

Book Reviews

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EU Environmental Law, Governance and Decision-Making

by Maria Lee

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*Lucas Bergkamp**

Toward a Transformative, Liberatory Hermeneutics of EU Risk Regulation?

The second edition of Maria Lee's book is a cautiously evaluative contribution to the debate on environmental governance and risk regulation. It is of significant interest to all who desire to understand some of the key points of contention in the public debate on the EU's governance of risk. The book's central theme is the perceived tension between science and democracy, or expertise and politics, in the process of risk regulation. Acknowledging that both facts and values are necessary to decision-making, Lee analyzes the processes employed by the EU to give each a place. As the book is well written, it is a pleasant, albeit not necessarily easy, read.

This second edition comes out nine years after the first edition,¹ and, as Lee notes in the preface, she has been "undisciplined" about "relying on its words."² When the first edition came out, the author was a Senior Lecturer in Law at King's College London; she now is Professor of Law at University College London, where she teaches and researches EU environmental law. Her credentials have contributed much to the book's strong academic quality and its generally tentative, reflective tone. Whilst phrased in seemingly balanced legal terminology, however, the book reflects a definite post-modern approach to legal scholarship.³ In some parts of the book, this approach dominates Lee's thinking; in those parts, reality and clarity are relegated to the backseat (see further below). If you like reading Michel Foucault, you will like reading Maria Lee's book; if you do not, you will need to work a bit harder on the evaluative parts.

I. The book's organization

Like the first edition, which received good reviews,⁴ the second edition is relatively short. The author did not attempt to cover all areas of EU environmental

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- 1 M. Lee, *EU Environmental Law: Challenges, Change, and Decision-Making*. Oxford: Hart, 2005.
- 2 M. Lee, *EU Environmental Law, Governance and Decision-Making*, Oxford: Hart Publishing, Second Edition, 2014 (hereafter "EU Environmental Law"), Preface.
- 3 The post-modern approach is characterized by the rejection of, inter alia, universal rationality, objectivity, reductionism, and absolutes. Instead, it emphasizes the social construction of reality, social subjectivism, holism, and relativism. In this view, any knowledge, including scientific knowledge, reflects specific interests and serves as an instrument for domination. "The theme that underlies all Foucault's work is the relationship between power and knowledge, and how the former is used to control and define the latter. What authorities claim as 'scientific knowledge' are really just means of social control." Philip Stokes, *Philosophy*: 100

Essential Thinkers (London: Arcturus, 2004), at p. 157 (discussing the theories of Michel Foucault). See also Michel Foucault, *The Birth of Biopolitics: Lectures at the Collège de France, 1978–1979*, Translated by Graham Burchell (London: Palgrave Macmillan, 2008). Put differently, science, law, and other domains of influence are instruments to effect the human "will to power." Friedrich Nietzsche, *Beyond Good and Evil* (1886), trans. Walter Kaufmann, New York: Vintage Books, 1966. Cf. Gary Minda. *Postmodern Legal Movements: Law and Jurisprudence at Century's End*. New York: New York University Press, 1995. M. Foucault, Nietzsche, Freud, Marx (1964). Paul Ricoeur called these three thinkers masters of the "school of suspicion," because they look for concealed motives, such the will to power (Nietzsche), sexual desire (Freud), and class interest (Marx). P. Ricoeur, *Freud and Philosophy*, translated by D. Savage, New Haven: Yale University Press, 1970, p. 32.

- 4 Abbot opined that "[h]er analysis of the challenges [the EU] faces and the extent to which it has responded is both innovative and stimulating." C. Abbot. Book review of Maria Lee, *EU Environmental Law: Challenges, Change, and Decision-Making* (2005), 69(5) *Modern Law Review* 2006, 855-868.

law. Rather, the book's objective is to provide "a relatively concise examination of some key issues in EU environmental law and governance, through the mechanisms of selected areas of substantive law."⁵ Whilst this approach has resulted in a somewhat eclectic collection of subjects reflecting the authors' interests, the book has a clear structure. It comprises four related parts.

The first part (chapters 1-3) covers the core principles of environmental governance as set forth in the Treaties, and related ideas, such as sustainable development. In the second part (chapters 4-6), regulatory techniques (instruments) and governance themes are explored, including the regulation of industrial pollution and climate change. The third part (chapters 7 and 8) focuses on public participation in environmental decision-making, both at the Member State level in the context of environmental assessment, and at EU level in the context of environmental decision-making in general. In the fourth part (chapters 9 and 10), the regulation of chemicals and genetically modified organisms (GMOs) is discussed. With respect to GMOs, but not chemicals, the focus is on the scope of Member State autonomy to regulate after EU regulation has been enacted. The fourth part suffers somewhat from the author's apparent lack of practical experience with the regulatory regimes she reviews; few of the issues faced by practitioners are covered.⁶

II. Questions and Definitions

Because Lee does not shy away from addressing the thorny policy issues, the book is engaging. The descriptive sections are kept to the minimum necessary to understand the context in which the issues arise. Clearly, the author has given much thought to the "hidden sides" of EU risk governance, and her readers benefit from her searching mind, as Lee surveys many of the key problems. In general, rather than trying to give definite answers, Lee is more concerned with identifying the right questions. This is admirable, since it enables the reader to pursue his own enquiry in a more effective and targeted manner. But Lee goes far in avoiding judgment, and at some point the reader may start to wonder what her opinion is.

Apparently, Lee believes that the right questions can be identified without defining key concepts. Given the book's length (or rather lack thereof), Lee in-

deed could not spend many words on definitions, even if she wanted to. In several instances, this is a significant problem; as discussed below, the reader is left guessing what the meaning is of key concepts in her analysis, such as "value" and "minority science." Further, in a few instances, Lee "assumes the problem away." For instance, in the preface, Lee first acknowledges that "political" is sometimes used as a synonym for "self-interested," and then declares that "[p]olitical decisions are normative decisions based on values (as well as facts)." She goes too quickly here. Is this all that should be said about the important distinction between public interest and public choice⁷ theories? To those who work in the real world of EU policy making and implementation, an assumption that political decisions are based solely on values and facts, and do not reflect special interests, does not sound plausible. Incentives are important, and politicians are exposed to incentives (such as those arising from the desire to be re-elected) that may be incompatible with value- or fact-based decision-making. For bureaucrats, the incentive structure is generally more complicated,⁸ but not at all limited to finding the relevant facts and values to reach decisions. This, *a priori*, is so for those who represent environmental NGOs, which must raise funds with the public, and companies, which must make a profit. In the environmental area, rent-seeking⁹ is big business, as a recent study on renewable energy policy once again demonstrated.¹⁰ The conceptualiza-

5 EU Environmental Law, Preface

6 For a discussion of practical issues arising under the REACH Regulation, see, for example, Lucas Bergkamp (editor), *The European Union REACH Regulation for Chemicals*, Oxford: Oxford University Press, 2013.

7 See, for instance D. Black, *The Theory of Committees and Elections*, Cambridge: Cambridge University Press, 1958. K.J. Arrow, *Social Choice and Individual Values*. Second Edition, Wiley, New York, 1963.

8 W.A. Niskanen, Jr., *Bureaucracy and Representative Government*, New York, Aldine, 1971. W.A. Niskanen, Jr., "Bureaucrats and Politicians," *Journal of Law and Economics*, December 1975, pp. 617–43. M. Ott, "Bureaucracy, Monopoly, and the Demand for Municipal Services," *Journal of Urban Economics*, November 1980, pp. 362–82.

9 A. Krueger, "The Political Economy of the Rent-Seeking Society," *American Economic Review* 1974, 64 (3): 291–303.

10 McKenzie Funk, *Windfall: The Booming Business of Global Warming*, New York: Penguin, 2014. An example in Belgium is the recent demise of Electrawinds, which received some EUR 140 million in subsidies. *Bestuur Electrawinds wacht gespannen af*, available at <http://www.gva.be/nieuws/economie/aid1498300/bestuur-electrawinds-wacht-gespannen-af.aspx> (visited May 1, 2014). See also W. Van Den Eynde, L. Pauwels, *De keizer van Oostende*, Van Halewyck, 2012.

tion of political decision-making therefore is not just some minor detail, but a critically important element in any attempt aimed at understanding how facts and values¹¹ are, and should be, reflected in the process.

III. Elements of EU risk regulation

In many ways, chapter 2, which is primarily concerned with “administrative decisions, such as the setting of detailed rules and standards,”¹² is the book’s cornerstone. Building on the principles and ideas reviewed in the first chapter, it discusses a range of important features of the EU process of risk-related decision-making, including risk assessment and cost-benefit analysis, and how expertise and politics manifest themselves in agencies and the comitology process. At critical junctures, Lee raises issues but does not clearly identify the strengths and weaknesses of the available options to solve specific problems. In addition, Lee evaluates the obligation under EU law to state reasons for decisions. As she points out, this requirement improves the quality of decisions and enables the public to assess and understand the decisions made and the court to review decisions that are challenged. In the remainder of this review, I focus mainly on this chapter, but before doing so, I offer a further observation.

The topic of transparency and public participation is not discussed in chapter 2, but in chapter 8. A disadvantage of this choice is that the relations between transparency and other key elements of the regulatory process, such as the use of science and the development of scientific advice, are not analyzed to any significant extent. In the next edition, the author may want to consider integrating these subjects in a

comprehensive analysis of the design of the EU’s risk governance system. A rigorous understanding of a risk governance system should explore the interrelations between system design, policies, and the institutions/agencies and their powers and responsibilities (including independence, staffing and expertise, etc.), and pay close attention to procedures for decision making, the administrative record, transparency, participation and consultation, expertise and scientific advice, risk assessment, cost/benefit analysis and impact assessment, ex post regulatory assessment, accountability and oversight, and administrative appeal and judicial review. In addition to an increased focus on substantive requirements, the analysis would also benefit from a strong dose of realism: how do these processes play out in the real world? Such integrated, realistic treatment of related topics might enable the author to come up with some recommendations on how to improve the current situation. It might also influence the author’s views on the tension between science and democracy as well as on some of the other issues she discusses.

IV. Is there tension between science and democracy (or expertise and politics)?

Lee asserts that there is “no crude bright line between expertise and politics” and that “the tension between these modes of reasoning is a key issue in EU environmental law.” Rather than explaining what she means by this, she expresses the hope that it will become clear in the course of her discourse.¹³ Indeed, the “tension thesis” seems to be the conventional wisdom,¹⁴ and Lee cites a few of the numerous publications that have developed this theme. But is there actually any such tension, and, if so, how exactly should this tension be conceptualized? How useful is it to characterize the interaction between the two systems as tension? Unfortunately, Lee does not attempt to understand these “modes of reasoning;”¹⁵ had she done so, she might have reached different conclusions.

It seems that Lee uses the term science in a loose way. The question arises whether it makes sense to speak generically of “science” without making further distinctions. For instance, should the natural sciences, including the biological sciences, which are key to risk regulation, be distinguished from the so-

11 The terms fact and value are likewise left undefined.

12 EU Environmental Law, p. 44.

13 EU Environmental Law, p. 28.

14 See, for instance, A. Liberatore, and S. Funtowicz, ‘Democratizing expertise, ‘expertising’ democracy: what does this mean, and why bother?, *Science and Public Policy*, 30: 3, 2003, pp 146-150. A. Blok, Experts on public trial: on democratizing expertise through a Danish consensus conference, *Public Understanding of Science* 2007; 16, pp. 163-182. M. Lengwiler, Participatory Approaches in Science and Technology: Historical Origins and Current Practices in Critical Perspective. *Science, Technology and Human Values*, 33; 2, 2008, pp 186-200.

15 EU Environmental Law, p. 28.

cial sciences?¹⁶ Roughly, the natural sciences are concerned with objective realities and the physical world, while the social sciences focus on subjective experiences and human behavior: this difference is fundamental and should have consequences. Further, can fundamental, applied, translational, and regulatory science all be included under one generic concept of science? Lee even seems to regard scientific policy advice as part of one eclectic concept of “science.”

To take the analysis further, it would have been useful to distinguish these various science-related activities. Doing so would clarify some of the issues with which Lee struggles. Of course, all of these activities are human activities, and, as such, none of them are entirely “neutral” and “value-free.” But there is a big difference between acknowledging that values may help identify what we should look for and how we look for it (e.g., in human subjects research), and arguing that any scientific activity is value-laden. Sure, the less settled the science is, and the less value consensus surrounds an issue, the larger the opportunities for manipulating scientific policy advice and decision making.¹⁷ The significance of the role played by values varies, and generally increases as we move from fundamental science to scientific policy advice. In a rather limited and often not very relevant sense, Lee is right where she speaks of “the inevitability of value judgments within technical assessment,”¹⁸ but is this is a tension between science and democracy? Isn’t this the way democracies make science useful to society within the constraints imposed by law? The real issue would seem to be whether decision making is rational and science-based or non-rational and non-scientific,¹⁹ which does not imply tension between science and democracy, unless one assumes that democratic decision making, by definition, is non-rational and non-scientific.

With respect to the perceived tension between the “modes of reasoning,” do science and politics employ different ways of reasoning? The answer to that question is not as obvious as it may seem. Science and politics have been conceived as different spheres of human activity, and both can play useful roles in society. In a democracy, politics needs science to make effective and efficient decisions, and science needs politics for funding and other support. Modern society prospers in no small part thanks to science and other useful expertise and knowledge. Indeed, as Post

put it, “[a] people without knowledge is a people without power or sovereignty.”²⁰ Knowledge and science in particular require rigorous rational reasoning; politics requires no mode of reasoning at all, or, rather, politicians employ any mode of reasoning that seems opportune to them. In what sense does this create a tension?

V. The missing piece: people, incentives, and science as political power

Because Lee’s definition of politics, to some extent, “assumes the problem away,” her analysis should be enriched with a good dose of realism to bring the issues into sharper focus. Being a lawyer, rather than an economist or political scientist, Lee is acutely aware of process and substantive requirements, but, by and large, ignores the people operating these processes (politicians, bureaucrats, and scientists²¹), their behavior in the real world, and the incentives to which they are subject. In a preceding section, I referred to the incentives to which politicians are subject. These incentives do not include “take science-based policy action,” except if such action has prior-

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- 16 See, for example, K. Popper, *The Poverty of Historicism* (1957), Routledge and Kegan Paul, 1974. C. W. Mills: *The Sociological Imagination*, London: Oxford University Press, 1959. S. Andreski, *Social Sciences as Sorcery*, London: Andre Deutsch, 1972.
 - 17 Pielke distinguishes between four idealized roles of scientists in the policy area and politics: pure scientist, science arbiter, issue advocate, and honest broker of policy alternatives. These distinctions are based on two views of science (linear model and stakeholder model) and two views of democracy (Madison and Schattschneider). R.A. Pielke, Jr., *The Honest Broker: Making Sense of Science in Policy and Politics*. Cambridge: Cambridge University Press, 2007, Chapter one.
 - 18 In my view, there is no reason to believe that the risk of unauthorized values intruding in scientific advice and assessment is beyond control. For the classical statement on the “objectivity” and “value-neutrality” of social research, see Max Weber on *The Methodology of the Social Sciences*, translated and edited by Edward A. Shills and Henry A. Finch, Glencoe, Illinois: The Free Press, 1949.
 - 19 Science-based decision making, of course is not ‘scientism,’ the belief in the universal applicability of the scientific method and approach. See F.A. von Hayek, *The Counter-Revolution of Science; Studies on the Abuse of Reason*. New York: MacMillan, 1955.
 - 20 R.C. Post, *Democracy, Expertise, Academic Freedom: A First Amendment Jurisprudence for the Modern State*. New Haven: Yale University Press, 2012, p. 95.
 - 21 Kuhn has shown that paradigm shifts in science are not a logically determinate process, but have much to do with non-scientific factors including possibly vested interests. T. Kuhn. *The Structure of Scientific Revolutions*. Third edition. Chicago: The University of Chicago Press, 1996.

ity²² and happens to be endorsed by the politician's constituency, which depends on a numbers of factors, including public perception²³ and the media attention²⁴ the issue receives.

Because science can enhance the ability of politicians and bureaucrats to pursue their agendas (or provide them with new ideas to put on their agenda), the political interest in science is strong. This implies that scientists may face pressure to produce science that supports intended policies or decisions, rather than science that is irrelevant to or contradicts them. Scientists that are or want to get involved in policy advice face similar temptations.²⁵ In short, there is a risk that science becomes politicized,²⁶ resulting in *policy-based science* rather than *science-based policy*.²⁷ This interaction, of course, has significant ramifications for both the pursuit of science and of politics, but Lee does not pay much attention to these issues, and endorses the common belief that "independence" of scientific committees from industry and government institutions will take care of the issue.²⁸

VI. The precautionary principle

Unfortunately, the precautionary principle has aggravated this problem by lending credence to scien-

tific policy advice phrased in inherently unscientific terms, e.g., "it cannot be excluded that A cause adverse effect X" or "there is a possibility that B causes adverse effect Y," the kinds of statements that can be made without any empirical data or in the face of empirical data that contradict the claim. To her credit, Lee is critical of the precautionary principle. She observes that there are risks associated with both regulating where it is not justified and not regulating where it is justified. That should lead her to conclude, absent any further relevant evidence, that any systematic bias for or against regulation is undesirable.

Surprisingly, having conceded that the precautionary principle "adds nothing to good practice" inasmuch as any EU environmental measure can also be justified in the absence of the principle,²⁹ Lee claims, in post-modern lingo, that the principle's main merit is that it "has the potential to open up a space for normative deliberation of the dilemmas sometimes posed by uncertainty, demanding attention to the process by which decisions are reached." But why would one need a vague principle to deliberate normative issues, or draw attention to a decision-making process? There is no restriction on deliberation, and any normative issue can be debated in the absence of the principle. If this is true, the precautionary principle, according to Lee's own logic, would be pointless. But then, maybe Lee is just trying to deal with the fact that the precautionary principle is in the Treaty and therefore should be given some meaning.

VII. Facts, values, and perception

In risk regulation, science is a prime source of facts, but by no means the only source. An important rationale for public consultation is to supplement the record with other relevant facts. For instance, companies may be able to provide facts that are directly relevant to issues of occupational or environmental exposure (e.g., with respect to the use of substance). Although this is the main justification for public consultation with respect to risk regulatory initiatives, Lee also focuses on process (or 'input') rationales.³⁰ Under the process approach, the justification of public consultation is not the collection of additional information. Rather, public consultation would be "an inherently beneficial (and indeed necessary) contri-

22 B.D. Jones, *The Politics of Attention: How Government Prioritizes Problems*. Chicago: The University of Chicago Press, 2005.

23 P. Slovic *The Perception of Risk*, *Science*, Vol. 236, No. 4799 (Apr. 17, 1987), pp. 280-285. Slovic argues that how people perceive risk is a function of many factors, such as whether the risk is voluntary or involuntary, whether it is old or new, known or unknown, etc.

24 Paul Slovic, James Flynn and Howard Kunreuther (editors), *Risk, Media and Stigma: Understanding Public Challenges to Modern Science and Technology*. London: Earthscan, 2001.

25 A career in scientific advice might be particularly attractive to those scientists who have an interest in policy and politics, and whose career options in the academic world are less than stellar.

26 See, for example, Michael Gough (editor), *Politicizing Science: The Alchemy of Policymaking*. Palo Alto: Hoover Institute Press Publication, 2003. Naomi Oreskes, Erik M. Conway, *Merchants of Doubt: How a Handful of Scientists Obscured the Truth on Issues from Tobacco Smoke to Global Warming*. New York: Bloomsbury Press, 2010.

27 Cf. Weingart, who claims that the scientificisation of politics and the politicisation of science have "destructive effects." P. Weingart, *Scientific expertise and political accountability: paradoxes of science in politics*, *Science and Public Policy* (1999) 26 (3): 151-161.

28 EU Environmental Law, p. 46.

29 EU Environmental Law, p. 5.

30 EU Environmental Law, p. 176-177.

bution to democracy,” as “citizens have a right to be involved in decisions that shape their world.”³¹ Lee does not explain how this squares with her observation that “it is not realistic to expect widespread participation of individual citizens in EU decision-making.”³² She might say “right” does not imply “duty,” and having the opportunity to participate is in itself important. But is this true also if democratic input is not believed to have any influence on the outcome?

In analyzing the fact/value distinction and the concept of evidence, Lee is disposed to relativize, destabilize, and deconstruct. She entertains the idea of injecting precautionary values into science. According to Lee, “the facts are less self-evident than they sometimes appear to be” and “uncertainty is always important.”³³ The “salience of an absence of proof,” Lee proclaims, “depends on whether values and interests are divided.”³⁴ Why would that be so? Lee provides no answer and no examples, so her readers are left in the dark where she is taking them. Her discussion is reminiscent of the “post-normal science” advocated a few decades back, which did not get much traction.³⁵ The ideas did not disappear, however, but continued to exercise a more subtle, hidden influence on thinking, and even lawyers that would not adopt its philosophy wholesale, could come under its spell. In this vein, based on the logic of “public perception of risk equals risk,” Lee also advocates labeling of consumer products to indicate the presence of chemicals, irrespective of actual risk.³⁶ Unfortunately, when the lines between fact and value, between science and pseudo-science, and between reality and perception become blurred, risk regulation will suffer.

VIII. Post-modern science

There are several ways science and other methods of fact-finding can be rendered “post-modern,” “post-normal” or “precautionary,”³⁷ most of which Lee entertains. First, resort can be had to “minority science,” instead of the scientific majority. Although the concept is wholly undefined, Lee opines that “minority science, quite rightly, is a legitimate basis for a decision at all levels.”³⁸ Whilst not explaining the reasons for her position, she acknowledges the risks associated with minority science, but does not suggest any limits on its use. It is conceivable that a lone scientist in hindsight turns out to a Galileo,³⁹ but there

is also a risk that he/she turns out to be a charlatan or otherwise wrong. Is the body politic capable of determining whether minority science is science, opinion, or junk science, and whether the scientist concerned is a Galileo or a charlatan? Wouldn't it be preferable to leave the assessment of such minority science to scientific advisory bodies?

Second, as Lee discusses elsewhere, risk assessment does not have to be quantitative, but may be, partially or completely, qualitative.⁴⁰ If risks are no longer quantified, even the most remote, smallest, and entirely unquantified risks detected in some study can feature prominently on the risk management stage. Lee endorses qualitative risk assessment, but does not discuss the effect it will have on the utility of risk assessment and on risk-related science. While she correctly states that unknown probability is not the same as low probability, she neglects to add that detection of a small effect requires a larger cohort, and, thus, at a fixed cohort size, smaller effects are less likely to be detected than larger effects;⁴¹ in a qualitative risk assessment, such a possible unquantified risk can feature prominently. That being the case, how useful is a fully qualitative risk assessment to a rational decision-maker?⁴²

31 EU Environmental Law, p. 177.

32 EU Environmental Law, p. 193.

33 EU Environmental Law, p. 38.

34 EU Environmental Law, p. 39.

35 Post-normal science focuses on “aspects of problem solving that tend to be neglected in traditional accounts of scientific practice: uncertainty, value loading, and a plurality of legitimate perspectives.” S.Funtowicz and J. Ravetz, *Post-Normal Science*, Internet Encyclopaedia of Ecological Economics, February 2003. It is a method of inquiry for cases in which “facts are uncertain, values in dispute, stakes high and decisions urgent.” S.O. Funtowicz and J.R. Ravetz, *A New Scientific Methodology for Global Environmental Issues*, In: *Ecological Economics, The Science and Management of Sustainability*. Ed. Robert Costanza. New York: Columbia University Press, 1991, pp. 137–152.

36 EU Environmental Law, p. 211.

37 Given the lack of any sufficiently precise and commonly agreed definitions, no distinctions can be made between these three terms.

38 EU Environmental Law, p. 53.

39 P.W. Huber, *Galileo's Revenge: Junk Science in the Courtroom*. Harper Collins: Basic Books, 1991.

40 EU Environmental Law, p. 35.

41 Steven Piantadosi. *Clinical Trials: A Methodologic Perspective*, 2nd Edition, Hoboken: Wiley, 2005, p. 251–277.

42 See L. Bergkamp, *The Quite Revolution in EU Administrative Procedure: Judicial Vetting of Precautionary Risk Assessment*, EJRR 2014, pp. 102 – 110.

Third, a “weight of the evidence” approach can be applied to a body of evidence.⁴³ This approach can be used instead of selection of the “best” (methodologically or otherwise) study from a series of studies. Under the weight of the evidence approach, which Lee does not discuss, weight can be given to methodologically or otherwise inferior studies that identify a risk. This approach creates the GIGO (“garbage in, garbage out”) problem: poor studies are also more likely to find risk, but a weight of the evidence approach does not exclude studies that are methodologically weak, statistically “underpowered,” or otherwise unreliable.⁴⁴ Like qualitative risk assessment, this practice creates incentives for choosing unproven sensitive methodologies that are likely to find an effect.

Fourth, to the extent that risk can be quantified, the statistical significance threshold or safety factors can be manipulated to lower the threshold for signaling a problem. Statistical significance is the probability of obtaining the results in fact obtained, assuming the null hypothesis (i.e. that there is no risk) is true. This is expressed in a value known as the P-value.⁴⁵ A P-value of 0.05, which is widely used in clinical research, means that there is a 5% chance that the results suggest an effect although there is none. Of course, in some sense, the 0.05 value is arbitrary; it could also be set at 0.005 or 0.5. Of these possible

values, 0.5 is the “most precautionary,” because it labels positive risk findings as statistically significant, even though there is a 50% risk that the finding is random. Would Lee be comfortable with this kind of precautionary science? She does not tell the reader, but, if so, wouldn’t it be troubling that such unreliable results are labeled statistically significant?

Fifth, thresholds, safety factors, study duration, and other “subjective” and “value-laden” elements of science can be manipulated to cause science to be more sensitive to potential effects, small effects, long term effects, upstream changes, and remote risks. Lee is silent on this point, but based on her general thesis of “value-laden” science, she might understand of such tactics.

Sixth, as noted above, even if nothing else changes, the conclusions of a scientific study can be phrased in post-modern terms to focus on what is unknown and uncertainty. An example is the following entirely non-scientific conclusion: “unintended direct or indirect metabolic consequences of the genetic modification cannot be excluded;”⁴⁶ indeed, effects can never be excluded. In Lee’s conception of risk regulation, these strategies could be used to create “space for the consideration of values.”⁴⁷

IX. Uncertainty revisited

Uncertainty, in a broad sense, is ubiquitous. But it can mean many things, and is not a useful concept without further definition. In her analysis, Lee is obsessed with uncertainty, and attempts to define what she means by it. Unfortunately, her attempt leads her in the wrong direction, and she gets pulled into some confused and troublesome thinking.

Lee suggests that uncertainty can present itself in several forms. It may be due to data gaps and lack of information.⁴⁸ This kind of uncertainty does not trouble Lee too much, and she seems to believe that research will solve it, although there will always be “new questions and new gaps.”⁴⁹ Ignorance, “we don’t know what we don’t know,” as Rumsfeld once famously proclaimed in relation to the presence of weapons of mass destruction in Iraq,⁵⁰ is a more “profound” kind of uncertainty. According to Lee, one instance would be “our brutal ignorance of the impact of chemicals on people and the environment.”⁵¹ The emphasis on the unknown, of course, is the hallmark of “post-modern science.”⁵² Even if there is no empir-

43 ECHA, How to report weight of the evidence, Practical Guide 2, European Chemicals Agency, 2010.

44 A panel report identifies issues that are likely to arise in WOE judgments and suggests the need for some guidelines to enhance rigor, predictability, and credibility. A. Abelkop et al. SCIENTIFIC AND POLICY ANALYSIS OF PERSISTENT, BIOACCUMULATIVE, AND TOXIC CHEMICALS: A COMPARISON OF PRACTICES IN ASIA, EUROPE, AND NORTH AMERICA. Report of a Consensus Panel, 2014.

45 In science, it has been said, there is only one value: the P-value.

46 Joël Spiroux de Vendômois, François Roullier, Dominique Cellier, and Gilles-Eric Séralini, A Comparison of the Effects of Three GM Corn Varieties on Mammalian Health, *Int J Biol Sci* 2009; 5(7):706-726.

47 EU Environmental Law, p. 56.

48 EU Environmental Law, p. 32.

49 EU Environmental Law, p. 32.

50 Department of Defense News Briefing - Secretary Rumsfeld and Gen. Myers, February 12, 2002, available at <http://www.defense.gov/transcripts/transcript.aspx?transcriptid=2636>

51 EU Environmental Law, p. 203. The reference to “brutal ignorance” is probably intended to suggest that there are serious adverse impacts.

52 Jean-Francois Lyotard, *The Postmodern Condition: A Report on Knowledge*. Manchester: Manchester University Press, 1984, p. 60.

ical evidence, this kind of uncertainty, Lee suggests, may in some cases be a legitimate basis for risk regulation if there has been a “democratic discussion about the acceptability of hypothetical risk.” This is in particular the case if the contested activity raises ethical concerns of has doubtful social benefits. “Ignorance” can be “a good reason for a decision,” Lee teaches us. Really? Should we endorse regulation of some activity or product posing a hypothetical risk of which we are completely ignorant based solely on “ethical concerns”? It is not hard to come up with some examples that demonstrate the perils of her proposal. The more remote a novel risk is and the smaller its magnitude or severity, the higher the level of uncertainty will be. An entirely unquantifiable hypothetical risk could be nothing but a figment of the imagination. In any event, Lee’s suggestion would lead to the paradoxical situation that we could end up regulating extremely remote unquantifiable risks, but not comparable larger risk that we are able to quantify.

But this is not all. When Lee goes on to discuss another form of uncertainty, indeterminacy, we enter the dark core of post-modernist thinking, where anything that smacks of rationalism is carefully purged. We now learn that “no matter how sophisticated the model, it will only ever provide a representation of reality, and can never completely capture an open system,”⁵³ and “uncertainty underlies our understanding of effects in ecosystems.” This, of course, is the post-modern stance against science’s “reductionism,” and for full recognition of system complexity forever beyond human comprehension.⁵⁴ On top of ecosystem indeterminacy, there is also “social system indeterminacy,” which is the “failure of human beings and human systems to behave consistently with the assumptions made in risk assessment.”⁵⁵ For reasons that Lee does not explain, this seems to lead necessarily to bad outcomes: bee populations, for instance, were adversely affected by unpredicted use of neonicotinoids. In an attempt to deal the final blow to science, Lee proclaims that such uncertainty “cannot be resolved by more or better science.”⁵⁶

Can science indeed be declared powerless in the face of uncertainty and indeterminacy? In biology, including human medicine, data, theories, and models have proved to be reliable and useful in solving complex problems (e.g., the role of insulin in diabetes). Although such models, of course, do not rep-

resent the entire organism, but only aspects of its functioning, they are capable of aiding decision making. Maybe Lee has the models in mind that are used to predict the effects of climate change. Indeed, these models are currently problematic because they attempt to predict changes in an incredibly complex global system: as has been said about bottom-up models and the prediction of the rise of the sea level, “the global system simply defies accurate and quantitative prediction because of its complexity.”⁵⁷ But Lee does not believe this; she believes that “the unconstrained addition of carbon to the atmosphere would be disastrous.”⁵⁸ Had she been true to her own teaching, she should have said that we do not know what the consequences of climate change will be. Or does the systemic indeterminacy Lee emphasizes somehow apply only to the absence of evidence of adverse effects, not to evidence of adverse effects?

If Lee says science is about things we do know and, by implication, in some sense, about things we do not know, but never about things “we do not know we don’t know,” then her statement is unhelpful and philosophically unsound; by definition, we do not know what we don’t know. But her conclusion that the degree of indeterminacy of ecological systems (or social systems for that matter) cannot be resolved by more or better science is questionable and shows pessimism bias. Echoing the post-modern critique of science, she seems to be saying that if one can think up one question about a potential or hypothetical risk that science cannot answer (which is not hard, since science cannot answer all questions, in particular non-scientific questions), regulation of the risk may be justified, if it proceeds pursuant to a “democratic discussion.” Should the law offer no protection at all against such arbitrary regulation with no basis in fact? If so, Lee does not think that it will come from the precautionary principle.

53 EU Environmental Law, p. 33.

54 S.Funtowicz and J. Ravetz, Post-Normal Science, Internet Encyclopaedia of Ecological Economics, February 2003.

55 EU Environmental Law, p. 33.

56 EU Environmental Law, p. 34.

57 Orrin H. Pilkey and Linda Pilkey-Jarvis, *Useless Arithmetic: Why Environmental Scientists Can’t Predict the Future*. New York: Columbia University Press 2007, p. 76.

58 EU Environmental Law, p. 37.

X. The role of values revisited

Lee's post-modernist inklings also dominate her views on the role of values in decision-making in the face of uncertainty. Her assumption seems to be that decisions have to be made, and cannot be postponed until there is further evidence. She seems to be suggesting that even if there is no or little evidence of a risk, values would be able to lead us to a decision. But what could these values involve? They cannot be the core values of environmental protection and human health protection, because these values cannot operate if no comparative risk analysis can be undertaken; they do not argue for or against regulation of a risk in the abstract. So the values Lee has in mind have to involve something else, but she is by and large silent on what that could be. With respect to almost any possible regulation, there is a series of competing values (liberty, innovation, efficiency, equality, justice, etc.) relevant to the decision to be made.

We get a hint, however, of the kinds of values that Lee deems relevant. First, not all values are equally important: only those values count that are held by the "community of reference,"⁵⁹ an undefined concept that will likely be a rich source of political quarreling. Whether efficiency is a value at all, according to Lee, "is enormously contentious."⁶⁰ Apparently, an ethic of productivity is not Lee's thing. The area of agricultural biotechnology offers some insight into how this might play out in a specific case. In deciding how to regulate biotech farming, Lee suggests that account be taken of the interests of small and organic farmers, and, as a related matter, of the societal interest in limiting corporate control of food production.⁶¹ But how are these values relevant to regulating health, safety, and environmental risks? The "risk" that small and organic farmers may have a hard

time competing with biotech farmers, is only remotely, if at all, related to such risks. Moreover, is the protection of small, organic, and apparently uncompetitive and inefficient farming a value? Maybe, but it has little to do with the risks of biotechnology that can justify regulation. Likewise, the "risk" of large corporate food production is an issue only if one believes that corporations should not be involved with food production. If these values are deemed important, they should play a role not only where risk is uncertain, but in any situation where they are relevant. Accordingly, where Lee discusses REACH authorization, a highly regulated process in which the EU legislature intentionally limited the discretion of administrative decision makers, she submits that it would be appropriate to consider "who bears risks, who benefits from risks, and which risks are 'acceptable'."⁶² The legal problem, which Lee ignores, is that such values may have no place in environmental, health and safety risk regulation, because they do not relate to environmental, health or safety effects. Giving these values any weight in risk regulatory decision making may meet demands of "democracy" and "inclusiveness", but will have an adverse effect on legality and accuracy.⁶³ In other words, contrary to what Lee asserts, these values may well be "an illegitimate intruder into 'objective' decision-making."⁶⁴

XI. Risk assessment and cost-benefit analysis

Lee pursues this thread in the areas of risk analysis and cost-benefit analysis (CBA). According to Lee, CBA and risk assessment have very little to contribute to the biotechnology debate. In risk assessment, Lee posits, choices are made. Neither CBA nor risk assessment "provide a single neutral assessment, which stands above politics and values."⁶⁵ Political choices, Lee asserts, must be made about the distribution of harms and benefits. Economic methods of quantifying benefits or costs that place "the same weight on everyone's money, rich or poor, [are] likely to prioritise the environmental problems of the rich."⁶⁶ This is the typical academic criticism of CBA and risk assessment, but is it accurate?

Of course, risk assessment and CBA are not "value-free," but the role of value judgments is often grossly exaggerated. Where particular normative is-

59 EU Environmental Law, p. .

60 EU Environmental Law, p. 36.

61 EU Environmental Law, p. 36.

62 EU Environmental Law, p. 219.

63 J. D. Trout, Democracy and scientific expertise: illusions of political and epistemic inclusion, *Synthese*. May 2013, Volume 190, Issue 7, pp 1267-1291.

64 EU Environmental Law, p. 38.

65 EU Environmental Law, p. 37.

66 EU Environmental Law, p. 35.

sues arise, they are often situation- and context-specific. There is no question that regulation informed by CBA has advantages over regulation informed by the decision making unaided by CBA or aided by the main alternatives to CBA. CBA is not inherently biased in the way benefits and costs are computed.⁶⁷ In the real world, situations where values play significant roles in CBA are rare.⁶⁸ Moreover, the way CBA is conducted itself can be regulated, and the values used and uncertainties in the analysis can be stated explicitly. Whether doing so in all cases serves a useful purpose is a different question; characterization of uncertainties about probabilities, for instance, may provide no or little information to decision makers.⁶⁹

XII. Conclusions

Maria Lee should be commended on a job well done. Reflecting strong scholarship and prudent judgment, her new book deserves to be read widely. Her admirable attempt to throw light in the dark corners of EU risk decision making will be of great value to those who want to understand its essence. Although it does not give the reader the full picture, it discusses the key issues related to the big picture, which is no easy job indeed. And whilst it does not attempt to answer the multitude of questions raised by the EU's risk governance system, it brings up interesting issues and asks the right kind of questions. Thus, Lee's book is of greater value in raising questions than in answering them.

The reader who is well versed on risk governance will be able to discern the threads of post-modern thinking in Maria Lee's narrative and the potential subversive influence thereof on the legality and accuracy of outcomes. To a substantial degree, Lee's "transformative, liberatory hermeneutics"⁷⁰ of EU risk regulation endorses the thinking of those who advocate the need for a "new science" and a "new relationship between science and governance."⁷¹ This school of thought has identified some issues that require attention, but it has not provided the right answers. The book should therefore be supplemented with other publications that highlight different ways of thinking about the same problems, in particular the rational and neo-rational approaches which focus more on ensuring the legality and accuracy of outcomes.

I already look forward to the third edition of Maria Lee's book, which, based on my own scientific, value-free extrapolation, will come out in 2023.⁷²

Empirical Views on European Gambling Law and Addiction

by Simon Planzer

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David Miers*

There has, of late, been no shortage of activity at the level of the European Union concerning its institutions' reach over or their ambitions for the regulation of both remote and non-remote gambling within and across the Member States. In 2012 the Commission published its Communication *Towards a comprehensive European framework for online gambling* and later that year the resulting Road Map, whose two-fold Initiative, *Recommendations on common protection of consumers and responsible gambling advertising*, aims to advance the EU's public interest in the protection of the consumers of internet gambling services.¹ Over the past 18 months there has at the European Parliament been a succession of Questions for Written Answer to the Commission concerning online gambling, children's access to

67 John D. Graham, *Saving Lives Through Administrative Law and Economics*, 157 U. PA. L. REV. 395 (2008).

68 Cass R. Sunstein, *The Real World of Cost-Benefit Analysis: Thirty-Six Questions (and Almost as Many Answers)*, *Columbia Law Review*, Vol. 114, No. 1, 2014, pp. 167-211

69 Louis Anthony Cox Jr., Gerald G. Brown and Stephen M. Pollock, *When Is Uncertainty about Uncertainty Worth Characterizing?*, *Interfaces*, Vol. 38, No. 6 (Nov. - Dec., 2008), pp. 465-468.

70 Cf. Alan Sokal, *Transgressing the Boundaries: Towards A Transformative Hermeneutics of Quantum Gravity*, *Social Text*, 46/47, Summer 1996, pp. 217-252.

71 Silvio Funtowicz, Iain Shepherd and David Wilkinson, *Science and governance in the European Union: a contribution to the debate*, *Science and Public Policy* (2000) 27 (5): 327-336.

72 The formula is year of publication of next edition = year of publication of most recent edition plus 9 years.

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1 European Commission, *Towards a comprehensive European framework for online gambling* Strasbourg, 23 October 2012, Com (2012) 345 final; *Recommendation on common protection of consumers of gambling services* DG MARKT UNIT E3 (11/2012). http://ec.europa.eu/smart-regulation/impact/planned_ia/docs/2013_market_022_023_gambling.pdf.