Administrative Legitimacy and Risk Regulation in the European Union and the United States

Christopher Paul Anderson

Faculty of Laws
University College London

Thesis submitted to UCL for the degree Doctor of Philosophy

June 2016

‘ I, Christopher Paul Anderson, 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

The thesis is a comparative study of administrative law and risk regulation in the European Union and the United States. The analysis proceeds from the premise that the main objective of administrative law is to reconcile the exercise of bureaucratic power with liberal democratic values. In this way, administrative law constructs the legal legitimacy of administrative regulation, including administrative risk regulation. As such, administrative law systems are expressions of legal culture. The thesis argues that the most important differences between European and American risk regulation are better explained as expressions of the normative commitments of the two constitutional systems rather than as the product of different attitudes toward technological risk. Methodologically, the thesis is a comparative study of legal doctrine and, thus its goal is to understand the unique contribution of law as a discourse to the social phenomenon of risk regulation.

After setting out the theoretical framework in chapter 1, the thesis compares three major aspects of EU and US administrative law in the context of risk regulation. Chapter 2 addresses the institutional structures of the two administrations, as well as European and American theories of delegation. Chapter 3 considers legal approaches to defining the public interest in risk regulation through a study of the roles of the precautionary principle and cost-benefit analysis in the two jurisdictions. Chapter 4 considers the concept of administrative rationality in the EU and the US, with a focus on the role of science in risk regulation. In chapter 5, the thesis pulls together the various strands of doctrine discussed in the earlier chapters and synthesises them into general reconciliations of administrative risk regulation with EU and US constitutional values. The final chapter, chapter 6, reflects on the normative visions of administration implied in the two jurisdictions' administrative law doctrines.

Acknowledgments

No one ever accomplishes anything meaningful on his or her own, and that is emphatically true of this thesis. Without the encouragement, mentoring, and support of many, it would not have been finished.

As a law student, I was lucky to have great teachers. By way of an omnibus footnote, I want to acknowledge the influence of Christopher Edley, Gerald Frug, Morton Horwitz, Elena Kagan, Richard Lazarus, Daniel Meltzer, Arthur Miller, David Rosenberg, Laurence Tribe, and Kip Viscusi; their ideas are on every page of this thesis. Above all, I am grateful to Lani Guinier, whose support has never wavered.

Here at UCL, my greatest thanks go to Richard Rawlings and Maria Lee, who have been an unsurpassable supervisory team. Their patience, insight, and good humour have improved every aspect of the thesis. Thanks also go to Carol Harlow for constant encouragement.

Law is foremost a profession, and I have learned much from my colleagues in practice: most of all, Judge Bruce Selya, for whom I was privileged to clerk, but also my mentors at Arnold & Porter, especially Thomas Milch, Michael Gerrard, Mary Gabrielle Sprague, and Michael Daneker.

Finally, and far from least, I owe an enormous debt to my family and friends. My father and sister have both put up with bad tempers and missed holidays, but have always been there to cheer me on. Joy Twesigye has been by my side, in spirit if not always in body, since we were twelve. Even more than these, I could not have completed this thesis without the love and encouragement of my partner, Sean O'Neill, who put his career on hold (and gave up many other irreplaceable things besides) to move to London for no better reason than to make me happy.

My deepest thanks, however, go to my late mother, Pamela Bell Anderson, who worked tirelessly so that my sister and I could have every opportunity available and only ever asked that we make use of them. Without her love and support, this thesis simply would not have happened. It will always be a great sorrow to me that she did not live to see me "Piled higher and Deeper," as she would have put it in her own wry way. This thesis is dedicated to her.

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1

Introduction— Administrative Law, Risk, and Legitimacy

This thesis is an essay in comparative administrative law. Its aim is to explore the different ways in which administrative law constitutes, structures, and legitimates public administration in the European Union and the United States. Administrative law is a broad and not always clearly defined field. In its most general sense, it is that body of law that is concerned with the reconciliation of the exercise of power by bureaucracies with constitutional and rule of law values.[1] In this way, administrative law is fundamentally concerned with the legitimation of bureaucratic power. My primary interest in this thesis is in analysing and comparing the concept of legitimate administration in EU and US law.

Administrative regulation is a complex phenomenon and can fruitfully be explored from many disciplinary and methodological perspectives. In recent years, interdisciplinary scholarship has come to the fore, and much valuable work has been done that combines legal analysis with economic, political science, and sociological perspectives. Often, however, the broader perspective of interdisciplinary scholarship comes at the expense of disciplinary depth. In this thesis, I have chosen to take the other side of that trade-off and analyse administration solely from the perspective of law. Even more unfashionably, my focus will be on legal doctrine, by which I mean authoritative legal materials and the processes of reasoning about those materials applied in judicial proceedings. In other words, this thesis is concerned with the ways in which lawyers make sense of the phenomenon of public administration within the

[1] Cf. Fisher, *Risk Regulation and Administrative Constitutionalism* (Hart 2007) 24.

framework of constitutional democracy. Thus, I am interested in administrative law as an idealist system, rather than as an object for empirical study.[2] This type of analysis may seem old fashioned, even misguided, in the face of challenges to the coherence of law as an academic discipline. As an intellectual descendent of the American legal realists, I am acutely aware that law is not autonomous, but is instead a product of its social context.[3] Nonetheless, law is a distinct discourse for analysing social problems, with its own modes of reasoning and its own distinctive normative commitments.[4] Moreover, law is a real locus of power in liberal democratic systems, including the EU and the US, both of which espouse the rule of *law*. Thus, for all its artificiality, an understanding of law as an intellectual system must be part of our understanding of social relations. And, as an object of comparative study, law is all the more interesting for its social constructedness.[5]

This thesis is thus unapologetically a comparative study of legal doctrine, rather than a study of administrative regulation more generally. My intention, however, is to go beyond merely describing legal rules and to try to tease out some of the broader principles and normative commitments that animate the doctrine. By doing so, we may begin to understand not just how the EU and US address regulatory problems differently, but also how the EU and US legal systems understand regulatory problems differently.[6] A better understanding of these deep conceptual differences should open up new avenues for comparative analysis and new possibilities for regulatory learning and cooperation.

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[2] Cf. Mashaw, 'Explaining Administrative Process: Normative, Positive, and Critical Stories of Legal Development' (1990) 6 J.L.Econ&Org. 267, 267–69.

[3] Fisher, Horwitz, and Reed, *American Legal Realism* (OUP 1993) 164–71.

[4] Merryman and Pérez-Perdomo, *The Civil Law Tradition* (3d ed., Stanford 2007) 150–51; Monaghan, '"Marbury" and the Administrative State' (1983) 83 Colum.L.Rev. 1, 4.

[5] Örücü, *The Enigma of Comparative Law* (Martinus Nijhoff 2004) 123–27.

[6] Cf. Bell, *French Legal Cultures* (Butterworths 2001) 14–16; Ewald, 'Comparative Jurisprudence (I): What Was It like to Try a Rat?' (1995) 143 U.Pa.L.Rev. 1889, 1987–89.

This thesis is about administrative law, but it is also about risk regulation. Risk regulation may be defined as the field of regulation that attempts to identify and prevent or ameliorate potential adverse effects of technology. My concern in this thesis is only with technological risk. In recent years, the rhetoric of risk regulation has expanded from its origins in health, safety, and environmental regulation to areas such as criminal law and financial market regulation.[7] These domains of risk present many fascinating problems and deserve to be studied, but they also present distinct issues that cannot be addressed within the scope of a single thesis. Limiting the discussion to issues of technological risk allows for deeper analysis of the special problems associated with regulation of technological risk, in particular the role of scientific expertise in administrative decisionmaking.

In addition to being limited to a certain type of risk, the thesis is limited to a certain aspect of regulation, namely standard setting, which can be defined as the promulgation of generally applicable rules permitting or prohibiting products or processes[8] under specified conditions.[9] Standard setting broadly encompasses activities such as setting air quality standards, setting limits on pesticide residues in food, or authorising the marketing of particular products. It excludes, however, other types of regulatory activities, such as enforcement actions or the

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[7] Black, 'The Emergence of Risk Based Regulation and the New Public Management in the UK' [2005] PL 512, 516–18; Fisher, 'The Rise of the Risk Commonwealth and the Challenge for Administrative Law' [2003] PL 455, 456–60; Monahan and Skeem, 'Risk Redux: The Resurgence of Risk Assessment in Criminal Sanctioning' (2014) 26 Fed.Sentencing.Rptr. 158; Rothstein, Borraz, and Huber, 'Risk and the Limits of Governance: Exploring Varied Patterns of Risk-Based Governance Across Europe' (2013) 7 *Regulation & Governance* 215, 216–18.

[8] Some common types of risk regulation include restrictions on products (e.g., restrictions on the sale of pesticides) and restrictions on processes (e.g., limits on the discharge of effluent into a water body). For brevity, I will henceforth just use the term "products" to refer to any risk-producing phenomenon.

[9] Cf. Fisher, 'Drowning by Numbers: Standard Setting in Risk Regulation and the Pursuit of Accountable Public Administration' (2000) 20 OJLS 109, 111–12.

funding of research. A focus on standard setting is particularly appropriate in a comparative analysis involving the EU because the large majority of the EU's regulatory activities take this form.[10] Limiting the range of administrative actions under consideration also helps to focus the inquiry on a narrower range of legal issues.

Several aspects of risk regulation make it an attractive topic for a study of comparative administrative law. For the last forty years or more, risk regulation has become an increasingly important regulatory focus on both sides of the Atlantic. One by-product of the prominence of risk regulation is that many of the most important administrative law debates of recent years have occurred in this context. In particular, risk regulation has been the main point of reference for debates over the proper role of scientific and technical expertise in regulatory decisionmaking.[11] Additionally, risk regulation is often held up as a prime example of divergent European and American regulatory approaches[12]

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[10] Brandsma and Blom-Hansen, 'Controlling Delegated Powers in the Post-Lisbon European Union' [2015] JEPP 1, 1. The increasing role of the EU in implementing the norms it produces should not be ignored. E.g., van Cleynenbreugel, *Market Supervision in the European Union: Integrated Administration in Constitutional Context* (Brill 2014) 9–12. For now, however, the focus of risk regulation at EU-level remains on norm production (standard setting).

[11] Azoulay, 'The Judge and the Community's Administrative Governance' in Joerges and DeHousse (eds.), *Good Governance in the European Union* (OUP 2002) 112–14; Edley, *Administrative Law: Rethinking Judicial Control of Bureaucracy* (Yale 1990) 118–23; Fisher (n.1), chs. 3, 6; Joerges, 'Scientific Expertise in Social Regulation and the European Court of Justice: Legal Frameworks for Denationalized Governance Structures' in Joerges, Ladeur, and Vos (eds.), *Integrating Scientific Expertise into Regulatory Decision-Making* (Nomos 1997) 296; Stewart, 'The Development of Administrative and Quasi-Constitutional Law in Judicial Review of Environmental Decisionmaking: Lessons from the Clean Air Act' (1977) 62 Iowa.L.Rev. 713, 737–40.

[12] E.g., Alemanno, 'The Science, Law and Policy of Neonicotinoids and Bees: A New Test Case for the Precautionary Principle' (2013) 4 EJRR 191, 200–03; Brickman, Jasanoff, and Ilgen, *Controlling Chemicals: The Politics of Regulation in Europe and the United States* (Cornell 1985); Jasanoff, *Designs on Nature* (Princeton 2005); van Zwanenberg and

and, as such, we might expect to find interesting differences in the ways EU and US law address the issue.

My intention, however, is for the analysis of risk regulation presented in this thesis to be more than just a case study for the investigation of administrative law doctrine. A great deal of valuable comparative work has been done on EU and US risk regulation, but most of this scholarship has focused on regulatory outcomes[13] or on the operation of specific regulatory concepts in isolation (e.g., precaution).[14] As a consequence, this work tends to downplay or even ignore the importance of systemic legal concerns in the practice of risk regulation.[15] The failure to attend to legal context leaves an important gap in the scholarship because, as this thesis will show, much of the legal discourse on risk regulation is an outgrowth and reflection of administrative law principles that developed in response to normative concerns other than risk. For example, theories of delegation are crucial to understanding how the EU and US courts construe administrative authority to regulate risk, but those theories developed long before risk regulation was a common regulatory activity. My hope is that this thesis will contribute to the comparative literature on risk regulation, as well as the literature on administrative law, by demonstrating the connections between administrative law doctrines and the ways in which risk is framed and regulated in the two jurisdictions.

In the remainder of this introductory chapter, I address two issues. First, I examine in some detail the concept of risk and the complications of risk science. Although these issues are not the focus of the thesis, a basic knowledge of them is necessary both to understand the particular

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Millstone, *BSE: Risk, Science, and Governance* (OUP 2005) 19–28; Vogel, *The Politics of Precaution* (Princeton 2012).

[13] E.g., Harrington, Morgenstern, and Sterner, *Choosing Environmental Policy* (RFF 2004); Wiener, Rogers, Hammitt, and Sand (eds.), *The Reality of Precaution: Comparing Risk Regulation in the United States and Europe* (RFF 2011); Vig and Faure (eds.), *Green Giants?: Environmental Policies of the United States and the European Union* (MIT 2004).

[14] E.g., Sunstein, 'Beyond the Precautionary Principle' (2003) 151 U.Pa.L.Rev. 1003.

[15] Fisher (n.1), 14–16.

challenges posed by risk regulation and to evaluate the adequacy of the responses. Second, I explain my methodological approach. One weakness of doctrinal scholarship is that it tends to cover up its own theoretical commitments. By explaining my methodology in detail, I hope to clarify my understanding of the methods and goals of doctrinal analysis, as well as to define the boundaries of the thesis.

I. The Concept and Perception of Risk

A. The Meaning of Risk

One of the problems with the term "risk" is that it is a portmanteau word that is used to convey different meanings in different contexts. Indeed, many of the controversies over risk regulation could be reframed as debates about the meaning of "risk" itself. Although the meaning of risk continues to be debated, it is no longer seriously disputed that it is a complex concept with empirical, normative, psychological, social, and political dimensions, and there is an enormous literature exploring various aspects of the concept.[16]

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[16] It is not possible in the space of this thesis to attempt to address this literature comprehensively. Two good brief overviews of some of the key concepts are Fisher, 'Risk and Environmental Law: A Beginner's Guide' in Richardson and Wood (eds.), *Environmental Law for Sustainability* (Hart 2006) and Lee, *EU Environmental Law* (2d ed., Hart 2014), 28–44. Other useful general works include Beck, *Risk Society* (Sage 1992) (offering an influential sociological account of the role of risk as an organising theme in contemporary society); Bernstein, *Against the Gods: The Remarkable Story of Risk* (Wiley 1998) (chronicling the history of the concepts of probability and risk); Breyer, *Breaking the Vicious Circle* (Harvard 1993) (elaborating an empiricist and expert-driven approach to risk regulation); Douglas and Wildavsky, *Risk and Culture* (University of California 1983) (discussing the role of culture in the identification and evaluation of risk); Hood, Rothstein, and Baldwin, *The Government of Risk* (OUP 2001) (reviewing several existing approaches to the regulation of health risks); Kysar, *Regulating from Nowhere* (Yale 2010) (discussing the limits of expert evaluation in the appraisal of risks); Rodricks, *Calculated Risks* (2d ed., CUP 2006) (providing a nontechnical review of issues in toxicology and quantitative risk assessment); Schrader-Frechette, *Risk and Rationality* (University of California 1991) (giving a philosophical

Broadly speaking, risk can be understood as incorporating two types of judgments about a technology. On one hand, risk is an empirical phenomenon, i.e., a probabilistic prediction of observable physical events that the technology may cause.[17] The classic example of this type of risk is the probability that a specific exposure to an identified chemical will result in the exposed individual contracting cancer. An empirical conception of risk underlies scientific, and in particular quantitative, risk assessment and tends to deemphasise the personal or social significance of technological hazards. On the other hand, risk can also be understood as a set of value judgments about a technology.[18] On this view, the significance of a risk is assessed not solely (or even at all) in terms of the probability of a physical response, but also in terms of the values that a technology implicates. For example, a risk of harm that is involuntarily imposed on an individual may be judged to be worse than a statistically equivalent risk that is voluntarily incurred because involuntarily imposed risks infringe values of personal autonomy and bodily integrity in a way

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account of risk that focuses on the role of values but also defends the use of quantitative risk assessment); Steele, *Risks and Legal Theory* (Hart 2004) (discussing how various legal theorists have formulated and used the concept of risk, including contexts other than risk regulation); Sunstein, *Risk and Reason* (CUP 2004) (developing a theory of risk regulation based on an empiricist view of risk).

Several reports discussing risk and its regulation have also been commissioned by government bodies. Some important examples include: Expert Group on Science and Governance, *Taking European Knowledge Society Seriously* (European Commission 2007) 31–42; National Research Council, *Understanding Risk: Informing Decisions in a Democratic Society* (NAP 1997); National Research Council, *Risk Assessment in the Federal Government: Managing the Process* (NAP 1983) (the "*Red Book*"); Royal Commission on Environmental Pollution, *21st Report: Setting Environmental Standards* (HMSO 1998) (particularly chapter 4).

[17] E.g., Breyer (n.16), 10–29; Rodricks (n.16), 202–04; Sunstein (n.16), 29–33.

[18] Ackerman and Heinzerling, *Priceless* (New Press 2004) 210–23; Kysar (n.16), 222–24; Wynne, 'Creating Public Alienation: Expert Cultures of Risk and Ethics on GMOs' (2001) 10 *Science as Culture* 445, 456–57.

that voluntarily incurred risks do not.[19] Although these two aspects of risk are conceptually distinct, in practice individual appraisals of risk incorporate both types of judgments and may not be fully analysable into empirical and normative components.[20]

In addition to conceptual analyses of risk, a large body of scholarship has examined risk as a cognitive phenomenon.[21] Much of this work has focused on the role of heuristics in individuals' judgments about risk.[22] A heuristic is simply a cognitive short-cut that can be used when better information is unavailable or the available information is too complex to be easily digested into an intuitive judgment.[23] For example, people tend to view risks associated with unfamiliar technologies to be worse than those associated with familiar ones.[24] Heuristics and values are not the same things. Heuristics are psychological processes by which people make empirical estimations.[25] Values are one way in which people give meaning to social and empirical phenomena.[26] The relationship between the two, however, is complex and there is controversy regarding how they should be distinguished.[27] The central role of cognition in the formation

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[19] Schrader-Frechette (n.16) 97; Slovic (ed.), *The Perception of Risk* (Routledge 2000) 94.
[20] National Research Council, *Science and Decisions: Advancing Risk Assessment* (NAP 2009) 31–32.
[21] The pioneering work was done by Daniel Kahneman, Paul Slovic, and Amos Tversky. Kahneman, Slovic, and Tversky (eds.), *Judgment Under Uncertainty: Heuristics and Biases* (CUP 1982); Kahneman and Tversky, *Choices, Values, and Frames* (CUP 2000); Slovic (n.19).
[22] Kahneman, *Thinking Fast and Slow* (Penguin 2012); Sunstein, *Laws of Fear: Beyond the Precautionary Principle* (CUP 2005) 35–49, 64–88.
[23] Sunstein (n.22), 36.
[24] Slovic (n.19), 140–43.
[25] Kahneman, Slovic, and Tversky (n.21), 3–4.
[26] Anderson, *Value in Ethics and Economics* (Harvard 1995) 2–4.
[27] See, e.g., the debate between Sunstein, who interprets heuristics as a form of bounded rationality, and Kahan and Slovic, who see values at work in cognitive heuristics. Kahan, Slovic, Braman, and Gastil, 'Fear of Democracy: A Cultural Evaluation of Sunstein on Risk' (2006) 119 HLR 1071 (reviewing and critiquing Sunstein (n.22)); Sunstein, 'Misfearing: A Reply' (2006) 119 HLR 1110; and Kahan and Slovic, 'Cultural

of judgments about risk adds another layer of complication to risk evaluation. It also raises difficult questions about how regulators should respond to public judgments about risk that may be based on heuristics, particularly the extent to which such judgments may justify the imposition of regulatory controls.[28]

The complex nature of individuals' judgments about risks raises a number of interesting legal, regulatory, and policy problems. Most fundamentally, the complexity of risk and the multiplicity of perspectives means that regulatory judgments about risk will always be controversial to some degree.[29] The inevitable persistence of controversy creates a need for some process by which "closure" on the characterisation of risks can be reached so that regulatory decisions can be made.[30] As will be explained in the following chapters, administrative law principles are often central to determining how and when closure on risk evaluation will be reached and by whom.

B. The Regulation of Risk

Although there is broad agreement that risk is a complex concept that incorporates both empirical and normative judgments, the issue of how regulators should respond to the phenomenon of risk remains highly controversial. That controversy persists, in part, because the nature of risk as a concept cannot resolve disputes about how society should respond to it. Rather, normative questions about risk regulation can only be answered by reference to political theories about (among other things) the role and limits of government, the nature of democracy, and the

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Evaluations of Risk: "Values" or "Blunders"?', 119 Harv.L.Rev.Forum 1110 (2006).

[28] See the discussion cited ibid.

[29] Douglas and Wildavsky (n.16), 4.

[30] Jasanoff, 'Science, Politics, and the Renegotiation of Expertise at EPA' (1992) 7 *Osiris* 194, 201; Stirling, 'Risk, Uncertainty and Precaution: Some Instrumental Implications from the Social Sciences' in Berkhout, Leach, and Scoones (eds.), *Negotiating Environmental Change* (Edward Elgar 2003) 62–63.

proper ends of regulation.[31] And with respect to the focus of this thesis—administrative risk regulation—there is yet another layer of questions regarding the role of the administration and its relationship with other organs of government. Failure to address these questions explicitly helps to explain why writers on different sides of risk regulation debates so often seem to talk past one another. A goal of this thesis is to make explicit the links between normative commitments of the EU and US legal systems and the approach taken by those systems toward risk.

Although it is an oversimplification, one can usefully divide views on the appropriate goals and scope of risk regulation into two competing frameworks.[32] The first framework conceptualises risk in terms of threats to safety, i.e., the propensity of a product to cause physical harm to humans or the environment, and understands the end of risk regulation to be the prevention or amelioration of those harms. The risk-as-safety framework relies heavily on science to characterise hazards and to predict their likelihood.[33] It is not, however, limited to empirical concerns, but may also consider other factors such as the distribution of risks in society, as well as public perceptions of risk to the extent that those perceptions may themselves cause harm.[34] The risk-as-safety framework is often associated with welfarist approaches to regulation that seek to maximise the net benefits of technology for society, but it is also compatible with other normative approaches.[35] The risk-as-safety framework does not, however, consider the broader social significance of technology. In this framework, the proper domain of risk regulation does

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[31] Craig, *Public Law and Democracy in the United Kingdom and the United States of America* (Clarendon 1990) 3–5.
[32] Cf. Exert Group (n.16), 24–27 (discussing "regimes of innovation"); Stirling (n.30), 53–55 (making a similar distinction between ways of framing the social problem of technological risk).
[33] E.g., Alemanno (n.12), 195–97; Breyer (n.16), 10–19; Graham and Wiener, *Risk Versus Risk* (Harvard 1995); Graham, 'Saving Lives through Administrative Law and Economics' (2008) 157 U.Pa.L.Rev. 395; Sunstein (n.16), 160–66.
[34] Graham (n.33), 516–24; Sunstein (n.22), 118–19.
[35] Graham (n.33), 438–48.

not extend to questions such as the ethical evaluation of technology or the effects of technology on social relations.

Within the risk-as-safety framework, risk evaluation is usually understood as a three stage process: risk assessment, risk management, and risk communication. This conceptual division was first suggested by the US National Research Council in the *Red Book*,[36] and has since been embraced by international organisations[37] and the European Commission.[38] Within this schema, risk assessment refers to the analysis and characterisation of a risk qualitatively and quantitatively, and it is at this stage that scientific analysis of risk is emphasised. Risk management concerns formulation of a regulatory response to the risk characterised at the risk assessment phase. This step includes consideration of risk acceptability as well as the choice of interventions to address unacceptable risk. The final stage, risk communication, focuses on communicating information about risks and regulatory responses to the public. Although this framework is more flexible than its critics sometimes portray it,[39] it is nonetheless designed to focus on a fairly narrow range of concerns regarding technology and is not well-suited to more open-ended consideration of the social significance of technological innovation.[40]

In contrast to the "risk-as-safety" framework, the second framework may be termed "technology choice".[41] Though it is also concerned with

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[36] *Red Book* (n.16), 18–19.

[37] Codex Alimentarius Commission, UN Food and Agriculture Organization, *Procedural Manual* (17th ed., UN 2007) 112–18.

[38] European Commission, 'Communication on the Precautionary Principle' COM(2000) 1 final, 2.

[39] Cf. van Zwanenberg and Millstone (n.12), 26.

[40] Expert Group (n.16), ch. 7.

[41] After Rayner and Cantor, 'How Fair Is Safe Enough? The Cultural Approach to Societal Technology Choice' (1987) 7 *Risk Analysis* 3. The term "technology choice" elides a number of related, but somewhat different approaches. Some useful literature in this vein includes Expert Group (n.16); Lee, 'Beyond Safety? The Broadening Scope of Risk Regulation' (2009) 62 CLP 242; Schwarz and Thompson, *Divided We Stand: Re-Defining Politics, Technology and Social Choice* (University of Pennsylvania 1990) 106–20; Stirling, '"Opening up" and "Closing down":

safety, the "technology choice" framework is concerned with a broader range of social consequences of technology. It treats technology itself, rather than technology's possible harmful effects, as the thing to be regulated.[42] The technology choice framework is concerned with how and by whom technology is governed in society. Rather than seeking to maximise social welfare, it tends either to focus on maximising social virtue or to adopt a deontological approach to regulation.[43] This difference is manifested in an emphasis on assessing the consistency of technology with a society's values independently of considerations of safety.[44] To a much greater extent than the risk-as-safety framework, the technology choice framework focuses on the distribution of both possible adverse effects and possible benefits of technology.[45] It is open to asking whether new technologies are likely to benefit society and allows the restriction or prohibition of technologies due to lack of benefit, even without a showing of possible harm, a course of action that is generally excluded in the risk-as-safety framework.[46]

In the following chapters, I will argue that the risk-as-safety framework predominates in the jurisprudence of both the EU and the US courts and that this preference can be explained by certain core normative commitments of European and American administrative law. That is not to say that preference for the risk-as-safety approach is—or should be—uncontroversial. To the contrary, the persistent framing of risk in terms of safety is the source of much of the public controversy surrounding the regulation of technology. The normative origins of the preference for a risk-as-safety framework do, however, demand that

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Power, Participation, and Pluralism in the Social Appraisal of Technology' (2008) 33 STHV 262.

[42] Rayner and Cantor (n.41), 6; Wynne (n.18), 447–48 (objecting to the reduction of the social significance of technology to questions of risk).

[43] Kysar (n.16), 41–45.

[44] Scott, 'On Kith and Kine (and Crustaceans): Trade and Environment in the EU and WTO' in Weiler (ed.), *The EU, the WTO, and the NAFTA: Toward a Common Law of International Trade?* (OUP 2000) 143–44; cf. Anderson (n.26), 163–67.

[45] Rayner and Cantor (n.41), 6.

[46] Lee (n.41), 248.

critics of that framework confront those normative commitments and their significance for administrative law generally, and not just within the confines of technology regulation.

C. Risk Science

If the concept of risk were not complex enough in itself, additional problems arise with respect to risk science. Few would dispute that science has a necessary and legitimate role to play in risk regulation. Science is necessary in the first place for the identification, and to some extent the definition, of technological risks.[47] Many adverse effects of technology are not directly observable, for example substances that cause disease only after long periods of latency. Even some immediate adverse effects may be difficult to link to specific causes. Asthma attacks, for example, may be caused by a variety of air pollutants, but they also have other causes and the link between the two can only be established through medical and epidemiological methods. In addition to being crucial for our understanding of technological risk, science frequently plays an important role in formulating responses to risk. Science is necessary to establish safe levels of exposure (when they exist), to identify lower risk substitutions, and to develop new technologies to prevent exposures. Without science, the range of possible responses to risks would be much more limited, and the ability to calibrate and evaluate responses would be much more crude.

There are, however, a number of difficulties with using science in risk regulation. First, as the last section showed, many aspects of risk are not readily susceptible to scientific analysis. But the problems of risk science run deeper. At bottom, they stem from the fact that all risk science is to a greater or lesser degree uncertain and ambiguous. Understanding the sources of that uncertainty is necessary for the analysis of the role of science within regulatory programmes.

When discussing risk science, it is useful to review some basic aspects of scientific inquiry itself. On the standard empiricist account, scientific knowledge is based on observation of the natural world and the

[47] Beck (n.16), 72.

testing of hypotheses. A hypothesis is a statement of a relationship between natural phenomena that is capable of falsification through empirical observation.[48] In the main, hypotheses can only be falsified; they cannot be (directly) confirmed. A hypothesis gradually achieves acceptance through the accumulation of observations that are consistent with the hypothesis and by the falsification of alternative hypotheses.[49] As such, though it is often stated otherwise, scientific knowledge is generally of a negative character. Science may be able to tell us what is not, but it is only able to provide us with ever more confident hypotheses of what is.[50]

One consequence of the structure of scientific knowledge is that science is best at answering questions that are readily capable of experimental testing. "Does substance X cause cancer?" is a difficult, but tractable, question for science to answer. "Is substance X safe?" is much harder, not just because of the definitional issues surrounding the concept of "safe", but also because any answer to the question would have to account for, at a minimum, a wide range of possible adverse effects, which would necessitate a much more complex experimental undertaking. And even when science has the tools to answer questions about whether a product may cause specific adverse effects, reliable information is often unavailable.[51] Indeed, creating (and funding) mechanisms for producing this much-needed information has become an important focus of risk regulation policy.[52] Because of these constraints, science's ability to provide answers to more complex (call them "real world") questions is quite limited. In most circumstances, all science can do is provide relevant information.

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[48] Popper, *The Logic of Scientific Discovery* (Routledge 2002) (1959) 17–20.
[49] Salmon, *The Foundations Of Scientific Inference* (University of Pittsburgh 1966) 18–24.
[50] For an introduction to scientific method and some of the philosophical problems associated with it, see Nola and Sankey, *Theories of Scientific Method: An Introduction* (Acumen 2007) 12–31.
[51] Rodricks (n.16), 209–13.
[52] Wagner, 'Commons Ignorance: The Failure of Environmental Law to Produce Needed Information on Health and the Environment' (2004) 53 Duke.L.J. 1619, 1736–45.

1. Quantitative risk assessment

Generally, we want to know more about a substance than simply whether it is capable of causing specific adverse effects. We want to know how likely the adverse effect is to come to pass, whether it is a mere theoretical possibility or a substantial threat to many people. Relatedly, many regulatory programmes seek to establish "safe" levels of exposure to chemical substances, which require regulators calculate levels of exposure at which adverse effects are not expected to occur (or at least are expected to be quite rare).[53] It was through efforts to answer these sorts of questions that the science of quantitative risk assessment first developed.[54] At its most basic, quantitative risk assessment simply seeks to determine the probability that a specific adverse effect will occur in a subject at a given level of exposure to a substance.[55] It thus incorporates a narrowly empirical conception of risk. More advanced approaches to risk assessment attempt to predict the risk of adverse effects in real-world circumstances by estimating the level of exposure that would be expected in those circumstances. In theory, science is fully able to answer those questions. In practice, however, reliable answers are difficult to establish.

The obstacles to quantitative risk assessment are far greater than a mere lack of good data. The problem, rather, is that much of the data that would be necessary to perform an accurate quantitative risk assessment cannot be gathered through existing methodologies.[56] Some of it cannot be gathered for ethical reasons. For example, it would obviously be improper to use human subjects to test for toxic effects.[57]

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[53] E.g., Regulation 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) &c. [2006] O.J. L396/1, art. 60(2); Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. §§ 136–136y, § 136a(c)(5).
[54] Rodricks (n.16), 205.
[55] Ibid., 217.
[56] See generally McGarity, 'Substantive and Procedural Discretion in Administrative Resolution of Science Policy Questions: Regulating Carcinogens in EPA and OSHA' (1978) 67 Geo.L.J. 729.
[57] Cf. *NRDC v. EPA*, 658 F.3d 200, 206 (2d.Cir.2011).

Consequently, scientists use animal tests as a substitute, but at the expense of introducing a source of uncertainty.[58] Beyond ethical concerns, some data cannot be gathered for practical reasons. Much risk regulation is concerned with exposure to substances at very low doses, at which effects would only be expected to occur in a few subjects in a thousand or even a million. Experiments cannot directly test for effects at these levels because the numbers of research subjects required to achieve statistically valid results would be prohibitively expensive (putting aside the ethical concerns with running a single experiment on thousands of animals). To accommodate this problem, scientists typically test for adverse effects at high doses and use those results to estimate their occurrence at lower doses.[59] That approach also creates uncertainty because, despite significant research, there is no scientific consensus on methods for extrapolating from high to low does.[60]

When risk assessment moves from the lab to real-world situations, the problems become exponentially greater. Risk assessment requires an estimate of individuals' exposure to the substance in question, but measuring exposures in real-world situations is extremely difficult. Take for instance the expected exposure to a farm worker applying a pesticide. Any risk assessment will have to account for multiple paths of exposure (including inhalation, ingestion, and dermal exposure), none of which are easily measured. Exposure also depends on numerous variable factors, such as operator behaviour or weather conditions.[61] As a result of these complications, risk assessors are often forced to rely on educated guesses regarding likely exposure under various circumstances.[62]

These issues and many others will crop up in any quantitative risk assessment. They are sometimes termed trans-scientific issues because, while they are theoretically answerable through conventional scientific analysis, practical obstacles put the answers beyond the capabilities of

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[58] McGarity (n.56), 743–45; Rodricks (n.16), 68–69.
[59] McGarity (n.56), 734–36.
[60] Rodricks (n.16), 239–43.
[61] Wynne, 'Uncertainty and Environmental Learning: Reconceiving Science and Policy in the Preventive Paradigm' (1992) 2 GEC 111, 119.
[62] Rodricks (n.16), 213–14.

current scientific research.[63] Although advances in research techniques may eventually make some trans-scientific questions answerable, several decades of work on quantitative risk assessment techniques has not achieved much progress.[64] To overcome the problem of trans-science, risk assessors rely on what the US National Research Council calls "inference options" or "science-policy judgments".[65] Science-policy judgments are assumptions that are used to bridge gaps in empirically verifiable data. They are science judgments in the sense that they must be scientifically plausible. They are nonetheless policy judgments because the choice among the various scientifically plausible alternatives must be made by reference to normative considerations.[66] Because most regulatory risk assessments are carried out for the purposes of protecting health and the environment, regulators tend to use science-policy judgments that are conservative, in that they tend to err on the side of overstating risk.[67] But even when that goal is assiduously pursued, the uncertain nature of science-policy judgments means that we cannot be sure the risk has not been underestimated. In contemporary practice, regulators in both the EU and the US typically rely on elaborate risk assessment guidelines that specify default science-policy judgments and procedures for departing from those defaults.[68] By relying on guidelines, rather than case-by-case determinations, regulators attempt to minimise subjectivity in individual risk-science judgments.[69] In this way, EU and US regulators are able to prepare routine risk assessments that are

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[63] Weinberg, 'Science and Trans-Science' (1972) 10 *Minerva* 209; see also McGarity (n.56), 733–36.
[64] Rodricks (n.16), 260–72.
[65] *Red Book* (n.16), 28; For an updated assessment of regulatory practice, see National Research Council (n.20), ch. 2.
[66] National Research Council (n.20), 36.
[67] Rodricks (n.16), 230.
[68] E.g., EPA, *Guidelines for Carcinogen Risk Assessment* (3d ed., GPO 2006); EFSA, 'Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products' (2014) 12 *EFSA Journal* 3874.
[69] *Red Book* (n.16), 4.

objective in the narrow sense that competent risk assessors applying the same risk assessment guidelines will achieve similar results.[70]

2. Risk assessment and complexity

Although it can be extremely useful for regulators, the information provided by quantitative risk assessments is inevitably limited in important ways. Quantitative risk assessments typically provide a numerical assessment of one causal relationship only (e.g., cancer risk). They often do not account for cumulative exposures. They are only beginning to consider the possibility of synergistic effects (in which exposure to two or more substances creates risks that are greater or lesser than the sum of the risks from exposure to the substances individually), and then only in a rudimentary way.[71] Although they suffice for some types of regulatory programmes, they are an incomplete basis for many of the most pressing risk regulation problems. Issues such as climate change, genetically modified organisms, and industrial releases to the environment pose far more complex risk assessment issues. Accordingly, these problems call for broader approaches to risk assessment.

Many of the most highly salient risk regulation issues share one essential feature: complexity. All issues of risk, but particularly issues of ecological risk, concern effects on systems. The need to address systems creates problems for risk science because natural systems tend to be open-ended and poorly understood, and usually are not susceptible to the kind of experimental verification that is the gold standard for scientific knowledge.[72] These characteristics of systems create complexity, a situation in which cause-effect relationships cannot be isolated and the universe of possible outcomes often cannot be

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[70] Rodricks (n.16), 214.
[71] National Research Council (n.20), 219.
[72] Ibid., 16–21; additional sources on the problems of quantitative risk assessment in complex systems include Jaeger, Renn, Rosa, and Webler, *Risk, Uncertainty, and Rational Action* (Earthscan 2001) 159–208; O'Brien, *Making Better Environmental Decisions: An Alternative to Risk Assessment* (MIT 2000); Stirling (n.30); Wynne (n.61).

foreseen.[73] Additionally, complex systems are adaptive, in that the introduction of a new element into the system (say an industrial release) may change the operation of the system itself.[74] An element of complexity that is often relevant to risk regulation is human behaviour. Risk assessments often rely on assumptions about how people will behave in certain circumstances, yet human behaviour does not obey physical laws and is difficult to predict, especially over long time frames.[75]

Complexity does not render scientific analysis useless. Laboratory science can often provide useful information on possible (and sometimes impossible) effects. Knowledge of system behaviour gained through empirical observation can provide a basis—often a highly reliable basis—for predicting likely effects. Yet complexity does fundamentally change the nature of the information that science can provide. Most importantly, scientific analysis of complex situations inevitably takes on an interpretive character as scientists move from verifiable data and relationships to predictions about systemic effects.[76] One consequence of the interpretive nature of this type of analysis is that divergences of opinion are more likely to arise among scientists. Whereas routine quantitative risk assessment methodologies provide a process for ensuring consistency in results and for identifying discrete points of disagreement, the interpretive analysis required for risk assessment in complex systems is less easily rationalised.

In this type of risk assessment, scientific judgment comes to the fore. In the sense I am using it, scientific judgment is like other forms of judgment. It is a partly, sometimes largely, intuitive process by which scientists consider the available data, their theoretical knowledge, and their experience in the field to arrive at a conclusion about the most

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[73] Mitchell, *Complexity: A Guided Tour* (OUP 2011).
[74] Ibid.
[75] Stirling (n.30), 46–47; Wynne (n.61), 119; see also Bernstein (n.16), 330–32.
[76] Renn, *Risk Governance* (Earthscan 2008) 74–79.

likely answers to scientific problems.[77] Such judgments cannot be reduced to schematic form and reproduced,[78] although they may be falsifiable (at least in theory). For regulators, the task of responding to divergent scientific opinions requires the exercise of policy judgment. As such, regulators have to engage with scientific and non-scientific information through some form of deliberation, in the sense of "careful consideration with a view to decision".[79] Because many such decisions are made administratively, principles of administrative law have considerable influence on how this deliberation is conducted, by whom, and under what constraints.

Beyond complexity, risk assessment must also contend with ignorance. Ignorance, put simply, is the fact, established by Hume, that we cannot know what we do not know.[80] We may observe relationships in the world and infer a causal connection, but because we cannot observe causation directly we can never wholly exclude other possible explanations for the relationship.[81] As a result, it is never possible to be certain that a product will not produce adverse effects. Moreover, ignorance is ubiquitous and irreducible. We can never be more or less ignorant about anything. For these reasons, ignorance poses challenges for risk assessors and risk regulators. It cannot be managed in the same way as known risks, even highly uncertain known risks. Nor can it be

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[77] Cf. Dunbar and Khlar, 'Scientific Thinking and Reasoning' in Holyoak and Morrison (eds.), *The Oxford Handbook of Thinking and Reasoning* (OUP 2012).

[78] Kitcher, *The Advancement of Science* (OUP 1993) 93–105.

[79] This is the first sense of "deliberation" given by the OED. I do not mean to restrict it to the sense linked with theories of civic republicanism. E.g., Sunstein, 'Beyond the Republican Revival' (1988) 97 YLJ 1539.

[80] This is the sense in which ignorance is most often used in the risk regulation literature, e.g., Stirling (n.30), 46–47; Lee (n.16), 32; see also Funtowicz and Revetz, *Uncertainty and Quality in Science for Policy* (Kluwer 1990) 87–88. Smithson uses the term "meta-ignorance" to distinguish this definition of ignorance from other senses. Smithson, 'Social Theories of Ignorance' in Proctor and Schiebinger (eds.), *Agnotology: The Making and Unmaking of Ignorance* (Stanford 2008) 210.

[81] Hume, *An Enquiry Concerning Human Understanding* (Steinberg ed., 2d ed., Hackett 1977) (1776) 15–18.

ignored without leaving society exposed to potential harm. Accordingly, ignorance calls for its own regulatory strategies.[82]

3. Science and objectivity

Before leaving the topic of risk science, a brief word must be said about the deeper epistemological basis of science. Since at least Plato,[83] philosophers have been troubled by whether and how humans can know the world, and those preoccupations have spawned numerous critiques of the objectivity and completeness—or even the possibility—of scientific knowledge. Of particular relevance for present purposes, most contemporary philosophers would agree that scientific knowledge is to some extent the product of social practices and—to that extent—what counts as scientific knowledge is determined by those practices as well as by correspondence with reality.[84] Some sociologists of science, building on the work of Thomas Kuhn,[85] go further and take the position, commonly referred to as social constructivism, that scientific "facts" are nothing more than products of social discourse.[86] Proponents of social constructivism maintain either that there is no mind-independent reality or, if there is, that humans cannot know it.[87] One consequence of the social constructivist view is that science should not be privileged over

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[82] Stirling (n.30), 55–60; Wynne (n.61), 126–27.
[83] Plato, *Theaetetus* (Williams ed., Levett trans. (Burnyeat rev.), Hackett 1992).
[84] Goldman, *Knowledge in a Social World* (OUP 1999) 225–30; Kitcher (n.78) 87–89; Laudan, *Science and Values* (University of California 1984) 33–41; Longino, *Science as Social Knowledge* (Princeton 1990) 58–61.
[85] Kuhn, *The Structure of Scientific Revolutions* (50th anniversary ed., University of Chicago 2012) (1962).
[86] Two canonical works in this vein are Latour and Woolgar, *Laboratory Life: The Construction of Scientific Facts* (2d ed., Princeton 1986) and Shapin and Schaffer, *Leviathan and the Air-Pump* (Princeton 1985); see also Latour, *Science in Action* (Harvard 1987). A good short introduction to the constructivist view is Barnes and Bloor, 'Relativism, Rationalism, and the Sociology of Knowledge' in Hollis and Lukes (eds.), *Rationality and Relativism* (MIT 1982).
[87] Radder, 'Normative Reflexions on Constructivist Approaches to Science and Technology' (1992) 22 Soc.Studs.Sci. 141, 155–57.

other discourses—such as folk wisdom or religion—as a way of knowing the world. Perhaps more importantly, it calls into question the distinction between expert and lay knowledge regarding issues deemed scientific.[88] If accepted, the social constructivist view would have important implications for risk regulation. Notably, it would cast doubt on the necessity for scientific evidence as a basis for regulation, as well as the priority generally accorded to scientific views on certain issues.

Although a number of thinkers adhere to the social constructivist position, it has come under strong philosophical critique and is rejected by most contemporary philosophers of science.[89] In addition to its serious conceptual problems,[90] some commentators have also pointed out the severe difficulties of engaging in normative argument within the social constructivist framework. As Radder points out, if risks are merely artefacts of discourse, it is difficult to find a stable perspective from which to assign them a normative value.[91] For this reason, some commentators have suggested that many proponents of constructivism actually embrace at least limited forms of realism.[92]

This is a debate that obviously cannot be settled in a thesis about legal doctrine.[93] Fortunately, for many issues, it may not matter. One can be a committed realist and still accept the inherent uncertainty and ambiguity of risk science.[94] For example, one need not accept the social

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[88] Barnes and Bloor (n.86), 27; Eden, 'Public Participation in Environmental Policy: Considering Scientific, Counter-Scientific and Non-Scientific Contributions' (1996) 5 Pub.Understanding.Sci. 183, 191–92; Wynne, 'May the Sheep Safely Graze? A Reflexive View of the Expert-Lay Knowledge Divide' in Lash, Szerszynski, and Wynne (eds.), *Risk, Environment and Modernity* (Sage 1998) 57–61.

[89] Rosenberg, *Philosophy of Science* (3rd ed., Routledge 2012) 281–82; see also Goldman (n.84), 248–54; Kitcher (n.78), 160–69; Longino (n.84), 76–82.

[90] Boghossian, *Fear of Knowledge* (Clarendon 2006).

[91] Radder (n.87), 156–57 & n.60; see also van Zwanenberg and Millstone, 'Beyond Skeptical Relativism: Evaluating the Social Constructions of Expert Risk Assessments' (2000) 25 STHV 259, 260–61.

[92] Van Zwanenberg and Millstone (n.91), 262.

[93] It may well be unresolvable. Chakravartty, *A Metaphysics for Scientific Realism* (CUP 2007) 16–26.

[94] Kitcher (n.78), 164–65.

constructivist view to agree that the drawing of policy-relevant conclusions from scientific data requires an exercise of judgment, that those judgments will often, perhaps always, depend on policy-laden considerations, and that a system of administrative law must account for the contestable nature of those judgments.[95] Thus, the realist and the antirealist must largely face the same legal problems when considering the role of science in administrative risk regulation. The debate does matter, however, for the question whether science should be given some degree of priority in decisionmaking on risk and whether science can serve as a meaningful constraint on administrative discretion. The constructivist position implies scepticism on both counts, whereas those who reject constructivism generally see the priority of science as flowing from its epistemic superiority on certain matters and believe that scientific evidence can constrain administrative discretion.

My analysis in this thesis will reject strong constructivism. I do so, in part, because I find the critiques of constructivism persuasive, but more importantly because both the EU and US courts apparently reject constructivism. Both accept that, at a minimum, science is capable of providing information about risks that other perspectives are not, though they also acknowledge that scientific evidence is often uncertain and indeterminate.[96] Rather than rejecting this core premise, it is more interesting from a comparative perspective to investigate how the two jurisdictions have integrated this understanding of science into their jurisprudence. In later chapters, I will argue that the courts' judgments about the capacities of science are themselves bound-up with the normative concerns of administrative law. These connections will be most clearly illustrated in chapter 4, which analyses the idea of administrative rationality as it pertains to risk regulation, but they will also be addressed in chapter 6, which considers the normative commitments of the two systems of administrative law.

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[95] Van Zwanenberg and Millstone (n.91), 261.

[96] The courts' views on science are discussed in chapter 4.

II. Methodology and Scope

A. Old-Fashioned Doctrinal Analysis

As stated at the outset, my basic methodological approach in this thesis is traditional doctrinal legal analysis or what is sometimes known as legal idealism. Legal idealism analyses legal materials, especially judicial decisions, in an effort to uncover the principles that inform those materials and to reassemble those principles into a coherent normative picture. In the idealist vision, administrative law is "part of the general fabric of . . . public and constitutional law" and contributes "to the construction of an operationally effective and symbolically appropriate normative regime".[97] Put differently, administrative law reconciles bureaucratic power "with our fundamental (but perhaps malleable) images of the legitimacy of state action".[98]

In contrast to interdisciplinary approaches or empirical legal scholarship, legal idealism may seem a distinctly old-fashioned methodology. Some would even question its relevance in a world in which the law-in-action is widely assumed to deviate from the law-in-the-books.[99] No one doubts that law is much more than the text of judicial decisions. Doctrinal legal analysis nonetheless remains centrally important to the study of administrative law and public administration for two reasons. First, idealist legal discourse is a perspective for understanding administration that is distinct from other perspectives such as economics or sociology. Law is a specific form of social and cultural expression and comes with its own normative assumptions and frames for organising experience.[100] One cannot form a complete picture of any legal phenomenon, much less engage in comparative legal

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[97] Mashaw (n.2), 268.
[98] Ibid.
[99] E.g., McNollGast, 'Structure and Process, Politics and Policy: Administrative Arrangements and the Political Control of Agencies' (1989) 75 Va.L.Rev. 431, 435–40; Unger, 'The Critical Legal Studies Movement' (1983) 96 HLR 561, 575–76.
[100] On framing, see Goffman, *Frame Analysis: An Essay on the Organization of Experience* (Northeastern 1986) 1–16; Jasanoff (n.12), 23–25.

analysis, unless one understands this perspective. Second, legal idealism is the primary, often the exclusive, form of discourse used by EU and US courts. It is the form of reasoning in which litigants argue, judges deliberate, and decisions are justified. Whatever the shortcomings of legal idealism as a picture of reality, judicial decisions unquestionably have practical effects in the real world. Understanding this mode of discourse is therefore of the utmost practical importance.

The choice of legal idealism as my methodology also informs my choice of research question. The objective of this thesis is to compare the ways in which EU and US administrative law, understood in idealist terms, reconcile the phenomenon of administrative risk regulation with constitutional democracy. In this respect, my analysis draws heavily on the concept of "administrative constitutionalism" developed by Elizabeth Fisher.[101] Administrative constitutionalism resists succinct definition. It encompasses numerous concepts and relations, such as the scope (and limits) of administrative power; the institutional structure of the administration; the relationship of the administration to other constitutional bodies (the legislature, the executive, the courts); the mechanisms by which the administration is held to account; and the scope of individual rights. It is, in other words, not a single legal principle, or even a single conventional body of law, but rather a dense network of legal rules, principles, and conventions that defines the conceptual framework in which administration is understood, analysed, and evaluated from the perspective of law.[102] Administrative constitutionalism thus encompasses much more than legal doctrine. In this thesis, administrative constitutionalism will be the theoretical lens by which I relate my doctrinal analysis to broader normative questions.[103]

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[101] Fisher (n.1).

[102] Ibid., 22–26.

[103] Although I draw on Fisher's theoretical work, I do not use her rational-instrumental (RI) and deliberative-constitutive (DC) paradigms as categories for analysis. As developed by Fisher, the RI and DC paradigms are ideal types that demonstrate how the strands of administrative constitutionalism interact to define world-views on administration. Ibid., 27–28. Although the RI and DC paradigms are useful didactic tools, they

My focus on legal doctrine also accounts for my decision not to include case studies of specific regulatory programmes in this thesis. The omission is partly practical. Detailed comparison requires detailed analysis, and I do not believe it would be possible within a single thesis to give adequate attention to the nuances of legal doctrine and to provide robust empirical case studies. Because a fine-grained understanding of doctrine is a prerequisite for a legal analysis of regulatory practice, it seems preferable to focus on doctrine in this thesis and to defer case study work to later scholarship. There is also a methodological reason for not combining the two. Although case study research can provide valuable insights into the practice of regulation, it may not have as much value for understanding legal doctrine. In the main, courts decide cases on the basis of conceptual analysis and with an eye toward developing principles that will apply across a range of contexts. It is not clear that a focus on the detailed operation of a particular regulatory programme would provide much insight into that process. It might even be counterproductive. Because the cases that have driven the development of EU and US law on risk regulation have originated in a number of different regulatory programmes, a narrow focus on one or two programmes might skew the broader picture.[104] Case studies would also complicate comparative analysis by multiplying the number of variables that would have to be considered and accounted for. None of this is to

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are (by design) too generic to reflect the nuances of administrative constitutionalism in any specific jurisdiction. Ibid. That limitation is particularly important in a comparison of EU and US administrative law, inasmuch as each jurisdiction exhibits its own evolving paradigm of administrative-constitutionalism, neither of which is fully captured by either the RI or DC paradigm. For these reasons, I find it more useful to compare specific aspects of EU and US administrative constitutionalism directly rather than attempting to relate them to RI and DC paradigms.

[104] A similar point is made by Wiener who argues that a focus on particular case studies tends to skew general comparisons of EU and US risk regulation. Wiener, 'The Rhetoric of Precaution' in Wiener, Rogers, Hammitt, and Sand (eds.) (n.13), 24–27.

say that case study research is not extremely valuable.[105] To the contrary, I see the doctrinal analysis in this thesis as important groundwork for future research of that type, whether undertaken by myself or others.

B. Legitimacy and Administrative Risk Regulation

Legitimacy is a broad concept that has many meanings and can be approached from many angles. According to the OED, legitimacy is "[t]he condition of being in accordance with law or principle," but that definition clarifies little. Principle can easily be understood to encompass ideas as varied as democracy, morality, justice, efficiency, and many others, and conformity with each of these principles can be understood as different species of legitimacy. In keeping with my methodological commitment to legal idealism, this thesis will focus on just one aspect of legitimacy: legal legitimacy. As will become clear in subsequent chapters, however, legal legitimacy cannot be analysed in isolation. Instead, it must be understood in relation to other forms of legitimacy, including functional legitimacy and democratic legitimacy.

1. Legal legitimacy

In this thesis, I am primarily interested in legal legitimacy. In the sense I am using it, an institution or action is legally legitimate when it can be reconciled with authoritative legal materials (constitutions, treaties, statutes, judge-made law) and legal values in a way that respects the accepted rules of legal reasoning within a particular legal system.[106] For something to be legally legitimate, it is not necessary that the legal community be unanimous in its acceptance of any particular justification. In most cases there will be multiple, divergent justifications, and for any particular thing being studied there will likely be someone who rejects its legitimacy outright. It is sufficient that the explanation by

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[105] Excellent examples include Jasanoff (n.12); van Zwanenberg and Millstone (n.91); and Vogel (n.12).

[106] This understanding of legal legitimacy is obviously grounded in the positivist tradition of jurisprudence. Hart, *The Concept of Law* (Clarendon 1991) (1961); Tuori, *Critical Legal Positivism* (Ashgate 2002).

which something is reconciled with authoritative materials and legal values is recognised as an admissible form of justification by a substantial segment of the legal community, even if members of the community find the explanation unconvincing.

Used in this way, legal legitimacy may seem like a synonym for "legality" or "lawfulness", but there is an important difference. Legality and lawfulness can be understood as being synonymous with formal legality, i.e. the extent to which all applicable legal requirements are satisfied. Formal legality essentially involves box-ticking, though that is not to say that it cannot engender real controversies of its own. But in the way I am using it, legal legitimacy requires more than box-ticking; it requires that the thing under examination not only meet the formal requirements for legality but also that it admit of explanation in terms of the values that animate a legal system. While an investigation of formal legality invites a process of thinking along lines of proof, an analysis of legal legitimacy, because of its focus on explanation, encourages consideration of relationships among the thing being analysed, legal materials, and legal values so that even if part of the explanation eventually proves unsatisfying, the remainder may continue to provide insight and a basis for reconstruction of the unsatisfactory bit.[107]

2. Other forms of legitimacy

Although my focus is on legal legitimacy, other forms of legitimacy will also be relevant to the analysis. Taking a somewhat broader perspective, I will at points consider how legal legitimacy interacts with and contributes to the functional legitimacy of risk regulation. I will also consider how legal legitimacy overlaps with conceptions of democratic legitimacy.

"Functional legitimacy" is a broad form of legitimacy. In Scott's definition, functionally legitimate acts are "ones which are accepted and followed by those to whom they apply, irrespective of whether those

[107] Nozick, *Philosophical Explanations* (Belknap 1981) 13–18.

subject to them agree with them".[108] Functional legitimacy is essential to the viability of democratic systems. This sense of legitimacy is often what is at issue when people discuss the legitimacy of bureaucratic government or of the European Union in general.[109] Functional legitimacy is a psychological state. It concerns the way in which governmental institutions and actions are perceived and evaluated by the public. As such, it cannot be assessed solely in theoretical terms. One cannot, for example, analyse a regulatory process on paper and make a definitive judgment as to whether the process is functionally legitimate.[110] Instead, analysis of functional legitimacy requires the tools of social science. Ultimately, the question whether an act is functionally legitimate *vel non* is an empirical question. As a consequence, functional legitimacy cannot be investigated directly through the methodology of legal idealism.

Legal analysis is, however, relevant to assessments of functional legitimacy. It is a plausible (though not indisputable[111]) assumption that an act cannot be functionally legitimate in a liberal-democratic society unless it is legally legitimate. One common feature of all liberal democracies is the rule of law: the principle that official power in society is structured and limited by impersonal legal rules, made through public processes, and (more controversially) on which individuals may rely as a shield against the exercise of power that is not in accordance with those rules.[112] Put simply, without the rule of law, there is no liberal

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[108] Scott, 'Governing Without Law or Governing Without Government? New-Ish Governance and the Legitimacy of the EU' (2009) 15 ELJ 160, 161.

[109] Ibid., 160–61. In the US context, see Farina, 'The Consent of the Governed: Against Simple Rules for a Complex World' (1996) 72 Chi-Kent.L.Rev. 987, 988–89; cf. Frug, 'The Ideology of Bureaucracy in American Law' (1984) 97 HLR 1276, 1285.

[110] Farina (n.109), 992.

[111] Hyde, 'The Concept of Legitimation in the Sociology of Law' [1983] Wis.L.Rev. 379, 385–86.

[112] The rule of law is, of course, a capacious concept, to which this brief definition cannot do justice. See Craig, 'Formal and Substantive Conceptions of the Rule of Law: An Analytical Framework' [1998] PL 467 and Fallon, '"The Rule of Law" as a Concept in Constitutional Discourse' (1997) 97 Colum.L.Rev. 1.

democracy, which is the fundamental measure of legitimate government in modern Western societies.[113] Legal legitimacy is therefore a necessary, but not a sufficient, component of functional legitimacy.

In addition to questions of legal and functional legitimacy, administrative risk regulation raises issues of democratic legitimacy. Democratic legitimacy is concerned with whether governmental institutions or actions are consistent with a particular theory of democracy.[114] Democracy, of course, is an essentially contested concept.[115] As a consequence, a prerequisite for any analysis of democratic legitimacy is the specification of a theory of democracy. Only when we have a clear understanding of what democracy entails is it possible to assess the democratic character of an institution or action.[116] Unlike functional legitimacy, democratic legitimacy in the sense I am using it is a theoretical question. Like functional legitimacy, however, democratic legitimacy is not readily assessed with the tools of legal analysis. Instead, it is ultimately a matter of political theory.[117] Although legal analysis in democratic systems will necessarily incorporate premises about democratic government, the validity of those premises cannot be assessed from within law itself.

Because legal idealism is an essentially internal perspective on law and legal legitimacy, there are certain questions regarding the legitimacy of administrative risk regulation that I will not address. First, I will not enter into the complex debates on the legitimacy of the European Union itself[118] or the related, but much less urgent, debates regarding American

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[113] Oliver and Fusaro (eds.), *How Constitutions Change: A Comparative Study* (Hart 2011).
[114] Craig (n.31), 5.
[115] Gallie, 'Essentially Contested Concepts' (1955) 56 PAS 167, 183–87.
[116] Craig (n.31), 3–5.
[117] Ibid.
[118] A good overview is provided in Craig, 'Integration, Democracy, and Legitimacy' in Craig and de Búrca (eds.), *The Evolution of EU Law* (2d ed., OUP 2011).

federalism.[119] One of the fascinations of the EU as an object of study is its category-transcending nature. The inability to fit the EU comfortably within existing theories of liberal democracy makes questions about its legitimacy both persistent and important. At the same time, however, the problems should not be overstated. Many aspects of the EU can be readily reconciled with conventional theories of democracy, and the fact that no theory of European democracy has yet gained widespread agreement should not be taken as evidence (or at least not strong evidence) that the EU is somehow fundamentally illegitimate.[120]

Nor will I deal with debates regarding the fundamental legitimacy of bureaucratic administration. Bureaucracy, for all its problems, is necessary for modern governments to meet the demands of their populaces. For this reason, if no other, a largely unelected bureaucracy is a fact of life.[121] There are, of course, powerful critiques to be made of bureaucracy, and we should perhaps not be so ready to acquiesce in its inevitability.[122] But I will confess to an inability to imagine a world without it, much less how we could ever get to such a world from where we are now.[123] Thus, though I will be intensely interested in the ways in which the EU and US legal systems construct the legitimacy of bureaucracy, and will at times be critical of those constructions, I will not question the validity of the project itself.

3. Legitimacy as narrative

Having described my understanding of legal legitimacy, I now need to elaborate further on my methodological approach to it. As used in this thesis, legal legitimacy is a reconciliation of a government institution or action with authoritative legal sources and rule of law values. It is not

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[119] E.g., Galle and Seidenfeld, 'Administrative Law's Federalism: Preemption, Delegation, and Agencies at the Edge of Federal Power' (2008) 57 Duke.L.J. 1933.
[120] Craig (n.118), 31–33; Moravcsik, 'Reassessing Legitimacy in the European Union' (2002) 40 JCMS 603, 611–13.
[121] Fisher (n.1), 19–21.
[122] Frug (n.109), 1381–88.
[123] Cf. Craig (n.31), 400–07.

merely a state, but also an explanation. Being an explanation, it is also a narrative. Understanding legitimacy as a narrative provides a methodological framework in which we can reconstruct and compare ideas of legitimacy across the two jurisdictions.

A narrative is a "multidimensional purposive communication from a teller to an audience."[124] Because it is purposive, a narrative is "shaped in the service of larger ends."[125] Put in simpler terms, a narrative is a story told for a particular purpose. Narratives explain relationships between objects and events in a way that makes sense of them within a larger cognitive framework.[126] In this way, narratives constitute meaning. Narratives that offer explanations of the world or aspects of it are sometimes referred to as myths to indicate that they are constitutive of a community's sense of identity.[127] Constitutional theorists often use the concept of myth in this sense, to describe a narrative that explains the mutually constitutive relationship between constitutions and national identity.[128] My ambitions are more modest. The narratives I am interested in are those that explain how the exercise of power by bureaucratic administration is consistent with a particular constitutional system. These narratives both constitute the administration by describing its features and operations and legitimate it by reconciling those features with legal values that are themselves, to some extent, taken as given.

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[124] Herman, Phelan, Rabinowitz, Richardson, and Warhol, *Narrative Theory: Core Concepts and Critical Debates* (The Ohio State University 2012) 3.
[125] Ibid.
[126] White, *The Edge of Meaning* (University of Chicago 2001) 246–48.
[127] My theoretical approach in this regard is strongly influenced by the work of Lévi-Strauss. E.g., *Myth and Meaning* (Routledge 2001) (1978); see also Falck, *Myth, Truth, and Literature* (2d ed., CUP 1994) 34–54.
[128] E.g., Ackerman, *We the People: Foundations* (Belknap 1993) 34–41; Arnold, *The Symbols of Government* (Yale 1935); Della Sala, 'Political Myth, Mythology and the European Union' (2010) 48 JCMS 1, 10–13; Weiler, 'In Defence of the Status Quo: Europe's Constitutional *Sonderweg*' in Weiler and Wind (eds.) *European Constitutionalism Beyond the State* (CUP 2003); cf. Weiler, 'In the Face of Crisis: Input Legitimacy, Output Legitimacy and the Political Messianism of European Integration' (2012) 34 JEI 825, 832–35.

These legitimacy narratives do not operate linearly or deductively, but instead have multiple overlapping strands that grow or recede in prominence over time and in different contexts.[129] In a similar vein, Lord and Magnette have argued that a complete theory of legitimacy requires the analysis of multiple "legitimacy vectors", each of which corresponds to distinct values that are relevant to the overall concept of legitimacy.[130] Lord and Magnette use the term "vectors", because "they sometimes reinforce, and at other times, pull against one another".[131] It is through the use of multiple strands, or vectors, that legitimacy narratives create a convincing view of the world, which is necessary for a narrative to have explanatory power.

Three legitimacy vectors, in particular, will be central to my analysis: law, science, and democracy (or their alter-egos, law, fact, and policy). As Christopher Edley has shown, the primary preoccupation of administrative law is the drawing and re-drawing of boundaries between the domains of law, fact, and policy, as well as the boundaries between their corresponding modes of reasoning.[132] By assigning issues to one or more of these categories, legal doctrine constitutes the meaning of phenomena (within legal discourse), controls the modes by which they are discussed and disputed, and assigns responsibility for decisionmaking to various actors in the administrative process.[133] Although Edley's analysis is specific to the US, a similar use of these vectors is observable in EU legal doctrine.[134]

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[129] E.g., Harlow, 'Three Phases in the Evolution of EU Administrative Law' in Craig and de Búrca (eds.) (n.118); Rabin, 'Federal Regulation in Historical Perspective' (1986) 38 Stan.L.Rev. 1189.
[130] Lord and Magnette, 'E Pluribus Unum? Creative Disagreement about Legitimacy in the EU' (2004) 42 JCMS 183.
[131] Ibid., 184.
[132] Edley (n.11), 29–36. This idea of boundary drawing (or boundary work) also animates much of the sociological literature on risk regulation. Jasanoff (n.12), 26–27.
[133] Edley (n. 11), 98–105; Hart and Sacks, *The Legal Process* (Eskridge and Frickey eds., Foundation Press 2006) 4–6.
[134] Fisher (n.1), 238–41.

If legitimacy is to be understood as a narrative or a story, then we need some idea of the identity of the tellers.[135] A key feature of legal legitimacy narratives is that there is no single teller or group of tellers. Rather, they are told by a range of actors at a variety of times. Legislators, judges, administrators, and lawyers all take part in constructing the narrative. What unites these actors and makes the telling of a more-or-less coherent narrative possible is that the telling takes place within a single interpretive community: the legal profession.[136] Within this interpretive community, courts and judges have a privileged position because their versions of the narrative are authoritative. For a number of reasons, however, courts are not the only tellers of legitimacy narratives. Foremost, judicial decisions are, by their nature, sporadic and fragmentary and thus do not provide an effective medium for the telling of complete and coherent narratives. Additionally, norms of judicial self-restraint tend to prevent judges from developing narratives beyond the circumstances of the specific case. These limits are particularly relevant in the EU, in which judgments are issued in the name of the whole court and dissents are not published. Nor can judicial opinions be the sole source of legitimacy narratives because not all judges are telling the same story. Rather, judges, like other actors in the legal community, may tell different narratives that reflect their own interpretation of the legal materials. Judicial reliance on competing legitimacy narratives is particularly evident in common law countries in which the issuance of multiple opinions in individual cases is used by judges as a way of advocating differing narratives.[137]

Lawyers, by contrast, are more likely to tell relatively complete legitimacy narratives as part of their effort to persuade courts or agencies to accept their interpretations of legal materials. Works on advocacy

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[135] Herman, et al. (n.124), 15.
[136] Bell (n.6), 8–10; see also Fish, *Is There a Text in This Class? The Authority of Interpretive Communities* (Harvard 1980).
[137] A similar dynamic can be seen in the EU in exchanges between the Advocates General and the Court of Justice. Compare, e.g., Case C-50/00 P, *Unión de Pequeños Agricultores v. Council* [2002] ECR I-6677 with ibid., Opinion of A.G. Jacobs.

commonly advise that cases are won or lost on how the issues are framed, which often means how they are situated within a legitimacy narrative. Lawyers thus tell competing legitimacy narratives as part of a broader competition among their clients to set the terms of debate. The advocacy quality of most lawyering, however, means that these narratives are limited to the interests at hand, and are therefore also inevitably incomplete. In the end, it falls to academic lawyers to tell complete legitimacy narratives, as they are the only actors within the legal community who have the institutional space and freedom to integrate a broad range of legal materials apart from any instrumental purpose.[138] In large part, it is what we are for.

This thesis, therefore, while primarily a work of analysis is also a work of creation.[139] My task is to analyse the available legal materials and to construct one or more narratives that plausibly rationalise the existence of administrative risk regulation with authoritative legal materials and legal values. I can therefore make no claims of authority for the narratives presented, and alternative narratives will always be possible. That said, I am not advocating a standard of absolute relativism in legal scholarship.[140] Although multiple interpretations will usually be possible, legal materials are not endlessly malleable. What I present in this thesis are the narratives that I find most satisfying and persuasive. They are descriptive in the sense that they reflect my understanding of the materials studied. They are prescriptive in that I argue they are the best way of making sense of those materials. My challenge is to persuade the reader on both counts.

C. The Role of Legal Culture

My approach to legitimacy as narrative—the telling of a story—makes it important to consider the ways in which legal materials are presented

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[138] Posner, 'The State of Legal Scholarship Today: A Comment on Schlag' (2009) 97 Geo.L.J. 845, 854–55; van Gestel and Micklitz, 'Why Methods Matter in European Legal Scholarship' (2014) 20 ELJ 292, 295–96 .
[139] White (n.126), 221; White, *The Legal Imagination* (abridged ed., University of Chicago 1985) (1973) 245–50.
[140] Cf. Bell (n.6), 21

and debated, that is to say the vocabulary and grammar in which the narratives are told. Attention to these aspects of legitimacy narratives inevitably requires thinking about legal culture. Legal culture is troublesome as a basis for analysis, however, for two reasons: First, it is an indeterminate concept, which can mean different things depending on the analytical perspective taken.[141] Second, evidence of legal culture is often elusive and frequently insufficient as a basis for drawing generalisations.[142] Rather than being observed directly, the workings of legal culture must generally be inferred, which inevitably confers a subjective character on the evidence.

As to the first problem, for the purposes of this thesis I am interested in the aspect of legal culture that John Bell calls the "internal perspective" of official legal culture.[143] In describing the internal perspective, Bell states:

> [W]e are concerned here, for example, to explain the internal process of making sense of the Code as part of a legal argument. For this purpose, there are established ways in which interpretations can be accepted as valid. There are conventions within the legal community about what are appropriate arguments which support an interpretation—whether cases can be cited and from which courts, whether doctrinal legal writers can be cited as appropriate authorities. Education has an important role in the socialisation of participants into a culture.[144]

Put differently, legal culture in the sense I am using it is the framework by which meaning is created out of legal materials. In the context of legitimacy narratives, it is the internal perspective of legal culture that provides the tools for explaining administrative risk regulation in terms of

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[141] Nelken, 'Using the Concept of Legal Culture' (2004) 29 Austl.J.Leg.Phil. 1, 8–9.
[142] Cotterrell, 'The Concept of Legal Culture' in Nelken (ed.), *Comparing Legal Cultures* (Dartmouth1997) 13.
[143] Bell (n.6), 17.
[144] Ibid., 7.

legal materials and values.[145] At times, legal culture will itself be a source of those values.

The second problem is more difficult. An essential aspect of legal culture is its pervasiveness.[146] That pervasiveness makes legal culture crucial for understanding the operation of a legal system, but it also makes it difficult to get a hold of. Inevitably, analysis of legal culture is an act of interpretation and, as Bell notes, "[i]t has to be recognised that such analysis is a construction of the author."[147] In that sense, analysing legal culture is like constructing a legitimacy narrative and the two can even be seen as different manifestations of the same intellectual enterprise. But unlike legitimacy narratives, which are constructed from authoritative texts, legal culture is open-ended. The attendant danger is that subjective interpretation will outstrip evidence, and explanations of legal systems in terms of legal culture can quickly fall into speculation or oversimplification. To mitigate this danger, my focus will remain closely on administrative law doctrine and legal reasoning, rather than broader characterisations of legal culture (e.g., the oft-cited characterisation of American legal culture as a form of adversarial legalism).[148] In this way, I hope to avoid the problem of relying on generalisations about culture that are difficult to substantiate. At the same time, however, limiting the analysis in this way necessarily sacrifices some of the explanatory richness of a broader approach. This is another area in which I believe future work may be valuable.

D. Comparative Law

The project of constructing legitimacy narratives used to explain administrative risk regulation within any one jurisdiction could easily fill a thesis. Why then add complexity by undertaking a comparative study? There are two reasons: one methodological and one practical.

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[145] Ewald (n.6), 2127–28.
[146] Bell (n.6), 2–8.
[147] Ibid., 21.
[148] Kagan, *Adversarial Legalism: The American Way of Law* (Harvard 2001).

Comparative analysis is worthwhile foremost because it enriches the explanatory power of the narrative methodology I have been describing. A signal feature of legal culture and of legitimacy narratives is their background character.[149] Legal culture in particular is such an integral part of thinking and speaking about law that it becomes invisible, and its very pervasiveness makes it difficult to examine solely from within a particular legal tradition. Comparative analysis, on the other hand, tends to reveal the operation of legal culture. As Garapon puts it, "To grasp a culture . . . involves one in trying to formulate what is so obvious for the members that 'it goes without saying'. The best way of abstracting oneself from one's own culture is to look at it from the outside in confronting it with other cultures."[150] One of the goals of this thesis is to reveal some of what "goes without saying" in the administrative law of risk regulation, a goal which is made easier by the application of comparative analysis.

The practical justification for comparison is that, in my view, trans-Atlantic understandings of administrative law and risk regulation are in a bad state. Although there has been a lot of comparative work done in this area, the large majority of that work has focused on regulatory outcomes or on the operation of regulatory principles in isolation.[151] As valuable as this work is, it does little to explain differences between the two jurisdictions regarding the role of *law* in risk regulation. In doing so, it tends to overlook an important source of normative, as well as instrumental, influence on regulatory processes.[152] At times, it can even be counterproductive by analysing regulatory concepts outside of their

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[149] Jasanoff (n.12), ch. 1.
[150] Garapon, *Bien Juger*, as quoted in Bell (n.6), 21.
[151] Fisher (n.1), 2. There are obviously important exceptions, including the work of Fisher and Jasanoff. Excellent comparative work on administrative law has also been done recently by scholars such as Ackerman, Bignami, and Craig, but their work has not focused on the specific topic of risk regulation.
[152] Fisher (n.1), 23–25.

administrative-constitutional context, with the predictable result that the meaning of those concepts becomes distorted.[153]

This gap in scholarship is important because of the global positions of the EU and the US, both economically and as the leading exporters of regulatory norms.[154] As economic leaders, the EU and the US must increasingly cooperate on regulatory matters, and even with rising doubts about globalisation, there is no immediate prospect of a return to purely national forms of regulation. The ability of the two systems to cooperate will inevitably be hampered if the two sides fail to understand why the other approaches problems in the way it does and how those approaches respond to that system's specific needs. Similarly, the process of regulatory learning, either between the EU and US or between these and other jurisdictions, cannot achieve its full potential if the significance of regulatory principles and processes is not well-understood. Comparative lawyers have long warned of the dangers of transplanting legal artefacts from one context to another because of the possibilities of unexpected interactions.[155] The reverse is also true, however; the potential benefits that might come from attending to foreign regulatory approaches may not be realised if the full meaning of those approaches is not understood.

It should also be apparent from my focus on administrative constitutionalism and legal culture that my analysis is not going attempt

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[153] The poster child for the perils of this sort of analysis is Marchant and Mossman, *Arbitrary and Capricious: The Precautionary Principle in the European Courts* (AEI 2004), which tries to analyse the EU courts' jurisprudence on the precautionary principle without accounting for other basic aspects of EU law, such as proportionality and subsidiarity. As one might guess, the result is unrecognizable to a reader with a background in EU law. Some European descriptions of US law can seem equally bizarre to American readers. E.g., Portuese, 'The Principle of Proportionality as a Principle of Economic Efficiency' (2013) 19 ELJ 612.

[154] Palacios Lleras, for example, argues that virtually all reforms of Latin American competition law in recent decades have been directed at either Europeanising or Americanising indigenous systems. *Antitrust in Latin America: Law, Politics, Expertise* (unpublished PhD thesis, University College London) (2016).

[155] Kahn-Freund, 'On Uses and Misuses of Comparative Law' (1974) 37 MLR 1, 6–7.

to decide which system is "better". Indeed, on such issues the concept of better seems hopelessly indeterminate. For the avoidance of doubt, I will say up front that I think both systems are reasonably sound responses to the particular problems and cultural traditions at work in their respective jurisdictions. Neither is perfect, but no legal or regulatory system is. Nor do I think that either system would be materially improved by moving substantially closer to the other. That is not to say that I think the two systems cannot learn from one another, but the lessons I have in mind are at the margin and do not call on either system to alter its basic administrative-constitutional commitments. My purpose, however, is not to suggest reforms but to deepen understanding, which for the foregoing reasons I believe is a worthwhile project in its own right.

III. A Roadmap

A single thesis obviously cannot compare every aspect of risk regulation, and my focus will be on the way in which administrative law legitimates and shapes administrative risk regulation in the two jurisdictions. Even narrowed in this way, the ground is too broad for a single study to tackle. To make the task manageable and to limit it to a coherent set of themes, I will focus on a handful of issues that I believe are particularly essential to defining and distinguishing EU and US legal approaches to risk regulation. In selecting themes and issues for analysis in the doctrinal chapters, I have attempted to balance two goals. First, of necessity, I have tried to cover a broad enough sample of issues to inform the reader about the most important administrative law doctrines that bear on risk regulation and to situate those doctrines within a broader administrative-constitutional context. Chapter 2, for example, explains the institutional arrangements for administrative risk regulation in each of the two jurisdictions and lays essential groundwork for understanding the institutional suppositions that inform the doctrine. Chapter 2 also addresses theories of delegation, which are central to the definition of administration in both jurisdictions.

Second, in choosing issues to include in the doctrinal analysis I have focused on those aspects of legal doctrine and administrative

constitutionalism that give the two systems of risk regulation their individual characters. In chapter 3, I look at the role of law in constituting and limiting the aims of risk regulation through an examination of the roles of the precautionary principle and cost-benefit analysis. Chapter 4 examines the concept of administrative rationality in the two legal systems, including the relationship between scientific and political reasoning in conceptions of administrative rationality. Chapter 5 brings together the analysis of the foregoing chapters by reconstructing the narratives that legitimate administrative risk regulation in the EU and US legal systems. By offering integrated narratives, I aim to highlight the interconnectedness of the various issues under examination and to expose in a subtle way the unique characters of the two systems. Finally, in chapter 6, I reflect on the two narratives and the normative visions of administration they represent. In doing so, I identify some of the jurisprudential sources of conflicts over risk regulation and argue that responding to those conflicts requires thinking about the role of administration generally and not just about the special problems of risk.

2

Institutional Structures and Delegation

This chapter sets forth the broad constitutional and institutional framework for administration in the European Union and the United States. Aspects of this discussion will be familiar to many readers, but it is nonetheless worth taking time to examine the differences in the institutional arrangements of the two administrations because these arrangement are important—if often unstated—premises of many of the legal doctrines that govern the exercise of administrative power. Institutional arrangements, and in particular the internal organisation of administrative bodies, also control the way in which risk regulation standards are developed by determining the manner and timing by which various actors and considerations are introduced into the process.

The chapter begins by defining the administration in the two jurisdictions. It then considers the broad institutional arrangements of the two systems, including the mechanisms by which other institutions control the administration and hold it to account. It next looks in some detail at the administrations' internal structures, before drawing some broad comparisons between the roles of the administration in the two systems. Finally, this chapter considers the legal theory of delegation, which is the primary doctrinal mechanism by which the two systems of administrative law reconcile the exercise of bureaucratic power with democratic values.

I. The Administration and Its Role in the Constitutional Order

The analysis must begin by defining the administration in each system. This seemingly banal point actually raises one of the most important contrasts between the US and EU. Whereas the US definition of

administration is settled, the concept of EU administration is still very much evolving. This section also considers how the administration relates to other constitutional actors. In both systems, regulatory power is divided and shared among multiple institutions. Defining the administration thus not only requires an examination of the administration's own powers and prerogatives, but also the mechanisms available to other institutions for controlling the administration and holding it to account.

A. The US: Administration Within a Nation-State

1. Defining the administration

The concept of administration in US law is well-settled. The US federal administration[1] can be defined as those federal bodies, other than the judiciary, that implement US statutes and government programmes, pursuant to a delegation of authority set forth in a statute. In US parlance, the work of administration is done by agencies.[2] Within the field of risk regulation, six agencies are of particular importance: the Environmental Protection Agency (EPA), the Consumer Products Safety Commission (CPSC), the Food and Drug Administration (FDA), the Occupational Safety and Health Administration (OSHA), the National Highway Traffic Safety Administration (NHTSA) and the Nuclear Regulatory Commission (NRC). Many other agencies occasionally engage in risk regulation, but the bulk of US federal risk programmes are administered by these six. Of these agencies, EPA is far and away the

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[1] In this thesis, I am concerned only with the US federal government and not with the administrations of the several states. Similarly, I am concerned with administrative arrangements at EU level and not with Member State administrations, although the nature of EU administration (discussed below) is such that the interaction between Member State and EU administrations will at times be important.

[2] The Administrative Procedure Act (APA) defines "agency" as "each authority of the Government of the United States, whether or not it is within or subject to review by another agency", but excludes, among other entities, Congress and the courts. 5 U.S.C. § 551. The Supreme Court has also interpreted the APA not to apply to the president and vice-president. *Franklin v. Massachusetts*, 505 U.S. 788 (1992).

most important, both in terms of the number of programmes it administers and in terms of the role its activities have played in the development of the law in this area.

An essential characteristic of the federal administration is that it has been created entirely by, and derives all of its powers from, statute.[3] Although the Constitution contemplates the establishment of "Departments" and the appointment of "Officers", it creates no such entities or positions, nor does it contain any explicit provisions for their establishment or functioning. This constitutional lacuna has given rise to the great preoccupation of American administrative law, the place of the administration within the Constitution's scheme of separated powers.[4]

2. The US institutional framework

As is well known, the US federal government is organised according to a tripartite separation of powers, with the legislative, executive, and judicial powers assigned to Congress,[5] the president,[6] and the federal courts,[7] respectively. Because the Constitution gives the president some supervisory authority over the departments, and because the administration can be viewed as primarily executing laws passed by Congress, the administration is generally viewed as part of the Executive Branch.[8] Control and supervision of the administration is not limited to the president, however. To the contrary, each of the three branches has mechanisms for controlling the administration and holding it to account. Indeed, as Peter Strauss has argued, the Supreme Court's case law in

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[3] *Bowen v. Georgetown University Hospital*, 488 U.S. 204, 208 (1988).
[4] Mashaw, Merrill, and Shane, *Administrative Law: The American Public Law System* (6th ed., West 2009) 39–45; I Pierce, *Administrative Law Treatise* (4th ed., Aspen Law & Business 2002) 35–37.
[5] U.S. Const., Art. I.
[6] U.S. Const., Art. II.
[7] U.S. Const., Art III.
[8] Lessig and Sunstein, 'The President and the Administration' (1994) 94 Colum.L.Rev. 1, 12–13.

this area is best understood as requiring that all branches have a degree of authority over the administration.[9]

As the repository of legislative authority, Congress's greatest power over the administration derives from the requirement that all agencies be created by statute. Congress thus has broad power to shape the composition, powers, and procedures of agencies. The only structural limitation on this power is that Congress may not vest itself with supervisory authority over the administration at the expense of the president.[10] In addition to passing laws,[11] Congress must authorise the federal budget and frequently uses the appropriations process to influence agencies' policies and priorities. Both houses of Congress also exercise oversight over administrative and executive departments by conducting hearings and investigations.[12] The Senate (but not the House) must confirm the president's nominees to high-level positions within the administration,[13] and Congress may remove "civil Officers of the United States" by impeachment.[14]

Article II, section 1 of the Constitution vests "the Executive power" in "a" president. This Vesting Clause (along with the Opinion Clause[15]) is interpreted to give the president general supervisory power over the administration.[16] The president's greatest constitutional power to influence the administration is the power to appoint all "Officers of the United States", subject to confirmation by the Senate. The appointment power gives the president the ability to shape administrative policy by

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[9] Strauss, 'The Place of Agencies in Government: Separation of Powers and the Fourth Branch' (1984) 84 Colum.L.Rev. 573, 579–80.
[10] *Bowsher v. Synar*, 478 U.S. 714, 724–27 (1986). Strauss reaches a similar conclusion based on earlier case law. Strauss (n.9), 650–53.
[11] Congress's non-legislative powers to influence the administration are exhaustively catalogued in Beerman, 'Congressional Administration' (2006) 43 San.Diego.L.Rev. 61.
[12] Ibid., 126.
[13] U.S. Const., Art II, § 2.
[14] Ibid., Art. II, § 4.
[15] U.S. Const. Art II, § 2 ("[H]e may require the Opinion, in writing, of the principal Officer in each of the executive Departments, upon any Subject relating to the Duties of their respective Offices.").
[16] *See* Strauss (n.9), 646–48; Lessig and Sunstein (n.8), 12–13.

selecting administrative officials who share his or her policy preferences, a fact that has become central to contemporary understandings of administrative accountability. Most officers serve at the (unreviewable) pleasure of the president, although some—including the heads of some agencies—may only be removed for cause, which is understood to preclude removal of an official solely for political reasons.

The extent of the president's power over the administration is a topic of considerable debate, but there is no disagreement that it is broad.[17] The principal question discussed in the literature is whether the president is an "overseer", i.e. limited to exercising those oversight powers specifically granted by the Constitution or statute, or a "decider", i.e. constitutionally empowered to substitute his or her judgment for that of lower ranking executive or administrative officials. Supreme Court case law and constitutional tradition tend to favour the former interpretation, yet a strong minority of academics argue forcefully for the latter.[18] The question has never been squarely answered by a court, however.[19]

Though the constitutional position is unresolved, three points about presidential control over the administration are uncontroversial and important for the analysis in this thesis. First, numerous empirical studies have documented that presidents exercise enormous influence on

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[17] Compare Lessig and Sunstein (n.8), 118–19, with Calabresi and Prakash, 'The President's Power to Execute the Laws' (1994) 104 YLJ 541, 568–70. The principal arguments in this debate are reviewed from different perspectives in Kagan, 'Presidential Administration' (2001) 114 HLR 2245, 2319–31, Stack, 'The President's Statutory Powers to Administer the Laws' (2006) 106 Colum.L.Rev. 263, 270–74, and Strauss, 'Overseer or "The Decider"? The President in Administrative Law' (2007) 75 Geo.Wash.L.Rev. 696, 705–6. A lengthy historical analysis is offered in Bruff, *Balance of Forces: Separation of Powers Law in the Administrative State* (Carolina Academic Press 2005).

[18] I find the analysis presented in Strauss (n.17) in favour of the "overseer" hypothesis persuasive. The leading proponents of the "decider" thesis are Calabresi and Prakash (n.17). Their argument, though forceful, depends too much in my view on a hermeneutical analysis of constitutional text and pays insufficient attention to the long history of insulating administrative decisionmaking from direct presidential control.

[19] Strauss (n.17), 704.

administrative decisionmaking.[20] Second, for at least the last four decades, presidents have expended considerable effort to extend their control over the administration.[21] Third, these presidential efforts have been accompanied by a considerable development—both by academics and the courts—of the intellectual and doctrinal support for a strong presidential role in administrative decisionmaking. Defenders of "weak" presidentialism are a minority these days.[22] This last point is of particular importance because it has caused a substantial evolution in US legitimacy narrative.[23]

Finally, the Constitution establishes an independent judiciary with the Supreme Court at its apex. Unsurprisingly, given its culture of "adversarial legalism",[24] the availability of judicial review is an important part of US legitimacy narratives.[25] The Constitution does not, however, confer a right to judicial review, and the availability and scope of review are extensively regulated by statute.[26] Unlike the practice in the EU, judicial review is generally only available to individuals. Congress normally does not have standing to seek judicial review of administrative action.[27] Nor, absent unusual circumstances, may an agency or the president seek judicial review.[28]

Largely absent from this institutional picture are the several states. In contrast to the EU, in which the Member States have an important role in supervising the administration, US states have no formal role in federal

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[20] Stack (n.17), 298 (listing studies).
[21] Kagan (n.17), 2272–2319.
[22] See sources cited note 17 above.
[23] Chapter 4, section II.C.
[24] Kagan, *Adversarial Legalism: The American Way of Law* (Harvard 2001).
[25] Jaffe, *Judicial Control of Administrative Action* (Little, Brown & Co. 1965) 320 ("The availability of judicial review is the necessary condition, psychologically if not logically, of a system of administrative power which purports to be legitimate, or legally valid.").
[26] Stack (n.17), 300.
[27] Herz, '*United States v. United States*: When Can the Federal Government Sue Itself?' (1992) 32 Wm.&Mary.L.Rev. 893, 913.
[28] *Tennessee Valley Authority v. EPA*, 278 F.3d 1184, 1193 (11th.Cir.2002).

administrative processes. Although the states' views carry great weight with federal administrators, their rights in most standard-setting proceedings are no different from the rights of private individuals to participate and to seek judicial review.[29] The lack of formal state involvement in federal administrative processes gives the US administration a greater degree of unity and autonomy than its EU counterpart because there is no need to seek the approval of state governments as, for example, in the EU's comitology process.

B. The EU: Administration Beyond the Nation-State

1. Defining EU administration

Defining the EU administration is difficult, both because of the EU's *sui generis* nature—somewhere between an international organisation and a federal government—and because of its unique and uniquely complex institutional architecture. Of particular relevance to this thesis, the line between administrative and legislative acts is less sharp in the EU than in the US. Although I will distinguish the two on formal grounds, the EU's institutional processes give administrative acts (at least of the kinds used to set risk standards) certain characteristics that in the US might be described as legislative.

To understand EU administration, we must briefly consider the nature of the Union itself. The EU is an organisation established by Treaty. It began life in 1952 as the European Coal and Steel Community, to which the European Economic Community and the European Atomic Energy Community were added in 1957.[30] The EU began to take on its modern form in the 1980s, first with the Single European Act of 1986, which took the initial steps away from intergovernmentalism, and then with the establishment of the European Union by the Treaty of Maastricht in 1993. The 2007 Treaty of Lisbon is the latest in a series of

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[29] *Massachusetts v. Mellon*, 262 U.S. 447, 485–86 (1923); see also *Massachusetts v. EPA*, 549 U.S. 497, 536–37 (2007) (Roberts, C.J., dissenting).

[30] This history is recounted in Chalmers, Davies, and Monti, *European Union Law: Text and Materials* (3d ed., CUP 2014) 11–39.

significant post-Maastricht treaty revisions that have increased the scope of European-level competences and the ability of the EU to act independently of the control of the Member States.[31] Notably, the Treaty of Lisbon merged the formerly separate European Community (the successor of the EEC) and the European Union into a single legal entity with competence over not only economic integration, but also a number of other governmental and regulatory fields of common interest to the Member States.[32]

What exactly the European Union is today is a topic of considerable academic debate.[33] Formally, it remains an international organisation, established by treaty with the consent of each Member State. It is not, however, an international organisation in the traditional sense because its decisionmaking processes are not fully within the control of the Member States, and its power to make binding law is (usually) not subject to the consent of any individual Member State. But the EU is not a nation-state either because (among other reasons) it is not a self-authenticating legal order. Though the Member States may not be in full control of its decisionmaking, the force of EU law depends in the last instance on acts of the Member States as sovereigns, i.e. the Treaties.

The EU's uncertain constitutional status complicates the search for the "administrative" in EU law. At one extreme, the entirety of the EU can be conceived of as administrative. This thesis has been advanced by Peter Lindseth who argues that, because the EU only exercises power on the basis of a delegation from the Member States, its norm-setting power should also be understood solely in terms of delegated, rather than constitutive, authority.[34] In Lindseth's conception, the validity of any EU

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[31] See generally, Craig, *The Treaty of Lisbon: Law, Politics, and Treaty Reform* (OUP 2013).

[32] Before Lisbon, the EC, not the EU, had competence to regulate risk at European level. For ease of reference, I will use the term EU to refer to both the EU and the EC.

[33] These debates are summarised in Chalmers, et al. (n.30), 7–11.

[34] Lindseth, 'Democratic Legitimacy and the Administrative Character of Supranationalism: The Example of the European Community' (1999) 99 Colum.L.Rev. 628, 649–51.

regulation, whether in the form of EU legislation or of a delegated or implementing act, would be measured by reference to whether it furthered identifiable goals set forth in the Treaties, and it would be the responsibility of the courts to enforce the bounds of this delegation.[35] Although the EU does bear some resemblance to an administrative body, in that it ultimately derives its authority from democratically superior bodies, Lindseth's argument is unconvincing. His approach depends on a highly instrumental conception of the EU, yet the Treaties themselves express an intention that the EU should be a constitutive body capable of generating its own normative order. That intention is notably expressed in the articles on consumer, health, and environmental protection, in which the Treaties establish ambitious and open-ended objectives, including commitments to a high level of protection, sustainable development, and the precautionary principle.[36] Elaboration of these values requires a political process that can only be described as constitutive in nature.[37] The overriding impression of these provisions is of a European vision of health and environmental protection, separate from national approaches to those problems.

At the other end of the spectrum, it could be argued that all EU standard setting constitutes legislative activity and that no distinction should be made between legislative and administrative acts. Outside of narrow areas, the EU's regulatory powers are limited to rule generation, and historically there was formally no hierarchy of norms in EU law.[38] After Lisbon, which introduced specific categories of "delegated

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[35] Ibid., 657–62.

[36] See generally, Arts. 11, 12, 169, and 191 TFEU.

[37] Additionally, Article 10 TEU, which states, "The functioning of the Union shall be founded on representative democracy. . . . Citizens are directly represented at Union level in the European Parliament", and Article 9 TEU, which confers EU citizenship on all citizens of the Member States, suggest that the EU understands itself to derive a measure of political authority directly from European citizens. Lenaerts, 'The Principle of Democracy in the Case Law of the European Court of Justice' (2013) 62 Int'l&Comp.L.Q. 271, 275–79.

[38] Bieber and Salomé, 'Hierarchy of Norms in European Law' (1996) 33 C.M.L.Rev. 907, 915–17.

legislation" and "implementing acts", the view that all EU standard setting should be thought of as legislation is no longer tenable, however.[39] Additionally, by introducing the idea of an "ordinary legislative procedure", Lisbon created a special status for EU acts adopted via this method.[40] Even before Lisbon, the EU courts had at least implicitly recognised such a hierarchy in the context of acts adopted by the Commission pursuant to a legislative delegation.[41] Additionally, the Court of Justice has tended to apply stricter procedural requirements and substantive scrutiny to standards adopted by the Commission.[42] It is the existence of these separate and additional legal controls that sets administrative standard setting apart from legislation in the EU.

For purposes of this thesis, I will define EU administrative acts as those taken by the Commission, or less commonly the Council, pursuant to a delegation contained in legislation adopted through one of the EU's legislative processes. I will use the term "administration" to refer to the various institutions that cooperate in the production of these acts. That definition includes, but is not limited to, the Commission, European agencies, expert committees, and comitology committees. These various actors are described in the following section.

2. The EU institutional order

The unique nature of the EU has also resulted in an unusually complex institutional structure. At the top of the institutional hierarchy are the EU Institutions: the European Council, the European Parliament, the Council of Ministers (Council), the European Commission, and the Court of Justice of the European Union.[43] Of these Institutions, the Commission, Parliament, Council, and Court of Justice are most

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[39] Case C-583/11 P, *Inuit Tapiriit Kanatami v. Parliament and Council*, nyr, paras. 60–61.
[40] Craig (n.31), 250–52.
[41] Case 23/75, *Rey Soda v. Cassa Zucchero* [1975] ECR 1279, paras. 9–11.
[42] E.g., Case C-343/09, *Afton Chemical Ltd. v. Secretary of State for Transport* [2010] ECR I-7027, Opinion of A.G. Kokott, paras. 53–54.
[43] Article 13 TEU.

important for the administrative process. As the EU's main administrative body, the Commission is responsible for most administrative decisions and for the functioning of the administration generally. The Commission is responsible to the Parliament, which in conjunction with the Council acts as the EU legislature. Finally, the EU courts are responsible for upholding the rule of law and ensuring the legal accountability of the other Institutions.

The Parliament is the EU's only directly elected Institution. Like the US Congress, the Parliament's greatest power over the administration is its role in the legislative process, by which the terms of delegated power are fixed. Unlike Congress and the Member State legislatures, however, Parliament's role in the legislative process is circumscribed and it has very limited rights to initiate legislation.[44] The Parliament also possesses other powers for holding the administration to account. It must ratify the European Council's nominee for Commission President and subsequently approve the full slate of Commissioners.[45] It may form committees of inquiry and require members of the Commission to appear before it.[46] It may censor the Commission or any Commissioner, and it may force the resignation of the Commission as a whole.[47] As discussed below, it may comment on proposed implementing acts, and it may reject delegated acts adopted by the Commission in some circumstances.[48] Additionally, the Parliament exercises considerable control over the EU budget, which it may use to influence administrative priorities.[49]

The Council is primarily a legislative body. It is comprised of one representative "at ministerial level" of each Member State.[50] All EU legislation must be approved by the Council, but like the Parliament, it generally may not initiate legislation. Like the Parliament, the Council

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[44] Article 294 TFEU; Chalmers, et al. (n.30), 100–01.
[45] Article 17(7) TEU.
[46] Article 226 TEU.
[47] Article 17(8) TEU.
[48] Below, section II.B.4.
[49] Nugent, *The Government and Politics of the European Union* (7th ed., Palgrave Macmillan 2010) 185.
[50] Article 16(2) TEU.

may reject delegated acts and comment on implementing acts. In increasingly rare circumstances, the Council also acts as an administrative body by adopting implementing acts instead of the Commission.[51]

The Commission is primarily an administrative institution, but it also plays an important part in the legislative process. Normally, only the Commission may propose legislation to the Parliament and Council,[52] and it retains the right to modify its proposal or to withdraw it entirely at any time prior to final disposition by the Council.[53] This powerful role gives the Commission a great degree of influence on the content and scope of the delegations under which it will subsequently adopt administrative acts.

The Court of Justice of the European Union includes two courts, the Court of Justice and the General Court.[54] Direct access to the EU courts by private litigants is limited to addressees of the act in question or those who can show "direct and individual concern", meaning that the act must affect the applicant directly without the need for any further intervening act[55] and that it must only affect a group of individuals whose membership is fixed and numerable.[56] In the past, this restrictive test for standing was a serious hurdle for private parties seeking judicial review of administrative action.[57] The Treaty of Lisbon liberalised standing somewhat by providing that in suits "against a regulatory act . . . which . . . does not entail implementing measures" the applicant need only show

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[51] Article 291(2) TFEU.
[52] Article 17 TEU.
[53] Articles 293 and 294 TFEU.
[54] Article 19 TEU. Before Lisbon, the Court of Justice was known as the European Court of Justice and the General Court was known as the Court of First Instance. For ease of reference, I use the terms Court of Justice and General Court throughout.
[55] Hartley, *The Foundations of European Union Law* (8th ed., OUP 2014) 388.
[56] Ibid., 372.
[57] Harlow, 'Towards a Theory of Access for the European Court of Justice' (1993) 12 YEL 213, 241–45.

direct concern.[58] The Court of Justice has interpreted "regulatory acts" to mean acts of general applicability that are not adopted through a legislative procedure.[59] Accordingly, this provision will apply to most administrative measures, provided they do not require further implementation. Additionally, applicants who cannot show standing may still be able to access the EU courts indirectly via a reference from a national court.[60] One aspect of EU judicial practice that is quite distinct from the US is the common phenomenon of EU Institutions or Member States suing other Institutions over the legality of legislative or administrative acts.[61] This possibility gives the Institutions and Member States an additional route for exercising control over the administration indirectly, via the courts.

Finally, the Member States have an important place in the EU administrative constellation. Under the Treaties, the default assumption is that Member States are responsible for the implementation of EU law. Article 291 TFEU provides that the Member States' powers of implementation may be transferred to the Commission only when "uniform conditions for implementing legally binding Union acts are needed," thus arguably creating a principle of executive subsidiarity.[62] And even when implementing powers are exercised at EU level, the Member States retain important roles. In some regulatory programmes, Member States are responsible for much of the preparatory work for EU-level decisions. Additionally, the Member States exercise direct oversight of Commission implementing acts through the comitology process, described below.[63] Finally, the Member States are responsible for virtually all enforcement of EU law, meaning that the EU administration

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[58] Article 263 TFEU.
[59] *Inuit Tapiriit Kanatami* (n.39), paras. 60–61.
[60] E.g., Case C-132/03, *Ministero della Salute v. Codacons* [2005] ECR I-4167. This process has been more frequently used by regulated entities.
[61] E.g., Joined Cases C-14/06 and C-295/06, *Parliament v. Commission* [2008] ECR I-1649.
[62] Schütze, 'Executive Federalism in the (New) European Union' (2010) 47 C.M.L.Rev. 1385, 1411.
[63] Below, section II.B.4.

cannot set policy or fine-tune its risk standards through enforcement actions, a technique that is common among US agencies.

C. Sameness and Difference in the US and EU Institutional Orders

The foregoing rough sketches of the institutional architecture of the US and the EU reveals many important differences, but what is perhaps more striking are the broad similarities. First, both systems have complex institutional structures characterised by divided powers and checks and balances. By design, these systems create competition among institutions, which has the benefit of inhibiting the concentration of power, but at the cost of creating complex dynamics, the effects of which are hard to assess ex ante. Inevitably, these dynamics affect the way in which the administration does its work in that, at least over the medium- to long-term, the administration will have to maintain a measure of support from each institution.

The second similarity is that in both systems, the idea of administration is grounded in a theory of delegation, by which administrative bodies implement regulatory programmes established in the first instance by a legislature, which by hypothesis is the primary institution for expressing democratic preferences. The full implications of the delegation approach to administration are explored in Part III. For now, the important point is that a theory of delegation entails the subordination of the administration to other institutions to some degree. In the US, this subordination is nearly total, particularly if one accepts the view that the president is entitled to override administrators' decisions. By contrast, the degree of subordination of the EU administration is less. The Commission's constitutional status as a coequal Institution with the Council and the Parliament give it prerogatives in the administrative process, which it may enforce judicially.[64] Additionally, the Commission's legislative role provides it with a powerful weapon for defending its position.

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[64] E.g., Case C-257/01, *Commission v. Council* [2005] ECR I-345.

The third similarity is that a strong judiciary is central to the functioning of both systems. With so much institutional competition, a central referee is essential. But in neither system is the courts' role passively neutral. Rather, both systems' courts have asserted themselves in defining the role of the administration within the broader constitutional structure. Indeed, the ambiguities created by the division of powers among the other institutions has created greater opportunities for the courts to shape the role of the administration.

Despite these many similarities, there is one crucial difference between the two systems. Whereas the American federal government is a self-sufficient sovereign, the EU remains dependent in multiple ways on its Member States. Although US policymakers take state concerns quite seriously, no action of the federal government is dependent on state assent. The EU, by contrast depends in many ways on Member States for both resources and legitimacy.[65] Not only can the Member States block EU initiatives either through their representation on the Council or their role in comitology, the EU must rely on the Member States for most aspects of implementation. This situation leaves the EU with two options: it must either negotiate the multitude of Member State perspectives to find solutions that command broad support (at the cost of time, resources, and possible policy dilution) or it must evade Member State control (at the cost of deepening scepticism about its own democratic legitimacy). In practice, it does some of both, although its preference is for the former. In chapter 4, I will argue that this dynamic has affected the way in which the EU courts understand the process of administrative decisionmaking.

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[65] Joerges, 'Scientific Expertise in Social Regulation and the European Court of Justice: Legal Frameworks for Denationalized Governance Structures' in Joerges, Ladeur, and Vos (eds.), *Integrating Scientific Expertise into Regulatory Decision-Making* (Nomos 1997) 299.

II. Administrative Institutions

Having explored the broad institutional landscapes of the US and the EU and the administration's place within them, this section turns to the administration itself by looking at each jurisdiction's administrative institutions.

A. US Administrative Bodies and Process

1. Agencies

The primary organisational unit of US administration is the administrative agency, and virtually all administrative risk standard setting is undertaken by and within agencies. Although US agencies vary considerably in their organisational details and capacities, they are sufficiently similar to allow for reasonably accurate generalisations about their structure and workings.

Agencies are self-contained government entities. They have, in European parlance, legal personality. They may act on their own behalf and they generally have the authority to take legally binding decisions without having to seek the approval of any other government body.[66] Unlike the situation in the EU, in which the administration of regulatory programmes is undertaken by a complex set of institutions, American administrative agencies are "one stop shops", with capacities for research, policy development, adjudication, rulemaking, and enforcement all contained within a single organisational structure under the leadership of a single responsible agency head (although that "head" may be a multimember commission).

Broadly speaking, there are two types of US agencies: independent agencies (sometimes called "independent regulatory commissions") and executive agencies. The distinction between the two is entirely formal. An independent agency is one whose head does not serve at the pleasure of the president, whereas the heads of executive agencies may be removed at will.[67] Additionally, independent agencies are almost always headed by

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[66] I Pierce (n.4) 4–5.
[67] Mashaw, et al. (n.4), 28.

a multi-member commission rather than an individual. It is generally assumed that insulation from the president's removal power gives the independent agencies a greater ability to set regulatory policy independently of presidential preferences. The extent of that freedom is much debated, however.[68] In practice, most of the tools by which the president exercises oversight over administrative agencies apply equally to independent and executive agencies, and the analysis in this thesis is applicable to both types of agency. Of the six main risk regulation agencies, the CPSC and the NRC are independent agencies.

All agency heads are appointed by the president, subject to Senate confirmation. Agency heads may or may not possess technical qualifications. While the FDA Administrator is almost always a physician, most EPA Administrators have been lawyers. As a practical matter, the agency head is responsible for providing broad policy direction, representing the agency within the Executive Branch and before Congress, and making final decisions on issues of particular importance or public controversy.[69] Legally speaking, however, the agency head is responsible for every act of the agency.[70] That responsibility extends to an agency's expert reports and conclusions, and in US law agency heads are normally deemed to be experts in the areas for which their agencies are responsible.[71] In most cases, statutory delegations of regulatory authority are made to the agency head, rather than to the agency as an organisation.[72] In fact, an anachronistic convention persists by which lawsuits often name the head of the agency as the respondent, rather

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[68] Foote, 'Independent Agencies Under Attack: A Skeptical View of the Importance of the Debate' [1988] Duke.L.J. 223, 232–36.
[69] Mashaw, et al. (n.4), 19–23; McGarity, 'The Internal Structure of EPA Rulemaking' (Autumn, 1991) 54 LCP 57, 65.
[70] McGarity (n.69), 60–61; Metzger, 'Ordinary Administrative Law as Constitutional Common Law' (2010) 110 Colum.L.Rev. 479, 495.
[71] E.g., *Ethyl Corp. v. EPA*, 541 F.2d 1, 28 (D.C.Cir.1976).
[72] E.g., Occupational Safety and Health Act, 29 U.S.C. § 655 (delegating authority to the Secretary of Labor to promulgate workplace safety standards).

than the agency as a body.[73] In this case, legal theory mirrors popular perception, and the public will usually hold the agency head, if not the president himself, responsible for all acts of the agency.[74]

Agencies are staffed by a combination of political appointees and career civil servants. Relative to their European counterparts, US agencies tend to have a large number of political appointees.[75] This thick layer of appointees means that politically responsible individuals can be more involved in the day-to-day work of agencies. That involvement comes at the cost, however, of frequent turnover in agency management. It also creates opportunities for undue political pressure to be applied to an agency's technical analysis.[76] The vast majority of employees in US agencies are career civil servants who are appointed through a merit system and shielded from termination for political reasons.[77] Civil servants undertake background research, interact directly with the public, recommend courses of action, and draft the text of most agency standards. Thus, despite the presence of political appointees, civil servants play a large role in shaping administrative policy.

Agencies are usually organised into a number of offices or bureaus, typically based on either subject matter (e.g., the Office for Prevention, Pesticides, and Toxic Substances within EPA) or regulatory function (e.g.,

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[73] 14 Wright, Miller, and Cooper, *Federal Practice and Procedure* § 3655 (3d ed., West 1998). Indeed, in the extremely narrow circumstances in which judicial review is not provided for by statute, review must be sought against the agency head personally. Fallon, Meltzer, and Shapiro, *Hart and Wechsler's The Federal Courts and the Federal System* (4th ed., Foundation 1996).

[74] Lewis, *Presidents and the Politics of Agency Design* (Stanford 2004) 25–27.

[75] Spiller and Urbiztondo, 'Political Appointees vs. Career Civil Servants: A Multiple Principals Theory of Political Bureaucracies' (1994) 10 Eur.J.Pol.Econ. 465, 481–86. Up-to-date statistics on the number of political appointees are hard to come by, but they certainly number in the several thousands. Ackerman, 'The New Separation of Powers' (2000) 113 HLR 633, 704.

[76] Such pressure was widely seen as a problem during the Bush administration. Doremus, 'Scientific and Political Integrity in Environmental Policy' (2008) 86 Tex.L.Rev. 1601, 1603–19.

[77] Mashaw, et al. (n.4), 164–68.

NHTSA's Office of Rulemaking and Office of Enforcement).[78] Frequently, the heads of these divisions are political appointees. Regulatory standards are usually the work of a particular division; however, all agencies operate some form of intra-agency review process for soliciting input from other parts of the agency.[79]

All of the risk regulation agencies also undertake substantial scientific research. EPA, for example, operates a network of thirteen national laboratories.[80] The research divisions of the agencies may be called upon to support regulatory activities, for example by providing specialised expertise on a particular issue. They may also engage in research that is unrelated to immediate regulatory needs, although the results of this work may lead to new regulatory initiatives.[81] US agencies' capacity for both independent decisionmaking and scientific analysis means that most aspects of risk standard setting take place within a single organisation. Nonetheless, a complete picture of the US administration also needs to account for a handful of other institutional actors.

2. Other participants in the administrative process

Research Agencies and Scientific Committees. Although agencies' scientific and research capacities are primarily "in house", agencies also have access to expertise from other government bodies. One such source are research agencies, such as the Agency for Toxic Substances and Disease Registry or the National Institute for Occupational Safety and Health, which have research capacities but no regulatory powers. The reports authored by these agencies tend to carry great weight with regulators.

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[78] Ibid., 19–23.

[79] EPA has one of the most formalised intra-agency review processes, the details of which are set out in EPA Office of Policy, *EPA's Action Development Process* (revised March 2011). Some commentators argue that this review process hampers EPA's effectiveness by impeding the agency's ability to issue timely regulations and by biasing it toward conservatism in regulatory approach. E.g., McGarity (n.69), 91–92.

[80] http://www2.epa.gov/aboutepa#pane-5.

[81] Powell, *Science at EPA* (RFF 1999) 21–43.

Additionally, agencies may sometimes receive advice from advisory committees of outside experts. Some advisory committees, such as EPA's Science Advisory Board, are standing institutions. Others are convened on an ad hoc basis, often by the National Academy of Sciences (a federally chartered, non-governmental institution) at the request of a particular agency.[82] US advisory committees generally do not develop scientific analyses in the first instance. Instead, their function is usually to review and critique work done by the relevant agency in a form of peer review.[83] A few risk regulation statutes require the agency to consult expert committees before regulating, but more often the decision whether to do so is in the discretion of the agency. Agencies tend to be reluctant to resort to advisory committees because of the time and cost involved, as well as the burdensome procedures required by the Federal Advisory Committee Act.[84] Accordingly, agencies generally only consult advisory committees when the scientific issues are novel or controversial.[85]

The President. Besides agencies, the other significant actor in the administrative process is the president. As Chief Executive, the president has, at a minimum, general managerial authority over the agencies. Additionally, presidents endeavour to coordinate the work of the various administrative agencies and to impose a degree of prioritisation on agencies' work.[86] The president's managerial functions are exercised by the Executive Office of the President (EOP), often simply referred to as the White House. Within the EOP, the Office of Information and Regulatory Affairs (OIRA) (itself located within the Office of Management and Budget

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[82] Jasanoff, *The Fifth Branch: Science Advisors as Policymakers* (Harvard 1990) 45–49.
[83] Ibid., 95–97.
[84] Croley and Funk, 'The Federal Advisory Committee Act and Good Government' (1997) 14 Yale.J.Reg. 451, 472.
[85] US EPA, *Peer Review Handbook* (3d ed., GPO 2006) 45.
[86] Kagan (n.17), 2272–81.

(OMB)) has primary responsibility for regulatory oversight through its role in the regulatory review process mandated by Executive Order 12,866.[87]

3. US administrative process

The procedures used by US administrative agencies to set risk standards vary widely among agencies and programmes, and it would not be possible to describe a single typical process. Nonetheless, certain features are typical of US administrative processes. First, administrative actions are usually developed by a single agency, with initiation of the action, policy development, and expert analysis all taking place within one organisation. A trend in US administration, particularly at EPA, has been toward greater interaction between career staff and the agency's political leadership early in the process.[88] Second, agencies will usually consult widely with stakeholder groups while developing proposed actions. These consultations are more informal (and some would say more fruitful) than the formal consultation that takes place after an action is proposed.[89] Third, the final decision on the content of the regulatory proposal will either be made by the agency head or another high-level political appointee to ensure that the action is consistent with the agency's policy objectives. Finally, "major" agency actions involving large regulatory costs must be submitted to the OIRA for review to ensure that the action conforms to all applicable executive orders.[90]

Once OIRA has cleared the proposed action, it will generally be published for public comment. The comment process is one of the distinctive features of US administrative procedure and an important part of its legitimacy narrative. Virtually all rulemakings require notice-and-comment, in which a proposed rule is published and the public is invited to comment within a set time.[91] But even in contexts other than

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[87] Sunstein, 'The Office of Information and Regulatory Affairs: Myths and Realities' (2013) 126 HLR 1838. That process also includes review of the agency's cost-benefit analysis, discussed in chapter 3, section II.B.3.
[88] EPA (n.79), 10–11.
[89] Elliott, 'Re-Inventing Rulemaking' (1992) 41 Duke.L.J. 1490, 1495.
[90] This process is detailed in chapter 3, section II.B.3.
[91] 5 U.S.C. § 553.

rulemaking, agencies often are required to announce proposed decisions and to allow for public comment. Normally, any member of the public may comment without the need to demonstrate an interest in the outcome, and in most cases the agency must respond to all significant public comments.[92]. Most comment processes are conducted online.[93]

Notice-and-comment serves at least three important functions. First, it provides the agency with additional information relevant to the action. Although the agency will almost certainly have consulted with affected groups when developing the proposed action, it is always possible that it overlooked important information. Open comment creates an opportunity for these sources to come forward and, to the extent they have an interest in the outcome, they have a strong incentive to do so.[94] Second, it allows the agency to gauge reaction to its proposals. Third, and most importantly as a legal matter, the notice-and-comment process lays the groundwork for possible subsequent judicial challenges. Normally, a court reviewing a final agency action will not consider arguments that were not first presented to the agency.[95] It also creates a record on which a reviewing court can assess the reasonableness of the agency's action.[96]

In addition to these three functions, the notice-and-comment process has considerable, if hard to quantify, noninstrumental importance.[97] By giving any person the right to put issues before the agency and demand a response, it creates a mechanism for direct accountability of the administration to the public. Although this accountability mechanism carries only a very attenuated possibility of sanction, it may do much to support the perception that the bureaucracy is subject to public

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[92] I Pierce (n.4), 443–44.
[93] www.regulations.gov.
[94] Seidenfeld, 'A Civic Republican Justification for the Bureaucratic State' (1992) 105 HLR 1511, 1560.
[95] *National Wildlife Federation v. EPA*, 286 F.3d 554, 562 (D.C.Cir.2002).
[96] Pedersen, 'Formal Records and Informal Rulemaking' (1975) 85 YLJ 38, 78–82.
[97] These noninstrumental values may contribute to the constitutional acceptability of administrative regulation. Metzger (n.70), 489–90.

control.[98] For individuals who have a direct stake in the results of the action, it has a dignitary value by providing an opportunity for them to make their case before the agency.[99] Finally, it deepens the legitimising power of the giving reasons requirement by assuring that the agency responds to the issues that are of public concern, rather than merely providing generic justifications.

After the public comment period closes, the agency will prepare its response. The agency is free to withdraw or modify its proposed action or to proceed with it in its original form. If the modifications to the proposal are substantial, the agency may be required to submit the modified proposal to a new round of comment.[100] Once a decision is made, the agency publishes its action along with a detailed statement of reasons. Judicial review is then available to any individual with standing. Despite the significant number of cases, review is only sought in a small fraction of administrative actions.[101]

B. EU Administrative Bodies and Process

1. The European Commission

The most important EU Institution in administrative matters is the Commission, a body with no close equivalents outside the EU. The Commission itself is composed of a president and up to twenty-seven additional Commissioners. Each Member State nominates one Commissioner, although the Treaties require Commission members to act solely in the interest of the Union and prohibit them from taking instruction from their home state governments.[102] Apart from certain

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[98] West, 'Formal Procedures, Informal Processes, Accountability, and Responsiveness in Bureaucratic Policy Making: An Institutional Policy Analysis' (2004) 64 Pub.Admin.Rev. 66, 72–73.
[99] Verkuil, 'The Emerging Concept of Administrative Procedure' (1978) 78 Colum.L.Rev. 258, 293.
[100] *American Coke and Coal Chemicals Institute v. EPA*, 452 F.3d 930, 938–41 (D.C.Cir.2006).
[101] Coglianese, 'Empirical Analysis and Administrative Law' [2002] U.Ill.L.Rev. 1111, 1129.
[102] Article 17(3) TEU.

ministerial matters, Commission decisions are taken collectively and decisionmaking authority may not be delegated to a single Commissioner.[103] The Commission prefers to act by consensus, but when a vote is taken measures are carried by an absolute majority.[104]

The terms of the Commission and the Parliament coincide, and the Commission is "responsible to the European Parliament".[105] To reinforce the Commission's political accountability, the Treaty of Lisbon made adjustments to procedures for nominating and electing the Commissioners.[106] Under Lisbon, the European Council nominates the Commission President, who must then be elected by an absolute majority of Parliament. In making its selection, the European Council must "tak[e] into account the elections to the European Parliament".[107] As the Lisbon reforms were implemented in the 2014 election of Jean-Claude Junker, each parliamentary political group nominated a "Spitzenkandidat" before the election, and urged the European Council to nominate the Spitzenkandidat of the grouping that won the most seats. Although the European Council denied that it was under any obligation to do so, it ultimately followed that course.[108] Once the president has been elected by the Parliament, he or she works with the Council to select the remaining members of the Commission. The full slate of Commissioners is then subject to a vote of consent in Parliament.[109]

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[103] Case C-137/92 P, *Commission v. BASF* [1994] ECR I-2629, paras. 62–63.
[104] Chalmers, Davies, and Monti (n.30), 64; Commission Rules of Procedure [2000] OJ L308/27, art. 8.
[105] Article 17(8) TEU.
[106] The responsibility of the Commission to the Parliament is also reinforced by the new provisions in Article 290 on delegated acts, discussed below. Schütze, '"Delegated" Legislation in the (New) European Union: A Constitutional Analysis' (2011) 74 MLR 661, 685.
[107] Article 17(7) TEU.
[108] 'EU Leaders Decline to Endorse Juncker', *EU Observer*, May 28, 2014; 'The Battle for the European Commission: Has Merkel Lost Her Touch?', *Economist*, June 3, 2014; 'Jean Claude Juncker Nominated for European Commission President', *Financial Times*, June 27, 2014.
[109] Article 17(7) TEU.

Each Commissioner is responsible for a substantive portfolio. These portfolios are not fixed, but are defined as part of the process of forming a new Commission and are subject to modification during a Commission's term.[110] In the current Commission, at least five Commissioners have portfolios directly involved in risk regulation: Agriculture and Rural Development; Climate Action and Energy; Environment, Maritime Affairs, and Fisheries; Health and Food Safety; and Internal Market, Industry, Entrepreneurship, and SMEs.[111] Beyond the Commissioners, the remainder of the Commission staff is the EU's central civil service. Organisationally, this service is divided into a number of Directorates-General (currently thirty-three),[112] each of which focuses on a specific subject matter or administrative function. The DGs with primary responsibility for administering EU risk regulation programmes are Agriculture and Rural Development, Enterprise and Industry, Environment, and Health and Consumers (SANCO). DG staffs are relatively small, with few having more than 1,000 total employees. DG Environment and DG SANCO, for example, have 500 and 855 staff members, respectively.[113] By contrast, US EPA employs around 16,000 people; its Office of Pesticide Programs alone has about 850 employees.[114] Multiple DGs may have responsibility for a single regulatory programme.

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[110] Commission Rules of Procedure (n.104), art. 3.

[111] European Commission, Press Release, 'The Juncker Commission: A Strong and Experienced Team Standing for Change', IP 14/984, September 10, 2014. Note that all of these Commissioners have substantial responsibilities other than risk regulation.

[112] In addition to the DGs, the Commission houses eleven "services" that provide support across subject areas. Most of the services are administrative in character (e.g., the Publication Office), but others may have policy relevance, such as the Commission Legal Service and the Bureau of European Policy Advisers.

[113] European Commission, 2014 Human Resources Key Figures Card, available at http://ec.europa.eu/civil_service/docs/hr_key_figures_en.pdf. The Commission has a total staff of just over 33,000. Ibid. By way of comparison, the six key US risk regulation agencies collectively employ over 35,000 people.

[114] *See* EPA Budget and Spending, http://www2.epa.gov/planandbudget/budget.

For example REACH, the EU's main regulatory programme for chemicals, is jointly administered by DG Enterprise and DG Environment. Each DG has its own institutional character and priorities, which will reflect the way it approaches regulatory problems.[115] The importance of DG assignment is demonstrated by the public struggle between DG Enterprise and DG Environment over which would take the lead on the REACH regulation.[116]

The Commission's standard setting powers are derived principally from Articles 290 and 291 TFEU. Under Article 290, the EU legislature may "delegate to the Commission the power to adopt non-legislative acts of general application to supplement or amend certain non-essential elements of the legislative act." Article 291 provides that "[w]here uniform conditions for implementing legally binding Union acts are needed, those acts shall confer implementing powers on the Commission." These are the provisions that allow the Commission to issue risk regulation standards administratively. The differences between the two articles and their procedural consequences are explored in section 4 below.

2. Other EU administrative bodies

Although it may be seen as generally responsible for the implementation of EU law at EU level, the Commission is only one of a number of bodies that participate in EU administration. Largely because of the Commission's limited human and cognitive resources—but also because of the Member States' desire to limit the Commission's power—much of the work of administration, particularly the information gathering and analytical aspects, is done by bodies other than the Commission.[117] In

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[115] Nugent, *The European Commission* (Palgrave 2001), 159–61.
[116] Fisher, 'The "Perfect Storm" of REACH: Charting Regulatory Controversy in the Age of Information, Sustainable Development, and Globalization' (2008) 11 JRR 541, 551.
[117] Dehousse, 'Misfits: EU Law and the Transformation of European Governance' in Joerges and Dehousse (eds.), *Good Governance in Europe's Integrated Market* (OUP 2002) 216–20.

particular, the Commission often lacks necessary scientific expertise.[118] As a result, the Commission must supplement its own expert resources when setting risk standards. As the Commission's powers in this field have expanded, the supporting institutional structure has become more complex. This section briefly summarises this development and then examines in detail the structure of European agencies, which have emerged as the Commission's main partner in developing risk standards.

Early Approaches: Member States and Committees. Historically, the Commission turned to the Member States to supply the necessary expertise. One early approach was to assign complex scientific analyses to a particular Member State, whose national regulatory bodies would complete the analysis and return the results to the Commission for further action.[119] Though efficient, that approach has limitations. Not all Member States are equally capable of undertaking the necessary analysis, and other Member States might take issue with the assigned Member State's analysis. The need for some form of Union-level scientific review led to the establishment of the first EU expert committees, which could provide advice to the Commission that was not the product of a single Member State.[120] These committees were composed of scientists from throughout the Union with expertise on specific topics of regulatory concern. Some committees were set up on an ad hoc basis, but standing committees were established to support the most important programmes. These standing committees garnered a fair amount of prestige, and their opinions tended to carry great weight with the Commission.[121]

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[118] The Commission does possess some high-level research capacities in its Joint Research Centre, whose mission is "is to provide EU policies with independent, evidence-based scientific and technical support throughout the whole policy cycle". https://ec.europa.eu/jrc/en/about. Though its work is well-regarded, the JRC does not have the resources to supply all the Commission's needs for scientific advice.

[119] Krapohl, *Risk Regulation in the Single Market* (Palgrave Macmillan 2008) 70–74

[120] Ibid., 75–76; Vos, *Institutional Frameworks of Community Health and Safety Legislation* (Hart 1999) 140–43.

[121] Vos (n.120), 140.

In many ways the expert committee system worked well. It provided a relatively efficient and low cost way for the Commission to obtain expert input and also provided a forum in which unsettled or contentious scientific issues could be debated.[122] The system also had significant drawbacks, however. Perhaps most important, the committee members typically served on a part-time basis, and most maintained full-time employment elsewhere, usually with national regulatory bodies or academic institutions. As a result, committee members did not always have the time necessary to meet the Commission's need for information in a timely way.[123] Additionally, although the Commission provided the committees with a basic secretariat, their resources for conducting investigations were extremely limited.[124] Instead, committees typically reviewed the work of a rapporteur Member State and relied on the rapporteur to conduct any follow-up investigation.[125] Finally, the lack of an institutional home made it difficult for outsiders to follow the committees' work, and the committees were frequently criticised for not being sufficiently transparent.[126]

Although reliance on expert committees was already falling out of favour in some areas,[127] it was the BSE crisis that caused the EU to reassess the provision of expert advice, including a massive review and

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[122] Vos and Wendler, 'Food Safety Regulation at the EU Level' in Vos and Wendler (eds.), *Food Safety Regulation in Europe* (Intersentia 2006) 67–69.
[123] Vos, 'EU Food Safety Regulation in the Aftermath of the BSE Crisis' (2000) 23 J.Consumer.Pol'y 227, 244.
[124] A point implied by the Commission in its 'White Paper on Food Safety', COM(1999) 719 final, 19.
[125] Larsson and Murk, 'The Commission's Relations with Expert Advisory Groups' in Christiansen and Larsson (eds.), *The Role of Committees in the Policy-Process of the European Union* (Edward Elgar 2007) 74–75.
[126] Vos and Wendler (n.122), 69; European Parliament, 'Report on Alleged Contraventions or Maladministration in the Implementation of Community Law in Relation to BSE &c.', A4-0020/97/A (1997) (Medina-Ortega Report).
[127] Krapohl (n.119), 76.

overhaul of the EU's risk regulation policies and procedures.[128] A key finding of the Parliament's investigation into the crisis was that the committee system had failed. The expert committees had been unable to identify potential risks, had been slow to respond to new information, and had succumbed to political pressure.[129] In response, the Commission vowed to introduce substantial institutional changes.[130] The result was a shift to the use of European agencies as the main suppliers of scientific and technical expertise to the Commission in the area of risk regulation.

B. Agencies. European Agencies are another example of institutional innovation adapted to the unique nature of the EU. Despite their name, European agencies differ in many ways from agencies found in national governments, and the contrast with US agencies is particularly stark.[131] Perhaps the most important difference is that the EU legislature has until recently declined to delegate substantial decisionmaking powers to agencies.[132] Historically, this reticence was a consequence of the Court of Justice's hoary decision in *Meroni*,[133] which the Commission Legal Service interpreted as absolutely barring the delegation of discretionary decisionmaking powers to entities other than the Commission, despite calls from academics for a less restrictive reading.[134] The Court of Justice relaxed *Meroni* somewhat in *United Kingdom v. Parliament and Council*, in

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[128] Vincent, '"Mad Cows" and Eurocrats—Community Responses to the BSE Crisis' (2004) 10 ELJ 499, 510–16; Vos (n.123), 233–36.
[129] Medina-Ortega Report (n.126).
[130] COM(1999) 719 (n.124).
[131] Shapiro, 'The Problems of Independent Agencies in the United States and the European Union' (1997) 4 JEPP 276, 280–82.
[132] Chiti, 'An Important Part of the EU's Institutional Machinery: Features, Problems and Perspective of European Agencies' (2009) 46 C.M.L.Rev. 1395, 1404–06.
[133] Case 9/56, *Meroni & Co., Industrie Metallurgiche SpA v. High Authority* [1958] ECR 133.
[134] E.g., Chamon, 'EU Agencies: Between *Meroni* and *Romano* or the Devil and the Deep Blue Sea' (2011) 48 C.M.L.Rev. 1055, 1058–60; Griller and Orator, 'Everything Under Control? The "Way Forward" for European Agencies in the Footsteps of the *Meroni* Doctrine' (2010) 35 ELR 3, 27–29; Hofmann and Morini, 'Constitutional Aspects of the Pluralisation of the EU Executive Through "Agencification"' (2012) 37 ELR 419, 434.

which it upheld conferral on the European Securities Markets Authority (ESMA) of the power to prohibit short-selling temporarily if it found certain conditions to exist.[135] The court reasoned that the powers conferred on ESMA were "precisely delineated and amenable to judicial review" and did not, therefore, run afoul of *Meroni*.[136] The court's emphasis on the narrow range of discretion permitted by the delegating legislation, however, suggests that delegated powers calling for a large degree of policy judgment must still be conferred on the Commission.

Apart from legal obstacles, there are practical impediments to according agencies significant decisionmaking powers. The Commission would likely view any such delegation as a threat to its claimed role as the European executive.[137] Similarly, there are political risks for the Parliament and Council because their ability to influence decisionmaking in the agencies is not well tested.[138] There are also legitimacy concerns, in that decisionmaking by agencies would be even further removed from direct democratic legitimation than decisionmaking by the Commission. For now at least, the agencies active in the field of risk regulation have largely been denied substantial decisionmaking powers.

The second way in which European agencies differ from their American counterparts is in their leadership. In the US, agencies are led by presidential appointees, which presumably makes them responsive to presidential policy preferences.[139] By contrast, the leadership of European agencies is not beholden to a single political institution. All of the European risk management agencies are governed by a Management Board, most members of which are appointed by the Member States.[140]

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[135] Case C-270/12, *United Kingdom v. Parliament and Council* (*Short-Selling*), nyr, paras. 41–55.
[136] Ibid., para. 53.
[137] For example, the Commission took this position strongly in 'European Governance: A White Paper', COM(2001) 428 final, 24.
[138] Chiti (n.132), 1418–19; Everson, 'Independent Agencies: Hierarchy Beaters?' (1995) 1 ELJ 180, 199–201.
[139] Krent, *Presidential Powers* (NYU 2005) 24–36.
[140] Chiti (n.132), 1396–97.

The Management Board appoints the agency's Executive Director.[141] Together, the Management Board and Executive Director are responsible for setting the agencies' work programmes, overseeing fiscal and budgetary matters, supervising the agency's staff, and establishing the agency's procedural rules.[142]

The Management Board and Executive Director are not responsible for the agencies' substantive work, such as providing scientific advice to the Commission on regulatory matters. Instead, that work is performed by expert committees housed within the agencies and supported by the agency's permanent staff.[143] These expert committees are ultimately responsible for the quality of the agency's scientific and technical advice. A further important distinction between US and EU agencies is that the members of an EU agency's expert committees are not career agency staff. Rather, in a holdover from earlier practice, the members of an agency's expert committees are usually independent scientific experts selected from among the Member States.[144]

The choice to rely on committees composed of independent experts, rather than career staff, may affect the way in which scientific advice is provided to decisionmakers. Because the membership of expert committees is temporary and rotating, members may not develop the same sense of identification with the agency's regulatory mission that is said to characterise experts in US agencies.[145] Additionally, committee members may not develop the same level of expertise in regulatory programmes and policies possessed by US agency scientists who often spend a significant part of their career with the agency. These distinctions could be either advantages or disadvantages. On one hand, the transient membership of EU expert committees may provide fresh insight and help prevent the agency's advice giving from falling into

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[141] Ibid.
[142] Craig, *EU Administrative Law* (2d ed., OUP 2012) 162–64.
[143] Vos (n.120), 217–18; Chiti (n.132), 1397.
[144] Vos (n.120), 217–18.
[145] Ackerman and Hassler, *Clean Coal/Dirty Air* (Yale 1981) 79–81; Jasanoff (n.82), 3–4; Mashaw and Harfst, *The Struggle for Auto Safety* (Harvard 1990) 84–106.

cognitive ruts.[146] On the other, the lack of long-term agency affiliation may cause expert committees to be less adept at aligning their advice with the agency's policies and priorities. The changing composition of committees may also affect EU agencies' ability to attract permanent staff. If the advice used for regulatory decisionmaking is provided by committees rather than staff, a career with the agency may be less attractive to bright and ambitious experts who could never rise above providing support to committee members. Finally, reposing authority for providing scientific advice in a committee, the members of which have responsibilities to other institutions, may make collaboration among experts and other participants in the regulatory process more difficult.

3. Formulating administrative standards

As in the US, the procedures used by the EU administration to adopt risk regulation standards are too varied to allow for description of a generic process. But also as in the US, EU administrative procedures to have certain key characteristics that are common to the majority of regulatory programmes.

As an organisational matter, responsibility for initial development of new regulatory actions will usually fall to a bureau within one of the DGs. Under the Commission's new Better Regulation initiative, Commission staff must seek political clearance for new initiatives early in the development process.[147] The Commission is also likely to consult early with stakeholders and Member States. Once an initial proposal is developed, the Commission will almost always have to seek expert advice.[148] Most often, this process will involve referring the proposal to an

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[146] Blais and Wagner, 'Emerging Science, Adaptive Regulation, and the Problem of Rulemaking Ruts' (2008) 86 Tex.L.Rev. 1701.
[147] European Commission, 'Better Regulation Guidelines', SWD(2015) 111 final, 11–15.
[148] Risk legislation often explicitly requires the Commission to consult experts. E.g., Regulation (EC) 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) &c. [2006] OJ L396/1, art. 70. But even in the absence of legislative requirements, expert consultation may be required by the Court of

agency for an opinion. After considering the expert opinion and any minority views, the Commission will move toward a final decision. Depending on the outcome of the expert consultation, the Commission may undertake additional consultations. Once it is ready to proceed, the Commission will prepare a proposed action.

Notably absent from the EU administrative process is a horizontal requirement to submit proposed actions to open public consultation.[149] The issue of public participation in administrative processes has been a contentious one in the EU.[150] In its 2001 Communication 'European Governance: A White Paper', the Commission committed to expanding public participation as a means of enhancing the legitimacy of EU action, but resisted calls to establish a universal right to participation.[151] Many risk regulation programmes require some form of public participation, but the nature of the requirements vary. At times, participation occurs through consultation with advisory committees composed of stakeholders in the relevant area.[152] Other programmes require more open comment processes, but often limit comment to specific aspects of the proposed action.[153] If the Commission is required to prepare an impact assessment for the action, the impact assessment process will normally include a twelve week, internet-based consultation on the impact assessment.[154] As far as my research shows, no EU risk programme requires all aspects of a regulatory action to be submitted to an open public comment process.

Justice's case law. See Case C-212/91, *Angelopharm GmbH v. Freie Hansestadt Hamburg* [1994] ECR I-171, paras. 30–34.

[149] Case C-104/97 P, *Atlanta AG v. Commission* [1999] ECR I-6983, paras. 71–73.

[150] Bignami, 'The Democratic Deficit in European Community Rulemaking: A Call for Notice and Comment in Comitology' (1999) 40 Harv.Intl.L.J. 451, 469–72.

[151] COM(2001) 428 final, 14–18.

[152] Vos (n.120), 148–52.

[153] For example, REACH requires open comment on the draft report of the Socio-economic Analysis committee, but not the Risk Assessment Committee. REACH (n.148), arts. 70–71.

[154] SWD(2015) 2011 final, 17–18.

4. Comitology and the control of delegated acts

Once the Commission has finalised its proposed action, it is not immediately empowered to adopt that action. Instead, the Commission's exercise of its discretion is subject to a complex system of control mechanisms, either those described in Article 290 TFEU, as elaborated in the Common Understanding on Delegated Acts,[155] or to the "comitology" procedures set forth in the so-called Comitology Regulation.[156] These procedures add yet another layer to the networked aspect of EU administration.

The story of these control mechanisms is long and complex, but may be briefly recounted as follows:[157] Early in the history of the EEC, it became apparent that it would be necessary to delegate to the Commission the power to adopt implementing measures. This need was particularly acute in the field of agriculture, in which orders had to be issued rapidly to adjust to changing market circumstances. The Member States, however, were unwilling to grant such power to the Commission without some mechanism for controlling its exercise. Thus was born the comitology process, by which the Commission would be required to submit draft implementing measures to a committee of Member State representatives before the measures could take effect. A number of procedures developed for this process ranging from an advisory procedure, in which the Commission merely had to take "utmost account" of the committee's opinion, to a regulatory procedure, in which the lack of a positive opinion from the committee required the submission of the measures to the Council for further review. From the beginning, the Commission resisted comitology on the ground that it intruded into the Commission's "executive" prerogatives. The Parliament also resented comitology because it was generally excluded from the process, a concern

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[155] Council Document 8753/11 (April 10, 2011).
[156] Regulation 182/2011 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.
[157] This history is recounted more fully in, Bergström, *Comitology: Delegation of Powers in the European Union and the Committee System* (OUP 2005) 111–19.

that became more acute as its powers increased.[158] As a result, the entire comitology process simmered as a political and legal issue for decades.

The Lisbon Treaty brought about a new political and constitutional settlement on comitology. Henceforth, implementing measures would be divided into two categories: delegated acts and implementing acts. Delegated acts are "non-legislative acts of general application to supplement or amend certain non-essential elements of the legislative act". "Implementing acts" are not defined in the Treaties, but presumably are all those implementing measures that are not "delegated acts", i.e., those that do not "amend or supplement" the basic act. The dividing line between the two is far from clear.[159] The Commission set out its understanding of the divide at length in a 2009 Communication, in which it conveyed the sense that delegated acts should be reserved for significant issues of policy, whereas implementing acts would cover more run-of-the-mill situations in which established policies are applied to specific facts.[160] Recently, the Commission has proposed legislation that would classify existing delegations as either delegated or implementing acts according to these principles.[161]

The Commission's working assumption appears to be that all future legislation will specify the nature of any delegation in the basic act. Thus, although the decision whether to characterise a delegation as the power to adopt delegated or implementing acts will be guided by the Treaty provisions, the choice in borderline cases will be made politically in the legislative process. In a recent case, the Court of Justice has confirmed that although the choice between delegated and implementing acts is

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[158] Bradley, 'The European Parliament and Comitology: On a Road to Nowhere?' (1997) 3 ELJ 230, 231–41.

[159] Craig, 'Delegated Acts, Implementing Acts, and the New Comitology Regulation' (2011) 36 ELR 671, 672.

[160] European Commission, 'Communication on Implementation of Article 290 of the Treaty on the Functioning of the European Union', COM(2009) 673 final.

[161] Comitology Regulation (n.156), art. 13; European Commission, Proposal for a Regulation Adapting to Article 290 of the Treaty on the Functioning of the European Union a Number of Legal Acts Providing for the Use of the Regulatory Procedure with Scrutiny, COM(2013) 451 final.

subject to judicial review, "the EU legislature has discretion when it decides to confer a delegated power . . . or an implementing power" and that accordingly "judicial review is limited to manifest errors of assessment".[162]

The categorisation of an act as delegated or implementing has important procedural consequences. Article 290 abolished the comitology process for delegated acts. Instead, the Commission adopts delegated acts on its own, subject to a possible veto by either the Council or the Parliament. Additionally, legislation may give either the Council or the Parliament the power to revoke a delegation. Article 290 imposes no requirements on the Commission to consult with expert or Member State committees before adopting delegated acts. Under pressure from the Council, however, the Commission agreed in the Common Understanding to consult the Member States before adopting delegated acts.[163] The details of this consultation are not spelled out in the Common Understanding (presumably, they will vary based on the legislative context), and thus far the process remains opaque.[164]

Note, however, that the Common Understanding is not the only source of requirements that the Commission engage in some form of consultation. Much existing legislation that the Commission has proposed to transfer to the Article 290 procedure requires various forms of consultation as part of the process of developing a delegated act. For example, the Commission has proposed that the adoption of Restrictions under REACH be treated henceforth as delegated acts.[165] REACH requires the Commission to consider the opinions of the ECHA's Risk Assessment and Socio-economic Committees before adopting

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[162] Case C-427/12, *Commission v. Parliament and Council*, nyr, para. 40; Brandsma and Blom-Hansen, 'Controlling Delegated Powers in the Post-Lisbon European Union' [2015] JEPP 1, 9–10.
[163] Common Understanding (n.155), para. 4; see also the discussion of the consultation requirement in Craig (n.142), 126–30.
[164] Peers and Costa, 'Accountability for Delegated and Implementing Acts After the Treaty of Lisbon' (2012) 3 ELJ 427, 453–55.
[165] COM(2013) 451 final, annex, para. 39.

Restrictions.[166] Such requirements appear to remain untouched. More difficult to assess is whether the EU courts will extend the requirements for expert consultation found in the case law to measures adopted under Article 290. Inasmuch as the courts have found these requirements to flow form "the nature of things", i.e., the subject matter of the act, it seems they likely will, but that has not yet been confirmed.[167]

If a measure is designated an implementing act, the comitology process continues to apply, although the procedures have been simplified. Under the new Comitology Regulation, there are two procedures: an advisory procedure and an examination procedure. As before, the advisory procedure only requires the Commission to take "utmost account" of the Committee's opinion.[168] The examination procedure imposes greater constraints. If the committee delivers a positive opinion by a qualified majority, the Commission must adopt the proposed measure. If the committee delivers a negative opinion, the Commission may not adopt the proposed measure. If the committee fails to reach an opinion, then the Commission may (but need not) adopt the proposed measure, except that the Commission may not adopt the measure when (among other circumstances) the measure "concerns . . . the protection of the health or safety of humans, animals or plants."[169] Thus, in the risk regulation context, the Commission will normally only be able to adopt the proposed measure when the Committee delivers a positive opinion. Discussion in committees is not limited to approving or rejecting the Commission's proposal, and the Comitology Regulation contemplates that negotiations on the content of the draft act will take place. "[A]ny committee member may suggest amendments" and the Commission may modify its proposal at any time before the final committee vote.[170]

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[166] REACH (n.148), arts. 70–73.
[167] *Angelopharm* (n.148), paras. 30–34.
[168] Comitology Regulation (n.156), art. 4.
[169] Ibid., art. 5. Expedited procedures are available in cases of urgency. Ibid., arts. 7–8.
[170] Ibid., art. 3(4).

In the event that the comitology committee delivers a negative opinion or no opinion in circumstances that preclude the Commission from adopting the proposed measure, the Comitology Regulation provides that the Commission may either submit amended measures to the comitology committee or submit the original measure to an appeal committee,[171] which is comprised of representatives of the Member States at a higher political level.[172] Voting in the appeal committee is also by qualified majority. If the appeal committee delivers a positive opinion, the Commission must adopt the measure; if it delivers a negative opinion, it may not adopt the measure; and if it delivers no opinion, the Commission may adopt the measure.[173] Note that the exception for acts concerning the protection of health or safety does not apply when the appeal committee fails to deliver an opinion.

5. The "networked" EU administration

The notion that the EU employs a networked administration has been introduced in the foregoing description, but the concept merits some additional exploration. The term "network administration" is used to mean an organisational structure in which multiple, at least partially independent actors must coordinate with one another in the delivery of regulation. Coen and Thatcher suggest three key characteristics of network administration: the involvement of actors from different institutional levels (i.e., "multi-level governance"), a move away "from previously well-established levels to organisations or individuals whose main role is linking and co-ordinating actors", and a shift toward consultation and negotiation as the basis of decisionmaking.[174] Network administration is in many ways a logical response to the special problems

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[171] Ibid., art. 5(3)–(4).
[172] Rules of Procedure of the Appeal Committee [2011] OJ C183/13, art. 1(5); Brandsma and Blom-Hansen, 'The Post-Lisbon Battle Over Comitology: Another Round of the Politics of Structural Choice' (2011) EUI Working Paper SPS 2011/03, 23.
[173] Comitology Regulation (n.156), art. 6.
[174] Coen and Thatcher, 'Network Governance and Multi-Level Delegation: European Networks of Regulatory Agencies' (2008) 28 JPP 49, 50.

of EU administration. It allows the Commission to access expert and manpower resources that it lacks itself. It creates avenues for intergovernmental oversight and negotiation in a legal system that depends crucially on not only the acceptance of Member States but also their willingness to participate in implementation. It may also create opportunities for horizontal accountability as various actors in the network check one another.[175] Finally, it may reinforce the EU's notably weak democratic credentials through the participation of Member States with stronger claims to democratic legitimacy.[176]

The networked nature of EU administration affects the process of administrative decisionmaking, rendering it less hierarchical and potentially more "deliberative". This potential for deliberative decisionmaking has been identified by some theorists as a particular virtue of EU administration. Analysing the comitology process, Christian Joerges and Jürgen Neyer have characterised EU administrative decisionmaking as a form of "deliberative supranationalism".[177] In their view, the interactions among the Member States and the Commission in the comitology process deepen the quality and legitimacy of decisionmaking because the participants put aside their roles as representatives of preformed interests and engage in a deliberative process in search of a common, European interest. This process is to be contrasted with self-interested intergovernmental bargaining in which the outcomes are a function of power relationships among the participants. Deliberative processes can also overcome the problem of incorporating scientific knowledge into decisionmaking processes by creating a forum

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[175] Harlow and Rawlings, *Process and Procedure in EU Administration* (Hart 2014) 27–34; Scott, 'Accountability in the Regulatory State' (2000) 27 JLS 38, 50–54.

[176] Neyer, 'The Comitology Challenge to Analytical Integration Theory' in Joerges and Vos (eds.), *EU Committees: Social Regulation, Law and Politics* (Hart 1999) 228–32.

[177] Joerges and Neyer, 'From Intergovernmental Bargaining to Deliberative Political Processes: The Constitutionalisation of Comitology' (1997) 3 ELJ 273; Joerges, '"Good Governance" Through Comitology?' in Joerges and Vos (eds.) (n.176), 311; Neyer (n.176); Joerges, 'Deliberative Supranationalism: Two Defences' (2002) 8 ELJ 133.

in which expert advice is interrogated from a social perspective and, conversely, in which political positions can be assessed in light of evidence.[178] Joerges and Neyer support their theoretical analysis with considerable empirical work, which in their view indicates that decisionmaking in comitology committees is deliberative in practice. Despite that evidence, however, many remain sceptical that deliberative supranationalism is an accurate model of how comitology operates in practice and maintain that committee discussions more closely resemble bargaining, in which interests are traded off amongst the participants with little regard for the European good.[179]

Putting aside comitology, networked administration clearly has several advantage for the EU system in that creates opportunities for interaction between the Institutions and the Member States. It also has some significant disadvantages, however. To begin, there is the problem of coordination. The multiplicity of actors involved in EU administration almost necessarily increases inefficiencies. More subtle, but also more difficult to address, is the possibility that the various actors will not share common goals and will attempt to use their position within the network to pursue objectives that are at cross purposes. Perhaps the most fundamental objection to networked administration is that it hampers accountability. When administrative action is the product of many actors, no one actor owns the action, which is another way of saying there is no one actor who is responsible. This situation creates the possibility for displacement of blame as various parts of the network point fingers at one another for poor policy outcomes.[180] Conversely, it will be unclear whom to praise for positive outcomes, thus undermining

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[178] Joerges, 'Good Governance' (n.177), 329; Case C-77/09, *Gowan Comércio Internacional e Serviços Lda v. Ministero della Salute* [2010] ECR I-13533, paras. 31–44.

[179] Brandsma and Blom-Hansen (n.162), 17; Peters, 'Forms of Informal Governance: Searching for Efficiency and Democracy' in Christiansen and Larsson (eds.) (n.125), 52–60; see also Weiler, 'Epilogue: "Comitology" as Revolution—Infranationalism, Constitutionalism and Democracy' in Joerges and Vos (eds.) (n.176).

[180] The Parliament found this to be the case during the BSE crisis. Medina-Ortega Report (n.126).

incentives for good performance. Networked administration can also create problems for traditional forms of legal accountability, particularly judicial review, in that no forum may have jurisdiction to review the acts of the network as a whole.[181] Further, as Harlow and Rawlings show, the fact that networked administration may generate a measure of internal accountability does nothing to address the problem of public accountability, which is only exacerbated by the diffusion of decisionmaking across multiple actors.[182]

These are problems with which legal doctrine must deal if it is to maintain a cogent legitimacy narrative. To some extent, the Court of Justice has addressed these concerns (or ignored them) by holding the Commission responsible for the entirety of the administrative process.[183] Thus, the courts will annul administrative acts regardless of where in the administrative process the error occurred.[184] There are advantages to this solution. It prevents obvious gaps in the scope of legal protection and it allows for the application of legal concepts developed in the context of nation states to the EU. This latter is of particular importance as most EU administrative doctrine is judge-made, and the courts frequently justify their decisions by reference to the legal traditions of the Member States. There are also limits to this approach, however. For example, the court's jurisprudence has not yet developed analytical tools for dealing with the full complexity of the comitology process, such as the division of decisionmaking power between the Commission and the committee.

Much as the EU institutional architecture at a macro level is characterised by an interpenetration of the Member States and the EU legal order, the EU administration's internal organisation is characterised

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[181] Scott and Trubek, 'Mind the Gap: Law and New Approaches to Governance in the European Union' (2002) 8 ELJ 1, 8–9; Hofmann, 'Composite Decision Making Procedures in EU Administrative Law' in Hofmann and Türk (eds.), *Legal Challenges in EU Administrative Law* (Edward Elgar 2009) 151–63.

[182] Harlow and Rawlings, 'Promoting Accountability in Multilevel Governance: A Network Approach' (2007) 13 ELJ 542, 543.

[183] Scott and Trubek (n.181), 10–11.

[184] Case T-74/00, *Artegodan GmbH v. Commission* [2002] ECR II-4945, paras. 198–99.

by plurality. This plurality is the inevitable result of numerous institutional choices, which themselves may be seen as efforts to walk a line between supranational norm production and national sovereignty. The challenge for administrative law is to reconcile these innovative institutional forms with a legitimacy narrative based on traditional understandings of constitutionalism.

C. Two Different Visions of Administration

Whereas the broad institutional structures of the US and the EU revealed many similarities, the institutional and procedural arrangements of the two administrations themselves show almost nothing but difference. These differences are so substantial that it seems difficult to attribute them purely to historical accident or regional variation. Instead, the internal structures of the two administrations reveal very different visions of the administrative process.

These different visions are exemplified by a single fundamental institutional choice: the unitary nature of US administration versus the EU's networked structure. US administrative agencies are built for efficiency. Historically, one of the drivers for increased reliance on agencies in the US was the need to handle high volumes of decisionmaking for which Congress is ill-suited. US agencies are self-sufficient, in part, so that they may address issues quickly, as they come.[185] In keeping with the goal of efficiency, US agencies tend to be organised hierarchically, with clear lines of internal accountability (at least on the org chart). A second key purpose of agencies is to bring expertise to bear on regulatory problems. That, is they embody a normative choice about how regulatory problems should be addressed.[186] In Mashaw's phrase (drawn from Weber), they were created to "exercise

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[185] Of course, this goal is not always achieved, and the efficiency deficiencies of US agencies are notorious (if, perhaps, overblown). Edley, *Administrative Law: Rethinking Judicial Control of Bureaucracy* (Yale 1990) 48–52.

[186] Cf. Reich, 'The Law of the Planned Society' (1966) 75 YLJ 1227, 1242.

power on the basis of knowledge".[187] To fulfil this mission, US agencies are endowed with substantial expert resources and capacities for research. A necessary corollary of this administrative vision is that expert evaluation and political judgment cannot be separated; the administrator must be both expert and politically accountable. Finally, US administration has frequently been purposely directed at finding federal solutions to social problems at the expense of state regulation, not least in the area of risk regulation. Accordingly, US agencies act autonomously of the several states; even in programmes in which administration is shared, there is no question that the federal administration is in charge of the content of federal programmes.

Conversely, US agencies have not typically been thought of as fora in which political deliberation takes place. With the exception of a brief flirtation with "surrogate political processes" in the early 1970s;[188] administrative policy comes from Congress and from the president, either directly or via the agency head. That is not to say that agencies do not have substantial space to develop and elaborate regulatory policy; unquestionably they do. Indeed, they could not fulfil their Weberian role if they did not.[189] But the processes by which administrative policymaking are legitimated politically and democratically lie for the most part outside the agency. Public participation, despite its importance in the broader US legitimacy narrative, only indirectly supports democratic legitimacy.

The EU's networked approach reflects a different understanding of administration. Despite the Commission's aspiration to being *the* source of administrative policy, EU administrative arrangements have grown up to reflect the weak legitimacy of the Commission as a generator of norms and the desire of the Member States to retain a degree of control over the detailed implementation of EU law. Because of its networked nature, a primary task of the EU administration is to find, rather than impose, a

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[187] Mashaw, 'Small Things Like Reasons Are Put in a Jar: Reason and Legitimacy in the Administrative State' (2001) 70 Ford.L.Rev. 17, 23.
[188] Stewart, 'The Reformation of American Administrative Law' (1975) 88 HLR 1667, 1670; chapter 4, section II.C.
[189] Landis, *The Administrative Process* (Yale 1938) 52–60.

European policy. The Commission may be the most important protagonist in the process, but administrative risk standards only become valid through interaction between the Commission and the Member States. In this way, EU administration attempts to be self-legitimating in a way that US administration does not.

But EU administration is not simply a constitutive process of negotiation or supranational deliberation, it also has instrumental aspects. Like its US counterpart, it must solve regulatory problems posed by the legislature, and it too is expected to deliver those solutions in a timely and effective way. To accomplish this task, the EU administration must be able to access expertise. But even in this respect, the Commission is denied the necessary tools for independence. Expertise is not simply handed up the hierarchy, as in a US agency, but developed through a process that itself has aspects of deliberation. Taken together, the EU administration seems arranged to facilitate a process of achieving legitimacy by achieving assent. It is perhaps not surprising then that the weaknesses of EU administration are most evident when the political issues are most divisive and significant assent is withheld.[190]

There are of course many complications with this neat contrast. Although US agencies may be unitary organisations on paper, the size and complexity of some agencies belie the notion of a "single" agency. And, just as the Commission's discretion is constrained by the actions of other administrative bodies, a US agency's political leadership is constrained by the preparatory work of a large permanent bureaucracy.[191] Conversely, although the Commission usually enjoys no formal authority over European agencies, it has many tools for influencing the conduct of agency business.[192] The reality may therefore

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[190] For example, the persistent inability of the comitology committee to deliver an opinion on GMO authorisations or of the Council to assemble a qualified majority for or against. Lee, *EU Regulation of GMOs* (Edward Elgar 2009) 70–71; Vos, '50 Years of European Integration, 45 Years of Comitology' [2009] U.Maastricht.W.P. No. 3, at 26.

[191] Kagan (n.17), 2272–74.

[192] Busuioc, 'Accountability, Control and Independence: The Case of European Agencies' (2009) 15 ELJ 599, 610–13.

be that the differences between the "unified" US administration and the "networked" EU administration are narrower than they appear. The differences are substantial nonetheless and (what is more important for the present analysis) those differences have influenced the way the two legal systems understand the process of administrative decisionmaking, which in turn has influenced the ways in which those systems have responded to the legal problems raised by administrative risk regulation.

III. Delegation

One important institutional aspect of administrative risk standard setting shared by both the EU and the US administrations is that the administration derives its power to set standards from legislative delegations. The concept of delegation is essential to EU and US legitimacy narratives because it provides both a source of legal authority (the administration's power to set standard is underpinned by legislation) and a source of democratic legitimacy (the democratically accountable legislature has authorised the exercise of administrative power).[193] For the concept of delegation to fulfil these functions, the legislature must be able to specify the scope of the administration's authority and to set conditions on the manner of its exercise. It would also seem axiomatic that the legislature must be able to override the exercise of administrative authority through subsequent legislation. Delegation does not exclude the possibility of administrative policymaking or even broad administrative discretion; it does however relegate the administration to a subordinate policymaking role. These basic principles of delegation are common to both the EU and the US. Nonetheless, the details of delegation theory have developed somewhat differently in the two systems, largely as the result of their different institutional structures.

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[193] Lindseth, 'Delegation is Dead, Long Live Delegation: Managing the Democratic Disconnect in the European Market-Polity' in Joerges and Dehousse (eds.) (n.117), 151–53.

A. US

American delegation theory developed in response to constitutional challenges to the administrative state. In the early days of agencies, it was argued that because the Constitution vests "[a]ll legislative powers" in Congress, administrative agencies could not exercise rulemaking power. In a series of cases, the Supreme Court upheld the constitutionality of administrative rulemaking by making a distinction between "the legislative power" and the ability to make rules more generally.[194] Only Congress, the Court held, could exercise legislative power, but that did not prevent it from delegating the power to apply the principles announced in legislation in specific situations, including through the making of generally applicable rules.[195] Such delegations are valid, provided that Congress has provided an "intelligible principle" in to guide the agency's exercise of rulemaking power.[196] Confusingly, this principle has come to be known as the "nondelegation doctrine" to reflect the notion that core legislative power cannot be delegated.

The effect of the nondelegation doctrine on US law has been famously feeble. Only twice has the Supreme Court relied on the doctrine to invalidate administrative delegations. Both of those cases were decided in 1935 and concerned aspects of the National Industrial Recovery Act, a New Deal statute that attempted a transfer of authority to the president that has no parallel in other US legislation.[197] Other statutes delegating exceedingly broad authority to the administration, including statutes whose only apparent intelligible principle is that the agency act in the "public convenience, interest, or necessity",[198] have been upheld against nondelegation challenges.[199] Part of the weakness of the nondelegation

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[194] I Pierce (n.4), 86–88.
[195] *Field v. Clark,* 143 U.S. 649, 692 (1892).
[196] *J.W. Hampton, Jr. & Co. v. United States*, 294 U.S. 394, 409 (1928).
[197] I Pierce (n.4), 91–93. The cases are *A.L.A. Schechter Poultry Corp. v. United States*, 295 U.S. 495 (1935) and *Panama Refining Co. v. Ryan*, 293 U.S. 388 (1935).
[198] 47 U.S.C. § 303.
[199] Ibid.

doctrine is attributable to its tenuous conceptual distinctions.[200] Formulation of legal rules to define the necessary specificity with which Congress must legislate proved difficult for courts faced with a wide array of factual scenarios and increasing demands for government intervention brought about by industrialisation.[201] By the 1970s, the nondelegation doctrine was generally assumed dead.[202]

The wave of risk regulation legislation enacted in the 1970s launched a new round of nondelegation challenges, arguing that the authority apparently conferred by these statutes to determine the socially acceptable level of safety across broad sectors of the economy accorded too much discretion to the administration. Those challenges first reached the Supreme Court in the *Benzene* case, in which Justice Rehnquist argued in a concurrence that the Occupational Safety and Health Act was unconstitutional because it left to OSHA the determination of when a threat to worker health was sufficiently serious to require regulation.[203] Although his opinion was joined by no other justice, his arguments influenced the plurality, which justified its somewhat counterintuitive construction of the statute on nondelegation grounds.[204] *Benzene* encouraged further nondelegation challenges. In an important case, *International Union, UAW v. OSHA*,[205] the D.C. Circuit held that a different section of the OSH Act, as written, violated the nondelegation doctrine, but that the statute could be saved if the agency were to adopt criteria cabining its discretion.[206] On remand, the agency did as the court

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[200] Sunstein, 'Nondelegation Canons' (2000) 67 U.Chi.L.Rev. 315, 326–28.
[201] *Mistretta v. United States*, 488 U.S. 361, 415–16 (1989) (Scalia, J., dissenting); Scalia, 'A Note on the *Benzene* Case' (1980) 4 *Regulation* 25, 27.
[202] E.g., Ely, *Democracy and Distrust: A Theory of Judicial Review* (Harvard 1980) 132–33.
[203] *Industrial Union Dep't, AFL-CIO v. American Petroleum Inst.*, 448 U.S. 607, 688 (1980) (*Benzene)* (Rehnquist, J., concurring in the judgment).
[204] Ibid., 646 (plurality opinion).
[205] 938 F.2d 1310 (D.C.Cir.1991).
[206] Ibid., 1318. This approach had long had advocates in the scholarly literature. Davis, *Discretionary Justice* (Louisiana State University 1969) 216–21; Friendly, *The Federal Administrative Agencies* (Harvard 1962)

instructed, and a subsequent challenge was rejected.[207] The logic of *International Union* was used to more dramatic effect in *American Trucking Associations v. EPA* (*ATA)*[208] to declare the Clean Air Act's National Ambient Air Quality Standards programme unconstitutional, pending action by EPA to narrow its own discretion by rule.[209]

The logic of these cases is important because, as we will see, it was utterly repudiated by the Supreme Court. In both *International Union* and *ATA*, the DC Circuit held that to be valid, a legislative delegation must contain sufficient content to place identifiable boundaries on the range of permissible administrative outcomes and that the greater the scope of administrative power, the narrower the identifiable range had to be.[210] The court did not go so far as to suggest that the criteria had to point to a single, "right" outcome, nor did it exclude the possibility that the boundaries established might admit of arguable cases. What it essentially held was that the statute had to establish sufficient criteria so that the agency's decisionmaking process would be reproducible (in the court's words, it had to provide "determinate criteri[a]").[211] That is, two administrators applying the statutory criteria would arrive at the same range of potential outcomes, although they might differ regarding the best choice within that range. Failing the provision of such criteria in the authorising statue, it was incumbent upon the agency to establish its own binding criteria that would achieve the same effect. What doomed the statutes in *International Union* and *American Trucking* was that the criteria were so open-ended that two decisionmakers, both faithfully applying the statutory language, could arrive at two very different sets of possible outcomes. It was not enough for the agency to explain how it had arrived at the range of outcomes in a given case; it had to show why

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142–47. See also *Amalgamated Meat Cutters v. Connally*, 337 F. Supp. 737, 758–59 (D.D.C.1973) (Leventhal, J.) (three-judge court).
[207] *International Union, UAW v. OSHA*, 37 F.3d 665, 669 (D.C.Cir.1994).
[208] 175 F.3d 1027 (D.C.Cir.1999).
[209] Ibid., 1039–40.
[210] Ibid., 1036–37; *International Union* (n.205), 1318.
[211] *ATA* (n.208), 1034.

it was *required*, either by statute or its own established policy, to reach that result.[212]

The Supreme Court unanimously reversed in *Whitman v. American Trucking Associations*.[213] In doing so, the Court explicitly rejected the argument that an "intelligible principle" had to establish determinate criteria.[214] For the Court, there was nothing unintelligible in the statutory principle that NAAQS should be set at the level "requisite to protect public health with an adequate margin of safety",[215] and there was no constitutional bar to the delegation of that kind of policy judgment to the administration.[216] Nor did the lack of determinate criteria leave the agency's discretion unbounded. The agency's judgment still had to be a reasonable application of the "requisite to protect" standard, which the courts were competent to review in light of the agency's reasons and the factual record produced.[217]

In effect, the Court reaffirmed the constitutional legitimacy of administrative policymaking, even as to the essential aspects of a regulatory programme, a point that was central to its earlier decision in *Chevron*[218] (discussed in chapter 3). In so doing, it put to rest a purely instrumental understanding of US administration and affirmed a constitutive role for agencies in formulating regulatory policy. It also affirmed that the administration's power to make policy is subject to the superior authority of Congress, but left unresolved what, if any, additional limits the Constitution places on administrative policymaking.[219] The ruling is central for understanding contemporary US jurisprudence on administrative risk regulation because it undercuts arguments that agencies must set risk standards solely on the basis of

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[212] Ibid., 1035.
[213] 531 U.S. 457 (2001).
[214] Ibid., 475.
[215] 42 U.S.C. § 7409(b)(1).
[216] *Whitman* (n.213), 475–76.
[217] Ibid.
[218] *Chevron, U.S.A., Inc. v. NRDC*, 467 U.S. 837 (1984).
[219] As pointed out by Justice Thomas in his concurrence. *Whitman* (n.213), 487.

an objective (presumably scientific) analysis. To the contrary, it reaffirms the principle that agencies may also rely on their own understandings of good public policy in reaching their decisions.

One might be tempted to conclude that, following *Whitman*, the nondelegation doctrine really is dead, but that would premature. Although the doctrine has been rendered toothless in its classic form,[220] it persists in the courts' practice of interpreting statutory grants of authority narrowly when a broader interpretation would raise questions about the constitutional legitimacy of agency authority. This reinterpretation of the nondelegation doctrine has been advanced by Professor Sunstein, who identified a number of "nondelegation cannons" according to which agencies would be found to have authority to take certain types of action only if Congress had explicitly granted that authority.[221] Some of the canons identified by Sunstein include a presumption that agencies do not have the power to act extraterritorially or to promulgate regulations with retroactive effect.[222]

Sunstein's thesis can be broadened beyond specific canons of construction to explain decisions in which courts have construed statutes in nonobvious ways to narrow the scope of administrative discretion.[223] One prominent example is the *Benzene* decision. Another is *FDA v. Brown & Williamson Tobacco Corp.*,[224] in which the Court held that the Federal Food, Drug, and Cosmetic Act did not give FDA authority to regulate tobacco, even though nicotine fell within the literal terms of the statute's definition of "drug".[225] In these and other cases, the courts

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[220] Which is to say, it is not enforced by the courts. We should not, however, make the mistake of assuming something is constitutional simply because the courts will not declare it unconstitutional. Sager, 'Fair Measure: The Legal Status of Underenforced Constitutional Norms' (1978) 91 HLR 1212.
[221] Sunstein (n.200), 330.
[222] Ibid., 331–35.
[223] Rabin, 'Federal Regulation in Historical Perspective' (1986) 38 Stan.L.Rev. 1189, 1215 n.65 (making a similar point using historical examples).
[224] 529 U.S. 120 (2000).
[225] Ibid., 131–32, 161.

have expressed doubt that Congress could have intended the agency's result, even if the language of the statute would seem to permit it. In *Benzene*, it was the perception that OSHA's interpretation would allow, or even compel, the agency to impose potentially ruinous costs on any industry even over minor safety concerns.[226] In *Brown & Williamson*, it was the notion that Congress had somehow without saying so authorised an administrative agency to regulate a substance with a unique legal, historical, and cultural status.[227] These decisions depend not on any easily articulable rule of construction, but on the courts' subjective sense that the issue is just too important for administrative resolution.[228]

The continued relevance of nondelegation concerns, if not the nondelegation doctrine as such, to judicial decisionmaking is important for understanding US administrative law, particularly in the area of risk. There seems to be a limit, although it has not been well defined, on the extent to which administrative risk regulation can get ahead of the courts' understanding of Congress's policy goals. This unarticulated boundary is best explained in terms of the necessarily subordinate place of the administration in regulatory policymaking. Even as the courts have approved an expansive role for the administration in defining and elaborating risk regulation policy, they have not let go of the premise that all such policymaking must be sanctioned by legislation. The limits are thus grounded in delegation theory, but they also reflect a sensitivity regarding the exercise of executive power, which is itself related both to the ideal of separated powers and, perhaps, to a residual aversion to regulatory controls on private behaviour.[229] The subjective nature of this sensitivity is reflected in the fact that the Supreme Court often divides

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[226] *Benzene* (n.203), 646.

[227] *Brown & Williamson* (n.224), 159–61.

[228] A similar idea, for example, explains the majority opinion in *Gonzalez v. Oregon*, 546 U.S. 243, 267–68 (2006), in which the Court held that the Attorney General could not use his authority under the Controlled Substances Act to prohibit physician-assisted suicide. It also appears to animate part of Justice Scalia's dissent in *Massachusetts v. EPA*. *Massachusetts* (n.29), 558–59 (Scalia, J., dissenting).

[229] Sunstein, *After the Rights Revolution* (Harvard 1993) 36–37.

along ideological lines on such questions, even when so many of its administrative law decisions are unanimous. Note too that this sensitivity is fluid because it relates to the extent to which the action in question appears novel or seems to breach prevailing social understandings.[230] Thus, OSHA's assertion of authority to require that workplace exposure to any carcinogen be reduced to the extent feasible seemed to the Supreme Court in 1980 like an extravagant assertion of administrative authority to unsettle social and economic expectations. Yet the Court in 2001 found it obviously appropriate for an agency to determine when air pollutants threaten public health, even though that determination almost certainly has more profound social and economic effects. This dynamism is particularly relevant to risk regulation, which is fundamentally concerned with social responses to technology.

There is, of course, nothing wrong with the Supreme Court defining the permissible bounds of administrative authority, even if doing so at times requires an exercise of subjective judgment. Constitutional courts must sometimes make tough decisions about constitutional values. The problem with nondelegation as it continues to operate in the US case law is that it almost always does so *sub silentio*. It is detectable only in the Court's rhetoric, not in its reasoning. As a consequence, it can be difficult at times to rationalise the cases on the basis of the Court's stated reasons. Worse, it leaves unarticulated the reasons why the Court feels the limits of administrative authority were breached, making it difficult for the administration and Congress to respond.

B. EU

Turning to the EU, we can see that the Court of Justice's jurisprudence on delegation has developed from somewhat different premises, although the result is similar. Unlike the US situation, there has never been serious doubt in the EU as to the constitutionality of delegating power to adopt rules of general applicability to the administration. From the founding of the EEC, the Treaties have explicitly provided that the legislature may confer on the Commission (or in some cases the Council)

[230] Cf. Rabin (n.223), 1319–21.

the power to take implementing measures, and from an early time that provision has been understood to allow for the delegation of rulemaking powers.[231] Further, the Court of Justice has held that the power to delegate must generally be interpreted broadly to allow the EU to effectively fulfil the objectives of the Treaties.[232]

Nonetheless, the EU courts have, to a greater extent than the US courts, made an effort to put constitutional limits on the delegation of legislative authority to the administration. Even as the early case law established the legitimacy of broad delegations, it simultaneously affirmed that the "essential elements" of the legislative programme must be adopted by the legislature itself.[233] For the most part, the court has applied the concept of "essential elements" narrowly so as to allow the delegation of significant policymaking authority to the administration.[234] Recent case law, however, confirms that the Court of Justice is willing to draw difficult lines and rule some delegations out-of-bounds.[235] The court has not, however, provided clear guidance as to how distinguish essential from non-essential elements, instead applying something like a gestalt (or Rorschach) test to the legislation in question.[236] The court has indicated, however, that aspects of legislation that require "political choices" or may interfere with fundamental rights are more likely to constitute essential

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[231] Article 211 of the Treaty of Rome empowered the Commission to "exercise the powers conferred on it by the Council for the implementation of the rules laid down by the latter".
[232] Case 25/70, *Einfuhr- und Vorratsstelle für Getreide und Futtermittel v. Köster, Berodt & Co.* [1970] ECR 1161, para. 6; *Rey Soda* (n.41), paras. 9–11; Case C-240/90, *Germany v. Commission* [1992] ECR I-5383, paras. 36–39.
[233] *Rey Soda* (n.41), para. 9.
[234] Ibid., para. 10; *Germany v. Commission* (n.232), para. 37.
[235] Case C-355/10, *Parliament v. Council*, nyr, paras. 64–67; see also Case 22/88, *Industrie- en Handelsonderneming Vreugdenhil BV v. Minister van Landbouw en Visserij* [1989] ECR 2049, paras. 17–20.
[236] Chamon, 'How the Concept of Essential Elements of a Legislative Act Continues to Elude the Court: *Parliament* v. *Council*' (2013) 50 C.M.L.Rev. 849, 856.

elements.[237] Some cases have also suggested that delegation is appropriate when the relevant choices turn on technical analysis.[238]

The Court of Justice's delegation jurisprudence also differs from the US case law in that one of the court's principal concerns is that the legislature (or one branch thereof) not be able to use delegation to circumvent the institutional balance set up by the Treaties. That concern was especially salient in the past, when the EC Treaty set forth numerous different legislative procedures for different areas of EC competence. In particular, the Court of Justice was careful that delegation not be used to undercut the role of the Parliament in legislation (although it frequently took a narrower view of the Parliament's role than did Parliament itself).[239] Because of the centrality of this concern, the court's reasoning often focuses more on whether the prerogatives of all the relevant Institutions have been respected and less on the nature of the delegation itself.[240] Indeed, the Court of Justice has relied in part on the comitology system to uphold broad delegations of authority precisely because it ensured the ongoing involvement of the Council in delegated decisionmaking.[241]

Although the EU courts will uphold broad delegations of policymaking authority to the Commission, there is precedent to suggest that they, like

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[237] *Parliament v. Council* (n.235), paras. 76–78. Other cases, however, have allowed the delegation of questions touching on individual rights. E.g., *Germany v. Commission* (n.232), paras 32–33; Case 41/69, *ACF Chemiefarma NV v. Commission* [1970] ECR 661, paras. 64–66.
[238] *Short-Selling* (n.135), para. 52; Case C-66/04, *United Kingdom v. Parliament and Council* (*Smoke Flavourings*) [2005] ECR I-10553, para. 55.
[239] Case C-156/93, *Parliament v. Council* [1995] ECR I-2019, para. 18; Case C-133/06, *Parliament v. Council* [2008] ECR I-3189, paras. 45–50.
[240] Compare *Whitman*, in which the focus on the Supreme Court's analysis is solely on whether the Clean Air Act's provisions established an intelligible principle. *Whitman* (n.213), 912–13. Although it plays a lesser role, the question whether delegation may unsettle institutional prerogatives is sometimes raised in US materials. E.g., *Benzene* (n.203), 684 (Rehnquist, J., concurring); Ely (n.202), 131–34.
[241] E.g., *Köster* (n.232), para. 9; *Rey Soda* (n.41), para. 13; Bergström (n.157), 46–53.

the US courts, will at times construe legislation narrowly to avoid nondelegation concerns. In *Alliance for Natural Health*,[242] which concerned the authorisation of nutritional supplements, the court read the ambiguous language of Directive 2002/46[243] as requiring the Commission to evaluate substances for authorisation on the basis of whether they are safe for human health, and only on that basis.[244] The court expressed a concern that the grounds on which the administration could base its decision must be clearly defined for the delegation to be consistent with *Meroni*.[245] As a consequence, the permissible grounds for the administration's decision would have to be limited to the protection of health, as required by the Treaties, and not expanded to include other considerations unless the those considerations were clearly authorised by the delegating legislation.[246]

Advocate General Kokott applied similar reasoning in her opinion in *Smoke Flavourings*.[247] The directive at issue required the Commission to consider several factors when determining whether to authorise smoke flavouring products, but also permitted the Commission to consider "other legitimate factors" that might bear on the authorisation.[248] The Advocate General argued that the range of factors that could be considered "legitimate" had to be "delimited by reference to the general

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[242] Joined Cases C-154/04 and C-155/04, *R. ex p. Alliance for Natural Health v. Secretary of State for Health* [2005] ECR I-6451.
[243] Directive 2002/46/EC on the approximation of the laws of the Member States relating to food supplements [2002] OJ L183/51.
[244] *Alliance for Natural Health* (n.242), paras. 83–86.
[245] Ibid., paras. 90–92.
[246] Nondelegation concerns may also explain the General Court's otherwise surprising judgment in Case T-74/00, *Artegodan GmbH v. Commission* [2002] ECR II-4945, in which the court read the relevant legislation narrowly to limit the Commission's ability to revisit its earlier authorisation of a prescription weight loss aid. Ibid., para. 211. The court seemed concerned that the Commission not be given too much latitude to reconsider its risk assessment criteria and thereby limit the rights of traders. Ibid., paras. 194–95.
[247] Above n.238.
[248] Regulation 2065/2003 on smoke flavourings used or intended for use in or on foods [2003] L309/1, art. 9.

main aims of the present basic regulation, the aims of the legal basis in Article 95(1) EC, the criteria laid down and the regulatory context".[249] Specifically, any other legitimate factors had to bear on "the fundamental safety requirements for the use and marketing of smoke flavourings [or] the conditions of production".[250] A more open-ended interpretation, by contrast, would be an unlawful delegation regulatory power to the Commission. The court, however, did not rule on this aspect of the case.

Alliance for Natural Health and *Smoke Flavourings* are particularly relevant for risk regulation because they are examples of the courts narrowly construing the range of factors that the administration may consider when setting risk standards. In both cases, the courts appeared to limit the Commission to regulating on the basis of safety. As discussed in chapter 1, however, the range of public concerns with regard to new technologies extends well beyond safety. These cases suggest that the EU administration's authority to take non-safety concerns into account may be limited. They can also be understood as expressing a tendency toward interpreting delegations to the administration in technical terms.[251]

Potentially more important, *Alliance for Natural Health* also addressed the types of reasons given by the administration. The court read *Meroni* to require that "[delegated] power is clearly defined and that the exercise of that power is subject to strict review in light of objective criteria."[252] That holding could be read as limiting the grounds for administrative regulation to rationales that the court deems "objective" and requiring regulation for other reasons to be adopted by the Union legislature.[253] For

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[249] *Smoke Flavourings* (n.238), Opinion of A.G. Kokott, para. 64.
[250] Ibid., para. 65.
[251] *Alliance for Natural Health* (n.242), para. 78; *Smoke Flavourings* (n.238), Opinion of A.G. Kokott, paras. 59, 66; see also chapter 4, section I.
[252] *Alliance for Natural Health* (n.242), para. 90.
[253] This idea has been explored by some commentators. For example, Majone distinguishes between grounds of low politics, which are appropriate for independent agencies, and high politics, which are not. Majone, *Regulating Europe* (Routledge 1996) 294–96; see also Craig (n.142), 184. The point is touched on in Griller and Orator (n.134), 21–23, in which it is argued that greater discretion to make decisions on

example, it might be that the consumer concerns that the Court of Justice upheld as sufficient to justify regulation in *Fedesa*[254] could not be relied on by the Commission acting under delegated authority.

There is reason, however, to be cautious about reading too much into the *Alliance for Natural Health* judgment. Foremost, the court's reliance on *Meroni* is strange. That case, as we have seen, focused on the question of what powers may be delegated to bodies other than the EU Institutions, and the judgment's limits on delegation have not been applied to delegations to the Commission. Although the *Alliance for Natural Health* judgment cites *Köster*, it does not attempt to reconcile *Köster*'s approval of broad delegations with the application of *Meroni* to the Commission. It may be, therefore, that the court's discussion of delegation was ill-considered and will not be followed. Nonetheless, given the important role played by the administration in EU risk regulation, the meaning of *Alliance for Natural Health* is an important open question, particularly in light of the *Smoke Flavourings* opinion.

C. Comparative Summary

In summary, we have seen that delegation theory is largely similar in the two jurisdictions. In both the US and the EU, the courts have upheld delegation of extensive policymaking authority to the administration, while at the same time reaffirming the primacy of the legislature. The exercise of broad, but subordinate, policymaking authority by the administrations places them in an intermediate position. On one hand, their role is not purely instrumental. Cases like *American Trucking Associations* and *Köster*, show that both administrations enjoy a legitimate role in elaborating and specifying policy ends as well as means. On the other hand, however, both systems see legislative sanction as essential to the legitimacy of regulatory policy. As a consequence, administrative regulation must be both authorised by and consistent

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nontechnical grounds requires stronger mechanisms for democratic legitimacy. Cf. *Short-Selling* (n.135), Opinion of A.G. Jääskinen, paras. 99–100.

[254] Case C-331/88, *R. v. MAFF, ex p. Fedesa* [1990] ECR I-4023.

with legislative enactments. This intermediate legal status creates a need for courts to police the boundaries of administrative authority. That is no easy task, however, as the question of how much policy authority is too much is necessarily one of degree, hence a question of judicial judgment.

In determining the acceptable scope of administrative policy judgment, courts look to the overall institutional structure of the administration. For example, in upholding broad delegations to the Commission, the Court of Justice has relied in part on the comitology system to provide a degree of political monitoring. Similarly in the US, the increasingly direct involvement of the White House in the affairs of administrative agencies has occurred in tandem with the liberalisation of the Supreme Court's delegation jurisprudence. Institutional considerations are only one part of the calculus, however. As will be explored in the next two chapters, courts have developed numerous substantive doctrines that are directed in part toward defining—and to some extend defending—the proper place of the administration within the two jurisdictions' overall institutional orders. Indeed, I will argue that these substantive doctrines can only be adequately understood in light of the two systems' institutional arrangements.

3

Substantive Principles for Risk Regulation: The Precautionary Principle and Cost-Benefit Analysis

This chapter analyses the role of two substantive principles—the precautionary principle and cost-benefit analysis—in EU and US administrative law. These principles have played outsized roles in debates over risk regulation and particularly in describing European versus American regulatory styles.[1] Broadly understood, the precautionary principle and cost-benefit analysis are regulatory philosophies that provide normative frameworks for how regulators should act. Rather than analysing the relative merits of those philosophies or assessing the extent to which they accurately characterise EU or US risk regulation, the focus of this chapter is more narrowly on how those principles operate as legal concepts within EU and US administrative law. I will argue that the two legal systems conceptualise precaution and cost-benefit analysis in very different ways and that they use those concepts to solve different legal problems. At bottom, the EU and US approaches to the precautionary principle and cost-benefit analysis are grounded less in different commitments to particular regulatory philosophies, and more in different understandings of how the public interest is constituted and of the role of law in that process.[2] Those understandings, in turn, may be traced to

[1] E.g., De Sadeleer, 'The Precautionary Principle in EC Health and Environmental Law' (2006) 12 ELJ 139, 171; Vogel, 'The Politics of Risk Regulation in Europe and the United States' (2003) 3 YEEL 1, 34–41; Wagner, 'The Precautionary Principle and Chemical Regulation in the US' (2000) 6 Hum.Eco.Risk.Assessment 459, 460.

[2] Feintuck, *"The Public Interest" in Regulation* (OUP 2004) 52–57.

differing basic theories underpinning the legitimacy of administrative regulation.[3]

I. The Precautionary Principle

A. The Precautionary Principle and Theories of the Public Interest

The meaning of the precautionary principle is famously hard to pin down. Fisher elegantly defines the core of the principle as providing that "in cases where there are threats to human health or the environment the fact that there is scientific uncertainty over those threats should not be used as *the* reason for not taking action to prevent harm".[4] Thus stated, the core of the precautionary principle is negative. It provides that a particular reason (scientific uncertainty) is not sufficient to justify a particular outcome (no regulatory action). Beyond that essentially procedural proposition, however, there is enormous debate as to the principle's normative content. For many, the precautionary principle implies not just a capacity, but also an obligation to act when there is a credible, if uncertain, threat of harm to health or the environment.[5] But that normative commitment in turn gives rise to a host of additional definitional issues: When is a threat credible? What constitutes harm? How aggressively must regulators act?[6] Because there is no general agreement on these issues, definitions of the principle are sometimes arrayed along a spectrum from weak to strong versions.[7] At the weak end, the principle is limited to Fisher's definition, i.e., it merely

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[3] Cf. Fisher, *Risk Regulation and Administrative Constitutionalism* (Hart 2007) 24–26.

[4] Fisher, 'Is the Precautionary Principle Justiciable?' (2001) 13 JEL 315, 316.

[5] Kysar, 'It Might Have Been: Risk, Precaution, and Opportunity Costs' (2006) 22 JLUEL 1, 7; see also Stewart, 'Environmental Regulatory Decisionmaking Under Uncertainty' (2000) 20 Res.L.&Econ. 71, 79–80 (collecting sources).

[6] Applegate, 'The Taming of the Precautionary Principle' (2002) 27 Wm.&Mary.Envtl.L.&Pol'y.Rev. 13, 17–21.

[7] Stewart (n.5), 75–78.

authorises action. At the strong end are versions of the principle that would "reverse the burden of proof" and require regulatory controls on new technologies in the absence of convincing evidence of safety.[8]

While it is difficult to find serious critics of weak versions of the precautionary principle, stronger versions have been sharply criticised by commentators on both sides of the Atlantic. In particular, Giandomenico Majone and Cass Sunstein have levelled detailed criticisms of strong versions of precaution.[9] For both Professors Majone and Sunstein, the fundamental vice of strong precaution is that it ignores the fact that in many situations regulatory intervention will itself create risks.[10] In these circumstances, particularly when the risks on both sides are uncertain, the precautionary principle fails to provide guidance.[11] Both also point specifically to the opportunity costs associated with the strong version's propensity to slow the introduction of new technology.[12]

The criticisms advanced by Sunstein and Majone rest on the premise that the goal of regulation is to maximise social welfare, that all harms to social welfare should be treated equally, and that the totality of benefits and harms of a particular regulatory decision should be balanced against one another.[13] On that premise, their analyses of strong precaution are compelling (although one should acknowledge that the strong version of the principle they critique does not reflect the way in which the principle is applied in practice, including in the EU). If, however, one were not to treat all threats to social welfare equally, but instead were to adopt a hierarchy of values associated with health and environmental risk, then the apparent rudderlessness of the principle disappears.[14] One might for example prioritise the loss of an endangered species over threats to

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[8] Ibid., 113–14. Sunstein, *Laws of Fear: Beyond the Precautionary Principle* (CUP 2005) 18–20.

[9] Majone, 'What Price Safety? The Precautionary Principle and Its Policy Implications' (2002) 40 JCMS 89; Sunstein, 'Beyond the Precautionary Principle' (2003) 151 U.Pa.L.Rev. 1003 (2003).

[10] Majone (n.9), 101–02; Sunstein (n.9), 1024–25.

[11] Sunstein (n.9), 1020–28.

[12] Majone (n.9), 105; Sunstein (n.9), 1023.

[13] Kysar (n.5), 6–8.

[14] Ibid.

human health. One might even adopt some system of lexical ordering in which certain risks must be eliminated or reduced to the greatest extent possible before other threats to welfare are considered.[15] Feintuck, for example, has argued that the precautionary principle should be understood to demand a hierarchy of values in which "common interests" are prioritised over economic interests.[16] Similarly, Kysar has argued against accepting the moral equivalence of prevented harms and foregone opportunities.[17]

These differing perspectives on the precautionary principle are, at bottom, different approaches for defining and constituting the public interest. Sunstein and Majone take an essentially consequentialist view, in which the public interest is to a large extent equated with social welfare.[18] Because it implicitly rejects choosing among competing visions of the public good, their approach is also essentially pluralistic. For Feintuck and Kysar, by contrast, the public interest is not the sum of individuals' conceptions of the public good, but rather a purposeful construction of what constitutes a good society.[19] This conception requires a process for evaluating and choosing among differing visions of the public interest. In Feintuck's view that definitional process must have democratic sanction, but it is not merely a question of majority preference.[20] Instead, formulation of the public interest also requires the application of moral reasoning, which leaves open a role for law—and by extension courts—in defining the public interest.

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[15] Cranor, *Regulating Toxic Substances* (OUP 1993) 168–75.
[16] Feintuck, 'Precautionary Maybe, but What's the Principle? The Precautionary Principle, the Regulation of Risk, and the Public Domain' (2005) 32 JLS 371, 398.
[17] Kysar (n.5), 51–55.
[18] Stewart is more explicit in this regard. Stewart (n.5), 82. None of these writers appears to deny that considerations other than welfare may be important; their claim is instead that welfare will normally be the central concern in risk regulation. Cf. Adler and Posner, *New Foundations of Cost-Benefit Analysis* (Harvard 2006) 53–54.
[19] Feintuck (n.2), 40–41; Kysar (n.5), 48–52.
[20] Feintuck specifically rejects pluralist bargaining as a basis for formulating the public interest, arguing instead that certain public values are inherent in the concept of democracy. Feintuck (n.2), 54–56.

As I will develop in the following sections, these differing perspectives on the meaning of the public interest are reflected in the different approaches taken to precaution by European and American public law. US law tends to reflect a pluralistic account of the public interest and to treat precaution as a function of political preference or, put differently, as a matter of policy. EU law, by contrast, tends to conceive of the public interest as a normative question distinct from political preferences. Although politics have hardly been banished from the EU's precautionary jurisprudence, the case law shows that the courts have employed their own understandings of the public interest, drawn from legal sources, in applying the precautionary principle. These different understandings of the public interest, I will argue, inform differences in the theories on which the two systems ground the constitutional legitimacy of regulation.

B. The Precautionary Principle in the European Union

The Treaty of Maastricht formally introduced the precautionary principle into EU law, by adding Article 130r to the EC Treaty, paragraph 2 of which provided:

> Community policy on the environment shall aim at a high level of protection taking into account the diversity of situations in the various regions of the Community. It shall be based on the precautionary principle and on the principles that preventive action should be taken, that environmental damage should as a priority be rectified at source and that the polluter should pay.

This language has been retained unchanged, except for the substitution of "Union" for "Community", in Article 191 TFEU. The roots of the precautionary principle in European law go back much farther than Maastricht, however. Its deepest origins lie in the constitutional obligations of many Member State governments to protect public health

and the environment.[21] Similar duties can also be found in the European Convention on Human Rights and the European Social Charter, both of which are binding on all Member States.[22] And at EU level, the Court of Justice has long recognised a duty on the part of the EU Institutions to take environmental and public health concerns into account when regulating.[23] In addition to recognising an affirmative obligation to protect public health, pre-Maastricht case law affirmed the authority of Member State governments to take regulatory action when the evidence of harm is uncertain. For example in *Sandoz*, the Court of Justice held that Member States could regulate potentially harmful substances without waiting for definitive proof.[24] The court reached a similar conclusions at EU level in *Fedesa*, in which it held that it was not necessary for the EU legislature to establish the existence of a risk scientifically before taking action.[25] Precautionary reasoning was thus an important aspect of EU law before the inclusion of the precautionary principle in the Treaties.[26] Indeed,

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[21] Vos, *Institutional Frameworks of Community Health and Safety Legislation* (Hart 1999) 15–17, 68; Koppen and Ladeur, 'Environmental Rights' in Cassese, Clapham, and Weiler (eds.), *Human Rights and the European Community* (Nomos 1991) 21–34; Micklitz, 'Consumer Rights' in ibid., 61–67; Boehmer-Christiansen, 'The Precautionary Principle in Germany—Enabling Government' in O'Riordan and Cameron (eds.), *Interpreting the Precautionary Principle* (Earthscan 1994) 32.

[22] Desgagné, 'Integrating Environmental Values into the European Convention on Human Rights' (1995) 89 AJIL 263, 265.

[23] Case 240/83, *Procureur de la Republique v. Association de defense des Bruleurs d'huiles usagées* [1985] ECR 531, para. 13; Case C-331/88, *R. v. MAFF, ex p. Fedesa* [1990] ECR I-4023, paras. 8–9; see also Case C-221/10 P, *Artegodan GmbH v. Commission*, nyr, Opinion of A.G. Bot, para. 96 (deeming public health a "primordial" principle).

[24] Case 174/82, *Criminal proceedings against Sandoz BV* [1983] ECR 2445, paras. 15–16; see also Case 247/84, *Criminal proceedings against Motte* [1985] ECR 3887 paras. 19–20; Case 54/85, *Ministère Public v. Mirepoix* [1986] ECR 1067, para. 14.

[25] *Fedesa* (n.23), paras. 16–17.

[26] Fisher (n.3), 209–10; Heyvaert, 'Facing the Consequences of the Precautionary Principle in European Community Law' (2006) 31 ELR 185, 203.

even after Maastricht, the courts continued to uphold precautionary regulation without explicitly relying on the precautionary principle.[27]

As a result of this deep constitutional history, the courts have extended the reach of the precautionary principle well beyond the confines of Article 191, so that its application is now mandatory whenever EU action touches on protection of health or the environment.[28] Significantly, the courts have accomplished this expansion by elevating the precautionary principle to the status of a general principle of EU law.[29] General principles are a foundational component of the EU legal system, with no direct parallel in US law. They are binding legal principles of a constitutional nature, derived by the EU courts from the legal traditions of the Member States. Because they have the status of primary law, "a measure, whether legislative or administrative, which infringes one of them is illegal and may be annulled by the Court".[30] Just as important, by designating it as a general principle, the courts have invested the precautionary principle with high normative status. General principles inhabit the realm of those foundational principles—human rights, proportionality, rights of the defence (natural justice)—that are constitutive of EU law's character and identity. They have moral, not just legal, force.[31]

In the last twenty years, the precautionary principle truly has become the *leitmotif* of European risk regulation.[32] It is cited as part of the legal

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[27] E.g., Case C-405/92, *Etablissements Armand Mondiet SA v. Armement Islais SARL* [1993] ECR I-6133, paras. 32–36; Case C-157/96, *R. v. MAFF ex p. National Farmers' Union* [1998] ECR I-2211, para. 63.

[28] Case T-392/02, *Solvay Pharmaceuticals BV v. Council* [2003] ECR II-4555, paras. 121–22.

[29] The General Court first recognised the precautionary principle as a general principle of law in Case T-74/00, *Artegodan GmbH v. Commission* [2002] ECR II-4945, para. 184. The Court of Justice has never explicitly referred to the precautionary principle as a general principle, but some recent decisions apparently treat it as such. E.g., Case C-269/13 P, *Acino AG v. Commission*, nyr, paras. 58–59.

[30] Tridimas, *The General Principles of EU Law* (2d ed., OUP 2006) 6.

[31] Ibid., 1, 3–5.

[32] Fisher (n.4), 315.

basis of almost all environmental, health, and safety legislation.[33] The Commission routinely alludes to it in official documents on various aspects of regulatory policy.[34] It is the frequent subject of litigation. In many ways, interpretation and application of the precautionary principle has come to structure the EU's framing of, and response to, problems of technological risk.[35] As such, it has become perhaps the most important conceptual foundation of EU risk regulation.

1. The precautionary principle as a source of regulatory authority

Although it is easy to identify the precautionary principle as an aspect of EU constitutional law, it is harder to specify its function. It is sometimes said that that precautionary principle increases the EU's power to take regulatory measures to address potential health and environmental risks by allowing it to act in advance of scientific certainty.[36] But as we have seen, the EU courts upheld numerous regulatory measures despite scientific uncertainty well before the precautionary principle was

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[33] E.g., 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] O.J. L68/1, recital 2; Regulation 528/2012 concerning the making available on the market and use of biocidal products [2012] O.J. L167/1 (Biocides Regulation), art. 1(1); Regulation 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) &c. [2006] O.J. L396/1, art. 1(3). Indeed, the principle is cited even when its relevance is not obvious, e.g., Regulation 66/2010 on the EU Ecolabel [2009] O.J. L27/1, recital 3.

[34] E.g., European Commission, Communication, 'Renewable Energy: Progressing towards the 2020 Target' COM(2011) 31 final, 4; European Commission, Communication, 'Regulatory Aspects of Nanomaterials' COM(2008) 366 final, 8.

[35] Fisher (n.3), 209–10; Joerges, 'Law, Science and the Management of Risks to Health at the National, European and International Level—Stories of Baby Dummies, Mad Cows and Hormones in Beef' (2001) 7 Colum.J.Eur.L. 1, 18–19.

[36] Heyvaert (n.26), 186; see also de Sadeleer (n.1), 165–66; Vos, 'Antibiotics, the Precautionary Principle, and the Court of First Instance' (2004) 11 MJECL 187, 194.

introduced. Thus, there would seem to be no need for the precautionary principle to expand the EU's regulatory powers in this regard. What the precautionary principle instead provides is a specific *legal* justification for those powers. As the EU's powers in the field of risk regulation became more expansive—and, in particular, as an increasing share of EU-level risk regulation came to be adopted administratively by the Commission—such a justification became necessary to reconcile precautionary risk regulation with European concepts of administrative legality.

To understand how the precautionary principle justifies EU risk regulation, it is necessary first to understand the limits on the EU's regulatory authority inherent in the concept of legality.[37] Historically, three general principles of law—fundamental economic rights,[38] proportionality, and equal treatment—have been used by the courts to place legal bounds on the EU's regulatory powers. In different ways, each of these principles protects individual economic liberty by requiring that regulation be directed toward a legitimate public aim and have an "objective" basis.[39] These principles have been used as the basis for arguments that the EU may not regulate without substantial scientific evidence of harm because to do so would be to act without an objective

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[37] This discussion assumes that the EU has competence to act under the Treaties. Given the EU's broad powers to harmonise the internal market, art. 114 TFEU, and its general competence to regulate for the protection of the environment, art. 192 TFEU, competence is usually not an issue in the area of risk regulation. The EU's powers in this field are not unlimited, however. E.g., Case C-376/98, *Germany v. Parliament and Council* [2000] ECR I-8419, paras. 83–84.

[38] "Fundamental economic rights" is short-hand for the right to property and other liberal economic rights recognised by the Court of Justice, e.g., the rights to pursue an occupation or to engage in economic activity. Case 11/70, *Internationale Handelsgesellschaft mbH v. Einfuhr- und Vorratsstelle für Getreide und Futtermittel* [1970] ECR 1125, paras. 3–4; Tridimas (n.30), 298–319.

[39] Case T-13/99, *Pfizer Animal Health SA v. Council* [2002] ECR II-3305, para. 478; Emiliou, *The Principle of Proportionality in European Law: A Comparative Study* (Kluwer 1996) 6–8; Tridimas (n.30), 83–84.

basis.[40] Proponents of that view argue that regulatory measures taken without such evidence arbitrarily restrict individual liberty and, as such, are contrary to the rule of law.

The obstacles to precautionary regulation posed by economic rights, proportionality, and non-discrimination could be overcome in at least two ways. One approach would be simply to deny that "objectivity" requires a high degree of scientific evidence, thereby removing the most important legal barrier to precautionary regulation. As Heyvaert argues, that was apparently the approach taken by the EU courts in the many cases upholding precautionary regulation without relying on the precautionary principle.[41] The effect of that approach would be to accord the Commission a wide discretion to determine the goals of EU risk regulation as well as the means necessary for achieving those goals. As we will see below, the US courts have taken such an approach to upholding precautionary regulation.

According the Commission such a wide margin of discretion is problematic, however, for EU administrative law. For one thing, it is unclear that the Commission possesses sufficient democratic legitimacy to sustain such a large margin of discretion. Unlike the administrations of many Member States, which bear a high degree of responsibility to their national parliaments, the democratic credentials of the Commission are relatively weak.[42] Whereas broad discretion may be appropriate when the EU acts legislatively, it is doubtful whether according the Commission a similar freedom of action would be acceptable to the Member States and the European public.[43] A second problem is that

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[40] Indeed, such arguments can be found even in recent literature. E.g., Bergkamp, 'The Quiet Revolution in EU Administrative Procedure: Judicial Vetting of Precautionary Risk Assessment' [2014] EJRR 102, 107–08; de Vries and Francot-Timmermans, 'As Good as It Gets: On Risk, Legality and the Precautionary Principle' in Besselink, Pennings, and Prechal (eds.), *The Eclipse of the Legality Principle in the European Union* (Kluwer 2011) 25–30.

[41] Heyvaert (n.26), 200.

[42] Chapter 2, section II.B.1.

[43] Cf. Case C-343/09, *Afton Chem. Ltd. v. Sec'y of State for Transp.* [2010] ECR I-7027, Opinion of A.G. Kokott, paras. 33–34.

according the administration a wide margin of discretion runs counter to the idea of the rule of law in the public law systems of some Member States, notably Germany. In these systems, the administration's exercise of discretion must be legally structured in ways that allow for effective judicial review.[44] Without such structure, administrative discretion is literally lawless.

Conceptualising the precautionary principle as a general principle of EU law, and not merely an aspect of the EU's environmental policy (as provided in the Treaties), provides an alternative way to reconcile regulation under conditions of scientific uncertainty with the principle of legality. It does so by modifying the meaning and scope of the other general principles, but without overriding them.[45] The precautionary principle in effect clarifies the meaning of objectivity by providing that neither scientific certainty nor even strong scientific evidence is required *in cases in which* the Commission is acting to protect health or the environment. It does not, however, simply leave the basis of regulation to administrative discretion. Instead, the courts have interpreted the precautionary principle to impose a limited hierarchy of values. Both the Court of Justice and the General Court have held that "protection of public health must unquestionably take precedence over economic considerations".[46] In other words, although the level of protection is a "political choice", the Institutions' freedom of choice is not unbounded

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[44] Below, p.142.

[45] Case C-491/01, *R. v. Secretary of State for Health, ex p. British American Tobacco* [2002] ECR I-11453, Opinion of A.G. Geelhoed, paras. 228–29; Case C-121/00, *Criminal proceedings against Hahn* [2002] ECR I-9193, para. 47.

[46] *Artegodan* (n.29), para. 173. The General Court has restated this principle on numerous occasions. E.g., Case T-483/11, *Sepro Europe Ltd. v. Commission*, nyr, para. 85; Case T-31/07, *DuPont de Nemours (France) v. Commission*, nyr, para. 132; Case T-475/07, *Dow AgroSciences Ltd. v. Commission* [2011] ECR II-5937, para. 143; Case T-158/03, *Industrias Quimícas del Vallés, SA v. Commission* [2005] ECR II-2425, para. 134; *Solvay Pharmaceuticals* (n.28), para. 121; Case T-70/99, *Alpharma Inc. v. Council* [2002] ECR II-3495, para. 356. This hierarchy of values was first announced by the Court of Justice in Case C-183/95, *Affish BV v. Rijksdienst voor de keuring van Vee en Vlees* [1997] ECR I-4315, para. 42.

and is subject to scrutiny by the courts.[47] At the same time, however, protection of economic rights and individual liberty is not simply set aside. Precautionary measures must still be proportionate and non-discriminatory, requirements that are again subject to judicial control.[48]

Thus, as interpreted by the courts, the precautionary principle elaborates a framework for assessing the compatibility of risk regulation with the general principles of EU law. The administration not only may, but arguably must, act to protect health and the environment and may do so on the basis of uncertain evidence. It must nonetheless respect individual liberty by not relying on purely hypothetical risks[49] and by ensuring that regulatory measures are neither disproportionate nor discriminatory.[50] Although it provides a fairly detailed rubric for decision, it should be obvious that this framework does not mechanically yield results when applied to particular facts. Rather, determining the compatibility of any particular measure with the general principles of law requires an act of judgment. Although the courts are the ultimate arbiters of whether the framework has been properly applied, they accord considerable deference to the Commission's own assessment.[51]

Relying on the precautionary principle to justify regulation under scientific uncertainty aligns EU law, to a degree, with the German approach to administrative discretion. Unlike American[52] or French[53] administrative law, both of which tend to draw a strong distinction between law and policy or law and discretion (*légalité ou opportunité*),

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[47] E.g., Case T-333/10, *Animal Trading Company (ATC) BV v. Commission*, nyr, para. 101.
[48] Case C-77/09, *Gowan Comércio Internacional e Serviços Lda v. Ministero della Salute* [2010] ECR I-13533, para. 76; Case C-6/99, *Association Greenpeace France v. Ministère de l'Agriculture et de la Pêche* [2000] ECR I-1651, Opinion of A.G. Mischo, paras. 71–72.
[49] *Gowan* (n.48), para. 78; The "no hypothetical risk rule" is discussed in chapter 4, section III.C.1.
[50] *ATC* (n.47), para. 101.
[51] Ibid., para. 82.
[52] Davis, *Discretionary Justice* (Louisiana State University 1969) 36–42.
[53] Brown and Bell, *French Administrative Law* (5th ed., Clarendon 1998) 256–61.

German administrative law tends to conceive of the two concepts as interwoven.[54] Indeed, in contemporary German administrative law, it is often asserted that legal rules allow for only one solution to regulatory problems and that the administration possesses no discretion.[55] From a German perspective, simply creating a zone of discretion in which the administration is free to act (or not) poses a serious threat to the rule of law.[56] It is therefore no surprise that the precautionary principle was initially developed in Germany in part as a means of creating a legal basis for overcoming obstacles to environmental regulation posed by proportionality and economic rights.[57] Although the EU courts' application of the precautionary principle is broadly aligned with this approach, it also shows the influence of other legal traditions by allowing the Commission a considerable margin of discretion in how the legal framework is applied.[58]

Relying on the precautionary principle, rather than on an expansive notion of administrative discretion, has certain practical legal effects. Whereas simply expanding administrative discretion would leave the Commission free to regulate or not as it deemed appropriate, the precautionary principle operates in one direction only: in favour of greater protection. If the Commission declines to regulate when presented with evidence of potential but uncertain risk, its decision gains no

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[54] Maurer, *Allgemeines Verwaltungsrecht* (17th ed., Verlag C.H. Beck 2009) 135–43 ("Das Ermessen gibt der Verwaltung die Möglichkeit zur eigenverantwortlichen, *wenn auch gesetzlich gelenkten* Entscheidung." (emphasis supplied)); Singh, *German Administrative Law in Common Law Perspective* (2d ed., Springer 2001) 151–56; Nolte, 'General Principles of German and European Administrative Law—A Comparison in Historical Perspective' (1994) 57 MLR 191, 196–97.

[55] Nolte (n.54), 196; Singh (n.54), 151–54.

[56] Currie, *The Constitution of the Federal Republic of Germany* (University of Chicago 1995) 125–34; Schmidt-Aßmann, 'Verwaltungslegitimation als Rechtsbegriff' (1991) 116 Archiv.offen.Rechts 329, 384–87.

[57] Boehmer-Christiansen (n.21), 36–37; von Moltke, 'The Vorsorgeprinzip in West German Environmental Policy' in Royal Commission on Environmental Pollution, *Twelfth Report: Best Practicable Environmental Option* (HMSO 1988) 60–61.

[58] Cf. de Vries and Francot-Timmermans (n.40), 31–33.

protection from the precautionary principle.[59] Additionally, the hierarchy of values created by the principle makes it possible to argue that regulatory measures should be annulled because they are insufficiently precautionary. Such challenges have had limited success thus far, but there have not been many cases and, as Heyvaert notes, most of the challenges have been weak on the facts.[60] Finally, the hierarchy of values created by the courts' precautionary jurisprudence should push the administration to frame risk regulation problems in terms of protection first and economic development second. It would, of course, be a heroic assumption that administrators always act in conformity with the letter and spirit of judicial decisions, but it would also be farfetched to assume that they have no influence.[61] If nothing else, the court's articulation of a legal requirement that protection be given priority strengthens the position of those actors within the administration who advocate for more protective approaches.[62]

Nor should the normative force of the constitutionalisation of precaution be overlooked. A general principle, as Tridimas reminds us, "express[es] a core value of an area of law or the legal system as a whole".[63] Though their effect may be hard to pin down, there can be little doubt that such constitutional principles play an important role in setting the normative terms for legal and policy debate. Simply put, it is hard to argue that something is normatively desirable—that it furthers the public interest—if it is contrary to basic constitutional commitments.[64] It would be difficult, for example, for the Commission to

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[59] Case T-299/04, *Sweden v. Commission* [2007] ECR II-2437, paras. 172–86.
[60] Heyvaert (n.26), 194. At least one "insufficient precaution" challenge has been successful, *Sweden* (n.59), and another has been partly successful, Case C-3/00, *Denmark v. Commission* [2003] ECR I-2643.
[61] Consider in this regard, the Commission's acknowledgement of the courts' case law in its 'Communication on the Precautionary Principle' COM(2000) 1 final, 19.
[62] Cf. Pedersen, 'Formal Records and Informal Rulemaking' (1975) 85 YLJ 38, 59–60.
[63] Tridimas (n.30), 1.
[64] Feintuck (n.2), 183–88.

argue that economic concerns, even concerns for public interests such as employment or poverty relief, should be pursued at the expense of health or environmental protection.[65] This normative weight can be important in controversial areas. For example, REACH, which places heavy burdens on the large and powerful European chemicals industry, derived substantial rhetorical support from the precautionary principle.[66]

2. The precautionary principle as a norm of legislative interpretation

Although the bulk of scholarly work on the precautionary principle has focused on its meaning and application as an independently enforceable legal principle, the principle has perhaps had its greatest practical impact on EU law as a norm of legislative interpretation.[67] Legislation is the primary means by which the legislature exercises control over the administration, by providing instructions and setting boundaries on the Commission's scope of discretion. No matter how detailed, however, legislation, especially legislation setting up broad regulatory programmes, cannot definitively resolve the many varied questions that will arise in its application. For that reason, the interpretation of legislation is central to the definition of both the scope of a regulatory programme and the administration's role in it. Theories of legislative interpretation abound,

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[65] Of course, that difficulty may create an incentive for the EU administration to minimise its assessment of potential health and environmental risks or to overstate the protective capacities of regulation so that these goals do not come into conflict.

[66] European Commission, White Paper, 'Strategy for a Future Chemicals Policy' COM(2001) 88 final, 5, 20. While acknowledging the occasional rhetorical use of the precautionary principle, Heyvaert doubts that the content of REACH can be traced to an EU commitment to the principle. Heyvaert, 'Guidance Without Constraint: Assessing the Impact of the Precautionary Principle on the European Community's Chemicals Policy' (2006) 6 YEEL 27, 57–58.

[67] An important exception is the work of Nicolas de Sadeleer. E.g., *Environmental Principles: From Political Slogans to Legal Rules* (OUP 2002) 289–91; de Sadeleer (n.1), 145–46; 'The Precautionary Principle as a Device for Greater Environmental Protection: Lessons from EC Courts' (2009) 18 RECIEL 3, 7–8.

including approaches that focus on text, the intention of the legislature, or the underlying purpose of the legislation. None of these approaches, however, is capable of fully overcoming the indeterminacy of legislative language.[68] As a result, interpretation necessarily takes place against a background of legal and normative principles that create the context in which the meaning of legislative terms can be fixed.[69] The identification and interpretation of those background principles can thus have important consequences for the content of regulatory programmes and the administration's role in implementing them.

The elaboration of these interpretive norms by the judiciary is of particular consequence in the EU legal system. Unlike the US, where (as will be discussed below) agencies are given primary authority for interpreting the statutes they administer, legislative interpretation in the EU is emphatically a judicial function. In accordance with the civil law tradition on which EU administrative law is based,[70] the EU courts accord no explicit deference to the views of the other Institutions.[71] The EU courts' approach to interpretation is eclectic, but a purposive or teleological approach, in which the court interprets legislation to further the legislation's underlying goals rather than focusing on text or legislative intent, figures prominently.[72] The Court of Justice has offered

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[68] Sunstein, *After the Rights Revolution* (Harvard 1990) 117–23; Eskridge, 'Public Values in Statutory Interpretation' (1989) 137 U.Pa.L.Rev. 1007, 1019–33.

[69] Sunstein (n.68), 133–37, 144–47.

[70] Craig, 'Judicial Review of Questions of Law: A Comparative Perspective' in Rose-Ackerman and Lindseth (eds.), *Comparative Administrative Law* (Edward Elgar 2010) 461–62. Craig notes that substitution of judgment is also the norm for United Kingdom courts reviewing administrative action.

[71] In many cases, of course, an administrative body will have responsibility for interpreting legislation in the first instance, such as when adopting implementing acts or preparing guidance documents. Although the courts would accord no deference to those interpretations, obtaining judicial review may sometimes be difficult as a practical matter. Scott, 'In Legal Limbo: Post-Legislative Guidance as a Challenge for European Administrative Law' (2011) 48 C.M.L.Rev. 329.

[72] Arnull, *The European Union and Its Court of Justice* (2d ed., OUP 2006) 607–08.

various justifications for its use of a teleological approach,[73] but a particularly important consideration has been that much EU legislation is drafted in broad terms and that the resulting gaps and ambiguities often require the courts to go beyond the text to resolve specific cases.[74] In the absence of reliable legislative history, the teleological method provides a framework for this analysis.[75]

Application of the teleological approach necessarily depends on the establishment, implicitly or explicitly, of principles for the identification of the legislative *telos*, and the EU courts look to the Treaties and the general principles of law as the primary sources of those norms.[76] The elevation of the precautionary principle to a general principle of law means that all risk regulation legislation will be interpreted to the greatest extent possible to require a precautionary approach.[77] Although the courts have not attempted to define precisely the content of the precautionary principle as an interpretive norm, they have generally applied it to construe legislation to require a high—sometimes a very high—level of environmental and health protection. In this regard, the courts often combine the precautionary principle with the principle that

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[73] E.g., Case 283/81, *CILFIT v. Ministry of Health* [1982] ECR 3415, paras. 17–20. Arnull suggests that the teleological approach also has its roots in the civil law tradition. Arnull (n.72), 621; see also Koopmans, 'The Theory of Interpretation and the Court of Justice' in O'Keeffe and Bavasso (eds.), *Judicial Review in European Union Law* (Kluwer 2000) 47–51.

[74] E.g., Joined Cases C-68/94 and C-30/95, *France v. Commission* [1998] ECR I-1375, para. 168; Arnull (n.72), 615–16.

[75] E.g., Case C-245/01, *RTL Television GmbH v. Niedersächsische Landesmedienanstalt für privaten Rundfunk* [2003] ECR I-12489, para. 59; Arnull (n.72), 616–19.

[76] That said, the teleological approach is not the only interpretive approach taken by the courts and it would be wrong to suggest that the court does not pay close attention to text. Arnull (n.72), 612; Tridimas, 'The Court of Justice and Judicial Activism' (1996) 21 ELR 199, 205.

[77] Tridimas (n.30), 29. Cf. *Artegodan* (n.29), para. 192 ("*The precautionary principle requires* the suspension or withdrawal of a marketing authorisation where new data give rise to serious doubts as to either the safety or the efficacy of the medicinal product . . . .") (emphasis supplied).

the EU is to aim for a high level of protection,[78] so that "a high level of protection" is understood to be one that is precautionary regarding uncertain risk.[79]

One way in which the courts have applied precaution as an interpretive principle is to broaden the scope of EU regulation. An early example is *ARCO Chemie Nederland*,[80] in which the Court explicitly applied the precautionary principle in a teleological manner to hold that the concept of "waste" in the Waste Directive[81] should be interpreted broadly on the premise that greater environmental protection would be achieved by bringing more substances within the Directive's coverage.[82] In a similar vein, the Court of Justice has relied on the precautionary principle to avoid literal interpretations of legislative language that might result in gaps in protection. For example, in *Greenpeace France*[83] the Court relied on the principle to hold that Directive 90/220 on the release of GMOs permitted a Member State to withhold authorisation of a particular GMO on the basis of new information, even though the Directive did not explicitly provide for authorisation to be withheld in such circumstances.[84]

Both the Court of Justice and the General Court have also applied the precautionary principle more aggressively, particularly in their

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[78] This principle is also enshrined in the Treaties. Article 3(3) TEU; Articles 114(3), 168, 169, and 191(2) TFEU; Case C-284/95, *Safety Hi-Tech Srl v. S. & T. Srl* [1998] ECR I-4301, paras. 47–49.

[79] E.g., Case C-106/14, *Fédération des Entreprises du Commerce et de la Distribution v. Ministre de l'Écologie, du Développement Durable et de l'Énergie*, Opinion of A.G. Kokott, nyr, para. 81; Case C-113/12, *Brady v. Environmental Protection Agency*, nyr, para. 39; Case T-368/11, *Polyelectrolyte Producers Group v. Commission*, nyr, para. 62.

[80] Case C-418/97, *ARCO Chemie Nederland Ltd. v. Minister van Volkshuisvesting, Ruimtelijke Ordening en Milieubeheer* [2000] ECR I-4475.

[81] Directive 2008/98/EC on waste &c. [2008] O.J. L312/3.

[82] *Arco Chemie* (n.80), paras. 39–40; see also Case C-9/00, *Palin Granit Oy* [2002] ECR I-3533, para. 23.

[83] Above n.48.

[84] Ibid., paras. 44–47; see also Case C-236/01, *Monsanto Agricoltura Italia SpA v. Presidenza del Consiglio dei Ministri* [2003] ECR I-8105, paras. 110–12.

interpretation of the level of protection required by legislation. The two best examples of this phenomenon are *Waddenzee*[85] and *Sweden v. Commission*.[86] In *Waddenzee*, the Court of Justice interpreted Article 6(3) of the Habitats Directive[87] in light of the precautionary principle to prohibit national authorities from authorising an activity in a special protection area if "doubt remains as to the absence of adverse effects on the integrity of the site".[88] In *Sweden*, the General Court interpreted the Plant Protection Products Directive,[89] again in light of the precautionary principle, as prohibiting the authorisation of an active substance unless the Commission "establish[es] beyond a reasonable doubt" that the substance will not have any harmful effects on human or animal health or any unacceptable influence on the environment.[90] These are both very strong interpretations of language that could easily have been construed to permit greater flexibility. Moreover, this use of the precautionary principle can have a decisive effect on the regulatory outcome. In *Sweden*, the court applied its interpretation of the required level of

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[85] Case C-127/02, *Landelijke Vereniging tot Behoud van de Waddenzee v. Staatssecretaris van Landbouw, Natuurbeheer en Visserij* [2004] ECR I-7405.

[86] Above n.59.

[87] Directive 92/43/EEC on the conservation of natural habitats &c. [1992] O.J. L206/7.

[88] *Waddenzee* (n.85), paras. 57–58. Article 6 of the Directive prohibits Member States from authorising projects in special areas of conservation unless they first assess their "implications for the site in view of the site's conservation objectives" and determine on the basis of the assessment that they "will not adversely affect the integrity of the site concerned". The Court of Justice interpreted "will not adversely affect" to require that "no reasonable scientific doubt remains as to the absence of such effects" and that, accordingly, projects may not be authorised "in the face of uncertainty". Ibid., paras. 67–68.

[89] Directive 91/414/EEC concerning the placing of plant protection products on the market [1991] O.J. L230/1.

[90] *Sweden* (n.59), para. 170. Article 5 of the Directive provides that active substances may only be authorised if "it may be expected that . . . their use . . . does not have any harmful effects on human or animal health or any anacceptable [sic] influence on the environment". It is not obvious that "may be expected" should be equated with "beyond a reasonable doubt".

protection and found that the Commission had not made the necessary evidentiary showing to support the authorisation. Accordingly, the court annulled the authorisation, despite the fact that the relevant expert committee had recommended authorisation and the majority of Member States voting in the comitology committee had agreed.[91]

Unlike the courts' use of the precautionary principle to expand administrative authority by limiting other general principles, the use of precaution as an interpretive norm can be seen as increasing judicial authority at the expense of administrative, and to a lesser extent legislative, authority by framing the level of protection as an issue of law rather than as an issue of policy. By aggressively applying precaution as a strong interpretive norm, the courts make it more difficult for the legislature to enact policies calling for a lower level of protection.[92] Further, because the courts accord no special weight to the Commission's views on legislative interpretation, framing the level of protection as a question of law acts as a powerful constraint on administrative discretion.

The strong use of precaution as an interpretive norm demonstrates the importance of the recognition of the precautionary principle as a general principle of law, even though the courts have been reluctant to use the principle on its own to annul legislative or regulatory measures. While it is true that implementing the precautionary principle primarily through legislative interpretation leaves opportunities for the legislature to adopt less precautionary policies, the courts' reliance on precaution as an interpretive norm has nonetheless resulted in consistently strong interpretations of legislative language.[93] At the same time, by giving no

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[91] Ibid., para. 42; this aspect of *Sweden* is discussed in chapter 4, section III.D.

[92] A great deal of political science literature has shown that it is more difficult to form legislative majorities to overcome legal default rules. Mashaw, *Greed, Chaos, and Governance: Using Public Choice to Improve Public Law* (Yale 1997) 96–105.

[93] That the courts rely on the principle to adopt strong interpretations of risk legislation does not mean that precaution is the only relevant value or that courts will always choose the most precautionary reading. For

special weight to the Commission's views, the courts limit opportunities for the administration to adjust the level of protection downward through implementation. In this way, judicial interpretations of precaution, and of the public interest in risk regulation more broadly, act as meaningful legal constraints on administrators' policy choices.

C. Precaution in the United States

Perhaps the most striking thing about the precautionary principle in US law is its near absence. The term "precautionary principle" does not appear in the United States Code or the Code of Federal Regulations, and it is rarely adverted to in documents prepared by US administrative agencies.[94] Mentions of the principle are similarly rare in US case law, and to date no judicial decision has relied on it by name. Nor is there a history in US constitutional law, as there is in Europe, of recognising affirmative obligations on the part of the federal government to protect health or the environment.[95]

The absence of an official embrace of the precautionary principle should not, however, be taken to imply that US law rejects precautionary

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example, in Joined Cases C-58/10 and C-68/10, *Monsanto SAS v. Ministre de l'Agriculture et de la Pêche* [2011] ECR I-7763, the Court of Justice had to decide which of two legislative provisions governed the adoption of safeguard measures with respect to GMOs. The court rejected France's argument that the precautionary principle required it to choose the provision that accorded the Member States greater freedom to adopt safeguard measures unilaterally. Instead, the court held that the clear language of the legislation controls. Ibid., para. 60. The court also held, however, that the standards would have to be applied in light of the precautionary principle. Ibid., para. 71. Indeed, the Advocate General's opinion supports the analysis presented in this chapter, in that he argued that the precautionary principle required the Member States and the Institutions to apply a similarly high level of protection regardless of the precise legislative language. Ibid., Opinion of A.G. Mengozzi, para. 64.

[94] Wood, Wood, and Wood, 'Whither the Precautionary Principle? An American Assessment from an Administrative Law Perspective' (2006) 54 AJCL 581, 583–85.

[95] Sax, 'The Search for Environmental Rights' (1990) 6 JLUEL 93, 94. Such constitutional obligations are recognised in some state constitutions, however. E.g., Michigan Const., Article IV, § 52.

regulation. Many US health, safety, and environmental statutes have been interpreted to require a precautionary approach, in the sense that they require regulatory intervention in response to less-than-certain evidence of harm, and American law is generally not anti-precautionary. Nonetheless, precaution as an independent legal principle plays very little role in contemporary US discourse on risk regulation.

It was not always obvious that this would be the case. Although it predated widespread use of the term "precautionary principle", early US case law on risk regulation was often infused with strongly precautionary reasoning. Since the mid-1980s, however, such reasoning has been in marked decline. This change is partly the result of shifting views on risk regulation policy,[96] but the more important cause has been significant changes in US administrative law regarding the appropriate roles of courts and agencies in the regulatory process.

1. 1970s environmentalism and precaution in American law

Precautionary reasoning in US law had its heyday in the 1970s.[97] This decade saw the explosion of risk regulation programmes, and with them a palpable reordering of social priorities. 1970s environmentalism stressed health and environmental protection as primary public goals and generally denied that these goals could or should be balanced against economic concerns.[98] Several of the new risk statutes called on the newly created agencies to set health standards with "an adequate margin of safety"[99] or to reduce risk to the greatest extent "feasible".[100]

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[96] *See* Kysar (n.5), 5–6.

[97] Lazarus, *The Making of Environmental Law* (University of Chicago 2004) 80–83; Melnick, *Regulation and the Courts: The Case of the Clean Air Act* (Brookings 1983) 1–11; Sunstein, *Risk and Reason* (CUP 2004) 11–18.

[98] Sunstein (n.97), 17–18; Kysar (n.5), 6.

[99] E.g., Clean Air Act, 42 U.S.C. §§ 7401–7671q.

[100] E.g., Occupational Safety and Health Act (OSH Act), 29 U.S.C. §§ 651–678; *American Textile Manufacturers Institute, Inc. v. Donovan*, 422 U.S. 490, 530 (1981) (*Cotton Dust*).

Other statutes were interpreted to apply to potential as well as scientifically established risks.[101]

The courts were not unaware of the public and congressional mood.[102] Thus, in a statement that could have been lifted from a judgment of the European Court of Justice, the D.C. Circuit declared, "fundamental personal interests in life, health, and liberty . . . have always had a special claim to judicial protection, in comparison with . . . economic interests . . .".[103] Relying on the special status of interests in health and environmental protection, courts construed early environmental statutes aggressively in an effort to maximise protection for those interests.[104] In part, these decisions were motivated by an effort to give effect to what the courts perceived to be Congress's intent.[105] But it is also apparent that the courts viewed special solicitude for health and environmental protection as an independent and judicially enforceable legal principle.[106]

Unlike in the EU, there has never been a serious argument in the US that precautionary regulation is unconstitutional. The US Constitution does not separately recognise economic rights,[107] nor does it incorporate

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[101] E.g., Clean Water Act, 33 U.S.C. §§ 1251–1387; *Reserve Mining Co. v. EPA*, 514 F.2d 492, 520 (8th.Cir.1975); Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. §§ 136–136y; *EDF v. EPA*, 465 F.2d 528, 535–36 (D.C.Cir.1972).

[102] Oakes, 'The Judicial Role in Environmental Law' (1977) 52 N.Y.U.L.Rev. 498, 511–16.

[103] *EDF v. Ruckelshaus*, 439 F.2d 584, 598 (D.C.Cir.1971); see also *International Harvester Co. v. Ruckelshaus*, 478 F.2d 615, 615 (D.C.Cir.1973) (affirming "all humanity's interest in life, health, and a harmonious relationship with the elements of nature"); *Calvert Cliffs Coordinating Committee v. Atomic Energy Commission*, 449 F.2d 1109, 1109 (D.C.Cir.1971) (welcoming "a flood of new litigation . . . seeking judicial assistance in protecting our natural environment").

[104] Lazarus (n.97), 80–82; Melnick (n.97), 69–70, 356–57; Sunstein (n.97), 11–16; Glicksman and Schroeder, 'EPA and the Courts: Twenty Years of Law and Politics' (Autumn, 1991) 54 LCP 249, 273–75.

[105] *Calvert Cliffs* (n.103), 1109; Melnick (n.81), 374–75.

[106] Melnick (n.97), 64–65, 357; Sunstein (n.68), 24–31; Glicksman and Schroeder (n.104), 271.

[107] Stewart and Sunstein, 'Public Programs and Private Rights' (1982) 95 HLR 1193, 1250–51.

the proportionality principle.[108] Instead, US law protects those interests through the Due Process Clauses of the Fifth and Fourteenth Amendments, which are understood to contain a substantive component prohibiting arbitrary infringements of liberty or property interests.[109] Since the 1930s, however, when it ended the *Lochner*[110] era of aggressive substantive due process review, the Supreme Court has held that substantive due process requires only that legislation "have a reasonable relation to a proper legislative purpose".[111] The adoption of this "rational basis test" was a purposeful choice by the Supreme Court to limit constitutional constraints on economic and social regulation.[112] In practice, the scrutiny applied under the rational basis standard is so weak that, according to Professor Tribe, the courts will uphold legislation "for virtually no substantive reason at all".[113] Because the constitutionality of risk regulation programmes is evaluated under this standard,[114] it is simply implausible to argue that the Constitution prohibits precautionary regulation.[115]

Although the constitutionality of precautionary regulation was never in doubt, some precautionary measures have been challenged as a matter of administrative law. Unlike EU law, US public law makes a clear distinction between constitutional and administrative judicial review, with the latter being grounded primarily in statutory and common law principles. Administrative regulation is generally reviewed under the APA's "arbitrary and capricious" standard, which requires a stronger

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[108] Sullivan and Frase, *Proportionality Principles in American Law* (OUP 2009) 61–63.
[109] 1 Tribe, *American Constitutional Law* (3d ed., Foundation Press 2000) 1332–43.
[110] *Lochner v. New York*, 198 U.S. 45 (1905); see also *Hammer v. Dagenhart*, 247 U.S. 251 (1918).
[111] *West Coast Hotel v. Parrish*, 300 U.S. 379, 397–99 (1937).
[112] Sunstein, 'Lochner's Legacy' (1987) 87 Colum.L.Rev. 873, 874 & nn.6–8.
[113] Tribe (n.109), 1362.
[114] E.g., *Goldblatt v. Town of Hempstead*, 369 U.S. 590, 595–96 (1962).
[115] Stewart and Sunstein (n.107), 1255; Mashaw (n.92), 52–55.

demonstration of means-ends rationality than the rational basis test.[116] As such, arguments have been made (and sometimes still are made[117]) that administrative regulation without a reasonably certain scientific basis is arbitrary. There are some well-known, older cases in which courts accepted such arguments, but they have not been widely followed.[118] By the end of the 1970s the majority view in the courts of appeals was that administrators could regulate on a precautionary basis, unless that approach was precluded by statute.[119] Although the Supreme Court has never passed explicitly on the compatibility of precautionary reasoning with the arbitrary and capricious standard, it has held repeatedly that agencies are not required to support their decisions with "anything approaching scientific certainty" to meet that standard.[120]

Thus, during the 1970s and early 1980s US administrative law saw a number of developments, both statutory and judicial, that firmly enabled American regulatory agencies to engage in precautionary risk regulation. Some courts went further and appeared to lay the jurisprudential foundation for an affirmative obligation on the administration to take precautionary approaches, at least in some cases.[121] The latter trend would not last, however. In the 1980s the Supreme Court fundamentally recast the relationship between law and discretion in administrative law or, put differently, the relationship between courts and administrative agencies. These changes would not result in new legal barriers for

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[116] *Motor Vehicle Manufacturers Association v. State Farm Mutual Automobile Insurance Co.*, 463 U.S. 29, 42–43 & n.9 (1983).
[117] E.g., *Mississippi v. EPA*, 744 F.3d 1334, 1343–44 (D.C.Cir.2013).
[118] Chapter 4, section II.A.
[119] E.g., *Ethyl Corp. v. EPA*, 541 F.2d 1, 13–15 (D.C.Cir.1976); *Society of the Plastics Industry, Inc. v. OSHA*, 509 F.2d 1301, 1304 (2d.Cir.1974) (Clark, J.).
[120] *FCC v. Fox Television Stations*, 556 U.S. 502, 520 (2009); *Massachusetts v. EPA*, 549 U.S. 497, 534 (2007); *Industrial Union Department, AFL-CIO v. American Petroleum Institute*, 448 U.S. 607, 609 (1980) (*Benzene*).
[121] Rabin, 'Federal Regulation in Historical Perspective' (1986) 38 Stan.L.Rev. 1189, 1303.

precautionary regulation, but they would end any trend toward the development of a substantive precautionary principle in US law.

2. The shift from precaution to policy

The decline in the US courts' reliance on precautionary reasoning may be traced to several factors. A series of economic downturns in the 1970s dampened public and congressional enthusiasm for aggressive health and environmental regulation.[122] At the same time, a wave of scholarship emerged calling into question the success of regulatory programmes, particularly health and environmental programmes, at meeting their aims.[123] Somewhat counterintuitively, much of this scholarship argued that the courts' enthusiasm for health and environmental protection had actually hindered the achievement of its protective goals by too rigidly limiting the administration's discretion to balance competing concerns.[124] This shift in attitudes was accompanied by a sharp decline in the use of precautionary rhetoric in US judicial decisions. Whereas courts had previously treated the goals of health and environmental legislation as legal questions, they now began to treat them as questions of policy. The results of this shift are perhaps best illustrated by the US courts' changing approach to the interpretation of regulatory statutes.

Before 1984, judicial review of administrative statutory interpretation was "erratic".[125] Although the Supreme Court had long held that courts should accord a degree of deference to agencies' interpretations of the statutes they administer, there was another "equally impressive" line of cases that apparently accorded no deference to agency interpretations.[126] These lines of cases were "analytically in conflict" with the result that

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[122] Lazarus (n.97), 94–97.
[123] E.g., Mendeloff, *The Dilemma of Toxic Substances Regulation* (MIT 1988); Wildavsky, *Searching for Safety* (Transaction 1988).
[124] E.g., Ackerman and Hassler, *Clean Coal/Dirty Air* (Yale 1981) 111–15; Mashaw and Harfst, *The Struggle for Auto Safety* (Harvard 1990) 247–52; Melnick (n.97), 110–12; see also Horowitz, *The Courts and Social Policy* (Brookings 1977) 284–93.
[125] Starr, 'Judicial Review in the Post-*Chevron* Era' (1986) 3 Yale.J.Reg. 283, 283.
[126] Ibid., 292–93.

lower courts were left to choose between them as they thought appropriate.[127] Throughout the 1970s, reviewing courts tended to show relatively little deference to administrative interpretations of environmental statutes. Instead, they applied the principle that health and the environment merited special legal protection to override interpretations they found insufficiently protective.[128]

That approach to review was dramatically altered by the Supreme Court's decision in *Chevron*, which came down firmly on the side of deference to administrative interpretations. Henceforth, courts were to apply a two-part test: "First, always, is the question whether Congress has directly spoken to the precise question at issue." If so, then "the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress".[129] If, however, the statute is ambiguous, then courts must defer to the agency's interpretation, "unless [it is] arbitrary, capricious, or manifestly contrary to the statute".[130] Following *Chevron*, courts became much less assertive in their use of background policy norms to interpret regulatory legislation.[131] Rather than relying on their own understandings of legislative policy and the public interest, courts were increasingly prepared to accept the administration's view as to whether a given statute should (or should not) be read to require precautionary action. As a result, whether US risk regulation would take a precautionary approach came to depend on the policy preferences of the incumbent president.

That the shift away from precautionary reasoning in judicial review was driven primarily by changing understandings of the proper roles of the administration and the courts is indirectly confirmed by comparing cases in which courts review administrative decisions with cases in which the courts themselves apply risk statutes. For example, under

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[127] *Pittston Stevedoring Corp. v. Dellaventura*, 544 F.2d 35, 49 (2d.Cir.1976) (Friendly, J.).
[128] Melnick (n.97), 11–13.
[129] *Chevron, U.S.A., Inc. v. NRDC*, 467 U.S. 837, 842–43 (1984).
[130] Ibid., 844.
[131] Sunstein (n.68), 142–44; Glicksman and Schroeder (n.104), 286–97; Starr (n.125), 294–95.

sections 7002 and 7003 of the Resource Conservation and Recovery Act, the federal courts may order injunctive relief to address releases of hazardous waste that "may present an imminent and substantial endangerment to health or the environment".[132] Consistently with the judicial approach to precaution that prevailed in the 1970s, early cases interpreted this language broadly, holding that it empowered the courts to address "any risk".[133] Despite the decline in precautionary reasoning in administrative cases following *Chevron*, the courts have continued to apply these provisions in a highly precautionary manner.[134]

The US courts' tendency post-*Chevron* to treat precaution as a question of policy has also been reinforced by a trend toward markedly more lenient substantive review.[135] During the 1970s, courts relied on a precautionary philosophy not only in their interpretation of regulatory statutes, but also in their substantive review of agency decisions, sometimes leading them to vacate those decisions as insufficiently precautionary.[136] This trend too was to fall off in the 1980s, largely as the result of Supreme Court decisions reemphasising the importance of deference to agencies' scientific and policy judgments.[137] On one hand, renewed emphasis on restrained judicial review supported the pre-existing trend toward recognising the legality of precautionary regulation, and recent case law is virtually uniform in accepting precautionary

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[132] 42 U.S.C. §§ 6972, 6973.

[133] *United States v. Price*, 688 F.2d 204, 213–14 (3d.Cir.1982); see also *Dague v. City of Burlington*, 935 F.2d 1343, 1355–56 (2d.Cir.1991) ("An 'imminent hazard' may be declared at any point in a chain of events which may ultimately result in harm to the public." (quoting *EDF* (n.101), 535)).

[134] E.g., *Maine People's Alliance v. Mallinckrodt, Inc.*, 471 F.3d 277, 286–93 (1st.Cir.2006); *Interfaith Community Organization v. Honeywell International Inc.*, 399 F.3d 248, 258–59 (3d.Cir.2005).

[135] Chapter 4, section II.D.

[136] E.g., *NRDC v. Train*, 545 F.2d 320, 327–28 (2d.Cir.1976); *EDF* (n.103), 598.

[137] E.g., *Marsh v. Oregon Natural Resources Council*, 490 U.S. 360, 378 (1989); *Baltimore Gas and Electric Co. v. NRDC*, 462 U.S. 87, 103 (1983).

approaches.[138] On the other, however, courts have usually been just as willing to uphold regulation that rejects precaution.[139] The principal exceptions are all found in statutory programmes that unambiguously require precautionary approaches.[140] The result, as with statutory interpretation, is that the degree to which US risk regulation is precautionary is largely a function of the policy preferences of the incumbent administration.[141]

D. European and American Approaches to Precaution Compared

The foregoing analysis shows that, as a matter of public law, the EU and US take fundamentally different approaches to precautionary regulation and the precautionary principle. EU administrative law explicitly incorporates the precautionary principle, and the constitutional status of precaution within the EU legal order is now beyond question. US law, by contrast, neither requires nor rejects precaution. These different approaches are only partly attributable to the normative judgments that inform the principle itself. Much more significant are the two systems' different understandings of the appropriate role for law in constituting and limiting regulatory objectives. In more practical terms, the divergence in approaches to precaution can be understood as a consequence of differences in the ways in which the two systems draw lines between law and policy or between law and discretion. In other words, it is a function of how the question of precaution is framed. In the EU, precaution is framed as a question of law, hence a matter for judicial resolution. In the

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[138] E.g., *American Farm Bureau Federation v. EPA*, 559 F.3d 512 (D.C.Cir.2008); see also *Upper Blackstone Water Pollution Abatement District v. EPA*, 690 F.3d 9, 23–24 (1st.Cir.2012); *Miami-Dade County v. EPA*, 529 F.3d 1049, 1065 (11th.Cir.2008).

[139] *Marsh* (n.137), 385; *Lands Council v. McNair*, 537 F.3d 981, 997–99 (9th.Cir.2008) (en banc).

[140] Most notably, the Clean Air Act: *American Lung Ass'n v. EPA*, 134 F.3d 388, 389 (D.C.Cir.1998).

[141] *National Association of Home Builders v. EPA*, 682 F.3d 1032, 1043 (D.C.Cir.2012).

US, it is framed as a question of policy on which the courts should take no position.

The differing placement of the line between law and policy in the two systems is not merely a matter of historical accident. Rather, it is an outgrowth of underlying theories on which the legitimacy of administrative regulation is premised. The EU, as a supranational organisation with an uncertain constitutional status, has always relied heavily on law and legality to legitimate its actions.[142] Because its democratic foundations are weak, the EU administration cannot rely on an electoral mandate to justify its exercise of regulatory power. Instead, it must rely on the authority it derives from the Treaties and EU legislation, as filtered through a shared European legal culture. For this approach to be credible, the Commission's regulatory discretion must be legally cabined and subject to judicial control. The centrality of legality to regulatory legitimacy is not unique to the EU, but rather is shared by many of its Member States.[143] Within this framework, the precautionary principle, as a legal principle, plays an important role by providing both an affirmative legal justification for regulatory action and by creating a basis for judicial review. By expanding the domain of legality, the EU approach, at least rhetorically, limits administrative discretion and thereby increases its legitimacy.

The theories underlying the legitimacy of American administrative regulation have undergone substantial transformations in the last forty years. Legality as a basis for administrative legitimacy was at its zenith in the 1970s, and the case law of that period shows the courts attempting to work out the proper goals of risk regulation through legal analysis, including by adopting precautionary reasoning. Since *Chevron*, however, the courts have relied increasingly on the administration's democratic accountability as a basis for regulatory legitimacy. At the same time, experience with strong judicial involvement in regulation and concerns about unintended consequences gave rise to considerable scepticism

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[142] Everson, 'Administering Europe?' (1998) 36 JCMS 195, 203–04, 213.
[143] Schwarze, *European Administrative Law* (Sweet and Maxwell 1992) 230–32.

regarding the ability of even the best intentioned courts to contribute to good regulatory policy. These developments resulted in a narrowing of the range of issues deemed appropriate for legal analysis, with a corresponding increase in the number of issues designated as matters of policy and hence beyond judicial competence. Just as a high degree of judicial control is necessary to make the EU approach to regulatory legitimacy credible, a high degree of democratic control is essential to the credibility of the US approach. For the theory to have any functional legitimating power, presidential elections must matter for administrative policy and, just as importantly, they must be seen to matter. As a consequence, administrative law must be sufficiently flexible to allow for relatively frequent policy change, and conceptualising precaution as an issue of policy facilitates that flexibility. In contrast to EU law, in which administrative discretion is seen as undermining regulatory legitimacy, US law takes the idea of administrative discretion and transforms it into a source of legitimacy, by leaving the administration free(er) to pursue democratically endorsed preferences.

At an even broader level, the differences in the European and American approaches to the precautionary principle can be traced to different understandings of the role of law in constituting the public interest. In the EU, as well as in many of its Member States, law is understood as possessing its own normative authority. To say that an administrative act is "lawful" is not merely to say, as in American-style positivism, that the act does not transgress any legal boundary or prohibition,[144] but also to say that it comports with ideas of the public good embedded within legal doctrine.[145] Thus, an act that is lawful is also normatively commendable, and its legitimacy is thereby enhanced. In this way, law partially constitutes and limits the public interest by placing bounds on the field of good public values. The point should not be overstated; the EU is no jurocracy, and the EU political Institutions remain the primary sources of risk regulation policy. Nonetheless, there

[144] Cf. Holmes, 'The Path of the Law' (1897) 10 HLR 457, 458–60.
[145] Verhoeven and Widdershoven, 'National Legality and European Obligations' in Besselink, et al. (n.40), 56–58.

is a discernible sense in which the law, particularly the general principles, have something to say about the ends of regulation, not just its means.[146] Nor should the EU's reliance on legality as a source of legitimacy be seen as a second-best approach, only adopted in default of more robust democratic processes. A core component of the European project has always been the building of a normative order that would, by virtue of its inherent merit, earn the loyalty of the European public and that would stand out as an example for the rest of the world.[147] The EU courts' approach to administrative legality contributes to this project, not least through application of the precautionary principle.

The US legal system, by contrast, has a deeply rooted scepticism toward judicial declaration of the public interest, particularly in the areas of economic and social regulation. This scepticism has its origins in the *Lochner* era, in which constitutional adjudication was used to thwart highly popular regulatory initiatives. It was substantially reinforced during the 1970s when decisions on controversial social questions, particularly abortion, powerfully called into question the capacity of courts to arbitrate public values. The result of this scepticism is that in the US the public interest (outside of certain areas[148]) tends to be understood in pluralist terms, as the preference of the prevailing electoral majority. Again, the point should not be overstated. American constitutional law places numerous limits on majoritarian law making, and certain core constitutional values undoubtedly carry great normative weight. But those values are for the most part negative in the sense that they define limits on governmental power rather than attempting to advance their own coherent theory of the public interest. It is difficult to

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[146] Tridimas (n.30), 14–17.

[147] Article 3 TEU; European Council, Copenhagen Declaration on European Identity (Dec. 1973) 12 *Bulletin of the European Communities* 118; Lenaerts, '"In the Union We Trust": Trust-Enhancing Principles of Community Law' (2004) 41 C.M.L.Rev. 317, 342–43. Cf. Manners, 'Normative Power Europe: A Contradiction in Terms?' (2002) 40 JCMS 235, 252.

[148] Especially the protection of minorities. Ely, *Democracy and Distrust* (Harvard 1980) 145–70.

find a place for the precautionary principle in such a system, but there is also less need for one.

II. Cost-Benefit Analysis

Having addressed the understanding of the precautionary principle within the administrative law systems of the EU and the US, this section turns to the topic of cost-benefit analysis. Whereas there are considerable differences in the ways in which the EU and US legal systems conceptualise and employ ideas of precautionary regulation, I will argue in this section that the two legal systems treat the issue of cost-benefit analysis in broadly similar ways. In neither system is cost-benefit analysis an important legal principle, yet executive action in both systems has made cost-benefit analysis a central part of the regulatory process. Although cost-benefit analysis is currently more prominent in US regulation, there is reason to believe that the EU and US are converging in this respect.

A. Defining Cost-Benefit Analysis

Like the precautionary principle, cost-benefit analysis has no fixed definition, and (again like the precautionary principle) much debate over the appropriateness of cost-benefit analysis is obscured by definitional ambiguity.[149] Cost-benefit analysis, at bottom, is a systematic comparison of the estimated costs with the estimated benefits of a proposed action. At one extreme, it can refer to nothing more than Franklin's "moral algebra", by which he meant the listing and reflective weighing of pros and cons.[150] At the other extreme, cost-benefit analysis can involve elaborate mathematical models that attempt to quantify, monetise, and balance all aspects of a proposed action. And of course

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[149] Posner, 'Cost-Benefit Analysis: Definition, Justification, and Comment on Conference Papers' (2000) 29 J.Legal.Studs. 1153, 1154–56; Sen, 'The Discipline of Cost-Benefit Analysis' (2000) 29 J.Legal.Studs. 931, 935–39.
[150] Letter from Benjamin Franklin to Joseph Priestly (Sept. 19, 1772) in Mott and Jorgenson (eds.), *Benjamin Franklin: Representative Selections* (American Book Co. 1936) 348–49.

there are many intermediate approaches. The meaning of cost-benefit analysis also varies regarding the role of the analysis in decisionmaking.[151] In some cases, cost-benefit analysis is merely one source of information, to be considered as part of a broader decisionmaking process. In others, cost-benefit analysis is a rule of decision, in which regulatory measures should be taken if, but only if, they result in a net increase in total welfare.[152] As a consequence, the meaning of cost-benefit analysis is highly context-dependent. Because cost-benefit analysis is such a flexible concept, it can be used as a means of inscribing policy preferences into regulatory decisionmaking. By specifying which costs and benefits must be analysed and the methodology by which they are to be compared, political principals (e.g., the White House and the European Commission) can use cost-benefit analysis requirements to provide guidance on how administrators should evaluate various policy choices.

Like the weak version of precaution, weak versions of cost-benefit analysis seems generally uncontroversial; few argue that regulatory decisionmaking should be blind to possible negative consequences.[153] Controversy arises as one moves toward greater quantification and rigidity in decisionmaking criteria. There are difficult economic and ethical issues regarding the quantification of certain goods (most prominently, human lives) and the comparison of incommensurable values (environmental integrity, economic wealth) along a single, uniform metric, and most critiques of cost-benefit analysis are directed at these

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[151] Sinden, 'Formality and Informality in Cost-Benefit Analysis' [2015] Utah.L.Rev. 93, 107–20.

[152] Posner (n.149), 155–56.

[153] Richardson, 'The Stupidity of the Cost-Benefit Standard' (2000) 29 J.Legal.Studs. 971, 973; Sen (n.149), 934. See also *Whitman v. American Trucking Ass'ns*, 531 U.S. 457, 496 (2001) (Breyer, J., concurring). Some commentators go further and argue for the moral importance of accounting for the welfare effects of regulation. E.g., Adler and Posner (n.18), 52–56; Graham, 'Saving Lives through Administrative Law and Economics' (2008) 157 U.Pa.L.Rev. 395, 411–13.

concerns.[154] Especially controversial are approaches to cost-benefit analysis that attempt to treat it as a rule of decision or that may preclude regulatory action when benefits are difficult or impossible to quantify. As discussed below, such strong forms of cost-benefit analysis are extremely rare in either US or EU regulation. Instead, cost-benefit analysis is more often used to guide decisionmaking while acknowledging that regulatory decisions must ultimately be based on policy (and political) judgment.

B. Cost-Benefit Analysis in the US

Given the frequent characterisations of US law as being based on cost-benefit analysis, it is striking how rare such requirements are in constitutional, statutory, and judge-made law.[155] Instead, these sources of law are ambivalent, and perhaps even somewhat antagonistic, toward the use of cost-benefit analysis in regulatory decisionmaking.

1. Constitutional and statutory requirements

The US Constitution imposes no requirement that the administration rely on cost-benefit analysis. As discussed above, risk regulation measures are subject to constitutional review only for minimum rationality. Just as that highly constrained review unquestionably allows for precautionary regulation, it cannot mandate cost-benefit analysis. Indeed, the defining aspect of modern substantive due process jurisprudence is the rejection of the *Lochner* era's intensive judicial scrutiny of means-ends balancing.[156]

Although the Constitution does not require it, Congress is free to specify the considerations the administration must take into account in setting standards and may impose cost-benefit analysis requirements by statute. Such requirements are not especially prominent in US risk legislation, however. Rather, risk statutes take widely varied approaches to the weighing of benefits and costs. A handful have been read to

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[154] Richardson (n.153), 972–73; Ackerman and Heinzerling, *Priceless* (New Press 2004). For responses, see Adler and Posner (n.18), 154–84.
[155] Farber, 'Rethinking Cost-Benefit Analysis' (2009) 74 U.Chi.L.Rev. 1355, 1372–79.
[156] 1 Tribe (n.109), 1346–48, 1361–62.

preclude the consideration of cost entirely.[157] Many allow the consideration of costs, but only in determining whether regulatory standards are feasible.[158] Others require the consideration costs, but do not specify how they are to be weighed against other considerations.[159] Some are completely silent on the issue.[160] Only a tiny number explicitly require cost-benefit analysis,[161] and just four statutes are commonly cited in the literature as mandating cost-benefit analysis.[162] As far as my research shows, no US risk statute has been interpreted to impose a rigid requirement that benefits be shown to exceed costs before a regulation may be promulgated.[163]

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[157] Most famously, section 109 of the Clean Air Act, 42 U.S.C. § 7409(b)(1); *Whitman* (n.153), 471.
[158] E.g., section 6(b)(5) of the OSH Act, 29 U.S.C. § 655(b)(5); *Cotton Dust* (n.100), 513.
[159] E.g., section 2 of FIFRA, 7 U.S.C. § 136.
[160] E.g., section 316 of the Clean Water Act, 33 U.SC. § 1326; *Entergy Corp. v. Riverkeeper, Inc.*, 556 U.S. 208, 222 (2009).
[161] One analysis looked at thirty-one statutes and found that only two explicitly required cost-benefit analysis. Center for Progressive Reform, Comments Regarding Executive Order on OMB Regulatory Review (March 16, 2009), http://www.progressivereform.org/articles/CPR_Comments_New_EO_Reg_Rev.pdf.
[162] E.g., Adler, 'Risk, Death, and Harm: The Normative Foundations of Risk Regulation' (2003) 87 Minn.L.Rev. 1293, 1391–92; Coglianese and Marchant, 'Shifting Sands: The Limits of Science in Setting Risk Standards' (2004) 152 U.Pa.L.Rev. 1255, 1337; Sunstein, 'Cost-Benefit Default Principles' (2001) 99 Mich.L.Rev. 1651, 1666–67. The statutes commonly cited are the Consumer Products Safety Act, FIFRA, the Toxic Substances Control Act (TSCA), and the Safe Drinking Water Act (SDWA). There is not even universal agreement that FIFRA, TSCA, and SDWA require cost-benefit analysis. Center for Progressive Reform (n.161).
[163] In *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201 (11th.Cir.1991), the Eleventh Circuit came close to interpreting TSCA as imposing such a requirement. Ibid., 1222–23. Even that decision, however, did not require strict use of cost-benefit analysis as a rule of decision. Ibid. Moreover, judicial interpretations of TSCA are not uniform. In *National Association of Homebuilders v. EPA* (n.141), the D.C. Circuit held that although TSCA "expressly requires the Administrator to consider the economic consequences of action taken under the Act, this does not mean that the regulation's benefits must outweigh its costs". Ibid., 1039.

2. Judge-made law

Judicial decisions are also an important source of US administrative law, so it might reasonably be supposed that the courts have been active in creating requirements that the administration employ cost-benefit analysis. Courts could create such requirements either by applying principles of statutory construction to interpret ambiguous statutes as requiring cost-benefit analysis or by independently creating cost-benefit analysis requirements through their exercise of substantive review under the APA's arbitrary and capricious standard. Some commentators, notably Professor Sunstein, have argued that courts should use one or both of these methods to create a general presumption that agencies should regulate on the basis of cost-benefit analysis.[164] Recent decisions in the Supreme Court and the courts of appeals, however, have declined to take up these suggestions.

On the issue of statutory interpretation, the leading case is *Entergy Corp. v. Riverkeeper Inc.*,[165] which addressed EPA's authority to balance costs against benefits when selecting the "best technology available" under section 316(b) of the Clean Water Act. That provision is silent on whether costs may be considered, and the Court concluded that, under *Chevron*, EPA's interpretation had to be upheld if reasonable.[166] In doing so, the Court rejected the argument that statutory silence should normally be taken to prohibit the consideration of costs and instead held that the issue must be considered in light of the statute as a whole.[167] *Entergy* did not, however, create a general presumption in favour of cost-benefit analysis. Instead, as in earlier cases,[168] the Court's analysis

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[164] Sunstein, 'Regulating Risks after "ATA"' [2001] Sup.Ct.Rev. 1; Sunstein (n.162); Sunstein, 'Is the Clean Air Act Unconstitutional?' (1999) 98 Mich.L.Rev. 303.

[165] Above n.160.

[166] Ibid., 218–19.

[167] Ibid., 222–23.

[168] In at least two earlier cases, the Supreme Court rejected arguments that statutory ambiguity should normally be construed to require cost-benefit analysis: *Whitman* (n.153), 464–71 and *Cotton Dust* (n.100), 508–12. Additionally, the Court declined to address the issue in *Benzene*

focused on specific statutory language, rather than on generalities about good regulatory policy. Indeed, although the court approved EPA's specific interpretation—i.e., that the agency could consider whether the costs of a particular technology were "significantly greater than the benefits"—it also expressed scepticism that "a more rigorous form of cost-benefit balancing" would be consistent with the Clean Water Act's protective goals.[169]

The Supreme Court clarified *Entergy* somewhat in its recent decision in *Michigan v. EPA*.[170] First, the Court held that "expansive" terms, such as "appropriate and necessary", should normally be interpreted to require the consideration of cost, though not necessarily cost-benefit analysis.[171] Second, the Court, relying on *Whitman v. American Trucking Associations*,[172] held that when Congress instructs the agency to regulate on the basis of a factor that "on its face does not include cost, the Act normally should not be read as implicitly allowing the Agency to consider cost anyway".[173] These holdings suggest that the Supreme Court continues to view the question whether a statute requires cost-benefit analysis to be one that needs to be decided on a case-by-case basis. More importantly, it indicates that the Court considers the use of cost-benefit analysis *vel non* to be an issue of regulatory policy for which general legal presumptions are inappropriate.

Regarding the requirements of the APA, the Court held unanimously in *Michigan v. EPA* that administrative decisions that failed to consider costs "*at all*" would normally be arbitrary and capricious, unless

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(n.120), 609. Sunstein distinguished these cases on the ground that the statutes at issue all clearly precluded the consideration of costs. Sunstein (n.162), 1670–71, 1683–85.

[169] Entergy (n.160), 223.

[170] 135 S.Ct. 2699 (2015).

[171] Ibid., 2709, 2711.

[172] Above n.153.

[173] Ibid., 2709. This aspect of *Michigan* calls into question the D.C. Circuit's "settled law" that "only where there is clear congressional intent to preclude consideration of cost [will the court] find agencies barred from considering costs". *Michigan v. EPA*, 213 F.3d 663, 667 (D.C.Cir.2000).

Congress had precluded the consideration of cost.[174] Notably, however, the Court also held that how costs are considered is a matter for the agency's discretion, and it specifically declined to require cost-benefit analysis.[175] That holding is consistent with the case law in the courts of appeals. While the lower courts have held that costs are normally a "relevant factor"[176] that must be considered, they have also uniformly declined to interpret the APA to require cost-benefit analysis.[177] As with the question whether statues should be interpreted in a precautionary manner, the courts have shown a distinct lack of appetite for wading into an area of regulatory practice they see as primarily dependent on policy considerations.

In sum, the traditional sources of US law cannot be characterised being as based on or expressing a strong preference for cost-benefit analysis. At the same time, however, these sources of law invite, and sometimes require, administrative agencies to consider costs in a variety of ways. It is also true that in cases of ambiguity courts have usually allowed agencies to consider costs (though not necessarily to engage in strict cost-benefit balancing). But courts have not created horizontal legal requirements that agencies use cost-benefit analysis. Rather, like the precautionary principle, the use of cost-benefit analysis is understood as a question of policy on which the judiciary should take no position. One consequence of treating cost-benefit analysis as a matter of policy is that the role of costs in US regulation will depend heavily on current political preferences. Indeed, as will be explained in the next section, those preferences have pushed US risk regulation toward greater use of cost-benefit analysis.

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[174] *Michigan* (n.170), 2706; ibid., 2714 (Kagan, J., dissenting) (agreeing with the majority that agencies must normally consider cost).
[175] *Michigan* (n.170), 2711.
[176] *State Farm* (n.116), 43.
[177] E.g., *National Association of Home Builders* (n.141), 1039–40; *Village of Barrington v. Surface Transportation Board*, 636 F.3d 650, 670–71 (D.C.Cir.2011); *ConocoPhillips Co. v. EPA*, 612 F.3d 822, 838–42 (5th.Cir.2010).

3. Executive Orders mandating cost-benefit analysis

Although statute and judge-made law rarely require cost-benefit analysis, every president, Democrat and Republican, since Richard Nixon has used Executive Orders (EOs) to require the administration to engage in cost-benefit analysis in some situations.[178] Since 1981, those policies have been generalised to apply to most regulatory activities.[179] The most important of the orders, EO 12,866 issued by President Clinton in 1993, contains a "Statement of Regulatory Philosophy and Principles" that all agencies should follow to the extent permitted by law. That Statement covers a wide range of principles of good regulation, including public participation, transparency, and federalism. Perhaps most prominent, however, is cost-benefit analysis.

It is important at the outset to understand the legal status of EOs. They are instructions from the president, as chief executive, to subordinate government officials. Practically, if not legally, they are binding on the officers and agencies to whom they are addressed,[180] but they cannot bind the public or organs of the government that do not fall under the president's authority. Unless they clearly provide to the

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[178] This history and development of executive direction of regulatory policy is reviewed in McGarity, *Reinventing Rationality* (CUP 1991) 17–25 and Copeland, 'The Role of the Office of Information and Regulatory Affairs in Federal Rulemaking' (2006) 33 Ford.Urb.L.J. 1257.

[179] The dynamic nature of the OIRA process is illustrated by the history of revisions to the EOs creating general cost-benefit analysis requirements. The first such order was EO 12,291, 46 Fed. Reg. 13,193 (Feb. 17, 1981), issued by President Reagan. President Clinton repealed and replaced that order with EO 12,866, 58 Fed. Reg. 51,735 (Sept. 30, 1993). President Bush made minor procedural changes in EO 13,258, 67 Fed. Reg. 9,385 (Feb. 26, 2002) and issued further substantive amendments in EO 13,422, 72 Fed. Reg. 2,763 (Jan. 18, 2007). President Obama revoked the Bush amendments in EO 13,497, 74 Fed. Reg. 6,113 (Jan. 30, 2009), so that EO 12,866 is currently effective in its original form. In 2011, President Obama issued EO 13,563, 76 Fed. Reg. 3,821 (Jan. 21, 2011), which supplements EO 12,866.

[180] The extent to which EOs legally bind officials in agencies other than the Executive Office of the President is an unresolved question. Strauss, 'Overseer or "The Decider"? The President in Administrative Law' (2007) 75 Geo.Wash.L.Rev. 696, 716–17.

contrary, EOs do not create legal rights and normally cannot be enforced judicially.[181] They are internal executive branch directives and, as such, they are interpreted, applied, and enforced by the executive branch.[182]

EO 12,866 should thus be understood as a set of instructions from the president to federal agencies regarding how they should go about exercising their regulatory authority. Regarding cost-benefit analysis, section 1(b)(6) provides:

> Each agency shall assess both the costs and the benefits of the intended regulation and, recognizing that some costs and benefits are difficult to quantify, propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs.

That provision unambiguously requires agencies to use cost-benefit analysis, but to understand what that means, one must delve further. Several points are important:

First, the requirements of EO 12,866 apply only "to the extent permitted by law".[183] Executive orders cannot amend or override higher sources of law, and judicial review may be invoked to set aside agency action that follows an EO but violates a statute.[184] EO 12,866 therefore does not override statutory provisions that either prohibit the use of cost-benefit analysis or constrain the way in which it is used. Second, the order does not mandate fully quantitative cost-benefit analysis. Section 1 provides that "[c]osts and benefits shall be understood to include both quantifiable measures (to the fullest extent that these can be usefully estimated) and qualitative measures of costs and benefits that are difficult to quantify, but nevertheless essential to consider".[185] President Obama's EO 13,563 reinforced this point by stating that "each agency

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[181] *Helicopter Association International, Inc. v. FAA*, 722 F.3d 430, 439 (D.C.Cir.2013).

[182] On the legal status of executive orders, see Stack, 'The Statutory President' (2005) 90 Iowa.L.Rev. 539, 585–99.

[183] EO 12,866, section 1(b).

[184] Whitman (n.157), 471 n.4.

[185] EO 12,866, section 1(a).

may consider (and discuss qualitatively) values that are difficult or impossible to quantify, including equity, human dignity, fairness, and distributive impacts".[186] Third, EO 12,866 does not require agencies to make decisions solely on the basis of cost-benefit analysis. Instead, it requires them to make a "reasoned determination" that the benefits of regulation "justify its costs". The use of the term "justify" was a purposeful change from President Reagan's EO 12,291, which on its face required a showing that benefits exceed costs.[187] Additionally, EO 13,563 emphasises that when comparing costs and benefits, agencies must consider "potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity".[188] Thus, the orders by their terms require only a fairly weak form of cost-benefit analysis and are unspecific regarding when benefits will "justify" costs. Above all, the terms used in the EOs are ambiguous, so that their practical meaning depends on how they are applied by the current administration.

EO 12,866 is enforced through a regulatory review process run by the Office of Information and Regulatory Affairs (OIRA). OIRA is a division of the Office of Management and Budget, which is itself a component of the Executive Office of the President. OIRA applies and enforces the EOs by reviewing agencies' regulatory measures before they are published. The OIRA review process covers the entire substance of the proposed action, and OIRA will frequently use the review process to solicit input on the proposal from other parts of the executive branch.[189] According to three recent OIRA Administrators, cost-benefit analysis is often not the central

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[186] EO 13,563, section 1(c).
[187] EO 12,291, section 2(b); DeMuth and Ginsburg, 'White House Review of Agency Rulemaking' (1986) 99 HLR 1075, 1075; Pildes and Sunstein, 'Reinventing the Regulatory State' (1995) 62 U.Chi.L.Rev. 1, 43–45.
[188] EO 13,563, section 1(b)(4).
[189] Sunstein, 'The Office of Information and Regulatory Affairs: Myths and Realities' (2013) 126 HLR 1838, 1844–68.

concern of OIRA reviews.[190] That said, cost-benefit analysis of the proposed action is an important aspect of the process. OIRA checks that the agency's analysis has been prepared in accordance with the EOs and OIRA guidance documents. It also assesses the adequacy of the agency's conclusion that benefits justify costs, and may ask the agency to undertake further analysis in that regard. According to most accounts, the majority of OIRA's analysis is focused on technical concerns, but political considerations, i.e., the alignment of the proposed action with the president's policy preferences, are important as well. At the conclusion of its review, OIRA may clear an action as proposed or may suggest changes to the originating agency.[191] If agreement on changes is not reached, the agency may withdraw the action, or OIRA may "return" it for reconsideration. Normally, when an action is withdrawn or returned, the agency will not proceed without making substantial changes and reinitiating OIRA review. There are examples, however, of agencies going ahead with returned actions, despite failing to secure OIRA clearance.[192]

The ambiguous language of the EOs allows OIRA to apply the review process differently depending on the policy views and regulatory priorities of the current president. Whereas OIRA under Presidents Reagan and George H.W. Bush tended to emphasise quantification and to demand a showing that regulatory benefits exceeded costs, the Clinton Administration OIRA tended to apply cost-benefit analysis more holistically and to put greater stress on distributive concerns.[193] Similar changes in emphasis can be observed in the George W. Bush and Obama administrations.[194] In other words, EO 12,866's cost-benefit analysis mandate is flexible enough to accommodate different presidents' policy priorities, and OIRA review is one means by which the White House

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[190] Ibid., 1868–69; Graham (n.153), 458–59, 465–66; Katzen, 'OIRA at Thirty: Reflections and Recommendations' (2011) 63 Admin.L.Rev. 103, 105–08.
[191] Sunstein (n.189), 1854–59.
[192] Copeland (n.178), 1278.
[193] Katzen (n.190), 104.
[194] Compare Graham (n.153), 456–59, with Sunstein (n.189), 1864–66.

exercises control over policymaking throughout the administration.[195] The EOs are designed to facilitate this process of policy transfer; they are couched in such general terms that changes in the application of cost-benefit analysis can occur without any formal legal action (such as a new EO) or even any public acknowledgement that a change has been made. Recall that President Bush retained President Clinton's EO 12,866 with only minor changes, yet the practice of review differed considerably in the two administrations.[196]

Cost-benefit analysis in US administrative law should therefore be understood primarily as a managerial tool that facilitates the transmission of presidential policy preferences across a large bureaucracy, rather than as a well-defined regulatory philosophy. That is not to say that the substantive commitments to cost-benefit analysis set forth in the EOs are not genuine. Ronald Reagan and his advisors believed that regulation could only be justified if it increased net social welfare,[197] just as Barak Obama and his advisors believe that the systematic assessment of regulatory benefits and costs will result in better public policy.[198] But although the substantive commitment to cost-benefit methodology should not be gainsayed, it should not be allowed to obscure the more important control and coordination functions served by the OIRA process.

Although the US courts have not mandated the use of cost-benefit analysis, they have facilitated its rise to prominence. By drawing a sharp distinction between questions of law and questions of policy, US administrative law has allowed successive administrations to pursue their preferred regulatory philosophies with minimal judicial interference. The courts' jurisprudence has also promoted a pluralist conception of the public interest, which tends to focus on maximising social welfare rather

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[195] Kagan, 'Presidential Administration' (2001) 114 HLR 2245, 2284–2309.
[196] General Accounting Office, *Rulemaking: OMB's Role in Reviews of Agencies' Draft Rules and the Transparency of Those Reviews* (GPO 2003) 5.
[197] DeMuth and Ginsburg (n.187), 1080–82.
[198] Sunstein (n.97), 19–27.

than on prioritising particular public values. US administrators may trade-off values like environmental protection to advance other public goals such as full employment without transgressing legal conceptions of the public good. Further, by increasingly focusing on the president's democratic mandate as a source of administrative legitimacy, US administrative law has encouraged presidents to be more assertive in enforcing their policy views throughout the administration.[199] If administrative policymaking is legitimated by presidential leadership, then *a fortiori* it is appropriate for presidents to insist that their policy preferences are followed.

C. Cost-Benefit Analysis in the EU

In general, the use of cost-benefit analysis has a lower profile in the EU than in the US. Nonetheless, it would be wrong to assume that cost-benefit analysis plays no role in EU risk regulation. As in the US, there are few legal mandates that regulators use cost-benefit analysis. Since the announcement of the Lisbon Strategy in 2000, however, the Commission has increased its reliance on cost-benefit analysis as a component of regulatory impact analysis. As with the EO 12,866 process, the Commission's use of impact analysis appears to be directed, at least in part, towards reinforcing the Commission's policy priorities throughout the regulatory process.

1. Treaty and legislative provisions

In general, the Treaties have little to say regarding the use of cost-benefit analysis. An important exception, however, is Article 191(3) TFEU which provides that "[i]n preparing its policy on the environment, the Union shall take account of . . . the potential benefits and costs of action or lack of action". This provision is applicable to the EU's environmental policy and any legislation adopted in accordance with that policy.[200] There is

[199] Kagan (n.195), 2372–83.
[200] Case T-370/11, *Poland v. Commission*, nyr, paras. 108–09.

almost no case law interpreting Article 191(3).[201] On its face, however, it only requires that the EU consider costs when regulating and does not mandate strict cost-benefit analysis.

As in the US, EU risk legislation takes a variety of approaches to the consideration of costs. Much legislation, especially older legislation, is silent on the issue.[202] While such silence does not necessarily preclude the consideration of costs,[203] the administration may not rely on cost considerations to undermine legislative objectives.[204] The trend in more recent legislation is to require consideration of costs in some form. For example, the Industrial Emissions Directive defines "best available techniques" for pollution control to mean (in relevant part) "those developed on a scale which allows implementation in the relevant industrial sector, under economically and technically viable conditions, taking into consideration the costs and advantages".[205] Other legislation qualifies regulatory requirements by providing that they should not require "disproportionate costs"[206] or "significant economic or practical disadvantage".[207] Somewhat more obliquely, REACH embeds a requirement to consider costs within a requirement for a broader

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[201] The Court of Justice has occasionally mentioned the provision without analysing it in detail. E.g., ibid., paras. 110–11.

[202] E.g., Directive 67/548/EEC on the approximation of laws &c. relating to the classification, packaging and labelling of dangerous substances [1967] O.J. Spec. Ed. 234; Directive 76/160/EEC concerning the quality of bathing water [1976] O.J. L31/1; Regulation (EEC) 793/93 on the evaluation and control of the risks of existing substances [1993] O.J L84/1.

[203] Case T-257/07, *France v. Commission* [2011] ECR II-5827, para. 221.

[204] Joined Cases C-14/06 and C-295/06, *Parliament v. Commission* [2008] ECR I-1649, paras. 74–76.

[205] Directive 2010/75/EU on industrial emissions (integrated pollution prevention and control) (Recast) [2010] O.J. L334/17, art. 3(10)(b). The same definition is used for purposes of the Waste Directive (n.81), art. (3)(20).

[206] E.g., Directive 2008/50/EC on ambient air quality and cleaner air for Europe [2008] O.J. L152/1, arts. 15(1), 16(1), 17(1).

[207] E.g., Biocides Regulation (n.33), art. 23(3)(a); a similar formulation is used in Regulation (EC) 1107/2009 concerning the placing of plant protection products on the market &c. [2009] O.J. L291/1, art. 50(1)(b).

socioeconomic analysis.[208] Still other legislation requires the Commission to study the costs of regulation without specifying how they should factor into subsequent regulatory decisions.[209] As far as my research shows, no EU risk legislation requires decisions to be made on the basis of cost-benefit analysis.[210]

In recent legislation, it seems that costs are most frequently used as a basis for making exceptions to risk standards, rather than as the basis for setting the standards themselves. For example, the Biocides Regulation generally requires substitution of less risky products for more risky products, unless such substitution would result in "significant economic or practical disadvantages".[211] These provisions can be interpreted as relying on cost as a safety valve: standards should in principle be set without regard to cost. If, however, the cost in a particular case would be disproportionate, the requirement can be relaxed if the risk is otherwise acceptable. Understood in that way, these provisions are expressions of both Article 191(3) TFEU and the proportionality principle. It also suggests the EU Legislature believes costs are relevant to risk regulation but should be secondary considerations, an attitude that is consistent with the courts' holding that the "protection of public health must unquestionably take precedence over economic considerations".[212]

2. Judicial requirements

In addition to the Treaties and legislation, the EU courts have addressed the consideration of costs in risk regulation. Most importantly, all EU acts must be in conformity with the principle of proportionality, which is

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[208] REACH (n.33), art. 68(1) (restrictions process).
[209] E.g., Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms &c. [2001] O.J. L106/1, art. 31(7)(d).
[210] Wiener, 'Better Regulation in Europe' (2006) 59 CLP 447, 467.
[211] Biocides Regulation (n.33), art. 23(3)(a). For a similar approach, see REACH (n.33), art. 60(4).
[212] See cases cited n.46.

perhaps the most fundamental general principle of EU law.[213] As summarised by Advocate General Poiares Maduro, "the principle of proportionality entails a consideration of the costs and benefits of a measure . . . in the light of the different interests which Community rules deem worthy of protection".[214] Proportionality in EU law is generally described as a three-part inquiry. First, the measure in question must be appropriate for achieving a legitimate public purpose. Second, it must be the least restrictive alternative available. Finally, the restrictions imposed must not be disproportionate to the aims to be achieved.[215]

Interpreted rigidly, proportionality might result in a fairly rigorous form of cost-benefit balancing. As applied by the EU courts, however, proportionality is much more flexible. For one thing, proportionality is not concerned with costs and benefits as such, but with those "interests which Community rules deem worthy of protection".[216] The "costs" to which proportionality is principally addressed are not economic costs, but rather restrictions on protected interests, including economic liberty.[217] The two are of course related, but it seems that the monetary costs need not be considered independently of a measure's impact on protected interests. For example, although the Court of Justice has never decided the issue, two Advocates General have suggested that proportionality does not preclude risk regulation measures based solely on an assessment of health effects.[218] The courts also show flexibility by

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[213] Tridimas (n.30), 136–39; *see also* Case C-120/94, *Commission v. Greece* [1996] ECR I-1513, Opinion of A.G. Jacobs, para. 70 ("As for the principle of proportionality, there are few areas of Community law, if any at all, where that is not relevant.").

[214] Case C-434/04, *Criminal proceedings against Ahokainen* [2006] ECR I-9171, Opinion of A.G. Poiares Maduro, para. 23.

[215] Craig, *EU Administrative Law* (2d ed., OUP 2012) 591–92; de Búrca, 'The Principle of Proportionality and its Application in EC Law' (1993) 13 YEL 105, 113–14. Note that the third step of the analysis is frequently omitted in the EU case law. Tridimas (n.30), 139.

[216] *Ahokainen* (n.214), Opinion of A.G. Poiares Maduro, paras. 23–26; de Búrca (n.215), 106–07.

[217] Ibid.; Tridimas (n.30), 139.

[218] Case C-127/05, *Commission v. United Kingdom* [2007] ECR I-4619, Opinion of A.G. Mengozzi, para. 140; Case C-434/02, *Arnold André*

according the other Institutions a great deal of leeway in their assessment of the second and third prongs of the analysis.[219] In the risk regulation context, the courts have gone so far as to indicate that a measure will not be held to be disproportionate unless the Institutions have made a manifest error of assessment.[220]

The link between proportionality and cost-benefit analysis was explored to some extent in *Pfizer* and *Alpharma*. The General Court raised eyebrows in those cases when it stated that it "considers that a cost/benefit analysis is a particular expression of the principle of proportionality in cases involving risk management".[221] Further, the Council's apparent concession that "the Community institutions were obliged to carry out such an analysis", suggested agreement that an obligation existed to conduct cost-benefit analysis.[222] Despite these indications, however, no robust cost-benefit analysis requirement has emerged in the case law.

In hindsight, the General Court's focus in *Pfizer* and *Alpharma* on cost-benefit analysis appears to have been more a product of how the litigants framed their arguments than the articulation of a legal rule.[223] To begin with, the court at no point suggested that it understood "cost/benefit analysis" to mean formal cost-benefit analysis, much less quantitative cost-benefit analysis. Instead, the court seemed to find sufficient the general weighing of the advantages and disadvantages contained in various international reports on antibiotics as livestock growth promoters.[224] Additionally, the court seemed less concerned with the economic effects of the ban and more with unintended adverse consequences or "risk-risk trade-offs". That point came across more

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GmbH & Co. KG v. Landrat des Kreises Herford [2004] ECR I-11825, Opinion of A.G. Geelhoed, para. 63.

[219] Craig (n.215), 593–99; Tridimas (n.30), 142–49.

[220] E.g., *Gowan* (n. 48), para. 82; *Pfizer* (n.39), para. 412.

[221] *Alpharma* (n.46), para. 323; *Pfizer* (n.39), para. 410.

[222] *Alpharma* (n.46), para. 322; *Pfizer* (n.39), para. 409. See also Communication on the Precautionary Principle (n.61), 18–19.

[223] *Alpharma* (n.46), para. 321; *Pfizer* (n.39), para. 408.

[224] *Alpharma* (n.46), para. 263; *Pfizer* (n.39), para. 469.

clearly in *Alpharma*, in which the applicant alleged that banning antibiotics as growth promoters would lead to increased cases of salmonella poisoning.[225] Finally, in the dozen years since *Alpharma* and *Pfizer* were decided, the courts have done nothing to develop the suggestion that proportionality requires cost-benefit analysis, and very few risk cases even mention cost-benefit analysis.[226] As the case law currently stands, proportionality cannot be said to require cost-benefit analysis in any strict sense.

3. Better Regulation and Commission initiatives on impact assessment

As in the US, the main impetus for the increased use of cost-benefit analysis in EU regulation has come not from the courts or the legislature, but from the executive. As part of its Better Regulation initiative, the Commission has imposed on itself a requirement to conduct impact analyses as part of its development of regulatory proposals.[227] Although the Commission tends to avoid the term cost-benefit analysis,[228] quantitative assessment of costs and benefits is often a significant component of impact assessment.

Greater use of impact assessment is a central component of the Commission's efforts to implement the Lisbon Strategy, under which the EU aims to be "the most competitive and dynamic knowledge-based economy in the world, capable of sustainable economic growth with more

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[225] *Alpharma* (n.46), paras. 327–39. On risk-risk trade-offs, see Graham and Wiener, *Risk Versus Risk: Tradeoffs in Protecting Health and the Environment* (Harvard 1995).

[226] My research found no risk regulation case since *Alpharma* and *Pfizer* in which cost-benefit analysis was significantly discussed. One case currently pending before the General Court appears to raise the issue. Case T-429/13, *Bayer CropScience AG v. Commission* [2013] O.J. C325/37.

[227] European Commission, Communication, 'Better Regulation for Better Results—An EU Agenda' COM(2015) 215 final; see also Meuwese, *Impact Assessment in EU Lawmaking* (Kluwer 2008) 20–22.

[228] Lee, 'Experts and Publics in EU Environmental Law' in Arnull and Chalmers (eds.), *The Oxford Handbook of EU Law* (OUP 2015) 1001.

and better jobs and greater social cohesion".[229] Both the Lisbon Strategy and Better Regulation are responses to perceived economic weakness in the EU, particularly sluggish growth and high unemployment. As in the US at the end of the 1970s, overregulation has often been identified (rightly or wrongly) as a prime contributor to this stagnation. The move toward greater use of impact analysis has also been driven, in part, by the experience of some Member States, particularly the Netherlands, Sweden, and the United Kingdom, as well as by the OIRA process.[230]

The Commission first outlined its approach to impact assessment in its 2002 Communication on Impact Assessment.[231] Following a pilot programme, the Commission issued Impact Assessment Guidelines in 2005,[232] and updated these in 2006 and 2009. In May 2015, the Commission replaced these with new Better Regulation Guidelines.[233] Under the new Guidelines, an impact assessment "is required for Commission initiatives that are likely to have significant economic, environmental or social impacts".[234] The form of the action is immaterial, "impact assessments should be carried out for both legislative and non-legislative initiatives as well as delegated acts and implementing measures, taking into account the principle of proportionate analysis".[235] The 2015 Guidelines' extension of the impact assessment process to delegated acts is an important change from previous practice, in which the focus of the impact assessment process was on the preparation of

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[229] Presidency conclusions, Lisbon European Council (March 23–24, 2000), para. 5, http://www.europarl.europa.eu/summits/lis1_en.htm.
[230] Rowe, 'Tools for the Control of Political and Administrative Agents: Impact Assessment and Administrative Governance in the European Union' in Hofmann and Türk (eds.), *EU Administrative Governance* (Edward Elgar 2006), 451–52; Wiener (n.210), 469–71.
[231] COM(2002) 276 final.
[232] European Commission, Impact Assessment Guidelines, SEC(2005) 791.
[233] SWD(2015) 111 final.
[234] Ibid., 17.
[235] Ibid.

legislation, and its use for implementing measures was optional and inconsistent.[236]

Each Directorate General is responsible for preparing the impact assessment for its own proposals.[237] All impact assessments are reviewed by the Regulatory Scrutiny Board,[238] which is composed of the Chair, three Commission officials, and three independent members, all of whom are appointed by the College of Commissioners on the recommendation of the Commission President.[239] The Regulatory Scrutiny Board performs "its tasks independently and prepare[s] its opinions autonomously from any national or European institution, body, office or agency".[240] The Board issues opinions on the quality of impact assessments and may make suggestions for revision or improvement. A positive opinion of the Board is necessary before an interservice consultation can proceed, thus giving the Board significant power to hold up proposals.[241] The impact assessments are also reviewed by the other DGs as part of the interservice consultation, and some DGs have issued negative opinions on proposals based on the results of an impact assessment or on the basis that the impact assessment is inadequate.[242]

An impact assessment will often, but not always, include a cost-benefit analysis. The 2015 Guidelines and accompanying "Toolbox" provide extensive guidance regarding how impacts, both positive and negative, are to be identified, assessed, and weighed.[243] Although the Guidelines require that "[a]ll relevant impacts should be assessed

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[236] Alemanno and Meuwese, 'Impact Assessment of EU Non-Legislative Rulemaking: The Missing Link in "New Comitology"' (2013) 19 ELJ 76, 79–81.
[237] Better Regulation Guidelines (n.233), 17.
[238] Ibid., 18.
[239] Decision of the President of the European Commission on the establishment of an independent Regulatory Scrutiny Board, C(2015) 3263 final, art. 3.
[240] Ibid., recital 4, art. 4.
[241] Better Regulation Guidelines (n.233), 16.
[242] Ibid., 9; Meuwese (n.227), 72.
[243] Better Regulation Guidelines (n.233), 24–30; European Commission, Better Regulation Toolbox (2015), http://ec.europa.eu/smart-regulation/guidelines/toc_tool_en.htm, 96–233.

quantitatively, if possible",[244] they also recognise that quantitative cost-benefit analysis is not always suitable.[245] Additionally, the Guidelines stress the importance of including unquantified impacts in the evaluation of proposals.[246] Despite these caveats, the Better Regulation Guidelines place noticeably greater emphasis on quantification than did the 2009 Impact Assessment Guidelines.[247] The 2015 Guidelines also provide greater detail on the classes of impacts that must be assessed, helping to align the impact assessment process with the political priorities set forth in the Commission's 2015 Communication on Better Regulation, including subsidiarity, regulatory simplification, and a preference for market-based regulation. The political nature of the Better Regulation programme is also underscored by the Guidelines' clear statement that impact assessments are informational only and that regulatory decisions are ultimately a matter of political judgment.[248]

The Commission's choice to rely on soft law instruments to give substantive content to the impact assessment process is significant for two reasons: First, it arguably (see below) cuts the EU courts out of the process of interpreting the Better Regulation requirements, leaving their content and application solely in the hands of the Commission. Second, the use of soft law instruments gives the Commission significant flexibility to withdraw or amend those instruments to reflect changing political priorities without needing to engage in lengthy procedures. This malleability enhances the usefulness of the impact assessment process as a means of transmitting political priorities, suggesting a parallel between the Commission's use of impact assessment and OIRA's use of cost-benefit analysis.

The new Better Regulation programme raises a number of legal questions, including the extent to which the Commission's compliance with the Better Regulation Guidelines may be subject to judicial review.

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[244] Better Regulation Guidelines (n.233), 27.
[245] Ibid., 27–28.
[246] Ibid., 28.
[247] Cf., e.g., European Commission, Impact Assessment Guidelines, SEC(2009) 92, at 32.
[248] Better Regulation Guidelines (n.233), 4.

Historically, the Commission has taken the position that the procedural commitments it makes in soft law instruments like the Guidelines do not create rights in individuals and are not judicially enforceable.[249] Alemanno nonetheless argues that by purporting to impose procedural requirements on itself, the Commission has opened itself up to review of its compliance with those requirements. He notes that in the past the courts have enforced procedural rules contained in soft law instruments in cases brought under the Staff Regulations and in competition enforcement proceedings. Relying on those precedents, Alemanno argues that various general principles of law, including equal treatment and legitimate expectations, create a legal basis for the courts to enforce compliance with purportedly nonbinding guidelines.[250]

To date, the question of reviewability has not been answered by the EU courts. A few points seem important, however. First, as Alemanno acknowledges, it would be one thing for the courts to enforce the Guidelines procedurally and another for them to review the substance of an impact assessment. For reasons discussed in the next chapter, the courts are much more likely to undertake the former than the latter. Second, the precedents on which Alemanno relies all address circumstances in which individuals were asserting a right to certain procedural protections. Many regulatory measures are of general applicability, however, and it is less clear that soft law guidelines can be considered binding in that context.[251] Finally, if the courts determine that the Guidelines are judicially enforceable it could, depending on the nature of review, limit their usefulness as a means for transmitting policy preferences. The greater the courts' willingness to review compliance with the Guidelines, the more restricted will be the Commission's flexibility to modify them in response to current political priorities. Judicial review

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[249] Alemanno, 'The Better Regulation Initiative at the Judicial Gate: A Trojan Horse Within the Commission's Walls or the Way Forward?' (2009) 15 ELJ 382, 392.
[250] Ibid., 392–94.
[251] Nehl, *Principles of Administrative Procedure in EC Law* (Hart 1999) 48–49.

could thus result in the impact assessment process taking on a more legalistic and entrenched character than the OIRA process.

D. American and European Approaches Compared

Unlike the two systems' approaches to the precautionary principle, which rest on fundamentally different premises, the approaches taken by US and EU administrative law to cost-benefit analysis are broadly similar. In neither system is cost-benefit analysis legally required, although both systems generally allow the administration to rely on the technique when doing so would not run contrary to legislative mandates.

Despite its minor significance as a legal principle, cost-benefit analysis has become an important part of regulatory practice on both sides of the Atlantic as a result of executive action. As such, the use of the technique tends to respond to executive interests. Both administrations use cost-benefit analysis as means of policy coordination and harmonisation across large bureaucracies. By issuing detailed guidance and instituting centralised review processes, executives in both jurisdictions are able to reinforce their political priorities by controlling the process of regulatory analysis. Both administrations have also used the technique to respond to criticisms that regulatory programmes are either poorly designed or serve special interests at the expense of the commonweal.[252] Finally, the increased prominence of cost-benefit analysis in both systems can be seen as a reaction to the rise of an accountability culture that increasingly demands extensive, analytical, and preferably numerical justification for regulatory action.[253]

Although there are strong parallels in the use of cost-benefit analysis in the US and the EU, it is important to underscore that those parallels are mostly procedural. Because both administrations use cost-benefit analysis as a tool for transferring political priorities, the way in which cost-benefit analysis is applied in the two jurisdictions will vary to reflect

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[252] Pildes and Sunstein (n.187), 3–4; Meuwese (n.227), 20–23.
[253] Harlow, *Accountability in the European Union* (OUP 2002); McGarity (n.178), 3–16; Fisher, 'Drowning by Numbers: Standard Setting in Risk Regulation and the Pursuit of Accountable Public Administration' (2000) 20 OJLS 109, 126–29.

different policy preferences and political pressures. It is by no means clear that a cost-benefit analysis approved by OIRA and one approved by the Regulatory Scrutiny Board would reach the same conclusions. Consequently, any comparison of the technique in the two jurisdictions must look beyond labels to the details of administrative practice.

III. Conclusion

The precautionary principle and cost-benefit analysis are important in both EU and US risk regulation, but contrasting US and EU law on risk regulation solely in terms of those concepts can be seriously misleading. Numerous examples of both precautionary and cost-benefit approaches can be found in both systems, and attempts to understand differences between the two solely in terms of those concepts will inevitably be inconclusive.[254]

Viewed from the perspective of administrative law, we can see that instead of defining different substantive approaches to risk regulation, the differences between the EU and US legal systems with respect to the roles of precaution and cost-benefit analysis lie in the ways in which those concepts are used to justify and legitimate the exercise of regulatory power. Stated broadly, EU administrative law places significant emphasis on the principle of legality as a source of administrative legitimacy. Within this framework, the precautionary principle performs an important function by authorising regulatory intervention in cases of uncertainty and by providing justiciable guidance for the exercise of administrative discretion. US administrative law, by contrast, is relatively sceptical about the ability of law to guide regulatory aims. Instead, it relies more heavily on the democratic mandate the administration derives from its oversight by the elected president. One consequence of this theory of administrative legitimacy is that issues of precaution tend to be treated as questions of policy rather than law, leaving little room for precaution as a legal principle. Although these

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[254] Compare, e.g., Wiener, Rogers, Hammitt, and Sand (eds.), *The Reality of Precaution: Comparing Risk Regulation in the United States and Europe* (RFF 2011), with Vogel, *The Politics of Precaution* (Princeton 2012).

characterisations do much to explain the different approaches to precaution taken in EU and US administrative law, it is important to bear in mind that these are only tendencies and not stark contrasts. Both jurisdictions care about law and about democracy.

Cost-benefit analysis, by contrast, illustrates an area in which the EU and US administrations have faced broadly similar problems and pursued similar solutions. Administrative law in both jurisdictions has facilitated greater use of cost-benefit analysis without appreciably shaping how it is applied. Rather than responding to legal requirements, the use of cost-benefit analysis on both sides of the Atlantic has largely been a response to criticisms of the quality of regulatory policymaking as well as demands for greater accountability. Executives in both jurisdictions have also used the inherent flexibility of cost-benefit analysis methodology to transmit policy preferences throughout the administration. As long as administrators continue to see them as useful tools for meeting their political and policy objectives, cost-benefit analysis and impact assessment are likely to remain prominent features of both EU and US regulatory practice.

4

Administrative Rationality and Risk Regulation

In this chapter, the focus of the analysis turns from substantive legal principles applicable to administrative risk regulation to the process of administrative decisionmaking. In both the US and the EU, administrative decisionmaking, to be lawful, must be "rational", or "reasonable", or "non-arbitrary".[1] That obligation, which derives from the rule of law, can be understood to require that administrative action be explainable as a process of rational decisionmaking.[2] Some commentators have gone further and linked the requirement of administrative rationality to fundamental rights by describing it as a right to a certain type of administrative decisionmaking process.[3]

Although the requirement of rational administrative decisionmaking is well-established, its content is hard to pin down. Taken in the abstract, the term "rational" connotes a decision grounded in reasons and logic, and indeed, for an administrative decision to be rational it must be backed by reasons and those reasons must logically support the regulatory outcome. But the administrative law demand for rationality goes deeper. It is not sufficient that the administration give reasons; they

[1] Craig, *EU Administrative Law* (2d ed., OUP 2012) 408–15; II Pierce, *Administrative Law Treatise* (4th ed., Aspen 2002) 767–814.
[2] *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 415–17 (1971); Case 46/87, *Hoechst v. Commission* [1989] ECR 2859, para. 19.
[3] Azoulay, 'The Judge and the Community's Administrative Governance' in Joerges and DeHousse (eds.), *Good Governance in the European Union* (OUP 2002) 112–14; Sunstein, *After the Rights Revolution* (Harvard 1993) 28–30.

must also be the right kinds of reasons.[4] Some of these requirements are uncontroversial. For example, for a decision to be rational in the administrative law sense, the reasons given for it must show that it was plausibly in the public interest.[5] They must also show that the action was consistent with the administrator's legal mandate as specified in applicable legislation.[6] Courts reviewing an administrative decision for rationality sometimes go further, however, and consider whether the evidence relied on was sufficient or whether the administration's scientific or economic reasoning was sound.[7] In some cases, courts may even demand that administrators apply particular analytical methodologies or prioritise particular values in their reasoning.[8] As courts become more intensive in their demands for particular forms of rationality, they can come to exercise considerable legal control over both the process and content of administrative decisionmaking.[9]

In both the US and the EU, courts are empowered to answer these difficult questions through their exercise of substantive review. In the US, such review is usually taken under the Administrative Procedure Act's arbitrary and capricious standard[10] and is therefore often referred to as "arbitrariness review". In the EU, rationality review is generally

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[4] Craig (n.1), 412–13; Diver, 'Policymaking Paradigms in Administrative Law' (1981) 95 HLR 393, 401; Shapiro, 'The Giving Reasons Requirement' [1992] U.Chi.L.Forum 179, 185–87.

[5] Harlow, *Accountability in the European Union* (OUP 2002) 8–9; Mashaw, 'Reasoned Administration: The European Union, the United States, and the Project of Democratic Governance' (2007) 76 Geo.Wash.L.Rev. 99, 117–18; cf. Scott and Sturm, 'Courts as Catalysts: Re-Thinking the Judicial Role in New Governance' (2006) 13 Colum.J.Eur.L. 565, 571.

[6] *Massachusetts v. EPA*, 549 U.S. 497, 532–34 (2007); Case C-154/04, *R. ex rel. Alliance for Natural Health v. Secretary of State for Health* [2005] ECR I-6451, para. 90.

[7] E.g., *Gulf South Insulation v. CPSC*, 701 F.2d 1137, 1142–43 (5th.Cir.1983); Case T-229/04, *Sweden v. Commission* [2007] ECR II-2437, paras. 172–81.

[8] E.g., *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201, 1218–19 (5th.Cir.1991); Case C-183/95, *Affish BV v. Rijksdienst voor de keuring van Vee en Vlees* [1997] ECR I-4315, para. 42.

[9] Diver (n.4), 411–13; Shapiro (n.4), 186–88.

[10] 5 U.S.C. § 706; II Pierce (n.1), 805.

conducted under the rubrics of manifest error of assessment and proportionality.[11] Terminology aside, this form of review in both jurisdictions is directed at essentially the same questions: Do the reasons offered by the administration support the decision taken? Are they sufficient to sustain the action? Has the administration dealt adequately with any contrary reasons offered by objectors? The focus of this chapter is on understanding how courts in the two jurisdictions address the substance of these questions in the context of risk regulation.

Rationality review is a fascinating topic for study because the law in this area is almost entirely judge-made. Although legislation often provides guidance on how administrators must approach specific regulatory problems, general principles of administrative decisionmaking, applicable across a range of substantive areas, are far less often specified in legislative or constitutional provisions. Instead, these principles take shape over time as courts decide individual cases by applying their own general suppositions about the public interest, how the administration should further it, and what legal controls on administrative decisionmaking are necessary or appropriate. Because rationality review is the product of judicial decisionmaking, it presents a particularly *legal* view of good administration, in that the values that motivate decisions in this area are drawn from legal sources rather than public policy discourse. Further, judicial understandings of administrative rationality are powerfully shaped by constitutional theories regarding the legitimacy both of regulation and of the administration itself. Rationality review can thus be understood as a prominent, and particularly complex, manifestation of administrative constitutionalism.[12]

In both jurisdictions, understandings of what it means to regulate risk rationally have been highly controversial. In particular, rationality review has been one of the main battlegrounds on which disputes about the proper roles of scientific and policy considerations in risk regulation have been contested, with proponents of various positions hoping to have

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[11] Article 263 TFEU; Craig (n.1), 408–09; 592–93.

[12] Fisher, *Risk Regulation and Administrative Constitutionalism* (Hart 2007) 124.

their vision engrafted into the legal definition of rational risk regulation. These disputes are in part epistemological debates about the capacity of risk science to provide answers to regulatory problems. To a much greater extent, however, these are normative debates about the circumstances in which administrative power may legitimately be exercised to restrict or prohibit activities in which individuals wish to engage. Because these debates take place in the language of rationality, however, their connection to normative commitments about the exercise of state power is not always apparent. One of the objectives of this chapter is to expose those connections.

To make these connections more apparent, this chapter adopts a historical approach. Starting with the US, I show how conflicts over rational risk regulation have evolved in tandem with theories about the legitimacy of the administrative state. I conclude that in contemporary American jurisprudence, risk regulation is understood to require the exercise of both scientific and policy judgment and that administrative rationality requires the coherent exercise of both. Moving to the EU, I again show that understandings of rational risk regulation have evolved alongside changes in the identity and role of the EU administration. Unlike the US courts, however, current EU jurisprudence understands risk regulation as a policymaking activity, although it also requires the administration to seek scientific advice both as a means of informing the administration's policy judgment and as a basis for holding the exercise of that judgment to account. I then compare the consequences of these differing conceptions of administrative rationality.

I. Framing the Problem of Risk Regulation

Before analysing courts' attempts to develop principles of rational risk regulation, it is necessary to address the prior question of framing. As discussed in chapter 1, framing concerns the way in which questions for regulatory analysis, deliberation, and decision are presented and structured.[13] Framing is thus central to ideas about administrative

[13] Chapter 1, section I.B.

rationality because it will determine in large part what constitutes a rational response to a particular regulatory problem.[14] Framing is a way of determining what kinds of reasons are or are not germane to a regulatory decision, as well as to the ways in which those reasons should be weighed.

Although the problem of risk regulation can be framed in many ways,[15] both US and EU administrative law consistently frame risk regulation in terms of safety, which is to say the protection of humans or the environment from physical harm that may be caused by a product. Harm in this framing is defined in terms of empirically observable physical changes and, as such, is understood to be an appropriate subject for scientific analysis. Put differently, both the US and EU courts have framed risk in terms of a specific type of concern about technology, i.e., scientifically backed concerns that a product or process may be detrimental to the physical well-being of humans or the environment.[16]

Although they have reached similar conclusions about the framing of risk, the US and EU courts have done so for somewhat different reasons. In the US, the framing of risk in terms of safety has its basis in legislation. US risk regulation legislation frequently requires administrators to regulate on the basis of "the best available science" or similar formulations, and courts have understood such requirements to indicate a legislative intention that regulatory efforts should be focused on scientifically analysable concerns.[17] More broadly, US courts have interpreted regulatory legislation that speaks in terms of "public health" or "safety" (the Clean Air Act, for example), to require administrators to set regulatory standards on the basis of health effects, which in turn are

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[14] Edley, *Administrative Law: Rethinking Judicial Control of Bureaucracy* (Yale 1990) 98–105; Fisher (n.12), 90–93.
[15] Chapter 1, section I.B.
[16] Hilson, 'Beyond Rationality—Judicial Review and Public Concern in the EU and the WTO' (2005) 56 N.Ire.L.Q. 320, 332.
[17] E.g., *Chlorine Chemistry Council v. EPA*, 206 F.3d 1286, 1290 (D.C.Cir.2000).

understood as medically observable effects.[18] The US courts have tended to reach these conclusions either on the basis of their perception of the plain meaning of the statue[19] or the legislative history.[20] For the most part, US courts have not engaged with other possible framings of risk, possibly because US risk regulators have rarely attempt to justify their actions on grounds other than the physical protection of health or the environment. Because the issue has received so little attention from the courts, it is unclear what, if any, limits there are on the extent to which administrative agencies may regulate technological risks on the basis of concerns other than safety.[21]

For a long time, the EU courts equivocated on the framing of risk regulation.[22] In *Fedesa*, the Court of Justice held that the EU's ban on the use of hormones for fattening beef cattle could be upheld as a response to public anxiety without the need to show a scientifically backed health concern,[23] and the *BSE Cases* seemed to reaffirm that position.[24] By contrast, cases like *Angelopharm*[25] and *Bergaderm*[26] required the administration to demonstrate evidence of potential risks to health. The issue seems to have been settled, however, by *Pfizer*[27] and

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[18] E.g., *American Trucking Associations v. EPA*, 175 F.3d 1027, 1052 (D.C.Cir.1999); *NRDC v. EPA*, 824 F.2d 1146, 1163 (D.C.Cir.1987) (en banc).
[19] *Chlorine Chemistry Council* (n.17), 1290.
[20] *NRDC* (n.18), 1160–63.
[21] Although US administrative law frames risk in terms of safety, that does not mean that agencies may not consider non-safety factors when regulating. E.g., NRDC (n.19), 1163; Executive Order 12,898, 59 Fed. Reg. 7,629 (Feb. 11, 1994) (requiring all federal agencies to take account of environmental justice concerns when issuing regulations).
[22] Hilson (n.16), 330–32.
[23] Case C-331/88, *R. v. MAFF, ex p. Fedesa* [1990] ECR I-4023, paras. 7–9.
[24] Case C-180/96, *United Kingdom v. Commission* [1998] ECR I-2265, paras. 120–21.
[25] Case C-212/91, *Angelopharm GmbH v. Freie und Hansestadt Hamburg* [1994] ECR I-171, para. 38.
[26] Case T-199/96, *Laboratoires Pharmaceutiques Bergaderm SA* v. *Commission* [1998] ECR II-2805, paras. 63–65.
[27] Case T-13/99, *Pfizer Animal Health SA v. Council* [2002] ECR II-3305, paras. 135–44.

Artegodan,[28] in which the General Court came down firmly in favour of framing risk in terms of safety.

The General Court's decision to frame risk in terms of safety was rooted in concerns about the powers of the Commission.[29] The court recognised that the precautionary principle had the potential to expand greatly the scope of the Commission's regulatory discretion. In response, the court attempted to place bounds on that authority by narrowing the range of concerns to which the principle is applicable.[30] Concerns about the scope of administrative discretion were even more evident in *Alliance for Natural Health*, in which the court interpreted the relevant directive as conferring on the Commission regulatory authority only for the purpose of protecting public health.[31] As discussed in chapter 2,[32] the Court of Justice was explicit that delegations of regulatory authority to the Commission required clear bounds.[33] That constitutional requirement prompted the court to conclude that authority to regulate a potentially risky product should be limited to the protection of health—which in turn is defined in terms of scientifically backed concerns— and not expanded to include other considerations unless the inclusion of such considerations is clearly authorised by the delegating legislation. Arguably, *Alliance for Natural Health* went further than *Pfizer* and *Artegodan* by suggesting that limiting risk regulation to issues of safety was constitutionally necessary when regulatory decisions are made administratively, rather than by the EU legislature.

Framing risk regulation in terms of safety has important implications for rationality review. Most importantly, the requirement that the administration base its actions on scientifically backed concerns means that administrators will have to offer scientific reasons to support their

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[28] Case T-74/00, *Artegodan GmbH v. Commission* [2002] ECR II-4945, paras. 183–86.
[29] Heyvaert, 'Facing the Consequences of the Precautionary Principle in European Community Law' (2006) 31 ELR 185, 201–03.
[30] *Pfizer* (n.27), paras. 170–72; *Artegodan* (n.28), paras. 184–85.
[31] *Alliance for Natural Health* (n.6), paras. 83–86.
[32] Below section III.B.
[33] *Alliance for Natural Health* (n.6), paras. 90–92.

actions. It does not necessarily preclude administrators from also relying on other types of reasons, such as distributional concerns or public anxiety regarding certain technologies, but it does mean that non-science reasons will be limited to justifying particular responses to scientifically backed concerns, rather than constituting independently sufficient bases for regulatory action. The effect of this framing, therefore, will inevitably be to marginalise non-scientific concerns to some degree and to focus both administrative and judicial attention first on the validity of the asserted scientifically backed concern and second on the effectiveness of the administration's chosen response, which will itself be analysed primarily in scientific terms.[34]

Given the limits of risk science,[35] however, rational administrative decisionmaking in this area can never be simply about getting the facts right. Instead, models of rational risk regulation must also account for how scientific conclusions are drawn, by whom, and on what basis. They must also be able to accommodate the fact that such judgments will very often be disputed. In the usual case, reaching scientific conclusions about risk will not be a matter of right or wrong but of choosing from among multiple plausible interpretations of incomplete and ambiguous data. As a result, the line between scientific conclusions and policy judgments begins to blur. Models of administrative rationality must also be able to deal with this overlap.

II. Rationality Review in the United States

The early US case law on risk regulation is notoriously difficult to reconcile. To understand the source of this confusion, it is necessary to understand the ways in which the explosion of risk regulation agencies and regulatory programmes in the 1970s fundamentally challenged the then-prevailing administrative law settlement in the US. In particular, three aspects of the new risk regulation programmes required courts to reassess their approach to judicial review. First, the new risk regulation

[34] Cf. Lee, 'Beyond Safety? The Broadening Scope of Risk Regulation' (2009) 62 CLP 242, 258.
[35] Chapter 1, section I.C.

programmes contemplated that most regulatory activity would take the form of administrative rulemaking. Although rulemaking had always been a part of US administrative practice, the primary mode of regulation before 1970 was adjudication. Administrative agencies adjudicated various types of licencing proceedings and enforcement actions, and made policy incrementally through their decisions in individual cases. Much of the theory underlying American administrative law at this time implicitly relied on this court-like approach to regulation.[36] Regulation by rulemaking upset those premises by requiring administrators to make broad policy choices that in their effects were indistinguishable from legislation. As a result, courts were put in the position of reviewing administrative actions that looked like the work of legislatures without any clear guidance on what the courts' role in that process should be.[37]

The second challenge posed by risk regulation was the need for specialised scientific expertise in standard setting. Although expertise had historically been an important justification for administrative delegation, the kind of expertise being called upon in risk regulation programmes was qualitatively different. The New Deal agencies' expertise was what might be called managerial expertise, i.e., the kind of expertise that is acquired from long experience with a particular industry.[38] Expertise of this kind does not typically yield definitive solutions, but rather informs the judgment of administrators.[39] The scientific expertise called for by the new risk regulation programmes, by contrast, seemed like it should be capable of providing objective answers to questions such as whether a substance causes cancer. Yet in practice, the scientific analysis relied on by agencies failed to offer clear conclusions. Judges

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[36] Mashaw and Harfst, *The Struggle for Auto Safety* (Harvard 1990) 21–27; Scalia, '*Vermont Yankee*: The APA, the D.C. Circuit, and the Supreme Court' [1978] Sup.Ct.Rev. 345, 376–82.

[37] Fisher (n.12), 110–12; Leventhal, 'Environmental Decisionmaking and the Role of the Courts' (1974) 122 U.Pa.L.Rev. 509, 510; Pedersen, 'Formal Records and Informal Rulemaking' (1975) 85 YLJ 38, 46–50.

[38] Friendly, *The Federal Administrative Agencies* (Harvard 1962) 74–78; Landis, *The Administrative Process* (Yale 1938) 22–26.

[39] Cf. Landis (n.38), 142–45; Scalia (n.36), 380–81.

unversed in risk science had difficulty discerning the significance of this uncertainty, especially the extent to which it might be attributable to failings in the agency's analysis.

The third challenge is more impressionistic. The powers being granted to administrative agencies in the risk regulation era represented a step-change in the scope of administrative power.[40] Whereas the New Deal agencies typically focused on a single industry and regulated incrementally, the new risk agencies, most notably the EPA, had the power to issue regulations that would, at a stroke, impose significant costs on every sector of the economy.[41] The obvious example is the Clean Air Act, which directly or indirectly imposes compliance costs on virtually anyone who uses energy, including both businesses and consumers. These massive stakes—for both the economy and public health—caused disquiet among the courts. The crucial constitutional questions were the extent to which such significant policy choices could be made by administrative agencies and the forms of legal control that would be necessary to render them constitutionally legitimate.

These three challenges completely upended the administrative law settlement that prevailed at the beginning of the 1970s. It should be no surprise, therefore, that the era of risk regulation also introduced a period of controversy and convulsion in rationality review. Indeed, it would take more than two decades for the Supreme Court and the courts of appeals to work out a new settlement. The development of this new settlement would result in a revised understanding of the place of the administration within the US system of government. To understand this development, it is necessary first to examine the lines of the debate that animated the 1970s case law.

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[40] Cf. *American Petroleum Institute v. OSHA*, 581 F.2d 493, 502 (5th.Cir.1978); *International Harvester Co. v. Ruckelshaus*, 478 F.2d 615, 640–41 (D.C.Cir.1973).

[41] *Industrial Union Department, AFL-CIO v. American Petroleum Institute*, 448 U.S. 607, 674–75 (1980) (*Benzene*) (Rehnquist, J., concurring in the judgment).

A. Early Approaches in the Courts of Appeals

Given the magnitude of these challenges, it should be unsurprising that the courts of appeals initially took divergent approaches to rationality review in the risk regulation context, and the case law of the 1970s can be said to have given birth to the perception that US judicial review is hopelessly unpredictable.[42] Despite this enormous variation, however, decisions from the 1970s and into the early 1980s generally followed one of two models of judicial review, which Professors Stewart and Sunstein have dubbed the "private law" and "public law" models.[43] The distinguishing features of the two models were the purposes of judicial review and the role of the administration in setting regulatory policy.

Under the private law model, the reviewing court's primary duty was to ensure that individual liberty was not unlawfully constrained by administrative action. As a consequence, the focus of review was on the rights of the regulated party and not on potential regulatory beneficiaries.[44] The key legal premise of the private law model was that restrictions on individual liberty are only lawful when authorised by the legislature.[45] Accordingly, regulatory legislation had to be interpreted so that all important policy decisions were made by Congress, leaving the administration only a narrow discretion to fill "interstitial" gaps.[46] Because the focus was on protecting the rights of regulated entities, courts adjudicating within the private law model tended to review administrative rulemakings as they would enforcement actions, i.e., by asking whether the administration had proved that its action was authorised by statute. That focus in turn led courts to dwell on determining the administration's burden of proof and on assessing

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[42] Davis, *Administrative Law of the Seventies* (Lawyers Co-operative Press 1976) 377–85.
[43] Stewart and Sunstein, 'Public Programs and Private Rights' (1982) 95 HLR 1193, 1232–33; Sunstein, 'Deregulation and the Hard-Look Doctrine' [1983] Sup.Ct.Rev. 177, 179–89.
[44] Sunstein (n.43), 179.
[45] Ibid.
[46] Cf. Monaghan, '"Marbury" and the Administrative State' (1983) 83 Colum.L.Rev. 1, 6.

whether the evidence presented by the agency sufficed to meet that burden.[47] In the private law model, the agency's job was not to set risk regulation policy, but to gather evidence and determine—on that basis—whether the relevant statute required the imposition of regulatory controls. Accordingly, administrative rationality in the private law model was essentially limited to instrumental rationality, and the courts assessed administrative decisionmaking accordingly.

The private law model was particularly associated with the Court of Appeals for the Fifth Circuit, which applied that model in several well-known (and much criticised)[48] decisions, including *Aqua Slide 'N' Dive*, *American Petroleum Institute v. OSHA*, and *Gulf South Insulation*. In each of these cases, the agency had adduced evidence of possible, but uncertain harm, and had chosen to regulate. The courts reviewing those regulations focused on whether the agency had met a burden of proof. For example, in *American Petroleum Institute*, the agency had ample evidence that benzene could cause leukaemia at concentrations greater than 10 ppm, but little or no direct evidence of its effects below that level.[49] Due to this uncertainty, which is a pervasive feature of risk science, the court set aside the challenged regulation. An important feature of cases following the private law model is that the scope of agencies' discretion did not extend to determining when uncertain evidence of risk was sufficient to justify the imposition of regulatory controls.[50] That question had to be reserved to Congress, which in effect

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[47] Sunstein (n.43), 179; *Aqua Slide 'N' Dive Corp. v. CPSC*, 569 F.2d 831, 839–40 (5th.Cir.1978).

[48] The literature criticising these cases is enormous. A few prominent examples include: Ashford, Ryan, and Caldart, 'A Hard Look at Federal Regulation of Formaldehyde: A Departure from Reasoned Decisionmaking' (1983) 7 Harv.Envtl.L.Rev. 297, 363–68 (1983), McGarity, 'Some Thoughts on "Deossifying" the Rulemaking Process' (1992) 41 Duke.L.J. 1385, 1423; Pierce, 'Seven Ways to Deossify Agency Rulemaking' (1995) 47 Admin.L.Rev. 59, 61–62; and Wagner, 'The Science Charade in Toxic Risk Regulation' (1995) 95 Colum.L.Rev. 1613, 1662–63.

[49] *American Petroleum Institute* (n.40), 501.

[50] *Aqua Slide 'N' Dive* (n.47), 841–42; *Gulf South* (n.7), 1145.

turned it into a question of law for the reviewing court to decide when interpreting the statute.

Although the Fifth Circuit (and later the Eleventh) long adhered to the private law model, by the end of the 1970s other courts of appeals, led by the DC Circuit, had begun applying what Stewart and Sunstein call the public law model.[51] Instead of focusing on protecting the rights of regulated entities, the role of the court in the public law model is to ensure that the administrative agency is adequately implementing regulatory legislation. That obligation includes ensuring not only that the agency is not unjustifiably infringing individual liberty, but also that the agency is protecting the interests of regulatory beneficiaries.[52] The basic premise of the public law model is that by enacting risk regulation legislation, Congress intended to protect the public and the environment from the covered risks, an objective that could just as easily be threatened by under-regulation as by over-regulation. In the public law model, scientific uncertainty is not treated as a barrier to regulation, but as a policy problem for the agency to address. Recognising the inherent uncertainty of risk science and the need to weigh competing social policies in determining when to regulate, several reviewing courts held that administrators must make "an essentially legislative policy judgment, rather than a factual determination, concerning the relative risks of underprotection as compared to overprotection".[53] The public law model thus posited a very different role for the administration from the

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[51] Some prominent examples of the public law model include *Ethyl Corp. v. EPA*, 541 F.2d 1 (D.C.Cir.1976) (en banc); *Society of the Plastics Industry, Inc. v. OSHA*, 509 F.2d 1301 (2d.Cir.1975) (Clark, J.); *Industrial Union Department, AFL-CIO v. Hodgson*, 499 F.2d 467 (D.C.Cir.1974).

[52] Sunstein (n.43), 187.

[53] *Hodgson* (n.51), 475. *Hodgson*'s approach to scientific uncertainty was adopted by several other circuit courts. E.g., *BASF Wyandotte Corp. v. Costle*, 598 F.2d 637, 647–48 (1st.Cir.1979); *Society of the Plastics Industry* (n.51), 1304; *American Iron and Steel Institute v. OSHA*, 577 F.2d 825, 833–34 (3d.Cir.1978); *Arkansas-Best Freight System, Inc. v. Occupational Safety and Health Review Commission*, 529 F.2d 649, 653–54 (8th.Cir.1976); *ASARCO, Inc. v. OSHA*, 746 F.2d 483, 490–91 (9th.Cir.1984).

private law model. Instead of being confined to the narrowly instrumental task of collecting and assessing evidence, the administration in the public law model has an essentially constitutive role in elaborating regulatory policy. Although the administration's policymaking authority remains subordinate to that of Congress, the public law model recognises that a great deal of discretion and judgment is required to concretise the broad policy goals set out in risk legislation and to apply them on the basis of uncertain and ambiguous scientific evidence. By entrusting the administration with responsibility for this elaboration, courts in the public law model narrowed the scope for judicial policymaking through judicial review. At the same time, however, courts in this model claimed an important judicial power—largely absent from the private law model—to ensure that the agency was living up to the responsibilities assigned to it by Congress.[54]

The differences between the private law and public law models of judicial review can be understood as differences in the role of the administration in setting risk regulation policy. In keeping with traditional delegation theory, the private law model placed policy decisions with Congress and sharply limited the administration's discretion outside of technical issues. In this model, science is viewed as a largely objective and determinate method for selecting the appropriate regulatory action to implement fixed legislative instructions. That approach had the virtues of being consistent with then-prevailing administrative and judicial practice, as well as being easily reconcilable with separation of powers theory.[55] But those virtues came at the cost of potentially crippling the effectiveness of risk regulation programmes.

The public law model, by contrast, proceeded from a much more realistic understanding of the complexities inherent in the regulation of emerging and scientifically uncertain risks.[56] It appreciated that administrative decisionmaking could not be captured in the adjudicative

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[54] Stewart and Sunstein (n.43), 1216–18.
[55] Cf. Scalia (n.36), 375–77.
[56] Jasanoff, *The Fifth Branch: Science Advisers as Policymakers* (Harvard 1990); Wagner, 'Ethyl: Bridging the Science-Law Divide' (1995) 74 Tex.L.Rev. 1291, 1293–95.

metaphor of burdens of proof, but instead required the weighing of competing social priorities in light of the agency's regulatory mandate.[57] In this model, science is understood as a source of information that guides administrative policymaking, but does not dictate outcomes.[58] To allow the administration to deal with the complexity inherent in setting risk standards, courts applying the public law model were prepared to accord the administration an essentially constitutive role in setting risk policy. The problem, however, was that the then-dominant technocratic theories of administrative law were insufficient to legitimate that policymaking authority. If scientific expertise was necessarily an insufficient basis for risk regulation, then a technocratic model of administration was also insufficient to justify vesting regulatory power in administrative agencies.[59] Some courts attempted to fill the gap by crafting a "surrogate political process", but that effort was short-lived (and largely unsatisfactory).[60] Others courts simply skirted the issue.[61] Until a cogent theory could be found to legitimate the extent of administrative policymaking that modern risk regulation programmes seemed to require, the debate between the private law and public law models could not be resolved.

B. Risk Regulation in the Supreme Court

Risk regulation first reached the Supreme Court in the *Benzene* case,[62] which was an appeal from the Fifth Circuit's private law model decision in *American Petroleum Institute*. Although the *Benzene* decision was much-anticipated, the Court failed to reach a majority in support of any

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[57] Cf. Fuller, 'The Forms and Limits of Adjudication' (1978) 92 HLR 353, 370–72.
[58] *Society of the Plastics Industry* (n.51), 1308 ("[T]hough the factual finger points, it does not conclude.").
[59] Stewart, 'The Reformation of American Administrative Law' (1975) 88 HLR 1667, 1681–88.
[60] Ibid., 1760–62.
[61] E.g., *Ethyl* (n.51), 20.
[62] Above n.41.

opinion, depriving the judgment of precedential authority.[63] As Justice Scalia (then a law professor) put it, the *Benzene* decision "literally provides no conclusive answer to any legal question more general than whether the benzene exposure regulation . . . is valid."[64] Despite that important limitation, the case is worth careful examination because it shows the Supreme Court actively working through some of the challenges posed by risk regulation.

Writing for a four-justice plurality, Justice Stevens's central concern was OSHA's Cancer Policy, under which the agency asserted that once a substance was determined to be a carcinogen, the Occupational Safety and Health Act required it to impose the most stringent controls technically and economically feasible because no level of exposure to a carcinogenic substance could be considered safe. The plurality was transparent in its uneasiness with the scope of authority that the Cancer Policy seemed to claim for the agency and with the regulatory costs that it potentially entailed.[65] In that regard, the mood of the plurality opinion was of a piece with the more generalised anxiety regarding the marked increase in administrative power brought about by the new risk regulation programmes. The plurality's solution was to cabin that power.[66] Relying on a convoluted construction of statutory language, Justice Stevens held that the Act only gave the agency power to regulate risks that rendered a workplace "unsafe", a term he equated with "significant risk".[67] The agency was therefore required to make a finding that a substance posed a significant risk before regulating; such risk could not be presumed from the presence of a hazardous property as under the Cancer Policy. The plurality hastened to add in the very next sentence, however, that the agency was "not required to support its

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[63] *Marks v. United States*, 430 U.S. 188, 193 (1977).
[64] Scalia, 'A Note on the *Benzene* Case' (1980) 4 *Regulation* 25, 25.
[65] *Benzene* (n.41), 639–40. That uneasiness was even more pronounced in Justice Powell's and Justice Rehnquist's concurrences. Ibid., 668–69 (Powell, J, concurring in part), 672 (Rehnquist, J., concurring in the judgment).
[66] Chapter 2, section III.A.
[67] *Benzene* (n.41), 655.

finding that a significant risk exists with anything approaching scientific certainty".[68] Because OSHA had not made the necessary finding, its rule was invalid. The plurality never resolved the question whether there was adequate evidence in the record to support a finding of significant risk. Indeed, it explicitly noted that it was declining to resolve that question.[69]

Although it did not definitively determine what reasons OSHA would need to give to support a finding of substantial risk, the plurality did offer some clues. Unfortunately, those clues point in different directions. On one hand, the plurality held that the agency bore a burden of proof to show that "it is at least more likely than not" that a substance poses a significant risk.[70] To that extent, the plurality seemed to conceive of the question of significance as an evidentiary threshold, echoing the private law model employed by the court below. On the other hand, however, the plurality clearly did not understand the question of significance in purely scientific terms. Drawing heavily on cases applying the public law model,[71] the plurality stated, "while the Agency must support its finding that a certain level of risk exists by substantial evidence, we recognise that its determination that a particular level of risk is 'significant' will be based largely on policy considerations."[72] Importantly, the plurality noted its agreement on this point with Justice Marshall's dissent for four justices. Thus, at least seven justices in the *Benzene* case agreed that a finding of significant risk would have to be based on a combination of scientific and policy considerations.

It is also important to note what the *Benzene* plurality did *not* hold. As noted above, it did not hold that the evidence in the administrative record was insufficient to support a finding of significant risk. Instead, it remanded the rule to the agency to consider that question in the first instance. It most certainly did not, despite certain ill-advised dictum,

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[68] Ibid., 656.
[69] Ibid., 660.
[70] Ibid., 653.
[71] In fact, the only precedents cited in this part of the plurality opinion are two public law model cases. Ibid., 656 (citing *Hodgson* (n.51) and *Society of the Plastics Industry* (n.51)).
[72] Ibid., 655 (quoting ibid., 706 (Marshall, J., dissenting)).

hold that OSHA could only regulate on the basis of a quantitative risk assessment.[73] To the contrary, both the plurality and the dissent explicitly recognised that significance could not be determined with mathematical precision.[74]

Because of its opacity, *Benzene* did little to clarify how agencies should approach the problem of risk regulation. The Supreme Court next returned to the problems of risk regulation in *Baltimore Gas and Electric Co. v. NRDC*,[75] which concerned a rule promulgated by the Nuclear Regulatory Commission providing that, for purposes of considering licensing applications, long term storage of nuclear waste would be deemed to have no environmental impact. *Baltimore Gas* was the second time that rule had been to the Court. The first was *Vermont Yankee*,[76] in which the court famously declared that courts could not impose procedural requirements on agencies beyond those specified in legislation. Following remand, the DC Circuit had once again vacated the rules but this time of the basis that they were substantively irrational. The crux of the circuit court's ruling was that it found the challengers' view of the evidence to be more credible than the Commission's.[77] As in *Vermont Yankee*, the Supreme Court unanimously reversed.

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[73] Puzzlingly, several commentators have nonetheless claimed that *Benzene* does require quantitative risk assessment, at least as a practical matter. E.g., Bergkamp, 'The Quiet Revolution in Administrative Procedure: Judicial Vetting of Precautionary Risk Assessment' [2014] EJRR 102, 107; Charnley and Elliott, 'Risk Versus Precaution: Environmental Law and Public Health Protection' (2002) 32 Env.L.Rptr. 10363; Latin, 'Good Science, Bad Regulation, and Toxic Risk Assessment' (1988) 5 Yale.J.Reg. 89, 93. That interpretation has been consistently rejected by the courts of appeals, however. E.g., *National Maritime Safety Association v. OSHA*, 649 F.3d 743, 751 (D.C.Cir.2011); *Miami-Dade County v. EPA*, 529 F.3d 1049, 1069 (11th.Cir.2008); *Cactus Corner, LLC v. Department of Agriculture*, 450 F.3d 428, 433 (9th.Cir.2008); *American Dental Association v. Martin*, 984 F.2d 823, 827 (7th.Cir.1993) (Posner, J.).

[74] *Benzene* (n.41), 655.

[75] 462 U.S. 87 (1983).

[76] *Vermont Yankee Nuclear Power Corp. v. NRDC*, 435 U.S. 519 (1978).

[77] *NRDC v. NRC*, 685 F.2d 459, 484 & n.129 (D.C.Cir.1982).

Writing for the Court, Justice O'Connor held that "a reviewing court must remember that the Commission is making predictions, within its area of special expertise, at the frontiers of science. When examining this kind of scientific determination, as opposed to simple findings of fact, a reviewing court must generally be at its most deferential."[78] This holding, which draws on language first used by the D.C. Circuit in *Hodgson*,[79] came to be known as the "frontiers of science doctrine".[80] How to interpret that doctrine, however, continues to be a matter of dispute. Some take it to mean that when agencies are regulating on the basis of highly technical scientific conclusions, courts must be especially deferential. On this interpretation, agencies' scientific determinations are entitled to greater deference, even "super-deference," because of the agency's relatively greater competence to evaluate sophisticated scientific issues. [81] Proponents of the super-deference interpretation therefore argue that *Baltimore Gas* creates an incentive for agencies to couch the justification for their rules in complex scientific terms, even when decisions are actually being made for other reasons.[82]

Careful analysis of Justice O'Connor's opinion, however suggests that the super-deference interpretation is incomplete. The Court in *Baltimore Gas* was particularly concerned that courts not set aside agency action merely because it is based on science that is uncertain, or even substantially uncertain.[83] The crucial issue was how the agency should

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[78] *Baltimore Gas* (n.75), 103.
[79] *Hodgson* (n.51), 474.
[80] Shapiro, 'The Frontiers of Science Doctrine: American Experiences with the Judicial Control of Science-Based Decision-Making' in Joerges, Ladeur, and Vos (eds.), *Integrating Scientific Expertise into Regulatory Decision-Making* (Nomos 1997) 331.
[81] Meazell, 'Super Deference, the Science Obsession, and Judicial Review as Translation of Agency Science' (2011) 109 Mich.L.Rev. 733, 763–64 (collecting sources).
[82] Ibid., 781–82; Wagner (n.48), 1640.
[83] In support of this point, the Court cited to passages in both the plurality and dissenting opinions in *Benzene* emphasising that agencies cannot be expected to eliminate uncertainty from their scientific conclusions. *Baltimore Gas* (n.75), 105.

address that uncertainty.[84] Although it required the NRC to bring its technical expertise to bear on the issue, the Court openly acknowledged that the final decision depended on an exercise of judgment. Indeed, what sets an issue "on the frontiers of scientific knowledge" apart from "a simple finding of fact" is that the issue cannot be resolved by scientific methods alone but instead requires the agency to exercise its "policy judgment".[85] Deference is owed at least as much because of the policy-laden nature of the agency's conclusion, as because of the complexity of the science.[86] In effect, the Court held that when scientific information is uncertain, the agency's exercise of its expert judgment and its policy judgment are inseparable.[87]

The unanimous opinion in *Baltimore Gas*, along with the plurality and dissenting opinions in *Benzene*, show a strong majority of the Supreme Court endorsing a public law model of judicial review and administrative rationality, along the lines elaborated by the D.C. Circuit. What continued to be missing, however, was a cogent theory of how conferring such broad policymaking discretion on administrative agencies could be reconciled with democratic values and the separation of powers. That issue would be resolved by the Supreme Court in a series of cases that fundamentally reshaped US administrative law.

C. The True Reformation of American Administrative Law

That the challenges posed by the explosion of risk regulation programmes (among other causes) had thrown American administrative law into a state of turmoil was obvious even to contemporary observers. In his justly

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[84] *Baltimore Gas* (n.75), 105; Shapiro (n.80), 332.
[85] *Baltimore Gas* (n.75), 105.
[86] Ibid., 105–06. This reading is further supported by the Court's reliance on *Bowman Transportation, Inc. v. Arkansas-Best Freight System, Inc.*, 419 U.S. 281 (1974), a case which turned on the reasonableness of the agency's policy judgment and involved no scientific or technical issues.
[87] Shapiro (n.80), 334; see also *NRDC. v. EPA*, 902 F.2d 962, 971 (D.C.Cir.1990).

famous 1975 article 'The Reformation of American Administrative Law',[88] Richard Stewart analysed judicial responses to this upheaval and concluded that the courts were responding by replacing the traditional, Weberian theory of administrative legitimacy with a pluralist interest representation model, in which administrative procedure would create a "surrogate political process" that would in turn legitimate administrative decisionmaking.[89] Opening the administrative process to a wide range of interests was thought both to compensate for administrators' limited democratic mandate and to create safeguards against capture of regulatory agencies by regulated interests.[90]

At the time he wrote, Stewart's prognostication seemed like a good bet, based as it was on decisions by influential circuit court judges. In a trio of landmark decisions, however, the Supreme Court would reject the interest group representation approach to administrative law and instead formulate a much different response to the challenges posed by administrative risk regulation. This new theory would attempt to reconcile the exercise of administrative power with the tripartite framework of government by reaffirming the technocratic nature of administration, while at the same time linking administrative policymaking to the elected president. It would also fully endorse the public law model of judicial review, in which courts are tasked with ensuring that agencies live up to their regulatory obligations.

The decision that started the reformation was *Vermont Yankee*,[91] in which the Court held that judges may not impose additional procedural

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[88] Above n.59.
[89] Ibid., 1670.
[90] Following George Stigler's publication of 'The Economic Theory of Regulation' (1971) 2 Bell.J.Econ.Mgmt.Sci. 3, capture theory came for a time to dominate US public administration scholarship. Capture theory basically asserts that, for structural reasons, regulated entities will often be able to dominate regulators' decisionmaking processes thereby allowing those entities to use regulation to extract benefits at the expense of the public. Ibid., 17–18; see also Carpenter and Moss (eds.), *Preventing Regulatory Capture* (CUP 2013). Stewart believed that many judges had read and accepted the literature on capture. Stewart (n.59), 1685.
[91] Above n.76.

requirements on agencies beyond those required by statute. The court of appeals had remanded an NRC rule and required the agency to provide public interest intervenors with greater opportunities to "ventilate" certain scientific issues. The Supreme Court unanimously reversed. In language that dripped with disdain for the DC Circuit's approach, the Court held that, absent highly unusual circumstances, courts could not use rationality review to impose procedural requirements on agencies beyond those specified in the APA or other applicable legislation.[92] The decision had the immediate effect of terminating any attempt by the lower courts to foster a surrogate political process through administrative law. It also had additional significance for the interest group theory of administrative legitimacy. By rejecting interest group pluralism, the Court reaffirmed that the legitimacy of administrative policymaking is not dependent on the participation of interested parties.[93] The Court also implicitly rejected the partnership model of administration advanced by some judges, in which the agencies and the courts would act in partnership in setting regulatory policy.[94] For the *Vermont Yankee* Court, regulatory policy was a matter for the administration itself, and courts were not to interfere except to police constitutional and statutory bounds.

The next step in the reformation was *State Farm*,[95] which concerned the National Highway Traffic Safety Administration's decision to rescind a safety standard requiring passive restraint systems in new automobiles.[96] Affirming the court of appeals, the Supreme Court vacated the rescission on the ground that it was arbitrary and capricious in light of the evidence before the agency. *State Farm*'s significance for the new legal settlement was threefold: First, it affirmed the "hard look" approach to arbitrariness

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[92] Ibid., 547–48.
[93] Ibid., 545.
[94] E.g., *Kennecott Copper Corp. v. EPA*, 462 F.2d 846, 848–49 (D.C.Cir.1972); *Greater Boston Television Corp. v. FCC*, 444 F.2d 841, 851–52 (D.C.Cir.1970); cf. Byse, 'Vermont Yankee and the Evolution of Administrative Procedure: A Somewhat Different View' (1978) 91 HLR 1823, 1828.
[95] *Motor Vehicle Manufacturers Ass'n v. State Farm Mutual Automobile Insurance Co.*, 463 U.S. 29 (1983).
[96] Ibid., 36–38.

review, thereby ensuring that courts would continue to engage in searching substantive review.[97] Second, it rejected a legal preference for non-regulation or deregulation, in effect rejecting the common law regime as the baseline for social ordering.[98] Third, it rejected a conception of judicial review in which the task of courts is primarily to protect private interests from government overreach. Instead, it forwarded a conception of judicial review as protection of "a right to a process of decision designed to ensure that the relevant public values will be properly identified and implemented."[99]

By embracing hard look review, *State Farm* also reaffirmed the centrality of technocratic rationality to judicial understandings of good administrative decisionmaking. In vacating the agency's decision, the Court closely examined the evidence before the agency and required it to produce a justification for its decision grounded in consideration of that evidence.[100] This approach to review reinforced the notion that it is the administration's job to gather and analyse information and to make decisions on the basis of that analysis rather than on the basis of political prejudgment.[101] The opinion should not, however, be read as denying a legitimate role for administrative policy judgment.[102] The Court recognised that often "the available data does not settle a regulatory issue and the agency must then exercise its judgment in moving from the facts . . . to a policy conclusion".[103] Writing for four justices, Justice Rehnquist went further and recognised that an agency's policy conclusions will be influenced by the political views of the incumbent president.[104] In this way, Justice Rehnquist, apparently for the first time in the Supreme

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[97] Ibid., 43; Garland, 'Deregulation and Judicial Review' (1985) 98 HLR 505, 526; Sunstein (n.43), 196.
[98] Sunstein (n.43), 213.
[99] Ibid., 212.
[100] *State Farm* (n.95), 47–49.
[101] Garland (n.97), 556; Sunstein (n.43), 209.
[102] *Contra* Watts, 'Proposing a Place for Politics in Arbitrary and Capricious Review' (2009) 119 YLJ 2, 5.
[103] *State Farm* (n.95), 52.
[104] Ibid., 59 (Rehnquist, J., concurring in part and dissenting in part).

Court's case law, identified this connection to the president as a basis for the legitimacy of administrative policymaking.[105]

The final piece of the reformation was the unanimous decision in *Chevron*,[106] which in retrospect can fairly be said to have revolutionised American administrative law. The importance of *Chevron* for the interpretation of regulatory statutes and the allocation of authority between agencies and courts was explored in chapter 3.[107] *Chevron*'s significance extends beyond statutory interpretation, however, because the case dealt at some length with the theoretical basis for the legitimacy of administrative decisionmaking. At the outset of the opinion, the Court emphasised the agency's expertise as the source of its superior competence for setting regulatory policy, particularly in technical areas.[108] That justification was consistent with the traditional technocratic understanding of administration as an alternative to politics for certain types of decisionmaking. Later in the opinion, however, the Court articulated a second basis for the legitimacy of administrative policymaking, grounded in the agency's democratic mandate derived from its oversight by the president:

> [A]n agency to which Congress has delegated policy-making responsibilities may, within the limits of that delegation, properly rely upon the incumbent administration's views of wise policy to inform its judgments. While agencies are not directly accountable to the people, the Chief Executive is, and it is entirely appropriate for this political branch of the Government to make such policy choices . . . .[109]

This rationale picked up on Justice Rehnquist's opinion in *State Farm*, but in this case it was embraced by a unanimous Court. It was by far the Court's strongest endorsement to that point of the democratic legitimacy of administrative agencies.

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[105] Ibid.
[106] *Chevron, U.S.A., Inc. v. NRDC*, 467 U.S. 837 (1984).
[107] Chapter 3, section I.C.2.
[108] Ibid., 865.
[109] Ibid.

Chevron is a powerful statement on the nature of the administration in two ways: First, it openly acknowledges the indeterminacy inherent in most regulatory statutes.[110] In doing so, it undermines the notion, crucial to the private law model, that administrative rationality could be purely instrumental in nature. Second, the Court made a self-conscious decision to place primary responsibility for the elaboration of regulatory policy the administration. By empowering the administration in this way, the Court affirmed an important constitutive role for the administration. To be sure, the administration's constitutive role is a subordinate one; plenary power to issue regulatory commands remains the monopoly of Congress. But the size and complexity of the modern regulatory state ensures that the administration will have significant power to shape regulatory policy. Crucially, *Chevron* reconciles the exercise of that constitutive power with the tripartite constitutional structure by tying administrative authority to the president's electoral mandate.[111]

Taken together, the frontiers of science doctrine elaborated in *Baltimore Gas* and the *Vermont Yankee-State Farm-Chevron* trilogy present a coherent picture of administrative rationality when making decisions on risk regulation. *State Farm* requires that the agency undertake a thorough scientific investigation of the potential risk in question.[112] This requirement is consistent with the longstanding American view that administrative regulation is legitimate, in part, because it is capable of bringing expertise to policymaking that other government actors (Congress, the courts) do not possess.[113] *Baltimore Gas* recognises, however, that scientific analysis will be an insufficient basis for many, perhaps most, risk regulation decisions and that when

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[110] Chapter 3, section I.C.2.

[111] Farina, 'The "Chief Executive" and the Quiet Constitutional Revolution' (1997) 49 Admin.L.Rev. 179, 182–83.

[112] *Gas Appliance Manufacturers Association v. Department of Energy*, 998 F.2d 1041, 1046 (D.C.Cir.1993).

[113] Mashaw, 'Small Things Like Reasons Are Put in a Jar: Reason and Legitimacy in the Administrative State' (2001) 70 Ford.L.Rev. 17, 23; Rabin, 'Federal Regulation in Historical Perspective' (1986) 38 Stan.L.Rev. 1189, 1219–20, 1263.

science runs out, the agency must exercise its policy judgment. Courts owe such policy judgments no less—and perhaps more[114]— deference than the agency's technical determinations. Finally, *Chevron* supplies the theoretical foundation for the legitimacy of administrative policymaking by stressing the president's democratic mandate.

In the model of administrative rationality described by these cases, scientific evaluation and policy judgment are essentially inseparable. Because of this inseparability, the focus of judicial review is less on the truth or falsity of the agency's scientific conclusions and more on whether the agency has offered evidence and reasons to show that its decisionmaking process has been directed at furthering the purposes of the underlying statute. In effect, the Supreme Court accepted the public law model as the correct approach to administrative rationality and judicial review.

D. Judicial Review After the Reformation

The Supreme Court's landmark decisions of the early 1980s did not change the lower courts' approach to risk regulation overnight. Initially, there was considerable debate in the courts of appeals regarding the application of these cases, and it would be several years before they fully worked out the implications of the Supreme Court's reasoning. Eventually, however, two trends emerged in the case law. First, following the logic of *Baltimore Gas*, courts increasingly came to see questions of risk science and questions of risk policy as inextricably intertwined, thereby rejecting the notion that such issues could be definitively settled on an objective basis. As a result, courts increasingly expressed the view that the interpretation of scientific evidence was inevitably a matter of judgment that invoked the agency's policymaking authority, as well as its scientific expertise.

The second trend was the forging of a link between agencies' judgment on disputed scientific questions and the rationale of *Chevron*, which held that statutory ambiguity should normally be interpreted as a

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[114] *Competitive Enterprise Institute v. NHTSA*, 956 F.2d 321, 323–24 (D.C.Cir.1992); Edley (n.14), 29–30.

delegation of policymaking authority to the administration. Following this logic, some courts have treated statutory silence (hence, ambiguity) regarding scientific issues as an implicit delegation of authority to agencies to rely on policy considerations in their interpretation of scientific evidence. The significance of the courts' reliance on *Chevron* is that it grounds deference to administrative science-policy judgments not only in the agencies' technical expertise, but also in their putative democratic legitimacy.

A prominent early case that touches on both these themes is the D.C. Circuit's unanimous en banc judgment in *Natural Resources Defense Council, Inc. v. EPA*.[115] The case is interesting because while the court recognised that regulatory decisions about risk "depend to a greater extent upon policy judgments", it nonetheless interpreted the Clean Air Act,[116] to require the agency to exercise its expertise and "determine an acceptable risk to health".[117] The case underlines the tension at the heart of the Supreme Court's case law: a recognition that science does not provide a politically neutral basis for decisionmaking coupled with a continued commitment to a Weberian conception of administration in which expertise is central to the legitimacy of administrative policymaking. What the court of appeals essentially required EPA to do was to make a policy judgment, but to do so on the basis of its best assessment of the available scientific evidence.[118] The case is also important because it is one of the earliest examples of the court explicitly linking administrative evaluation of risk to the *Chevron* framework.[119]

The D.C. Circuit further developed the application of *Chevron* to review of risk regulation in *Edison Electric Institute v. EPA*.[120] The issue in

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[115] 824 F.2d 1146 (D.C.Cir.1987) (en banc).
[116] Specifically, section 112 regarding controls on hazardous air pollutants. 42 U.S.C. § 7412.
[117] *NRDC* (n.115), 1163.
[118] EPA had attempted to avoid the issue by substituting a feasibility analysis for risk assessment. The court ruled that approach unlawful. Ibid., 1164–65.
[119] Ibid.
[120] 2 F.3d 438 (D.C.Cir.1993).

that case was whether EPA had permissibly adopted a "generic mismanagement scenario" for determining whether wastes are hazardous, instead of assessing the management of each waste separately.[121] The court held that statutory silence regarding risk assessment methodology should be interpreted as a delegation of policymaking authority and that, accordingly, EPA's choice of methodology was entitled to deference.[122] Because EPA's preferred approach was consistent with the underlying goals of RCRA, the court upheld the agency's decision. The relationship between *Chevron* and agencies' scientific judgment was raised again in *Chemical Manufacturers Association v. EPA.*[123] In that case, the court held that because the Clean Air Act was silent on the matter, *Chevron* deference extended to EPA's development of an air dispersion model for estimating pollutant concentrations.[124] In doing so, the Court stressed that the choice of modelling parameters was not a narrow technical issue but a question of policy, and that such policy judgments could not be overcome with technical arguments.[125] Both *Edison Electric* and *Chemical Manufacturers* are examples of courts reviewing issues that might be regarded as largely scientific—how to estimate risk from hazardous waste disposal, how to model dispersal of an air pollutant—using the *Chevron* framework. In both cases, the court acknowledged that the determinations the agency was required to make were not simple matters of empirically determinable fact, but instead required the agency to make a judgment about the significance of the available evidence. The court then framed those judgments as matters of policy and relied on *Chevron* to hold that it must defer to such judgments.

Since the 1980s, cases acknowledging the importance of policy judgment in reaching scientific conclusions have become common, and

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[121] Ibid., 443.
[122] Ibid., 445.
[123] 28 F.3d 1259 (D.C.Cir.1994).
[124] Ibid., 1264 (holding that *Chevron* requires courts to defer to agencies' risk assessment methodologies if the statute "can reasonably be read to authorize the agency's choice").
[125] Ibid., 1264–65.

explicit discussions of the role of policy in formulating scientific conclusions can be found in virtually every circuit.[126] In addition, courts have been increasingly ready to re-characterise challenges to agency science as challenges to agency policy choices.[127] The sheer ubiquity of these statements suggests that the courts have rejected the instrumentalist premises of the classical account, and that they have accepted that (in many circumstances) an agency's scientific conclusions will also embody policy judgments about how scientific evidence should be interpreted. The courts have been less consistent in linking deference to agency science with the *Chevron* framework, although many examples can be found.[128] But even when they do not rely upon it expressly, *Chevron*'s influence can be felt throughout the case law. As several commentators have observed, *Chevron* is part of a major theoretical shift in American administrative law away from a technocratic theory of administrative legitimacy and toward a president-centred democratic

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[126] That said, it is important to acknowledge that the case law is not perfectly uniform, and it is possible to find relatively recent examples of courts seeming to treat scientific conclusions as matters of objective of fact. E.g., *Sierra Club v. EPA*, 671 F.3d 955 (9th.Cir.2012); *Bluewater Network v. EPA*, 370 F.3d 1 (D.C.Cir.2004); *Dithiocarbamate Task Force v. EPA*, 98 F.3d 1394 (D.C.Cir.1996). The existence of counter examples does not, however, undermine the broader point that cases treating issues of risk science in this manner have become rare.

[127] E.g., *Mississippi v. EPA*, 744 F.3d 1334, 1343 (D.C.Cir.2013).

[128] E.g., *Catawba County v. EPA*, 571 F.3d 20, 35 (D.C.Cir.2009); *Miami-Dade County* (n.73), 1063 (linking *Chevron* to the approach to review outlined in *Ethyl*); *American Coke and Coal Chemicals Institute v. EPA*, 452 F.3d 930, 945 (D.C.Cir.2006); *BCCA Appeal Group v. EPA*, 355 F.3d 817, 841 (5th.Cir.2003); *National Wildlife Federation v. EPA*, 286 F.3d 554, 560 (D.C.Cir.2002) (linking the rationales of *Chevron* and *Baltimore Gas*); *Allied Local and Regional Manufacturers Caucus v. EPA*, 215 F.3d 61, 70 (D.C.Cir.2000); *Animal Legal Defense Fund, Inc. v. Glickman*, 204 F.3d 229, 234 (D.C.Cir.2000); *Maier v. EPA*, 114 F.3d 1032, 1043 (10th.Cir.1997); *Troy Corp. v. Browner*, 120 F.3d 277, 283 (D.C.Cir.1997); *Schering Corp. v. FDA*, 51 F.3d 390, 397–98 (3d.Cir.1995); *Alliance for Cannabis Therapeutics v. DEA*, 930 F.2d 936, 939 (D.C.Cir.1991).

theory.[129] When courts invoke the greater legitimacy of administrative agencies as policymakers, they are drawing on that trend.

This evolution in the US case law has been accompanied by an important shift in US legal culture. Three decades of experience has made the phenomenon of administrative risk regulation familiar and, to that extent at least, less threatening. When the controversial cases of the 1970s and early 1980s were decided, administrative regulation on the scale, and with the economic consequences, of modern risk regulation was new and seemed to unsettle established understandings of the proper role of administration. As we have seen, that anxiety animated many of the problematic cases of the 1970s, as well as the Supreme Court's *Benzene* decision. Today, though specific regulatory actions are often controversial, the idea that they should be undertaken by administrative agencies is not. That increased level of comfort with administrative risk regulation likely results in a less sceptical attitude on the part of courts towards agencies' judgments.[130] At the same time, decades of scholarship and policy analysis, not least of all several important reports by the National Academy of Sciences,[131] have made conventional the understanding that science cannot eliminate the need for judgment in risk regulation. Judges who accept this proposition are unlikely to find irrational agency action taken on that basis. Today, it is not unusual to find passages like this excerpt from the D.C. Circuit's recent decision in *Mississippi v. EPA*:

> The force of Mississippi's position . . . assumes only one standard . . . can be "requisite" . . . . But of course, this idea presupposes scientific certainty in an area actually governed by policy-driven approaches to uncertain science.

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[129] Farina (n.111), 180–83; Kagan, 'Presidential Administration' (2001) 114 HLR 2245, 2272–74; Strauss, 'From Expertise to Politics: The Transformation of American Rulemaking' (1996) 31 Wake.Forest.L.Rev. 745, 766–67.

[130] Cf. Rabin (n.113), 1319–21.

[131] E.g., National Research Council, *Risk Assessment in the Federal Government: Managing the Process* (1983); National Research Council, *Science and Decisions: Advancing Risk Assessment* (2009).

> . . . Mississippi's position—though perhaps an arguable thesis—collapses under the weight of reality.[132]

This is a very different reality indeed than the one inhabited by earlier courts following the private law model.

E. Rationality Review in the US Today

The trend in the case law toward understanding risk regulation as requiring the exercise of policy judgment has caused the US courts to become substantially less interventionist in their review of administrative risk regulation. They have not, however, abandoned substantive review. To the contrary, US courts continue to require that agencies present scientific support for their risk standards and to give sustained attention to agencies' technical justifications. These requirements are in accord with an understanding of administrative rationality that requires agencies' policy judgments to be based on their assessment of the available evidence. In keeping with this understanding, courts continue to vacate risk standards on scientific grounds in three situations.

First, courts will invalidate an agency standard if a petitioner can show that it is based on a demonstrably incorrect scientific conclusion. The classic example is *Chemical Manufacturers Association v. EPA*, in which the court vacated an EPA rule that assumed a substance behaved as a gas at a temperature at which that substance is solid.[133] It is important, however, to emphasise the narrowness of the circumstances in which a court will overturn an agency's scientific findings. The rule in *Chemical Manufacturers* was vacated because EPA's assumption bore "no rational relationship" to the physical properties of the substance in question.[134] In other words, there must be no room for disagreement that the agency was in error. It is not enough to show that there is scientific disagreement, or even that there is a "better" scientific view.[135] When

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[132] *Mississippi* (n.127), 1342–43.
[133] *Chemical Manufacturers Association* (n.123), 1266.
[134] Ibid.
[135] *Troy Corp.* (n.128), 290.

scientific disagreement exists, the courts are uniform in holding that the agency's position on that issue is a question of policy to which the courts must normally defer.[136]

The second circumstance in which courts will vacate risk standards on scientific grounds is when the agency's regulatory decision is apparently at odds with its own scientific conclusions. Although courts accord agencies wide discretion in reaching their scientific conclusions, once an agency has made scientific findings, it must accept their implications for its policy analysis. The bite in this requirement comes from the fact that agencies frequently engage in scientific analysis either during the early stages of rulemaking or in separate administrative proceedings.[137] In subsequently formulating its regulatory proposals, the agency's action must be consistent with those earlier scientific analyses or the agency must explain the reason for the inconsistency.

A good example is *American Lung Association v. EPA*,[138] in which the court remanded EPA's rule setting air quality standards for sulphur dioxide. In the course of revising the standards, EPA had conducted a number of analyses of the health effects of sulphur dioxide in the ambient air. One EPA analysis concluded that between 180,000 and 395,000 "exposure events," in which asthmatics suffer heavy breathing and discomfort could be expected to occur annually under the existing standard.[139] Nonetheless, EPA declined to tighten the standard. Without even considering the petitioners' challenges to the agency's scientific analysis, the court remanded because EPA had not explained how failing to act in the face of its own prediction of several hundred thousand annual exposure events was consistent with the statutory requirement

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[136] *Marsh v. Oregon Natural Resources Council*, 490 U.S. 360, 378 (1989); *American Forest and Paper Association, Inc. v. EPA*, 294 F.3d 113, 121 (D.C.Cir.2002); *Cellular Phone Task Force v. FCC*, 205 F.3d 82, 89 (2d.Cir.2000).

[137] Powell, *Science at EPA* (RFF 1999) 21–43.

[138] 134 F.3d 388 (D.C.Cir.1998).

[139] Ibid., 391.

that standards be set at a level "requisite to protect the public interest with an adequate margin of safety."[140]

Similarly, in *Chlorine Chemistry Council v. EPA*,[141] the court vacated an EPA standard under the Safe Drinking Water Act that had been based on the assumption that the carcinogenic risk of chloroform had no threshold. In a separate administrative proceeding, however, EPA had concluded that such a threshold exists.[142] Nonetheless, EPA adhered to the nonthreshold assumption in its SDWA rulemaking on the grounds that it was longstanding EPA policy and that EPA's Science Advisory Board had not yet completed its review of the threshold conclusion.[143] The court of appeals remanded the action, holding that EPA could not rely on scientific conclusions that the agency itself had determined were no longer accurate.

Requiring consistency between an agency's scientific conclusions and its policy choices can be seen as an application of *State Farm*'s requirement that agencies demonstrate "a rational connection between the facts found and the choice made."[144] The significance for risk regulation is that the "facts found" will not be facts in the sense of adjudicative facts, but rather complex judgments that involve both "factual" scientific analysis and the application of science-policy judgments. By holding agencies to their scientific conclusions, judicial review should cause agencies to consider their science-policy judgments carefully, knowing that they will restrict the range of possible regulatory outcomes. And by requiring agencies to make a connection between their scientific conclusions and their regulatory outcomes, courts also underscore that although scientific judgments often entail a large measure of policy choice, agencies may not make decisions without consideration of what scientific evidence is available.

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[140] Ibid., 392.
[141] Above n.17.
[142] Ibid., 1288.
[143] Ibid*;* see also *City of Waukesha v. EPA*, 320 F.3d 228, 252 (D.C.Cir.2003).
[144] *State Farm* (n.95), 42.

The third circumstance in which a court will set aside agency action on the basis of scientific consideration is when agencies are inconsistent in their approach to scientific issues. The key recent case for this principle is *American Farm Bureau Federation v. EPA*,[145] in which the DC Circuit partially vacated a rulemaking under the Clean Air Act because the agency had treated data from short-term epidemiological studies differently than it had in earlier rulemakings.[146] The court acknowledged that the agency was entitled to change its approach, but only if it provided a cogent explanation for doing so.[147] The rationale for requiring agencies to behave consistently over time is to guard against opportunistic decisionmaking.[148] If agencies must provide adequate reasons to justify departure from past practice, it will be more difficult for them to act out of political expediency.[149] Also, it is at least plausible that if agencies are required to be consistent they will tend to act with an eye toward long-term policy, which should promote better decisionmaking over time.[150] Indeed, in some recent cases, it appears that the courts applied this principle to test for undue political influence over agency decisionmaking.[151]

What ties all of these strands of case law together is an understanding of administrative agencies as unitary, expert decisionmakers. Because the agency is conceived of as a single mind, rational decisions must be consistent across all aspects of the analysis.[152] Courts take apparent disconnects between scientific analysis and policy judgments or unexplained changes in agencies' approach to science as evidence that the agency is not acting on the basis of its evaluation of the evidence but rather on the basis of some other, undisclosed, motive. The concern is

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[145] 559 F.3d 512 (D.C.Cir.2009).
[146] Ibid., 520.
[147] See also *FCC v. Fox Television*, 556 U.S. 502, 514–15 (2009); *National Association of Home Builders v. EPA*, 682 F.3d 1032, 1037 (D.C.Cir.2012)
[148] *See* II Pierce (n.1), 815–16.
[149] Sunstein (n.43), 187.
[150] *See* Stewart (n.59), 1680.
[151] E.g., *American Farm Bureau Federation* (n.145), 521.
[152] Above chapter II, section II.A.1.

that the agency is serving purely political interests, "naked preferences" in Sunstein's terminology,[153] rather than furthering the goals of the statute. Pursuit of such interests is not only contrary to the principle that agencies must exercise power on the basis of knowledge, but also runs afoul of the principle that agencies only enjoy the powers delegated to them by Congress. Accordingly, rationality review continues to discharge an important function by keeping the administration within its constitutionally permissible role.

F. A Coda: *Massachusetts v. EPA*

The prevailing view of the US courts that issues of science and policy are inseparable and that administrators' are entitled to exercise their judgment on both, came under strain during the George W. Bush administration, during which certain White House officials—relying broadly on the contingent and subjective nature of science—used various forms of influence in an effort, sometimes successful, to cause administrative agencies to produce scientific findings that would support predetermined policies. The cause célèbre, of course, is climate change, for which the Bush administration confidently asserted there was little scientific evidence, but other examples have been documented.[154]

The Bush administration in some ways upturned conventional positions on science and policy. Whereas regulated interests have often tried to impose "good science" requirements in an effort to limit

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[153] Sunstein, 'Naked Preferences and the Constitution' (1984) 84 Colum.L.Rev. 1689.

[154] A number of examples are discussed in McGarity and Wagner, *Bending Science* (Harvard 2010). Other sources include Doremus, 'Science Plays Defense: Natural Resource Management in the Bush Administration' (2005) 32 ELQ 249 and Shapiro, '"Political" Science: Regulatory Science After the Bush Administration' (2009) 4 Duke.J.Const.L.Pub.Pol'y 31. For one preliminary view on the Obama administration's record, see Kitrosser, 'Scientific Integrity: The Perils and Promise of White House Administration' (2011) 79 Ford.L.Rev. 2395.

regulatory intervention,[155] environmental groups now found themselves advocating for an emphasis on science over politics in decisionmaking.[156] The Bush administration's practices challenged the traditional view of science and policy issues at a much deeper level, however. Although US courts had long recognised that policy and science could not be separated, they had continued to insist that administrative regulation be based substantially on expert analysis. In this way, the scope of political discretion was limited to the range of options that could be justified scientifically. The Bush administration's assertion that it could act without regard to science or, worse, that it could use political means to dictate scientific outcomes threatened that understanding and with it the theory on which the legitimacy of administrative regulation rests.

The most high-profile case challenging the Bush administration's approach to science was brought by Massachusetts against EPA's denial of a rulemaking petition seeking limits on greenhouse gas emissions from mobile sources.[157] In denying the petition, EPA had refused to decide whether greenhouse gases "endanger public health".[158] Instead, the agency declined to regulate on the grounds that it preferred other strategies for addressing possible climate change. At first instance, Judge Randolph, writing the lead opinion for the DC Circuit, held that by citing numerous policy reasons weighing against greenhouse gas regulation EPA had offered a supportable rationale for denying the petition. Notably, Judge Randolph's opinion relied heavily on *Ethyl*.[159]

The Supreme Court reversed. Writing for a five justice majority, Justice Stevens held that EPA's proffered reasons for declining to regulate were arbitrary. First, the Court held that it was incumbent upon the agency to make an endangerment finding. If the agency thought the evidence too inconclusive to justify action it was required to make a

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[155] Wagner, 'The "Bad Science" Fiction: Reclaiming the Debate over the Role of Science in Public Health and Environmental Regulation' (Autumn, 2003) 66 LCP 63, 109–13.
[156] E.g., McGarity and Wagner (n.154), 293–95.
[157] *Massachusetts v. EPA*, 415 F.3d 50 (D.C.Cir.2005).
[158] This is the statutorily required finding. 42 U.S.C. § 7521(a)(1).
[159] *Massachusetts* (n.157), 57–58.

finding of no endangerment and to support that finding with reference to the uncertainty of the evidence.[160] Second, the statute limited the considerations EPA could take into account when deciding whether to regulate. In the Court's view, EPA had to make its decision solely by reference to whether public health was endangered.[161] The other considerations EPA had offered for declining to regulate, whatever their merit, were irrelevant and reliance on them was therefore arbitrary.[162]

The Court's decision in *Massachusetts v. EPA* engaged in a more assertive form of judicial review than has been typical in recent cases. Part of the explanation for that scrutiny was the Court's apparent, if implicit, scepticism that EPA was treating the scientific issues openly and honestly. It is also possible, however, that the Court was reasserting the primacy of scientific considerations over policy in setting risk standards. Indeed, at least two scholars have argued that the Court's message was that politics needed to take a back seat to expertise in administrative decisionmaking.[163]

The court's opinion unquestionably sets limits on the role of policy considerations in this area. Most importantly, it reaffirms that only policy considerations germane to goals of the governing statute may be taken into account in administrative decisionmaking.[164] In effect, it is a reminder that *Chevron*'s recognition of administrative power to elaborate statutory goals is not a license to rewrite legislation, no matter how reasonable the administration's approach may be.[165] It reaffirmed, in other words, that the administration is only a subordinate law maker. It also suggested that the integrity of the agency's scientific findings matters and that courts need not always assume an agency's conclusions

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[160] *Massachusetts* (n.6), 533.
[161] Ibid., 533–34.
[162] Ibid.
[163] Freeman and Vermeule, '*Massachusetts v. EPA*: From Politics to Expertise' [2007] Sup.Ct.Rev. 51, 52.
[164] Ibid., 534.
[165] Indeed, Justice Steven's majority opinion relied heavily on his earlier opinion in *Chevron*.

were reached in good faith.[166] The Court did not, however, clearly sanction judicial second-guessing of administrative science-policy judgments absent some indication of undue political influence. Of course, the Court left to the lower courts the task of deciding what constitutes undue political influence and how best to ferret it out.

All-in-all, it seems doubtful that the *Massachusetts* Court was advocating a significant retreat from the prevailing judicial understanding of risk regulation as requiring a large measure of policy judgment. Indeed, its discussion of EPA's refusal to make an endangerment finding suggested that the Court understood that when science is uncertain an agency will have to look to policy considerations to reach the necessary conclusions.[167] The Court's opinion instead seems to be a reminder that the exercise of administrative policy discretion must also be based on the agency's expert evaluation. By upholding a decision based on policy considerations with no grounding in scientific analysis and no discernible relationship to the goals of the Clean Air Act, the D.C. Circuit had tipped the balance too heavily in favour of indulging the agency's policy preferences. The Supreme Court's opinion should not, however, be read to fundamentally question the relevance or legitimacy of administrative policy judgment in risk regulation. Thus far, the lower courts appear to have interpreted the decision in this way, and recent cases do not show a trend away from the understanding that risk regulation demands the exercise of both scientific and policy judgment.[168]

G. US Summary

The story of the evolution of arbitrariness review of administrative risk regulation has been the story of evolving theories of administrative

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[166] Compare *Massachusetts* (n.6), 507–09 with ibid., 534.
[167] Ibid., 534–35.
[168] E.g., *Center for Biological Diversity v. EPA*, 749 F.3d 1079, 1088 (D.C.Cir.2014); *Coalition for Responsible Regulation, Inc. v. EPA*, 684 F.3d 102, 120 (D.C.Cir.2012) rev'd in part on other grounds sub nom. *Utility Air Regulatory Group v. EPA*, 134 S.Ct. 2427 (2014); *Upper Blackstone Water Pollution Abatement District v. EPA*, 609 F.3d 9, 23 (1st.Cir.2012); *Miami-Dade County* (n.73), 1063.

legitimacy. When the explosion of risk regulation programmes occurred in the early 1970s, administrative legitimacy was theorised in highly instrumental terms.[169] Agencies were to be Congress's faithful servants and were to base their decision on a rigorous technical analysis of how best to achieve Congress's ends. Although the need for administrative discretion was recognised, that discretion was limited to exercises of professional judgment.[170] What is more, the overriding focus of courts was on the protection of individual liberty from administrative overreach, with little consideration given to the effectiveness of risk regulation programmes or the interests of regulatory beneficiaries.[171] This judicial mind-set was doomed to failure in the era of risk regulation. Strong political forces, not least of all Congress itself, demanded regulatory action that could not be accommodated by common law categories.[172] Moreover, the context-specific nature of so many risk issues, combined with the need to make assessments "on the frontiers of science", required administrators to elaborate regulatory policy in ways that could not be based solely on analysis of legislative text. The old "private law" model of judicial review simply could not keep pace with these developments.

In the 1970s, courts and judges offered a number of new theories to reconcile the broad administrative discretion that risk regulation seemed to require with constitutional structure and rule of law values.[173] Some of these, such as interest group pluralism, had a moment of prominence and then were discarded. The only theory that proved to have the necessary staying power accorded broad constitutive authority to the administration while grounding the legitimacy of that authority in the administration's connection to the democratically elected president. A

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[169] Stewart (n.59), 1673–74.
[170] Landis (n.38), 69–70; Mashaw and Harfst, 'Regulation and Legal Culture: The Case of Motor Vehicle Safety' (1986) 4 Yale.J.Reg. 257, 269; cf. *Amalgamated Meat Cutters v. Connally*, 337 F. Supp. 737, 758–59 (D.D.C.1971) (Leventhal, J.) (three-judge court).
[171] Sunstein (n.3), 18–21.
[172] Sunstein, *Risk and Reason* (CUP 2004) 12–18.
[173] Stewart (n.59), 1688–1715.

theory that Justice Kagan has dubbed "Presidential Administration".[174] The rise of Presidential Administration among the courts as the dominant theory of administrative legitimacy saw a concomitant decrease in the intensity of judicial review. The more courts conceived of risk regulation as demanding the exercise of policy judgment, the less they felt capable of second-guessing administrative decisions. Whereas commentators have widely decried the intrusive and meddling courts of appeals of the 1970s, by the end of the century the question could fairly be asked whether the courts had become too lax. Were the rights of both regulated entities and regulatory beneficiaries being infringed by a politicised administration that made decisions first and asked questions later?

Judicial review in the last twenty years or so has thus tried to strike a difficult balance between enabling the broad administrative risk regulation programmes the public has demanded, while maintaining rule of law constraints on executive power. In part, the courts have threaded this needle by holding to the original premises of the American administrative state that administrative power could be legitimate only if exercised on the basis of knowledge. Thus, even as they have recognised that policy cannot be separate from science in risk regulation, the courts have attempted to reinforce science's role by requiring the administration to demonstrate a connection between its scientific analysis and its policy judgment. Whether the current approach can keep pace with the steady expansion of executive power remains to be seen.

III. Rationality Review in the EU

As in the US, judicial review of risk regulation in the EU has evolved significantly over time. This evolution, too, is traceable to substantial changes in the nature of the EU administration. Specifically, the evolution of EU understandings of administrative rationality is an outgrowth of the greatly expanded range of EU regulatory competences and obligations following the Single European Act and the Treaty of Maastricht, and the emergence of a distinct identity for the EU

[174] Kagan (n.129).

administration. This evolution has required the EU courts to adopt theories of administrative rationality that balance the interests of individuals in fair administrative proceedings with the inevitably political nature of risk regulation, including the Commission's need to be responsive to the concerns of Member States. Also as in the US, competing models of rational risk regulation can be found in the case law. The dominant approach, exemplified by *Pfizer* and its progeny, has strong resonances with the American public law model, though it differs in several particulars. A competing approach, represented by the General Court's judgment in *Sweden v. Commission*, has parallels with the private law model seen in older US cases in that it focuses on the administration's burden of proof.

A. Early Case Law

Traditionally, EU courts exercised their substantive review powers with a light touch, setting aside acts only if the court found a glaring error on the face of the measure. Proportionality review was largely limited to assessing whether the reasons provided showed that the measure was an appropriate means for achieving its stated goal.[175] Proportionality *strictu sensu* was rarely addressed and review of the sufficiency of the evidence supporting the measure was virtually non-existent.[176] The Court of Justice justified this weak approach to review largely on the ground that the weighing of competing considerations, i.e., the making of "complex assessments", was a political exercise unsuitable for judicial intervention.[177]

The classic example of the traditional approach is *Fedesa*.[178] In reviewing the decision to ban the use of hormones as growth promoters in livestock, the Court of Justice was content to accept the Council's

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[175] Craig (n.1), 439–446.
[176] Ibid., 445.
[177] Case 98/78, *Firma A. Racke v. Hauptzollamt Mainz* [1979] ECR 69, paras. 5–6; Fritzsche, 'Discretion, Scope of Judicial Review and Institutional Balance in European Law' (2010) 47 C.M.L.Rev. 361, 374–77.
[178] Above n.23.

statement that the available scientific information was conflicting and held that it was within the Council's discretion to determine how best to respond to that information to achieve its goal of harmonising the internal market.[179] The court never reviewed the evidence on which the Council's conclusions were based, nor did it distinguish clearly between the objectives of protecting public health and of restoring confidence in the market for beef, both of which it viewed as legitimate.[180] The *Fedesa* approach imposed virtually no limits on the EU Legislature's freedom of assessment beyond a minimal check that the measure in question fell within the EU's competence and that there was a discernible connection between the reasons stated and the measures taken.[181] Many other examples of this type of review can be found in the case law.[182]

Fedesa concerned measures adopted by the EU legislature (at the time, the Council acting on a proposal from the Commission). As such, it is tempting to explain the court's deference as grounded in respect for legislative judgments. Cases contemporary with the *Fedesa* judgment, however, show that the Court of Justice did not at that time draw a clear distinction between legislative and administrative rulemaking and that the court was prepared to adopted a similarly deferential approach when reviewing administrative decisions. The clearest examples can be found in the cases reviewing Commission competition decisions. In cases such as *Remia*[183] and *British-American Tobacco*,[184] the court again invoked the rhetoric of "complex assessments" and deferred to the Commission's judgments.[185] These cases suggest that during this period the court was

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[179] Ibid., paras. 8–9.
[180] Ibid., para. 38; Hilson (n.16), 322–23.
[181] This approach to review parallels the US courts' post-*Lochner* approach to substantive due process review. Chapter 3, section I.C.1.
[182] Craig (n.1), 660 (collecting cases); Türk, *Judicial Review in EU Law* (Edward Elgar 2009) 136–37.
[183] Case 42/84, *Remia BV v. Commission* [1985] ECR 2545, para. 34.
[184] Joined Cases 142 and 156/84, *British American Tobacco v. Commission* [1987] ECR 4487, para. 62.
[185] Bailey, 'Scope of Judicial Review under Article 81 EC' (2004) 41 C.M.L.Rev. 1327, 1336, 1342; Craig (n.1), 409–15; Fritzsche (n.177), 380.

just as unwilling to scrutinise administrative decisionmaking as it was to second-guess legislative judgments.

Although it avoids judicial interference with the other Institutions' policy choices, the *Fedesa* approach provides at best minimal judicial protection for individuals who may be adversely affected by regulatory measures.[186] While this hands-off approach may be defensible in the context of broad legislative measures of general applicability, it legitimacy in the context of measures affecting specific individuals—in which the right to effective judicial protection takes on greater importance—is harder to justify.[187] That distinction between legislative and individualised measures became increasingly important following adoption of the Single European Act, as an increasing number of EU regulatory programmes required the Commission to determine individual applicants' right to various regulatory benefits, such as product authorisations or tax exemptions.

In this new environment, the courts' approach to judicial review came to be questioned, particularly from the perspective of legal traditions in which a strong form of judicial review is seen as essential to the rule of law.[188] That controversy came to a head in *Technische Universität München* (*TU München*),[189] which concerned the denial of a customs duty exemption on the basis of a technical evaluation of equivalence. The national court not only referred the question of the decision's validity, but also pointedly suggested that if the decision could not be reviewed substantively then the legislative scheme itself might be unlawful as violating the right to judicial protection.[190]

In his opinion, Advocate General Jacobs agreed with the national court that the Court of Justice's then-standard approach to manifest

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[186] Craig (n.1), 445–46.
[187] Azoulay (n.3), 130–32; Türk (n.182), 137 (collecting cases).
[188] Nehl, *Principles of Administrative Procedure in EC Law* (Hart 1999) 106–09; Schwarze, *European Administrative Law* (Sweet and Maxwell 1992) 298–300.
[189] Case C-269/90, *Hauptzollamt München-Mitte v. Technische Universität München* [1991] ECR I-5469.
[190] Ibid., Opinion of A.G. Jacobs, paras. 10–11.

error was deficient.[191] He denied, however, that the court had the capacity to engage in its own detailed review of questions in a "technical domain".[192] Instead, he viewed the court's role as ensuring that the administration undertook a careful evaluation of the relevant technical issues. If the court were satisfied that the administration met the requisite level of care, it could limit its review to manifest error without undermining the right to judicial protection.[193]

The court's judgment did not embrace the entirety of the Advocate General's reasoning. Most importantly, it dodged the question of the compatibility of its deferential approach to review with the right to judicial protection. It did, however, hold that when the administration was called upon to make "complex technical appraisals," the competent Institutions would be required "to examine carefully and impartially all the relevant aspects of the individual case" and to respect "the right of the person concerned to make his views known and to have an adequately reasoned decision."[194] In effect, the court imposed upon the Commission an administrative duty of care when regulating in the field of risk.[195] *TU München* thus marked an important shift in the courts' approach towards greater judicial scrutiny. That scrutiny would not, however, be focused on the substance of the administrative decision, but rather on decisionmaking procedure.[196]

The *TU München* decision had tremendous significance for the new generation of EU risk regulation programmes, many of which required the Commission to make decisions regarding the compatibility of individual products with broad legislative standards. Examples in the field of risk regulation include the Plant Protection Products Directive,[197]

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[191] Ibid., paras. 13–16.
[192] Ibid., para. 15.
[193] Ibid., para. 16.
[194] Ibid., para. 14.
[195] Nehl (n.188), 132–35.
[196] Azoulay (n.3), 112–19.
[197] Directive 91/414/EEC concerning the placing of plant protection products on the market [1991] O.J. L230/1.

the Cosmetics Directive,[198] and the GMO Deliberate Release Directive,[199] among others. Thus, in cases like *Angelopharm* and *Bergaderm*, both of which concerned the authorisation of cosmetic products, the court took an approach similar to *TU München* (although neither judgment actually relied on it), and carefully reviewed the adequacy of the Commission's evaluation process. In both cases, input from qualified experts was held to be necessary for adequate regulatory consideration.[200] Indeed, in *Angelopharm*, the court went so far as to state that expert advice was necessary "in the nature of things".[201] These cases show the courts looking to science and scientific assessment as a means of disciplining administrative decisionmaking, as well as a mechanism for judicial control through imposition of procedural requirements.

It is also notable that in these cases the courts' focus was on protecting the rights of applicants from unlawful (or unwarranted) regulation. The introduction of an administrative duty of care and the recognition of the applicant's right to be heard can thus be seen as related to the courts' broader jurisprudence on the rights of defence, which was also undergoing substantial development at this time.[202] In this respect, these decisions can be seen as akin to early US decisions following the private law model in that their focus is on ensuring that the administration's reasons are adequate to justify the imposition of regulatory burdens on private parties. In similar fashion, these decisions give a great deal of attention to the adequacy of the administration's evidence, suggesting that the administration bears a burden of proof

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[198] Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products [1976] O.J. L262/169.
[199] Directive 90/220/EEC on the deliberate release into the environment of genetically modified organisms [1990] O.J. L117/15.
[200] *Angelopharm* (n.25), paras. 37–38; *Bergaderm* (n.26), para. 64.
[201] *Angelopharm* (n.25), paras. 40–41; Joerges, '"Good Governance" Through Comitology?' in Joerges and Vos (eds.), *EU Committees: Social Regulation, Law and Politics* (Hart 1999) 332–34.
[202] Bignami, 'Creating European Rights: National Values and Supranational Interests' (2005) 11 Colum.J.Eur.L. 241, 284–91; Nehl (n.188), 91–99.

when regulating.[203] Despite these similarities, however, the EU courts did not engage in anything like the intense factual review undertaken by US courts applying the private law model. That difference suggests that although they harboured similar concerns regarding the lawfulness of administrative regulation, the EU courts were prepared to recognise a role for administrative discretion in determining when scientific evidence was sufficient to justify regulation.

B. The Importance of the BSE Crisis

Had circumstances been different, EU judicial review of risk assessment might have remained focused on the protection of regulated entities, with the corresponding implications for administrative rationality. History intervened, however, in the form of Bovine Spongiform Encephalopathy. BSE was a crisis not only for public health, but also for public confidence in EU regulation, which in turn threatened commitment to the single market.[204] In the wake of such a significant regulatory failure, the EU's entire approach to risk regulation had to be reassessed. For its part, the Commission issued a series of communications and policy papers vowing to increase the rigour and transparency of EU regulation and to improve the quality of the scientific advice on which it relied.[205] The courts, too, would have to respond to the changed circumstances brought about by

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[203] Cf. Case T-5/02, *Tetra Laval BV v. Commission* [2002] ECR II-4381, para. 155; Vesterdorf, 'Certain Reflections on Recent Judgments Reviewing Commission Merger Control Decisions' in Hoskins and Robinson (eds.), *A True European: Essays for Judge David Edwards* (Hart 2003) 138–40.

[204] E.g., Little, 'BSE and the Regulation of Risk' (2001) 64 MLR 730; van Zwanenberg and Millstone, *BSE: Risk, Science, and Governance* (OUP 2005); Vos, 'Food Safety Regulation in the Aftermath of the BSE Crisis' (2000) 23 J.Consum.Pol'y 227.

[205] E.g., 'Communication on Consumer Health and Food Safety', COM(1997)183 final, 9–10; 'White Paper on Food Safety', COM(1999) 719 final, 6–7; 'Communication on the Precautionary Principle', COM(2000) 1 final, 15–16; 'European Governance: A White Paper', COM(2001) 428 final, 19; 'Communication on the Collection and Use of Expertise by the Commission: Principles and Guidelines', COM(2002) 713 final, 9–10; see also van Zwanenberg and Millstone (n.204), 219–22.

the BSE crisis. In particular, they would have to address how, if at all, administrative law would contribute to ensuring that the EU administration would meet its responsibility to protect public health.[206]

When BSE finally reached the courts, the Court of Justice seemed to revert to the *Fedesa* approach. In the *BSE Cases*,[207] the court's focus palpably shifted away from safeguarding the rights of regulated entities and toward affirming that the EU Institutions possessed sufficient discretion to deal with public health problems as they arose. In contrast to cases like *Bergaderm*, which had reviewed the Commission's scientific analysis in some detail, the court only briefly addressed the evidence on which the measures were based.[208] For the court, it was sufficient that there was some evidence of serious health risks. Its analysis instead focused on the importance of policy considerations—and of the regulatory objectives to be achieved (i.e., the protection of public health)—in assessing the lawfulness of measures taken in response to concerns about safety.[209] The court's language suggests that it was not simply deferring to the Commission's scientific analysis, but that, in light of the undisputed potential seriousness of the threat, further scientific analysis was largely beside the point.[210] Additionally, as in *Fedesa*, the court upheld the Commission's reliance on a mix of concerns regarding risk to consumer health and the need to restore consumer confidence in the market, thus reinforcing the characterisation of the regulatory problem as one of agricultural policy, rather than scientific risk evaluation.[211]

This approach to review is similar to the public law line of cases in the US and, indeed, both the Advocate General's opinion and the Court of Justice's judgments have strong resonances with the DC Circuit's

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[206] Vos (n.204), 246.
[207] Case C-157/96, *R. v. MAFF, ex p. National Farmers' Union* [1998] ECR I-2211; *United Kingdom* (n.24).
[208] *NFU* (n.207), paras. 62–76.
[209] Ibid., para. 61 ("[T]he Community legislature has a discretionary power which corresponds to the political responsibilities given to it . . . .").
[210] *United Kingdom* (n.24), paras. 61–63.
[211] *NFU* (n.207), paras. 42–46.

decision in *Ethyl*. The focus is on whether the Commission is regulating appropriately to protect public health. Although the interests of regulated entities are not irrelevant, protection of those interests must give way to the interests of the public at large. Striking the appropriate balance is a question of regulatory policy for the Commission. Although rational administrative decisionmaking must have due regard for the available facts, rationality *vel non* is determined by the reasonableness of the Commission's policy analysis and not by the quality of its scientific reasoning. The court's role is to confirm that the Commission's decision conforms to its regulatory mandate and that is consistent with the regulatory policies enshrined in the Treaties and the General Principles, including the principle that the EU must pursue a high level of protection.[212]

The *BSE Cases* were also notable for their reliance on the logic of the precautionary principle, even if the principle itself was not named. In its judgment, the court recognised that "[a]t the time when the contested decision was adopted, there was great uncertainty as to the risks posed".[213] That uncertainty did not, however, vitiate the lawfulness of the measures: "Where there is uncertainty as to the existence or extent of risks to human health, the institutions may take protective measures without having to wait until the reality and seriousness of those risks become fully apparent".[214] By reaffirming that scientific uncertainty is no bar to regulation, the court seemed to expand the scope of the Institutions' policy discretion while simultaneously limiting the role of judicial review.[215] It also repudiated an approach to judicial review structured in terms of burdens of proof in favour of a more context-sensitive approach to administrative rationality.

The *BSE Cases* were, in part, a product of their circumstances, and the court's lack of attention to the rule of law concerns raised in *TU München* is understandable in light of the dramatic context. It was

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[212] Chapter 3, section I.B.1; *NFU* (n.207), paras. 20, 29.
[213] Ibid., para. 62.
[214] Ibid., para. 63.
[215] Cf. Hilson (n.16), 331–32.

inevitable, however, that in less politically charged circumstances the tension between the need for judicial control and the discretion-enhancing effects of the precautionary principle would resurface. The legal problem for the courts was to find a means of extending adequate judicial control over administrative decisionmaking without undermining the flexibility introduced by the precautionary principle. The General Court would finally confront these challenges in its landmark judgments in *Pfizer* and *Alpharma*.

C. *Pfizer* and Its Aftermath

Pfizer and *Alpharma*[216] both concerned challenges to the validity of directives withdrawing authorisation for the use of certain antibiotics as feed additives. These directives had been adopted by the Council under authority delegated by an earlier directive (following the failure of the comitology committee to adopt an opinion).[217] The scientific evidence relied on by the Commission was admittedly thin. Although there was some evidence that the use of antibiotics as growth promoters could promote antibiotic resistance in humans, that evidence was far from conclusive and the relevant expert committee issued an opinion finding no immediate need for action.[218] Nonetheless, concerned about the potentially grave threat to health, the Council pressed ahead with a ban. In mounting its challenge, Pfizer relied heavily on cases like *Angelopharm* and *Bergaderm*, as well as the courts' Article 30 jurisprudence, which emphasised the importance of scientific analysis and the protection of individuals from unjustified regulatory burdens. The Council, unsurprisingly, focused on the holdings in *Fedesa* and the *BSE cases*, which had upheld broad discretion to address potential threats to public

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[216] Case T-70/99, *Alpharma Inc. v. Council* [2002] ECR II-3495. The two judgements are extremely similar and for the remainder of the chapter, I will only refer to *Pfizer*.

[217] Regulation (EC) 2821/98 of 17 December 1998 amending, as regards withdrawal of the authorisation of certain antibiotics, Directive 70/524/EEC concerning additives in feeding stuffs [1998] O.J. L351/4, recital 35.

[218] *Pfizer* (n.27), para. 53.

health. The court was thus required to re-assess the boundaries of the domain of risk regulation, as well as to consider what qualified as a rational administrative decision within those bounds, particularly in light of the precautionary principle.

1. Does *Pfizer* impose a burden of proof?

Pfizer argued, in effect, that the courts' case law imposed on the Commission a burden of proof. While it did not go so far as to demand scientific certainty, it argued that withdrawal of the authorisation could only be lawful if the administration could "demonstrate that . . . the use of the additive in question is a hazard to human health and to show the level of risk associated with it."[219] The court's response to this argument was ambiguous. Although it made clear that certainty would not be required—which would be inconsistent with the precautionary principle—it also suggested that regulatory measures needed "to be adequately backed up by the scientific data available at the time".[220] Perhaps more importantly, the court prohibited regulatory measures based solely on "a purely hypothetical approach to the risk, founded on mere conjecture which has not been scientifically verified".[221] Interpretation of the no hypothetical risk rule has proved to be difficult and controversial. The court's phrasing could be interpreted as creating a burden of proof, requiring the administration to produce a certain type and quantum of evidence as a precondition for taking regulatory measures.[222] Other cases, such as *Solvay Pharmaceuticals*,[223] which focus on whether the administration has produced "solid evidence" of risk, seem to support the burden of proof interpretation, as do some of the courts'

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[219] Ibid., para. 132.
[220] E.g., ibid., para. 144.
[221] Ibid., para. 143.
[222] E.g., Alemanno, Comment, Case C-79/09 [sic], *Gowan Comércio Internacional e Serviços Lda v. Ministero della Salute* (2011) 48 C.M.L.Rev. 1329, 1344.
[223] Case T-392/02, *Solvay Pharmaceuticals BV v. Council* [2003] ECR II-4555, para. 129.

contemporaneous Article 36 (ex Article 30) TFEU cases, such as *Commission v. Netherlands*.[224]

Subsequent judgments cast doubt on the burden of proof interpretation, however. First, if the rule imposes a burden of proof, the hurdle is exceedingly low.[225] In *Pfizer* itself, it appeared that a risk would not be deemed hypothetical if the administration could produce any plausible scientific basis to support a concern, even if there were also substantial evidence suggesting the absence of risk.[226] Subsequent cases have also clarified that empirical evidence is not necessary to support risk concerns; a grounding in scientific theory is enough.[227] Finally, later cases have upheld regulatory measures based on an absence of evidence of safety, rather than a positive showing of risk. In the context of plant protection products, for example, the courts have upheld a positive authorisation procedure that forbids the Commission from granting authorisation unless the applicant can produce sufficient evidence to show that an active substance does not pose specified risks.[228]

These cases suggest that the no hypothetical risk rule is better understood not as a burden of proof, but as a limitation on the types of reasons on which the administration may rely. Specifically, the no hypothetical risk rule requires the administration to justify regulatory measures on the basis of specifically identified concerns that are at least theoretically capable of scientific verification. In this way, the no hypothetical risk rule reinforces the courts' framing of risk in terms of

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[224] Case C-41/02, *Commission v. Netherlands* [2004] ECR I-11375, para. 49.
[225] Case C-269/13 P, *Acino AG v. Commission*, nyr, para. 81; Heyvaert (n.29), 200–01.
[226] *Pfizer* (n.27), para. 221.
[227] *Solvay Pharmaceuticals* (n.223), paras. 140–42; Case C-14/10, *Nickel Institute v. Secretary of State for Work and Pensions* [2011] ECR I-6609, paras. 71–75.
[228] Case C-77/09, *Gowan Comércio Internacional e Serviços Lda v. Ministero della Salute* [2010] ECR I-13533, paras. 77–78.

scientifically backed concerns regarding health or the environment.[229] Thus interpreted, the primary role of the no hypothetical risk rule is to define the framing of rational decisionmaking on risk. It does not, however, address the further question of the kind of reasoning that must link the identification of a scientifically backed concern and the decision on whether and how to regulate.

2. *Pfizer*'s reconciliation of scientific and political judgment

Like *TU München*, *Pfizer* addressed review of administrative risk regulation largely through the lens of procedure. Fundamental to the court's analysis was its acceptance of the separation of risk assessment from risk management along the lines described by the Commission in its Communication on the Precautionary Principle.[230] As formulated by the Commission, risk assessment is an analytical scientific process that must be committed to experts and insulated from political influence. Risk management, by contrast, is a decisionmaking process for which political methods are appropriate.[231] In this way, the court was able to address the technical and policy aspects of risk regulation separately and to require the administration to apply distinct modes of reasoning to each.

The court discussed risk assessment in terms of building an information base for decisionmaking on risk management. Before regulating, the Institutions must first undertake "as thorough a scientific risk assessment as possible".[232] Absent "exceptional circumstances",[233] the Institutions must entrust the risk assessment to experts, whose work must be undertaken on the basis of "excellence, independence, and transparency".[234] The Institutions are not bound by the experts' opinion,

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[229] Cf. Feintuck, 'Precautionary Maybe, but Where's the Principle? The Precautionary Principle, the Regulation of Risk, and the Public Domain' (2005) 32 JLS 371, 384.
[230] COM(2000) 1 final, 12.
[231] Ibid., 2; *Pfizer* (n.27), paras.149–51; see also Chapter 1, Section I.B.
[232] *Pfizer* (n.27), para. 162.
[233] Ibid., para. 270.
[234] Ibid., para. 159.

but if they depart from it, they must provide reasons for doing so, which "must be of a scientific level at least commensurate with that of the opinion in question".[235] Although it addressed risk assessment largely as an objective inquiry, the court was careful to add that when "a Community authority is required to make complex assessments in the performance of its duties, its discretion also applies, to some extent, to the establishment of the factual basis of its action."[236] In formulating these requirements, the court relied heavily on the *TU München* judgment and the administrative duty of due care.[237]

By contrast to its focus on the need for expert evaluation in risk assessment, the court was absolutely clear that it viewed risk management—and by extension the ultimate regulatory outcome—as primarily a question of politics.[238] Risk management is informed by risk assessment, but is not controlled by it. Importantly, decisionmaking on risk management is not limited to scientific concerns, but extends to the full range of issues that affect public acceptability of risk, as well as practical considerations that inform the choice among various potential regulatory measures.[239] Because questions of risk management are ultimately political, they must be decided by politically legitimate means. As such, they may not be delegated to expert bodies, but must be undertaken by institutions with political responsibilities.[240] Furthermore, the courts may not second-guess the substance of those decisions but must confine their review to assuring that the chosen measures fall within the scope of the decisionmaker's authority and are not vitiated by manifest error.[241]

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[235] Ibid., para. 199.
[236] Ibid., para. 168.
[237] Ibid., paras. 171–72.
[238] E.g., ibid., paras. 151, 201, 283, 288, 412.
[239] Ibid., para. 151; see also Corkin, 'Science, Legitimacy and the Law: Regulating Risk Regulation Judiciously in the European Community' (2008) 33 ELR 359, 368–69.
[240] *Pfizer* (n.27), para. 201.
[241] Ibid., para. 412.

Pfizer thus suggests that rational risk regulation calls for two separate modes of reasoning. Scientific reasoning is applied to risk assessment, which is understood as an empirical and analytical exercise that informs regulatory decisionmaking.[242] The final regulatory decision, by contrast, is framed as a question of policy, which the Commission not only may, but must, decide through the application of political (including normative) reasoning.[243] By its nature, such political reasoning is susceptible of only limited judicial review.[244] Instead of reviewing the administration's risk management choices directly, the court attempts to bolster their legitimacy by ensuring that they are taken "in full knowledge of the facts",[245] rather than on the basis of misinformation or prejudgment.[246] The requirement of a risk assessment may be seen as a logical outgrowth of *TU München*, in that the legal determination of whether a measure is arbitrary depends not on the substance of the decision but on the thoroughness of the administration's consideration of the problem. In this way, the right to judicial protection from arbitrary administrative decisionmaking is upheld while minimising the need for the court to arbitrate the weighing of competing concerns.[247]

Passages in the *Pfizer* opinion suggest that the court also saw risk assessment as reinforcing the legitimacy of political decisionmaking in a subtler way, by reinforcing political accountability. In this regard, the court required not only that the administration complete a risk assessment, but also that the assessment be independent and transparent.[248] Independence requires that the risk assessment be conducted without regard to political considerations, so that the risk assessment does not end up being nothing more than a post-hoc

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[242] Scott and Sturm (n.5), 584–85.
[243] *Pfizer* (n.27), para. 201
[244] Ibid., para. 412
[245] *Pfizer* (n.27), para. 288; see also *Artegodan* (n.28), para. 198; *Bergaderm* (n.26), para. 64; *Angelopharm* (n.25), paras. 31–32.
[246] Scott and Sturm (n.5), 582.
[247] Corkin (n.239), 368–72.
[248] *Pfizer* (n.27), para. 172.

justification.[249] And, when coupled with transparency, independence reinforces political accountability.[250] A risk assessment that is prepared independently of the political decisionmaking process provides a benchmark against which the public can evaluate the administration's risk management choices. It also provides courts with a basis for review. For risk assessment to fulfil that role, it is not necessary to assume scientific analysis is objective in some neutral sense; it is sufficient that it provides an analysis of the problem that is not wholly dependent on political preferences, so the significance of the Commission's policy choices is made more apparent. The Commission itself has suggest that independence and transparency of risk assessment can contribute to accountability in these ways.[251] The viability of this solution, however, depends on the framing of risk in terms of scientifically backed concerns. If risk regulation were not limited to such concerns, the ability of the risk assessment to act as a sufficient procedural constraint on administrative decisionmaking would be undermined. Similarly, it would become difficult to argue that the courts' procedural approach adequately implements the right to judicial protection.

Pfizer represents an effort by the EU courts to reconcile an essentially public law vision of administrative risk regulation—in which rational decisionmaking depends on the administration's ability to link its evaluation of the evidence to public-regarding regulatory goals—with the protection of individual rights, including the right to judicial protection. It affirms the centrality of scientifically backed concerns, but at the same time it seems to open up decisionmaking to nonscience reasons. It aims to protect regulated entities by insisting on a thorough and impartial investigation of the relevant facts, but it does not carve out a regulatory no-go area by imposing a rigid burden of proof. The central insight of *Pfizer* is the recognition that scientific and political legitimacy are not independent values, but that scientific legitimacy can buttress political

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[249] Ibid., para. 268; 'White Paper on Food Safety' (n.205), para. 41.
[250] Curtin, *Executive Power in the European Union* (OUP 2009) 258–59.
[251] 'White Paper on Food Safety' (n.205), paras. 41–42, 63.

legitimacy, both by guarding against the excesses of politics and by enhancing the accountability of political actors.

The General Court's approach to rationality review in *Pfizer* was echoed by the Court of Justice in its judgment in *Gowan*,[252] in which the applicant challenged restrictions on the use of the active substance fenarimol imposed by the Commission as part of its reauthorisation under the Plant Protection Products Directive. During the authorisation procedure, the rapporteur Member State, upon completing the risk assessment, recommended reauthorisation without restrictions and that recommendation had been confirmed by the Evaluation Working Group of the Standing Committee on the Food Chain and Animal Health. Initially, the Commission had accepted that recommendation, but after hearing concerns from several Member States regarding fenarimol's possible endocrine disrupting properties and seeking additional advice from the Scientific Committee on Plants, the Commission proposed a more restricted authorisation for a shorter time period. When the comitology committee failed to deliver an opinion on that proposal, the Commission re-evaluated its position and proposed a much more limited authorisation to the Council. After the Council failed to act, the Commission adopted its revised proposal.[253]

The Court of Justice's opinion was much more cursory than the General Court's in *Pfizer* and for that reason is open to competing interpretations. On one hand, it can be seen as a retreat from *Pfizer* in that the Court of Justice seemed less willing than the General Court to examine closely the procedure that had yielded the risk assessment.[254] On the other, several aspects of the judgment are consistent with the General Court's decision. First, the Court of Justice relied on *TU München* as the basis for its analysis.[255] In doing so, it reinforced the link between administrative rationality and the administrative duty of care. Second, the *Gowan* court reaffirmed the regulatory measures could not

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[252] Above n.228.
[253] Ibid., paras. 33–44.
[254] Alemanno (n.222), 1345–47.
[255] Ibid., para. 57.

be based on "purely hypothetical considerations", but it did not treat that prohibition as imposing a burden of proof.[256] For the court, it was sufficient that certain Member States had put forward scientific evidence suggesting a possible concern.[257] Finally, the court reaffirmed that the scope of the necessary risk management measures is a question for political resolution. The risk assessment was only a starting point. How the Commission responded to that assessment, in conjunction with the Member States through comitology, was a matter of policy judgment, the legality of which "can be affected only if the measure is manifestly inappropriate".[258]

Gowan is also important because it shows that in the EU, administrative risk regulation is not just a political choice, but also a negotiated one. Initially, the Commission was prepared to propose and unrestricted authorisation. It was only through the comitology process that the Commission's position evolved as it sought to secure a qualified majority.[259] The court shows itself entirely comfortable with that evolution, indicating that it does not understand administrative rationality in purely instrumental terms, but rather as (at least partially) a constitutive process. In other words, rational administrative decisionmaking must be able to account for the process of negotiating a European position out of potentially divergent views of various actors in the regulatory process. One consequence of the negotiated character of EU decisionmaking is that administrative rationality does not (cannot) require the Commission to demonstrate that its decision is a logical outgrowth of the risk assessment, but merely that the risk assessment was completed and considered in the decisionmaking process. That

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[256] Ibid., para. 78.

[257] By contrast, Alberto Alemanno argues that in its analysis of hypothetical risk, the court "refused to effectively scrutinize whether this evidentiary threshold for precautionary action had been met". Alemanno (n.222), 1342. For precisely that reason, I would argue that a better interpretation of the no hypothetical risk rule is that it demands a *type* of reason rather than an evidentiary threshold.

[258] *Gowan* (n.228), para. 82.

[259] Cf. Case T-240/10, *Hungary v. Commission*, nyr, paras. 23–41.

understanding of the relationship between the risk assessment and the regulatory decision marks an important contrast to the US approach to administrative rationality, in which the administration, conceived as a unitary actor, is required to show consistency across all aspects of the decisionmaking process.

Another important recent case in the *Pfizer* mould is *France v. Commission*,[260] which concerned a challenge to a Commission regulation relaxing certain safeguards concerning transmissible spongiform encephalopathies (TSEs). The case is important because it shows both the General Court and the Court of Justice applying the *Pfizer* framework in a case in which the applicant, a Member State, argued that the Commission's decision was insufficiently protective of public health. In this case, France argued that the Commission violated the precautionary principle by relaxing the safeguards despite opinions from EFSA and a French expert body concluding that doing so would increase the risk of transmission of TSEs to humans.[261]

In upholding the Commission's decision, the General Court focused on the fact that the Commission was aware of the expert opinions as well as of the uncertainties regarding the risk assessment.[262] Having demonstrated that it possessed "full knowledge of the facts", it was up to the Commission to make a political determination regarding the level of risk acceptable to society, giving due regard to the Treaties' mandate that the EU pursue a high level of protection.[263] The fact that the expert evaluation indicated that the measure could increase risk was not dispositive.[264] Addressing the substance of the Commission's risk management decision, the court found that France had not shown the

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[260] Case T-257/07, [2011] ECR II-5827. The General Court's judgment was affirmed by the Court of Justice in Case C-601/11 P, nyr.
[261] *France* (n.260), para. 203.
[262] Ibid., paras. 97, 132.
[263] Ibid., para. 77.
[264] Ibid., para. 79 (citing Case C-284/95, *Safety Hi-Tech Srl v. S. & T. Srl* [1998] ECR I-4301, para. 49).

Commission's evaluation of the risk's acceptability was unreasonable, and thus it had to be upheld.[265]

France v. Commission reinforces the conclusion that the role of scientific analysis in the EU courts' model of administrative rationality is essentially procedural and focused on the compilation of an adequate information base for political decisionmaking. By undertaking a risk assessment and examining the evidence submitted by France, the Commission discharged its obligation to consider the scientific issues. Absent a showing that its scientific conclusions were implausible, the Commission was entitled to act on the basis of that evaluation, and its decision could be subject to only highly circumscribed review by the court. As discussed in the next section, however, this model is not the only one to be found in the EU courts' case law.

D. An Alternative Approach: *Sweden v. Commission*

Although *Pfizer* has come to dominate judicial review of EU risk regulation, it has not fully settled doctrine in this area. In *Sweden v. Commission*,[266] the General Court annulled the Commission's authorisation of the active substance paraquat under the Plant Protection Products Directive,[267] relying in part on its own evaluation of the scientific evidence. The approach taken in *Sweden* relies on a different model of administrative rationality from the one advanced in *Pfizer* with regard to both the role of science in administrative rationality and the place of the Commission in the overall regulatory process.

Sweden challenged the Commission's authorisation of paraquat on both procedural and substantive grounds. On the procedural claims, the court ruled, in essence, that the authorisation had to be annulled because the scientific committee had failed to document its evaluation of all of the relevant issues.[268] That ruling was fully consistent with

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[265] Ibid., para. 262.
[266] Above n.7.
[267] Above n.197. Paraquat was added to the list of authorised active substances by Commission Directive 2003/112/EC [2003] O.J. L321/32.
[268] Ibid., paras. 108–110.

Pfizer.[269] If anything, by focusing on the transparency of the Commission's analysis, this aspect of the judgement reinforces the idea that a central purpose of risk assessment is to enhance the administration's accountability, rather than to dictate outcomes.

In its substantive challenge, Sweden argued that the authorisation of paraquat was contrary to the principle of integration, the principle of a high level of protection, and the precautionary principle.[270] Sweden's argument was not merely that the Commission had breached these principles by giving inadequate consideration to potential safety concerns, but rather that the existence of evidence indicating possible adverse effects required the Commission—as a matter of law—to deny the authorisation. Specifically, Sweden argued that, under the terms of Directive 91/414, as interpreted in light of the precautionary principle, the Commission could not authorise a substance unless "it has been proved beyond a reasonable doubt that a product containing that active substance can be used with complete safety in at least one representative type of use."[271] In Sweden's view, the existence of studies showing adverse effects from paraquat exposure meant that the Commission could not meet that standard.

The court largely accepted Sweden's argument. First, it construed Directive 91/414 to require proof beyond a reasonable doubt that use of a substance will cause no harm to health or the environment.[272] Rather than expanding the administration's discretion in matters of risk regulation, the *Sweden* court applied the principle as a restraint, all but eliminating the Commission's flexibility "to determine the level of protection which [it] deem[s] appropriate for society."[273] The most interesting aspect of the *Sweden* judgment, however, is not its interpretation of the directive, but that the court went on to evaluate the available evidence and to determine—with little apparent regard for the

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[269] *Pfizer* (n.27), paras. 159, 184.
[270] *Sweden* (n.7), para. 129.
[271] Ibid., para. 140.
[272] This aspect of *Sweden* is discussed more fully in chapter 3, section I.B.2.
[273] *Pfizer* (n.27), para. 151.

Commission's (or the comitology committee's) views—whether that standard was met. Relying on its own reading of a single study,[274] the court explicitly rejected the scientific committee's weight of evidence evaluation and instead determined that the study constituted "solid evidence which may reasonably raise doubts as to the safety of paraquat for operators" and on that basis held that the authorisation violated the directive.[275] In a subsequent section of the judgment, the court engaged in a similar evaluation of the evidence with respect to ecological risks.[276]

The *Sweden* court's evaluation of the evidence marks a substantial departure from the *Pfizer* approach. Rather than evaluating whether the administration had undertaken an adequate scientific evaluation, the court evaluated whether the Commission had met a judicially determined burden of proof. In effect, the court treated the risk assessment as a question of basic fact rather than as a complex evaluative judgment. Nowhere to be found in the *Sweden* judgment is the principle, central to the *Pfizer* approach, that when "a Community authority is required to make complex assessments in the performance of its duties, its discretion also applies, to some extent, to the establishment of the factual basis of its action."[277] Yet the *Sweden* judgment seems to assume that such determinations can be made unproblematically by the court on the basis of its review of the submitted studies. What is more, the *Sweden* court effectively transformed the question of the appropriate level of protection into a question of law for judicial resolution.

The judgment in *Sweden* thus demonstrates an understanding of the administration's role in risk regulation very different from *Pfizer*'s. Instead of a process of political decisionmaking about the implications of scientific evidence, the *Sweden* court seemed to view the administration's task as a largely mechanical one of verifying whether a substance meets

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[274] The "Guatemalan study"; the rapporteur's report had found the study to be of limited significance to the conditions of use in Europe. *Sweden* (n.7), para. 178. The focus on a single study can be seen as a case of "analytical opportunism". Fisher (n.12), 121–22.
[275] Ibid., paras. 180–82.
[276] Ibid., paras. 229–52.
[277] *Pfizer* (n.27), para. 168.

legally prescribed criteria. In this approach to risk regulation, scientific evidence is the overriding basis for administrative decisionmaking. There is little need for discretionary evaluation and, consequently, a much larger role for the court in determining risk acceptability through its interpretation of legislative thresholds and application of the precautionary principle. The *Sweden* approach can be seen as essentially the inverse of the private law model in the US. Like the private law model, administrative rationality is structured in terms of burdens of proof, and the lawfulness of the administration's regulatory decision depends primarily on the sufficiency of the evidence supporting it. It is the inverse of the private law model because rather than using these burdens to protect the interests of regulated entities, the *Sweden* court applied them to prohibit the Commission from authorising a potentially risk product. Although some might approve of this use of burdens of proof, inasmuch as it would seem to promote greater protection of public health, there is also good reason to be cautious. As we saw in chapter 1, judgments about risk are inherently contextual, and it will often be impossible to capture that complexity in terms of a burden of proof. Were the *Sweden* approach to become dominant, it could greatly impoverish EU discourse on risk regulation and exacerbate conflicts among the various stakeholders. The result might be greater regulatory controls on potentially risky technologies, but it is far from clear that it would foster greater functional legitimacy of EU risk regulation.

E. EU Summary

The foregoing analysis has illustrated the relationship between the EU courts' jurisprudence on risk and their understanding of the role of the administration within the EU's institutional structure. Stepping back from the facts of the cases, it becomes possible to draw connections between the EU courts' evolving conceptions of rational risk regulation and concerns about the constitutional legitimacy of administrative power. Recognising these connections helps to clarify the bases for the competing models of administrative rationality and judicial review found in the case law.

The first observation to make is that the EU courts have begun to treat legislation and administrative standard setting differently, and to apply greater scrutiny to the latter. This heightened scrutiny is rooted, in part, in the courts' understanding of the administration as a subordinate policymaker.[278] Additionally, the increasingly individualised nature of much EU risk regulation, exemplified in the granting or withholding of authorisations for particular products, has led to the imposition of procedural obligations to protect the fairness of proceedings. Judicial control of these procedures is linked to the right to judicial protection, which is recognised as a general principle of EU law.[279] The resort to procedure appears to be motivated by a desire to vindicate rule of law values while maintaining a large measure of flexibility for administrative decisionmaking. The effect is to create a distinctively administrative process of regulatory decisionmaking on risk.

Less clear is the extent to which the courts are prepared to endorse a role for the EU administration in making policy judgments on risk. In the dominant approach represented by *Pfizer*, risk regulation is understood as an inherently policy-laden process. Although the identification, and to some extent the characterisation, of the risk depends on science, the content of the regulatory response is understood primarily as a question of policy.[280] On this view, the administration is a legitimate, albeit subordinate, policymaker, and the legality of administrative risk regulation is grounded in a combination of political authority and procedural mandates meant to ensure that the Commission's discretion is exercised in an informed manner.[281]

In the *Pfizer* approach, science contributes to the legitimacy of risk regulation in two ways. First, it attempts to promote high quality decisionmaking by ensuring that the Commission exercises its discretion on the basis of adequate information. This aspect of *Pfizer* is directed

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[278] Case C-343/09, *Afton Chemical Ltd. v. Secretary of State for Transport* [2010] ECR I-7027, Opinion of A.G. Kokott, paras. 66–67.
[279] *TU München* (n.189), para. 14; Tridimas, *The General Principles of EU Law* (2d ed., OUP 2006) 6.
[280] *Pfizer* (n.27), paras. 288, 443.
[281] Ibid., para. 201.

both at the substantive quality of the decision and at the fairness of the administrative proceeding vis-à-vis the individual affected.[282] Second, science enhances the administration's accountability by providing a reference against which the administration's decisions may be judged.[283] To a limited extent, this accountability takes place in the courts, but other fora, such as the Parliament, the Council, and national parliaments—as well as the public at large—are likely to be more important.[284] On the whole, science plays an integral, but fairly weak, role in legitimating risk regulation. The role of law as a source of legitimation is also weak in the *Pfizer* approach. Because the regulatory decision is understood as a political choice, the room for judicial review of the substance of the decision is narrow. The court's role is confined to policing the bounds of delegations, enforcing procedures, and protecting specific rights. In this way, judicial review ensures compliance of administrative risk regulation with the rule of law,[285] but it does not provide a robust basis for the regulation's functional legitimacy. The administration may, for example, comply with the letter of the courts' procedural prescriptions while ignoring their spirit, with only a small chance of being rumbled by a reviewing court.[286]

The legitimacy of risk regulation in the *Pfizer* model must therefore rest primarily on the Commission's exercise of its policy judgment. It is at this point that the *Pfizer* approach is least satisfying because the sources of the EU administration's democratic legitimacy are weak.[287] The *Pfizer*

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[282] Ibid., paras. 171–72; see also *TU München* (n.189), para. 14.
[283] *Pfizer* (n.27), paras. 203–04.
[284] On the role of fora in holding actors to account, see Bovens, 'Analysing and Assessing Accountability: A Conceptual Framework' (2007) 13 ELJ 447, 450–52.
[285] *TU München* (n.189), Opinion of A.G. Jacobs, paras. 13–16.
[286] Hilson (n.16), 332.
[287] A separate, but equally important question, is the extent to which the Commission is prepared to *exercise* its political judgment. See Weimer and Pisani, 'Expertise as Justification—The Contested Legitimation of the EU "Risk Administration"' in Weimer and de Ruijter (eds.), *Regulating Risks in the European Union—The Co-production of Expert and Executive Power* (Hart 2016) (forthcoming).

court relied primarily on the legitimacy the Commission derives from oversight by the Parliament[288] and, to a lesser extent, oversight through the comitology process.[289] Though both of those sources are real, neither is overwhelming, and the political legitimacy of the Commission remains very much contestable. In any event, the court does not question the reality of the Commission's legitimacy (perhaps it feels itself constitutionally barred from doing so). In stark contrast to their treatment of the scientific aspects of risk regulation, the courts have not attempted to bolster the Commission's political legitimacy through procedural requirements or other means.[290] Of course, the nature of political legitimacy is itself open to dispute, and it need not be limited to a majoritarian form of democratic legitimacy.[291] For example, the Commission might also derive a measure of legitimacy from its own constitutional role as guardian of the Union interest.[292] The court never discusses these questions, however.

Sweden adopts a much narrower vision of the administration's role in risk regulation. In this approach, the administration is merely a tool of the legislature, tasked with collecting and evaluating the scientific evidence. It is accorded little, if any, role in formulating the regulatory

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[288] *Pfizer* (n.27), para. 201.

[289] Ibid., para. 288.

[290] Scott and Vos, 'The Juridification of Uncertainty: Observations on the Ambivalence of the Precautionary Principle within the EU and the WTO in Joerges and Dehousse (n.3), 284–85; Ladeur, 'The Introduction of the Precautionary Principle into EU Law: A Pyrrhic Victory for Environmental and Public Health Law? Decision-Making Under Conditions of Complexity in Multi-Level Political Systems' (2003) 40 C.M.L.Rev. 1455, 1464–65.

[291] E.g., Dehousse, 'Institutional Reform in the European Community: Are There Alternatives to the Majoritarian Avenue?' (1995) 18 W.Eur.Pol. 118, 129–31; Majone, 'Europe's "Democratic Deficit": The Question of Standards' (1998) 4 ELJ 5, 5–7.

[292] In the view of some commentators, the Commission also enjoys a limited constitutional power to define the "community interest", in addition to the political legitimacy it derives from the Parliament. E.g., Majone, 'Delegation of Regulatory Powers in a Mixed Polity' (2002) 8 ELJ 319, 326–28. Arguably, the exercise of this power also contributes to the legitimacy of risk regulation, but the courts have not explored this possibility.

response to that evidence, in particular with regard to judgments about the acceptability of risk. In *Sweden*, there is no explicit discussion of political legitimacy, but by relying on the directive to define risk acceptability, the *Sweden* judgment implicitly locates political legitimacy in the legislative, not the administrative, process. As in *Pfizer*, the reality of that legitimacy is not considered. Instead of viewing risk regulation as a complex, contextual judgment, *Sweden* seems to view the process as the straightforward application of facts to a fixed legal standard. The primary source of regulatory legitimacy thus becomes neither science nor politics, but law. As such, like the private law model in the US, it tends to increase the role of the courts setting risk policy.

The case law of the EU courts shows them grappling with the same problems as their American counterparts in their effort to define what it means for administrators to make rational decisions about risk. The EU courts' approach to these issues has also changed over time in response to the growth and changing institutional structure of EU risk regulation. Although the *Pfizer* approach has become the dominant approach to these questions, cases like *Sweden* suggest that jurisprudence in this area may not yet be fully settled, and quiescence may have to await a broadly accepted and explicit theory of the democratic legitimacy of EU administration.

IV. Comparing Rational Risk Regulation in the US and the EU

The foregoing analysis shows courts in both jurisdictions grappling with the problem of reconciling the need for administrators to make highly technical and politically laden administrative judgments with rule of law values, particularly judicial control of bureaucracy. Though the basic problems are the same—how to account for both the scientific and policy aspects of risk regulation and how to reconcile the exercise of bureaucratic power with liberal democracy—the solutions developed by the US and EU courts differ in important ways. Those differences reflect the history and institutional characteristics of the two administrations.

Before considering the differences, however, it is important to stress the substantial similarities. Foremost, the common framing of risk regulation in terms of safety means that courts in both jurisdictions understand the regulatory problem in essentially the same way. In particular, by limiting administrators to acting on the basis of scientifically backed concerns, both jurisdictions require the administration to incorporate scientific evidence into regulatory decisionmaking, and in both jurisdictions the demand for scientific reasons fundamentally shapes what it means for an administrative decision to be rational.[293] Courts in both jurisdictions also acknowledge, however, that science is always uncertain and that the appropriate regulatory response is a normative, not an empirical, question.[294] Accordingly, both recognise that science alone is an insufficient base for decisionmaking and that regulatory decisions inevitably depend on administrators' policy choices. The result of this shared understanding of administrative risk regulation is that while both jurisdictions demand that the administration demonstrate careful consideration of relative scientific evidence, their approaches to administrative rationality are shaped more by their understanding of the appropriate scope of administrative policymaking than by concerns for scientific analysis. As a result, the jurisdictions' different models of administrative rationality reflect different understandings of the administration's institutional role within the broader constitutional framework. They are, at bottom, traceable to different theories of how the exercise of bureaucratic power can be rendered constitutionally and democratically legitimate.

Although the idea that expertise is a sufficient basis for administrative legitimacy has long since been consigned to history, the US courts remain faithful to the Weberian premise that bureaucratic power, to be legitimate, must be exercised on the basis of knowledge.[295] The ideal US administrator is therefore a subject matter expert, and the courts require her to demonstrate that she exercised her judgment on the basis of her

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[293] *NRDC* (n.18), 1165; *Pfizer* (n.27), para. 151.
[294] *Mississippi* (n.127), 1343; *France* (n.260), para. 78.
[295] Mashaw and Harfst (n.170), 292.

expertise.[296] At the same time, contemporary US administrative law sees administrators as democratically legitimate decisionmakers, who are directly accountable to the electorate through their responsibility to the president and indirectly through their oversight by Congress.[297] Because US courts understand administrators to possess both these qualities and because they view questions of science and policy judgment as essentially inseparable in the setting of risk standards, the case law often does not make a clear distinction between questions of science and questions of policy. As a result, the hallmark of administrative rationality in US administrative law is consistency of reasoning, including consistency between scientific findings and policy judgments.

The requirement that US agency's risk decisions be consistent with their scientific conclusions makes science a more important constraint on administrative decisionmaking than it is in the EU. The important thing to note, however, is that the source of constraint is the *agency's* scientific conclusions, rather than science in the abstract.[298] Because US doctrine allows agencies to take policy considerations into account when making scientific judgments, agencies are being constrained by their earlier science-policy decisions, not by some ostensibly value-free body of scientific knowledge. The focus on the agency's own scientific conclusions does not exclude the possibility that a court will set aside an agency's action on the basis of scientific error, but examples of courts acting on that basis are rare. Since the reformation of the early 1980s, the trend in the case law has been toward greater emphasis on the policy dimension of risk regulation. The administration's legitimate policymaking authority is not of a plenary, legislative kind, however. Whereas Congress may act on the basis of will alone, administrators must act on the basis of reason.[299] Distinguishing between reasoned policy judgments and lightly

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[296] *NRDC* (n.18), 1163; *Lead Industries Association v. EPA*, 647 F.2d 1130, 1145 (D.C.Cir.1980).
[297] *Chevron* (n.106), 865.
[298] Cf. *Communities for a Better Environment v. EPA*, 748 F.3d 333, 337 (D.C.Cir.2014); *Mississippi* (n.127), 1355.
[299] Mashaw (n.113), 20–21.

clothed, but otherwise naked, preferences continues to be a challenge for the courts, however.

The EU courts, by contrast, have established a model that separates scientific analysis from policy judgment. The model EU administrator is a policymaker, not a technocrat, a characterisation that emphasises the essentially political nature of risk regulation. As in the US, however, the EU administration does not enjoy the same freedom to set policy as the legislature. Although it is accorded great discretion, the EU administration is under a legal obligation—derived from the amorphous but constitutionally important EU concept of good administration[300]—to exercise its discretion responsibly. Discharge of that responsibility requires administrators to undertake an adequate investigation of the facts relevant to the decision at hand and to treat all affected interests fairly.[301] In this model, administrative policymakers are required to consult scientific experts, but they remain free to disagree with their conclusions as long as they are able to provide reasons for doing so. Because the courts do not require a close connection between the results of the scientific evaluation and the substance of the regulatory decision, administrative rationality in the EU is defined mainly in terms of process.[302] Science can therefore be seen as a weaker source of legitimation for administrative decisionmaking in the EU than it is in the US. The authority of the administrative decisionmaker is not derived from its qualification as an expert (real or fictional), but instead derives from its status as the constitutionally appropriate decisionmaker.

Although science plays only a supporting role in the EU courts' theory of administrative legitimacy, it is nonetheless essential for three reasons. First, it ensures that the Commission's political decision is made by reference to an adequate information base. This aspect of the EU model of rationality promotes the quality of risk decisions. Second, it provides a

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[300] Harlow and Rawlings, *Process and Procedure in EU Administration* (Hart 2014) 87–91; Nehl (n.188), 106–09; Smith, 'Developing Administrative Principles in the EU: A Foundational Model of Legitimacy?' (2012) 18 ELJ 269, 278–81.

[301] *TU München* (n.189), para. 25.

[302] Azoulay (n.3), 112–18; Corkin (n.239), 383–84.

means for judicial control of administrative decisionmaking and a degree of procedural protection for affected interests. This use of science promotes ideas of procedural fairness. Finally, science provides one benchmark (though, it should be emphasised, not the only benchmark) for evaluating the reasons given by the Commission in support of its decision. In this way, science enhances administrative legitimacy by enhancing administrative accountability.

The EU separation of scientific analysis from policymaking also responds to the plural and networked nature of EU governance, in which outcomes must be negotiated not only among the Institutions but also frequently with the Member States. Regardless whether such negotiations are seen in positive terms as a manifestation of deliberative supranationalism[303] or negatively as deals transacted among elites, the courts cannot ignore their necessity to EU decisionmaking. The inherently negotiated nature of EU regulation, including administrative regulation, tends to reinforce the understanding of regulatory decisions as political rather than as the result of a unitary, rationalised process. Perhaps for this reason, the EU courts have focused less on the internal consistency of administrative reasoning and more on its compatibility with broad constitutional values such as the precautionary principle and proportionality. As we saw in the last chapter, the courts have relied on constitutional values such as precaution to construct a legal framework to guide the administrative policymaking in this area.[304]

The US and EU models could perhaps be contrasted in this way: US law seeks the judgment of a politically accountable expert, whereas the EU prefers the judgment of a scientifically informed policymaker. The difference is subtle, and it is not at all clear that it will lead to different results in the mine run of cases. It does however mean that regulatory decisionmaking will follow different paths in the two jurisdictions and that the influences of science and law will operate in different ways. What the foregoing analysis has attempted to show is that those different models of rational administrative risk regulation reflect not just different

[303] Chapter 2, section II.B.5.
[304] Chapter 3, section I.B.1.

solutions to the problem of incorporating both scientific expertise and political judgment, but also different understandings of how administrative power can be legitimated within a liberal democracy. In other words, the differences between the US and EU models of rational administrative risk regulation can be traced to differences in the US and EU administrative-constitutional frameworks.

V. Conclusion

In this chapter, I have attempted to show two things. First, through a close reading of the case law, I have tried to come to grips with the idea of rational administrative risk regulation in US and EU jurisprudence. Courts rarely talk explicitly about their models of rationality, but their decisions inevitably rest on premises about what rational administrative decisionmaking entails. By uncovering those premises, I have attempted to reconstruct the models of rationality implicit in the case law so that they can then be subjected to comparative analysis. I have also tried to show how those models have evolved over time. The purpose of the historical analysis is to make clear the connections between judicial conceptions of administrative rationality and broader concerns about the legitimacy of administration within the US and EU constitutional orders.

Second, in my comparative analysis, I have tried to show that the significant differences between the US and EU models of rational administrative risk regulation are attributable primarily to different theories of how administrative regulation can be made constitutionally legitimate, and not to different views about the substance of risk regulation policy. In particular, I have attempted to show that both jurisdictions frame the problem of risk regulation in similar ways and that they have similar understandings of the capacities and limits of risk science for addressing those problems. The two jurisdictions do differ, however, with regard to their institutional structures and their constitutional theories of how the exercise of bureaucratic power can be reconciled with a commitment to liberal democracy. Perhaps most importantly, the two jurisdictions differ in their understandings of what the administration is and what it is meant to be doing when it sets risk

standards. Those understandings are rooted in history and legal culture and, as with their approaches to precautionary regulation, are not primarily the product of substantive views on risk.

5

Retelling the Legitimacy Narratives

The last three chapters have looked in detail at some central doctrines of European and American administrative law. In each of these chapters, we saw that various aspects of EU and US law on risk regulation developed in response to concerns about the constitutional legitimacy of administrative regulation. In this chapter, I endeavour to pull together those distinct threads and restate them into coherent legitimacy narratives that reconcile administrative risk regulation with each jurisdiction's administrative-constitutional framework. I then attempt to explain some of the factors that have caused the EU and US narratives to develop different features.

I. Putting the Doctrine Together

In this section, the analysis steps back from doctrinal specifics and consider the broader legitimacy narratives implied by the courts' case law. Though the EU and US narratives differ in many particulars, both are similar in that they are built out of three basic themes or legitimacy vectors:[1] democracy, expertise, and law.[2] A further commonality is that no single vector is sufficient to sustain the constitutional legitimacy of the administration. Instead, the three vectors mutually reinforce one another to create a complete account of administrative legitimacy. Accordingly, all three are essential to each legitimacy narrative, and modifications in any one vector would require corresponding modifications in the others for the narrative to remain coherent.

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[1] Lord and Magnette, 'E Pluribus Unum? Creative Disagreement about Legitimacy in the EU' (2004) 42 JCMS 183, 184.
[2] Edley, *Administrative Law: Rethinking Judicial Control of Bureaucracy* (Yale 1990) 29–36.

Before proceeding, it is important to recall that the construction of legitimacy narratives is a process of interpretation and reconstruction. Legitimacy narratives are theoretical tools, not restatements of the law. The following narratives should thus be understood as an effort to produce coherent understandings of the two bodies of case law as a whole. Beyond making sense of legal doctrine, I will argue that these narratives provide a means for explaining certain aspects of EU and US risk regulation.

A. Democracy

Democracy is the fundamental basis of the constitutional and functional legitimacy of government in both the EU and the US.[3] As such, a narrative that failed to reconcile the exercise of bureaucratic power with democratic government would fail by definition. The difficulty for both jurisdictions is that, as a matter of history, culture, and public perception, the administration is generally deemed to be undemocratic or at best weakly democratic. In particular, the democratic credentials of the administration, which is staffed by unelected officials, are contrasted with those of the popularly elected legislature, which is understood to be the principal repository of democratic authority.[4] It is therefore necessary to construct a narrative that convincingly explains how the administration either possesses sufficient democratic legitimacy in its own right, via means other than direct election, to justify its exercise of

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[3] Arts. 2 and 10 TEU; U.S. Const. Amend. XV; Lincoln, Gettysburg Address (November 19, 1863), http://www.ourdocuments.gov/doc.php?flash=true&doc=36&page=transcript. A full account of European and American understandings of democracy is beyond the scope of this thesis. Ultimately, however, some definition of democracy is needed for evaluation of public law institutions. Craig, *Public Law and Democracy in the United Kingdom and the United States of America* (Clarendon 1990) 5–9.

[4] Craig, *EU Administrative Law* (OUP 2012) 109–11; Lowi, *The End of Liberalism* (2d ed., Norton 1979) 272–74; von Bogdandy and Bast (eds.), *Principles of European Constitutional Law* (2d ed., Hart 2010) 267–73; Farina, 'The Consent of the Governed: Against Simple Rules for a Complex World' (1996) 72 Chi-Kent.L.Rev. 987, 1018–19.

governmental power or is made democratically legitimate through its control by other actors. Reconciling bureaucratic power with democracy is the essential problem that haunts both systems of administrative law, and it is one that neither system has been able to solve fully. It may even be a problem that, by its nature, is unsolvable.[5]

It is important to bear in mind the distinction between *democratic* legitimacy and *legal* or *constitutional* legitimacy. An exercise of government power enjoys democratic legitimacy if it receives the necessary democratic sanction within a particular political theory of democracy. An exercise of government power is constitutionally legitimate when it is consistent with the requirements of primary law.[6] The two concepts are related, but they are not coextensive. The focus in this section is on the ways in which the two narratives use democracy to support the constitutional legitimacy of administrative regulation. As we will see, that constitutional analysis frequently relies on disputable jurisprudential premises about democratic legitimacy.

Despite persistent doubts about the administration's democratic legitimacy, both the EU and the US narratives rely heavily on the presumed existence of democratic controls on administration to sustain the constitutional legitimacy of the exercise of bureaucratic power. Just as important, having posited that the administration possesses a degree of democratic legitimacy, both narratives use the existence of that—suspect—legitimacy as the primary reason for limiting judicial power to review the content of administrative decisions.[7] Democracy thus has a Janus-like character in both narratives. On one hand, the administration's questionable democratic legitimacy poses the most basic challenge to its constitutional legitimacy and justifies the imposition of various legal controls on administrative power. On the other, both narratives posit democratic control of the administration as a fundamental, perhaps *the* fundamental, basis for the legitimacy of

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[5] Farina (n.4), 1037; Frug, 'The Ideology of Bureaucracy in American Law' (1984) 97 HLR 1276, 1295–96.

[6] Chapter 1, section II.B.1.

[7] Chapter 4, sections II.E and III.E.

bureaucratic policymaking, which, to be effective, requires the courts to accord great deference to administrative policy judgments. It is this core tension that makes administrative law so contentious.

1. EU

What is most striking about the European approach to reconciling administrative regulation with democracy is how little the EU courts have explicitly addressed the problem. Although the case law is filled with statements that risk standards are ultimately political decisions for the Institutions,[8] there is almost no discussion as to why the Institution that makes most of those decisions—the Commission—is competent to decide weighty matters of policy. In most instances, the courts simply ignore the problem of the Commission's democratic legitimacy.[9] In the few cases in which the courts have considered the basis for this legitimacy, they have grounded it primarily in the Commission's accountability to Parliament.[10]

It seems clear that the courts' first approach—simply assuming the Commission's democratic legitimacy—is insufficient. An institution cannot be made democratic, either as a matter of political theory or as a matter of public perception, merely by declaring it to be so. As a matter of constitutional law, however, it is not so absurd. The Treaties themselves announce that "[t]he functioning of the Union shall be founded on representative democracy",[11] and the Treaties were agreed and ratified

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[8] Case C-77/09, *Gowan Comércio Internacional e Serviços Lda. v. Ministero della Salute*, nyr, para. 82; Case C-154/04, *R. ex p. Alliance for Natural Health v. Secretary of State for Health* [2005] ECR I-6451, para. 52; Case C-180/96, *United Kingdom v. Commission* [1998] ECR I-2211, para. 97; Case T-70/99, *Alpharma Inc. v. Council* [2002] ECR II-3495, para. 164.

[9] E.g., Case C-66/04, *United Kingdom v. Parliament and Council* (*Smoke Flavourings*) [2005] ECR I-10553, Opinion of A.G. Kokott, paras. 57–62; *United Kingdom v. Commission* (n.8), para. 97; Case 22/88, *Industrie- en Handelsonderneming Vreugdenhil BV v. Minister van Landbouw en Visserij* [1989] ECR 2049, paras. 16–17.

[10] Case T-13/99, *Pfizer Animal Health SA v. Council* [2002] ECR II-3305, para. 201; Case C-270/12, *United Kingdom v. Parliament and Council*, nyr, Opinion of A.G. Jääskinen, para. 85.

[11] Article 10(1) TEU.

voluntarily by democratic states on the basis of democratic processes. The Treaties also explicitly provide that the Commission, in conjunction with the larger EU administration, shall adopt delegated and implementing measures when such measures are authorised by EU legislation. The democratic legitimacy of the Commission can therefore be seen as a constitutional premise engrafted in the Treaties. On that view, the Court's role is not to concern itself with the democratic legitimacy of the Commission, as such, but rather to ensure that the Commission does not overreach the limits of its constitutionally sanctioned powers.[12]

The courts' other approach to the Commission's democratic legitimacy—basing it on the Commission's responsibility to the Parliament—is even less satisfying. Whereas the former approach has the virtue of absolving the courts from any obligation to justify Commission policymaking in terms of democracy, the latter approach seems to require them to make an unconvincing argument. As explored in chapter 2, the Parliament's, and for that matter the Council's, means of overseeing the Commission and holding it to account are far from illusory.[13] Before the

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[12] Cf. Azoulay, 'The Court of Justice and the Administrative Governance' (2001) 7 ELJ 425, 437–39; Everson, 'Administering Europe?' (1998) 36 JCMS 195, 202–04. This possibility goes to one of the central tensions of EU law: the mismatch between the EU's democratic ambitions and the realities of European political integration. Craig, 'Integration, Democracy, and Legitimacy' in Craig and de Búrca (eds.), *The Evolution of EU Law* (2d ed., OUP 2011) 33–40. To be sure, there is nothing obviously *un*democratic about the EU. The Parliament is popularly elected, and the Council is composed of members of elected governments. The problem is not, or at least not principally, one of design, but rather one of practical realisation. In particular, it is a problem of public connection to the EU as a political project. Weiler, 'In the Face of Crisis: Input Legitimacy, Output Legitimacy and the Political Messianism of European Integration' (2012) 34 JEI 825, 828–29. This disconnect demonstrates the importance of distinguishing between (theoretical) democratic legitimacy and functional legitimacy and, in particular, highlights the limits of law for addressing the latter. Scott, 'Governing Without Law or Governing Without Government? New-Ish Governance and the Legitimacy of the EU' (2009) 15 ELJ 160, 170–72; cf. Hyde, 'The Concept of Legitimation in the Sociology of Law' [1983] Wis.L.Rev. 379, 386–89.

[13] Chapter 2, section I.B.2.

Treaty of Lisbon, however, those means were considerably weaker than the corresponding powers possessed by political principals in the Member States. To say that it was appropriate for the Commission to make admittedly delicate policy decisions on the basis of that level of democratic control strains credulity. Things may now be different. The Lisbon reforms, particularly as implemented in the selection of the Junker Commission, have brought the EU considerably closer to a parliamentary model in which the Commission bears real responsibility to the Parliament.[14] In light of these reforms, it is no longer as far-fetched to argue that the Commission is subject to real democratic accountability. Nonetheless, the sufficiency of that accountability remains controversial and is insufficient in itself to sustain the Commission's authority.[15]

The Commission might also derive a measure of democratic legitimacy from the fact that it only adopts implementing acts in conjunction with review by a comitology committee and that its decisions on delegated acts are subject to Parliament and Council oversight.[16] Surprisingly, however, the courts have largely ignored this possibility.[17] Although comitology committees are not without their own accountability problems, the participation of Member State representatives in decisionmaking would seem to reinforce the democratic quality of Commission decisionmaking. That potential is all the greater with oversight of delegated acts, although much depends on how the Parliament and Council use their new powers.[18] For now, however, the EU narrative does not rely on these

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[14] Ibid.; Craig, *The Lisbon Treaty* (rev. ed., OUP 2013) 115–21.
[15] Cf. Curtin, *Executive Power in the European Union* (OUP 2009) 275–76.
[16] Chapter 2, section II.B.4.
[17] The Court of Justice did rely in part on the possibility of committee oversight in upholding delegations to the Commission in Case C-25/70, *Einfuhr- und Vorratsstelle für Getreide und Futtermittel v. Köster and Berodt & Co.* [1970] ECR 1161, para. 9, but it has not followed up on that suggestion.
[18] Stack, 'The Irony of Oversight: Delegated Acts and the Political Economy of the European Union's Legislative Veto Under the Treaty of Lisbon' (2014) 2 Theory.Pract.Legis. 61.

mechanisms to reinforce the democratic quality of administrative decisionmaking.

Despite lacking a robust account of the Commission's democratic legitimacy, the EU courts nonetheless rely on the administration's putative democratic mandate as the starting point for their approach to the constitutional legitimacy of administrative risk regulation. That reliance is shown most clearly in the courts' application of the manifest error standard to the administration's policy choices, which the courts justify on the ground that the Commission is the appropriate body to make political decisions.[19] That degree of deference is especially notable because many Member State courts exercise much more intensive review over their national administrations.[20] Without a strong theory to support the presumption that the administration's policy choices are democratically legitimate, such a deferential stance would seem to require substantial procedural or legal safeguards,[21] and the EU courts have responded by developing a number of mechanisms to control the Commission's exercise of discretion.

There is some indication that the courts' traditional reluctance to engage in substantive review is changing, and some recent decisions have been more intensive in their examination of the Commission's policy choices.[22] These recent decisions may indicate doubts on the part of the courts that the Commission's democratic legitimacy (whatever it may be) is sufficient to sustain the constitutional legitimacy of administrative

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[19] Corkin, 'Science, Legitimacy and the Law: Regulating Risk Regulation Judiciously in the European Community' (2008) 33 ELR 359, 365; Fritzsche, 'Discretion, Scope of Judicial Review and Institutional Balance in European Law' (2010) 47 C.M.L.Rev. 361, 367–71.

[20] Schwarze, *European Administrative Law* (Sweet and Maxwell 1992) 212–32.

[21] Azoulay, 'The Judge and the Community's Administrative Governance' in Joerges and DeHousse (eds.), *Good Governance in the European Union* (OUP 2002) 112–19.

[22] Craig (n.4), 415–29; chapter 4, section III.C.2. Examples include Joined Cases C-14/06 and C-295/06, *Parliament v. Commission* [2008] ECR I-1649, paras. 50–79; Case T-446/10, *Dow AgroSciences Ltd. v. Commission*, nyr, paras. 61–76; Case T-333/10, *Animal Trading Company (ATC) BV v. Commission*, nyr, paras. 70–94.

regulation and that complementary sources of legitimacy need to be reinforced. Nonetheless, the courts have mostly adhered to their highly deferential approach, and the strong presumption that the Commission is a constitutionally appropriate policymaking body remains the backbone of the broader legitimacy narrative. Perhaps more importantly, the courts have not attempted to force the Commission or the other Institutions to take steps, such as procedural reforms, that would reinforce the Commission's democratic accountability. The courts' reluctance in this regard may suggest that they see such reforms as outside judicial competence. Until a strong theory of the Commission's democratic legitimacy emerges, however, this will remain the least satisfying and most disputed aspect of the EU narrative.

2. US

Unlike the EU, in which the Commission's authority to make regulatory decisions is provided for in the Treaties, the US courts could never take the constitutionality or the democratic legitimacy of the administration for granted. Indeed, the constitutionality of administrative government—particularly the power of administrative agencies to issue generally applicable rules (including risk regulation standards)—is still not universally accepted.[23] As a consequence, American courts have had to grapple directly with the apparent disconnect between the practice of administrative regulation and the Constitution's vision of representative government and the separation of powers.

The courts' earliest approach to the democratic legitimacy of administrative regulation was to deny that it mattered. Administration

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[23] E.g., Schoenbrod, *Power Without Responsibility: How Congress Abuses the People Through Delegation* (Yale 1993) 155–64; Lawson, 'The Rise and Rise of the Administrative State' (1994) 107 HLR 1231, 1233–41. During the past Supreme Court term, Justice Thomas twice questioned the fidelity of the Court's administrative law jurisprudence to constitutional principles. *Perez v. Mortgage Bankers Association*, 135 S.Ct. 1199, 1215–21 (2015) (Thomas, J., concurring in the judgment); *Department of Transportation v. Association of American Railroads*, 135 S.Ct. 1225, 1240–52 (2015) (Thomas, J., concurring in the judgment).

was understood to be the more-or-less mechanical implementation of legislative instructions, and the residual discretion possessed by administrators was understood to fall comfortably within the concept of executing the law.[24] This "transition belt" approach to administration was reformulated by the Progressive movement into a commitment to professionalized administration. Epitomised by the New Deal agencies, this approach sought to take certain policy problems out of the political process entirely and to place them instead in the hands of expert administrators.[25] The Progressives were motivated in part by a desire to remove administrative decisions from routine politics, which were seen as corrupting, and in part by a faith in the ability of experts to formulate efficient policies that would redress widely recognised social problems.[26] On this theory, the only democratic sanction needed was Congress's decision to delegate matters to the administration. More extensive democratic control was actually undesirable due to its tendency to promote irrational results.[27]

The notion that experts could be trusted to determine good policy without further democratic input came into widespread disrepute in the 1970s. In fact, it was to a large extent the rise of risk regulation programmes that laid bare the disputed value judgments inherent in much administrative regulation. That recognition, accompanied by the doubt cast on the administrative process by capture theory, required the courts to develop a new approach for reconciling the exercise of

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[24] Rabin, 'Federal Regulation in Historical Perspective' (1986) 38 Stan.L.Rev. 1189, 1240; Landis, *The Administrative Process* (Yale 1947) 50–54.

[25] Cook, *Bureaucracy and Self-Government* (Johns Hopkins 1996) 82–86; Stewart, 'The Reformation of American Administrative Law' (1975) 88 HLR 1667, 1677–78.

[26] Cook (n.25), 86–94; Horwitz, *The Transformation of American Law, 1870–1960* (OUP 1992) 222–25.

[27] Friendly, *The Federal Administrative Agencies* (Harvard 1962) 165–67 (describing the positions of New Deal-era commentators); Landis (n.24), 62–72; see generally Nelson, 'The Quest for Scientific Morality' in *The Roots of American Bureaucracy* (Harvard 1982).

bureaucratic power with democratic government.[28] The first, short-lived, effort was expansion of administrative procedure to create a "surrogate political process", in which the lack of electoral control over administrative agencies would be remedied by encouraging broad participation of affected interests in the administrative process.[29] In practice, however, the surrogate political process approach seemed to create paralyzing procedural delay without addressing the constitutional tension between administrative policymaking and *electoral* democracy. A sceptical Supreme Court stamped it out in *Vermont Yankee*.[30]

The courts' theory shifted again in the early 1980s, as they began to rely quite heavily on the president as the source of the administration's democratic legitimacy.[31] The Presidential Administration theory is elegant: the president is the sole federal actor to enjoy a truly national constituency. By virtue of the Take Care Clause,[32] the president has both the responsibility and the constitutional authority to oversee the work of the federal administration.[33] That being the case, the policy choices made by agencies are presumptively democratic, hence legitimate, and courts have no warrant to second-guess them.[34] Since 1984, when the Court decided *Chevron*,[35] some version of this theory has dominated American administrative law.

As elegant as it is, the Presidential Administration model is both problematic and incomplete. It is problematic, above all, because the picture of presidential control it posits is a highly imperfect reflection of

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[28] Reich, 'The Law of the Planned Society' (1966) 75 YLJ 1227, 1243–47; Stewart (n.25), 1684–88.
[29] Stewart (n.25), 1670.
[30] *Vermont Yankee Nuclear Power Corp. v. NRDC*, 435 U.S. 519 (1978).
[31] Farina, 'The "Chief Executive" and the Quiet Constitutional Revolution' (1997) 49 Admin.L.Rev. 179, 182–85; Kagan, 'Presidential Administration' (2001) 114 HLR 2245, 2272–76.
[32] US Const. Art. II, § 3, cl. 3.
[33] Lessig and Sunstein, 'The President and the Administration' (1994) 94 Colum.L.Rev. 1, 97–103.
[34] Calabresi and Prakash, 'The President's Power to Execute the Laws' (1994) 104 YLJ 541, 661–62.
[35] *Chevron, U.S.A., Inc. v. NRDC*, 467 U.S. 837, 866 (1984).

reality. Although the president may be the only federal official elected by the nation as a whole, the strength of the president's electoral mandate is far from clear.[36] Moreover, given the vast scope of the federal bureaucracy, the idea that a single individual, or even the entire White House organisation, could actively supervise more than a small minority of agency actions is fanciful.[37] While it may be true that politically or economically significant issues will receive attention at the highest levels of the White House,[38] there remains a huge number of more mundane actions—including much risk regulation—that goes unreviewed. And while it is true that the president selects the agency's leadership, management by presidential appointees is a very indirect form of political accountability.[39] When these realities are considered, most administrative risk standards can be said to reflect the president's democratic choices only in an attenuated way.

The second weakness of the Presidential Administration theory is that it rests on a controversial interpretation of the Constitution.[40] Because the debate is as much about questions of political and constitutional theory as it is about historical evidence and judicial precedent, it is doubtful that it can ever be resolved. This inherent contestability limits the legitimating force of the Presidential Administration theory because there will always be some who view the theory as not merely insufficient or incomplete, but as unfaithful to basic constitutional principles.[41] Because democracy has become the dominant theme of the US legitimacy

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[36] Farina (n.4), 992–1002; Farina (n.31), 185–86.
[37] The OIRA process helps to make presidential management of administrative rulemaking effective, but even this process only extends to a limited sample of regulatory actions. Chapter 3, section II.B.3.
[38] Kagan (n.31), 2307; Sunstein, 'The Office of Information and Regulatory Affairs: Myths and Realities' (2013) 126 HLR 1838, 1850–53.
[39] Chapter 2, section II.A.1.
[40] For some of the main literature in this debate see chapter 2, n.17.
[41] E.g., Farina (n.4), 1007–18; Rakove, *Original Meanings: Politics and Ideas in the Making of the Constitution* (Knopf 1996) 209–14.

narrative, the inherent weaknesses of the Presidential Administration theory threaten to destabilise the entire narrative.[42]

Despite these doubts, the Presidential Administration has had impressive staying power. More than thirty years after *Chevron*, it has if anything grown stronger.[43] While it is true that some recent cases, such as *Massachusetts v. EPA*,[44] have confirmed that there are limits to presidential control of administrative decisionmaking, there is no indication that the Supreme Court is prepared to retreat significantly from the model.[45] Presidential Administration now frames the overall US legitimacy narrative, including the roles of law and expertise.

With respect to law, Presidential Administration, most notably as manifested in *Chevron* and its progeny, has greatly limited the courts' ability to rely on legal analysis to constrain administrative policymaking.[46] Whereas courts once took the lead in interpreting the content of regulatory legislation, including the goals of the legislation, primary responsibility for concretising legislation now falls to the administration.[47] This shift has confirmed an important constitutive role

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[42] Consider the continued resistance to Chevron in some quarters. E.g., Beermann, 'End the Failed *Chevron* Experiment Now: How *Chevron* Has Failed and Why It Can and Should Be Overruled' (2010) 42 Conn.L.Rev. 779; Garry, 'Accommodating the Administrative State: The Interrelationship Between the *Chevron* and Nondelegation Doctrines' (2006) 38 Az.St.L.J. 921; Molot, 'Reexamining *Marbury* in the Administrative State: A Structural and Institutional Defense of Judicial Power over Statutory Interpretation' (2002) 96 Nw.U.L.Rev. 1239.

[43] *City of Arlington v. FCC*, 133 S.Ct. 1863, 1872–73 (2013); *Barnhart v. Walton*, 535 U.S. 212, 221–22 (2002); *Smiley v. Citibank (South Dakota) N.A.*, 517 U.S. 735, 739–43 (1996).

[44] 549 U.S. 497 (2007).

[45] Recent cases, e.g., *Utility Air Regulatory Group v. EPA*, 134 S.Ct. 2427 (2014) and *EPA v. EME Homer City Generation, L.P.*, 134 S.Ct. 1584 (2014), have shown that justices from across the ideological spectrum accept the Presidential Administration model. Only Justice Thomas appears to have serious reservations about Presidential Administration (above n.23).

[46] Breyer, 'Judicial Review of Questions of Law and Policy' (1986) 38 Admin.L.Rev. 363, 376–79.

[47] Chapter 3, section I.C.2.

for the administration in elaborating regulatory policy by effectively conferring on it the power to define the ends of legislation, not just the means for their achievement.[48] To be sure, US courts have not wholly abdicated their power to review administrative interpretations of legislation,[49] but the importance of the shift in interpretive authority should not be understated.

Presidential Administration has also brought about a substantial change in the role of expertise in the US legitimacy narrative by replacing it as the primary basis for judicial deference to administrative decisions. Once the US courts openly recognised that expert analysis entails a large degree of judgment, often including important value judgments, the administration's expertise became insufficient to justify judicial deference to its scientific conclusions.[50] Presidential Administration filled this gap by shifting the theory of deference from one based on comparative institutional competence, to one based on comparative institutional legitimacy. By making this shift, Presidential Administration—and hence democracy—has come to underwrite the legitimacy of both the administration's policy and its expert judgments.

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This section began by observing that democratic legitimacy is the central problem for both EU and US administrative law, and so it is unsurprising that both narratives conclude that bureaucratic regulation is consistent with democratic government. It is important to observe, however, that neither narrative is able to conclude that administrative decisionmaking is democratic in itself. Instead, both narratives posit a view of the administration as incompletely democratic. Both narratives must therefore find ways of closing the remaining legitimacy gap. The primary sources of supplemental legitimacy drawn on by both narratives are expertise (science) and law. The centrality of democracy to the two

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[48] Chapter 4, section II.G.

[49] E.g., *Michigan v. EPA*, 135 S.Ct. 2699, 2707 (2015); *UARG* (n.45), 2442–44.

[50] This is the constitutional problem opened up by *Ethyl Corp.* and its progeny. *Ethyl Corp. v. EPA*, 541 F.2d 1, 20 (D.C.Cir.1976) (en banc); chapter 4, section II.A.

legitimacy narratives lies in the fact that the roles of these supplemental sources of legitimacy in the overall narratives are, in large part, dictated by the role of democracy, or more precisely by its shortcomings.

B. Expertise

It is probably inevitable that in a field so shot through with complex questions of technical fact and scientific prediction, that administrative law would turn to expertise as a mechanism of reinforcing the legitimacy of risk regulation.[51] Indeed, to the extent that risk regulation is framed in terms of safety and relies on essentially factual predictions of the effect of products on human health or the environment, it is difficult to conceive of how risk standards could be functionally legitimate without being able to claim a defensible scientific basis.[52]

Unsurprisingly then, both the EU and US legitimacy narratives are premised on the view that scientific expertise can contribute to the standard setting process in ways that other legitimacy vectors (democracy, law) cannot. In particular, both narratives rely on scientific expertise as a basis for distinguishing arbitrary from non-arbitrary decisionmaking, i.e., decisionmaking based on insufficient or improper reasons. The role of expertise in the two narratives differs in important ways, however. In the EU, requirements that the Commission obtain scientific advice developed as a procedural protection for regulated entities. As such, expertise is primarily directed at ensuring the fairness of administrative processes.[53] And although the role of expertise has been

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[51] For the time being, I put to one side the complexities of risk science. See chapter 1, section I.C. I return to these issues and their implications for the two legitimacy narratives in the next chapter, section I.A.

[52] Jasanoff, *The Fifth Branch: Science Advisers as Policymakers* (Harvard 1990) 16–17, 239–40; Jasanoff, *Designs on Nature* (Princeton 2005) 287–89; Joerges, 'The Law's Problems with the Governance of the European Market' in Joerges and Dehousse (eds.), *Good Governance in Europe's Integrated Market* (OUP 2002) 22–24.

[53] Azoulay (n.21), 118–23; Joerges, 'Scientific Expertise in Social Regulation and the European Court of Justice: Legal Frameworks for Denationalized Governance Structures' in Joerges, Ladeur and Vos (eds.),

expanded somewhat in more recent case law,[54] the EU courts continue to analyse it mainly in procedural terms.[55] In the US, expertise is a definitional aspect of "administrative", as opposed to political or legal, decisionmaking.[56] The US narrative posits that this form of decisionmaking, in which science and politics are combined, will—in appropriate settings—produce regulatory standards that are superior to standards that could be produced on the basis of political decisionmaking alone. Accordingly, expertise in the US narrative is directed values of efficiency and effectiveness.

1. EU

The consistent framing by the EU courts of risk standard setting as "a political choice"[57] necessarily limits science to a supporting role in the EU legitimacy narrative. That does not, however, mean that expertise is not essential. To the contrary, the Court of Justice's case law makes clear that expert investigation is necessary to guarantee the fairness of administrative proceedings, as well as to ensure that policy decisions are made on the basis of adequate information.

As we saw in chapter 4, the EU courts first began to demand that the Commission seek expert advice in the context of granting or denying authorisations for the marketing of certain products.[58] These decisions

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Integrating Scientific Expertise into Regulatory Decision-Making (Nomos 1997) 315–19.

[54] *Gowan* (n.8), paras. 52–67; Case T-257/07 R, *France v. Commission* (Interim Measures) [2007] ECR II-4153, paras. 69–86.

[55] Case C-269/13, *Acino AG v. Commission*, nyr, paras. 83–87; Case T-71/10, *Xeda International SA v. Commission*, nyr, paras. 64–71.

[56] Landis (n.24), 22–24; Mashaw and Harfst, 'Regulation and Legal Culture: The Case of Motor Vehicle Safety' (1986) 4 Yale.J.Reg. 257, 313–15; Short, 'The Political Turn in American Administrative Law: Power, Rationality, and Reasons' (2012) 61 Duke.L.J. 1811, 1819–20.

[57] E.g., *Pfizer* (n.10), para. 468; Case T-257/07, *France v. Commission*, nyr, para. 78.

[58] Chapter 4, section III.A. E.g., Case C-212/91, *Angelopharm GmbH v. Freie Hansestadt Hamburg* [1994] ECR I-171, paras. 37–38; Case T-199/96, *Laboratoires Pharmaceutiques Bergaderm SA v. Commission* [1998] ECR II-2805, para. 60.

could be distinguished from legislative measures, like those at issue in *Fedesa*,[59] both because they were being made by the Commission through an administrative process and because they directly concerned the interests of specific individuals or entities. That latter aspect also implicated those entities' individual rights, spurring the courts to demand procedural guarantees to protect rule of law values.[60] Perhaps the most significant development in this regard was the imposition of an administrative duty of care, which included the obligation to consult qualified and impartial experts.[61] Because its origins are in the protection of regulated entities, the administrative duty of care can be seen as akin to the rights of the defence. That connection was made explicit in *Pfizer* and *Alpharma*, in which the General Court characterised the risk assessment requirement as one of the "guarantees conferred by the Community legal order in administrative proceedings".[62] Thus, one way expertise contributes to the EU legitimacy narrative is by promoting the fairness of decisions regarding individual circumstances.[63] It may be that the courts see this procedural guarantee as all the more important in that EU law makes clear that economic rights must give way to protection of health and the environment, which can justify imposing "even substantial adverse consequences" on individual traders.[64]

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[59] Case C-331/88, *R. v. MAFF, ex p. Fedesa* [1990] ECR I-4023.
[60] Case C-269/90, *Hauptzollamt München-Mitte v. Technische Universität München* [1991] ECR I-5469, Opinion of A.G. Jacobs, paras. 11–13.
[61] Chapter 4, section III.A; Nehl, *Principles of Administrative Procedure in EC Law* (Hart 1999) 132–35.
[62] *Pfizer* (n.10), para. 171.
[63] *TU München* (n.60), Opinion of A.G. Jacobs, paras. 42–43.
[64] Case C-183/95, *Affish BV v. Rijksdienst voor de Keuring van Vee en Vlees* [1997] ECR I-4315, para. 42; *Dow AgroSciences* (n.22), para. 66. A connection between procedural protections and burdens on economic rights was also made in Case C-59/11, *Association Kokopelli v. Graines Baumaux SAS*, nyr, para. 40 and in Case C-504/04, *Agrarproduktion Staebelow GmbH v. Landrat des Landkreises Bad Doberan* [2006] ECR I-679, paras. 37–40. The consequences for affected individuals can be serious indeed; recall that the directive challenged in *Bergaderm* led to the applicant's bankruptcy. *Bergaderm* (n.58), para. 27.

Expertise in the EU narrative is not limited to the protection of individuals, however, but also extends to ensuring the quality of administrative risk regulation. Following the BSE crisis, the Commission, in a bid to reinforce public trust in EU-level regulation, strengthened its commitment to science as a means of ensuring that EU regulation would deliver a high level of protection.[65] Specifically, the Commission resolved that in the future, EU food regulation would be grounded in scientific advice conforming to the principles of "independence, excellence, and transparency".[66] Not only is this use of science directed at the quality of regulation, it also tends to focus on protecting the interests of regulatory beneficiaries, rather than regulated entities. To this day, a focus on high-quality scientific advice as a protective measure continues to be a frequent theme in Commission publications on risk regulation.[67]

The General Court picked up on the principles of independence, excellence, and transparency in *Pfizer* and *Alpharma*. Ironically, however, it did so in the context of evaluating whether the authorisations for the applicants' products had been wrongly revoked, and science was once again invoked for the protection of regulated entities.[68] The courts' rhetoric, however, shifted somewhat away from the protection of economic rights and towards an understanding of science as a public health safeguard, and a couple of subsequent cases have indicated that adequate scientific analysis is necessary to ensure that the Commission is meeting its obligation to provide a high level of protection.[69] Like the

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[65] Van Zwanenberg and Millstone, *BSE: Risk, Science, and Governance* (OUP 2005) 219–22.

[66] European Commission, 'White Paper on Food Safety' COM(1999) 719 final, 16–20.

[67] European Commission, Communication, 'Innovating for Sustainable Growth: A Bioeconomy for Europe' COM(2012) 60 final, 40; European Commission, Communication, 'Towards a European Strategy for Nanotechnology' COM(2004) 338, at 5–6; European Commission, Communication, 'Community Strategy for Endocrine Disruptors' COM(1999) 706 final, 12.

[68] *Pfizer* (n.10), paras. 171–72.

[69] Case C-15/10, *Etimine SA v. Secretary of State for Work and Pensions* [2011] ECR I-6681, Opinion of A.G. Bot, para. 148; Case C-446/08,

earlier cases, expertise in these decisions is directed at accurate fact finding. But rather than securing fairness to regulated entities, accuracy in these cases protects the public interest in ensuring that regulatory measures are adequately protective.

Although science is understood as a procedural safeguard—whether of rights or of public health—the EU courts have not treated it as a burden of proof, which would more tightly constrain political decisionmaking.[70] Instead, the EU case law suggests that expert analysis protects the relevant interests in a softer way, by ensuring that the Commission's decision is adequately informed.[71] The judgments in *France v. Commission* make that point clear. So long as the Commission acts "in full knowledge of the facts", it is entitled to make its decision on the basis of its views as to wise policy.[72]

The EU case law on expertise in risk regulation demonstrates that, although risk standards are always questions of policy, political will alone is insufficient to render administrative risk regulation constitutionally legitimate.[73] Instead, the EU narrative requires the Commission to treat the important interests at stake in risk regulation, of both regulated entities and the public, with care. While there is an obvious connection between careful consideration and good decisionmaking, the emphasis is on respect for the interests themselves, a concern which sounds in fairness rather than substantive quality. Perhaps because of this focus on science as a procedural protection, the large majority of science-based

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Solgar Vitamins France v. Ministre de l'Economie, des Finances et de l'Emploi [2010] ECR I-3973. Opinion of A.G. Jääskinen, para. 84; *Smoke Flavourings* (n.9), para. 46; Case T-296/12, *Health Food Manufacturers' Association v. Commission*, nyr, paras. 64, 126–30; *France* (n.57), paras. 211–13; Case T-75/06, *Bayer CropScience AG v. Commission* [2008] ECR II-2081, para. 208; Case T-229/04, *Sweden v. Commission* [2007] ECR II-2437, paras. 167–70.

[70] Chapter 4, section III.C.1. If anything, recent decisions have reinforced the Commission's burden is only to identify a non-hypothetical possibility of harm. *Acino* (n.55), paras. 58–60.

[71] Scott and Sturm, 'Courts as Catalysts: Re-Thinking the Judicial Role in New Governance' (2006) 13 Colum.J.Eur.L. 565, 583–84.

[72] *France* (n.57), para. 77.

[73] Cf. Case T-240/10, *Hungary v. Commission*, nyr, para. 110.

challenges focus on whether regulatory restrictions are adequately justified rather than whether standards are adequately protective.[74] Although challenges by regulated entities are rarely successful, this skew in the character of the cases brought inevitably colours the way in which the role of science is analysed by the courts and may contribute to a perception that the role of science in EU administrative law tends to be anti-regulatory.

2. US

Unlike the EU narrative, the US narrative does not clearly subordinate expertise to politics. Instead, they are nearly co-equal. One of the most urgent problems for the US narrative is the reconciliation of administrative regulation with the tripartite separation of powers, especially the exercise of rulemaking power by administrative agencies.[75] Historically, a key aspect of the US narrative's solution to this problem has been the conceptualisation of administration as a process of decisionmaking distinct from the process of legislation.[76] Whereas legislation is the pure exercise of political will, administration combines both political judgment and scientific analysis; i.e., administration "exercise[s] power on the basis of knowledge".[77] Thus understood, administrative regulation does not displace legislation by Congress, but instead complements it.[78] On this theory, however, administrative decisions cannot be purely political. To be constitutionally legitimate

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[74] This tilt may also be the result of the courts' restrictive rules on standing. Chapter 2, section I.B.2. Standing cannot be the whole explanation, however, because public interest groups have had success with the preliminary reference procedure despite its shortcomings. E.g., Case C-6/99, *Association Greenpeace France v. Ministère de l'Agriculture et de la Pêche* [2000] ECR I-1651.

[75] Edley (n.2), 17–18.

[76] Horwitz (n.26), 222–25; chapter 4, section II.G.

[77] Mashaw, 'Small Things Like Reasons Are Put in a Jar: Reason and Legitimacy in the Administrative State' (2001) 70 Ford.L.Rev. 17, 23.

[78] This is one of the oldest ideas in US administrative law. Goodnow, *The Principles of the Administrative Law of the United States* (Lawbook Exchange 2012) (1905), 66–68.

within the US narrative, administrative decisions must also incorporate expert judgment.[79]

In the US narrative, expertise bolsters the legitimacy of administrative regulation in both positive and negative ways. On the positive side, the demand for expertise is based on a conviction that scientific analysis can improve government's ability to address social problems, however they may be defined. As Mashaw puts it: "The promise of the administrative state was to bring competence to politics. It is the institutional embodiment of the Enlightenment project to substitute reason for the dark forces of culture, tradition, and myth."[80] Expertise legitimises administration because it promises better social policies than democracy can deliver on its own.[81] On the negative side, expertise constrains politics by limiting the range of decisions that may be viewed as plausibly within the public interest.[82] Requiring administrators to exercise expert judgment is thought to limit the ability of the administration to cater to the self-interested preferences of private groups or, to use Sunstein's phrase, to pursue "naked preferences".[83]

Although the US legitimacy narrative puts great trust in expertise, it does not rely on a naïve view of expertise as neutrally objective or independently capable of generating policy solutions. As we have seen, belief in the neutrality of expertise was deeply shaken in the 1970s, resulting in a general upheaval in administrative law.[84] This doctrinal

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[79] *Massachusetts* (n.44), 533; *Motor Vehicle Manufacturers Association v. State Farm Mutual Automobile Insurance Co.*, 463 U.S. 29, 48 (1983); see also Bressman, 'Beyond Accountability: Arbitrariness and Legitimacy in the Administrative State' (2003) 78 N.Y.U.L.Rev. 461, 527–29; Freeman and Vermeule, 'Massachusetts v. EPA: From Politics to Expertise' [2007] Sup.Ct.Rev. 51, 82–83; Metzger, 'Ordinary Administrative Law as Constitutional Common Law' (2010) 110 Colum.L.Rev. 479, 490–93.
[80] Mashaw (n.77), 23.
[81] Ibid.; Landis (n.24), 57–59.
[82] *State Farm* (n.79), 47–51; *American Farm Bureau Federation v. EPA*, 559 F.3d 512, 518–20 (D.C.Cir.2009).
[83] Sunstein, 'Naked Preferences and the Constitution' (1984) 84 Colum.L.Rev. 1689, 1691; see also Seidenfeld, 'A Civic Republican Justification for the Bureaucratic State' (1992) 105 HLR 1511, 1554–58.
[84] Stewart (n.25), 1681–88.

crisis was ultimately solved not be reasserting the objectivity of expertise (as some advocated[85]), but by relying on agencies' democratic credentials to give authoritative effect to their disputable expert judgments.[86] The roles of expertise and democracy in the US legitimacy narrative thus became intertwined and mutually reinforcing. Democratic legitimacy is a prerequisite for the legitimacy of expert judgment, which in turn supports the legitimacy of administrative power, in part, by guarding against democratic abuses.

The US legitimacy narrative combines these demands by requiring administrative agencies to engage in a particular kind of decisionmaking, one in which a high level of expert analysis and a high level of political authority are embodied a single decisionmaker.[87] The relative roles of democracy and expertise will of course vary from decision to decision, but administrators are expected to give due regard to both aspects of an issue. It is for this reason that US courts, unlike EU courts, generally demand that administrative decisionmakers reach scientific conclusions and that they abide by the conclusions they adopt.[88] It also explains why courts remain willing to set aside agency actions on the basis that they are inadequately supported by technical analysis, despite the courts' enthusiasm for Presidential Administration as the cornerstone of administrative legitimacy.[89] An agency that fails to exercise its expert judgment fails to live up to its administrative role.

Because it is focused on improving the administration's fulfilment of legislative policy objectives, expertise does not have the same emphasis on protection of individual rights that it does in the EU narrative.[90] It is

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[85] E.g., Raul and Dwyer, '"Regulatory *Daubert*": A Proposal to Enhance Judicial Review of Agency Science by Incorporating *Daubert* Principles into Administrative Law' (Autumn, 2003) 66 LCP 7, 8–12.
[86] Chapter 4, section II.D.
[87] Chapter 4, section II.G; *Chevron* (n.35), 865–66.
[88] *American Farm Bureau Federation* (n.82), 17; chapter 4, section II.E.
[89] *Alpharma, Inc. v. Leavitt*, 460 F.3d 1, 6 (D.C.Cir.2006); *NRDC v. EPA*, 824 F.2d 1146, 1163 (D.C.Cir.1987) (en banc); see also *Bowen v. American Hospital Association*, 476 U.S. 610, 626–27 (1986).
[90] Some earlier decisions tended to focus on individual rights, chapter 4, section II.A.

true, of course, that the US narrative permits regulated entities to rely on science to argue that an administrative decision is flawed,[91] but it also provides the same opportunity to proponents of tighter standards and—in contrast to the EU—US courts routinely set aside administrative decisions because the scientific record suggested that a standard was insufficiently protective.[92] Expertise thus not only constrains discretion, but also helps to ensure that the administration meets its regulatory responsibilities.[93] Application of expertise in the US narrative is thus both a normative and a procedural obligation.

C. Law

As with expertise, law plays very different roles in the EU and US legitimacy narratives. In the EU, administrative compliance with the rule of law entails both compliance with positive legal requirements (e.g., procedural requirements, the limits of delegated authority), as well as conformity with legally embedded values (e.g., proportionality, the precautionary principle).[94] The latter, normative, aspect of the rule of law analysis is central to the idea of legally constrained government in European constitutional theory.[95] This understanding of the rule of law,

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[91] *Chemical Manufacturers Ass'n v. EPA*, 28 F.3d 1259, 1265 (D.C.Cir.1994).

[92] *State Farm* (n.79), 51; *NRDC v. EPA*, 735 F.3d 873, 881–84 (9th.Cir.2013); *American Farm Bureau Federation* (n.82), 519; *Bluewater Network v. EPA*, 370 F.3d 1, 21–22 (D.C.Cir.2004); *National Lime Association v. EPA*, 233 F.3d 625, 634–35 (D.C.Cir.2000); *American Lung Association v. EPA*, 134 F.3d 388, 329–93 (D.C.Cir.1998). But see *Center for Biological Diversity v. EPA*, 749 F.3d 1079, 1090 (D.C.Cir.2014) (upholding a standard that EPA acknowledged to be insufficiently protective because the agency adequately explained that the available data was too uncertain to allow for a reasoned decision and the agency was actively working on the issue).

[93] Sunstein, 'Deregulation and the Hard-Look Doctrine' [1983] Sup.Ct.Rev. 177, 187–88.

[94] Von Bogdandy and Bast (n.4), 20–28.

[95] Ibid., 33–35; Stone Sweet, 'Why Europe Rejected American Judicial Review and Why It May Not Matter' (2003) 101 Mich.L.Rev. 2744, 2766–69.

related to the German concept of *Rechtsstaatlichkeit*,[96] has provided occasion for the EU courts to develop legal principles that guide and constrain the policy content of EU risk regulation. In this way, law supports the EU legitimacy narrative by conferring the law's normative authority on administrative decisionmaking.

The American understanding of the rule of law shares the European commitment to the observance of positive legal requirements. It does not, however, entail a similar commitment to particular normative values. To the contrary, US legal theory favours the neutrality of legal principles as regards most matters of regulatory policy.[97] Rather than focus on substantive norms, US administrative law focuses on the allocation of decisionmaking authority and the maintenance of institutional roles.[98] The duty of the courts in this system is to police the process, while leaving matters of substance to governmental actors—including the administration—that can claim some democratic mandate.

1. EU

In the EU narrative, law supports the legitimacy of administrative regulation both procedurally and substantively. Procedurally, it safeguards ideas of fairness and due process, which are essential to the constitutional legitimacy of actions impinging on the rights of individuals. Substantively, it is concerned with giving content to the idea of the public interest by supplying essential norms of good regulation that provide a basis for justifying (and critiquing) administrative regulation independently of democratic preferences.[99]

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[96] On *Rechtsstaatlichkeit*, see Currie, *The Constitution of the Federal Republic of Germany* (University Of Chicago 1995) 18–20.
[97] Stewart, 'Regulation in a Liberal State: The Role of Non-Commodity Values' (1983) 92 YLJ 1537, 1540–43 see also Ely, *Democracy and Distrust* (Harvard 1980) 88–104; Wechsler, 'Toward Neutral Principles of Constitutional Law' (1959) 73 HLR 1, 10–20.
[98] Hart and Sacks, *The Legal Process* (Eskridge and Frickey eds., Foundation Press 2006) 158–67; Fallon, 'Reflections on the Hart and Wechsler Paradigm' (1994) 47 Vand.L.Rev. 953, 962–64.
[99] Cf. Case 294/83, *Les Verts v. Parliament* [1986] ECR 1339, para 23.

The most visible procedural influence has been the courts' jurisprudence on rights of defence, which has extended a number of procedural protections to regulated entities and has influenced the design of some risk regulation programmes.[100] These decisions vindicate those broadly shared principles, embodied in the British conception of natural justice, that have come to define the circumstances in which an adverse decision may be made against an individual.[101] More important for European risk regulation, however, has been the courts' elaboration of an administrative duty of care, which has been the primary doctrinal vehicle for defining the necessary role of expert advice in risk regulation.[102] Like the rights of defence, the EU courts have developed the duty of care as a means of ensuring the fairness of administrative proceedings.[103]

The importance of fairness to the legitimacy narrative should not be underestimated. One of the core constitutional concerns of both EU and US administrative law is that individuals should be treated justly and with dignity by administrative bodies,[104] and it should come as no surprise that courts have occupied themselves intensely with procedural matters. Fairness is equally essential to functional legitimacy. No matter

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[100] Joerges, '"Good Governance" Through Comitology?' in Joerges and Vos (eds.), *EU Committees: Social Regulation, Law and Politics* (Hart 1999) 332–38; Nehl (n.61), 8–12; Scott, 'REACH: Combining Harmonization and Dynamism in the Regulation of Chemicals' in Scott (ed.), *Environmental Protection: European Law and Governance* (OUP 2009) 73–75; Vos, *Institutional Frameworks of Community Health and Safety Regulation* (Hart 1999) 181, 239–40.

[101] Bignami, 'Creating European Rights: National Values and Supranational Interests' (2005) 11 Colum.J.Eur.L. 241, 278–93; Bignami, 'Three Generations of Participation Rights before the European Commission' (Winter, 2004) 68 LCP 61, 63–67.

[102] Chapter 4, section III.E.

[103] Nehl (n.61), 116–17; see also *Pfizer* (n.10), para. 171.

[104] Harlow and Rawlings, *Process and Procedure in EU Administration* (Hart 2014) 74–75; Mashaw, 'Reasoned Administration: The European Union, the United States, and the Project of Democratic Governance' (2007) 76 Geo.Wash.L.Rev. 99, 117–19; Nehl, 'Good Administration as a Procedural Right and/or General Principle?' in Hofmann and Türk (eds.), *Legal Challenges in EU Administrative Law* (Edward Elgar 2009) 345–48.

what its substantive merits, an administrative policy is unlikely to be accepted if it is imposed in ways that fail to respect the moral autonomy of those subject to it.[105] Just as any adequate legitimacy narrative must be able to reconcile administrative regulation with democracy, so too it must offer an explanation for the fairness of administration. Notably, in both narratives, this explanation is offered almost entirely in legal terms: administration is fair because it conforms to legal ideals of justice.

Substantively, the EU courts have influenced the process of administrative risk regulation by developing constitutional principles to give content to the idea of the public interest in risk regulation and by requiring the EU administration to demonstrate that its actions are consistent with those principles.[106] To a large extent, the courts have developed those principles from the Treaties, particularly the precautionary principle and the principle that the Union must pursue a high level of protection of human health and the environment.[107] But the courts have also gone beyond the Treaties and developed normative principles of good administration, including good risk regulation, based on general principles of law. In particular, the proportionality principle has figured prominently in many decisions on risk regulation.[108] Whether derived from the Treaties or other sources, these normative principles are largely the creation of courts and have been developed through jurisprudential methods.[109] They reinforce administrative legitimacy by insisting that there is more to good administration than political preference or even political preference tempered by scientific analysis. In this way, law attempts to make up (to some extent) for the democratic weakness of bureaucratic policymaking by supplying values that require

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[105] Mashaw, 'Administrative Due Process: The Quest for a Dignitary Theory' (1981) 61 B.U.L.Rev. 885, 887–88.

[106] Chapter 3, section I.B.1; Case T-74/00, *Artegodan GmbH v. Commission* [2002] ECR II-4945, paras. 184, 192. Tridimas, *The General Principles of EU Law* (OUP 2006) 307–11.

[107] Art. 191 TFEU.

[108] Case C-343/09, *Afton Chemical Ltd. v. Secretary of State for Transport* [2010] ECR I-7027, paras. 43–69; Case C-180/96, *United Kingdom v. Commission* [1998] ECR I-2265, paras. 96–111.

[109] Craig (n.4), 590–92; Tridimas (n.106), 25–29.

no democratic sanction.[110] Put differently, by validating particular regulatory decisions, law confers some of its own moral authority on the practice of administrative risk regulation.

This role for law in legitimising EU risk regulation is consistent with one understanding of the role of law in the overall European project. Throughout its history, the Court of Justice has used normative argument to buttress the legitimacy of the EU legal order.[111] Its project seems to have been not just the implementation of Treaty rules, but also the construction of a normative vision of the EU, the inherent merit of which would win the allegiance of Member States and European citizens. In its early days, that vision focused on the free movement of goods and people, the elimination of cross-national discrimination, and the integration of European law into the Member States' legal orders.[112] More recently, the court has focused on developing a European vision in the areas of individual rights and social policy, including in the field of risk regulation.[113] Lenaerts, for example, has referred to the "trust-enhancing" aspects of EU law in these areas.[114] By building a positive vision of the EU as a guarantor of (presumably) widely held public values, EU public law can be understood as attempting to create an additional basis for the legitimacy of EU regulation to supplement the EU's contested democratic legitimacy.[115]

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[110] Cf. Smismans, 'The European Union's Fundamental Rights Myth' (2010) 48 JCMS 45, 57–59; Neyer, 'Justice, Not Democracy: Legitimacy in the European Union' (2010) 48 JCMS 903, 911–12.
[111] Everson (n.12), 203–05; Poiares Maduro, *We the Court: The European Court of Justice and the European Economic Constitution* (Hart 1998) 154–57; Stone Sweet, *The Judicial Construction of Europe* (OUP 2004) 52–55.
[112] Poiares Maduro (n.111), 36–58; see, e.g., Case 26/62, *Van Gend en Loos v. Nederlandse Administratie der Belastingen* [1963] ECR 95; Case 6/64, *Costa v. ENEL* [1964] ECR 585; Case C-6/90, *Francovich v. Italy* [1991] ECR I-5357.
[113] Joined Cases C-402/05 and C-414/05 P, *Kadi v. Council and Commission* [2008] ECR I-6351; Case C-144/04, *Mangold v. Rüdiger Helm* [2005] ECR I-9981.
[114] Lenaerts, '"In the Union We Trust": Trust-Enhancing Principles of Community Law' (2004) 41 C.M.L.Rev. 317, 343–43.
[115] Ibid.; Chapter 3, section I.B.

The judicial elaboration of the normative foundations of European risk regulation is an important part of the EU legitimacy narrative. The EU narrative posits that administrative risk regulation is legitimate in part because EU law ensures that it furthers values that are (or should be) universally shared.[116] That idea may seem naïve in a world in which the ends and means of risk regulation are the subject of intense disagreement by people of good faith. It would be sad, however, to reject it out of hand for that reason. That there is a public institution open to discourse on the public good, independently of transient political preferences, is admirable. So too is the commitment to the idea that—at least within a given cultural and historical context— it is possible to identify shared public values.[117] The idea that the EU is a normative project, and not just an economic project, provides an important counterweight to the liberalising nature of the internal market. It also helps to reconcile the essentially liberal EU project with the European tradition of social democracy.[118] It supplies values that the European public can believe in and feel allegiance towards.[119] It makes the EU admirable, not just efficient.

Although the role for law in legitimating administration is potentially powerful, it is important to be realistic about its operation in practice. Despite occasionally strong rhetoric, the EU courts have for the most part been timid, and there is little evidence that they are prepared to scrutinise rigorously the political choices made by the Commission for compliance with public values.[120] There is also a serious question as to

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[116] Cf. Manners, 'Normative Power Europe: A Contradiction in Terms?' (2002) 40 JCMS 235, 241–42.
[117] Feintuck, *'The Public Interest' in Regulation* (OUP 2004) 55–57; Sunstein, 'Beyond the Republican Revival' (1988) 97 YLJ 1539, 1554–55. But see Sullivan, 'Rainbow Republicanism' (1988) 97 YLJ 1713, 1722–23.
[118] Cf. Stone Sweet (n.95), 2779; cf. Scharpf, 'The European Social Model' (2002) 40 JCMS 645.
[119] Cf. Weiler, 'Does Europe Need a Constitution? Demos, Telos and the German Maastricht Decision' (1995) 1 ELJ 219, 253–56.
[120] Craig (n.4), 418–19; Heyvaert, 'Facing the Consequences of the Precautionary Principle in European Community Law' (2006) 31 ELR 185, 200; Poiares Maduro (n.111), 74–76.

how successful the EU courts have been in articulating public values to guide risk regulation. The courts' decisions in this area have been critiqued from all sides. Many argue, for example, that the courts' precautionary jurisprudence is insufficiently respectful of individual autonomy and the social value of technology.[121] Others have argued that the courts have been too concerned about European uniformity and free movement, and have been insufficiently solicitous of national preferences regarding technological risk.[122] Thus, however admirable the project may be, it is not clear that it is actually winning much allegiance that could supplement the EU's contested democratic legitimacy. Indeed, given the current strains on European ideals brought about by the financial crisis and the effects of austerity,[123] there is all the more reason to be sceptical that law offers an efficacious forum for defining the public interest.

2. US

As in the EU, the role of law in the US legitimacy narrative has both procedural and substantive components. Procedurally, the US narrative parallels the EU narrative in many respects. Substantively, however, law plays a very different role in the US narrative. Rather than using law to develop a normative vision of good regulatory policy, the US narrative

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[121] Alemanno, Comment, 'Case C-79/09 [sic], *Gowan Comércio Internacional E Serviços Lda v Ministero Della Salute*' (2011) 48 C.M.L.Rev. 1329, 1344; Bergkamp, 'The Quiet Revolution in EU Administrative Procedure: Judicial Vetting of Precautionary Risk Assessment' [2014] EJRR 102, 109–110; Vogel, 'The Politics of Risk Regulation in Europe and the US' (2003) 3 YEEL 1, 30–31.

[122] Fisher, *Risk Regulation and Administrative Constitutionalism* (Hart 2007) 238–41; Ladeur, 'The Introduction of the Precautionary Principle into EU Law: A Pyrrhic Victory for Environmental and Public Health Law? Decision-Making under Conditions of Complexity in Multi-Level Political Systems' (2003) 40 C.M.L.Rev. 1455, 1469–71; Lee, 'Multi-level Governance of Genetically Modified Organisms in the European Union: Ambiguity and Hierarchy' in Bodiguel and Cardwell (eds.), *The Regulation of Genetically Modified Organisms: Comparative Approaches* (OUP 2010) 122; van Asselt and Vos, 'The Precautionary Principle and the Uncertainty Paradox' (2006) 9 JRR 313, 331–32.

[123] E.g., Dawson and de Witte, 'Constitutional Balance in the EU after the Euro-Crisis' (2013) 76 MLR 817, 826–28.

focuses on ensuring that the administration engages in a distinctive form of administrative decisionmaking and stays within its constitutionally sanctioned role.

The procedural aspect of law in the US narrative can be addressed briefly. As in the EU, the US courts enforce a number of due process rights meant to ensure that individuals, particularly regulated entities, are treated fairly.[124] Also as in the EU, procedure in the US is concerned with ensuring an adequate information base, in addition to fairness. In particular, the US courts have elaborately embroidered the APA's notice-and-comment rulemaking process to ensure both that agencies receive information from a wide range of sources and that agencies' provisional conclusions are available for public evaluation and criticism.[125] Because they emphasise improving the information base for regulation, US procedural requirements are somewhat less focused on the interests of regulated entities than are their EU counterparts. Rather, they can be seen as reinforcing analytical quality in administrative decisionmaking.

If the procedural aspects of the role of law are broadly similar in the EU and US narratives, the substantive aspects could not be more different. As we saw in chapter 3, the Supreme Court's *Chevron* judgment marked a decisive turning point for the role of law in the US narrative, prompting courts to take a much narrower view of law's role in defining administrative aims.[126] The courts have not only accorded agencies primary authority for construing their own legislative mandates, but also framed the choice among regulatory ends primarily in terms of policy rather than law. Whereas the EU courts have relied on general principles of law to guide the substantive content of EU risk regulation, the US courts have rejected any such role. Perhaps the best example of this is the US courts' steadfast refusal to mandate (or even encourage) cost-

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[124] II Pierce, *Administrative Law Treatise* (5th ed., Aspen Publishers 2009) 559–612.

[125] Beermann and Lawson, 'Reprocessing Vermont Yankee' (2006) 75 Geo.Wash.L.Rev. 856, 892–900; Diver, 'Policymaking Paradigms in Administrative Law' (1981) 95 HLR 393, 410–12; Pedersen, 'Formal Records and Informal Rulemaking' (1975) 85 YLJ 38, 75–78.

[126] Chapter 3, section I.C.2.

benefit analysis, despite repeated calls to do so.[127] More broadly, several American commenters have urged the courts to engage with substantive policy in part as a means of counterbalancing the short-term bias of politics.[128] These suggestions have not been taken up, however. Instead, the notion that courts should not involve themselves in questions of good policy has become ever more entrenched in the decades following *Chevron.*[129] Far from legitimating administrative regulation, intensive judicial review of administrative policymaking has come to be seen as conflicting with democratic principles.[130]

Judicial withdrawal from questions of regulatory policy has not caused the US courts to abandon substantive judicial review, however. Instead, the focus on substantive review has shifted from the content of administrative decisions to the process of administrative decisionmaking and, in particular, to ensuring that agencies live up to their assigned role, i.e., that they faithfully pursue their legislative mandate and that they make decisions on the basis of expert analysis as well as political judgment.[131] In particular, courts have developed rationality review as a means for testing whether agencies have engaged in "administrative" decisionmaking by exercising both expert and policy judgment.[132] In most cases, when courts set aside agency action on substantive grounds their apparent concern, though often unstated, is that the action under review was made on the basis of political expediency rather than reflective

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[127] Chapter 3, section II.B.2; *Entergy Corp. v. Riverkeeper, Inc.*, 556 U.S. 208, 223 (2009).
[128] Edley (n.2), 221–34; Farina (n.4), 1023–26; Sunstein, *After the Rights Revolution* (Harvard 1993) 169–86.
[129] Bressman (n.79), 554–55; Strauss, 'Presidential Rulemaking' (1996) 72 Chi-Kent.L.Rev. 965, 968–75.
[130] E.g., *City of Arlington* (n.43), 1872–73; *Chevron* (n.35), 865.
[131] Garland, 'Deregulation and Judicial Review' (1985) 98 HLR 505, 553–58; cf. Fisher, Pascual and Wagner, 'Rethinking Judicial Review of Expert Agencies' (2015) 93 Tex.L.Rev. 1681, 1716–18.
[132] Chapter 4, section II.E.

analysis.[133] Such "naked" policymaking, as we have seen, is inconsistent with other aspects of the US narrative.[134]

The substantive aspect of law in the US narrative can thus be understood as defining the administration's institutional identity and its place within the larger framework of government. This "legal process" approach to substantive review is consistent with the peculiar emphasis of American public law on the allocation of decisionmaking authority among various government actors, which itself is rooted in the US Constitution's commitment to separation of powers and checks-and-balances.[135] On this understanding, the principal task of judicial review is to ensure that the administration stays within its assigned role, including by adopting a discernibly administrative approach to regulatory problems. In exercising this function, the courts cannot of course wholly avoid substantive questions, and deciding whether the agency has undertaken an appropriate analysis will have its own substantive overtones.[136] Nonetheless, by refraining from the development of general substantive principles, the US courts have carved out a very different role for legal analysis in legitimating administrative regulation.

D. Summary

As the foregoing reconstructions show, the EU and US legitimacy narratives are complex and resist straightforward comparison. One useful way of summarising and distinguishing the two narratives is to focus on the distinct ways in which they conceptualise the administration and administrative regulation. In the EU narrative, administrative

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[133] E.g., *Massachusetts* (n.44), 533–34; *American Farm Bureau Federation* (n.82), 520; see also Freeman and Vermeule (n.79), 93–96.
[134] Sunstein (n.83), 1692.
[135] Hart and Sacks (n.98), 158–61; Horwitz (n.26), 253–58. The legal process school was an approach to legal analysis that dominated American academic thinking after World War II. One of its signature characteristics was a focus on the allocation of decisionmaking authority among different institutions according to their comparative strengths. Eskridge and Frickey, 'The Making of "The Legal Process"' (1994) 107 HLR 2031, 2040.
[136] Edley (n.2), 92–95.

standard setting is understood as an extension of the legislative process.[137] The various strands of the EU narrative can be read as portraying administrative standard setting as a form of idealised legislation, in which the administration apprises itself of all relevant information and considers the interests of affected parties fairly and impartially. Because it lacks the full democratic accountability of the legislature, the administration must meet higher standards of rationality and fairness in its decisionmaking.[138] The EU narrative also recognises that the administrator-legislator exercises political discretion, but requires that it do so by reference to impersonal regulatory values that are enshrined in law and sufficiently concrete to allow for objective judicial review.[139] In this way, the administration's discretion is sufficiently cabined that its limited democratic legitimacy is constitutionally adequate.[140]

By contrast, the US narrative posits a conception of administration that is discontinuous from the legislative process.[141] Administrators in the US narrative make decisions on the basis of rigorous technical analysis and judgments as to which course of action will best effectuate legislative goals.[142] This commitment to the exercise of power on the basis of knowledge distinguishes the administration from the legislature[143] and justifies its otherwise anomalous presence within a system based on the

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[137] Bieber and Salomé, 'Hierarchy of Norms in European Law' (1996) 33 C.M.L.Rev. 909, 912; see also European Commission, Communication, 'Implementation of Article 290 of the Treaty on the Functioning of the European Union' COM(2009) 673 final, 3.
[138] Azoulay (n.12), 439; *TU München* (n.60), para. 14; cf. *Afton Chemical* (n.108), Opinion of A.G. Kokott, paras. 53–54.
[139] *Gowan* (n.8), para. 76; Case C-333/08, *Commission v. France* [2010] ECR I-757, paras. 91–95; *ATC* (n.22), paras. 98–101.
[140] Cf. Neyer (n.110), 917–19.
[141] Shapiro, *Who Guards the Guardians?* (University of Georgia 1988) 42–44.
[142] Landis (n.24), 22–24; Mashaw, 'Prodelegation: Why Administrators Should Make Political Decisions' (1985) 1 J.L.Econ&Org. 81, 94–95; see also *State Farm* (n.79), 48–50.
[143] Indeed, there is a strand of American legal thought that tends to see legislation as deeply irrational. Horwitz (n.26), 27–31.

tripartite separation of powers.[144] At the same time, the US narrative recognises that science alone is insufficient for decisionmaking.[145] Like EU administrators, US administrators are therefore accorded substantial policy discretion.[146] Rather than constraining this discretion through law, however, the US narrative finds legitimacy for administrative policymaking in the president's democratic mandate.

Although the two narratives differ in many respects, an important commonality is that they both rely on multiple legitimacy vectors to provide a complete account of administrative legitimacy. Both narratives place great weight on democracy as the touchstone for the legitimate exercise of governmental power, but in neither is democracy sufficient. Risk regulation must be democratic, but it must also be scientifically defensible and it must be consonant with values of justice and fairness. Each of these legitimacy vectors responds to specific legal and constitutional concerns, but none acts in isolation. Rather, they are interdependent and mutually reinforcing. Thus, the function of each vector within the overall legitimacy narrative is defined by reference to the other two. Consequently, as the role of any one vector in the narrative evolves, it simultaneously brings about changes in the roles of the other two. That interdependence is amply demonstrated by the evolution of the legitimacy narratives in both jurisdictions in recent decades.

Analysis of the two narratives confirms Fisher's argument that differences between systems of risk regulation cannot be reduced to preferences for democracy versus science.[147] Instead, the key differences lie in the ways in which scientific analysis and democratic processes interact in the production of regulation. In addition, one has to consider

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[144] Goodnow (n.78), 68–69; Shapiro and Levy, 'Heightened Scrutiny of the Fourth Branch: Separation of Powers and the Requirement of Adequate Reasons for Agency Decisions' [1987] Duke.L.J. 387, 425–28.
[145] *Baltimore Gas and Electric Co. v. NRDC*, 462 U.S. 87, 105–06 (1983); Shapiro, 'The Frontiers of Science Doctrine: American Experiences with the Judicial Control of Science-Based Decision-Making' in Joerges, et al. (eds.) (n.53), 327–29.
[146] *Ethyl* (n.50), 20.
[147] Fisher (n.122), 14–18.

the role of law, both with regard to its role in structuring the relationship between democracy and science and as a source of normative frameworks and values in its own right.

Because the roles of democracy, science, and law are complex and interdependent, regulatory systems cannot be compared linearly. Instead, comparisons must consider how the separate vectors interact in the context of particular aspects of the regulatory process. Analysis of the EU and US legitimacy narratives also demonstrates the law's essential role in constituting bureaucratic legitimacy. Law structures the interaction of the three legitimacy vectors, and law provides the discourse in which they combine into a coherent narrative. Legal values and legal reasoning thus define what it means for administrative risk regulation to be legitimate within each constitutional system.

II. Explaining the Differences

Thus far, I have endeavoured to recount the EU and US legitimacy narratives and to identify some of the key differences. In this section, I suggest some of the reasons for those differences. I say some; I do not make any claim that the following discussion exhausts the universe of possible causes for the divergence in the two narratives. Instead, my analysis is limited to a few possible causes that to me seem highly significant. In keeping with the focus of the thesis on legal doctrine, the explanations discussed in this section focus on aspects of the two jurisdictions' administrative law frameworks. Other possible causes, such as political dynamics and cultural attitudes toward certain technologies, are excluded, although I would readily acknowledge their importance in comparing EU and US risk regulation programmes overall.[148]

[148] The importance of these factors is well-documented by two of the most serious observers of EU and US risk regulation. Jasanoff, *Designs on Nature* (n.52), 273–87; Vogel, *The Politics of Precaution* (Princeton 2012) 34–42.

A. Institutions

The differences in the EU and US legitimacy narratives can be explained in important ways by differences in the two jurisdictions' institutional frameworks. It is well accepted in the literature that institutional structures can have profound effects on the ways in which administrative bodies make decisions and on the way in which administrative regulation develops.[149] Less noticed is the effect that institutional structures have on the way in which administration is conceptualised within legal doctrine. Because courts have limited control over institutional arrangements, they have little choice but to formulate their theories of administrative legitimacy in ways that justify existing administrative institutions. In some cases, of course, the courts have the option of declaring institutional arrangements incompatible with primary law,[150] but that option is exceedingly costly both for society and for the courts' own authority.[151] Further, some institutional arrangements will be set in primary law, making them insusceptible to judicial invalidation. In the usual case, therefore, courts must formulate their legitimacy narratives to reflect institutional arrangements as they find them.

In chapter 2, we saw how the EU administration is characterised by networked institutions with responsibility and authority for administrative decisionmaking spread across multiple bodies. US administration, by contrast, is characterised primarily by fully integrated and autonomous administrative agencies.[152] To some extent, these

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[149] Krapohl, *Risk Regulation in the Single Market* (Palgrave Macmillan 2008) 2–5; Lindner and Rittberger, 'The Creation, Interpretation, and Contestation of Institutions: Revisiting Historical Institutionalism' (2003) 41 JCMS 445, 451–52.

[150] E.g., Case 9/56, *Meroni & Co., Industrie Metallurgiche, SpA v. High Authority* [1958] ECR 133, 154; *Bowsher v. Synar*, 478 U.S. 714, 733–34 (1986).

[151] Consider the (entirely justified) backlash to the Court of Justice's Opinion 2/13, nyr. Eekhout, 'Opinion 2/13 on EU Accession to the ECHR and Judicial Dialogue—Autonomy or Autarky?' (2015) JMWP 01/15, at 39.

[152] Chapter 2, section II.A.1.

characterisations oversimplify institutional reality,[153] but they are the models around which the two legitimacy narratives are built. Looking specifically at risk regulation, several differences in the two legitimacy narratives can be explained in terms of these differing institutional structures. In chapter 4, for example, I argued that the principal difference in the two jurisdictions' models of rational administrative risk regulation is the division in the EU between risk assessment and risk management and the integration of the two processes in the US.[154] Perhaps the most straightforward explanation for why the EU and US have taken divergent approaches on this issue is that a separated framework is easier to reconcile with the EU's networked institutional arrangements, whereas an integrated framework better fits the US's consolidated agencies.[155]

Under existing EU law, the Commission is responsible for making most decisions regarding regulatory standards, at least formally. The Commission, however, is a generalist policy-making body with limited expert resources. It must, therefore, seek expert advice from other bodies. At the same time, the ECJ's *Meroni* jurisprudence has, at least until recently, seemed to preclude the establishment of agencies possessing both significant expert capacity and policymaking power.[156] Given these constraints, the separation of risk assessment from risk management is unsurprising. So long as it is accepted that functionally legitimate risk standard setting requires both expert input and politically responsible decisionmaking, and so long as the EU's institutional structure prevents those two decisionmaking inputs from being integrated in the same body, the expert and political aspects of risk regulation must remain divided.

Institutions also help to explain the nature of scientific advice in the EU. Because EU agencies are themselves networked bodies, rather than monolithic institutions, they are more disposed to formulating scientific

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[153] Chapter 2, section II.C.

[154] Chapter 4, section IV.

[155] On the comparison between the EU's networked administrative structure and the US's preference for consolidated agencies, see chapter 2, section II.C.

[156] Chapter 2, section II.B.2.

opinions in ways that make the influence of multiple perspectives explicit. For example, EU agencies allow for the inclusion of minority views in scientific opinions.[157] The presence of national diversity, as well as expert diversity, reinforces this tendency. Comitology in particular creates opportunities for Member States to voice differing interpretations of scientific evidence, which themselves are likely to reflect national values and policy preferences in addition to more narrowly scientific considerations.[158] By contrast, the integrated structure of US agencies tends to submerge divergent expert views within internal agency processes so that the agency can be seen as speaking with one voice.[159]

Institutional arrangements help to explain not just the process and content of scientific advice giving, but also the relative roles of politics and science in the two narratives. One consequence of placing scientific analysis and political decisionmaking into separate, non-hierarchically related institutions is to separate responsibility for those aspects of standard setting. The expert body, be it an agency or a committee, is responsible only for providing scientific advice. The Commission is responsible only for the political decision leading to the final standard. Indeed, the principle of independence would seem to preclude the Commission from taking responsibility for, and thus inevitably influencing, the content of scientific advice.[160] This separation of responsibility tends to reinforce the framing of administrative standard setting as a question for political resolution because it makes clear that expert opinion cannot bind the Commission as the final decisionmaker. Although the Commission is free to accept the recommendations of

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[157] EFSA, 'Scientific Opinion on Bisphenol A' (2010) 8 *EFSA Journal* 1829; EFSA, 'Joint Scientific Opinion of the GMO and BIOHAZ Panels on the "Use of Antibiotic Resistance Genes as Marker Genes in Genetically Modified Plants"' (2009) 7 *EFSA Journal* 1108; Smith, Terry, and Detken, '10 Years of the European Food Safety Authority (EFSA) and the EU Food Safety System' (2012) 7 EFFL 111, 114.

[158] E.g., Short Report of the Meeting of the Standing Committee on the Food Chain and Animal Health (Phytopharmaceuticals Section) Held on 3 October 2003, SCFA 4/2003.

[159] Wagner, *Science in Regulation* (2013) 132–34.

[160] White Paper on Food Safety (n.66), 17.

experts—and most often does—it has less room to claim, as American agencies sometimes have done,[161] that scientific analysis left it with no choice in the matter.

Institutional arrangements have had very nearly the opposite effect on the US legitimacy narrative. In part because the administration is treated as a single entity and often personified in a single person, agencies are treated in American law as individual minds.[162] This conceptualisation of the administration has led the US courts to hold that agencies' scientific and political conclusions must be consistent.[163] Just as it would be nonsensical for a single person to conclude simultaneously that a substance is highly dangerous and that the substance should not be regulated under a statute that requires regulation of dangerous substances, so too it would be irrational for an agency to reach a scientific conclusion and then to make a regulatory decision that is inconsistent with that conclusion.[164]

The structure of American agencies also tends to reinforce a particular way of looking at science. Because agencies are unitary entities, they are generally assumed to reach unitary conclusions on scientific issues. That is not to say that either agencies or the courts do not realise that scientific conclusions are virtually always uncertain or that other supportable views exist.[165] Rather, it means that agencies generally take a single position based on their evaluation of the evidence, even if that position is that the evidence is too uncertain to draw firm conclusions.[166] Additionally, US agencies do not have the built-in

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[161] Coglianese and Marchant, 'Shifting Sands: The Limits of Science in Setting Risk Standards' (2004) 152 U.Pa.L.Rev. 1255, 1268–69.
[162] E.g., *American Trucking Associations, Inc. v. EPA*, 283 F.3d 255, 373 (D.C.Cir.2002); Magill and Vermeule, 'Allocating Power Within Agencies' (2011) 120 YLJ 1032, 1036–38.
[163] Chapter 4, section II.E.
[164] *American Lung Association* (n.92), 236–37.
[165] *American Forest and Paper Association, Inc. v. EPA*, 294 F.3d 113, 121 (D.C.Cir.2002); *Cellular Phone Task Force v. FCC*, 205 F.3d 82, 89–91 (2d.Cir.2000).
[166] *Massachusetts* (n.44), 534; *Center for Biological Diversity v. EPA*, 749 F.3d 1079, 1087–88 (D.C.Cir.2014).

diversity of viewpoints exhibited by EU advisory committees and, especially, comitology committees. Agencies' scientific staff tend to be career civil servants who have worked at the agency (and together) for a number of years, and who therefore come to share a common professional outlook.[167] Outside review by expert advisory committees, when it occurs, tends to focus on whether the agency's position is supportable, rather than on reviewing the full range of plausible opinions.[168] This disposition toward the agency adopting "a" view tends to lessen the need for US administrative law to accommodate diverse scientific opinions. It is enough if the agency's view is supportable and consistent with its own prior pronouncements; the fact that there are other views, perhaps even better views, is largely irrelevant.[169]

A further aspect of the institutional structures of the two systems that affects the legitimacy narratives is the relationship of the administration to other government institutions. As we have seen, EU administration is largely continuous with other aspects of EU governance, and even as certain forms of risk standard setting have taken on a distinctively administrative character, significant continuity and overlap with the legislative process remains.[170] In the US, by contrast, a fairly sharp distinction is made between the administration and the constitutional branches of government.[171]

In many ways, the continuity of administration and legislation in the EU reflects the EU's multilevel, networked character, in which decisionmaking almost always involves a process of negotiation among multiple institutions and between the EU and the Member States through comitology committees and the Council. In particular, the need

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[167] Landy, Roberts, and Thomas, *The Environmental Protection Agency: Asking the Wrong Questions* (OUP 1990) 34; McGarity and Shapiro, *Workers at Risk: The Failed Promise of the Occupational Safety and Health Administration* (Praeger 1993) 47–79; Wagner (n.159), 26.
[168] Jasanoff, *Fifth Branch* (n.52), 89–99; Wagner (n.159), 152–54; see also, e.g., EPA*, Peer Review Handbook* (3d ed., GPO 2006) 57–59.
[169] *Marsh v. Oregon Natural Resources Council*, 490 U.S. 360, 378 (1990); *Hüls America Inc. v. Browner*, 83 F.3d 445, 453 (D.C.Cir.1996).
[170] Chapter 2, sections II.B.3 and II.B.4.
[171] *Bowen v. Georgetown University Hospital*, 488 U.S. 204, 208 (1988).

to ensure the broad acceptability of both process and outcomes to all Member States tends to make negotiation and deliberation the preferred form of decisionmaking, whether the particular forum is legislative or administrative.[172] In the US, by contrast, the distinctiveness of the administrative process is the basis of most theories of administrative legitimacy. The delegation of standard setting authority to bodies outside the constitutional branches is permissible, in part, because the administration has the capability to address problems in a way that the legislature cannot. On that theory, however, administrative agencies may not simply act like legislatures; they must apply a distinctive form of administrative rationality, including expert analysis, to the resolution of regulatory problems.[173]

This difference in the relationship between the administration and other institutions helps to explain the relative prominence of political decisionmaking in the EU legitimacy narrative versus the prominence of expertise in the US because it explains what the courts think the administration should be doing. The EU administration's goal is to find regulatory solutions that, while respecting the available scientific evidence, are acceptable to the broadest possible constituency of Institutions and Member States.[174] Hence, the EU legitimacy narrative emphasises the political and negotiated nature of decisionmaking, and only focuses on science when restrictions on individual liberty—i.e., considerations that are not thought proper for political resolution—are at issue.[175] The purpose of American administration is to provide expert analysis to produce better policy solutions; purely political questions can be decided by Congress or the president within their respective spheres. Expertise must therefore be an integral component of all administrative decisionmaking.[176]

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[172] Harlow and Rawlings (n.104), 78; Joerges and Neyer, 'From Intergovernmental Bargaining to Deliberative Political Processes: The Constitutionalisation of Comitology' (1997) 3 ELJ 273, 289–92.
[173] Rabin (n.24), 1267; Shapiro (n.141), 74–75.
[174] Cf. Poiares Maduro (n.111), 164–66.
[175] E.g., *Bergaderm* (n.58), paras. 58–59.
[176] *State Farm* (n.79), 48–49.

Legitimacy narratives reconcile government practices with constitutional values. For the most part, institutional structures are given premises around which those narratives must be constructed, and those premises affect the shape of the subsequent narratives. What is particularly worth noting is that the institutional arrangements that have had such a profound effect on the ways in which the EU and the US regulate risk were initially created without regard to the particular problems or needs of risk regulation. American administrative agencies are the product of nineteenth century government reform movements, working long before risk regulation was an important administrative task.[177] The EU's networked administration initially developed to implement market regulation, particularly in the agricultural sector.[178] Yet in both jurisdictions these early institutional arrangements have become the default pattern for administration generally and have produced many of the assumptions about what administration is and how it works.[179] Institutional arrangements are thus prime examples of how the broader administrative-constitutional framework shapes the practice of risk regulation independently of concerns specific to risk regulation itself.

B. Legal Culture

A second partial explanation for the divergence between the EU and US legitimacy narratives is legal culture. As discussed in chapter 1, legitimacy narratives are necessarily intertwined with legal culture because it is legal culture that, to a large extent, determines the plausibility of legitimacy narratives. Legal culture is also complex and many-layered. That is especially the case with EU legal culture, which is only slowly emerging from the mingling of many European legal cultures. Accordingly, it would not be possible in this space to attempt to address all of the aspects of legal culture that contribute to differences between

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[177] Rabin (n.24), 1207.
[178] Craig (n.4), 6–8; Vos, *Institutional Frameworks of Community Health and Safety Legislation* (Hart 1999) 113–14.
[179] Krapohl (n.149), 25–27; Stone Sweet (n.111), 31.

the EU and US legitimacy narratives. Instead, this section will focus on just two aspects of legal culture that I believe are particularly relevant to the differences observed in the two narratives. The first concerns styles of legal reasoning and, in particular, the rejection of categorical legal reasoning in American legal culture. The second, which is closely related to the first, concerns the proper roles of courts and agencies within a democratic system of government.

1. Categorical legal reasoning and legal realism

"Categorical legal reasoning", also sometimes known as "formalist reasoning", is an approach to legal analysis that attempts to resolve legal questions by deductive reasoning from basic legal concepts or categories.[180] This type of reasoning prevailed in the nineteenth century in both common law and civil law systems and continues to be common in civil law systems today.[181] In the US, however, categorical legal reasoning came under sustained intellectual assault in the early twentieth century by the legal realists. As a result, categorical legal reasoning is much less accepted as a valid mode of legal argument in contemporary American legal culture.[182]

Legal realism was a multifaceted movement in American jurisprudence that extended from the late nineteenth century to approximately the 1940s. The central insight of legal realism was the recognition of the logical impossibility of deciding most cases by deductive reasoning from abstract legal concepts.[183] Thus, any legal decision ultimately required a disputable act of judgment, and realism sought to lay bare this value-laden aspect of judging. As a result of this

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[180] Horwitz (n.26), 17–19; Merryman and Pérez-Perdomo, *The Civil Law Tradition* (3rd ed., Stanford 2007) 62–63; Poiares Maduro (n.111), 16–20.
[181] Horwitz (n.26), 16–17; Merryman and Pérez-Perdomo (n.180), 66.
[182] Horwitz (n.26), 210–11; Singer, 'Legal Realism Now' (1988) 76 Cal.L.Rev. 465, 503–04.
[183] Horwitz (n.26), 200–02; Singer (n.182), 499–503; see also Cohen, 'Transcendental Nonsense and the Functional Approach' (1935) 35 Colum.L.Rev. 809, 820–21.

critique, American lawyers, both academic and practicing, broadly accept that judicial decisions are a kind of law making.[184] One consequence of this critique was that legal rules could only be evaluated by their social effects, a task for which the intellectual tools of categorical legal reasoning were unsuited. Instead, these effects had to be studied using the tools of sociology, economics, and political science.[185] The realists' commitment to social science as the basis for law reform provided much of the intellectual foundation of the New Deal administrative state. Agencies could regulate more effectively than common law courts because they had the capacity to engage in empirical analysis, and this capacity was vital to the legitimacy of the new agencies.[186]

European lawyers might respond—with some force—that the realist critique is overdrawn and that categorical legal reasoning within the civil law tradition is much more sophisticated than the nineteenth century American version against which the realists were reacting.[187] However one resolves that debate, the persistence of categorical legal reasoning in Europe and its rejection in the US has resulted in real differences in the ways in which questions of administrative law are framed and analysed, and it has contributed to the differences in which the two legitimacy narratives are formulated.

Several aspects of the US narrative are related to the pervasive influence of legal realism on American legal culture. First, the rejection of conceptual legal analysis explains the lack of reliance on legal concepts—e.g., the precautionary principle, proportionality, legitimate expectations—as mechanisms for judicial control of administration. Because these concepts are indeterminate, they cannot, on the realist view, guide judicial decisions. Second, the realist focus on empiricism helps to explain the prominent role of expertise in the US narrative. From a realist perspective, it is the practical effects of regulation that most matter, and these can only be assessed empirically. Agencies are capable

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[184] Singer (n.182), 503.
[185] Horwitz (n.26), 208–12.
[186] Ibid., 222–25; see also Goodnow (n.78), 8–9.
[187] Merryman and Pérez-Perdomo (n.180), 64–67.

of this type of analysis, whereas other government bodies are not. Finally, the emphasis on the importance of administrative discretion reflects the realist belief that effective regulation depends more on careful attention to the specific facts of each problem, than on the consistent application of general rules.[188]

Although the realists' work is not unknown to European lawyers, it has not had nearly so great an influence on European legal culture. More so than even nineteenth century common law, traditional civil law analysis relies heavily on categorical reasoning. And much more so than in contemporary American law, that mode of analysis continues to persist in civil law systems.[189] EU law is largely based on civil law and, probably more importantly, almost all EU judges, as well as the majority of the lawyers working in the Institutions, have been trained in the civil law tradition. The result is that judgments of the EU courts continue to employ categorical legal reasoning to an extent that can be striking to an American reader.[190] The most obvious example in the area of risk regulation is the EU courts' jurisprudence on the precautionary principle, but similar differences can be found in other doctrinal areas, such as EU delegation doctrine's focus on the essential elements of policy choices[191] or the focus on the core nature of economic rights in determining the limits of the EU's regulatory powers.[192]

Just as the influence of realism helps to explain various aspects of the American narrative, the continued reliance on categorical reasoning helps to explain various aspects of the European narrative. Of particular importance, the continued acceptance of categorical legal reasoning provides important support for the normative aspects of EU law on risk

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[188] Horwitz (n.26), 225.
[189] Merryman and Pérez-Perdomo (n.180), 148–49; Poiares Maduro (n.111), 20–22.
[190] E.g., *United Kingdom* (n.10), Opinion of A.G. Jääskinen, paras. 38–47; Case C-427/12, *Commission v. Parliament and Council*, nyr, Opinion of A.G. Cruz Villalón, paras. 35–43.
[191] *Smoke Flavourings* (n.9), Opinion of A.G. Kokott, paras. 50–61.
[192] Case C-280/93, *Germany v. Council* [1994] ERC I-4973, para. 78; Tridimas (n.106), 313–14.

regulation. Whereas realism renders concepts like precaution or the public interest hopelessly vague, categorical legal reasoning reaffirms the possibility of a conceptual, idealistic approach to questions of public policy.[193] Put differently, it allows the EU courts to avoid distinguishing sharply between legal and normative questions, a distinction that has arguably hindered the development of a robust normative discourse on risk regulation in US law.[194]

2. The role of courts and the "countermajoritarian difficulty"

The broad acceptance of legal realism reinforced another aspect of American legal culture that has profoundly affected the US narrative: anxiety over the legitimacy of judicial review or what Alexander Bickel famously dubbed the "countermajoritarian difficulty".[195] Put simply, the countermajoritarian difficulty accepts that judicial decisions are a type of law making and then demands to know why judicial law making is legitimate in a democratic society, particularly when it involves setting aside the contrary judgments of democratic institutions.[196] Since Bickel published his famously limited defence of judicial review, doubts regarding its legitimacy have been a key feature of American public law. Those doubts were reinforced by some of the Supreme Court's controversial decisions of the 1970s, particularly *Roe v. Wade*,[197] which found a constitutional right to elective abortion in certain circumstances.[198] By wading into areas in which moral opinion was

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[193] Cf. Stone Sweet (n.95), 2751–56.
[194] Cf. Kysar, 230–32.
[195] Bickel, *The Least Dangerous Branch* (2d ed., Yale 1986) 16–18.
[196] E.g., Waldron, 'The Core of the Case Against Judicial Review' (2006) 115 YLJ 1346.
[197] 410 U.S. 113 (1973); see Ely, 'The Wages of Crying Wolf: A Comment on *Roe v. Wade*' (1973) 82 YLJ 920.
[198] Other important examples included the Court's decisions upholding mandated bussing as a remedy for historical school segregation, e.g., *Swann v. Charlotte-Mecklenburg Board of Education*, 402 U.S. 1 (1970), and its criminal procedure decisions protecting the rights of the accused, e.g., *Miranda v. Arizona*, 384 U.S. 436 (1966).

sharply divided, the Court helped to fuel a strong backlash against "government by judges".[199] This scepticism toward judicial review creates strong pressure for American judges to avoid passing on policy questions (or, on a more cynical view, to conceal that they are doing so).

Although concerns with the countermajoritarian difficulty originally focused on policymaking by courts, those concerns were soon extended to administrative policymaking. Critics began to ask why it should be acceptable for "unelected bureaucrats", any more than unelected judges, to make policy decisions of enormous significance.[200] An early, but extremely powerful, example of that anxiety can be seen in the various opinions in the *Benzene* case, most prominently that of Justice Rehnquist who argued that vesting such policymaking discretion in agencies was flatly unconstitutional.[201] As Lisa Bressman shows, countermajoritarian concerns strongly influenced both academic and judicial writing on administrative law and contributed to the rise of political accountability as the primary concern of administrative law and the shift toward Presidential Administration.[202] At the same time, concern over the countermajoritarian difficulty helps to explain the increasing reticence of courts to set aside agency actions on substantive grounds. That is particularly so as the current generation of judges were trained in an era in which academic concern over the countermajoritarian difficulty was at its height.

As Craig and Stone Sweet, among others, have observed, continental legal cultures exhibit much less anxiety over the countermajoritarian difficulty in judicial review.[203] Quite the contrary, the prevailing attitude

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[199] Luker, *Abortion and the Politics of Motherhood* (University of California 1985).

[200] Bressman (n.79), 481–82.

[201] *Industrial Union Department, AFL-CIO v. American Petroleum Institute*, 448 U.S. 607, 686–87 (1980) (Rehnquist, J., concurring in the judgment). Justice Thomas has recently revisited these concerns, above n.23.

[202] Bressman (n.79), 480–85.

[203] Craig (n.4), 494–95; Stone Sweet (n.95), 2779. The countermajoritarian difficulty is a concern in British legal culture, although to a lesser extent than in the US. In particular, several British commentators have criticised the "activist" approach of the Court of

is that robust judicial review is an important check on democratic decisionmaking.[204] Acceptance of substantive judicial review is related to the tendency of European legal cultures to draw sharper distinctions between legal and political questions, which is itself made possible by the persistence of categorical legal reasoning. If anything, that tendency is magnified in the EU context, in which the attenuated nature of democratic control would seem to justify a more robust judicial role.[205] Comparatively lesser concern regarding judicial policymaking, especially as regards rights and general principles of law, facilitates greater involvement by the EU courts in developing a normative framework around risk regulation. More broadly, it has allowed the emergence of a prominent role for law and legal analysis in contributing to the legitimacy of EU risk regulation.

Just as different idealised conceptions of the administration have shaped the two narratives, so too have different ideal understandings of the judiciary. In particular, differences in European and American attitudes toward the involvement of courts in policymaking have contributed to different understandings of the relative roles of courts, administrators, and other government institutions in the administrative process, and have resulted in different allocations of authority for various aspects of decisionmaking on risk. Because different government actors rely on different discourses of justification for their actions, these allocations of authority also contribute to the ways in which the two legitimacy narratives combine law, expertise, and policy to legitimate administrative standard setting.

Justice. Tridimas, 'The Court of Justice and Judicial Activism' (1996) 21 ELR 199, 207 (defending the European Court of Justice against charges of activism); see also Hartley, 'The European Court, Judicial Objectivity and the Constitution of the European Union' (1996) 112 LQR 95.

[204] Van Bogdandy and Bast (n.4), 345–47.

[205] Everson (n.111), 213–14; Poiares Maduro (n.111), 70–72, 166–68; cf Weiler, *The Constitution of Europe* (CUP 1999) 107–16.

III. Conclusion

The narratives the EU and US courts tell to explain the legitimacy of administrative risk regulation are textured and complex. Though they are built of the same basic elements, they depict very different visions of the administration, its capacities, and its relationships to law, expertise, and politics. These differing visions of administration, in turn, help to explain the different ways in which courts in the two jurisdictions approach the legal problems of risk regulation. In particular, they help to define the role of law in constituting the legitimacy of administrative risk regulation. In doing so, they demonstrate that the solutions adopted by each jurisdiction would face serious problems if adopted by the other. They also show the connections in both jurisdictions between the law of risk regulation and basic normative commitments regarding good government. In the next and final chapter, I dig deeper into these normative commitments and explore whether they have produced coherent models of risk regulation and what implications they might have for reform of the regulatory process.

6

Conclusion—
The Legitimacy Narratives as
Responses to the Social Problem of Risk

In the last chapter, I pulled together various elements of EU and US administrative law doctrine and restated them as narratives that explain the constitutional legitimacy of administrative risk regulation in each system. I also showed how those narratives related to each system's basic commitments regarding constitutional government and the administration's place within it. Taken on their own terms, from the internal perspective of the two legal systems, both narratives tell coherent stories about why aspects of risk regulation are entrusted to the administration and why doing so is consistent with basic constitutional commitments to democracy, rights, and fairness. That is not to say that either narrative is impervious to internal attack, and both narratives remain controversial within their own legal systems. Both narratives should, however, be seen as organic expressions of each jurisdiction's constitutional culture and as capable of making sense of risk regulation within their respective public law traditions.

In this final chapter, I turn the analysis around and examine the two legitimacy narratives as legal responses to the social problem of technological risk. In particular, I look at two aspects of risk regulation that have often proved controversial: the incorporation of scientific expertise and the consideration of socio-political concerns. In some ways, of course, science and socio-political concerns are two sides of the same coin. Making an analytical distinction between them, however, helps to illuminate different aspects of the narratives. I first consider whether the two narratives incorporate realistic understandings of risk science and its

limitations. I argue that both narratives take a reasonable approach to science and that current doctrine is flexible enough to allow administrators to rely on science in a variety of appropriate ways. Second, I look at how well the two narratives respond to the range of social concerns posed by technology. I argue that when the problem of risk regulation is framed in terms of safety, both narratives are adequate legal responses to the social problem of risk. I also argue, however, that both narratives are resistant to a broader framing of risk in terms of technology choice, and that as a result neither system of administrative risk regulation is well-suited to addressing the full range of social concerns posed by technology. As a consequence, the prevailing narratives will likely prove unsatisfactory whenever non-safety concerns regarding technology come to the fore. In a brief conclusion, I reflect on the implications of this thesis for future comparative research on EU and US risk regulation.

I. The Legitimacy Narratives as Responses to the Problem of Technological Risk

A. Science

Systems of risk regulation that rely on science to inform the standard setting process must incorporate a realistic understanding of the types of information that science can (and cannot) provide. From time to time, both the EU and the US systems of risk regulation have been criticised for failing in this regard, particularly for assuming that science can provide a neutral basis for setting risk standards.[1] If those criticisms are correct, they raise serious doubts about the adequacy of the narratives because, as we have seen, in both jurisdictions the incorporation of

[1] Wagner, 'The Science Charade in Toxic Risk Regulation' (1995) 95 Colum.L.Rev. 1613, 1661–67; Coglianese and Marchant, 'Shifting Sands: The Limits of Science in Setting Risk Standards' (2004) 152 U.Pa.L.Rev. 1255, 1274–82; van Asselt and Vos, 'The Precautionary Principle and the Uncertainty Paradox' (2006) 9 JRR 313, 324–29; van Zwanenberg and Stirling, 'Risk and Precaution in the US and Europe: A Response to Vogel' (2003) 3 YEEL 43, 44–49.

scientific expertise into the regulatory process is necessary to provide a complete account of the constitutional legitimacy of administrative risk regulation. In reviewing these objections, there are two aspects to consider. First, how realistic is the courts' understanding of science in the case law, and second, how does the role of science in the narratives interact with the larger administrative process.

1. Science in the courts' case law

The complexities of risk science were discussed extensively in chapter 1 and can be reviewed briefly.[2] For a number of reasons, scientific knowledge on most risk regulation questions is uncertain to highly uncertain, which means that regulators will have to make decisions on the basis of incomplete information.[3] Moreover, because scientific evidence on risk issues it typically incomplete and ambiguous, that evidence will often be open to competing interpretations.[4] Finally, issues of complexity and ignorance mean that even when very reliable scientific information is available, knowledge of risk will never be complete.[5] For these reasons, risk science will almost always be contestable. This contestability is particularly salient for risk assessment, in which the results will often depend heavily on how the assessment is framed.[6] Scientific conclusions on risk are thus always the product of judgment, although the expert judgment applied in reaching those conclusions may

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[2] Chapter 1, section I.C.
[3] McGarity, 'Substantive and Procedural Discretion in Administrative Resolution of Science Policy Questions: Regulating Carcinogens in EPA and OSHA' (1979) 67 Geo.L.J. 729, 736.
[4] Renn, *Risk Governance* (Earthscan 2008) 74–79.
[5] Stirling, 'Risk, Uncertainty and Precaution: Some Instrumental Implications from the Social Sciences' in Berkhout, Leach, and Scoones (eds.), *Negotiating Environmental Change* (Edward Elgar 2003) 45–47.
[6] Fisher, 'Risk and Environmental Law: A Beginner's Guide' in Richardson and Wood (eds.), *Environmental Law for Sustainability* (Hart 2006) 100.

be distinguished from other types of judgment necessary to the regulatory process.[7]

Bearing these characteristics in mind, analysis of the case law shows that neither narrative rests on fundamentally mistaken understandings of science or its capabilities. To the contrary, courts in both jurisdictions have grappled in various ways with scientific indeterminacy. While the case law is not sufficiently detailed to show that judges have a deep theoretical understanding of risk science, it does show that they have grasped the nub of the problem. And although cases can be found in both jurisdictions that seem to portray science as a neutral, objective, and determinate source of knowledge, it is much more common to find examples of courts recognising the need for judgment in interpreting and applying scientific advice.

First, both the EU or the US courts have acknowledged that science is an insufficient basis for risk standard setting in most circumstances. That recognition is most explicit in the EU, in which the political nature of risk regulation is a steady refrain,[8] but there are also numerous examples of US courts holding that standard setting calls for a "legislative policy judgment".[9] At a minimum, these cases show that both EU and US courts understand that risk standards must be based on policy considerations, in addition to science. There is also ample evidence that courts understand the inherent uncertainty of risk science and the need for judgment in drawing conclusions from scientific evidence. In the EU, this understanding is best exemplified by the courts' recognition of the legitimacy of minority scientific positions as a basis for standard

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[7] National Research Council, *Science and Decisions: Advancing Risk Assessment* (NAP 2009) 31; see also Kitcher, *The Advancement of Science* (OUP 1993) 182–88; Longino, *Science as Social Knowledge* (Princeton 1990) 76–82.

[8] Case C-77/09, *Gowan Comércio Internacional e Serviços Lda. v. Ministero della Salute* [2010] ECR I-13533, para. 82; Case T-13/99, *Pfizer Animal Health SA v. Council* [2002] ECR II-3305, para. 201.

[9] *Industrial Union Department, AFL-CIO v. Hodgson*, 499 F.2d 467, 475 (D.C.Cir.1974); accord *Mississippi v. EPA*, 744 F.3d 1344, 1355 (D.C.Cir.2013).

setting,[10] and by their frequent holding that when the administration is making complex assessments, its "discretion also applies, to some extent, to the establishment of the factual basis of its action."[11] Some American courts have gone further, frankly acknowledging that scientific conclusions are matters of expert and policy judgment and that conflicting views among experts often cannot be settled definitively.[12] Finally, courts in both jurisdictions have held that drawing conclusions from inevitably uncertain science is the prerogative of the administration, subject to only narrow judicial review.[13] In this regard, courts have implicitly viewed matters of scientific judgment as implicating questions of policy and have assigned responsibility for those policy choices to the administration.[14]

Although courts in both jurisdictions recognise that risk science is inherently uncertain and indeterminate, they both also appear to view science as a discourse independent from politics and the normative evaluation of technology.[15] That view assumes the existence of at least some ascertainable facts and the possibility of evaluating the reliability of various methodological approaches for ascertaining those facts. This understanding of science is integral to the role of science in the legitimacy narratives as a basis for informing and constraining administrative decisionmaking because it creates an independent

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[10] *Gowan* (n.8), para. 77.
[11] Case T-75/06, *Bayer CropScience AG v. Commission* [2008] ECR II-2081, para. 141; *Pfizer* (n.8), para. 168.
[12] *Marsh v. Oregon Department of Natural Resources*, 490 U.S. 360, 378 (1989); *Cellular Phone Task Force v. FCC*, 205 F.3d 82, 90–92 (2d.Cir.2000).
[13] Case C-601/11 P, *France v. Commission*, para. 142; Case T-475/07, *Dow AgroSciences Ltd. v. Commission* [2011] ECR II-5937, para. 280; *Baltimore Gas and Electric Co. v. NRDC*, 462 U.S. 87, 103 (1983).
[14] *Pfizer* (n.8), para. 201; *Baltimore Gas* (n.13), 105; cf. Edley, *Administrative Law: Rethinking Judicial Control of Bureaucracy* (Yale 1990) 112.
[15] Chapter 4, section IV.

benchmark by which the conformity of administrative decisions with legislative goals and the public interest may be judged.[16]

This understanding of science is also controversial. As discussed in chapter 1, the social constructivist view of science denies that scientific knowledge is independent from the social structures that produce it. On this account, scientific conclusions are inherently socio-political, such that reliance on science as a benchmark by which to assess administrative policymaking is circular.[17] There is no easy answer to this objection inasmuch as one's position depends ultimately on one's view of basic epistemological questions.[18] When thinking about how courts approach science, however, it may be useful to consider the interaction between understandings of science and other aspects of legal doctrine. As discussed more fully below, both systems rely on an essentially liberal view of the legitimacy of the exercise of coercive government power.[19] That view, in turn, relies on the ability of the government to provide objective reasons for restricting individual liberty.[20] Frequently, such reasons are grounded in understandings of the functioning of the external world, and that is particularly the case with risk regulation. The difficulties a constructivist view poses for normative evaluation of technology would greatly complicate the administration's ability to offer adequate reasons to justify risk regulation within a liberal theory of government.[21] For this reason, the rejection of constructivist approaches

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[16] Seidenfeld, 'Hard Look Review in a World of Techno-Bureaucratic Decisionmaking: A Reply to Professor McGarity' (1997) 75 Tex.L.Rev. 559, 562–65; Everson and Vos, 'European Risk Governance in a Global Context' in Vos (ed.), *European Risk Governance* (Connex 2008) 25–29.
[17] Thorpe, 'Political Theory in Science and Technology Studies' in Hackett, Amsterdamska, Lynch, and Wajcman (eds.), *The Handbook of Science and Technology Studies* (3d ed., MIT 2007) 64–66.
[18] Chakravartty, *A Metaphysics for Scientific Realism* (CUP 2007) 16–26.
[19] Section B.2.
[20] 1 Tribe, *American Constitutional Law* (3d ed., Foundation Press 2000) 1332–43; Tridimas, *The General Principles of EU Law* (2nd ed., OUP 2006) 311–13.
[21] Chapter 1, section I.C.3; Radder, 'Normative Reflexions on Constructivist Approaches to Science and Technology' (1992) 22 Soc.Stud.Sci. 141, 156–57.

to science can be seen as not just an epistemological assumption, but also a normative commitment of both legal systems. That commitment may seem misplaced to adherents of the social constructivist position, but its existence underscores the point that these debates cannot be resolved solely by reference to the nature of concepts like science or risk, but must be extended to include basic questions about the necessary conditions for the legitimate exercise of government power.

2. Science in the administrative process

We can reject, therefore, any conclusion that courts are simply operating on the basis of erroneous understandings of science. But the fact that courts have a reasonable grasp of the limits of risk science does not mean that their jurisprudence reflects the realities of the administrative process. Recognising the judgment-laden nature of scientific advice, both jurisdictions' legitimacy narratives attempt, in different ways, to subject scientific advice to democratic control.[22] Yet at the same time, both narratives rely to some extent on science and expertise to constrain political decisionmaking.[23] These goals are in obvious tension, and the two jurisdictions manage that tension in markedly different ways.

As we saw in chapter 4, the EU courts approach the tension rather straightforwardly by bifurcating the standard setting process into a scientific and a political component.[24] In this way, regulatory decisionmaking stays firmly in political hands, while scientific advice giving remains independent from politics, thereby providing a basis for the evaluation of political judgment.[25] The virtues of this approach are that it is easy for courts to administer and that it unambiguously places responsibility for standard setting on political decisionmakers. The main

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[22] Christoforou, 'The Precautionary Principle and Democratizing Expertise: A European Legal Perspective' (2003) 30 Sci.Pub.Pol'y 205, 209–10; Doremus, 'Scientific and Political Integrity in Environmental Policy' (2007) 86 Tex.L.Rev. 1601, 1639–41.
[23] Chapter 5, section I.B.
[24] European Commission, 'Communication on the Precautionary Principle' COM(2000) 1 final, 12.
[25] Everson and Vos (n.16), 25.

drawback is that it tends to disregard the normative judgments that must take place in the formulation of scientific advice. Excluding overt consideration of policy from the scientific advice-giving process, creates a lacuna in which important political choices may be made without the processes necessary to render them legitimate. What is more, it tends to obfuscate important aspects of the decisionmaking process, thereby impeding accountability.[26]

In evaluating these objections, we should first note that the separation of risk assessment from risk management is not as sharp as the courts' language might suggest. For example, political actors play an important role in framing the questions posed to expert bodies. Often the salient issues are specified by the EU legislature in primary law,[27] and in most cases expert opinions are rendered in response to requests from the Commission, which gives the Commission considerable influence over how the assessment is framed. In some cases, the Treaties themselves frame the risk in important ways.[28] Additionally, the Commission has the power to respond to expert opinions by requesting clarifications or additional advice, a power that has been employed in response to issues that have arisen during the comitology process.[29] This practice helps to ensure that the advice being given responds to the concerns of the relevant political actors.

In addition to the Commission's ability to influence the risk assessment process, there are good reasons to believe that regulatory decisionmakers are well-equipped to review expert recommendations critically. First, although the Commission lacks deep expert resources, it cannot be considered an uninformed consumer of scientific information, and Commission staff generally have deep familiarity with the issues they work on, including the key scientific issues.[30] The staff's knowledge can also be supplemented by the Commission's own, albeit limited, expert

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[26] Lee, *EU Environmental Law* (2d ed., Hart 2014) 52–56.
[27] E.g., Regulation (EC) 1107/2009 concerning the placing of plant protection products on the market &c. [2009] OJ L309/1, Annex II.
[28] E.g., Case C-1/00, *Commission v. France* [2001] ECR I-9989, para. 24.
[29] E.g., *Gowan* (n.8), paras. 30–44.
[30] Nugent, *The European Commission* (Palgrave 2001) 179.

resources.[31] Second, EU administrative procedure builds-in many opportunities for scrutiny of expert advice. One forum for that scrutiny is the expert committee itself, which is meant to bring together a number of experts with diverse backgrounds and institutional affiliations.[32] Expert advice is also scrutinised by the Member States in the comitology process. Even more so than the Commission, the Member States are well-placed to evaluate expert advice critically, and there are several examples of Member States challenging the scientific conclusions of EU bodies.[33] Finally, expert advice is at times actively scrutinised by other actors including the European Parliament and both environmental and business NGOs.[34] Although scrutiny from these bodies is more ad hoc, it can be especially effective in broadening the range of perspectives brought to bear on scientific issues.

There is thus good reason to believe that the EU's approach can work, but there are also reasons for caution. The EU system has failed in the past, most notably during the BSE crisis.[35] That episode changed attitudes in the EU toward risk regulation, however, resulting in a much

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[31] Chapter 2, section II.B.1.

[32] Chapter 2, section II.B.2. The reality of this diversity is questionable, however; see below.

[33] Consider, for example, the circumstances recounted in *Gowan* (n.8); Case T-240/10, *Hungary v. Commission*, nyr, paras. 23–41; Case T-229/04, *Sweden v. Commission* [2007] ECR II-2437, paras. 32–41; Weimer and Pisani, 'Expertise as Justification—The Contested Legitimation of the EU "Risk Administration"' in Weimer and de Ruijter (eds.), *Regulating Risks in the European Union—The Co-production of Expert and Executive Power* (Hart 2016) (forthcoming).

[34] Greenpeace, *The EU GMO Environmental Risk Assessment Needs Reforming* (September 2008), http://www.greenpeace.org/eu-unit/en/Publications/2009-and-earlier/Reform-of-EU-GMO-risk-assessment; American Chemistry Council and Cefic, Joint Statement on WHO-UNEP 2012 report on Endocrine Disruptors (March 2014), http://www.cefic.org/Policy-Centre/Environment--health/Endocrine-Disruption-Modulators.

[35] European Parliament, 'Report on alleged contraventions or maladministration in the implementation of Community law in relation to BSE &c.', A4-0020/97 (1997); van Zwanenberg and Millstone, *BSE: Risk, Science, and Governance* (OUP 2005) 181–95.

stronger culture of vigilance.[36] Europe's experience with BSE may, therefore, actually be a reason for increased confidence. More recently, concerns have been raised—most prominently by the Parliament—about diversity and balance on expert committees, with the charge being that they are tilted in favour of industrial perspectives.[37] The European Ombudsman also conducted an Own Initiative Inquiry into the composition of expert committees and concluded that the Commission could make several improvements in its selection process.[38] Those concerns must be taken seriously, as biased committees could undermine one of the most important safeguards in the EU system. At the same time, however, the fact that this issue has been pressed and is receiving attention at the highest political levels suggests that there are sufficient overlapping sources of critical oversight to make a system-wide failure unlikely.

Although there have been many calls in the US to adopt a bifurcated approach similar to the EU's,[39] those calls have not been heeded, and US administrative law has generally refused to draw a sharp distinction between the political and scientific aspects of standard setting.[40] Instead,

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[36] Vogel, *The Politics of Precaution* (Princeton 2012) 76; Vos, 'EU Food Safety Regulation in the Aftermath of the BSE Crisis' (2000) 23 J.Consumer.Pol'y 227, 233–36.

[37] Nielsen, 'MEPs Withhold Millions from EU Commission over Transparency' (October 22, 2014) *EU Observer*, https://euobserver.com/justice/126194.

[38] European Ombudsman, Own-initiative inquiry OI/6/2014 concerning the composition of Commission expert groups; see also Lee, 'Accountability and Co-Production Beyond Courts: The Role of the European Ombudsman' in Weimer and de Ruijter (n.33).

[39] Such calls prompted the analysis that resulted in the 1983 Redbook, although the authors of that report declined to endorse a rigid separation. National Research Council, *Risk Assessment in the Federal Government: Managing the Process* (NAP 1983) 140–43. More recent calls for partial separation include Bagley and Revesz, 'Centralized Oversight of the Regulatory State' (2006) 106 Colum.L.Rev. 1260, 1323–24 and Graham, 'Saving Lives Through Administrative Law and Economics' (2008) 157 U.Pa.L.Rev. 395, 464–65.

[40] This is another area in which it is important to note that administrative practice varies, and some programmes are more separated

the US manages the tension by placing politically responsible administrators in charge of the provision of scientific advice.[41] Involving political decisionmakers in the production of scientific advice decreases the risk that the perspectives of experts will dominate the political debate, but it increases the risk that political actors will apply pressure to skew scientific advice-giving.[42] The result may be that decisions made on purely political grounds can be cloaked in scientific conclusions and to some extent immunised from political scrutiny.[43]

Just as the EU approach requires robust political scrutiny of expert advice, the reliability of the US approach depends upon the existence of mechanisms for evaluating the process of expert advice-giving to ensure that political influence is kept in check. To an extent, that function is performed by independent advisory committees, but resort to such committees in the US is inconsistent and not always well-publicised.[44] Judicial review is a more important source of scrutiny, and as discussed in chapter 4, one focus of contemporary US judicial review is on ferreting out possible illegitimate political influence on scientific analysis.[45] Finally, many of the procedural aspects of US administrative law are directed at facilitating scrutiny of administrative decisions, not only by courts, but also by interested parties,[46] and both industry and pro-regulatory groups make frequent use of these mechanisms to interrogate agency science. The system is thus not without safeguards.[47] At the same time, however, scrutiny of regulatory science is less institutionalised in

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than others. US *administrative law* has never imposed a separation requirement similar to the EU principle of independence, however.

[41] Chapter 2, section II.A.1.

[42] Chapter 4, section II.F.

[43] Wagner (n.1), 1651–54.

[44] Wagner, *Science in Regulation* (2013) 152–54.

[45] Section II.E.

[46] *American Radio Relay League, Inc. v. FCC*, 524 F.3d 227, 237–38 (D.C.Cir.2008); *United States v. Nova Scotia Food Products Corp.*, 568 F.2d 240, 251 (2d.Cir.1977); Leventhal, 'Environmental Decisionmaking and the Role of the Courts' (1974) 122 U.Pa.L.Rev. 509, 540–41.

[47] Wagner, Barnes and Peters, 'Rulemaking in the Shade: An Empirical Study of EPA's Air Toxic Emission Standards' (2011) 63 Admin.L.Rev. 99, 136–42.

the US than in the EU. There is no guarantee, for example, that every regulatory decision will be scrutinised by a capable NGO or that courts will successfully detect inappropriate political influence. There may, therefore, be greater possibilities for "science bending" to go uncorrected.

In sum, there is reason to conclude that both the EU and the US administrations possess sufficient freedom to make appropriate use of scientific advice. Whether they actually do so is a much more difficult question that would require extensive empirical investigation that cannot be pursued in this thesis. Mostly likely, the answer varies, perhaps considerably, among regulatory programmes and regulatory bodies. We may conclude on the basis of doctrinal analysis, however, that when administrators fall short in their use of science, blame for that failure lies with the administrators themselves. Though the EU and US narratives channel the role of scientific expertise in the administrative process in various ways, neither materially impedes a range of sensitive and appropriate uses of science in the regulatory process.

But is it enough not to impede? Should the courts go further and push administrators in the direction of better uses of science? On the whole, such efforts seem unadvisable, at least so long as other fora remain available for proposing reforms. In the first place, it is not clear that courts are especially competent to engage with these issues in detail. Although I have argued that courts grasp the basic problems of risk science, it seems unlikely that many judges have studied them closely, much less devoted substantial thought to how administrators can best manage the limits of risk science. These issues are not simple, and there is substantial risk courts would worsen existing practice rather than improve it.[48] In particular, courts have a tendency to push administrators in the direction of trial-like procedures, but in many circumstances such procedures are likely to be poorly suited to addressing the role of science in regulation.

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[48] Certainly, the US experience with judicial innovation in administrative procedure has been much-criticised. E.g., Pierce, 'Seven Ways to Deossify Agency Rulemaking' (1995) 47 Admin.L.Rev. 59, 60–66.

An additional reason to reject greater judicial intervention is that procedures for incorporating science into regulatory decisionmaking are controversial. Although there may be general agreement on the limits of risk science, there is legitimate—and I would argue fruitful—disagreement about how to respond to those limits. There are also difficult questions about trade-offs between more elaborate procedures, including greater or more intensive public participation, and other considerations, such as cost and regulatory delay. Legal analysis simply does not provide the necessary tools for resolving these questions, which are better suited to democratic debate and regulatory experimentation. The latter is particularly important, as problems of risk regulation continue to arise in new contexts. One feature of adjudication is that it tends strongly toward path-dependency and ossification.[49] Although it is not inevitable, there is a real danger that greater judicial involvement in deciding how risk science is produced and used will lead to a loss of flexibility, dampening political discourse and making it more difficult for administrators to respond as knowledge and circumstances evolve.

None of this is to say that courts have no contribution to make, and many general administrative law doctrines tend to improve the use of science by administrators. Judicial decisions that promote transparency, that require administrators to articulate reasons, and that guard against inappropriate political influence all create tools for holding administrators to account for their use of science. One of the virtues of these doctrines is that they derive from essentially legal values and apply to administrative decisionmaking generally.[50] When courts attempt to go beyond these basic norms of good administration, however, they are less likely to make a positive contribution.

Viewed as a whole, then, I conclude that that both legitimacy narratives appropriately incorporate realistic understandings of risk science. That is not to say that either jurisdiction's doctrine or practice

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[49] Shapiro and Stone Sweet, *On Law, Politics, and Judicialization* (OUP 2002) 112–17.

[50] Scott and Sturm, 'Courts as Catalysts: Re-Thinking the Judicial Role in New Governance' (2006) 13 Colum.J.Eur.L. 565, 572.

could not be improved, and recent case law shows courts in both jurisdictions making marginal, if important, advances.[51] Rather than focusing on courts or legal doctrine, however, efforts to reform the use of science would be better directed at administrators or legislators. In some ways, those paths are more difficult, and resistance from opposed interests should be expected. But the legal process poses its own obstacles, and focusing on more overtly political avenues has the virtue of allowing the role of science in risk regulation to be addressed frankly as a matter of social policy and political choice.

B. Socio-political concerns

Although I would argue that both legitimacy narratives are premised on realistic understandings of risk science and its limitations, an adequate approach to science is only half the problem. As discussed in chapter 1, regulatory responses to technological risk implicate a broad range of socio-political concerns. At the most basic level, risk regulation involves choices about the role of technology in society and about the distribution of harms and benefits associated with that technology. The legitimacy narratives must therefore also be evaluated in terms of how well they accommodate those social considerations. In particular, a successful risk regulation programme must allow space at some point in the process for normative evaluation of the risk in question and must do so in ways that are consistent with constitutional commitments.

Evaluating the narratives as responses to the socio-political aspects of risk regulation is made difficult, in part, because the nature of the evaluation depends on how the problem of risk regulation is framed and thus the range of socio-political concerns that are relevant. In chapter 4, I argued that administrative law in both jurisdictions tends to frame risk in terms of safety, i.e., the propensity of a product to cause physical harm to humans or the environment.[52] Equating risk with safety is a narrow way to frame risk regulation, however, and in chapter 1 I

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[51] Ibid., 582–92; Fisher, Pascual, and Wagner, 'Rethinking Judicial Review of Expert Agencies' (2015) 93 Tex.L.Rev. 1681, 1715–21.
[52] Chapter 4, section I.

described a broader framing of risk that includes the social implications of technology, which I termed "technology choice".[53] In this section, I first consider whether the two narratives allow adequate scope for response to socio-political concerns within the dominant risk-as-safety frame. I then consider whether they are adequate to sustain regulation on the basis of concerns beyond safety.

1. Risk regulation within the safety frame

Both EU and US administrative law allow administrators to take account of a number of considerations beyond science in setting risk standards. Courts have been quite explicit in this regard with respect to the question of risk acceptability.[54] They have also generally recognised that administrators must take into consideration non-science factors in determining when scientific evidence is sufficient to justify regulation.[55] Other considerations that courts have recognised as legitimate include distributional concerns and (to an extent) public anxiety.[56] Courts are therefore clear that risk standard-setting must be a normative, as well as a technical, exercise. Indeed, it is the courts' recognition of the importance of non-science concerns that has led the legitimacy narratives to rely foremost on democracy, not science, as the basis for the legitimacy of administrative risk regulation.[57]

Despite the recognition that risk regulation is an inherently normative question, however, both narratives place limits on administrators' ability

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[53] Chapter 1, section I.B.

[54] *Gowan* (n.8), paras. 78–79; Case T-257/07, *France v. Commission* [2011] ECR II-5827, paras. 78–80; *Whitman v. American Trucking Associations*, 531 U.S. 457, 475–76 (2001); *Ethyl Corp. v. EPA*, 541 F.2d 1, 29 (D.C.Cir.1976) (en banc).

[55] *Pfizer* (n.8), paras. 200–01; Case C-269/13, *Acino AG v. Commission*, nyr, paras. 63–64; *BP Exploration & Oil, Inc. v. EPA*, 66 F.3d 784 (6th.Cir.1995); *Ethyl* (n.54), 20–21.

[56] Case 331/88, *R. v. MAFF ex p. Fedesa* [1990] ECR I-4023, paras. 13–14; Case C-121/00, *Criminal proceedings against Hahn* [2002] ECR I-9193, paras. 44–46; *EPA v. EME Homer City Generation, LP*, 134 S.Ct. 1584, 1606–07 (2014); *Hoosier Environmental Council v. U.S. Army Corps of Engineers*, 722 F.3d 1053, 1063 (7th.Cir.2013).

[57] Chapter 5, section I.D.

to consider broader socio-political concerns. The main doctrinal source of these limits is delegation theory, which provides that administrators may only take into account those concerns that fall within the scope of the relevant delegation.[58] Both the EU and US courts have generally framed the delegations narrowly in terms of safety due to concerns about according broad policymaking discretion to the administration.[59] As a consequence, both the EU and US administrations are generally prohibited from acting on the basis of considerations that do not relate in some way to the safety of a product, and both the EU and US courts have set aside administrative actions that appear to be motivated by other concerns.[60] That said, the courts have tended to interpret the concept of safety flexibly, so that both EU and US administrative law have been able to accommodate many non-science concerns regarding technological risk even within a safety framework.

It still could be argued, however that although courts allow administrators to consider socio-political concerns related to safety, aspects of legal doctrine encourage administrators to focus on scientific issues at the expense of other considerations. It has been argued, for example, that science-focused decisions are easier to defend on judicial review, and that administrators will therefore give other considerations short shrift.[61] It is certainly true that both legitimacy narratives require the administration to demonstrate that it has incorporated scientific

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[58] Chapter 2, section III.

[59] Chapter 4, section I. This is an area in which statutory language matters a great deal. Cf. Scott, 'European Regulation of GMOs: Thinking About Judicial Review in the WTO' (2004) 57 CLP 117. Nonetheless, as I argued in chapter 2, general delegation concerns influence the ways in which legislation is interpreted and constrain the administration's ability to account for broad socio-economic factors. Chapter 2, section III.

[60] Case T-74/00, *Artegodan GmbH v. Commission* [2002] ECR II-4945, para. 175–77; Case T-333/10, *Animal Trading Company (ATC) BV v. Commission*, nyr, paras. 86–88; *Massachusetts v. EPA*, 549 U.S. 497, 534–35 (2007); *Tummino v. Hamburg*, 936 F.Supp.2d 162, 170–71 (E.D.N.Y.2013).

[61] Coglianese and Marchant (n.1), 1292–98; Meazell, 'Super Deference, the Science Obsession, and Judicial Review as Translation of Agency Science' (2011) 109 Mich.L.Rev. 733, 772–78; Wagner (n.1), 1661–67.

expertise into its decisionmaking process, while leaving administrators' obligations with regard to socio-political concerns largely undefined. To that extent, it is fair to say that the case law in both jurisdictions tends to give greater prominence to the scientific aspects of risk regulation. There is not a lot of evidence, however, that courts are more likely to uphold science-heavy, versus policy-heavy, decisions. In the US, the opposite may be true, as some US courts have held that greater deference is owed to an agency's policy choices than to its scientific conclusions.[62] In the EU, the limited evidence from the case law suggests that because of the operation of the precautionary principle, courts are more likely to defer to highly protective standards than to less protective standards, regardless whether the reasons underlying the standard are science- or policy-based.[63] Scientific reasons can, of course, be highly compelling—particularly when they provide evidence of potentially serious harm to public health—and for that reason administrators may frequently focus on scientific issues as a means of persuading not just the courts, but also the public, of the appropriateness of their decision. Science also provides a vocabulary for explaining why evidence motivated a specific outcome, which administrators, who are often required by legislation to set numerical risk standards, may find particularly congenial.[64] It is far from clear, however, that administrative law encourages administrators to emphasise science at the expense of policy considerations.

Another way in which both regulatory systems may unduly constrain the scope of the regulatory inquiry is through reliance on analytical techniques such as cost-benefit analysis and impact assessment. Many have argued that a focus on this type of analysis results in

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[62] *Competitive Enterprise Institute v. NHTSA*, 956 F.2d 321, 323–24 (D.C.Cir.1992); Edley (n.14), 33–34; Williams, 'The Roots of Deference' (1991) 100 YLJ 1103, 1106–08.

[63] Chapter 3, section I.B.1. I would stress that the evidence from the case law is *very* limited and any conclusions in this regard must be treated as tentative. E.g., *France* (n.54), para. 214.

[64] Coglianese and Marchant (n.1), 1264–66; Fisher, 'Drowning by Numbers: Standard Setting in Risk Regulation and the Pursuit of Accountable Public Administration' (2000) 20 OJLS 109, 128.

administrators taking an artificially narrow view of risk, mostly at the expense of socio-political considerations.[65] Although I argued in chapter 3 that both administrations apply those frameworks flexibly, it is unquestionably true that impact assessment and cost-benefit analysis reinforce the prominence of certain values and perspectives in the regulatory process. In itself, however, that is no criticism, as there is simply no way to design a process for regulatory decisionmaking that is free of normative commitments or that does not privilege certain values.[66]

What is important to recognise for present purposes, is that in neither jurisdiction has the choice to rely on impact assessment and cost-benefit analysis been made by the courts. Although administrative law permits, and in some ways facilitates, the use of those methodologies, reliance on them is not a part of either the EU or the US legitimacy narrative, and there is nothing in the Court of Justice's or the Supreme Court's case law that suggests that the constitutional legitimacy of administrative risk regulation would be in question if those methodologies were abandoned. Instead, the choice to rely on cost-benefit analysis and impact assessment has been made by administrators themselves, often with explicit backing at the highest political levels.[67] Nor can it reasonably be maintained, in light of the extensive policy literature addressing these issues, that the administrators who endorse those methodologies are ignorant of the value choices implicit in them. The decision to employ those methodologies should therefore be understood as a political choice to embrace the normative vision of risk regulation they imply.[68] There are

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[65] See sources cited chapter 3, section II.A.

[66] Craig, *Public Law and Democracy in the United Kingdom and the United States of America* (Clarendon 1990) 5. This is true even of deliberative approaches to policymaking. Epstein, 'Modern Republicanism, or the Flight from Substance' (1988) 97 YLJ 1633; Sullivan, 'Rainbow Republicanism' (1988) 97 YLJ 1713.

[67] E.g., European Commission, Communication, 'Better Regulation for Better Results—An EU Agenda' COM(2015) 215 final; EO 12,866, 58 Fed. Reg. 51,735 (Sept. 30, 1993).

[68] E.g., Adler and Posner, *New Foundations of Cost-Benefit Analysis* (Harvard 2006) 25–61; Graham (n.39), 404–11.

also, of course, many reasons to reject that vision,[69] and the debate between these positions cannot be resolved here. I would argue, however, that regardless of one's position on the use of cost-benefit analysis and impact assessment, the existence of intense controversy among thoughtful people of good faith suggests that any resolution is likely to have greater functional legitimacy if adopted through political processes than if adopted by the judiciary, if only because political processes are better adapted to the continual adjustment of whatever settlement is reached. For that reason, the courts should be applauded for refusing to take sides on the issue.[70]

Thus, taken as a whole, both legitimacy narratives accord administrators sufficient flexibility to take account of an appropriate range of socio-political considerations that bear on the regulation of technological risk within the confines of a risk-as-safety frame. In particular, both jurisdictions allow the administration to consider the public acceptability of safety risks, as well as their empirical probability. Whether administrators adequately address socio-political concerns in practice is a separate question beyond the scope of this thesis, but it seems safe to say that the records of both administrations are mixed in this regard. It must also be stressed, however, that there are important limits to the risk-as-safety frame, and that this finding of adequacy is similarly limited. Accommodation of concerns other than safety within the existing narratives is a much more difficult problem.

2. Beyond safety?

As discussed in chapter 1, safety, though perhaps most prominent, does not begin to exhaust the range of social concerns posed by technology. New technologies, especially biotechnologies, have the potential to bring about significant changes in the social order and to redefine humanity's relationship with the environment.[71] Many of these issues touch on deep

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[69] E.g., Kysar, *Regulating from Nowhere* (Yale 2010) 46–67.
[70] Cf. Byse, 'Vermont Yankee and the Evolution of Administrative Procedure: A Somewhat Different View' (1978) 91 HLR 1823, 1831–32.
[71] Jasanoff, *Designs on Nature* (Princeton 2005) 94–118.

questions of value, and many calls for regulation of new technologies are grounded at least as much in concerns for those values as they are in concerns for physical safety.[72] Indeed, many of the most controversial and divisive technologies implicate just these concerns.

Are the EU and US systems of administrative risk regulation well-suited for addressing concerns beyond safety? The short answer is no. Both legitimacy narratives incorporate certain premises about the scope and nature of administrative decisionmaking that are incompatible, or at least in tension, with regulation on the basis of non-safety concerns. As a consequence, the EU and US legitimacy narratives are powerful barriers to expanding administrative risk regulation from questions of safety to larger questions of the role of technology in society.

The central challenge for both EU and US constitutionalism posed by administrative regulation on the basis of non-safety concerns lies with one of the core premises of both systems regarding the legitimate exercise of government power: that restrictions on individual autonomy are only justified when they are adopted through democratic means and further a legitimate public purpose.[73] As such, not all restrictions on individual liberty, even if backed by a democratic majority, are constitutionally legitimate.[74] Restrictions must also be imposed for acceptable reasons.[75] The roots of this premise lie in liberal political theory and the protection of individual autonomy from majoritarian restriction.[76] In European and American constitutional law, it is uncontroversial that preventing physical harm to people or the environment is a legitimate pubic purpose

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[72] Lee, 'Beyond Safety? The Broadening Scope of Risk Regulation' [2010] CLP 242, 244–49.
[73] Case 11/70, *Internationale Handelsgesellschaft mbH v. Einfuhr- und Vorratsstelle für Getreide und Futtermittel* [1970] ECR 1125, paras. 3–4; *West Coast Hotel Co. v. Parrish*, 300 U.S. 379, 398 (1937).
[74] E.g., *Lawrence v. Texas*, 539 U.S. 558, 571 (2003).
[75] Ely, *Democracy and Distrust* (Harvard 1980) 14–20; Rawls, *Political Liberalism* (expanded ed., Columbia 2005) (1993) 98.
[76] Sunstein, *After the Rights Revolution* (Harvard 1993) 36–37.

and thus an appropriate reason for restricting autonomy.[77] By contrast, other asserted grounds for regulating technology—such as respect for traditional ways of life, some types of distributional concerns, and ethical or religious theories regarding alteration of nature—are constitutionally controversial. In particular, much liberal constitutional theory is sceptical of regulation on moral grounds, which in the context of risk regulation includes ideas about what is (or is not) "natural".[78] Many concerns regarding technology go to just such issues, however,[79] meaning that attempts to regulate on those bases are prone to raise constitutional concerns. That is not to say that regulation on such grounds is necessarily illegitimate, as a matter of either constitutional law or political theory. It is only to say that the legitimacy of regulation for these reasons is disputed, and it is the very existence of these controversies about the use of governmental power that poses problems for administrative regulation beyond the realm of safety. Because administrative regulation in both jurisdictions is seen as democratically suspect, both legitimacy narratives tend to restrain administrative power to enter into constitutionally controversial areas.

Perhaps the most important obstacle to expansion of risk regulation beyond safety lies is the administration's status, in both jurisdictions, as a subordinate law maker. The theories of delegation that form the backbone of both legitimacy narratives reconcile administrative regulation with democratic government by requiring that the most important value judgments be made by the legislature.[80] This requirement comes across more clearly in the European case law, which explicitly reserves to the legislature basic value choices about

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[77] Ibid.; see also Mill, *On Liberty* (Rapaport ed., Hackett 1978) (1859); Nagel, *Equality and Partiality* (OUP 1991) 155; Schroeder, 'Rights Against Risks' (1986) 86 Colum.L.Rev. 495, 501–02.
[78] Hart, *Law, Liberty, and Morality* (OUP 1963); see also Rawls (n.75), 174–76; Schroeder (n.77), 512–13.
[79] Kysar (n.69), 191–94; Lee (n.72), 247–48; cf. Jasanoff (n.71) 146–48.
[80] Chapter 2, section III; Lindseth, 'Delegation Is Dead, Long Live Delegation: Managing the Democratic Disconnect in the European Market-Polity' in Joerges and Dehousse (eds.), *Good Governance in Europe's Integrated Market* (OUP 2002) 146–50.

regulation,[81] but it is also evident in Supreme Court decisions that adopt narrow constructions of delegating legislation so as not to empower the administration to make fundamental social choices.[82] In both jurisdictions, the question whether a product or process is sufficiently safe—understood in terms of effects on human health or the physical environment—falls well within the range of questions that are appropriate for administrative resolution. But other questions, such as whether particular biotechnologies are innately immoral or whether a technology should be prohibited because it threatens certain interests, do not. The case law is far too sparse to draw any clear lines, but it is apparent that the more the reasons underlying regulation appear to turn on basic value choices regarding social relations, the more likely the courts are to redirect the decision back to the legislature.[83]

A second reason why questions beyond safety are difficult to accommodate within the EU or US legitimacy narratives is that resolution of these questions requires processes of decisionmaking that do not fit the models of administration posited by the narratives. The US narrative, in particular, relies on a model of the administrative process that includes expert analysis to justify delegation to extra-constitutional institutions; expertise is constitutive of legitimate administration. Although expertise does not serve the same role in the EU, it is still essential to the EU legitimacy narrative as a core aspect of the duty of care. Questions of safety, which are answered in part by reference to scientific analysis, are well-suited to these models of administration. Other kinds of concerns, particularly ethical concerns, are less amenable to expert analysis and are therefore more difficult to fit within these

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[81] Case C-355/10, *Parliament v. Council*, nyr, paras. 66–67; Case C-403/05, *Parliament v. Commission* [2007] ECR I-9045, Opinion of A.G. Kokott, para. 79; Chamon, 'How the Concept of Essential Elements of a Legislative Act Continues to Elude the Court: *Parliament* v. *Council*' (2013) 50 C.M.L.Rev. 849, 856–58.

[82] *Gonzalez v. Oregon*, 546 U.S. 243, 267–68 (2006); *Industrial Union Department, AFL-CIO v. American Petroleum Institute*, 448 U.S. 607, 646 (1980) (*Benzene*).

[83] Chamon (n.81), 859; cf. Lowi, *The End of Liberalism* (2d ed., Norton 1979) 94–97.

models of administration.[84] Instead, many non-safety concerns demand robust democratic engagement, yet in both systems the administrative process is understood—even presumed—to be the wrong forum for democratic debate.[85] As a consequence, the existing legitimacy narratives are incapable of validating administrative regulation on these grounds. Various ways of democratising the administrative process have been suggested in both jurisdictions, particularly through greater use of participative administrative procedures. As yet, however, no approach has managed to successfully bridge the gap between participative administrative processes and the constitutional designation of the legislature as the forum for deciding basic questions of value.[86] The challenge of rewriting the legitimacy narratives to accommodate value choices about technology thus requires not only revising the role of expertise but also reassessing the relationship between administrative regulation and democratic government.

Finally, regulation on the basis of non-safety concerns is difficult to fit within the legitimacy narratives because it will often require controversial decisions regarding the scope of fundamental rights. Many non-safety concerns touch on vaguely defined, but highly valued rights, such as human dignity, privacy, intellectual freedom, religious liberty, and free development of personality. Neither legitimacy narrative understands administrative regulation as the proper forum for defining the boundaries of these rights, at least in the first instance. Although the EU courts have not reached a definitive position on the subject, one strand of European constitutional thinking would put such questions beyond administrative

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[84] Ironically, the EU has tried to address this problem to some extent by turning ethical analysis into an expert discourse. E.g., Busby, Hervey and Mohr, 'Ethical EU Law? The Influence of the European Group on Ethics in Science and New Technologies' (2008) 33 ELR 803.

[85] Cf. Ehnert, 'The Legitimacy of New Risk Governance—A Critical View in Light of the EU's Approach to Nanotechnologies in Food' (2015) 21 ELJ 44, 65–66.

[86] Schmidt-Aßmann, 'Verwaltungslegitimation als Rechtsbegriff' (1991) 116 Archiv.offen.Rechts 329, 371–76; Stewart, 'The Reformation of American Administrative Law' (1975) 88 HLR 1667, 1802–05.

power entirely.[87] For their part, US courts have consistently interpreted regulatory statutes to avoid difficult constitutional questions, and in particular to constrain administrators' power to limit non-economic rights.[88] Again, for this reason, non-safety concerns would seem to require legislative, rather than administrative, resolution.

In arguing that the current legitimacy narratives tend to exclude conceptions of risk regulation that extend beyond safety, I do not intend to endorse the status quo.[89] Whether the tendency of the legitimacy narratives to exclude questions beyond safety is a virtue or a fault, depends on one's view of the proper reach and limits of government and of the administration's role in it. Once again, we are back to political theory.[90] What can be said is that limiting administrative risk regulation to questions of safety is strongly appealing from a classically liberal perspective, and that appeal likely accounts for its dominance in EU and US law. For a liberal, limiting the grounds on which administrators can regulate tends to protect individual freedom[91] by directing difficult value questions to "the governmental body best suited and most obligated to make the choice".[92] If disputable decisions about what constitutes a good society are to be made, they should only be made after the fullest political process constitutionally available.[93] Because liberal ideas underlie much of the public law theory and doctrine in the EU and the US, administrative law has evolved to reflect these views and as a result has

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[87] Von Bogdandy and Bast (eds.), *Principles of European Constitutional Law* (2d ed., Hart 2010) 390–94. The Court of Justice has expressed scepticism that such questions are appropriate for the administration. *Parliament v. Council* (n.81), paras. 76–78.

[88] *Gonzalez* (n.82), 267–68; *Kent v. Dulles*, 357 U.S. 116, 129 (1958).

[89] These are difficult questions of moral and political theory, an adequate treatment of which would require far more space than is available in a thesis about analysing existing judicial doctrine. It seems better to leave the question for another day than to make a jejune case here.

[90] Craig (n.66), 4–7; see also Fisher, *Risk Regulation and Administrative Constitutionalism* (Hart 2007) 250–54.

[91] Hart (n.78); Mill (n.77); Schroeder (n.77), 520.

[92] *Benzene* (n.82), 671 (Rehnquist, J., concurring in the judgment); see also Ely (n.75), 131–34.

[93] Lowi (n.83), 305–09.

created a number of barriers that prevent administrators from straying too far from the relatively noncontroversial grounds of safety.

Liberalism can, of course, be criticised on many grounds,[94] and its historical dominance in public law should not preclude us from considering whether that dominance is merited. Indeed, a strong argument can be made that the exclusion of administrators from difficult constitutional questions is simply unsustainable in modern "regulatory democracies". After all, "bureaucrats" routinely make decisions that greatly affect individuals' material circumstances—they can literally make or break people's lives.[95] Why should the question whether genetic modification is inherently immoral be any more sacrosanct? When the practical realities of contemporary regulation are considered, defining administrative risk regulation narrowly in terms of safety seems to ignore the fact that administrators cannot help but make far-reaching social choices. By excluding a range of valid and salient, if difficult, issues from regulatory consideration, it can be argued that the existing legitimacy narratives unjustifiably exclude one segment of interests from the regulatory process and thus undermine the broader, functional legitimacy of administrative risk regulation even as they preserve an outdated, legalistic form of legitimacy. The exclusion of non-safety concerns from administrative consideration is particularly problematic in the EU, which continues to struggle with its own democratic legitimacy. When the democratic validity of measures adopted by the EU legislature is itself in doubt, there would seem to be less reason for preferring legislative processes on democratic grounds.

Regardless of one's view of the proper role of the administration, it is apparent that the exclusion of non-safety concerns has created practical problems for both European and American risk regulation. By limiting the range of concerns that may be taken into account, administrative law sometimes requires administrators to formulate regulatory problems in ways that artificially exclude important aspects of public concern and

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[94] Thorpe (n.17), 69–73; see also generally Mulhall and Swift, *Liberals and Communitarians* (2d ed., Wiley-Blackwell 1996).
[95] Mashaw, *Bureaucratic Justice* (Yale 1985).

encourage regulatory advocates to shoe-horn normative objections into doubts about safety.[96] Indeed, it is when non-safety concerns become highly salient that the weaknesses of the current legitimacy narratives become exposed. When the primary issue of public concern is safety, administrative risk regulation, though inevitably controversial, seems to function reasonably well. But when non-safety concerns come to the fore, as for example with GMOs in the EU or with emergency contraception in the US, the administrative process breaks down.[97] Arguably at least, the root cause of these breakdowns is the inability of the administrative process to deal with the real issues in controversy. Although Europeans have genuine concerns about the safety of GMOs and the adequacy of EFSA risk assessment procedures,[98] the high degree of controversy surrounding this particular technology has much more to do with the social ramifications of biotechnology.[99] It should be unsurprising, therefore, that an administrative process that can only discuss safety has been unsatisfactory. A similar analysis applies to the longstanding American controversy regarding over-the-counter sales of emergency contraceptives, in which the drug approval process has proved to be a totally inadequate forum for airing concerns about teenage sexuality.[100] So long as the issues animating public anxiety about technologies are excluded from the regulatory debate, the functional legitimacy of administrative risk regulation in both jurisdictions will be in doubt.

Given these experiences, one might reasonably argue that the scope of administrative risk regulation should be expanded to take account of concerns beyond safety. In either jurisdiction, however, such an

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[96] Lee (n.72), 276–77.

[97] Lee, *EU Regulation of GMOs* (Edward Elgar 2009) 98–104; Kritikos, 'Traditional Risk Analysis and Releases of GMOs into the European Union: Space for Non-Scientific Factors?' (2009) 34 ELR 405, 424–25; *Tummino* (n.60), 170–71.

[98] Greenpeace (n.34).

[99] Jasanoff (n.71), 94–118.

[100] Belluck, 'Judge Strikes Down Age Limits on Morning-After Pill' (5 April 2013) *New York Times*, http://www.nytimes.com/2013/04/06/health/judge-orders-fda-to-make-morning-after-pill-available-over-the-counter-for-all-ages.html?_r=0.

expansion would require a broad rethinking of the basis of administrative legitimacy. The challenge for advocates of regulation beyond safety is therefore in not just to convince regulators, politicians, and the public that risk regulation should be about more than safety, but also to construct new legitimacy narratives to support a broadened role for the administration in public law. As the analysis in this thesis shows, such a task would be formidable. It would require reassessing the relationship between the administration and other organs of government; it would require new standards for evaluating the procedural and substantive legality of administrative decisions; and it would probably require a new theory for democratic control of the administration. None of those tasks is simple or uncontroversial, and none can be addressed solely within the context of risk regulation. Instead, they would require a rethinking of EU and US administrative law *generally*.[101] The scale of the challenge is of course no reason not to make the attempt, but progress cannot be made unless the full stakes of the problem are acknowledged.

At bottom, the debate between advocates of the risk-as-safety and the technology choice frames is the fundamental conflict of administrative risk regulation in both the EU and the US. It is a conflict about legitimate administration and about legitimate government, and it must be addressed in those terms. Although questions regarding the role of scientific expertise in risk regulation continue to be (rightly) controversial, the limits of risk science are now widely understood and generally accepted. The significance of those limits, however, depends on the framing of the problem, and where one stands on that issue depends on one's views about the proper extent of regulatory power and the necessary conditions for its exercise to be legitimate. These are basic questions about the nature of a good society, and cannot be answered by focusing on the concept of risk in isolation.

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[101] Frug, 'The Ideology of Bureaucracy in American Law' (1984) 97 HLR 1276, 1382–88.

II. Conclusion

Throughout this chapter, and this thesis generally, I have focused on the many important differences in how EU and US administrative law respond to the problems of risk regulation. In this conclusion, however, I want to focus on the perhaps more important ways in which they are similar. To begin, both systems share a fundamental commitment to liberal democracy: that the exercise of government power requires democratic sanction and must be subject to the rule of law. Reconciling that commitment with the exercise of bureaucratic power is the fundamental challenge for both EU and US administrative law, regardless of the regulatory subject matter. Although the specific solutions developed differ in many respects, their basic approaches are similar. In both the EU and the US, the administration is seen as possessing a degree of democratic legitimacy, such that it is a constitutionally legitimate policymaker, but as being insufficiently democratic for its judgments to be valid on the basis of democracy alone. As a consequence, both jurisdictions have erected elaborate legal frameworks for the control of the administration. These frameworks rely on a complex of mutually reinforcing legitimacy vectors, including both scientific expertise and legal processes. It is the interplay of the various legitimacy vectors, rather than any one in isolation, that is essential for the reconciliation of administrative risk regulation with constitutional commitments to liberal democratic government.

This thesis has also shown that there is a large degree of similarity in the ways in which the two jurisdictions approach risk regulation as a legal matter. Most importantly, both EU and US law tend to frame risk in terms of safety, meaning that both systems regard the primary goal of risk regulation as the protection of human health and the environment from physical harms posed by technology. In both systems, that framing mandates a place for science in setting risk standards, as science is the primary discourse for assessing the propensity of technologies to cause harm. Both jurisdictions thus have a strong commitment to science as *a* basis for risk regulation. At the same time, however, both jurisdictions

recognise that risk regulation standards are ultimately political decisions and must be justified and legitimated as such.

At a high level, therefore, it is possible to see European and American approaches to risk regulation as similar. At a minimum, it is hard to escape the conclusion that the two systems are basically compatible in that they share similar constitutional values. That is not to minimise the many important differences in the two legitimacy narratives, but only to argue that we should not let attention to those differences crowd out recognition of the similarities. As a corollary, it is important to recognise that differences in policy preferences, even when deeply held, need not reflect differences in basic values. Questions of risk regulation are plenty complex and capacious that people of good faith, proceeding from similar premises, can sometimes reach very different conclusions.

It also is important to bear these fundamental similarities in mind when we undertake a comparative analysis of EU and US risk regulation. One of the motivations for this thesis was my observation that Europeans and Americans mostly misunderstand each other's systems of risk regulation, and that this was so despite a reasonably extensive comparative literature on the subject.[102] The cause of the misunderstanding, I believe, is an overemphasis on specific regulatory controversies, particularly in the context of trade disputes.[103] Indeed, I think it no great overstatement to say that the WTO Beef Hormones litigation has been responsible for spawning a generation-long cloud of misunderstanding on both sides of the Atlantic.[104] When the issue for

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[102] There are, of course, exceptions, including Elizabeth Fisher, e.g., (n.90), and Jonathan Wiener, e.g., 'Whose Precaution after All?: A Comment on the Comparison and Evolution of Risk Regulatory Systems' (2003) 13 Duke.J.Comp.Intl.L. 207. Sheila Jasanoff has also done important comparative work, although her research is not focused on doctrinal legal analysis. E.g., Jasanoff, *Risk Management and Political Culture* (Russell Sage 1986).

[103] Young, 'Confounding Conventional Wisdom: Political Not Principled Differences in the Transatlantic Regulatory Relationship' (2009) 11 BJPIR 666.

[104] By which I mean, it has become something of a political cypher. There has also been much thoughtful writing on the case. E.g., Fisher (n.90),

comparison is a specific regulatory outcome, it is natural for the analysis to focus on questions of good regulatory policy and to evaluate legal rules by reference to whether they promote that policy preference. There is of course nothing wrong with asking whether legal rules further good regulatory outcomes. The danger, however, is in committing the fallacy of concluding that a bad policy outcome must be the result of a bad legal rule. And the risk of confusion is all the greater when there is no prior agreement on what constitutes a good policy outcome.

My aim in this thesis has been to undertake a comparative analysis focused on legal principles rather than regulatory outcomes. By doing so, I have presented a quite different, and more complicated, comparative picture from that presented in outcome-focused analyses. On one hand, my analysis has shown that the differences in EU and US administrative law on risk regulation run much deeper than a predilection for precaution or economic efficiency, and extend to basic differences in how the exercise of bureaucratic power can be made constitutionally legitimate. On the other, it has shown that both systems share important similarities in that they both proceed from similar conceptions of liberal democracy and both frame risk in similar ways. This type of analysis does not readily lead to neat conclusions and often raises as many questions as it answers. What it achieves, however, is a better understanding of the contexts in which regulatory programmes develop and of the often unspoken assumptions and commitments that structure and animate those programmes. My hope is that better understanding can lead to better and more productive dialogue between these two regulatory systems and the people who study them.

185–200; Joerges, 'Law, Science and the Management of Risks to Health at the National, European and International Level—Stories on Baby Dummies, Mad Cows and Hormones in Beef' (2001) 7 Colum.J.Eur.L. 1, 9–14; Scott, 'On Kith and Kine (and Crustaceans): Trade and Environment in the EU and WTO' in Weiler (ed.), *The EU, the WTO, and the NAFTA: Toward a Common Law of Intenational Trade?* (OUP 2000), 144–62.

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