a finding of unlikeness, implying that such (NPR-)PPM-based measures would be subject to scrutiny under the TBTA (and GATT).<sup>1270</sup>

The approach to likeness grants Members some flexibility to argue that differently regulated products are not in a competitive relationship, thereby escaping some WTO disciplines. Arguments with respect to consumer tastes and habits for

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Discrimination to Harmonization' (2007) 6 Chinese Journal of International Law 269, 299–301.

<sup>1266</sup> Lester, Mercurio and Davies (n 1228) 306.

<sup>1267</sup> *US-Cloves* (AB) (n 1238) [117].

<sup>1268</sup> *EC-Asbestos* (AB) (n 1220) [102].

<sup>1269</sup> Not impossible in light of the AB's regard to sustainable development in its judgment in Appellate Body Report, *United States-Import Prohibition of Certain Shrimp and Shrimp Products (US-Shrimp)* (adopted 6 November 1998) WT/DS58/AB/R [129].

<sup>1270</sup> Gracia Marín Durán, 'NTBs and the WTO Agreement on Technical Barriers to Trade: The Case of PPM-Based Measures Following *US – Tuna II* and *EC – Seal Products*' in Christoph Herrmann, Markus Krajewski and Jörg Philipp Terhechte (eds), *European Yearbook of International Economic Law 2015* (Springer Berlin Heidelberg 2015) 114 if we accept that NPR-PPMs make a technical regulation.

example might work best with respect to risky technologies, although this may not adequately encapsulate the concerns and values of diverse, engaged publics. However, the lack of an explicit opportunity to raise such collective value judgments at this stage, along with ‘reliance on objective economic evidence and survey data’<sup>1271</sup> tend towards increased interference in Member regulatory choices.

### 3. Exceptions, justifications and legitimate objectives

That the WTO is concerned with more than trade liberalisation is clear, as evidenced in particular by the Preamble to the WTO Agreement.<sup>1272</sup> This recognises the role of trade in *inter alia* raising living standards, increasing employment and protecting the environment. While structured differently, both the GATT and TBTA contain provisions which recognise lawful reasons to introduce potentially trade-restrictive regulation. Under the TBTA, Members have a right to regulate in pursuit of their chosen policy objectives at their chosen levels.<sup>1273</sup> The exceptions in Article XX GATT are worded and interpreted fairly broadly but reflect the interests of the time of drafting and do not include certain current concerns, for example labour rights, human rights and the environment *per se*.<sup>1274</sup> As discussed below, that limitation may restrict the ability of Members to justify certain policy goals. That said, the AB provided, in *US-Shrimp*, that the WTO Agreement be read in the light of ‘contemporary concerns of the community of nations about the protection and conservation of the environment’, acknowledged ‘the objective of sustainable development’ in the WTO Agreement Preamble and characterised the language as evolutionary.<sup>1275</sup> This could permit regulation to address novel implications of technological innovation, for example the sustainability of producing substances

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<sup>1271</sup> Lang, *World Trade Law after Neoliberalism* (n 1218) 262.

<sup>1272</sup> Scott, *The WTO Agreement* (n 1224) 262–263.

<sup>1273</sup> Recital 6, TBTA; *US-Cloves* (AB) (n 1238) [94].

<sup>1274</sup> Paola Conconi and Tania S Voon, ‘EC-Seal Products: The Tension between Public Morals and International Trade Agreements’ [2015] SSRN Electronic Journal 9 <[https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2666997](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2666997)> accessed 25 June 2017.

<sup>1275</sup> *US-Shrimp* (AB) (n 1269) [129–130].

using synthetic biology techniques. However, the language of Article XX is ambiguous and interpretation has been inconsistent at times.<sup>1276</sup>

Once a panel/AB has determined whether a measure breaches Article 2.1 TBTA, it examines whether the objective pursued by the measure is legitimate and, as discussed in section 4, its proportionality. The TBTA sets up a finely-tuned balance between the right to regulate and the ‘desire’ to avoid creating unnecessary obstacles to international trade, familiar from the chapeau to Article XX, discussed below.<sup>1277</sup> There is no equivalent to Article XX under the TBTA. Perhaps in response to this absence, the AB has acknowledged that technical regulations, by their nature, establish distinctions between products according to their characteristics or ‘related PPMs’. Thus, under the TBTA (though not under the GATT<sup>1278</sup>), where a detrimental impact ‘stems exclusively from legitimate regulatory distinctions’, it will not necessarily breach Article 2.1. This is on the basis that the object of the TBTA is to strike a balance between trade liberalisation and Members’ right to regulate.<sup>1279</sup>

The concept of ‘legitimate regulatory distinction’ remains ill-defined. While the apparent deference may, in principle, support greater respect for national regulatory objectives, the legitimacy of such an overall objective, for example public health, will not automatically legitimise a regulatory distinction made ostensibly in its pursuit. A panel/AB essentially looks for even-handedness,<sup>1280</sup> a tougher standard to meet than non-discrimination which challenges Members’ response to national political realities, such as domestic industrial interests.<sup>1281</sup> In practice, the

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<sup>1276</sup> Steger (n 1240) 135.

<sup>1277</sup> *US-Cloves* (AB) (n 1238) [96].

<sup>1278</sup> Appellate Body Report, *EC-Measures Prohibiting the Importation and Marketing of Seal Products* (adopted 22 May 2014) WT/DS400-1/AB/R [5.97-5.125]. But see discussion of previous, conflicting case law in Donald H Regan, ‘How to Think about PPMs (and Climate Change)’ in Thomas Cottier, Olga Nartova and Sadeq Z Bigdeli (eds), *International Trade Regulation and the Mitigation of Climate Change* (CUP 2009) 120–122.

<sup>1279</sup> *US-Cloves* (AB) (n 1238) [174–175].

<sup>1280</sup> *ibid* [182]; Appellate Body Report, *United States–Measures Concerning the Importation, Marketing and Sale of Tuna and Tuna Products (US-Tuna II)* (adopted 13 June 2012) WT/DS381/AB/R [231].

<sup>1281</sup> Howse and Levy (n 1249) 344–345.

level of scrutiny of those distinctions has so far deprived Members of the in-principle benefit despite recognition of the legitimacy of the aims pursued, as shown by the decisions in *US-Cloves*, *US-Tuna II* and *US-COOL*. For example, the AB was not convinced that the risks cited by the US legitimised the distinction it drew between different types of flavoured cigarettes.<sup>1282</sup> It found therefore that the measure was discriminatory/not even-handed and so breached Article 2.1, though it accepted under Article 2.2 that the measure pursued the legitimate objective of protecting public health by reducing youth smoking.<sup>1283</sup> The intense scrutiny of the even-handedness of such measures means that any measure regulating, for example, a product of synthetic biology must be designed extremely carefully, if it is found to be in a competitive relationship with a conventional product.

Article 2.2 is closest to Article XX GATT, linguistically, but imposes an additional obligation, as opposed to an exception.<sup>1284</sup> It contains an indicative list of objectives considered legitimate, which ‘provide a reference point for other objectives that may be considered to be legitimate’.<sup>1285</sup> In determining whether a national regulatory objective is legitimate, panels are entitled to look to objectives acknowledged as legitimate in other covered agreements.<sup>1286</sup> It is likely therefore that the exceptions included in Article XX form legitimate objectives in their own right under the TBTA.<sup>1287</sup> This openness is helpful for Members seeking to respond to complex and often novel implications of risky technologies. Furthermore, panels/ABs have generally adopted a deferential attitude to reviewing the legitimacy of Members’ objectives.<sup>1288</sup> For example, the provision of information to consumers falls within the prevention of deceptive practices.<sup>1289</sup> It is also possible

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<sup>1282</sup> *US-Cloves* (AB) (n 1238) [225].

<sup>1283</sup> *ibid* [235-236].

<sup>1284</sup> Howse and Levy (n 1249) 349.

<sup>1285</sup> *US-Tuna II* (AB) (n 1280) [313].

<sup>1286</sup> *ibid*.

<sup>1287</sup> Durán (n 1270) 122.

<sup>1288</sup> Mavroidis (n 1221) 514–515.

<sup>1289</sup> Appellate Body Report, *United States-Certain Country of Origin Labelling (COOL) Requirements (US-COOL)* (adopted 23 July 2012) WT/DS384/AB/R and WT/DS386/AB/R [351].

that certain labour and human rights objectives, though perennially controversial within the WTO,<sup>1290</sup> could be squeezed into ‘the protection of human life and health’, although less likely where such measures lay down NPR-PPMs.<sup>1291</sup>

Under Article XX GATT, justifications include public morals (paragraph (a)), protection of human, animal or plant life or health (paragraph (b)), securing compliance with GATT-consistent laws or regulations (paragraph (d)) and the conservation of exhaustible natural resources (paragraph (g)). Paragraphs (b) and (g) (and their interpretation) affirm the lawfulness of regulating to protect public health<sup>1292</sup> and the environment, respectively. Under the former, relevant risks may be evaluated quantitatively or qualitatively and Members are entitled to determine their appropriate level of health protection regardless of whether the alternative also poses a risk.<sup>1293</sup> Under the latter exception, generous interpretation has determined clean air<sup>1294</sup> and sea turtles,<sup>1295</sup> despite their renewability, to be exhaustible natural resources.

Significant developments, for the purposes of endowing Members with flexibility to regulate risky technologies, have occurred with respect to public morality justifications. Article XX(a) is a provision of unclear scope and assessment of national policy relating to moral concerns is difficult.<sup>1296</sup> However, interpretation of this exception has been deferential,<sup>1297</sup> acknowledging that public morals may ‘vary in time and space’ and depend ‘on a range of factors, including prevailing social, ethical and religious values’. Members should also be permitted to define and apply

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<sup>1290</sup> Lang, *World Trade Law after Neoliberalism* (n 1218) 137–139.

<sup>1291</sup> Arthur E Appleton, ‘The Agreement on Technical Barriers to Trade’ in Patrick FJ Macrory, Arthur E Appleton and Michael G Plummer (eds), *The World Trade Organization: Legal, Economic and Political Analysis* (Springer 2005) 392.

<sup>1292</sup> As in *EC-Asbestos* (AB) (n 1220).

<sup>1293</sup> *ibid* [167-169].

<sup>1294</sup> Panel Report, *United States-Standards for Reformulated and Conventional Gasoline (US-Gasoline)* (adopted 20 May 1996) WT/DS2/R [6.37].

<sup>1295</sup> *US-Shrimp* (AB) (n 1269) [128].

<sup>1296</sup> Conconi and Voon (n 1274) 18.

<sup>1297</sup> Robert L Howse, Joanna Langille and Katie Sykes, ‘Pluralism in Practice: Moral Legislation and the Law of the WTO after *Seal Products*’ 48 *George Washington International Law Review* 81, 109.

their own public morals ‘according to their own systems and scales of values’,<sup>1298</sup> recognising their ‘inherent diversity’.<sup>1299</sup> It has covered instrumental measures concerning reviews of the content of imported cultural goods which could have a negative impact on public morals,<sup>1300</sup> and restrictions on online gambling due to its connection with money laundering, fraud, compulsive gambling and under-age gambling, implying that pornography and illegal drugs are probably covered too and perhaps alcohol and tobacco.<sup>1301</sup> These findings suggest that ethical or religious concerns over interference with nature, the blurring of boundaries between man and machine or the distribution of the impacts of technology within and between generations, for example, could justify regulation.

In a broadly positive move for regulatory pluralism,<sup>1302</sup> the AB in *EC-Seals*, found Article XX(a) covered the EU’s prohibition on the import of seal products addressing concerns about the participation of EU consumers in a market for products from inhumanely slaughtered seals.<sup>1303</sup> It was, furthermore, recognised that a measure could pursue multiple, perhaps competing, objectives at once.<sup>1304</sup> In that case, the Inuit exception to the ban attempted to mitigate its impact on indigenous, seal-hunting communities.<sup>1305</sup> The Panel in *EC-Seals* also found that public morals fell within the scope of Article 2.2 TBTA.<sup>1306</sup> Perhaps most significantly, the panel/AB did not require scientific evidence of harm,<sup>1307</sup> thus recognising the lawfulness of a measure based on intrinsic ethical beliefs which cannot be substantiated by

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<sup>1298</sup> Panel Report, *United States-Measures Affecting the Cross-Border Supply of Gambling and Betting Services* (adopted 20 April 2005) WT/DS285/R [6.461].

<sup>1299</sup> Howse, Langille and Sykes (n 1297) 117.

<sup>1300</sup> Appellate Body Report, *China-Measures Affecting Trading Rights and Distribution Services for Certain Publications and Audiovisual Entertainment Products* (adopted 19 January 2010) WT/DS363/AB/R [313].

<sup>1301</sup> Lester, Mercurio and Davies (n 1228) 374.

<sup>1302</sup> Howse, Langille and Sykes (n 1297) 88.

<sup>1303</sup> *EC-Seals* (AB) (n 1278) [5.225].

<sup>1304</sup> Howse, Langille and Sykes (n 1297) 115–116.

<sup>1305</sup> *EC-Seals* (AB) (n 1278) [5.167].

<sup>1306</sup> Panel Report, *EC-Measures Prohibiting the Importation and Marketing of Seal Products* (25 November 2013) WT/DS401/R [7.382, 7.418].

<sup>1307</sup> As the EU did in *Compassion* (n 1123). See Chapter Six.

science.<sup>1308</sup> The panel recognised that the primary purpose of the regulation was to respond to public moral concerns by reference to evidence presented by the EU on public opinion,<sup>1309</sup> confirmed by the AB.<sup>1310</sup> It has been disputed that the evidence entirely supports this conclusion,<sup>1311</sup> perhaps indicating a certain lightness of scrutiny on this point, or a willingness to accept responding to public opposition to an activity as a legitimate objective. It may also indicate a ‘de facto expanding [of] the closed list of legitimate objectives under the GATT’.<sup>1312</sup> On these bases, regulation to address ethical or religious attitudes to the manipulation of life, to express cultural or ethical judgments about the ‘naturalness’ of our food or concerns relating to the participation of consumers in a market for products which stimulated rainforest destruction, or which caused loss of livelihood for farmers, could survive this stage of analysis.

However, the panel arguably over-relied on public opinion,<sup>1313</sup> finding that evidence on public opinion did not suffice to prove that the Inuit exception was motivated by public morals.<sup>1314</sup> Alexia Herwig argues that the panel treated the question of whether public concerns over seal welfare were a legitimate objective as one of empirical fact, enquiring what public opinion was and whether that was reflected in EU law. It thus ignored the normative dimension of ‘legitimate’, failing to examine why seal welfare is, in itself, legitimate.<sup>1315</sup> As such, the report contains

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<sup>1308</sup> Alexia Herwig, ‘Too Much Zeal on Seals? Animal Welfare, Public Morals, and Consumer Ethics at the Bar of the WTO’ (2016) 15 *World Trade Review* 109, 131; Robert L Howse and Joanna Langille, ‘Permitting Pluralism: The *Seal Products* Dispute and Why the WTO Should Permit Trade Restrictions Justified by Noninstrumental Moral Values’ (2012) 37 *Yale Journal of International Law* 367, 412, 417–418.

<sup>1309</sup> *EC-Seals* (Panel) (n 1306) [7.383-7.402].

<sup>1310</sup> *EC-Seals* (AB) (n 1278) [5.166-5.167].

<sup>1311</sup> Nikolas Sellheim, ‘The Legal Question of Morality: Seal Hunting and the European Moral Standard’ (2016) 25 *Social & Legal Studies* 141; Elizabeth Whitsitt, ‘A Comment on the Public Morals Exception in International Trade and the *EC - Seal Products* Case: Moral Imperialism and Other Concerns Part IV: Case Notes’ (2014) 3 *Cambridge Journal of International and Comparative Law* 1376, 1382–1384.

<sup>1312</sup> Gracia Marín Durán, ‘Measures with Multiple Competing Purposes after *EC - Seal Products*: Avoiding a Conflict between GATT Article XX-Chapeau and Article 2.1 TBT Agreement’ (2016) 19 *Journal of International Economic Law* 467, 486.

<sup>1313</sup> Herwig (n 1308) 120–123, 137.

<sup>1314</sup> *EC-Seals* (Panel) (n 1306) [7.299-7.300]; *EC-Seals* (AB) (n 1278) [5.141-5.167].

<sup>1315</sup> Herwig (n 1308) 120–123.

little general guidance as to what constitutes a legitimate objective in terms of public morals, or how to substantiate it, other than with evidence of public opinion. This could be a source of uncertainty for Members wishing to justify measures on the grounds of public morals. On the one hand, inability to regulate on the basis of public morals unsupported by (sufficient) evidence of public opinion would significantly curtail Members' freedom to regulate.<sup>1316</sup> Members should be able to regulate, for example, to protect vulnerable communities against potentially uneven distributive impacts of synthetic biology on the basis of compelling evidence produced by NGOs or social science, or even on the basis of normative arguments with respect to public morals, even if the public as a whole is not fully apprised of the matter. That public opinion need not necessarily be decisive was at least acknowledged by the AB but without further guidance.<sup>1317</sup> On the other hand, focusing on empirical questions could indicate a reluctance by the panel to scrutinise national assessments of public morals too fiercely, thereby respecting Member autonomy. Overall, this approach to public morals (and general respect for differing national values) would seem to offer significant scope for the EU to address many implications of risky technologies, in particular, including concerns defined independently of scientific proof of harm and thereby enhance socio-technical integration in such regulation.

#### 4. Proportionality analysis

Each agreement contains an approximation of a proportionality test with which measures must comply. Under Article XX, measures must usually be 'necessary' to achieve the particular policy goal.<sup>1318</sup> Article 2.2 TBTA obliges Members to ensure that their technical regulations are 'not more trade-restrictive than necessary to fulfil a legitimate objective' with respect to their preparation, adoption or application, 'taking account of the risks non-fulfilment would create'. While much in this analysis follows the contours of the equivalent 'necessity' test under

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<sup>1316</sup> *ibid* 129.

<sup>1317</sup> *EC-Seals* (AB) (n 1278) [5.146].

<sup>1318</sup> Under Article XX(g), the requirement is 'relate to', most likely a lower standard, Lester, Mercurio and Davies (n 1228) 368.

Article XX, the TBTA departs from the GATT in that the ‘least restrictive measure test’ applies to every technical regulation, not just measures in breach of Article 2.1 TBTA. This has been described as a ‘paradigm shift... from a regime of non-discrimination to one of non-justified obstacles’.<sup>1319</sup>

The AB, in applying the necessity test under Article XX chapeau, apparently promotes a proportionality *stricto sensu* analysis requiring the weighing and balancing of the interests of trade against the importance of the policy goal pursued.<sup>1320</sup> Further, it has stated that ‘[t]he more vital or important those common interests or values are, the easier it would be to accept as ‘necessary’ a measure designed as an enforcement instrument’.<sup>1321</sup> Such an analysis would represent a significant interference with national regulatory autonomy. However, it has been convincingly argued that, despite repeated exposition of this test, the AB does not actually engage in a strict proportionality analysis but instead applies a ‘less restrictive alternative test’.<sup>1322</sup> A measure must make, or be ‘apt’ to make, a material contribution to the achievement of its objective.<sup>1323</sup> Analysis may be by way of comparison with a reasonably available, WTO-compliant alternative measure,<sup>1324</sup> which actually targets the risk at hand.<sup>1325</sup>

The standard is not challenging and perhaps implies a recognition that panels/ABs are ‘ill-equipped’ to pass judgment on such matters.<sup>1326</sup> Members have a right to

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<sup>1319</sup> Henrik Horn and Joseph HH Weiler, ‘European Communities - Trade Description of Sardines: Textualism and Its Discontent’, *The WTO Case Law of 2002* (CUP 2005) 252; Arwel Davies, ‘Technical Regulations and Standards under the WTO Agreement on Technical Barriers to Trade’ (2014) 41 *Legal Issues of Economic Integration* 37, 41.

<sup>1320</sup> A criterion of unclear origin, Lester, Mercurio and Davies (n 1228) 369.

<sup>1321</sup> Appellate Body Report, *Thailand-Customs and Fiscal Measures on Cigarettes from the Philippines (Thailand-Cigarettes (Philippines))* (adopted 15 July 2011) WT/DS371/AB/R [162].

<sup>1322</sup> Donald H Regan, ‘The Meaning of “Necessary” in GATT Article XX and GATS Article XIV: The Myth of Cost-benefit Balancing’ (2007) 6 *World Trade Review* 347.

<sup>1323</sup> Appellate Body Report, *Brazil-Measures Affecting Imports of Retreaded Tyres (Brazil-Tyres)* (adopted 17 December 2007) WT/DS332/AB/R [150].

<sup>1324</sup> *Thailand-Cigarettes (Philippines)* (AB) (n 1321) [165]; *US-Tuna II* (AB) (n 1280) [320].

<sup>1325</sup> *EC-Asbestos* (AB) (n 1220) [174].

<sup>1326</sup> Mavroidis (n 1221) 525.

choose their own level of (health) protection,<sup>1327</sup> and the AB's pledged respect here appears more supportive of flexibility in regulation and implies a reluctance to engage in such analysis.<sup>1328</sup> This deference is significant with respect to enabling the EU to respond to concerns regarding a technology with a high level of protection. Further evidence of this approach is perhaps the deference to the EC's own judgment of the importance of the moral questions at stake in *EC-Seals*, in which the AB refused to perform an analysis of regulatory consistency<sup>1329</sup> as it had in *Korea-Beef*.<sup>1330</sup> Furthermore, the AB does offer the unpredictable possibility of rescue, in *EC-Seals*, with its dictum that even a highly restrictive measure can still be found necessary subject to the result of a weighing and balancing exercise under the specific conditions of the case and in the light of the particular nature of the measure at issue.<sup>1331</sup>

The standard is lower under Article 2.2 TBT, reducing the overall intrusion this analysis requires into national regulation.<sup>1332</sup> There is no minimum threshold of fulfilment a measure must meet, respecting a Member's right to choose its level of protection<sup>1333</sup> and focusing instead on whether international trade is restricted more than necessary to achieve the degree of contribution the measure makes to the legitimate objective.<sup>1334</sup> Article 2.2 sets out indicative criteria for assessing the importance of the interest protected (expressed as the 'risks of non-fulfilment'), enabling analysis to draw on evidence from further afield. '[S]cientific and technical information' is one criterion but, as technical regulations are often applied to matters not closely related to biosafety, for example consumer protection,<sup>1335</sup> this could promote enquiry into different perspectives and evaluations of the relevant

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<sup>1327</sup> *EC-Asbestos* (AB) (n 1220) [168].

<sup>1328</sup> Lang, *World Trade Law after Neoliberalism* (n 1218) 323.

<sup>1329</sup> *EC-Seals* (AB) (n 1278) [5.200-5.201].

<sup>1330</sup> *Korea-Beef* (AB) (n 1238) [168-177].

<sup>1331</sup> *EC-Seals* (AB) (n 1278) [5.215]. The AB is keen to emphasise the flexibility of its weighing and balancing process here.

<sup>1332</sup> E.g. *Brazil-Tyres* (AB) (n 1323); Howse and Levy (n 1249) 335, 368-369.

<sup>1333</sup> Howse and Levy (n 1249) 335.

<sup>1334</sup> *US-COOL* (AB) (n 1289) [461].

<sup>1335</sup> Appleton (n 1291) 394.

risks and their consequences. However, with the kinds of technologies discussed in this thesis, this criterion may instead induce a panel/AB to base its analysis on scientific evidence, thereby tending to exclude other types of information (as use of scientific evidence often does, see Chapter Two), as opposed to investigating societal evaluations. The potential remains, though, as part of the ‘weighing and balancing’ process.<sup>1336</sup>

## 5. Method of application

In what has been described as a turn to a procedural approach, parallel to and separate from scrutiny of a Member’s substantive choices,<sup>1337</sup> a panel/AB will also scrutinise the application of a measure. A measure provisionally justified under Article XX must comply with the chapeau requirement that its application does not ‘constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on trade’. This aims to prevent abuse or misuse of the exceptions by the invoking Member.<sup>1338</sup> The flexible approach taken by panels/ABs to individual exceptions is absent in the more intrusive approach to examining compliance with the chapeau.<sup>1339</sup> Many provisionally-justified measures have fallen at this stage, as the examples below illustrate and the impact of the chapeau on regulatory autonomy is well-known.<sup>1340</sup> Indeed, this further layer of scrutiny is particularly important in counterbalancing the wide interpretation of Article XX with disciplining protectionism<sup>1341</sup> and thereby balancing trade liberalisation against other societal values.<sup>1342</sup>

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<sup>1336</sup> *US-Tuna II (AB)* (n 1280) [321].

<sup>1337</sup> Lang, *World Trade Law after Neoliberalism* (n 1218) 323–330.

<sup>1338</sup> Appellate Body Report, *United State-Standards for Reformulated and Conventional Gasoline* (adopted 20 May 1996) WT/DS2/AB/R 22.

<sup>1339</sup> Driesen (n 1256) 294–295.

<sup>1340</sup> Arwel Davies, ‘Interpreting the Chapeau of GATT Article XX in Light of the “New” Approach in *Brazil-Tyres*’ (2009) 43 *Journal of World Trade* 507, 508.

<sup>1341</sup> Howse, Langille and Sykes (n 1297) 119–120.

<sup>1342</sup> Philip Joseph Wells, ‘Unilateralism and Protectionism in the World Trade Organization: The Interpretation of the Chapeau within GATT Article XX’ (2014) 13 *Journal of International Trade Law & Policy* 222, 229.

The TBTA does not contain a directly equivalent provision, although elements of the assessment of ‘arbitrary or unjustifiable discrimination’ or a disguised restriction on trade under the chapeau surface in the TBTA test for ‘treatment no less favourable’.<sup>1343</sup>

In order to comply with the chapeau, Members should cooperate with (all<sup>1344</sup>) relevant foreign governments and consider the regulatory burden on foreign operators;<sup>1345</sup> avoid coercing the specific policies of other member governments without regard to their different conditions;<sup>1346</sup> and apply equal implementation periods.<sup>1347</sup> In *US-Gasoline*, while the ‘relating to’ standard under paragraph (g) was easier to meet, that flexibility evaporated under the heat of the AB’s chapeau analysis,<sup>1348</sup> arguably demonstrating insensitivity towards the fact that certain measures, for example for environmental protection, often stem from the political need to balance various different public interests.<sup>1349</sup> In both *US-Gasoline* and *US-Shrimp* the survival of trade-related environmental measures was contingent on fulfilling procedural requirements, implying the ascendancy of trade interests reinforced by the high standards for compliance with the chapeau.<sup>1350</sup>

Whether discrimination is justified is determined by the cause of, or the rationale for, the discrimination.<sup>1351</sup> The chapeau itself places no limit on possible justifications for discrimination.<sup>1352</sup> However, discrimination is unjustifiable where the rationale bears ‘no rational connection to’ or conflicts with the objective under Article XX providing provisional justification.<sup>1353</sup> This test has been criticised for

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<sup>1343</sup> Durán (n 1270) 117; *US-Cloves* (AB) (n 1238) [95].

<sup>1344</sup> *US-Shrimp* (AB) (n 1269) [166].

<sup>1345</sup> *US-Gasoline* (AB) (n 1338) 28-29.

<sup>1346</sup> *US-Shrimp* (AB) (n 1269) [164]; both the clarity of the analysis and the understanding of ‘coercion’ in it have been criticised, Regan (n 1278) 116–118.

<sup>1347</sup> *US-Shrimp* (AB) (n 1269) [174–175].

<sup>1348</sup> Chantal Thomas, ‘Should the World Trade Organization Incorporate Labor and Environmental Standards?’ (2004) 61 *Washington and Lee Law Review* 347, 362.

<sup>1349</sup> Steger (n 1240) 142.

<sup>1350</sup> Thomas (n 1348) 365.

<sup>1351</sup> *Brazil-Tyres* (AB) (n 1323) [226].

<sup>1352</sup> Marín Durán (n 1312) 475.

<sup>1353</sup> *Brazil-Tyres* (AB) (n 1323) [227].

being ‘excessively rigid’ and inappropriate for measures with more than one competing objective.<sup>1354</sup> In *EC-Seals*, a breach was found on the basis of the EU’s failure to ensure the welfare of seals in similarly inhumane Inuit, as well as commercial, hunts; a discrimination deemed to be irreconcilable with the professed policy objective of addressing moral concerns and not explained by the EU’s desire to mitigate the impacts of the ban on the relevant indigenous peoples.<sup>1355</sup> While the AB’s analysis concerning provisional justification accepted the balancing of multiple objectives in one measure, its chapeau analysis appears to reject that possibility by requiring that ‘any element of discrimination must be justified in terms of the *main* objective of Article XX(a)’.<sup>1356</sup>

This may be a problem when regulating the complex implications of technological innovation in accordance with variations in appetite for risk. For example, a country may wish to ban imports of substances (e.g. food ingredients, chemicals, cosmetics) produced by synthetic biology processes on the basis of an ethical objection to the manipulation of life employed in these process. It would seek to justify this ban on the basis of public morals (paragraph (a)). However, it may wish to make an exception for artemisinin on the public health basis that it represents a cheaper treatment for malaria. Such a ban would reflect the tendency amongst publics to accept higher trade-offs where the social benefit is high, such as medical breakthroughs, than where the social benefit is regarded as lower.<sup>1357</sup> It is doubtful, however, whether the current approach under the chapeau could accommodate such complexities.

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<sup>1354</sup> Marín Durán (n 1312) 475–477.

<sup>1355</sup> *EC-Seals* (AB) (n 1278) [5.320].

<sup>1356</sup> Howse, Langille and Sykes (n 1297) 121.

<sup>1357</sup> Macnaghten and Chilvers (n 27) 537.

## 6. The SPSA

### 6.1 Risk assessment

The SPSA expands upon Article XX(b) GATT<sup>1358</sup> and reaffirms Members' right to take SPS measures necessary to protect human, animal or plant life or health.<sup>1359</sup> It enlists the principles and processes of regulatory science to control the creation and application of regulation in this field,<sup>1360</sup> uniquely perhaps, though this innovation may be situated within an overall increase in prominence of technical expertise in the WTO.<sup>1361</sup> The core science-based obligations of the SPSA are found in Articles 2.2 and 5.1. The former obliges Members to ensure *inter alia* that their SPS measures are based on scientific principles and are not maintained without 'sufficient scientific evidence'. The latter obliges Members to ensure their SPS measures are based on a risk assessment. The two 'should constantly be read together'<sup>1362</sup> and are integrally linked through the presumption that a violation of Article 5.1, violates Article 2.2.<sup>1363</sup> The primacy of risk assessment seems assured in policing the quality of the scientific basis for national regulation of SPS risks.<sup>1364</sup> However, it has been argued that the plain wording of the SPSA accommodates diverse understandings of science and styles of risk regulation.<sup>1365</sup> Similarly, Members' ability to respond to the socio-political complexities of SPS risks (including those posed by technology) depends less on the SPSA requirement that measures be based on risk assessment *per se*, and more on whether panel/AB interpretation of the science-based obligations promotes a model of risk

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<sup>1358</sup> Recital 7 SPSA.

<sup>1359</sup> Art. 2.1 SPSA.

<sup>1360</sup> Lang, *World Trade Law after Neoliberalism* (n 1218) 251.

<sup>1361</sup> *ibid* 247–253.

<sup>1362</sup> Appellate Body Report, *EC-Measures Concerning Meat and Meat Products (Hormones)* (adopted 13 February 1998) WT/DS26/AB/R and WT/DS48/AB/R [180].

<sup>1363</sup> Appellate Body Report, *Australia-Measures Affecting Importation of Salmon* (adopted 6 November 1998) WT/DS18/AB/R [137–138].

<sup>1364</sup> Annex A(4) SPSA, contains two different definitions of risk assessment depending on the nature of the hazard. For a detailed discussion of the differences, see Scott, *The WTO Agreement* (n 1224) 91–96.

<sup>1365</sup> Jacqueline Peel, *Science and Risk Regulation in International Law* (CUP 2010) 183–185 and references therein.

assessment flexible and open enough to accommodate diverse values, concerns and framings in the evaluation of the relevant risks.<sup>1366</sup> The more open the model of risk assessment promoted, the less constrained the EU would be in seeking to enhance socio-technical integration in its regulation of risky technologies where the SPSA applies.

Article 5.2 obliges Members, during risk assessment generally, to take into account certain factors, including available scientific evidence, relevant PPMs, relevant ecological and environmental conditions, and quarantine or other treatment. This is not a closed list,<sup>1367</sup> implying that other things, for example consumer concerns, cultural or moral preferences and societal value judgments,<sup>1368</sup> may be considered in evaluating risk,<sup>1369</sup> and may indicate a legitimate rather than protectionist purpose.<sup>1370</sup> Nor are things that cannot be ascertained in a laboratory excluded; risks as they exist in the real world are included,<sup>1371</sup> perhaps in recognition of the contingency of risk on ‘particular social contexts’,<sup>1372</sup> or more ambitiously that the indeterminate social world itself constitutes risks<sup>1373</sup> and the relevance of other insights from the literature discussed in Chapter Two.<sup>1374</sup> Indeed, in *Hormones*, the AB found that risks arising from failure to comply with good veterinary practice in administering hormones may be taken into account under Article 5.2<sup>1375</sup> and held

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<sup>1366</sup> Elizabeth Fisher, ‘Beyond the Science/Democracy Dichotomy: The World Trade Organisation Sanitary and Phytosanitary Agreement and Administrative Constitutionalism’ in C Joerges and EU Petersmann (eds), *Constitutionalism, Multi-Level Trade Governance, and Social Regulation* (Hart 2006).

<sup>1367</sup> *Hormones* (AB) (n 1362) [187].

<sup>1368</sup> J Pauwelyn, ‘The WTO Agreement on Sanitary and Phytosanitary (SPS) Measures as Applied in the First Three SPS Disputes *EC - Hormones*, *Australia - Salmon* and *Japan - Varietals*’ (1999) 2 *Journal of International Economic Law* 641, 648.

<sup>1369</sup> Though probably within limits, Scott, *The WTO Agreement* (n 1224) 101.

<sup>1370</sup> *Hormones* (AB) (n 1362) [254]; Appellate Body Report, *United States/Canada-Continued Suspension of Obligations in the EC-Hormones Dispute (Hormones II)* (adopted 16 October 2008) WT/DS320-1/AB/R [535]; Peel, *Science and Risk Regulation* (n 1365) 194–195.

<sup>1371</sup> *Hormones* (AB) (n 1362) [187].

<sup>1372</sup> Winickoff and others (n 250) 98.

<sup>1373</sup> Wynne, ‘Risk and Social Learning’ (n 257).

<sup>1374</sup> Jacqueline Peel, ‘Of Apples and Oranges (and Hormones in Beef): Science and the Standard of Review in WTO Disputes under the SPS Agreement’ (2012) 61 *International and Comparative Law Quarterly* 427, 433.

<sup>1375</sup> *Hormones* (AB) (n 1362) [204, 206].

that panels have a duty to consider evidence of such abuse, where presented.<sup>1376</sup> This would ostensibly allow the EU to apply an SPS measure to, for example a novel food additive produced by synthetic biology, on the basis of risks arising from its actual use as opposed to studies under idealised lab-based conditions. However, the apparent immanent requirement for a scientific basis<sup>1377</sup> ‘for all risks of concern’ would seem difficult to satisfy with respect to this concern<sup>1378</sup> and the EC’s attempts at substantiating a ‘real world’ problem failed the specificity requirement, discussed below.<sup>1379</sup> Furthermore, the Panel in *EC-Biotech* refused to allow extrapolation of a ‘real world’ risk from a lab-based study as a justification for one of the safeguard measures challenged in that case,<sup>1380</sup> highlighting the difficulty of justifying an SPS measure on this basis.

Further flexibility for Members subsists in the ability to express risk in both quantitative and qualitative terms.<sup>1381</sup> An equivocal concession, perhaps, given the prohibition on theoretical uncertainty as a basis for an SPS measure,<sup>1382</sup> discussed below. Furthermore, risk assessments must be sufficiently specific in terms of the harm concerned and the precise causal agent.<sup>1383</sup> The specificity requirement may be a misinterpretation of the Article 5.1 obligation to base measures ‘on an assessment, as appropriate to the circumstances, of the risks’, given that risk-based programmes tend to address broad categories of risk.<sup>1384</sup> The impossibility of

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<sup>1376</sup> *Hormones II* (AB) (n 1370) [553].

<sup>1377</sup> *ibid* [591].

<sup>1378</sup> Peel, *Science and Risk Regulation* (n 1365) 199.

<sup>1379</sup> *Hormones* (AB) (n 1362) [207]; Peel, *Science and Risk Regulation* (n 1365) 209.

<sup>1380</sup> Panel Report, *EC-Measures Affecting the Approval and Marketing of Biotech Products (EC-Biotech)* (adopted 21 November 2006) WT/DS291-3/R [7.3098-7.3099]; Lee, *EU Regulation of GMOs* (n 35) 217–218.

<sup>1381</sup> *Hormones* (AB) (n 1362) [184].

<sup>1382</sup> J Scott, ‘On Kith and Kine (and Crustaceans): Trade and Environment in the EU and WTO’ in JHH Weiler (ed), *The EU, the WTO, and the NAFTA* (OUP 2001) 155.

<sup>1383</sup> Appellate Body Report, *Japan-Measures Affecting the Importation of Apples (Japan-Apples)* (adopted 10 December 2003) WT/DS245/AB/R [202].

<sup>1384</sup> Vern R Walker, ‘Keeping the WTO from Becoming the “World Trans-Science Organization”’: Scientific Uncertainty, Science Policy, and Factfinding in the Growth Hormones Dispute’ (1998) 31 *Cornell International Law Journal* 251, 300. See also Chapter Two on the appeal of risk in terms of aiding efficient use of resources, arguably diminished if resource-intensive, specific assessment are required to support each individual measure.

regulating risks not demonstrable ‘through particularized scientific studies’ (for example, in *Hormones*, the small health risks posed by hormone residues and their contribution to an overall onslaught of carcinogens and other hormones) also potentially encroaches upon Member freedom to select risks to tolerate or avoid.<sup>1385</sup> It potentially prioritises the disciplining of protectionism over national autonomy where scientific uncertainty exists<sup>1386</sup> and ‘raises a significant barrier to the regulation of small and diffuse risks’.<sup>1387</sup> The AB in *Hormones II* arguably tempered the specificity requirement by requiring only a demonstration of the *potential* for harm to arise from the hazard and that exposure to the hazard be ‘one of the factors contributing to the possible’ harm.<sup>1388</sup> It also interpreted the phrase ‘as appropriate to the circumstances’ qualifying risk assessment in Article 5.1 to recognise that the substance and risk being evaluated may pose particular methodological difficulties,<sup>1389</sup> perhaps acknowledging the challenges faced by Members. Ultimately though, the specificity requirement demotes studies highlighting uncertainties, which restricts scope for precautionary regulation,<sup>1390</sup> discussed further below.

Specificity may also undermine Member ability to use minority science to support their SPS measures; a right available provided there is a rational relationship<sup>1391</sup> between the science and the measure,<sup>1392</sup> and certain quality criteria are fulfilled.<sup>1393</sup> The AB’s scrutiny<sup>1394</sup> of the science cited by the EC in *Hormones* concluded that the scientific studies suggesting such hormone use was safe related specifically to hormone residues in meat from cattle treated with hormones for

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<sup>1385</sup> Alan O Sykes, ‘Domestic Regulation, Sovereignty and Scientific Evidence Requirements: A Pessimistic View’ in George A Bermann and Petros C Mavroidis (eds), *Trade and Human Health and Safety* (CUP 2006) 267.

<sup>1386</sup> *ibid* 270.

<sup>1387</sup> Lee, *EU Regulation of GMOs* (n 35) 215.

<sup>1388</sup> *Hormones II* (AB) (n 1370) [563]; Peel, *Science and Risk Regulation* (n 1365) 207–208.

<sup>1389</sup> *Hormones II* (AB) (n 1370) [562].

<sup>1390</sup> Peel, *Science and Risk Regulation* (n 1365) 208.

<sup>1391</sup> In itself unclear in terms of its relationship to the size of the minority, Scott, *The WTO Agreement* (n 1224) 107.

<sup>1392</sup> *Hormones* (AB) (n 1362) [194].

<sup>1393</sup> *Hormones II* (AB) (n 1370) [591].

<sup>1394</sup> Peel, ‘Of Apples’ (n 1374) 448.

growth promotion purposes while the minority science related to the carcinogenic potential of hormones generally.<sup>1395</sup> This may imply a requirement that minority science match the majority in its focus and parameters to assume authority. This seems to preserve for the majority some degree of ascendancy;<sup>1396</sup> even if the substance is not dispositive, the approach it takes may yet be the yardstick against which the minority approach is judged,<sup>1397</sup> potentially restricting Member ability to rely on certain minority science to contest the majority view. It may thereby also reduce the EU's ability to introduce (precautionary) regulation in reliance on alternative sources of science which more accurately reflect 'European' concerns about a risky technology.

References to differing yet equally justifiable responses by representative governments to risks<sup>1398</sup> would appear to acknowledge the contingency of scientific knowledge and validity of public input. However, the standard of review of the obligations in Articles 2.2 and 5.1 requires an objective or rational relationship between the measure and risk assessment,<sup>1399</sup> i.e. that the conclusions drawn by the Member are sufficiently supported by the scientific evidence relied upon.<sup>1400</sup> This raises questions about a panel/AB's competence to assess<sup>1401</sup> and potentially assigns exclusive relevance to scientific risk findings.<sup>1402</sup> Experts may be relied upon to perform this analysis.<sup>1403</sup> However, this risks panels 'defer[ring] to the 'epistemic superiority' of experts',<sup>1404</sup> whose ostensibly neutral and objective 'scientific' evaluation will likely reflect their own normative commitments and framings,<sup>1405</sup> and potentially substituting Member risk framings with those of the expert

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<sup>1395</sup> *Hormones* (AB) (n 1362) [198–201].

<sup>1396</sup> See also, Peel, *Science and Risk Regulation* (n 1365) 209.

<sup>1397</sup> See also, Howse, 'Democracy, Science, and Free Trade' (n 1245) 2345–2346.

<sup>1398</sup> *Hormones* (AB) (n 1362) [194].

<sup>1399</sup> *ibid* [191]; Appellate Body Report, *Japan-Measures Affecting Agricultural Products (Japan-Varietals)* (adopted 19 March 1999) WT/DS76/AB/R [84].

<sup>1400</sup> *Hormones II* (AB) (n 1370) [591].

<sup>1401</sup> Pauwelyn (n 1368) 661.

<sup>1402</sup> *Hormones* (AB) (n 1362) [193]; Peel, *Science and Risk Regulation* (n 1365) 197–198.

<sup>1403</sup> *Hormones II* (AB) (n 1370) [592].

<sup>1404</sup> Peel, *Science and Risk Regulation* (n 1365) 213 and references therein.

<sup>1405</sup> Wynne, 'Uncertainty and Environmental Learning' (n 135) 125.

advisers. Furthermore, the greater the emphasis the standard of review places on a strong relationship between the measure and the risk assessment, the more likely a panel is to exclude alternative risk framings and non-scientific contributions such as public opinion.<sup>1406</sup>

The AB in *Hormones II* arguably stipulated a more deferential procedural approach,<sup>1407</sup> limiting panels to determining whether the Member's risk assessment is objectively justifiable on the basis of coherent reasoning and respectable scientific evidence, not whether it is correct.<sup>1408</sup> This seems to conform roughly to the standard proposed by Vern Walker to preserve domestic regulatory autonomy from over intrusion.<sup>1409</sup> It also perhaps faintly echoes Robert Howse's<sup>1410</sup> proposed deferential procedural analysis<sup>1411</sup> which he argues could enhance legitimacy of, and trust in, regulatory decision-making,<sup>1412</sup> and national democratic deliberation by providing a foundation of all available, relevant scientific information,<sup>1413</sup> taking into account citizen determinations of risk acceptability.<sup>1414</sup>

By contrast, the far more rigorous standard of review in *Australia-Apples*<sup>1415</sup> distinguished between the scientific basis underlying the measure and the reasoning and conclusions of a risk assessor on the basis of that scientific evidence.<sup>1416</sup> The AB scrutinised the latter more fiercely than the former in terms of its objectivity, coherence and sufficiency of the scientific evidentiary support, requiring it to be 'reasoned and explained consistently with Articles 5.1 and 5.2',<sup>1417</sup>

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<sup>1406</sup> Peel, 'Of Apples' (n 1374) 433–434.

<sup>1407</sup> *ibid* 428, 447.

<sup>1408</sup> *Hormones II* (AB) (n 1370) [590–592]; Lester, Mercurio and Davies (n 1228) 597.

<sup>1409</sup> Walker (n 1384) 281.

<sup>1410</sup> And others, see Lang, *World Trade Law after Neoliberalism* (n 1218) 333–336.

<sup>1411</sup> Howse, 'Democracy, Science, and Free Trade' (n 1245) 2330.

<sup>1412</sup> *ibid* 2337–2338.

<sup>1413</sup> *ibid* 2335.

<sup>1414</sup> *ibid* 2356.

<sup>1415</sup> Appellate Body Report, *Australia-Measures Affecting the Importation of Apples from New Zealand* (adopted 17 December 2010) WT/DS367/AB/R [211–236].

<sup>1416</sup> For one explanation of the difference, see Lang, *World Trade Law after Neoliberalism* (n 1218) 336–338; they could also be examples of the two competing models discussed in Fisher, 'Beyond the Science/Democracy Dichotomy' (n 1366).

<sup>1417</sup> Peel, 'Of Apples' (n 1374) 450–451.

apparently slipping into substantive review.<sup>1418</sup> In this context, the position of a Member wishing to regulate a risky technology is uncertain. Whether its own risk framings and the conclusions it draws from the scientific evidence will be respected and what other input could be considered is unclear. If the approach taken in *Australia-Apples* points the way forward, the EU may be significantly constrained in regulating the risks of technologies as it sees and interprets them including by reference to the concerns of its publics.

## 6.2 *Precaution under the SPSA*

Measures subject to the SPSA may well concern matters characterised by uncertainty. There are faint glimmers of potential for precautionary action in the SPSA. For example, where there is sufficient evidence to perform a risk assessment but there is scientific uncertainty, a Member may resort to expert judgment to estimate the probability of ‘certain events’, though these conclusions are still subject to review against the requirements of coherence and objectivity.<sup>1419</sup> Furthermore panels, in determining whether an SPS measure is supported by sufficient scientific evidence, ‘should bear in mind that responsible, representative governments commonly act from perspectives of prudence and precaution where risks of irreversible, e.g. life-terminating, damage to human health are concerned’.<sup>1420</sup> The reference to representative governments may be an acknowledgement of the relevance of public opinion and underlines the AB’s inclination for some deference to Members’ decisions regarding health.<sup>1421</sup> However, it remains a high bar for precautionary action and far from fully recognises the potential value of public input in evaluating risk.<sup>1422</sup> Ultimately, the precautionary principle does not override the explicit wording of Articles 5.1 and

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<sup>1418</sup> Lang, *World Trade Law after Neoliberalism* (n 1218) 341.

<sup>1419</sup> *Australia-Apples* (AB) (n 1415) [240–242].

<sup>1420</sup> *Hormones* (AB) (n 1362) [124].

<sup>1421</sup> William J Davey, ‘Reflections on the Appellate Body Decision in the *Hormones* Case and the Meaning of the SPS Agreement’ in George A Bermann and Petros C Mavroidis (eds), *Trade and Human Health and Safety* (CUP 2006) 123.

<sup>1422</sup> Winickoff and others (n 250) 99–100.

5.2,<sup>1423</sup> perhaps indicating more generally a rejection of attempts to use ‘non-WTO’ law to influence the WTO’s ‘normative order’<sup>1424</sup> and a move away from the openness expressed in *US-Shrimp*.

Furthermore, the risk evaluated in a risk assessment must be ‘ascertainable’,<sup>1425</sup> despite a recognition that ‘theoretical uncertainty’ always exists.<sup>1426</sup> This ‘uncertainty paradox’<sup>1427</sup> is characterised by persistent evasion of the relevance of uncertainty<sup>1428</sup> and ignores the potential that uncertainty (theoretical included) itself reflects risk.<sup>1429</sup> It requires that any theoretical risk be tolerated, ‘regardless of the nature of the risk-generating activity and the social worth attaching to it’.<sup>1430</sup> It has been argued that this requirement influenced the CJEU in its findings on hypothetical risk, as discussed in Chapter Six, perhaps excessively restricting EU activity, given that this finding may be confined to Article 5.1 and not necessarily extended to Article 5.7.<sup>1431</sup> The intense uncertainty surrounding both the unprecedented level of manipulation of life within the ambition of synthetic biology and its benefits, as discussed in Chapter Five, surely makes acknowledging uncertainty as a valid consideration in regulatory decision-making all the more urgent. The WTO’s approach and its apparent influence on the EU here may indicate the current unlikelihood of that happening.

Article 5.7, perhaps provides most scope for precautionary action, allowing a Member, where relevant scientific evidence is ‘insufficient’, to provisionally adopt SPS measures on the basis of ‘available pertinent information’. This is not triggered by uncertainty<sup>1432</sup> and the interpretive emphasis on sufficiency potentially excludes

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<sup>1423</sup> *Hormones* (AB) (n 1362) [120, 125].

<sup>1424</sup> Lang, *World Trade Law after Neoliberalism* (n 1218) 150–151.

<sup>1425</sup> *Australia-Salmon* (AB) (n 1363) [125]; *Hormones II* (AB) (n 1370) [530, 569].

<sup>1426</sup> *Hormones* (AB) (n 1362) [185].

<sup>1427</sup> Van Asselt, Vos and Rooijackers (n 975).

<sup>1428</sup> *ibid* 381.

<sup>1429</sup> Walker (n 1384) 305.

<sup>1430</sup> Scott, ‘On Kith and Kine’ (n 1382) 157.

<sup>1431</sup> J Scott, ‘European Regulation of GMOs and the WTO’ (2003) 9 *Columbia Journal of European Law* 213, 228–229.

<sup>1432</sup> *Japan-Apples* (AB) (n 1383) [184]; arguably it should be, Peel, *Science and Risk Regulation* (n 1365) 232.

any scope for responding to uncertainty at all, even uncertainty persisting following risk assessment,<sup>1433</sup> as in *EC-Biotech*.<sup>1434</sup> However, it was unclear then what was meant by ‘uncertainties’ and whether it included ‘irreducible’ uncertainty.<sup>1435</sup> This is unlikely, especially given that theoretical uncertainty may not be relied upon.<sup>1436</sup>

Article 5.7 has been strictly enforced<sup>1437</sup> and four cumulative<sup>1438</sup> requirements must be satisfied to adopt and maintain a provisional measure under Article 5.7<sup>1439</sup> and avoid breaching Article 2.2.<sup>1440</sup> In *Japan-Apples*, the AB held that insufficient scientific evidence exists where ‘the body of available scientific evidence does not allow, in quantitative or qualitative terms, the performance of an adequate assessment of risks’ to SPSA standards.<sup>1441</sup> Questions regarding when a risk assessment is ‘adequate’ and when evidence is ‘reliable’ were left unresolved and ultimately, Member ability to regulate under Article 5.7 rests on ‘the preparedness of WTO decision-makers to recognise the context-dependent nature of questions surrounding the adequacy of risk assessment’, as influenced by, *inter alia*, the Member’s desired ALOP.<sup>1442</sup> However, respect for alternative Member risk framings or assessments of the salience of different sources of uncertainty seemed distant in the AB’s dismissal of Japan’s argument, in that case, that in relation to specific aspects of the spread of fire blight in apples evidence was insufficient.<sup>1443</sup> It found that the specificity or generality of the scientific information was irrelevant

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<sup>1433</sup> Scott, ‘European Regulation of GMOs’ (n 1431) 228–229.

<sup>1434</sup> Andrew Lang, ‘Provisional Measures Under Article 5.7 of the WTO’s Agreement on Sanitary and Phytosanitary Measures: Some Criticisms of the Jurisprudence So Far’ (2008) 42 *Journal of World Trade* 1085, 1101.

<sup>1435</sup> *ibid* 1103.

<sup>1436</sup> *Hormones* (AB) (n 1362) [186]; Lang, ‘Provisional Measures’ (n 1434) 1104; but see Scott, ‘European Regulation of GMOs’ (n 1431) 229.

<sup>1437</sup> Lester, Mercurio and Davies (n 1228) 585.

<sup>1438</sup> Confirmed in *Hormones II* (AB) (n 1370) [676]; Lang, ‘Provisional Measures’ (n 1434) 1106 but see Lang’s criticism.

<sup>1439</sup> *Japan-Varietals* (AB) (n 1399) [89].

<sup>1440</sup> *EC-Biotech* (Panel) (n 1380) [7.2975].

<sup>1441</sup> *Japan-Apples* (AB) (n 1383) [179].

<sup>1442</sup> Peel, *Science and Risk Regulation* (n 1365) 233.

<sup>1443</sup> *ibid*.

providing that overall, the relevant scientific evidence was sufficient to perform the necessary evaluation.<sup>1444</sup>

The AB potentially operates a double standard in its emphasis on, or dismissal of, specificity depending on context.<sup>1445</sup> In *Hormones* it found the studies relied upon to be insufficiently specific, demanding an assessment of the *specific* hormones used in a *specific* manner for *specific* purposes.<sup>1446</sup> By contrast, Japan was concerned about gaps in knowledge relating to the fate of the bacteria in immature apples and contamination pathways,<sup>1447</sup> preferring to hang onto its precautionary approach while those uncertainties obtained. The information lacking in each case is of a different kind, but arguably of a similar level of detail or specificity. In both cases the detail was absent but only in the former was that absence salient.<sup>1448</sup> The implication is that once a certain threshold of relevant scientific evidence is reached, the regulating Member will have to tolerate any remaining uncertainties.

This misses the point of precaution and undermines the AB's belief that the precautionary principle is reflected in Article 5.7,<sup>1449</sup> excluding assessment of risks according to different risk framings.<sup>1450</sup> It is uncertainty to which states require flexibility to respond, particularly where highly controversial technologies with deeply uncertain implications are concerned. Article 5.7 may indicate that the SPSA was designed to deal only with risks characterised by high certainty and high consensus<sup>1451</sup> such as quarantine risks, and not more intractable forms of uncertainty such as ignorance and indeterminacy.<sup>1452</sup> If correct, this highlights

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<sup>1444</sup> *Japan-Apples* (AB) (n 1383) [179–180]; cf. Lang, 'Provisional Measures' (n 1434) 1098.

<sup>1445</sup> The close relationship between Articles 2.2, 5.1 and 5.7, on the basis of the concept of 'sufficient scientific evidence', identified in *Japan-Varietals* (AB) (n 1399) [84], supports this comparison.

<sup>1446</sup> *Hormones* (AB) (n 1362) [200]; *Japan-Apples* (AB) (n 1383) [202].

<sup>1447</sup> Panel Report, *Japan-Measures Affecting the Importation of Apples* (adopted 10 December 2003) WT/DS245/R [8.217].

<sup>1448</sup> Although the EC declined to argue on this basis, *Hormones* (AB) (n 1362) [120].

<sup>1449</sup> *ibid* [124].

<sup>1450</sup> Peel, *Science and Risk Regulation* (n 1365) 233.

<sup>1451</sup> Winickoff and others (n 250) 104–106.

<sup>1452</sup> Jacqueline Peel, 'A GMO by Any Other Name . . . Might Be an SPS Risk!: Implications of Expanding the Scope of the WTO Sanitary and Phytosanitary Measures Agreement' (2006) 17 *European Journal of International Law* 1009, 1017–1018.

further the inadequacy of the provision to deal with the likely responses of some Members to the potential impacts of controversial and unpredictable emerging technologies such as synthetic biology (or GMOs)<sup>1453</sup> where risks are characterised by low certainty and low consensus amplifying the importance of public input,<sup>1454</sup> especially given the strictness with which it has been interpreted.<sup>1455</sup>

The benefit of focusing on insufficiency is perhaps the ability to force a resolution, preventing Members from endlessly pursuing certainty to delay relaxing their SPS measures.<sup>1456</sup> Members are entitled to determine their own ‘appropriate level of protection’ (ALOP)<sup>1457</sup> (including a ‘zero-risk’ ALOP<sup>1458</sup>). The SPSA nowhere stipulates what Members should take into account, presumably leaving Members free to consider the multiple concerns influencing attitudes to risk discussed in Chapter Two. However, this pragmatic approach could be seen as retrospectively eating into that right by dismissing some uncertainties and thereby squeezing exercise of precaution.<sup>1459</sup> It also renders the AB acknowledgement that a Member’s ALOP can influence the scope or method of its risk assessment<sup>1460</sup> almost meaningless given that an ALOP and associated risk assessment are likely to be informed (or framed) in part by concerns over uncertainty<sup>1461</sup> and conducted using non-scientific assumptions and judgments.<sup>1462</sup> Instead, scrutiny focuses solely on the relevant body of *scientific evidence* and its sufficiency for the purposes of a risk

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<sup>1453</sup> Winickoff and others (n 250).

<sup>1454</sup> *ibid* 105–106.

<sup>1455</sup> Scott, *The WTO Agreement* (n 1224) 117–119. The AB itself has held that as a qualified exemption from Article 2.2, Article 5.7 should not be given an ‘overly broad and flexible interpretation’, *Japan-Varietals* (AB) (n 1399) [80].

<sup>1456</sup> *EC-Biotech* (Panel) (n 1380) [7.1522–7.1524].

<sup>1457</sup> *Hormones* (AB) (n 1362) [172]; Scott, *The WTO Agreement* (n 1224) 35–37.

<sup>1458</sup> *Hormones* (AB) (n 1362) [186].

<sup>1459</sup> In other words ‘it makes little sense to claim that existing scientific evidence is sufficient for an adequate risk assessment if it fails to address risks that a particular community actually cares about’, Winickoff and others (n 250) 113.

<sup>1460</sup> *Hormones II* (AB) (n 1370) [685].

<sup>1461</sup> Winickoff and others (n 250) 94.

<sup>1462</sup> *ibid* 95, 113.

assessment, ignoring the roles of framing, context and values, apparently without reference to the ALOP.<sup>1463</sup>

Though the authority of the analysis is doubtful, this approach is illustrated in the Panel's treatment of sufficiency in *EC-Biotech*, in which it rejected the EC's argument<sup>1464</sup> that sufficiency should be judged in relation to the regulatory goals of the regulating authority, including, for example, its ALOP.<sup>1465</sup> In doing so, it appears to seek a 'complete, self-contained'<sup>1466</sup> risk assessment, objective, free of framing, regulatory culture and 'adequate for *all* purposes';<sup>1467</sup> similar to the 'view from nowhere' identified by Jasanoff as characterising US regulatory science and which it is deeply committed to promoting, internationally.<sup>1468</sup> The monolithic conception of risk pre-supposed (in which risk assessors need not know the level of risk their client seeks)<sup>1469</sup> is a vast simplification of the nuanced and complex understanding of risk discussed in Chapter Two.

This may contradict the SPSA's very own definition of risk assessment, at least in relation to pests and diseases, which requires evaluation 'according to the sanitary or phytosanitary measures which might be applied'.<sup>1470</sup> The latter could be interpreted as supporting, or even requiring, the combined treatment of risk management and risk assessment, arguably bolstered by the AB's acceptance that a Member's ALOP may influence its risk assessment including what is considered to be sufficient or insufficient scientific evidence<sup>1471</sup> and its rejection of the Panel's distinction between risk assessment and risk management.<sup>1472</sup> This perhaps

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<sup>1463</sup> *Hormones II* (AB) (n 1370) [686].

<sup>1464</sup> *EC-Biotech* (Panel) (n 1380) [7.3226-7.3227].

<sup>1465</sup> *ibid* [7.3234].

<sup>1466</sup> *ibid* [7.3188].

<sup>1467</sup> Peel, *Science and Risk Regulation* (n 1365) 253–254.

<sup>1468</sup> Jasanoff, 'Practices of Objectivity' (n 148).

<sup>1469</sup> *EC-Biotech* (Panel) (n 1380) [7.3243].

<sup>1470</sup> Annex A(4) SPSA.

<sup>1471</sup> *Hormones II* (AB) (n 1370) [534, 685].

<sup>1472</sup> *Hormones* (AB) (n 1362) [181]; Scott, *The WTO Agreement* (n 1224) 100.

indicates a sensitivity towards ‘value-infused scientific policymaking’<sup>1473</sup> and an understanding of risk more consonant with that examined in Chapter Two.<sup>1474</sup>

In addition, the AB has recognised that previously sufficient science may become insufficient, merely by new evidence ‘put[ting] into question the relationship between the body of scientific evidence and the conclusions concerning risk’.<sup>1475</sup> This characterises insufficiency as transitory, ignoring and excluding ‘more pervasive issues of ignorance and indeterminacy’ as reasons to adopt provisional measures under Article 5.7<sup>1476</sup> and ignoring the contingency of existing scientific knowledge. This is particularly relevant to pesticides, synthetic biology and other risky technologies which will still encounter ‘new, unprecedented conditions of deployment’, not covered by previous testing.<sup>1477</sup> That said, this approach does not appear to institute a tough and entirely inflexible threshold for the enactment of provisional measures. However, precaution may still depend on how strictly panels interpret ‘new scientific evidence’ and review Member interpretations of when such evidence ‘puts into question’ previous conclusions about risk, and the breadth of the expert advice taken as to its sufficiency.<sup>1478</sup> If it is as strict as the CJEU’s interpretation of ‘new scientific evidence’ under Article 114(5) TFEU, discussed in Chapter Six, then it may leave little room for manoeuvre. Alternatively, if this constitutes a recognition that risk assessment and determination of the sufficiency of scientific evidence require subjective judgments by risk assessors in the context of a particular community and/or chosen ALOP,<sup>1479</sup> it may leave more room for the EU to open up its own risk assessment and decision-making procedures.

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<sup>1473</sup> Winickoff and others (n 250) 96; but may be of limited effect, Davey (n 1421) 126.

<sup>1474</sup> *Hormones II* (AB) (n 1370) [541]; Michael Ming Du, ‘Autonomy in Setting Appropriate Level of Protection under the WTO Law: Rhetoric or Reality?’ (2010) 13 *Journal of International Economic Law* 1077, 1083.

<sup>1475</sup> *Hormones II* (AB) (n 1370) [703–705].

<sup>1476</sup> Peel, *Science and Risk Regulation* (n 1365) 234–239.

<sup>1477</sup> EGSG (n 6) 67–68.

<sup>1478</sup> Peel, *Science and Risk Regulation* (n 1365) 237.

<sup>1479</sup> Alessandra Arcuri, Lukasz Gruszczynski and Alexia Herwig, ‘Independence of Experts and Standards for Evaluation of Scientific Evidence under the SPS Agreement - New Directions in the SPS Case Law’ (2010) 1 *European Journal of Risk Regulation* 183, 187.

### 6.3 Proportionality and application

Necessity analysis under Article 5.6 SPSA requires that SPS measures are not more trade-restrictive than required to achieve the relevant ALOP, taking into account technical and economic feasibility. A footnote to the Article providing for compliance where, *inter alia*, there is no other reasonably available, significantly less trade-restrictive measure that achieves the ALOP<sup>1480</sup> suggests that *de minimis* differences are of no consequence.<sup>1481</sup> Nonetheless, a decision on this question can be controversial, cutting into national choice of appropriate measure to achieve the ALOP.<sup>1482</sup> While panels are not permitted to engage in a *de novo* review of the relevant science under Article 5.1, they are obliged, under Article 5.6 to evaluate the science on their own,<sup>1483</sup> suggesting a tightening of control on national regulatory autonomy at this stage.<sup>1484</sup> There is also the possibility that, where a Member does not comply with its apparent duty to determine its ALOP with sufficient precision,<sup>1485</sup> the measure it has implemented in order to achieve that ALOP is found to be unnecessary on the basis that it achieves a higher ALOP.<sup>1486</sup> Furthermore, where a measure pursues non-SPS purposes, those non-SPS benefits will not carry weight in the proportionality analysis.<sup>1487</sup>

Article 2.3 SPSA prohibits arbitrary or unjustifiable discrimination between Members ‘where identical or similar conditions prevail’.<sup>1488</sup> Article 5.5 SPSA contains the expanded<sup>1489</sup> and unusual requirement that Members avoid ‘arbitrary or unjustifiable distinctions’ in the ALOPs applied in different situations, ‘if such distinctions result in discrimination or a disguised restriction on international trade’. The aim is to achieve consistency in the application of the concept of the

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<sup>1480</sup> *Australia-Apples* (AB) (n 1415) [363].

<sup>1481</sup> Walker (n 1384) 271.

<sup>1482</sup> Pauwelyn (n 1368) 652.

<sup>1483</sup> *Australia-Apples* (AB) (n 1415) [356].

<sup>1484</sup> Lester, Mercurio and Davies (n 1228) 599–600.

<sup>1485</sup> *Australia-Salmon* (AB) (n 1363) [206–207].

<sup>1486</sup> Scott, *The WTO Agreement* (n 1224) 37–39.

<sup>1487</sup> *ibid* 20.

<sup>1488</sup> See *ibid* 140–142.

<sup>1489</sup> Lester, Mercurio and Davies (n 1228) 579.

ALOP.<sup>1490</sup> Analysis under Article 5.5 focuses specifically, first, on whether the distinctions are arbitrary or unjustifiable<sup>1491</sup> and secondly on whether such distinctions also result in discrimination or a disguised restriction on international trade, to be decided in each individual case.<sup>1492</sup>

With respect to the former criterion, a panel may consider the stringency of the ALOP in relation to the magnitude of the risk,<sup>1493</sup> the scale of regulatory intervention, and perhaps administrative difficulties and costs,<sup>1494</sup> though it is unclear how sensitive it would be towards distinctions which result from broader historical or cultural differences between Members.<sup>1495</sup> A panel may also accept distinctions based on the purposes of the activities to which different ALOPs apply, for example hormones administered for growth and therapeutic or zootechnical purposes.<sup>1496</sup> However, in *Hormones*, rigorous engagement with the relevant risk assessment to assess the scientific plausibility of the EC's response to the scientific uncertainty present revealed an unjustifiable distinction between carbadox and hormones.<sup>1497</sup> Acceptance however, that the EC could pursue different ALOPs for natural and synthetic hormones<sup>1498</sup> is significant for the purposes of any future attempt to discipline the regulation of substances produced by synthetic biology using Article 5.5. It is unclear however, whether the potential unsustainability of substances produced by synthetic biology as a factor influencing evaluations of risk and resulting in different ALOPs would be acceptable.

With respect to the latter criterion (whether the distinctions in ALOPs result in discrimination or a disguised restriction on international trade), the AB in *Australia-*

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<sup>1490</sup> *Hormones* (AB) (n 1362) [213].

<sup>1491</sup> Ming Du (n 1474) 1087.

<sup>1492</sup> *Hormones* (AB) (n 1362) [240].

<sup>1493</sup> Ming Du (n 1474) 1085.

<sup>1494</sup> *Hormones* (AB) (n 1362) [221]; Walker (n 1384) 307 who argues that benefits might also be justifications for comparison.

<sup>1495</sup> Sheila Jasanoff, 'Trading Uncertainties: The Transatlantic Divide in Regulating Biotechnology' (2008) 6 *Journal for Institutional Comparisons* 36.

<sup>1496</sup> Ming Du (n 1474) 1085.

<sup>1497</sup> Walker (n 1384) 308.

<sup>1498</sup> *Hormones* (AB) (n 1362) [221].

*Salmon* confirmed the use of three ‘warning signals’ and two ‘additional factors’ in assessing the measure distinguishing salmon and other fish.<sup>1499</sup> The detail of its inquiry perhaps suggests a genuine attempt to root out protectionism<sup>1500</sup> and thereby save *bona fide* SPS measures, perhaps seen too in *Hormones*, where the AB found significant evidence of consumer concern but no protective intent among the national regulators.<sup>1501</sup>

The AB has provided criteria for determining comparability, for example, where the same substance or the same adverse health effect<sup>1502</sup> or the same or similar disease<sup>1503</sup> is involved or where ‘common element or elements’ are judged sufficient for comparability.<sup>1504</sup> It has also recognised that different ALOPs may stem from voluntary exposure by the public to particular risks, for example those from traditional foods,<sup>1505</sup> acknowledging the significance of voluntary assumption in forming attitudes to risk (see Chapter Two), and perhaps trust in personally accumulated experience as opposed to scientific evidence of safety.<sup>1506</sup> It also highlights the difficulty in categorising sets of decisions as either consistent or inconsistent, particularly at a societal level.<sup>1507</sup> The use of the social science literature discussed in Chapter Two as evidence explaining different attitudes to risks would surely enhance this analysis.<sup>1508</sup> Recognition of voluntariness, purpose and naturalness as factors justifying inconsistency suggests a sensitivity to non-

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<sup>1499</sup> *Australia-Salmon* (AB) (n 1363) [177].

<sup>1500</sup> Although it is unclear whether Article 5.5 will serve this purpose, Jeffrey L Dunoff, ‘Lotus Eaters: Reflections on the *Varietals* Dispute, the SPS Agreement and WTO Dispute Resolution’ in George A Bermann and Petros C Mavroidis (eds), *Trade and Human Health and Safety* (CUP 2006) 169.

<sup>1501</sup> *Hormones* (AB) (n 1362) [245].

<sup>1502</sup> *ibid* [215]; SPS Committee, ‘Guidelines to Further the Practical Implementation of Article 5.5 (G/SPS/15)’ para A.2.

<sup>1503</sup> *Australia-Salmon* (AB) (n 1363) [146].

<sup>1504</sup> *Hormones* (AB) (n 1362) [217]; *Australia-Salmon* (AB) (n 1363) [146]; Davey is critical of this finding, Davey (n 1421) 131.

<sup>1505</sup> SPS Committee (n 1502) para A.8.

<sup>1506</sup> Echols (n 1082) ch 3.

<sup>1507</sup> Walker (n 1384) 269.

<sup>1508</sup> Vern R Walker, ‘Consistent Levels of Protection in International Trade Disputes: Using Risk Perception Research to Justify Different Levels of Acceptable Risk’ (2001) 31 *Environmental Law Reporter* 11317.

scientifically determinable considerations relevant to setting an ALOP and may be a step in the right direction. But this, plus the essential indeterminacy from which this comparison suffers and the plurality of cultures amongst Members, invites the question whether it is appropriate to scrutinise ALOP consistency more intensely than philosophical consistency (i.e. whether Members, for example in all areas of animal welfare, regulate according to a consistent moral standard) as the AB declined to do in *EC-Seals*, limiting its intervention in Member choice of level of protection.<sup>1509</sup>

## 7. Conclusion

Flexibility in one area matched by rigidity elsewhere pervades the above analysis, perhaps reflecting, not surprisingly, an overriding aim to balance national sovereignty to pursue democratically determined social ends and the disciplining of protectionism.<sup>1510</sup> With respect to the GATT, the Article XX exceptions are broadly worded and interpreted. The TBTA, and to a certain extent, panel and AB interpretations of its provisions, are full of opportunities, *in principle*, for Members to justify their regulation for example through the concepts of 'legitimate objectives' and 'legitimate regulatory distinctions'. Under all three agreements, Members may determine their ALOP and the ability under the SPSA to rely on minority science provides an opportunity for Members to cite, as justification, science which perhaps represents more closely the interests they wish to protect. Some<sup>1511</sup> also noted a turn to procedural away from substantive scrutiny in panel/AB interpretation of proportionality, the chapeau, and to a certain extent under the SPSA, and the intention to increase regulatory wriggle room.

However, this development may not ultimately achieve that intention for substantive decisions still underpin procedural analysis and the boundary between procedural and substantive review cannot easily be discerned. For example,

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<sup>1509</sup> Howse, Langille and Sykes (n 1297) 114–115.

<sup>1510</sup> Ming Du (n 1265) 271–273; Appleton (n 1291) 373; Sykes (n 1385) 268.

<sup>1511</sup> For example, Scott, 'On Kith and Kine' (n 1382); Lang, *World Trade Law after Neoliberalism* (n 1218) 317–343.

determining whether a risk assessment was conducted can merge into determining how it was carried out which entails questioning the substantive choices made during the risk assessment, as perhaps seen in *Australia-Apples*.<sup>1512</sup>

Furthermore, the flexibility identified above is perhaps constrained by other aspects of panel/AB interpretations of the three agreements. Under the SPSA, for example, autonomy in choosing an ALOP is undermined by the limited scope for precautionary action, a narrow understanding of uncertainty and an analysis of sufficiency of scientific evidence without appropriate reference to the Member's aims and concerns. Deference to Member risk assessments works alongside the hard edge of specificity. And the ability to rely on minority science may be constrained by a searching analysis of its scope by comparison against the majority approach in determining whether there is a rational relationship between the risk assessment and the measure. This perhaps approaches use of a particular conception of sound science to discipline Members' SPS measures.<sup>1513</sup> Overall, Members have a high hurdle to clear to maintain their SPS measures. In terms of the extent to which the EU may rely on risk assessments influenced by specifically 'European' values and concerns to justify its regulation of risky technologies, there is limited scope under the SPSA.

Similarly, the GATT and TBTA acknowledge many non-safety concerns as valid grounds for regulation, most notably public morality, and necessity is not impossible to prove. However, rigorous analysis under the chapeau and rejection of the regulatory purpose test which arguably preserved some measure of freedom, ultimately constrain national responses to such concerns. Under the TBTA, regulatory distinctions are minutely scrutinised and so far have been unconvincing; measures may fall, despite their pursuit of legitimate objectives, for reasons relating to their manner of application. While the TBTA holds out greater potential

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<sup>1512</sup> Lang, *World Trade Law after Neoliberalism* (n 1218) 344–348 and references therein.

<sup>1513</sup> Winickoff and others (n 250) 84–85.

for deference to national regulation than the SPSA, navigating to success is full of pitfalls.

Were the SPSA and the GATT and/or the TBTA to apply simultaneously, the question arises whether science would be called upon to determine the existence of a risk as grounds on which to accept the existence of a moral problem or whether the moral concern could exist and justify regulatory action in its own right. Current indications suggest that the latter is possible, though the evidentiary requirements are not entirely certain. A further question is whether, if a public morality justification were accepted under the TBTA, for example, this would have any bearing on AB/panel scrutiny of the supporting scientific evidence presented or its relationship to the level of protection sought under the SPSA.

## Chapter Eight – Innovate or die! Ideas as barriers to closing the policy-practice gap

### 1. Introduction

The previous four chapters constituted an enquiry across EU and WTO law for opportunities in which values other than safety may prompt or influence regulation of risky technologies. In other words, they asked how successfully they can compete with the benefits associated with trade, including the benefits that commercialisation of technology allegedly brings. They have attempted to uncover why, despite repeatedly professing a policy commitment to greater socio-technical integration, the EU has frequently failed to perform. Chapters Three-Five presented alternative ideas or frameworks for regulation/governance capable, if implemented ambitiously, of challenging the dominance of commercial economic values by permitting or encouraging the consideration of other, non-safety, concerns in decision-making. While conclusions have been different, a consistent theme has been that non-safety values occupy a vulnerable position vis-à-vis these economic values and ultimately, for different reasons, struggle to compete. They tend not to be recognised as factors influencing risk assessment and, as reasons to regulate, are tightly restricted.

This chapter steps back from the detail of science-society relations, specific technology regulation and trade law to examine some of the ideas which drive and consolidate the strength of such economic values in the EU, sometimes neglected by STS scholarship.<sup>1514</sup> To that end, it adopts some of the arguments and perspectives of those who perceive Western liberal democracies to be in a 'post-political' or 'post-democratic' state, characterised by the 'depoliticisation' of otherwise, or previously, political matters. The questions and concerns raised by risky technological innovation are irreducible to, for example, expert evaluations of risk. They are valid subjects of political debate in which the choices, assumptions and dictates of even the highest political level are admitted to scrutiny, and in which

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<sup>1514</sup> J Goven and V Pavone, 'The Bioeconomy as Political Project: A Polanyian Analysis' (2015) 40 *Science, Technology & Human Values* 302, 324–425.

genuine alternatives are available both in terms of solutions and societal futures. This chapter argues, however, that aspects of EU innovation (and related) policy exhibit characteristics of 'post-politics' and that they deprive many of the choices, questions and concerns associated with technological innovation of political oxygen.

Section 2 elaborates upon the notion of post-politics, setting out some of its theses against which aspects of EU policy are subsequently analysed. Section 3 identifies imaginaries which surface throughout that policy and argues that above all, the EU pursues a goal of economic competitiveness which it conditions on commercialisable scientific research, technology and innovation. Section 4 considers the master narratives which wrap around those policies and imaginaries, supporting and reinforcing them. In each section, I illustrate how policy closes down debate and 'depoliticises' underlying choices, questions and concerns which are properly regarded as political. Section 5 concludes. I acknowledge now, as I did at the beginning of Chapter Three, that neither the EU nor the Commission are monolithic sources of policy. However, the point, overall, of this chapter, is to show the sheer ideational weight in and behind much of EU innovation policy and the irresistibility of its general vision as evidence of the extreme difficulty of attempting anything which might disrupt its agenda, including increasing socio-technical integration in regulatory decision-making. To that end, the chapter focuses almost exclusively on policy. The influence of this framework on the law is addressed in Chapter Nine.

## 2. The 'political' and depoliticisation

Chantal Mouffe describes a 'post-political' vision of modern democracy. She differentiates 'politics'; the practices and institutions organising human coexistence,<sup>1515</sup> from 'the political' which she takes to refer to 'a space of power, conflict and antagonism'.<sup>1516</sup> For her, indelible antagonism and disagreement are

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<sup>1515</sup> Chantal Mouffe, *On the Political* (Routledge 2005) 9.

<sup>1516</sup> *ibid* 10.

the essence of the political and political questions 'are not mere technical issues to be solved by experts... [but] involve decisions which require us to make a choice between conflicting alternatives'.<sup>1517</sup> Similarly, the political is an 'index of the space for disagreement' and political actions are those that '[open] up the possibility for disagreement'.<sup>1518</sup>

The state of the 'post-political' denotes a formation in which former partisan conflicts are consigned to history<sup>1519</sup> and a belief that the 'passions' associated with those collective identifications will fade with the march of individualism and rationality.<sup>1520</sup> This wilting of the political is attributed to various causes. For example, 'the hegemony of liberalism' which, in its rationalism and individualism, may be unable to accommodate the conflicts, inevitable in a plural society, for which no rational solution is possible.<sup>1521</sup> Additional causes which have been cited include the increased power of corporate elites, deregulation, reducing the state etc. aided by globalisation and the shift by the left from its traditional support base and policies, to the centre.<sup>1522</sup> Neoliberal policy, it has also been argued, depoliticises economic regulation and strategy, placing previously contested policy fields 'off limits' for political discourse and in the domain of technocratic management.<sup>1523</sup> Likewise, the influence of neoliberal thought on WTO law entailed the rejection of the idea of economic governance as the pursuit of collective goals and values in the international economic order and, alongside the elevation of the importance of technical knowledge, has hindered discussion and debate over 'the possibility or desirability of collective projects of international economic order'.<sup>1524</sup> Finally, it has been argued that the complexity of the public sphere and the

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<sup>1517</sup> *ibid.*

<sup>1518</sup> Barry (n 46) 86.

<sup>1519</sup> Mouffe (n 1515) 1.

<sup>1520</sup> *ibid.* 6.

<sup>1521</sup> *ibid.* 10.

<sup>1522</sup> Colin Crouch, *Coping with Post-Democracy* (Fabian Society 2000) 11, 13–20, 25–26; see also, Mouffe (n 1515) 56–63.

<sup>1523</sup> Adam Tickell and Jamie Peck, 'Making Global Rules: Globalization or Neoliberalization?' in Jamie Peck and Wai-chung Yeung Henry (eds), *Remaking the Global Economy: Economic-Geographical Perspectives* (SAGE 2003) 177.

<sup>1524</sup> Lang, *World Trade Law after Neoliberalism* (n 1218) 7.

proliferation of independent agencies shields public policy from public gaze in a way that can also depoliticise.<sup>1525</sup>

Post-politics in the West is also characterised by ‘the growth of a managerial approach to government... deprived of its proper political dimension’,<sup>1526</sup> perhaps encapsulated in Michael Power’s, ‘risk management of everything’.<sup>1527</sup> In the EU a shift towards ‘managerial sensibility’ reliant on expertise and procedure which obscures underlying political choices has been discerned.<sup>1528</sup> In relation to regulatory science, despite the social science insights into values and culture discussed in Chapter Two, public management discourses maintain ‘a preference for rationalism and standardization in making public science accountable’ leading to ‘a conception of risk governance heavily framed by rationalized notions of a risk management process’.<sup>1529</sup> Power highlights the contestability of governance and the tension between its two logics of democracy and managerial process.<sup>1530</sup> It is within this management logic which risk analysis is now conducted and which, along with ideals of ‘good governance’, provides the framework for participation. While lay participation may still occur in risk regulation, the current organisational logic of risk analysis frames such exercises as strategies to manage public expectations, regarded as a source of risk in themselves, and to calm any public opposition with the generation of legitimacy.<sup>1531</sup> Persuasion and the manipulation of public opinion

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<sup>1525</sup> Claudio M Radaelli, ‘The Public Policy of the European Union: Whither Politics of Expertise?’ (1999) 6 *Journal of European Public Policy* 757, 759.

<sup>1526</sup> Slavoj Žižek, *Revolution at the Gates* (Verso 2004) 303; Erik Swyngedouw, ‘Depoliticized Environments: The End of Nature, Climate Change and the Post-Political Condition’ (2011) 69 *Royal Institute of Philosophy Supplement* 253, 266; Mouffe (n 1515) 58.

<sup>1527</sup> Power (n 306).

<sup>1528</sup> Mark Dawson, ‘Transforming into What - New Governance in the EU and the Managerial Sensibility in Modern Law Symposium: New Governance and the Transformation of Law’ (2010) 2010 *Wisconsin Law Review* 389.

<sup>1529</sup> Michael Power, *Organized Uncertainty: Designing a World of Risk Management* (OUP 2007) 18.

<sup>1530</sup> *ibid* 19; Gili S Drori, ‘Governed by Governance: The New Prism for Organizational Change’ in Gili S Drori, John W Meyer and Hokyu Hwang (eds), *Globalization and Organization: World Society and Organizational Change* (OUP 2006).

<sup>1531</sup> Power (n 1529) 20–21.

(along with increasingly sophisticated mechanisms of opening politics to scrutiny) are characteristic of, according to Colin Crouch, 'post-democracy'.<sup>1532</sup>

Despite the persistent state of disagreement at the heart of the political, common decisions are of course still required for government, though potentially arbitrary and lacking 'rational' justification.<sup>1533</sup> In a democracy, legislation may be justified by the need to reach agreement, if not by reason or consensus, while persistent disagreement on many of its aspects is acknowledged.<sup>1534</sup> The extent to which deliberation should seek consensus is a recurring question. Some emphasise that it should. Liberalism, it is argued, is convinced of the possibility of objective public knowledge and universal, rational consensus often by melding together plural values through dialogue.<sup>1535</sup> This is so notwithstanding that conditions for consensus are contingent – not necessarily indicating a proven truth<sup>1536</sup> - and that consensus in the eyes of the public may be forged by forces not recognised as 'rational' or 'scientific', for example the media.<sup>1537</sup> In the context of this thesis, expert risk assessment provides the 'objective public knowledge' which frames public debate and contributes to depoliticising EU decision-making on risky technologies.<sup>1538</sup> Others see consensus as unlikely in a plural society<sup>1539</sup> and emphasise a place for contestation, continued disagreement on the reasons behind an agreed decision,<sup>1540</sup> compromise and conflict<sup>1541</sup> and the engendering of mutual respect for conflicting values.<sup>1542</sup> How different to the EU's familiar dismissal of opposition on the basis of the deficit model.

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<sup>1532</sup> Crouch (n 1522) 1, 7.

<sup>1533</sup> Barry (n 46) 85.

<sup>1534</sup> *ibid* 87.

<sup>1535</sup> Mouffe (n 1515) 1, 10–11; Ezrahi (n 45) 254–255, 264.

<sup>1536</sup> Oreskes (n 302).

<sup>1537</sup> Gregory and Miller (n 190) 140–148.

<sup>1538</sup> Lee, 'GMOs in the Internal Market' (n 871) 333–334.

<sup>1539</sup> See discussion in Dryzek (n 331) 47–50.

<sup>1540</sup> *ibid* 71–80.

<sup>1541</sup> Sybille van den Hove, 'Between Consensus and Compromise: Acknowledging the Negotiation Dimension in Participatory Approaches' (2006) 23 *Land Use Policy* 10.

<sup>1542</sup> Bloomfield and others (n 337) 503.

Problem-solving approaches to deliberation require merely a shared commitment to solving a problem among participants but no consensus on values at any point in the process.<sup>1543</sup> Consensus has been criticised for suppressing the creative potential of conflict for solving problems by attempting to reconcile sometimes irreconcilable interests and for enabling manipulation of the process by dismissing certain interests, undermining its legitimacy.<sup>1544</sup>

Erik Swyngedouw summarises: '[p]ost-politicization reduces the political terrain to the sphere of consensual governing and policy-making centered on technical, managerial and consensual administration (policing) of environmental, social, economic or other domains'.<sup>1545</sup> In acutely contentious areas such as the environment, climate<sup>1546</sup> or here, technological innovation, consensus as a goal sought by rationalism, managerialism and technocracy epitomises the post-political condition due to its foundation in exclusion and 'annulment of dissensus' signifying 'the end of politics'.<sup>1547</sup> The 'post-politicizing environmental consensus' allows only discussion over 'technologies of management, timing of their implementation, arrangements of policing and the interests of those whose voices are recognized as legitimate'; conflicting or alternative trajectories are forestalled.<sup>1548</sup> Swyngedouw identifies a similar pattern to Power: disagreement and debate occur but only 'within a model of elite consensus and agreement subordinated to a managerial-technocratic regime' without trespassing into 'the socio-political framing of present and future natures'.<sup>1549</sup> Thus he argues 'the properly political' is evacuated from the public sphere.<sup>1550</sup>

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<sup>1543</sup> Steele (n 330) 433–435.

<sup>1544</sup> van den Hove (n 1541) 11–14.

<sup>1545</sup> Erik Swyngedouw, 'Depoliticized Environments and the Promises of the Anthropocene' in Raymond L Bryant (ed), *The International Handbook of Political Ecology* (Edward Elgar 2015) 138.

<sup>1546</sup> *ibid.*

<sup>1547</sup> Jacques Ranciere, 'Ten Theses on Politics' (2001) 5 Theory & Event; Swyngedouw (n 1545) 138; Mouffe (n 1515) 11 paraphrasing Carl Schmitt.

<sup>1548</sup> Swyngedouw (n 1545) 138.

<sup>1549</sup> *ibid* and references therein.

<sup>1550</sup> *ibid.*

In Mouffe's definition of 'the political' as antagonistic, opponents are perceived as enemies whose demands are illegitimate.<sup>1551</sup> A consensual approach, instead of creating conditions for a reconciled society, leads to the emergence of antagonisms which often manifest instead as moral conflicts between right and wrong (as opposed to, for example, left and right).<sup>1552</sup> These ideas are highlighted here for the additional insight they provide into the resilience of current institutions of risk regulation in the face of PES/'new scientific governance' initiatives for change and hence the limited progress towards socio-technical integration identified in this thesis. For example, criticisms of consensus shed light on the shortcomings of instrumental deliberation and attempts to overcome opposition, as discussed in Chapter Five. The analysis of 'the political' as antagonistic is helpful for understanding the extreme antagonism and dismissal of opposing concerns and viewpoints which characterise much societal interaction in relation to risky technologies, often marked by bitter disagreements and moralising.<sup>1553</sup> This political contestation rarely seems accommodated, in terms of a space for disagreement or respect for different values, in many of the decision-making structures discussed in this thesis. Thus, some aspects of depoliticisation echo processes which close down, rather than open up, debate over risky technologies.

Ultimately, it depends on how deliberation is used. Voices from STS have warned that the aim should not be consensus<sup>1554</sup> (though perhaps too often it is<sup>1555</sup>) but rather a pluralistic discourse to open up participatory appraisal.<sup>1556</sup> There is evidence that deliberation can engage society more closely and fruitfully in science and vice versa.<sup>1557</sup> However, highly controlled engagement pursuing consensus can

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<sup>1551</sup> Mouffe (n 1515) 20.

<sup>1552</sup> *ibid* 5.

<sup>1553</sup> For example, 'Laureates Letter Supporting Precision Agriculture (GMOs)' <[http://supportprecisionagriculture.org/nobel-laureate-gmo-letter\\_rjr.html](http://supportprecisionagriculture.org/nobel-laureate-gmo-letter_rjr.html)> accessed 6 October 2016. Similarly in the framing of concerns over the bioeconomy as unethical, due to its high stakes, Goven and Pavone (n 1514) 314–315.

<sup>1554</sup> Stilgoe, Irwin and Jones (n 7) 52–53; EGSG (n 6) 61.

<sup>1555</sup> Stilgoe, Lock and Wilsdon (n 368) 6.

<sup>1556</sup> Stirling, "Opening Up" and "Closing Down" (n 9) 282.

<sup>1557</sup> For example, Stilgoe (n 902).

stifle genuine debate as much as reductive assessment techniques and can close down choice over technological trajectories.<sup>1558</sup> With respect to the EU, Amandine Crespy has argued that it has adopted an 'elite-based and consensus-orientated understanding of deliberative democracy'.<sup>1559</sup> It is elite in the sense that deliberation occurs amongst national experts, NGOs, interest group spokespeople and union officials in the Brussels microcosm, remote from the public sphere while excluding the most contentious voices.<sup>1560</sup> Its pursuit of conflict avoidance, she argues, has led to the 'negation of politics and democracy'<sup>1561</sup> though conflict and contestation may actually be productive.<sup>1562</sup>

The antagonism, the disagreement central to the political and the criticism of 'rational' consensus all support a fundamental contention of this chapter and indeed this thesis; that the arrangement of institutions (science, innovation, markets, risk assessment, policy, even old technologies etc.) is a matter of choice dependant on ideas and the convictions and values of a society,<sup>1563</sup> regardless of what the policy discourses examined below argue or imply. The interpretive flexibility<sup>1564</sup> of technology and the existence of a choice are at the heart of constructivist thought on socio-technical development which *ipso facto* provides a rationale for 'a politics of technology' and participatory decision-making.<sup>1565</sup> The presence of choice evinces the intrinsic contingency and undecidability of every arrangement. However, that choice is currently restricted. My reason for focusing on imaginaries here is to pick out certain of the ideational forces restricting choice. My argument for sustainability and RRI (and mechanisms for opening up decision-making in general) is that they might reveal and challenge those forces.

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<sup>1558</sup> Stirling, 'Opening Up the Politics of Knowledge' (n 172).

<sup>1559</sup> Amandine Crespy, 'Deliberative Democracy and the Legitimacy of the European Union: A Reappraisal of Conflict' (2014) 62 *Political Studies* 81, 82.

<sup>1560</sup> *ibid* 86–87.

<sup>1561</sup> *ibid* 84.

<sup>1562</sup> *ibid* 82; Dryzek (n 331).

<sup>1563</sup> Lang, 'Reconstructing Embedded Liberalism' (n 1216) 84, 92, 96; Howse, 'From Politics to Technocracy' (n 1218) 116 with respect to trade regimes.

<sup>1564</sup> See Chapter One.

<sup>1565</sup> Bijker (n 22) 280–281.

To summarise, the following policy tendencies may be regarded as depoliticising. The expectation of and drive for a consensus on policy questions arrived at rationally, informed by the provision of expert knowledge; a rejection of the possibility of legitimate disagreement (or no acknowledgement of a (rational) alternative); and a managerial approach to problems, including the management or manipulation of public opinion and responses. These tendencies form the themes of EU innovation policy highlighted below.<sup>1566</sup>

### 3. The EU's imagined future

Ideas and imagination play a profound role in constituting our world and society.<sup>1567</sup> This is no less the case with the EU's innovation policy vision which this section examines through the prism of imaginaries, specifically socio-technical and economic imaginaries, in order to understand better their durability and power.

Imaginaries express collectively held beliefs or prescriptions about how society is or ought to be ordered, how social relations function, including understandings of good and evil, and the expectations that are normally fulfilled.<sup>1568</sup> They are, in a sense, circular; actions premised upon their validity confirm and produce their reality.<sup>1569</sup> Imaginaries are also future-orientated, ordaining possible, desirable or rightfully attainable destinies for society.<sup>1570</sup> Their power lies in their ability thereby to conjure political will or public determination to pursue such destinies.<sup>1571</sup>

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<sup>1566</sup> NB depoliticisation has not been the trend in all EU policy areas, Radaelli (n 1525) 766–767.

<sup>1567</sup> For example, Sheila Jasanoff, 'Future Imperfect: Science, Technology, and the Imaginations of Modernity' in Sheila Jasanoff and Sang-Hyun Kim (eds), *Dreamscapes of Modernity: Sociotechnical Imaginaries and the Fabrication of Power* (University of Chicago Press 2015) 5–10; Lang, 'Reconstructing Embedded Liberalism' (n 1216).

<sup>1568</sup> Jasanoff, 'Future Imperfect' (n 1567) 4, 7; Charles Taylor, *Modern Social Imaginaries* (Duke UP 2004) 23.

<sup>1569</sup> B Jessop, 'Cultural Political Economy and Critical Policy Studies' (2010) 3 *Critical Policy Studies* 336, 338; Levidow, Birch and Papaioannou (n 708) 42.

<sup>1570</sup> Jasanoff, 'Future Imperfect' (n 1567) 4–5.

<sup>1571</sup> Jasanoff and Kim (n 828) 123.

Different imaginaries can co-exist<sup>1572</sup> and indeed combine to shape societal futures. Socio-technical imaginaries consist of temporally- and culturally-situated imaginaries of societal futures ‘attainable through, and supportive of, advances in science and technology’.<sup>1573</sup> They may be articulated alongside shared fears over the consequences of (not) innovating.<sup>1574</sup> The particular value of socio-technical imaginaries here is their capacity to explain why some socio-technical arrangements are more durable than others.<sup>1575</sup> In this case, they may illuminate some of the reasons for the EU’s adherence to its particular framework of risk governance. Economic imaginaries endow the ‘economic’ field with meaning and shape, moulding discourses or ways of being around economic strategies, projects and visions which ultimately influence institutional orders and society.<sup>1576</sup> Socio-technical and economic imaginaries operate symbiotically here and it is this symbiosis which offers insight into EU’s current risk governance framework.

### 3.1 *A menagerie of imaginaries*

#### 3.1.1 *Past failure and bright futures*

Future and past imaginaries can shape each other.<sup>1577</sup> The EU’s reading of Europe’s innovation history is one of vast untapped innovative potential,<sup>1578</sup> too rarely translated into innovation. It has dawdled in pioneering new, marketable products depriving it of opportunities, businesses, jobs and competitive advantage,<sup>1579</sup> causing an ‘innovation deficit’ as compared with its more dynamic competitors.<sup>1580</sup> The theme running through all policy visions examined here is that of securing and

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<sup>1572</sup> Jasanoff, ‘Future Imperfect’ (n 1567) 4.

<sup>1573</sup> *ibid* 19–20.

<sup>1574</sup> *ibid* 5.

<sup>1575</sup> *ibid*.

<sup>1576</sup> Jessop (n 1569) 344 and references therein.

<sup>1577</sup> Jasanoff, ‘Future Imperfect’ (n 1567) 21; see also, Jasanoff and Kim (n 828) 124.

<sup>1578</sup> Commission, ‘Europe 2020 Flagship Initiative Innovation Union COM(2010) 546 Final’ 2.

<sup>1579</sup> Commission, *Open Innovation* (n 431) 11, 28; Commission, ‘Innovation in a Knowledge-Driven Economy COM(2000) 567 Final’ 12; Commission, ‘Green Paper on Innovation COM(95) 688 Final’ 5.

<sup>1580</sup> Commission, ‘Green Paper on Innovation’ (n 1579) 5; Commission, ‘Innovation in a Knowledge-Driven Economy’ (n 1579) 5.

maintaining Europe's competitiveness in a global market and it is the fear of failure on this front which ignites the palpable urgency firing the EU's commitments.

The EU's overarching vision for the 21<sup>st</sup> century is to become a 'smart, sustainable and inclusive economy, delivering high levels of employment, productivity and social cohesion'.<sup>1581</sup> 'Smart growth' expresses the goal of creating a knowledge- and innovation-driven economy, also known as the knowledge-based economy (KBE). The KBE reflects the vision of a society enriched by social and economic goods<sup>1582</sup> and 'societal progress'<sup>1583</sup> conditional on, *inter alia*, enhanced R&D, competitiveness, innovation and a completed internal market.<sup>1584</sup> Policy presents a stark choice: tackle the exigencies of *inter alia* post-financial crisis economic recovery, globalisation and societal challenges or face the desolation of lost wealth, a sluggish recovery, high unemployment and social distress.<sup>1585</sup>

The knowledge-based bioeconomy (KBBE), defined as 'the sustainable, eco-efficient transformation of renewable biological resources into health, food, energy and other industrial products',<sup>1586</sup> is an extension of the KBE.<sup>1587</sup> It promises to transform life sciences into new, sustainable, eco-efficient and competitive products,<sup>1588</sup> improve economic and environmental sustainability, reconcile food security, the use of renewable resources and environmental protection, while

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<sup>1581</sup> Commission, 'Europe 2020' (n 580) 3.

<sup>1582</sup> Commission, 'Growth, Competitiveness, Employment: The Challenges and Ways Forward into the 21st Century COM(93) 700' 62; Commission, 'Innovation in a Knowledge-Driven Economy' (n 1579); Commission, 'Europe 2020' (n 580) 10–12.

<sup>1583</sup> Commission, 'Innovation in a Knowledge-Driven Economy' (n 1579) 14.

<sup>1584</sup> 'Presidency Conclusions: Lisbon European Council 23 and 24 March 2000' <[http://www.consilium.europa.eu/en/uedocs/cms\\_data/docs/pressdata/en/ec/00100-r1.en0.htm](http://www.consilium.europa.eu/en/uedocs/cms_data/docs/pressdata/en/ec/00100-r1.en0.htm)> accessed 25 June 2017; Commission, 'Innovation in a Knowledge-Driven Economy' (n 1579) 4.

<sup>1585</sup> Commission, 'Europe 2020' (n 580) 8–9.

<sup>1586</sup> Kean Birch, Les Levidow and Theo Papaioannou, 'Sustainable Capital? The Neoliberalization of Nature and Knowledge in the European "Knowledge-Based Bio-Economy"' (2010) 2 Sustainability 2898, 2899.

<sup>1587</sup> Les Levidow, 'European Transitions towards a Corporate-Environmental Food Regime: Agroecological Incorporation or Contestation?' (2015) 40 Journal of Rural Studies 76, 81.

<sup>1588</sup> DG SANCO (n 130) 7.

achieving economic growth by producing ‘more with less’.<sup>1589</sup> It is justified by ‘unprecedented and unsustainable exploitation of [Europe’s] natural resources’, climate change, biodiversity loss and a growing world population.<sup>1590</sup> It is a narrative of particular relevance here due to synthetic biology’s promise of more efficient production, discussed in Chapter Five, and the KBBE’s role in achieving sustainability in Europe.

The life blood of these visions of global competitiveness is innovation,<sup>1591</sup> not merely as the driver of economic change but the means to whip the EU from the bleak jaws of economic obscurity and propel it into a technologically-enhanced future.<sup>1592</sup> They are expressions of a master narrative (discussed below) which claims that innovation is the only pathway to secure Europe’s future,<sup>1593</sup> manifested in the transformation of knowledge into products, services and processes which create new markets.<sup>1594</sup> This strand of the narrative goes hand-in-hand with fears that failure means the EU will not return to the path of economic growth;<sup>1595</sup> the foundation of the European quality of life and social model.<sup>1596</sup>

This imaginary seeks to galvanise wills to overcome obstacles<sup>1597</sup> to swift market access for research-based breakthroughs, bringing rapid benefits to citizens, prosperity<sup>1598</sup> and competitiveness gains.<sup>1599</sup> The dire alternatives and urgent societal challenges resemble Swyngedouw’s depoliticised ‘apocalyptic imaginaries’, foreclosing proper political framing and choice between alternative trajectories or

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<sup>1589</sup> Commission, ‘Innovating for Sustainable Growth: A Bioeconomy for Europe COM(2012) 60 Final’ 2–4.

<sup>1590</sup> *ibid* 2–3.

<sup>1591</sup> Commission, ‘Horizon 2020’ (n 350) 2; Commission, ‘Innovation Union’ (n 1578) 2.

<sup>1592</sup> For example, Commission, ‘Europe 2020’ (n 580) 11–12.

<sup>1593</sup> Commission, ‘Innovation Union’ (n 1578) 6.

<sup>1594</sup> Commission, *Open Innovation* (n 431) 11, 15, 17; Commission, ‘Innovation in a Knowledge-Driven Economy’ (n 1579) 4.

<sup>1595</sup> Commission, ‘Executive Summary of the Impact Assessment SWD(2012) 211 Final: A Reinforced European Research Area Partnership for Excellence and Growth’ 4.

<sup>1596</sup> Commission, ‘Innovation Union’ (n 1578) 2; Esko Aho (ed), *Creating an Innovative Europe. Report of the Independent Expert Group on R&D and Innovation* (EUR-OP 2006).

<sup>1597</sup> For example, Commission, ‘Innovation in a Knowledge-Driven Economy’ (n 1579) 12.

<sup>1598</sup> Commission, ‘The European Research Area: New Perspectives COM(2007) 161 Final’ 5.

<sup>1599</sup> Commission, ‘Innovation Union’ (n 1578) 2, 22–23; Aho (n 1596) VII, 1.

political programs in favour of techno-fixes<sup>1600</sup> and other ‘techno-managerial and behavioural transformations’ to ‘retrofit’ these problems, without ever challenging the current political order.<sup>1601</sup> Such imaginaries seek consensus around the problem while technical solutions check impulse towards a political solution.

### 3.1.2 *The EU’s problems*

The above socio-technical imaginaries are linked to economic imaginaries of the EU as a self-contained economic unit striving for its leadership position in the increasingly globalised, competitive and knowledge-driven world economy.<sup>1602</sup> This state of affairs is taken for granted<sup>1603</sup> and used, for example, to justify the EU’s biotechnology policy.<sup>1604</sup> Societal challenges are viewed as translatable into ‘business opportunities’<sup>1605</sup> for breakthroughs with a particular focus on those ‘with high potential for sustainable competitiveness, innovation and growth’.<sup>1606</sup> The aim is to enable European companies to lead in the development of new technologies and increase jobs.<sup>1607</sup>

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<sup>1600</sup> Les Levidow, Theo Papaioannou and Kean Birch, ‘Neoliberalising Technoscience and Environment: EU Policy for Competitive, Sustainable Biofuels’ in Luigi Pellizzoni and Marja Ylönen (eds), *Neoliberalism and Technoscience: Critical Assessments* (Ashgate 2012) 163–165. Or techno-knowledge fixes in the context of the KBBE, Birch, Levidow and Papaioannou (n 1586) 2904, 2907.

<sup>1601</sup> Swyngedouw (n 1545) 136–137.

<sup>1602</sup> Ben Rosamond, ‘Imagining the European Economy: “Competitiveness” and the Social Construction of “Europe” as an Economic Space’ (2002) 7 *New Political Economy* 157, 168; Levidow, Birch and Papaioannou (n 708) 43.

<sup>1603</sup> For example, Commission, ‘Innovation in a Knowledge-Driven Economy’ (n 1579) 4; Dryzek (n 528) 135.

<sup>1604</sup> Jasanoff, *Designs on Nature* (n 11) 84–85.

<sup>1605</sup> Commission, ‘Horizon 2020’ (n 350) 4.

<sup>1606</sup> Commission, ‘Consultation of the Horizon 2020 Advisory Groups – Providing Advice on Potential Priorities for Research and Innovation in the 2018-2020 Work Programme: Scene Setter’ (2016) 2–3.

<sup>1607</sup> Commission, ‘Innovation Union’ (n 1578) 22–23; Commission, ‘Innovation in a Knowledge-Driven Economy’ (n 1579) 14; Commission, ‘Innovating for Sustainable Growth’ (n 1589) 3.

The key, according to this policy vision, to fully realising the EU's imaginaries is the market,<sup>1608</sup> including the creation of new markets<sup>1609</sup> accessed via the internal market.<sup>1610</sup> The market will distribute the anticipated technological solutions thereby unlocking both their problem-solving and economic growth-promoting potential.<sup>1611</sup> Indeed, to the internal market is attributed European growth, jobs and the strengthened global competitiveness of European companies.<sup>1612</sup> The smooth functioning of the internal market is pursued by the framework regulating synthetic biology, discussed in Chapter Five. In KBE terms, knowledge will be transformed into socio-economic value.<sup>1613</sup> The EU's imaginaries are therefore also contingent upon completing the single market;<sup>1614</sup> market fragmentation is a running concern of policy.<sup>1615</sup> These policies appear to endorse the claimed ideological neutrality of the internal market and its prioritisation of market efficiency at the heart of European integration.<sup>1616</sup> However, markets are in fact 'politics by other means' and 'a specific and contentious way of distributing goods and bads';<sup>1617</sup> the internal market itself is a 'highly politicized choice of ethos, ideology, and political culture'.<sup>1618</sup> *The Aho Report* however, pre-empts concerns and reassures that a 'market-led vision' does not entail abandoning European

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<sup>1608</sup> For example, Commission, 'Horizon 2020' (n 350) 4–5, 9, 11; Commission, *Open Innovation* (n 431) 26–27; Commission, 'Innovation Union' (n 1578) 7, 27. The EU in general is a strong proponent of economic rationalism, Dryzek (n 528) 123.

<sup>1609</sup> Commission, *Open Innovation* (n 431) 11; Commission, 'Innovation Union' (n 1578) 23.

<sup>1610</sup> Commission, *Open Innovation* (n 431) 64; Commission, 'Innovation in a Knowledge-Driven Economy' (n 1579) 12; Commission, 'Europe 2020' (n 580) 22–24.

<sup>1611</sup> For example, Commission, 'Innovation Union' (n 1578) 23.

<sup>1612</sup> Commission, 'Upgrading the Single Market: More Opportunities for People and Business COM(2015) 550 final' 1.

<sup>1613</sup> Commission, 'Consultation of the Horizon 2020 Advisory Groups' (n 1606) 3.

<sup>1614</sup> Commission, 'Innovation Union' (n 1578) 15; Commission, 'Europe 2020' (n 580) 20.

<sup>1615</sup> For example, Commission, 'Innovation Union' (n 1578) 15; Commission, *Open Innovation* (n 431) 17; Commission, 'Innovation in a Knowledge-Driven Economy' (n 1579) 6; Commission, 'Green Paper on Innovation' (n 1579) 34; Commission, 'Europe 2020' (n 580) 20.

<sup>1616</sup> Weiler (n 1006) 2476–2478.

<sup>1617</sup> Noel Castree, 'Neoliberalising Nature: The Logics of Deregulation and Reregulation' (2008) 40 *Environment and Planning A* 131, 143.

<sup>1618</sup> Weiler (n 1006) 2477.

values but rather means using ‘the force of the market to preserve them’, alongside a ‘reformed social model conducive to innovation’.<sup>1619</sup>

The KBBE expresses this mutually reinforcing combination of economic and socio-technical imaginaries.<sup>1620</sup> Eco-efficiency becomes synonymous with sustainability through the technologically-enhanced productivity of abundant, renewable bio-resources as substitutes for fossil fuels and synthetic chemicals. In other words, ‘societal progress is equated with ‘sustainable’ economies, in turn dependent on eco-efficient innovations’ stimulated by markets.<sup>1621</sup> It also extends earlier policy frameworks promoting both biotechnology and the life sciences as symbols of Europe’s progress, and environmental protection.<sup>1622</sup> The EU seeks, by these visions, to ‘mobilize resources and policy support for such markets’.<sup>1623</sup>

In sum, EU innovation policy defines two key problems both of which must be tackled by innovation. Firstly the existence of a global competition in which Europe must succeed in order to afford its social model<sup>1624</sup> underpinned by the disproven,<sup>1625</sup> linear model of innovation.<sup>1626</sup> Secondly, the inefficient use of resources, treatable only with ‘resource-efficient innovation through technoscientific advance as basis for societal progress’.<sup>1627</sup>

Problem definition or ‘framing’ can be a political act and may be used to manage conflict, for example, over biotechnology.<sup>1628</sup> It may depoliticise by marginalising

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<sup>1619</sup> Aho (n 1596) 3.

<sup>1620</sup> Levidow, Birch and Papaioannou (n 708) 42.

<sup>1621</sup> *ibid* 48–49; perfectly summarised in Commission, *A Bioeconomy Strategy for Europe: Working with Nature for a More Sustainable Way of Living* (EUR-OP 2013).

<sup>1622</sup> Levidow, Birch and Papaioannou (n 708) 48–49.

<sup>1623</sup> Levidow, Papaioannou and Birch (n 1600) 160.

<sup>1624</sup> EGSG (n 6) 25.

<sup>1625</sup> Sheila Jasanoff, ‘Imagined and Invented Worlds’ in Sheila Jasanoff and Sang-Hyun Kim (eds), *Dreamscapes of Modernity: Sociotechnical Imaginaries and the Fabrication of Power* (University of Chicago Press 2015) 328 and references therein.

<sup>1626</sup> Discussed in Les Levidow and Claudia Neubauer, ‘EU Research Agendas: Embedding What Future?’ (2014) 23 *Science as Culture* 397, 402.

<sup>1627</sup> *ibid* 399, 402 and references therein. For example, Green Paper on R&I Funding 2011, *ibid* 402.

<sup>1628</sup> Goven (n 377) 106–107.

proposals and concerns that fall outside its bounds<sup>1629</sup> and pre-empt alternatives.<sup>1630</sup> Framing, which involves making judgments regarding which issues to discuss and what evidence is deemed relevant in a particular context, can influence discussions over governance and may limit opportunities for democratic and open debate.<sup>1631</sup> In Chapter Two, I discussed framing as an integral part of risk assessment and as a factor contributing to the contingency of assessments of risk. Participatory processes are as sensitive as risk assessment to framing conditions such as process design, choice of focus, phrasing of questions, characterisation of alternatives etc.,<sup>1632</sup> increasing the likelihood that public debate will conform to an accepted framework.<sup>1633</sup> Framing may also prevent examination of whether our political/economic system is in fact at least partly at fault.<sup>1634</sup> For example, a low efficiency problem, rather than a resource demand problem, mandates increased production and consumption as the solution delivered by an eco-efficiency technofix which ‘accommodate[s] global markets as if these were exogenous’ to the relevant production system.<sup>1635</sup>

This approach has been described elsewhere as ‘solutionism’ – a predilection for narrow-minded and speculative technological fixes to solve ‘complex, fluid and contentious’ problems without first thoroughly investigating those problems.<sup>1636</sup> Solutionism generally and associated problem framings specifically ignore the

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<sup>1629</sup> *ibid.*

<sup>1630</sup> Levidow and Neubauer (n 1626) 400.

<sup>1631</sup> Irwin (n 48) 590.

<sup>1632</sup> Andrew Stirling, ‘Analysis, Participation and Power: Justification and Closure in Participatory Multi-Criteria Analysis’ (2006) 23 *Land Use Policy* 95.

<sup>1633</sup> Irwin (n 48) 592.

<sup>1634</sup> Amy Diedrich and others, ‘Framing Environmental Sustainability Challenges for Research and Innovation in European Policy Agendas’ (2011) 14 *Environmental Science & Policy* 935, 936.

<sup>1635</sup> Levidow, Birch and Papaioannou (n 708) 52; Commission and Directorate-General for Research and Innovation, *Where Next for the European Bioeconomy?* (EUR-OP 2014) 6; SCAR, ‘Sustainable Agriculture, Forestry and Fisheries in the Bioeconomy: A Challenge for Europe’ (DG Research and Innovation 2015) 17.

<sup>1636</sup> Jim Thomas, ‘Constructing a “Futurology from Below”: A Civil Society Contribution toward a Research Agenda’ (2015) 2 *Journal of Responsible Innovation* 92, 93; Evgeny Morozov, *To Save Everything, Click Here: The Folly of Technological Solutionism* (Penguin Books 2014) 5–6.

immense complexity of environmental sustainability (and other) challenges of modern society<sup>1637</sup> and may, by their simplicity, spawn unproductive diagnoses and policy measures, while still shaping society.<sup>1638</sup> Alternative innovative approaches based on, for example, behavioural changes and lower consumption require more comprehensive framing of society's relationship with natural resources, for example. They also require greater involvement by other forms of expertise, such as the social sciences, opening up problem definitions to include our markets and models of trade themselves, and potentially, different societal futures.<sup>1639</sup>

Master narratives of societal progress contingent on technological advance and the global competitive race still pulse through EU innovation policy veins. However, as discussed in Chapter Three, there is increasing recognition of the need to encourage innovation which contributes to society at large.<sup>1640</sup> 'Societal challenges' therefore increasingly justify research agendas.<sup>1641</sup> However, societal challenges such as environmental sustainability also risk being framed by dominant political-economic interests which promote policy emphasis on more efficient production methods or bringing more products to market for increasing economic competitiveness, as a solution.<sup>1642</sup> For example, 'European Technology Platforms' (ETPs) are 'industry-led stakeholder fora that develop short- to long-term research and innovation agendas and roadmaps for action at EU and national level to be supported by both private and public funding'.<sup>1643</sup> The rationale for their existence is, again, catching up with global competitors and boosting jobs and growth in the EU.<sup>1644</sup> The Strategic Research and Innovation Agendas (SRAs) they produce identify regulatory and non-

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<sup>1637</sup> Morozov (n 1636) 6.

<sup>1638</sup> EGSG (n 6) 22.

<sup>1639</sup> Diedrich and others (n 1634) 937.

<sup>1640</sup> Wilkinson, Franke and Stroyan (n 440) 40.

<sup>1641</sup> von Schomberg (n 429) 58–59.

<sup>1642</sup> Diedrich and others (n 1634) 936.

<sup>1643</sup> Commission, 'Strategy for European Technology Platforms: ETP 2020 SWD(2013) 272 Final' 2.

<sup>1644</sup> *ibid* 3.

technological barriers<sup>1645</sup> and exhibit a similar balance of priorities displayed in EU policy.<sup>1646</sup>

Although ETPs are supposed to involve ‘all relevant stakeholders’,<sup>1647</sup> ETPs in the agri-food-forestry-biotech industries were mainly initiated by industry organisations led by multinational corporations.<sup>1648</sup> Even the Commission acknowledges the difficulty for SMEs in participating and the potential for capture by ‘big’ players<sup>1649</sup> perhaps squeezing dissent or insights from, for example, the social sciences.<sup>1650</sup> Indeed, the Commission has been the subject of a partially successful complaint to the European Ombudsman with respect to alleged industry dominance of the biofuels ETP and lack of objectivity in its advice.<sup>1651</sup> ETPs operate in partnership with the Commission, which ‘undertakes to take full account of relevant aspects of [their] research and innovation agendas’ and Commission representatives will ‘actively participate in the work of respective ETPs’.<sup>1652</sup> Indeed, state agencies and the Commission often defer to ETPs as the main experts, for example, in defining societal challenges<sup>1653</sup> and advice in implementing *Horizon 2020*.<sup>1654</sup> ETPs have successfully ‘contribut[ed] to the definition of research priorities including those under the Research Framework Programmes’,<sup>1655</sup> for example the KBBE.<sup>1656</sup> This ETP influence occurs through particular framings of

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<sup>1645</sup> *ibid* 4.

<sup>1646</sup> Plants for the Future ETP, ‘Strategic Research Agenda 2025 Summary’ (2007) 3.

<sup>1647</sup> Diedrich and others (n 1634) 937.

<sup>1648</sup> Levidow, Birch and Papaioannou (n 708) 50.

<sup>1649</sup> Commission, ‘ETP Strategy’ (n 1643) 3.

<sup>1650</sup> Diedrich and others (n 1634) 937.

<sup>1651</sup> The industrial focus was not a problem provided the ETP sought other views, Draft recommendations in complaint 1151/2008/(DK)ANA against the European Commission [33]. Discussed in Maria Lee, ‘Accountability and Co-Production Beyond Courts: The Role of the European Ombudsman’ in M Weimer and A De Ruijter (eds), *Regulating Risks in the European Union: The Co-production of Expert and Executive Power* (Hart forthcoming).

<sup>1652</sup> Commission, ‘ETP Strategy’ (n 1643) 3–4.

<sup>1653</sup> Levidow, Birch and Papaioannou (n 708) 61; Diedrich and others (n 1634) 936–937 in relation to the food and fuel ETP agendas.

<sup>1654</sup> Commission, ‘ETP Strategy’ (n 1643) 2.

<sup>1655</sup> *ibid*.

<sup>1656</sup> Levidow, Birch and Papaioannou (n 708) 50–51. ETPs can and do offer alternative visions of the KBBE, Levidow, ‘European Transitions’ (n 1587) 82–84.

natural resources, future markets and societal progress which informs broad research and innovation policy.<sup>1657</sup>

According to Jasanoff, the EU had to invent the discourse of problem-solving in order to justify its support of biotechnology. This involved identifying structural problems in healthcare and agriculture, emphasising the urgency of addressing them and positioning biotechnology as solution.<sup>1658</sup> Synthetic biology has been described as ‘awash with solutionism’<sup>1659</sup> and it now justifies itself on the basis of solving certain societal problems. In doing so, according to J. Benjamin Hurlbut, it ‘constructed itself as *able to respond*, and thus as *the right response*, to basic problems of human welfare and security’.<sup>1660</sup> This alchemy of societal challenges and innovation in yielding future economic gold can be seen in specific sectors. For example, the ‘Plants for the Future’ ETP advocates a coordinated innovation effort by industry, academic and farmers associations to feed the world. It projects that this will simultaneously cause the development of a sustainable, highly productive and competitive European plant sector and contribute to economic growth and job creation.<sup>1661</sup>

Sustainable development is a vague and almost infinitely malleable term.<sup>1662</sup> As such, it – and perhaps other generally framed societal challenges – could be a site for debate over alternatives, as promoted by RRI. In Chapter Three, I discussed its potential to respond ambitiously to many of the concerns relating to pesticide use. *Horizon 2020* provides that ‘all challenges should contribute to the overarching objective of sustainable development’.<sup>1663</sup> But whether contributions genuinely respond to societal needs or concerns is related to who has framed societal

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<sup>1657</sup> Levidow, Birch and Papaioannou (n 708) 51.

<sup>1658</sup> Jasanoff, *Designs on Nature* (n 11) 77–78; Herbert Gottweis, *Governing Molecules: The Discursive Politics of Genetic Engineering in Europe and the United States* (MIT Press 1998) 174.

<sup>1659</sup> Thomas (n 1636) 93.

<sup>1660</sup> Hurlbut, ‘Reimagining Responsibility’ (n 989) 113.

<sup>1661</sup> Plants for the Future ETP, ‘Building Sustainable Innovation Leadership in European Agriculture: An Innovation Action Plan to 2020’ (undated) 5.

<sup>1662</sup> Ross (n 528) 33.

<sup>1663</sup> Recital 12 Horizon 2020 - specific programme (n 390).

challenges and how. Any research activity could be described as contributing to sustainable development in the absence of any intellectual work to inject explicit substance or handle tensions among the possible aims of sustainable development.<sup>1664</sup> As discussed in Chapter Four, sustainability can be understood unambitiously. If framing problems or societal challenges pre-empts broader political debate, this raises questions over the existence of policy appetite or space for competing visions or socially-defined research agendas such as those potentially generated through RRI activities discussed in Chapter Three. Meanwhile, though the targets and justifications for research have changed (now societal challenges), the proposed solutions have remained capital-intensive innovation which can be brought to market with minimal consideration of its social or sustainability aspects.<sup>1665</sup>

Innovation, in the broadest possible terms, can unquestionably contribute to fulfilling social needs.<sup>1666</sup> There are fleeting suggestions in EU innovation policy that the EU views innovation broadly (despite the lack of an official definition of innovation<sup>1667</sup>), including for example social innovation or behavioural changes.<sup>1668</sup> However, the lack of interest in non-scientific/non-technological innovation or innovation which will not return a profit is palpable<sup>1669</sup> and overall, the dominant policy framework constrains such activity.<sup>1670</sup>

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<sup>1664</sup> Levidow and Neubauer (n 1626) 405.

<sup>1665</sup> Sybille van den Hove and others, 'The Innovation Union: A Perfect Means to Confused Ends?' (2012) 16 *Environmental Science & Policy* 73, 74–75; Levidow and Neubauer (n 1626) 408.

<sup>1666</sup> van den Hove and others (n 1665) 74. For example, John Bessant, 'Innovation in the Twenty-First Century' in Richard Owen, JR Bessant and Maggy Heintz (eds), *Responsible Innovation: Managing the Responsible Emergence of Science and Innovation in Society* (Wiley 2013).

<sup>1667</sup> van den Hove and others (n 1665) 74.

<sup>1668</sup> Horizon 2020 - specific programme (n 390); Commission, 'Horizon 2020' (n 350) 9; Commission, 'Innovation Union' (n 1578) 2, 18, 21.

<sup>1669</sup> Levidow and Neubauer (n 1626) 403.

<sup>1670</sup> *ibid* 405.

### 3.1.3 Governable emergence

EU innovation policy resembles Hurlbut's imaginary of governable emergence, which illustrates how the broader societal implications of technological emergence can become marginalised in innovation governance and regulation. According to Hurlbut, this imaginary has three dimensions. Firstly, technoscience is privileged as the source of novelty driving historical and social change. This, in turn, 'ascribes priority of agency to science'; technology emerges independently of any social context with society's role becoming merely reactive.<sup>1671</sup> Secondly, this conception of technoscience grants a 'scientific community' 'competence (and responsibility) to generate and adequately characterise novelty and decree what forms of novelty warrant societal attention'.<sup>1672</sup> Thirdly, granting scientists this role comes with a 'vision of the right allocations of responsibility between institutions of governance'. Technology thus conceptualised as a site of social emergence has the consequence that 'governance rests on epistemic questions about the nature of the technology': its newness, predictable consequences etc. are questions for regulatory science and therefore experts.<sup>1673</sup> Here, science is imagined as the institution most capable of governing technological emergence. 'Normative questions of what is at stake, what is the public good and who has the authority to define benefits and harms are thereby rendered subsidiary to expert assessments of novelty'<sup>1674</sup> and the types of questions which can be raised are limited.<sup>1675</sup>

Each dimension of this imaginary can be detected in the EU policy on innovation examined in this chapter. For example, both the policy emphasis on technological innovation as driver of social and economic change through providing solutions to European problems, identified above, and the idea of technology as neutral and not

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<sup>1671</sup> Hurlbut, 'Remembering the Future' (n 1008) 128.

<sup>1672</sup> *ibid.*

<sup>1673</sup> *ibid* 128–129.

<sup>1674</sup> *ibid* 129.

<sup>1675</sup> J Benjamin Hurlbut, 'Limits of Responsibility: *Genome Editing, Asilomar, and the Politics of Deliberation*' (2015) 45 *Hastings Center Report* 11, 12.

socially shaped, discussed in section 3.1.4, privilege technoscience as the source of novelty.

Furthermore, the EU identifies a need to build the 'right regulatory environment'.<sup>1676</sup> It perceives (outdated or unnecessary) regulatory procedures or over-regulation in approval procedures as obstacles to industry and innovation,<sup>1677</sup> raising development costs and increasing time to market.<sup>1678</sup> According to the Plants ETP, there is too big a separation between the policy goals of stimulating innovation and health/consumer protection policy seeking to control market access for innovations; a divide which creates a huge gap between areas of the world embracing plant-based innovation and Europe, where promising innovations remain blocked in the pipeline.<sup>1679</sup> New techniques and technologies should be regulated in a 'fair and transparent manner on the basis of an independent, objective safety assessment and without political interference'.<sup>1680</sup> It cites GM crops as an example of a technology whose development regulation severely limited, hindering transition to the KBE, and warns of the consequences of a repeat with other technologies essential for Europe's future global economic competitiveness.<sup>1681</sup> Improving and harmonising regulation here is part of the EU's project to reduce fragmentation in its internal market and innovation system to enable businesses to maximise their returns on the resources allocated to innovation,<sup>1682</sup> release the potential of the internal market to incentivise innovation<sup>1683</sup> and transform innovation into wealth.

Risk assessment, particularly as source of apparently rational and objective scientific evidence for decision-making, as discussed in Chapter Two, slots neatly

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<sup>1676</sup> Commission, *Open Innovation* (n 431) 18–21; Commission, 'Innovation in a Knowledge-Driven Economy' (n 1579) 5, 9, 18; Commission, 'ERA New Perspectives' (n 1598) 7.

<sup>1677</sup> Commission, 'Innovation in a Knowledge-Driven Economy' (n 1579) 9, 15, 18; Commission, 'Innovation Union' (n 1578) 7.

<sup>1678</sup> Commission, 'Innovation in a Knowledge-Driven Economy' (n 1579) 9, 18.

<sup>1679</sup> Plants for the Future ETP (n 1661) 8.

<sup>1680</sup> *ibid* 7.

<sup>1681</sup> *ibid*; Plants for the Future ETP (n 1646) 4.

<sup>1682</sup> Commission, *Open Innovation* (n 431) 17; Aho (n 1596) 5–7.

<sup>1683</sup> Commission, 'Innovation in a Knowledge-Driven Economy' (n 1579) 6; Aho (n 1596) 5.

into this framework. Appeals in policy for science-based regulation alongside initiatives to educate the public about change, innovation and its benefits indicates both how responsibility for defining which novel implications deserve societal attention has been allocated (i.e. to scientific experts) and that the relevant questions are regarded as epistemic rather than normative.

Risk-based regulation, in which effort and resources are channelled towards the most risky activities or entities, is apparently rational and its deregulatory<sup>1684</sup> effect is to protect a space of freedom and opportunity for enterprise.<sup>1685</sup> Risk assessment as a form of measurement can (though not always<sup>1686</sup>) depoliticise,<sup>1687</sup> constraining scope for disagreement and implying that political contestation is over. Opposition based on uncertainty may be marginalised as partisan and poor regulatory science.<sup>1688</sup> However, the impression that political and moral questions have been resolved is often inappropriate in the sometimes bitterly contested terrain of technological innovation where there have been increasing demands for politicisation<sup>1689</sup> and where politicians have been criticised for using expert advice to avoid responsibility for decisions.<sup>1690</sup>

The imaginary of governable emergence casts the law as permanently lagging, reactive and potentially inhibitory of scientific progress<sup>1691</sup> where it should facilitate. While criticism of those characteristics is commonly expressed, Hurlbut argues that this lag is in fact deemed 'necessary', liberating science to produce novelty.<sup>1692</sup> Thus, scientific risk assessment demands restraint from the law pending confirmation that a particular form of novelty warrants legal response.<sup>1693</sup> The

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<sup>1684</sup> Fisher, 'Risk and Environmental Law' (n 17) 104–108.

<sup>1685</sup> Power (n 1529) 22.

<sup>1686</sup> Barry (n 46) 89–90, 93–94.

<sup>1687</sup> Lee, 'GMOs in the Internal Market' (n 871) 333–334.

<sup>1688</sup> Jamey Essex, 'Biotechnology, Sound Science, and the Foreign Agricultural Service: A Case Study in Neoliberal Rollout' (2008) 26 *Environment and Planning C: Government and Policy* 191, 194.

<sup>1689</sup> Barry (n 46) 92.

<sup>1690</sup> Levidow, 'European Public Participation' (n 969) 24; Kearnes and others (n 4) 297.

<sup>1691</sup> Hurlbut, 'Remembering the Future' (n 1008) 127.

<sup>1692</sup> *ibid* 130.

<sup>1693</sup> *ibid* 129.

epistemological framework it sets up converts moral uncertainties into questions of risk, extinguishing space for other moral framings.<sup>1694</sup> This responsibility for predicting risks and benefits delegated to science by law,<sup>1695</sup> though perhaps not *necessarily* deregulatory, can be exploited in expedient arguments, depending on the goal of the communication, about the newness or sameness of, for example, (bio)technology,<sup>1696</sup> which can condition regulatory responses and facilitate technological development.<sup>1697</sup> It may, in particular, limit regulatory responses sensitive to any implications of innovation not assessable by science. This establishes a rather incremental approach to governance and regulation. For example, with respect to the (inherited<sup>1698</sup>) regulation of synthetic biology, it ‘authorizes science to measure new and ungoverned potentialities against known forms of novelty thereby delimiting uncertainty to defining strategies for the containment of discernible risks’.<sup>1699</sup> The presence of this imaginary certainly does not indicate regulatory frameworks supportive of the promised socio-technical integration and suggests that only the worst consequences of market liberalisation, for example in the environmental sphere, are regulated.<sup>1700</sup>

Thus, the familiar dichotomy between facts and values is reproduced, with normative questions following expert assessments of novelty.<sup>1701</sup> Novelty’s reprieve from wider social assessment obscures the extent to which it is itself constructed in socio-technical terms.<sup>1702</sup> Hurlbut attributes this to an imagination of society’s capacity, through its governance mechanisms, to assimilate new technologies and contain their potential for harm interfering only where risks

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<sup>1694</sup> *ibid* 140.

<sup>1695</sup> *ibid* 146.

<sup>1696</sup> Phil Macnaghten, ‘Researching Technoscientific Concerns in the Making: Narrative Structures, Public Responses, and Emerging Nanotechnologies’ (2010) 42 *Environment and Planning A* 23, 33.

<sup>1697</sup> Elen Stokes, ‘Regulatory Domain and Regulatory Dexterity: Critiquing the UK Governance of “Fracking”’ (2016) 79 *The Modern Law Review* 961.

<sup>1698</sup> For example, Stokes, ‘Recombinant Regulation’ (n 131). See Chapter Five.

<sup>1699</sup> Hurlbut, ‘Remembering the Future’ (n 1008) 147. See also Jasanoff and Kim (n 828).

<sup>1700</sup> Castree (n 1617) 143.

<sup>1701</sup> Hurlbut, ‘Remembering the Future’ (n 1008) 129.

<sup>1702</sup> *ibid*.

genuinely demand, leaving clear passage for the emergence of good technologies via the market. Thus, according to Hurlbut, ‘science has authority to construct – and constrain – public imagination of what counts as legitimate and valuable progress’.<sup>1703</sup>

#### 3.1.4 *Innovation as both neutral and inherently good*

Despite the presence of research-orientating societal challenges, the narrative arcs of economic competitiveness and social progress contingent on technological advance arguably reflect the implicit dogma of EU innovation policy that all and any innovation, though neutral and directionless, is inherently socially beneficial.<sup>1704</sup> For the EU, innovation becomes an end in itself.<sup>1705</sup> This dogma follows a ‘framing narrative’ that knowledge and the innovation it produces are not socially shaped which persists even despite acknowledgment that risk knowledge may be.<sup>1706</sup> This perpetuates the assumption that scientific research questions are independent, reproducing the self-governing scientific community in its role of truth producer, and the model of facts before values.<sup>1707</sup> The assumption is hard to sustain given the economic values which underpin much of the EU’s innovation policy and the type of innovation it appears to promote, discussed above.

Likewise, simplistic diagnoses of an insufficiently innovation-friendly European market<sup>1708</sup> ignore the underlying *reasons* for controversies and the fact that one man’s silver bullet is another’s WMD. This denies the interpretive flexibility of innovation,<sup>1709</sup> ignores the politics of artefacts which can reinforce existing inequalities<sup>1710</sup> and that technology itself can be shaped through, for example, visions and the policies built on them.<sup>1711</sup> It obscures in particular the politics and

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<sup>1703</sup> *ibid.*

<sup>1704</sup> von Schomberg (n 429) 58; for example Commission, ‘Innovation in a Knowledge-Driven Economy’ (n 1579) 25.

<sup>1705</sup> von Schomberg (n 429) 54.

<sup>1706</sup> EGSG (n 6) 75.

<sup>1707</sup> *ibid.*

<sup>1708</sup> Aho (n 1596) vii.

<sup>1709</sup> Bijker (n 22).

<sup>1710</sup> Winner (n 20).

<sup>1711</sup> Jasanoff and Kim (n 828) 120.

(primarily economic) values behind this construction of innovation while simultaneously implicating those politics. It both assumes and prescribes the unfolding of innovation in a certain way without human agency and, as a narrative, extinguishes space for alternatives.<sup>1712</sup> It cloaks the political choice which this chapter seeks to uncover and which frameworks such as RRI could re-open. Political contestation is arguably further displaced by the vagueness of ‘societal challenges’ which eliminates cause for disagreement, even though they include climate change, which is surely one of the most politically-charged contours of the modern era.

The EU’s conception and expectations of innovation are full of assumptions. Innovation is frequently a double-edged sword<sup>1713</sup> and its macroeconomic benefits, for example GDP growth, do not necessarily spur improvements in health, well-being or sustainability.<sup>1714</sup> It does not necessarily drive economic growth<sup>1715</sup> nor create more, or better, jobs;<sup>1716</sup> indeed, the Commission cited the tendency of pesticides to reduce the need for labour as a benefit.<sup>1717</sup> The overall predisposition of technology to deskill<sup>1718</sup> demands deeper questioning of the assumption that innovation will create better jobs. However, despite clear public concern generally over the speed of innovation,<sup>1719</sup> policy sees only the speed of innovation processes as capable of modulation,<sup>1720</sup> so as to accelerate products to market and increase returns on R&D investment.<sup>1721</sup>

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<sup>1712</sup> EGSG (n 6) 75–76.

<sup>1713</sup> This thesis, passim; van den Hove and others (n 1665) 76, although these are often externalised as mistaken technological (rather than political) choices or as public misperception of technology’s advances and benefits, EGSG (n 6) 76–77.

<sup>1714</sup> van den Hove and others (n 1665) 75. Already synthetic artemisinin seems not to be fulfilling its original hype, Mark Peplow, ‘Synthetic Biology’s First Malaria Drug Meets Market Resistance’ (2016) 530 *Nature News* 389.

<sup>1715</sup> EGSG (n 6) 21.

<sup>1716</sup> van den Hove and others (n 1665) 76.

<sup>1717</sup> Commission, ‘Towards a Thematic Strategy’ (n 514) 11.

<sup>1718</sup> Sismondo (n 23) 97.

<sup>1719</sup> Macnaghten and Chilvers (n 27) 536.

<sup>1720</sup> For example, Commission, *Open Innovation* (n 431) 38, 42; Wilkinson, Franke and Stroyan (n 440) 42–43.

<sup>1721</sup> Levidow and Neubauer (n 1626) 403; Wilkinson, Franke and Stroyan (n 440) 42–43.

### 3.1.5 *The public as resource and obstacle*

Improvements are required of the European public and culture which are currently not producing the right type of consumers. For example, the lower growth rate identified in Europe before the economic crisis is attributed to, *inter alia*, ‘reluctance in some parts of our societies to embrace innovation’ and an insufficiently innovation-friendly EU market<sup>1722</sup> which may stem from cultural or institutional factors<sup>1723</sup> and a ‘weak understanding of science, technology and change’.<sup>1724</sup> *The Aho Report* reported a lack of ‘demanding and novelty-seeking customers’ as a major barrier in service innovation<sup>1725</sup> and called for a shift to a culture which celebrates and embraces innovation and risk-taking.<sup>1726</sup> The achievement of all objectives realisable by innovation requires a society open to innovation.<sup>1727</sup>

Citizens have a role, certainly, but perhaps not necessarily one which involves debating ‘what science (and innovation) for what society?’ (and vice versa);<sup>1728</sup> rather one confined within the pre-defined innovation policy framework and its justifications and commitments. There is a degree of resemblance to contemporary frameworks for participation described by Power and Crouch above. For example, citizens may be seen partly as a resource in innovation systems, providing knowledge and ideas, co-creating new products, creating demand, providing funding and even the necessary trust<sup>1729</sup> but not as originators of alternative collective visions.

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<sup>1722</sup> Commission, ‘Europe 2020’ (n 580) 7; Commission, ‘Innovation Union’ (n 1578) 7; Aho (n 1596) 1.

<sup>1723</sup> Commission, ‘Innovation in a Knowledge-Driven Economy’ (n 1579) 15.

<sup>1724</sup> *ibid* 24.

<sup>1725</sup> Aho (n 1596) 5.

<sup>1726</sup> *ibid* 23–24.

<sup>1727</sup> Commission, ‘Innovation in a Knowledge-Driven Economy’ (n 1579) 16.

<sup>1728</sup> ‘Science With and For Society’ Advisory Group, ‘Strategic Opinion for Research and Innovation in the Horizon 2020 Work Programme 2018-2020’ (2016) and references therein.

<sup>1729</sup> Commission, *Open Innovation* (n 431) 13–14, 17. 30; Commission, ‘Innovation Union’ (n 1578) 12.

In contrast to much of the slightly confused but relatively optimistic policy examined in Chapters Three and Five on taking into account public concerns and values in research and innovation, models for governance expressed elsewhere in EU innovation policy frequently ignore those initiatives and their reasoning. For example, running in parallel to a scientific evidence-based regulatory framework, a reductive and instrumental agenda for securing public trust in scientific and technological breakthroughs provides for ‘transparent information and involvement of citizens’ thereby ensuring a favourable environment for investment.<sup>1730</sup> The assumption seems to be that transparency and token involvement thrown in while the bio-cultured future ferments is sufficient, ignoring how scientific evidence, information and citizen involvement will interact. The Plant ETP provides a striking example of this disconnect. Having called for public involvement in discussing R&D goals, rebuilding trust and integrating ethical issues into research agendas, it immediately declares that the public does not understand that the ‘EU has established a rigorous safety-based regulatory system that evaluates crop plants before they can be placed on the market’.<sup>1731</sup>

Similarly, in the context of KBBE policy, participative governance, dominated by the transmission of information, seems founded on the cognitive deficit model.<sup>1732</sup> Here, science and innovation are the basis both for policy-making and ‘informed societal choices’<sup>1733</sup> with even socio-economic studies being used to ‘design new ways of attracting and informing consumers about [the] benefits’ of innovative bio-products.<sup>1734</sup> And, specifically with respect to food, enhancing consumer trust and protection is regarded as contingent on ‘[f]ood safety innovations, improved tools for risk and risk-benefit assessment and for risk communication and improved food safety standards’,<sup>1735</sup> with socio-economic, cultural and ethical questions relegated

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<sup>1730</sup> Commission, ‘Innovation Union’ (n 1578) 12.

<sup>1731</sup> Plants for the Future ETP (n 1646) 11.

<sup>1732</sup> Hurlbut, ‘Remembering the Future’ (n 1008) 144 and references therein.

<sup>1733</sup> Commission, ‘Innovating for Sustainable Growth’ (n 1589) 7, 9.

<sup>1734</sup> Commission, *A Bioeconomy Strategy for Europe* (n 1621) 3.

<sup>1735</sup> Horizon 2020 - specific programme (n 390).

to a vague intention to address ‘other aspects’.<sup>1736</sup> Again, science is granted priority in defining relevant problems.

In its report, *Taking European Knowledge Society Seriously*, the EGSG identified an ambiguity in the Lisbon Strategy between translating research into commodities and a commitment to public engagement,<sup>1737</sup> also identifiable in subsequent policy (see for example that discussed in Chapter Five). According to Les Levidow and Claudia Neubauer, the EU opted for the former and initiatives based on the latter have remained marginal in policy and research funding.<sup>1738</sup> That might appear a little strong given the resources now ploughed into RRI initiatives, discussed in Chapter Three, but perhaps is still reasonable given the risk RRI runs of instrumentalisation for commercial ends or pre-committed policies.<sup>1739</sup> Furthermore, the emphasis on provision of information perhaps betrays a post-political assumption of the impossibility of any rational disagreement with the ‘objective’ truth enshrined in the EU’s policy goals and attempts to manoeuvre public opinion into the correct position.

### 3.1.6 Summary

EU innovation policy exhibits certain logics and assumptions. Its depoliticising tendencies may be construed in, for example, simplistic statements about the choice facing Europe. The undesirable alternative to innovation-driven competitiveness is such as to expect consensus around its vision and to cast disagreement as irrational. In this conception, politics is perhaps ‘either the irrational opposite or the rational application of science’.<sup>1740</sup> (Bio-)technological innovation is isolated as the only, or at least, primary means to secure Europe’s future. The economic rationalism of the discourse re-makes EU citizens as apolitical consumers.<sup>1741</sup> More products and/or services in the marketplace leads to more

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<sup>1736</sup> *ibid* 2.2.3.

<sup>1737</sup> EGSG (n 6) 11.

<sup>1738</sup> Levidow and Neubauer (n 1626) 400.

<sup>1739</sup> Stilgoe, Lock and Wilsdon (n 368) 8; Owen, Macnaghten and Stilgoe (n 350).

<sup>1740</sup> Meyer (n 930) 434.

<sup>1741</sup> Dryzek (n 528) 134, 136.

consumption which creates growth and jobs and thereby increased well-being. However, the logic behind this innovation imperative is not necessarily beyond political contestation.<sup>1742</sup> Moreover, the policy is notably light on analysis of the socio-political causes of challenges<sup>1743</sup> (characteristic of ‘solutionism’) and details as to how environmental, social and economic sustainability will emerge as a natural consequence of this model, especially since technological innovation has often been the cause of societal problems.<sup>1744</sup> There is, furthermore, evidence of public scepticism and disapproval of this expectation of increased consumption.<sup>1745</sup>

### 3.2 *The power of imaginaries*

State power and resources can endow imaginaries with a particular durability, true too of the EU whose policy engine is well-equipped to define and sustain visions for its future and roadmaps for their achievement.<sup>1746</sup> As an example, the EU’s above imaginaries are partly enshrined in Article 179(1) TEU: ‘The Union shall have the objective of strengthening its scientific and technological bases by achieving a European research area in which researchers, scientific knowledge and technology circulate freely, and encouraging it to become more competitive, including in its industry...’.<sup>1747</sup>

Part of the power of imaginaries resides in their ability to inform strategies to accrue institutional, political and material backing for their priorities and to line up support for their achievement from wider policies.<sup>1748</sup> This is seen, perhaps, in the explicit call for innovation to become the EU’s overarching policy goal to which all activity under other policies contributes with the highest political level setting the

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<sup>1742</sup> van den Hove and others (n 1665); Bessant (n 1666) 1.

<sup>1743</sup> Goven and Pavone (n 1514) 315; Vincenzo Pavone, Joanna Goven and Riccardo Guarino, ‘From Risk Assessment to in-Context Trajectory Evaluation - GMOs and Their Social Implications’ (2011) 23 *Environmental Sciences Europe* 3.

<sup>1744</sup> van den Hove and others (n 1665) 74.

<sup>1745</sup> Phil Macnaghten and Julia S Guivant, ‘Converging Citizens? Nanotechnology and the Political Imaginary of Public Engagement in Brazil and the United Kingdom’ (2011) 20 *Public Understanding of Science* 207, 215, 217.

<sup>1746</sup> Jasanoff and Kim (n 828) 123–124.

<sup>1747</sup> Levidow, Birch and Papaioannou (n 708) 48.

<sup>1748</sup> *ibid* 60; Jasanoff and Kim (n 828) 120.

strategic agenda.<sup>1749</sup> The mobilisation of such support and resources for technological innovation may thereby change institutional practices, especially in funding priorities;<sup>1750</sup> funds distributable under *Horizon 2020* are intended for projects contributing to the realisation of the EU's imaginaries. Depoliticising education and communication strategies to persuade citizens of the pre-determined benefits as opposed to listening to, reflecting on, learning from and responding to their thoughts and concerns, discussed too in Chapter Five, are perhaps further manifestations of these phenomena, reinforced by calls for science-based indications of appropriate interventions, reminiscent of the imaginary of governable emergence.

This last point speaks to a further quality of imaginaries. In addition to corralling support, they may justify countering or silencing political opposition,<sup>1751</sup> for example by 'reconfigur[ing] actors' sense of the possible spaces of action'.<sup>1752</sup> Although socio-technical orders are not natural nor intrinsic to humans or things<sup>1753</sup> meaning that we have choices, in the EU's imaginaries there is little room to question the origin of the accepted definition of society's problems or the accepted understanding of a 'worthwhile' objective or outcome.<sup>1754</sup> The coherence of the visions of Europe's gilded future spun from imaginary thread through its prodigious output of policy enables Europe to justify interventions, promote specific policy changes and pre-empt or marginalise 'disruptive public responses'<sup>1755</sup> and the consideration of alternatives. For example, FP7 funding priorities dominated by a life sciences vision of the KBBE and capital-intensive research agendas aimed at increasing efficiency marginalised alternative visions, agendas<sup>1756</sup> or

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<sup>1749</sup> Commission, 'Innovation Union' (n 1578) 2.

<sup>1750</sup> Levidow, Birch and Papaioannou (n 708) 41.

<sup>1751</sup> Jasanoff and Kim (n 828) 120, 123.

<sup>1752</sup> Jasanoff, 'Future Imperfect' (n 1567) 23.

<sup>1753</sup> Jasanoff, 'Imagined and Invented Worlds' (n 1625) 339.

<sup>1754</sup> EGSG (n 6) 76.

<sup>1755</sup> *ibid* 75.

<sup>1756</sup> Levidow, Birch and Papaioannou (n 708) 51–52; Birch, Levidow and Papaioannou (n 1586) 2899; Commission, 'ERA New Perspectives' (n 1598) 18.

imaginaries.<sup>1757</sup> EU policy on ‘the Knowledge Society’ and ‘the Knowledge Economy’ though ostensibly disinterested, reveals its politics in the privileging of certain types of knowledge; the bioeconomy (and its attendant problem definitions) rather than the eco-economy is chosen.<sup>1758</sup> Within that choice, the life sciences vision prevails over an agro-ecological vision.<sup>1759</sup> And within that choice again, certain *types* of advanced biotechnology are privileged, marginalising others *and* other innovations.<sup>1760</sup>

Similarly, though he uses different language, many features of Hurlbut’s imaginary are identifiable as characteristic of post-politics. For example, the rush to rationalism in the prioritisation of expert over political judgments; faith in management in the idea of governability – restricted to containing risk – and the control of public reaction; and state intervention through defining, controlling and being seen to control those risks. These are assisted by the predictability of the linear model of innovation. All these arrangements lock out others from the construction of those technological futures by stipulating who, how and in what they are competent to participate.<sup>1761</sup>

Another facet to this circumstance is visibility. Imaginaries may determine which goals or concerns are visible or important by constructing, training and delimiting what a viewer may perceive. They can simplify an infinitely complex world by attributing meaning to some aspects of life over others,<sup>1762</sup> privileging certain attainable and desirable future economic relations, thereby pre-figuring and

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<sup>1757</sup> OECD policy on the bioeconomy almost seems to fear alternative solutions, suggesting that the aim is not actually to solve the problems but rather tackle them in a particular way, Goven and Pavone (n 1514) 315.

<sup>1758</sup> Andy Stirling, ‘Power, Truth and Progress: Towards Knowledge Democracies in Europe’ in James Wilsdon and Robert Doubleday (eds), *Future Directions for Scientific Advice in Europe* (Centre for Science and Policy 2015) 135–136.

<sup>1759</sup> Levidow, Birch and Papaioannou (n 708) 61; Vanloqueren and Baret (n 707).

<sup>1760</sup> Stirling, ‘Power, Truth and Progress’: (n 1758) 136; Goven and Pavone (n 1514) 313.

<sup>1761</sup> Hurlbut, ‘Remembering the Future’ (n 1008) 141–142; Jasanoff, ‘Imagined and Invented Worlds’ (n 1625) 329.

<sup>1762</sup> Jessop (n 1569) 338.

facilitating their realisation.<sup>1763</sup> For example, economic competition occurs but, in imaginary terms, forms a simplified structure for guiding economic action which smooths the grain of cause and effect.<sup>1764</sup> According to Jasanoff, sight is conditioned by history with 'its choices and exclusions' determining what is (in)visible,<sup>1765</sup> reinforced by a sense of 'the rightness of action' which imaginaries can confirm.<sup>1766</sup> On this analysis, the EU may have become blind to other perspectives, problem framings and concerns by the cloud of its past failures or the promising glare of the visions to which it remains committed. The type of public concern still visible is risk, as demonstrated by the calls for science- or evidence-based governance. Vision, and other techniques (such as metaphors,<sup>1767</sup> or linking new ideas (eco-efficiency) with established ones (sustainability)) naturalise and familiarise so organised criticism or opposition may never occur.<sup>1768</sup> Part of the potential of alternative narratives and frameworks, such as sustainability and RRI, is as contrasting ways of viewing the world, making its problems and possible futures visible again by challenging and disrupting the dominance of current narratives, imaginaries and frameworks. As discussed in the following chapter however, these alternatives are fragile and the task is a delicate one.

Any (official) space for political disagreement is restricted. 'Different visions' implied by references to the 'European social model' or the 'European way of life', are absorbed (or perhaps, better, appropriated) into the imaginaries of Europe's future, contingent on innovation-driven progress. The EU's official language of 'common visions' for a future Europe 'downplay[s] societal tensions and reinforce[s] dominant political-economic actors as neutral experts',<sup>1769</sup> again

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<sup>1763</sup> B Jessop, 'Cultural Political Economy, the Knowledge-Based Economy, and the State' in Andrew Barry and Don Slater (eds), *The Technological Economy* (Routledge 2005) 147; Levidow, Birch and Papaioannou (n 708) 60.

<sup>1764</sup> Ngai-Ling Sum and Bob Jessop, 'Competitiveness, the Knowledge-Based Economy and Higher Education' (2012) 4 *Journal of the Knowledge Economy* 24, 26.

<sup>1765</sup> Jasanoff, 'Future Imperfect' (n 1567) 13 and references therein.

<sup>1766</sup> *ibid* 23.

<sup>1767</sup> Levidow, Papaioannou and Birch (n 1600) 172.

<sup>1768</sup> Jasanoff, 'Future Imperfect' (n 1567) 14.

<sup>1769</sup> Levidow, Birch and Papaioannou (n 708) 61.

disguising underlying political choices and the uncollaborative and undemocratic shaping of these imaginaries.<sup>1770</sup> Trade-offs such as environmental or health risks are dissolved through the rhetoric of reconciliation or governable emergence with its assurances of management and control and exclusion of alternative visions, concerns or problem definitions. The KBBE provides an example of this, perhaps dubious, reconciling in its promise to de-couple economic growth from unsustainability and environmental harm.<sup>1771</sup> Such a 'win-win' promise reinforces the durability and consensus-generating power of this imaginary by offering something meriting universal approbation.<sup>1772</sup> To some extent, these visions resemble sustainability; vague enough to accrue mass support but malleable enough to be co-opted by specific interests which are able to take advantage of that support to push their agendas and conceal underlying political choices.

This, and the enormous amount of work EU policy expends on promoting and generating acceptance for its imaginaries, may suggest, in certain senses, that the EU is aware of their fundamental fragility. This is perhaps best illustrated by the absurdity of the contention, patent once disinterred from EU policy logic, that 'European culture' in all its vastness, maturity and diversity, is ill-adapted to innovation, rather than that the type of innovation pushed is ill-adapted to European culture. People oppose or support a specific technology as a synecdoche for the future.<sup>1773</sup> In short, the EU's imaginaries again depoliticise by helping occlude alternative values and visions. When that filter falters and those values become visible, they are reconcilable. If they are not reconcilable, they are worth sacrificing for the benefits.

The purpose of this section has been to demonstrate how the allure of the EU's imaginaries can partially explain its unswerving commitment to their achievement, at almost any cost. The greatness of both the potential prize and loss in the event of failure perhaps steels its reluctance to apprehend concerns over uncertainties,

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<sup>1770</sup> EGSG (n 6) 46.

<sup>1771</sup> Commission, *A Bioeconomy Strategy for Europe* (n 1621) 3. And Chapter Nine.

<sup>1772</sup> Goven and Pavone (n 1514) 307.

<sup>1773</sup> Felt (n 206) 121.

the speed or ambiguous implications of innovation and proposals for alternative problem-definitions and solutions which it views as threatening to derail progress. The post-political search for a rational consensus perhaps encourages the channelling of such concerns into risk assessment as a means to avoid derailment by dispelling disagreement with 'objective facts'.

#### 4. Narrative reinforcements

The EU's self-imposed 'innovate or die!' mandate is not the complete picture. Imaginaries are reflected in, sustained and guided by master narratives which perform various legitimating functions.<sup>1774</sup> Master narratives are 'sweeping, entrenched accounts' which 'define horizons of possible and acceptable action, reproduced as normal and taken-for-granted and may lie beyond rational debate or deliberate re-design such that supporting evidence is no longer required';<sup>1775</sup> they themselves provide justification or explanation.<sup>1776</sup> From an unchallengeable vantage they both describe and prescribe, serving 'as prior framing, starting-point, justification and mode of sense-making for the policy domain'.<sup>1777</sup> They operate as an immutable constant, though, like imaginaries, account for society's historical path 'while also constraining that society to performing the imagined lines of the story'.<sup>1778</sup> Like imaginaries too, they can 'orient policymaking and thereby direct resources to particular forms of technoscience'.<sup>1779</sup> They therefore wield a great deal of power in controlling imagination.<sup>1780</sup> Here, they link ideas of progress to science and technology.<sup>1781</sup>

It is worth picking out certain narrative threads in the warp and weft of the above imaginary weave which contribute to reinforcing the EU's imaginaries. Firstly, the

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<sup>1774</sup> Agnes Heller, 'European Master Narratives about Freedom' in Gerard Delanty (ed), *Handbook of Contemporary European Social Theory* (Routledge 2005) 257.

<sup>1775</sup> EGSG (n 6) 73–74.

<sup>1776</sup> Jasanoff and Kim (n 828) 123.

<sup>1777</sup> EGSG (n 6) 75–76.

<sup>1778</sup> Jasanoff, 'Future Imperfect' (n 1567) 20.

<sup>1779</sup> Levidow, Birch and Papaioannou (n 708) 40.

<sup>1780</sup> Heller (n 1774) 257.

<sup>1781</sup> EGSG (n 6) 12.

master narrative of science, technology and progress which conflates societal ‘progress’ with ‘technological advance’ and privileges scientific knowledge,<sup>1782</sup> as embodied in the KBE.<sup>1783</sup> This master narrative has exercised a powerful influence over public science policy since before the Enlightenment, in its original formulation in Francis Bacon’s powerful declaration in 1605 that a purpose of science discovery should be ‘the relief of man’s estate’.<sup>1784</sup> Here, it operates in contrast to the imaginary of Europe’s unrealised innovation potential, implying that Europe will be on the wrong side of history if it does not improve.<sup>1785</sup>

Again, innovation is unequivocally good. Problem definitions and proposed solutions are unquestioned. There is no debate over what ‘progress’ looks like or alternatives, so democratic input is minimised and the real risks stem from failure to innovate<sup>1786</sup> blamed on European risk aversion at odds with the tide of technoscientific progress. This master narrative perhaps helps maintain the imaginary of governable emergence in two ways. Firstly by characterising social mechanisms to control technology, such as law, ethics or serious public engagement as lagging behind or braking progress,<sup>1787</sup> even though the law can in fact anticipate.<sup>1788</sup> Secondly, (and particularly where novelty is downplayed while control, improvement and precision are played up<sup>1789</sup>) by reinforcing a minimalist approach to social oversight due to science and technology’s unambiguous status as social saviour.<sup>1790</sup> This master narrative contains many elements in common with the imaginaries discussed in section 3.1. The difference is that set in a master

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<sup>1782</sup> *ibid* 73–74.

<sup>1783</sup> Birch, Levidow and Papaioannou (n 1586) 2899.

<sup>1784</sup> Macnaghten and Guivant (n 1745) 213; JJ Ramsden, ‘For the Relief of Man’s Estate?’ (2008) 8 *Journal of Biological Physics and Chemistry* 71, 71.

<sup>1785</sup> For example, Aho (n 1596).

<sup>1786</sup> EGSG (n 6) 76–77.

<sup>1787</sup> *ibid* 77.

<sup>1788</sup> Brownsword (n 1000) 28–30.

<sup>1789</sup> As with genetic engineering and nanotechnology Macnaghten (n 1696) 25, 33; Macnaghten and Guivant (n 1745) 213 and references in both.

<sup>1790</sup> Macnaghten (n 1696) 33.

narrative they form part of a justifying, historical and universal arc, thereby reinforced.

Secondly, the master narrative of objectivity and rationality, which makes depoliticising calls for evidence-based decision-making while rarely questioning the origin of the required expertise or the problem definitions to be addressed. It assumes, reinforcing the imaginary of governable emergence, that science facts should first establish a framework for subsequent, rational discussion of alternatives, values or regulation thereby deemed relevant. As discussed in Chapter Two, this model of perfectly separated facts and values and purely objective regulatory science is flawed, yet its sedimentation here in risk assessment-based regulation places it beyond easy challenge.<sup>1791</sup>

A third master narrative simultaneously praises the public for its role as supporter and consumer in diffusing innovation while blaming its ignorance for obstructing the technological path towards solving urgent societal challenges and economic growth. The response is public engagement but, though a right to participate may increase rhetorically, those framings of resource/obstacle persist and may restrict even upstream engagement,<sup>1792</sup> reflecting a post-political tendency to manage and manipulate, discussed in section 2. The more comprehensive framework of RRI could provide a partial solution, discussed further in Chapter Nine. However, as discussed in Chapter Five, policy on participation is confused as to its aim, partly due to those constructions of the public. In addition, urgency and the leadership imperative 'inhibits our capacity and/or willingness to experiment with alternatives' in our search for progress and to 'assess the potential of scientific knowledge against the objective we want to achieve with it'.<sup>1793</sup>

Finally, the narratives above are set in a master economic narrative of increasing global economic competition as a result of intensifying globalisation and the rise of

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<sup>1791</sup> EGSG (n 6) 77.

<sup>1792</sup> *ibid* 78.

<sup>1793</sup> *ibid* 79.

new powers, such as China and India.<sup>1794</sup> The EU regarded these developments as threatening its global economic competitiveness<sup>1795</sup> and therefore future prosperity and living standards, coming at a time (1980s and 1990s) of low growth and ‘techno-economic’ decline, amongst other things.<sup>1796</sup> The European response to the perceived threat was a commitment to providing an innovation-friendly market for businesses,<sup>1797</sup> the lack of which was the main barrier to investment, in order to catch up.<sup>1798</sup>

As discussed, the KBE is a particular incarnation of the economic competitiveness narrative. Pointing to its depoliticising effect, its position in EU-wide and national policy frameworks and configuration by R&I policy elites arguably removes the need for popular acceptance, acquiescence or even awareness.<sup>1799</sup> For example, the sedimentation of the ideas of competitiveness as common-sensical and beyond discussion<sup>1800</sup> or likewise of innovation as universal salve, could discourage scrutiny of the choice to pursue primarily economic ends, the compatibility of that goal with addressing societal challenges, the presentation of potential benefits as certainties and the types of benefits seen as worthwhile. Indeed, the pervasiveness of this discourse in policy, despite academic scepticism,<sup>1801</sup> reveals its power and ubiquity in policy circles.<sup>1802</sup> Spokespersons for scientific institutions complain that policy-makers ‘take unsubstantiated concerns of environmental groups at face value’,<sup>1803</sup> while those spokespersons themselves take unsubstantiated technological

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<sup>1794</sup> Commission, ‘ERA New Perspectives’ (n 1598) 2, 5.

<sup>1795</sup> A highly contested concept, Sum and Jessop (n 1764) 26–27.

<sup>1796</sup> Ngai-Ling Sum, ‘The Production of Hegemonic Policy Discourses: “competitiveness” as a Knowledge Brand and Its (Re-)Contextualizations’ (2009) 3 *Critical Policy Studies* 184, 187.

<sup>1797</sup> On the potential influence of external forces here, see Bastiaan Van Apeldoorn, ‘Transnational Class Agency and European Governance: The Case of the European Round Table of Industrialists’ (2000) 5 *New Political Economy* 157, 159.

<sup>1798</sup> Aho (n 1596) vii; Levidow and Neubauer (n 1626) 399.

<sup>1799</sup> Birch, Levidow and Papaioannou (n 1586) 2905.

<sup>1800</sup> Rosamond (n 1602) 158, 165.

<sup>1801</sup> For example, Paul Krugman, ‘Competitiveness: A Dangerous Obsession’ (1994) 73 *Foreign Affairs* 28.

<sup>1802</sup> Rosamond (n 1602) 172.

<sup>1803</sup> Volker ter Meulen, ‘Time to Settle the Synthetic Controversy’ (2014) 509 *Nature News* 135.

promises at face value.<sup>1804</sup> This is unsurprising perhaps, in light of the master narratives discussed above, which corroborate the apparent common sense of that position, placing it beyond dispute.

## 5. Conclusion

While the ideas examined in this chapter operate many orders above the comparatively minute regulatory decisions concerning individual technologies with which the rest of this thesis is engaged, their existence and power is, I argue, essential to the EU's failure to fulfil its promise of greater socio-technical integration at all levels of governance, including, importantly, downstream regulation and regulatory science. In the final chapter, I link these arrangements specifically to the technologies examined in this thesis and their regulation. Many of the concerns repeatedly expressed with respect to risky technologies relate to the very constituent parts of these ideas; speed, commercialisation, productive employment of nature, distribution of risks and benefits which, in particular, in a liberalised trade paradigm, could legitimately be ignored.<sup>1805</sup> These are not just political concerns but concerns which target the specific political choices of the prevailing EU ideational architecture. Meanwhile, the above analysis is intended to show that, partly for this reason, the strength of the EU's commitment to a certain vision of its future, bolstered by each, galvanising imaginary and reinforcing narrative, is unlikely to soften easily. That commitment is well equipped to fend off challenges with its unreflexive armoury of depoliticising mechanisms which promote rational consensus around expertise and sedimentation which clouds choice and denies the possibility of legitimate, political disagreement about the definition of problems, their solutions, the means to achieve or distribute them and their justification. While the current order prevails, action remains 'trapped within its configuration of forces'.<sup>1806</sup>

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<sup>1804</sup> Marris (n 909) 95.

<sup>1805</sup> Lang, 'Reconstructing Embedded Liberalism' (n 1216) 100–101.

<sup>1806</sup> Mouffe (n 1515) 63.

## Chapter Nine – Conclusion

### 1. Introduction

Attitudes to technology, innovation and risk frequently relate to broader political questions about what kind of a society we want to live in. These questions form a direct link between an isolated, regulated technology; an organism, pesticide, nanomaterial etc. and deeply held political convictions or imaginaries about what is good and right for society or what kind of society a technology might create or consolidate. Discussion of these political concerns may occur but, as a force for change, they are inevitably constricted by the EU's encompassing ideational architecture. This concluding chapter describes how a consequence of this architecture and the depoliticising tendencies of some of its elements is that the EU is prevented from making good on its policy promise to enhance socio-technical integration in its regulation of risky technologies. In short this architecture, it is argued, prevents the EU from closing the gap between its policy on science and society and its practice.

Depoliticising occludes the fact that many of the institutions governing/influencing the way the EU regulates are shaped by political values and ideas and that technology trajectories have already been plotted through ideational forces in operation at times and spaces far beyond the reach of a regulatory hand at the snapshot of authorisation. Two ideas were examined in this thesis (sustainability and RRI) for their potential to open up or re-politicise some of the debate by disrupting sedimented modes of thinking and practice. In other words, as ambitiously implemented frameworks, they could aid the EU in realising its promise of greater socio-technical integration throughout the governance and regulation of risky technological innovation.

In the following section, I draw direct links between features of the regulation discussed in Chapters Four and Five respectively and the ideational architecture elaborated in Chapter Eight. Part of that architecture relates to markets and the impetus to complete the EU internal market to help the EU achieve leadership in innovation and economic competitiveness. I argue, with respect to sustainability, that the sustainability discourse has largely been absorbed into that architecture

through its redefinition as ‘efficiency’ or ‘risk reduction’ with a corresponding reduction in its ability to invite the consideration of concerns not relating to safety in regulatory decision-making. With respect to RRI, I argue that, while it is perhaps too early to tell whether it will ultimately aid greater socio-technical integration, it does appear to be struggling against the force of the commitments examined in Chapter Eight which may curtail its potential.

In section 3, I build on section 2 by drawing together some of the themes which have surfaced throughout this thesis. In large part, these represent a continuation of previous criticisms highlighting the shortcomings of the public engagement with science movement or ‘new scientific governance’, discussed in Chapter Two. The combination of these shortcomings with the ideational framework discussed in Chapter Eight and their mutual reinforcement provide the most potent force working against increasing socio-technical integration and closing the policy-practice gap. Section 4 presents a final conclusion.

## 2. Alternatives to the EU order and their fate

### 2.1 *Sustainability and pesticides: keeping the apolitical, apolitical*

Various elements of sustainability were identified in Chapter Three as enablers of reflection on the problems associated with pesticide use and as a foundation on which to build a framework sensitive to those problems. On the one hand, as a mature and socially-embedded technology, pesticides could be described as apolitical,<sup>1807</sup> with the dominance of high-input, monocultural agriculture which their use supports now thoroughly sedimented. On the other hand, the various controversies surrounding pesticides identified in Chapter Four demonstrates the potential for politics to erupt into this apparently settled model. Ambitiously implemented, sustainability could have helped unearth some of the politics, choices and dispositions underlying this model. However, as argued in Chapter

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<sup>1807</sup> Jasanoff, *Designs on Nature* (n 11) 206–207.

Four, in the Sustainable Use Directive<sup>1808</sup> sustainability is, instead, unambitiously equated with risk reduction and efficiency.

EU innovation policy is not directly addressed to mature technologies. However, aspects of that policy which relate to research for agriculture evince a reluctance to wander far from current paths and trajectories. For example, a high-capital input life sciences vision of the KBBE at least partially locks out agroecology,<sup>1809</sup> and policy emphasises biotechnology, whose current limited output consists partly of crops modified to withstand pesticides. Both reflect a tendency in agricultural science to seek minor changes, leaving unquestioned the monocultural model of agriculture itself and unconsidered the need for radical alternatives under increasing pressure from, for example, climate change or rising energy costs.<sup>1810</sup> Pesticides sit upon the second horn of Collingridge's dilemma of control<sup>1811</sup> and path dependency in this field is a concern. Change is possible<sup>1812</sup> but requires political will which is contingent on the relevant political choices (sometimes decades old<sup>1813</sup>) becoming visible again.

Perhaps strangely, given the apolitical promotion of a (risk) management fix in the SUD and related policy, there is a crystallisation of Mouffe's antagonistic conception of 'the political'<sup>1814</sup> in the law. As discussed in Chapter Four, the main disagreement during consultation was between use/dependency or risk reduction. Unresolved prior to casting in legislation, there are also references to use/dependency reduction.<sup>1815</sup> That disagreement could be evidence of a deeper politics;<sup>1816</sup> use reduction indicating a desire to shift from the current industrial

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<sup>1808</sup> SUD (n 55).

<sup>1809</sup> Vanloqueren and Baret (n 707); Levidow, Birch and Papaioannou (n 708).

<sup>1810</sup> Vanloqueren and Baret (n 707) 977.

<sup>1811</sup> Collingridge (n 28) 17–20.

<sup>1812</sup> For example with CFCs. See also Collingridge (n 28).

<sup>1813</sup> Vanloqueren and Baret (n 707) 977 and references therein.

<sup>1814</sup> Mouffe (n 1515) 8–24.

<sup>1815</sup> Recitals 5, 18, Articles 4(1) and 15(2)(c) SUD.

<sup>1816</sup> For, example, Industry appears to prefer a risk reduction approach, while green NGOs prefer use reduction 'Stakeholders' Conference on the Development of a Thematic Strategy on the Sustainable Use of Pesticides: Conference Report' (2002) 11–14.

model of agriculture by weening society off pesticides and risk reduction suggesting a reluctance to disrupt current practices. The ultimate goal of both, however, as uncollaboratively defined by policy, is still ensuring safety by reducing risks so competing political visions remain confined within those bounds, compressed into a battle between different fixes. More positively, while the conflict between risk and use reduction could be regarded as incoherence in the law, the presence of both could equally be viewed as providing flexibility. These represent two different solutions to the 'pesticide question'. If, in the future, aspiration grows for transition from our current industrial model of agriculture towards a low-input model, a (partial) legal basis will be there, to encourage and support such transition (perhaps with the aid of ambitious interpretation), in the more ambitious elements of the SUD.

Overall, however, as discussed in Chapter Four, pesticides policy and legislation promotes a traditional conception of sustainable development in agriculture as optimising pesticide input while minimising harm,<sup>1817</sup> a principle of (eco-)efficiency also reflected throughout the EU policy examined in Chapter Eight, particularly that relating to the KBBE. It is unlikely to precipitate radical change and, instead, forms part of a discourse which assumes resource use inefficiency requiring further intensification facilitated by new knowledge and technology and which accepts and accommodates global economic competition as a given. Indeed, it sees these environmental problems as opportunities for societal progress, provided 'barriers to technoscientific development [are] removed'.<sup>1818</sup> As such, the approach will perhaps harden existing resource-intensive monocultural agriculture in pursuit of increased agricultural competitiveness.<sup>1819</sup> Ultimately, if we are looking for a discourse with which to repoliticise an apolitical technology such as pesticides, sustainability (re)defined as efficiency, may be a dead end.

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<sup>1817</sup> Carr (n 637) 170.

<sup>1818</sup> Birch, Levidow and Papaioannou (n 1586) 2908.

<sup>1819</sup> *ibid* 2907–2909.

The depoliticising force of sustainability-as-efficiency comes in its promise to reconcile the previously irreconcilable. Dominique Pestre has argued that sustainable development replaced the tension between discourses of boundless technological development for resource-intensive growth and alternative ideas of development, displacing the latter and dulling challenges to technology-contingent problem-solving.<sup>1820</sup> While sustainable development did originally develop to 'dissolve the conflicts between environmental and economic values'<sup>1821</sup> this could be understood and implemented far more ambitiously than expecting reconciliation through increased (eco-)efficiency. The approach advocated in Chapter Three would have acknowledged the tensions and the challenges presented by the co-existence of the three pillars.<sup>1822</sup> It would also perhaps have attempted to keep them alive during the national planning process envisaged in Article 4 SUD; the kind of approach necessary to accept the validity of positions attached to these interests and to take those viewpoints into account. By contrast, an approach characterised by risk reduction and efficiency promises the continued reaping of the socio-economic benefits of pesticide use while reducing environmental harm, without considering the overall (un)sustainability of the agricultural system at stake, its drivers, distributive effects or necessary trade-offs between competing goods.<sup>1823</sup> This approach manoeuvres opposing viewpoints out of consideration. The euphemistic language of balancing and reconciliation employed by AG Léger in *First Corporate Shipping*,<sup>1824</sup> a case which clearly involved

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<sup>1820</sup> Dominique Pestre, 'Challenges for the Democratic Management of Technoscience: Governance, Participation and the Political Today' (2008) 17 *Science as Culture* 101, 110–111.

<sup>1821</sup> Dryzek (n 528) 16.

<sup>1822</sup> Lee, *EU Environmental Law* (n 51) 67.

<sup>1823</sup> Gordon Conway and Edward Barbier, *After the Green Revolution: Sustainable Agriculture for Development* (Earthscan 1990) 10. There is apparently increasing scepticism among experts as to the compatibility of economic growth and sustainability, in the agricultural sector, Daniel Mützel, 'Agricultural Policy: At the Limits of Green Growth' (Sam Morgan tr, *EurActiv.com*, 26 September 2016) <<http://www.euractiv.com/section/agriculture-food/news/hold-for-sragricultural-policy-at-the-limits-of-green-growth/>> accessed 26 September 2016.

<sup>1824</sup> Case C-371/98 *R v Secretary of State for the Environment, Transport and the Regions, ex parte First Corporate Shipping Ltd* [2000] ECR I-9235, Opinion of AG Léger (n 537) [54].

a trade-off between environmental and economic interests, seems another symptom of a detachment in the EU from substantive engagement with these intensely political questions.<sup>1825</sup>

This reductive reconciliation discourse is also familiar from the socio-technical imaginaries of EU innovation policy and its equation of sustainability with eco-efficiency through ‘techno-fixes’ spurred by market competition to ensure conservation of natural resources.<sup>1826</sup> In the case of pesticide use, it is not an innovation-based techno-fix but rather a management fix, transferring responsibility for appropriate resource use from the state to non-state stakeholders<sup>1827</sup> for example to professional users, distributors and advisors<sup>1828</sup> and the general public.<sup>1829</sup> The potential value of these measures in improving protection through educating, training and advising the relevant actors is not disputed. However, the pattern of an increased burden of responsibility on private actors and citizens and a reduced, meta-governance (or ‘governance of governance’) role for the state<sup>1830</sup> suggests little political appetite to engage with concerns not already addressed by the SUD’s risk reduction regime. Indeed the overall approach to increasing state intervention is extremely cautious; reflection on *further regulation* is required<sup>1831</sup> rather than on *unsustainable practices and pesticide-related concerns* as a way of prompting change.

A lack of engagement with the drivers of unsustainable pesticide use and related concerns may be partly explained by the long-standing faith in the ability of sustainability-as-efficiency to reconcile competing values reinforced by the

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<sup>1825</sup> Perhaps this is not surprising in the formality expected of court proceedings. However, Sharpston AG, in an even more highly politically-charged case, acknowledged the politics at stake, *Land Oberösterreich*, Opinion of AG Sharpston (n 1181) [143–145].

<sup>1826</sup> Levidow, Papaioannou and Birch (n 1600) 163; Commission, *A Bioeconomy Strategy for Europe* (n 1621) 3.

<sup>1827</sup> Castree (n 1617) 148–150.

<sup>1828</sup> Articles 5, 6, 13 SUD.

<sup>1829</sup> Article 7 SUD.

<sup>1830</sup> John Walls and others, ‘The Meta-governance of Risk and New Technologies: GM Crops and Mobile Telephones’ (2005) 8 *Journal of Risk Research* 635, 638–639.

<sup>1831</sup> For example, Art. 4(1) fourth sub-paragraph SUD; Commission, ‘Impact Assessment’ (n 545).

asymmetric assumption that technologies, including pesticides, tend to produce socio-economic benefits and environmental harms.<sup>1832</sup> Those convictions appear to have provided pre-made problem framings for policy analysis of the pesticide question. The question is in fact far more complex (see Chapter Four) but such problem definitions may obscure the need for more profound policy consideration of ethical or distributive questions or ‘what matters’. Where distribution is the combined gift of technological innovation and the market, as discussed in Chapter Eight, that question may seem to be out of political hands. Alternatively, a more ambitious approach to environmental protection may be seen as a luxury until high real incomes are produced.<sup>1833</sup> That may be for the best from a capitalist, free market perspective<sup>1834</sup> which, in its professed neutrality<sup>1835</sup> and suspicion of sustainable development,<sup>1836</sup> may balk at the more substantive aim of just distribution of the costs and benefits of pesticide use.<sup>1837</sup> And if trade-offs are pre-empted, there is perhaps little cause to consider what matters or alternative solutions. Thus, the win-win of reconciliation may extinguish any reason to raise other concerns which challenge the prevailing order. The thread of competitiveness also runs through EU pesticide policy,<sup>1838</sup> agriculture policy<sup>1839</sup> and, indeed, environmental policy<sup>1840</sup> which, as argued in Chapter Eight, perhaps further blinds the EU to contestation which could threaten to divert it from that course.

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<sup>1832</sup> Commission, ‘Towards a Thematic Strategy’ (n 514) 11–12; Commission, ‘Thematic Strategy’ (n 515) 3; Art. 60(4) REACH (n 63). Chapters One and Eight generally.

<sup>1833</sup> Howse, ‘From Politics to Technocracy’ (n 1218) 104.

<sup>1834</sup> *ibid.*

<sup>1835</sup> Dobson (n 178) 141.

<sup>1836</sup> Dryzek (n 528) 162.

<sup>1837</sup> Lee, *EU Environmental Law* (n 51) 79; Jane Holder, ‘Building Spatial Europe: An Environmental Justice Perspective’ in Joanne Scott (ed), *Environmental Protection: European Law and Governance* (OUP 2009).

<sup>1838</sup> EESC, ‘Opinion of the European Economic and Social Committee on the Proposal for a Directive of the European Parliament and of the Council Establishing a Framework for Community Action to Achieve a Sustainable Use of Pesticides’ (2007) para 4.5.

<sup>1839</sup> Commission, ‘Towards a Thematic Strategy’ (n 514) 18. A global policy despite its negative aspects, according to Niels Röling, ‘The Human and Social Dimensions of Pest Management for Agricultural Sustainability’ in Jules N Pretty (ed), *The Pesticide Detox: Towards a More Sustainable Agriculture* (Earthscan 2005) 107–110.

<sup>1840</sup> Commission, ‘Towards Sustainability’ (n 509) 20; Commission and others (n 514) Article 2(1); Bosselmann (n 532) 194.

The emphasis on risk reduction and efficiency is closely tied to measurement and use of indicators, echoing to some extent the technical predisposition in the EU to measure and monitor sustainable development.<sup>1841</sup> Chapter Four identified some opportunities for the exercise of value judgments in the definition of indicators but on the whole these are constrained by the SUD's overall goal of risk reduction and discussion may therefore be unlikely to rise beyond that frame. While measurement can sometimes ignite fervent political debate,<sup>1842</sup> the risk management/indicator-monitored approach adopted by the SUD is perhaps more likely to confirm rather than challenge the *status quo* in its reduction of the normativity of fully-realised sustainability to the 'neutrality' of numbers.

In sum, I have tried to demonstrate how certain elements of the EU's policy architecture examined in Chapter Eight manifest in the more specific context of policy and legislation relating to pesticide use. Their operation in the context of pesticide use has a similar, depoliticising effect in forming a framework built on an asymmetric understanding of technology, the re-imagination of sustainability as efficiency, reconciliation and measurement which could discourage acknowledgement of the political side to pesticide use and its role in supporting modern, arguably unsustainable, agricultural systems. This, I argue, results in a deep reluctance, or even inability to countenance the existence of, let alone yield to, concerns over pesticide use not already recognised by that framework. The framework's emanation from the highest political level, pervasiveness in policy and the long history of some of its themes further militate against the integration of other concerns such that the gap between the EU's policy and practice persists.

## 2.2 *RRI and synthetic biology: fermenting a rational consensus*

The discussion of RRI and its four dimensions in Chapter Three highlighted various aspects of that framework which could open up decision-making with respect to synthetic biology and challenge the policy commitments examined in Chapter Eight. For example, the role of anticipation in prompting consideration of contingencies

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<sup>1841</sup> Commission and Eurostat (n 581); Lee, *EU Environmental Law* (n 51) 74.

<sup>1842</sup> See Barry (n 46) 92–94 on the fallout from the Hatfield train crash.

disputes the existence of an objective truth discoverable through expert perception and may elaborate alternatives to the EU's imaginaries. Reflexivity, in encouraging consideration of the commitments behind a research endeavour along with alternative framings,<sup>1843</sup> challenges the EU's instrumental drive for commercialisable innovation.<sup>1844</sup> Essentially, RRI takes little for granted; not the economic competitiveness discourse,<sup>1845</sup> nor the centrally promulgated problem definitions and societal challenges,<sup>1846</sup> nor the inherent beneficence of innovation, nor the possibility of a true determination of risk, nor the necessary validity of regulation based on it, nor the EU's visions of its future society.

Nevertheless, the unequivocal determination in EU policy suggests a compulsion to forge ahead. The belief in the existence of a universal, expert-determined and guided true mode of regulatory science, still implies the expectation of a rational (and anti-political) consensus on the basis of expert knowledge. The corollary is an inability to recognise that any disagreement with the EU's policy commitments could be valid. It is this determination, expectation and inability which I identify as running through EU policy and legislation in relation to synthetic biology and which I argue could ultimately prevent the EU from realising its commitment to greater socio-technical integration in this field, despite the potential of RRI.

To start with a familiar observation: both the legislation and policy on synthetic biology consistently privilege expert-determined safety, despite the limitations of this approach discussed in Chapter Two. The requirement for risk assessments in both the Contained Use Directive (CUD)<sup>1847</sup> and Deliberate Release Directive (DRD)<sup>1848</sup> reflects high-level policy calls for evidence-based regulation, as discussed in Chapter Eight, reminiscent of Hurlbut's imaginary of governable emergence.<sup>1849</sup> For example, the siting of public consultation by the DRD after the conduct of the

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<sup>1843</sup> Stilgoe, Owen and Macnaghten (n 29) 1571.

<sup>1844</sup> Levidow and Neubauer (n 1626) 406.

<sup>1845</sup> Stilgoe, Owen and Macnaghten (n 29) 1573; von Schomberg (n 429) 58.

<sup>1846</sup> Stilgoe, Owen and Macnaghten (n 29) 1572.

<sup>1847</sup> Art. 4(1) CUD (n 743).

<sup>1848</sup> Arts 4(2) and 6(2)(a) DRD (n 744).

<sup>1849</sup> Hurlbut, 'Remembering the Future' (n 1008).

Environmental Risk Assessment<sup>1850</sup> asserts science's priority of agency to define legitimate causes for public concern, significantly reducing terrain for political debate. So, while the EU is keen to draw on the public as a resource in generating innovation,<sup>1851</sup> it provides no opportunity for the public to confirm that the result was what they wanted. That arrangement can perhaps again be attributed to the EU's pervasive asymmetric policy assumption that the anticipated socio-economic benefits of innovation can be left to the care of the market as anticipated by EU innovation policy, while expert hands deftly manage any threats to human health or the environment. Consultation under the DRD and CUD occurs within the limits of policy assumptions and scientifically-defined concerns, hardened in the purpose of the relevant legislation to ensure safety.<sup>1852</sup> The participation provisions in the DRD reinforce the educational nature of participation while preventing real dialogue and presuming consensus on the underlying political agenda.<sup>1853</sup>

As discussed in Chapter Five, the restrictive conditions for consultation under the DRD reduces space for disagreement, limits potential to challenge regulatory science-informed authorisation and aids the EU's general policy commitment to speed innovation to market. That commitment to speed (though not in relation to authorising) was perhaps also evident in the CJEU's refusal to grant Austria a right to be heard under Article 114(5) TFEU with respect to Austria's application to derogate from the DRD, on the grounds that speedy completion of the procedure in Article 114(6) was required for the proper functioning of the internal market.<sup>1854</sup> In a move of particular salience in the context of the EU's innovation policy, the Court prioritised the completion of the internal market over deeper scrutiny of a highly political question at the heart of Austrian identity.<sup>1855</sup> In general, the

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<sup>1850</sup> Art. 24(1) DRD.

<sup>1851</sup> For example, Commission, *Open Innovation* (n 431) 13–14, 17, 30.

<sup>1852</sup> Art. 1 CUD, Art. 1 DRD. Lee, 'Beyond Safety?' (n 12) 265.

<sup>1853</sup> Maria Paola Ferretti and Matteo Lener, 'Lay Public or Experts? E-Participation in Authorization for GMO Products in the European Union' (2008) 25 *Review of Policy Research* 507, 512, 521.

<sup>1854</sup> Cases T-366/03 and 235/04 *Land Oberösterreich and Austria v Commission* [2005] ECR II-4005 [40–41]; see also *Denmark v Commission* (n 1196).

<sup>1855</sup> Felt (n 206).

competitiveness imperative rings through the legislation and policy. Both the CUD<sup>1856</sup> and the DRD<sup>1857</sup> assume the economic benefits for the EU of developing biotechnology and pave the path to the market, the EU's primary concern,<sup>1858</sup> as committed to in policy.

In addition, the lack of opportunity to feed the outcomes of potential RRI-style anticipative, reflective or deliberative activities into the decision-making processes, under either the CUD or DRD, further allows decision-makers to ignore any outcome of such activities and proceed with authorisation on the basis of the product's expert-determined safety profile. Indeed, it is generally unclear how the principles of responsibility may be enforced.<sup>1859</sup> While both the novelty of the technology and its planned governance in accordance with RRI<sup>1860</sup> provide reasons for revising the legislation, the inheritance of old legislation, discussed in Chapter Five, and the disposition that controversial questions were settled the first time round,<sup>1861</sup> shuts down that opportunity for debate. In the language of 'the political', it looks like a case of legal depoliticisation. While some strands of policy have changed since the turn of the 21<sup>st</sup> century, for example the development of the science and society discourse, the focus of EU innovation policy, has perhaps evolved less. Biotechnology has long been seen as key to EU's development and prosperity.<sup>1862</sup> That does not imply an appetite for revising the relevant legislation, unless it be to aid authorisation.<sup>1863</sup>

The DRD does, however, allow Member States to raise objections to the placing of GMOs on the internal market<sup>1864</sup> and in doing so explicitly recognises the possibility, and even legitimacy, of disagreement on that front. The raising of an objection

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<sup>1856</sup> Recital 4 CUD.

<sup>1857</sup> Recital 7 DRD.

<sup>1858</sup> Poli (n 966) 40–41.

<sup>1859</sup> van Oudheusden (n 458) 74.

<sup>1860</sup> For example, 'Synenergene' (n 959).

<sup>1861</sup> Stokes, 'Recombinant Regulation' (n 131) 23–26.

<sup>1862</sup> Levidow, Birch and Papaioannou (n 708) 48.

<sup>1863</sup> House of Commons Science and Technology Committee (n 1125) 3–4.

<sup>1864</sup> Article 15(1) DRD.

initiates a comitology procedure<sup>1865</sup> which may provide the potential for political deliberation.<sup>1866</sup> However, the emphasis on consensus and the population of the committee by national experts<sup>1867</sup> would not necessarily guarantee an airing of the kinds of political concerns associated with synthetic biology, especially given the potential for political questions to be recast as technical questions.<sup>1868</sup> Moreover, where the required majority cannot be reached in committee, the ability of the Commission to take a decision in the most politically contentious cases<sup>1869</sup> is rather dismissive of valid political differences between Member States, especially given the Commission's commitments to such technologies in the policy examined in Chapter Eight. Likewise, the new Article 26b DRD enables national regulation of cultivation on the basis of diverse interests and values and offers some scope to promote RRI, even upstream. However, as discussed in Chapter Five, its potential to strengthen the technocratic nature of decision-making, for example, and its ultimate aim to facilitate authorisation and operation of the internal market<sup>1870</sup> suggests limited capacity to enhance socio-technical integration in this context.

Many of the features of the policy identified in Chapter Five indicate a reluctance to accept, as valid, opposition to the EU's intention to exploit the economic potential of synthetic biology. For example, the control over information and the language of addressing or overcoming concerns as if each is thereby extinguished and replaced with consensus, are a far cry from reflecting on the purposes of the research or the substance of public concerns, as envisaged by RRI. The instrumentalisation of engagement, reiteration of the deficit model, corresponding refusal to countenance the possibility of rational disagreement and dismissal of

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<sup>1865</sup> Article 30(2) DRD, Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers [2011] OJ L55/13.

<sup>1866</sup> Lee, *EU Environmental Law* (n 51) 50–51; Ellen Vos, '50 Years of European Integration, 45 Years of Comitology' [2009] Maastricht Faculty of Law Working Paper 20–23.

<sup>1867</sup> Lee, *EU Environmental Law* (n 51) 48–51.

<sup>1868</sup> Lee, *EU Regulation of GMOs* (n 35) 70.

<sup>1869</sup> Lee, *EU Environmental Law* (n 51) 50.

<sup>1870</sup> Recital 8 Directive 2015/412 (n 819).

concerns as ‘politically motivated’<sup>1871</sup> imply that political partisanship is inappropriate and deny the values driving EU innovation policy. Finally, seeking acceptability<sup>1872</sup> suggests inducing the resigned acceptance of a pre-made decision by an ‘irrational, scientifically ignorant and emotional’ laity,<sup>1873</sup> in line with a preference for markets as the location of decision-making,<sup>1874</sup> rather than active definition and endorsement of the ‘right impacts’ by an engaged citizenry. Establishing genuine acceptability requires the EU to relinquish applications which publics oppose and engage with the causes of that opposition,<sup>1875</sup> something which seems unlikely given the EU’s undiscerning appetite for any innovation.<sup>1876</sup> Overall, there is a lack of advocacy of debate where citizens might disagree over what is at stake<sup>1877</sup> though deliberation/debate may be crucial in revealing this, as a first step.<sup>1878</sup>

### 3. Continuity, patterns and the difficulty of change

Some of the reasons behind the EU’s failure to close the policy-practice gap, in relation to the specific technologies examined here, are symptomatic of deeper problems with the EU’s governance and regulation of technological innovation and its ongoing failure to improve socio-technical integration. This section identifies various themes and patterns which run through the law and policy discussed in the rest of the thesis and which operate against closing the policy-practice gap.

Chapter Two discussed the long-standing assumption underpinning regulation of risky technologies that (scientific) facts should precede value-based discussion of how to manage risks. Other concerns are frequently subordinated in procedures (for example in terms of the timing of their expression) and in substance. This assumption, which I have discussed with reference to the notion that science is

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<sup>1871</sup> Marris (n 909) 90–91.

<sup>1872</sup> DG SANCO (n 130) 23.

<sup>1873</sup> Armeni (n 905) 421–423.

<sup>1874</sup> Goven (n 377) 104.

<sup>1875</sup> *ibid* 107.

<sup>1876</sup> von Schomberg (n 429) 58.

<sup>1877</sup> Marris (n 909) 85.

<sup>1878</sup> Goven (n 377) 108; Bruna De Marchi, ‘Public Participation and Risk Governance’ (2003) 30 *Science and Public Policy* 171, 172.

granted priority of agency in policy- and decision-making, continues to pervade governance and regulation, as discussed in Chapters Five and Eight, and above. It also characterises the role of science in determining the lawfulness of restrictions on trade. This is so with respect to the areas of EU internal market law discussed in Chapter Six and with respect to scope for precautionary regulation under the SPSA, as discussed in Chapter Seven. This legal landscape is perhaps evidence of a tendency to see measures unjustified by science as evidence of protectionism<sup>1879</sup> and more broadly a general preference for technical expertise<sup>1880</sup> and a desire to keep ‘politics’ out of trade.<sup>1881</sup> The result may be states less responsive to their citizens;<sup>1882</sup> a problem for the EU’s promise of greater socio-technical integration in regulatory decision-making which entails responding to the concerns of European citizens.

By contrast, scope under the GATT and TBT to regulate on the basis of public morality, without scientific evidence of harm as a precondition of moral judgment as provided in *EC-Seals*<sup>1883</sup> is unlikely to help EU Member States. EU law, of course, still applies and requires ‘objective’ scientific evidence of harm before moral judgment may be exercised. Both the CJEU in *Commission v Poland* and AG Léger in *Compassion in World Farming* found that public morality was not a separate justification but rather related to the protection of human health and the environment,<sup>1884</sup> or protection of animal health.<sup>1885</sup> Scope for value judgments is similarly limited due to the dominance of scientific evidence and reasoning in the Court’s examination of precautionary regulation and regulation under Article 114(5) TFEU.

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<sup>1879</sup> Sabrina Safrin, ‘Treaties in Collision? The Biosafety Protocol and the World Trade Organization Agreements’ (2002) 96 *The American Journal of International Law* 606, 627.

<sup>1880</sup> Howse, ‘From Politics to Technocracy’ (n 1218) 98.

<sup>1881</sup> *ibid.*

<sup>1882</sup> Van Apeldoorn (n 1797) 160; Goven and Pavone (n 1514) 312.

<sup>1883</sup> *EC-Seals* (AB) (n 1278).

<sup>1884</sup> *Commission v Poland* (n 888) [55].

<sup>1885</sup> *Compassion* Opinion of AG Léger (n 1124) [104–106].

In terms of innovation governance, the attribution of priority of agency to science may stifle the operation of different forms of anticipation, as promoted by RRI, to consider other possible, desirable or unwanted futures before the potential of science becomes hardened into material artefacts and before regulatory science has defined the undesirable (i.e. safety-related) implications. Furthermore, this arrangement is frequently left unchallenged by the models of public engagement employed by the EU in governance and regulation. It is by no means always inappropriate to use an appraisal process (including public engagement) to ‘close down’ a decision-making process.<sup>1886</sup> However, an enduring criticism of public engagement has been that it is too often used instrumentally to close down, and not often enough to open up, debate. The discussion, in Chapter Five, of EU policy on public engagement in the governance of synthetic biology bears this criticism out.

This policy indicates employment of a conflict-avoidance model of dialogue and deliberation. Such use of engagement to close down rather than open up debate works alongside the depoliticising forces discussed in Chapter Eight. For example, the public often becomes merely another stakeholder; though in a democracy it should perhaps occupy a more privileged position, it may often appear only in the reduced capacity of ‘consumers’,<sup>1887</sup> rather than citizens. Discussing the UK, Charles Thorpe and Jane Gregory have argued that public engagement is viewed by policy-makers as a tool for creating the social conditions - consumer-citizens, markets, products - for innovation and is thus swept up into the overall drive to achieve economic competitiveness. In this capacity, it acquires a ‘therapeutic’ purpose to build consensus around those goals and promote commercialisation.<sup>1888</sup> A further criticism is that the utility of engagement is limited if no real choice exists between clearly differentiated alternatives.<sup>1889</sup> We can and should identify practical barriers

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<sup>1886</sup> Stirling, ‘Analysis, Participation and Power’ (n 1632) 101–102.

<sup>1887</sup> Goven (n 377) 104.

<sup>1888</sup> Charles Thorpe and Jane Gregory, ‘Producing the Post-Fordist Public: The Political Economy of Public Engagement with Science’ (2010) 19 *Science as Culture* 273.

<sup>1889</sup> Mouffe (n 1515) 3.

(see Chapter Five) to public participation which opens up decision-making processes. However, the weight of EU policy energy driving towards particular goals, discussed in Chapter Eight, raises significant doubts about the potential for even technically exemplary deliberative exercises conducted within that ideational architecture to re-open any of its assumptions and goals,<sup>1890</sup> let alone respond to any of its outcomes, either concerning the technology or the architecture itself.<sup>1891</sup>

For example, the EU has been criticised for steering clear of politically sensitive questions and making no effort to identify and understand commonalities and divergences amongst Members States.<sup>1892</sup> Furthermore, the objective of the FP7 Science in Society programme was to stimulate, *inter alia*, harmonious integration of science and technological endeavour in Europe by encouraging European scale reflection and debate on science and technology and their relation with society and culture. Its aim was to build an 'open, effective and democratic European Knowledge society' and involve society in setting research agendas.<sup>1893</sup> However, it still sits within confines: there is little countenancing of alternatives to science and technology to solve problems or alternative imaginaries of Europe's future. This seems to reproduce a more fundamental tension between enhancing democracy through engagement and commercial exploitation of technological innovation.<sup>1894</sup> As argued in Chapter Eight, political choices underlie the knowledge society. This at least should be divested of its apparent neutrality.

As discussed in Chapter Eight, the pursuit of consensus has been described as a depoliticising trend characteristic of the current post-political order. Alongside the potential of RRI to address isolated aspects of EU innovation policy commitments (therefore perhaps indirectly, their politics), the suggestion of a 'politics of RRI'

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<sup>1890</sup> On the constraining effects of a commitment to biotechnological innovation-contingent growth on engagement in different national contexts, see Les Levidow, 'Democratising Technology Choices? European Public Participation in Agbiotech Assessments' (IIED 2008).

<sup>1891</sup> Goven (n 377) 106.

<sup>1892</sup> Wilkinson, Franke and Stroyan (n 440) 46 in relation to the ethics theme in SiS.

<sup>1893</sup> Council Decision on the Specific Programme: 'Capacities' implementing the Seventh Framework Programme of the European Community for research, technological development and demonstration activities (2007 to 2013) [2006] OJ L400/299 338.

<sup>1894</sup> Thorpe and Gregory (n 1888) 275; Pestre (n 1820).

appears in von Schomberg's concern that RRI may contravene the general principle of modern liberal democracies to refrain from defining 'the good life' in directing science policy.<sup>1895</sup>

Despite von Schomberg's concern, a politics of RRI might be beneficial in terms of repoliticising the field. Indeed, 'productive engagement exercises typically open up areas of dissensus'.<sup>1896</sup> While that potential may exist, Michiel van Oudheusden criticises RRI as currently not attending to its own assumptions and politics, for example its privileging of a deliberative, process definition of democracy with its own questions of 'power, ends and authority'.<sup>1897</sup> '[I]ncluding wider publics (e.g. citizens) in science is not a politically neutral thing to do',<sup>1898</sup> although it is often presented as such.<sup>1899</sup> Invoking the non-political language of responsibility and innovation and an appearance of neutrality risks RRI becoming another means to 'rationalize actions and actors'<sup>1900</sup> and is hard to maintain substantively.<sup>1901</sup> Given the ambition of the policy changes RRI seeks, van Oudheusden recommends making its politics explicit.<sup>1902</sup> Indeed, the decision whether or not to frame current modes of governance, in or out of participation exercises aimed at influencing the direction of biotechnology policy, is a continuing design question.<sup>1903</sup>

With respect to nanotechnology, Phil Macnaghten warns that 'public reactions to emerging nano-technologies have the potential to become significant so long as the questions that appear to underpin emergent public attitudes remain occluded from

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<sup>1895</sup> von Schomberg (n 451) [2-3]. A concern also for sustainable development, Wouter Achterberg, 'Can Liberal Democracy Survive the Environmental Crisis? Sustainability, Liberal Neutrality and Overlapping Consensus' in Andrew Dobson and Paul Lucardie (eds), *The Politics of Nature: Explorations in Green Political Theory* (Routledge 1993).

<sup>1896</sup> Stilgoe, Lock and Wilsdon (n 368) 7.

<sup>1897</sup> van Oudheusden (n 458) 68–69, 73.

<sup>1898</sup> *ibid* 73; A Wesselink and R Hoppe, 'If Post-Normal Science Is the Solution, What Is the Problem?: The Politics of Activist Environmental Science' (2011) 36 *Science, Technology & Human Values* 389.

<sup>1899</sup> van Oudheusden (n 458) 80.

<sup>1900</sup> *ibid* and references therein.

<sup>1901</sup> *ibid* 81.

<sup>1902</sup> *ibid*.

<sup>1903</sup> Goven (n 377) 107.

public dialogue and processes of decision making'.<sup>1904</sup> Van Oudheusden's recommendation could repoliticise the policy field by throwing light on the choices underlying the current innovation-market-competitiveness-dominated political arrangement in the EU. This could help make concerns over innovation visible again and reintroduce the idea of legitimate disagreement. Until then, the impact of RRI may be limited and, if the deliberative elements of RRI ignore the broader political-economic context, for example the audience, whose response might be pre-determined by existing policy commitments, it may risk becoming impotent, irrelevant or instrumental.<sup>1905</sup>

It is, furthermore, possible to discern a pattern of ambitious ideas becoming 'euphemised'<sup>1906</sup> or repurposed in support of preserving the *status quo* as, for example, with the redefinition of sustainability as efficiency. Similarly, since its adoption, RRI in the hands of the EU has become somewhat 'Europeanised'. The EU has, for example, added six policy agendas relating to ethics, governance, gender equality, open access, science education and public engagement, which are 'more concrete normative orientations' to be furthered by RRI.<sup>1907</sup> The worth of these agendas is not disputed *per se*, although it depends on the use to which they are put. For example, 'governance' is contestable,<sup>1908</sup> education and public engagement can become manipulative and/or instrumental and open source/access may serve major industrial interests.<sup>1909</sup> The requirements for 'responsiveness and adaptive change'<sup>1910</sup> could also be read as criteria for the nimble innovation systems and markets desired to respond to economic rivals and assume competitive leadership. Furthermore, in some parts of EU policy, RRI has

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<sup>1904</sup> Macnaghten (n 1696) 34.

<sup>1905</sup> Goven (n 377) 108–109.

<sup>1906</sup> Pestre (n 1820) 110.

<sup>1907</sup> 'About RRI - RRI Tools' (n 466).

<sup>1908</sup> Cynthia Hewitt de Alcántara, 'Uses and Abuses of the Concept of Governance' (1998) 50 *International Social Science Journal* 105.

<sup>1909</sup> Goven and Pavone (n 1514) 322.

<sup>1910</sup> RRI Tools, 'RRI Tools: Towards RRI in Action' 2 <[https://www.rri-tools.eu/documents/10184/104615/RRI+Tools+Policy+Brief+\(EN\).pdf/82ffca72-df32-4f0b-955e-484c6514044c](https://www.rri-tools.eu/documents/10184/104615/RRI+Tools+Policy+Brief+(EN).pdf/82ffca72-df32-4f0b-955e-484c6514044c)> accessed 26 June 2017.

been reduced to ‘ethical acceptability and orientation to societal needs, both as opportunities for more successful innovation’ or to mean avoiding risky innovation, or preventing harmful/unethical research and innovation.<sup>1911</sup> Valuable and powerful in its original vision for socio-technical integration and for shaping innovation trajectories, RRI may be vulnerable to hijack by the EU’s economic competitiveness agenda and employment towards generating ‘acceptance’. If this happens, the potential of RRI (and sustainability) to enhance socio-technical integration will have been significantly reduced.

To be clear, the above is not a criticism of sustainable development/sustainability, RRI or its deliberative characteristics *per se*. Indeed, much of this thesis assumes the potential of deliberative processes to facilitate socio-technical integration and to counteract science-driven governance.<sup>1912</sup> It criticises the EU for not providing more, or better, opportunities for engagement. It is more a criticism of the framework in which it tends to occur, with its commitments to technological progress, management and ‘rational’, often risk-based, approaches to problems. In this paradigm, concepts with potential to enhance socio-technical integration at various stages of innovation, authorisation or use become redefined, repurposed (and depoliticised). Mouffe warns of the danger of identifying the interests of a particular hegemonic project with the interests of a concept, for it would treat any disagreement as an illegitimate challenge to its rational leadership.<sup>1913</sup> The example she gives is humanity. However, the warning is equally applicable to sustainability or responsibility or ‘European values’. We saw in Chapter Eight the strong identification between sustainability and capital intensive research and the EU’s exclusive imaginaries forged through the link of eco-efficiency, and between societal openness towards innovation and the treasured European way of life. The dismissal of opposition to certain types of technological innovation, ubiquitous in EU policy is arguably an illustration of the effect Mouffe describes. If so, this again

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<sup>1911</sup> Levidow and Neubauer (n 1626) 406–407 and references therein.

<sup>1912</sup> Weimer, ‘Risk Regulation and Deliberation’ (n 874) 624.

<sup>1913</sup> Mouffe (n 1515) 107.

could prove a significant impediment to enhancing socio-technical integration in decision-making.

The inherent flexibility of these concepts is both a boon and a disadvantage. Sustainability may have the potential to form (competing) imaginaries or generate its own politics but it is currently largely impotent in EU policy (see Chapter Four) and often operates within the overarching imaginary of technological innovation-driven economic competitiveness. It is perhaps too early to tell yet whether RRI will realise its potential. However, competitiveness discourses remain flexibly stable and there is evidence that such agendas are becoming revamped as ‘responsible’ or ‘green’ competitiveness.<sup>1914</sup> This may indicate the overall survival of the EU’s ideational architecture and diminished hope of major change, particularly with respect to increasing socio-technical integration, partly due perhaps to the phenomenon identified by Mouffe, above.

Chapter Eight discussed the potential for imaginaries to determine what is visible. Sustainability and RRI could render the previously invisible visible; in other words, repoliticise or open up pertinent questions. Within this framework of imaginaries, narratives and ideas, other concerns are perhaps not ‘seen’ or not seen as valid, however valid or rational they are demonstrated to be by the social sciences (see Chapter Two). Many of the types of concerns expressed in relation to risky technologies – speed of change, commercial purpose, corporate control, industrialisation of nature – are hallmarks of the prevailing policy, as argued in Chapter Eight. To integrate and respond to those concerns by adapting the current arrangements of evidence-based decision-making could represent a fundamental conflict with the precepts of that policy which has all those arrangements as vital to achieving its goal of EU economic competitive leadership, allegedly the only route to addressing European problems, societal challenges and to maintaining the European way of life. This impasse is further entrenched by the appropriation (discussed above) or possible instrumentalisation of certain potentially disruptive

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<sup>1914</sup> Sum (n 1796) 198 and references therein.

concepts, such as sustainability or responsibility, so weakening them as tools to re-politicise or creating an arguably false consensus around the words and associated agendas, but not their substance. Ultimately, intentions to realise policy commitments to enhance socio-technical integration made in one area of policy seem overwhelmed by imperatives defined elsewhere. This implies that closing the policy-practice gap remains a distant prospect.

It is, admittedly, hard to see how this might change. As discussed in Chapters Five and Eight, deficit models of the public pervade EU innovation policy. Indeed, the imposition of a universal objective (risk-related) meaning on public questions regarding technological innovation and its implications imposes a model of a standard citizen who accepts such meanings and is incapable of constructing their own independent social meanings without the aid of expert framings of the relevant questions.<sup>1915</sup> This is also an instrumentalised model of citizens for whom safety is the ‘central end and meaning in public life’.<sup>1916</sup> It is possible that the reference in *Commission v Poland and Compassion* to science hints at the potential for a consensus to be formed around objective scientific evidence which again denies the rationality of different framings and pre-empts autonomous moral judgment. AG Léger’s approach in *Compassion* at least seemed to reflect a model of citizens who care only about safety and suggested the removal of the agency of morality to determine the (un)acceptability of a particular practice and, with it, cause to regulate on that ground. Such deficit models generally seem to disincentivise attempts to take valid public concerns seriously.

Technological determinism and the linear model of innovation also pervade EU policy on synthetic biology and innovation generally. As discussed in Chapter One, the assumption is that innovation shapes society rather than the other way round, again limiting reasons to imagine that publics may make valid contributions to deliberation over possible or desirable socio-technical futures. It is arguably not surprising then that engagement instead pursues public trust for these pre-

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<sup>1915</sup> Wynne, ‘Risk as Globalizing “Democratic” Discourse?’ (n 146) 71–72.

<sup>1916</sup> *ibid* 72.

determined pathways. As discussed in Chapter Eight, according to EU innovation policy, innovation drives socio-economic change. Economic interests prevail, or are seen as the means by which to protect or realise social, environmental or other values. As historical context, in framing its problems as insufficient economic competitiveness and a failure to keep up with the technological advances of their rivals, the EU in fact continues an ancient idea, dating back at least to rivalry between Athens and Sparta in the fifth century BC.<sup>1917</sup> Problem-framings, including assumptions of an anti-science culture, can be very resistant to change despite contrary evidence;<sup>1918</sup> this one particularly perhaps due to its longevity. Against this background, the chances of public concerns being heard, exerting influence and being responded to in decision-making, thereby contributing to closing the policy-practice gap, seem slim.

#### 4. Conclusion

I started this chapter with the observation that the question ‘what kind of society do we want?’ is often at the wellspring of the concerns, values and ideas expressed at every stage of innovation systems. It may be seen as inspiring reactions to innovation in the early stages of development and as informing the diverse attitudes expressed towards the risks of technological innovation downstream. At EU level, so far, the answer to this question seems to have been pre-determined: leadership in global economic competitiveness and resolved societal challenges, both driven by innovation distributed by the completed internal market. The durability of that vision is a testament to its flexibility and the myriad means it employs to secure support or assent, some of which I discussed in Chapter Eight and above. These include, most fundamentally, its ability to depoliticise by obscuring the existence of choice at all levels. Opposition to increments of technological innovation may indicate a broader dissatisfaction with a system in

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<sup>1917</sup> Tabachnick (n 2).

<sup>1918</sup> Steve Rayner, ‘Uncomfortable Knowledge: The Social Construction of Ignorance in Science and Environmental Policy Discourses’ (2012) 41 *Economy and Society* 107, 115–116.

which citizens are reduced to consumers,<sup>1919</sup> cultivated as a resource and educated out of irrational contumacy into apolitical acceptance and demand.

Some responsibility for the difficulty in achieving greater socio-technical integration must lie with the current shape assumed by the European and WTO trading regimes which may, at least partly, be attributable to aspects of the ideational architecture I discussed in Chapter Eight, particularly a commitment to governable emergence and the attribution to science of priority of agency. Trading regimes/markets do not emerge in isolation of human agency; they are constructed<sup>1920</sup> and they are currently constructed in a certain fashion. We could have trading regimes not constructed to appeal primarily to technical assessments to prove the lawfulness of regulation and which do not assume that certain trade-restrictive measures, if not justified by science, are protectionist.<sup>1921</sup> Efficiency need not always be the ultimate goal of innovation and its governance. Governments should be able to respond to cultural norms and concerns of citizens which recognise different framings of risk and uncertainty and that sometimes those contingencies are reflected in scientific evidence. This is partly about accepting different types of evidence. A changed trading regime which respected some of these values would think carefully and specify clearly the type of evidence which could be relied on, or the steps necessary to demonstrate the concerns are valid, such that an Austria could perhaps represent its cultural identity in relation to certain technologies in legal proceedings.

Of course, policy and regulation are not monolithic, as I have attempted to make clear in the foregoing chapters, and the wisdom of providing a single aetiology for a complex policy and regulatory disposition is questionable. However, the ideational architecture I have attempted to elaborate is also complex as well as

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<sup>1919</sup> Although consumption can have a political edge, Stokes, 'You Are What You Eat' (n 94) 192.

<sup>1920</sup> Lang, 'Reconstructing Embedded Liberalism' (n 1216) 102–105; Lang, 'Reflecting on "Linkage"' (n 998).

<sup>1921</sup> See Ruggie's take on so-called 'New Protectionism' and the growth of new trade barriers in the 1970s, Lang, 'Reconstructing Embedded Liberalism' (n 1216) 88–89.

long-standing and powerful and ultimately a major force, I argue, behind a reluctance in the EU to put its policy on socio-technical integration into practice. That is for both its normative and substantive effects. Substantive because of the irresistibility of its promises. Normative because of its tendency to throw an invisibility cloak over its choices and alternatives and an irrationality cloak over the concerns and objections of those who resist acceding to the 'rational consensus' around its substantive promises. The combination of those two elements, I argue, cannot otherwise than work to build support for the realisation of those promises by (almost) every means possible, particularly by keeping technology assessments technical and risk-based and thereby reducing opportunities for other concerns, perhaps trivial by comparison, to derail that realisation. It is hard to prove causation but, in that context, trade-offs to which risk assessments contribute seem already tipped in favour of the course of action (usually authorisation) most likely to produce the economic and social benefits expected to flow from technological innovation. And it is perhaps no surprise then, in that context, that economic and social drawbacks tend not to be identified and weighed in the balance against commercialisation. Not authorising a technology, after all that, would seem to dash all those dreams in one fell swoop.

However, that vision is one vision amongst many. We have choices; about the future of Europe and European society; about the types of innovation pursued; about the way we solve problems and address societal challenges; about which problems and challenges we discern and how we frame them (with, not subsequent to, science) and about the type of markets and economy we create. The existence of a choice is central to the constructivist thinking, which defines the approach I have adopted to science and technology, and to the market,<sup>1922</sup> and challenges the assumption that things (technologies, markets etc.) spontaneously emerge without human agency but rather are made up of ideas.<sup>1923</sup> Now, different ideas are needed, of which sustainability and responsibility are two. The task is considerable, not least

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<sup>1922</sup> *ibid* 92–93.

<sup>1923</sup> *ibid* 108; Rosamond (n 1602).

because, in part, the *raison d'être* of the EU is at stake here; its identity, constitution, integration, legitimacy, success, its means to progress and survive. It has sought to define itself as a political entity through its biotechnology policy<sup>1924</sup> and as an economic unit against an external competitive threat.<sup>1925</sup> However, as Aristotle observed, the task of constitution-building is a kind of *techne*.<sup>1926</sup> And to this kind of *techne* at least, we should not be averse.

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<sup>1924</sup> Jasanoff, *Designs on Nature* (n 11) 77–78, 92–93.

<sup>1925</sup> Rosamond (n 1602).

<sup>1926</sup> Heller (n 1774) 261.

## CASES, STATUTES AND TREATIES

### EU Cases

#### ***European Court of Justice/Court of Justice of the European Union***

- Case 8/74 *Procureur du Roi v Dassonville* [1974] ECR 837
- Case 120/78 *Rewe-Zentral AG v Bundesmonopolverwaltung für Branntwein (Cassis de Dijon)* [1979] ECR 649
- Case 34/79 *R v Henn and Darby* [1979] ECR 3795
- Case 50/80 *Bernhard Schloh v Auto Contrôle Technique SPRL* [1986] ECR 1855
- Case 40/82 *Commission v United Kingdom* [1982] ECR 2793
- Case 174/82 *Officier van Justitie v Sandoz BV* [1983] ECR 2445
- Case 72/83 *Campus Oil Limited v Minister for Industry and Energy* [1984] ECR 2727
- Case 178/84 *Commission v Germany* [1987] ECR 1227
- Case 121/85 *Conegate Ltd v Commissioners of Customs and Excise* [1986] ECR 1107
- Case 118/86 *Nertsvoederfabriek* [1987] ECR 3883
- Case 302/86 *Commission v Denmark* [1988] ECR 4607
- Case 145/88 *Torfaen BC v B&Q plc* [1989] ECR 3851 (ECJ)
- Case 331/88 *R v MAFF, ex parte Fedesa* [1990] ECR I-4023
- Case 35/98 *Staatssecretaris van Financiën v BGM Verkooijen* [2000] ECR I-4071
- Case 452/01 *Ospelt v Schlössle Weissenberg Familienstiftung* [2003] ECR I-9743
- Case 452/01 *Ospelt v Schlössle Weissenberg Familienstiftung* [2003] ECR I-9743, Opinion of Advocate General Geelhoed
- Case C-23/89 *Quietlynn Limited and another v Southend Borough Council* [1990] ECR I-03059
- Case C-23/89 *Quietlynn Limited and another v Southend Borough Council* [1990] ECR I-03059, Opinion of AG Lenz
- Case C-2/90 *Commission v Belgium* [1992] ECR I-4431
- Case C-275/92 *HM Customs and Excise v Gerhart and Joerg Schindler* [1994] ECR I-01039
- Case C-183/95 *Affish BV v Rijksdienst voor de keuring van Vee en Vlees* [1997] ECR I-04315

Case C-368/95 *Vereinigte Familienpress Zeitungsverlags- und vertriebs GmbH v Heinrich Bauer Verlag* [1997] ECR I-368

Case C-1/96 *Compassion in World Farming* [1998] ECR I-1251

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