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Food Safety Crises as Crises in Administrative Constitutionalism

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FOOD SAFETY CRISES AS CRISES IN ADMINISTRATIVE CONSTITUTIONALISM

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The history of food safety regulation has been a history of food safety crises and regulatory responses to those crises.[1] As that is the case, most literature concerned with what can be learned from a food safety crises focuses on the strengths and weaknesses of regulatory regimes.[2] This is because central to any crisis is the role of regulation in identifying, assessing, and managing risks.[3]

Historically, regulators have primarily prevented the deliberate and grossly negligent contamination of food.[4] Increasingly, in the last forty years, food safety crises have involved more uncertain and complex health risks, risks that are socio-politically contentious and require considerable scientific resources for their assessment.[5] In such circumstances, the creation and operation of food safety regulation has largely been conceptualised as requiring a choice between whether the scientific and democratic inputs into decision-making should domi-

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[1] *See generally* MICHAEL FRENCH & JIM PHILLIPS, CHEATED NOT POISONED?: FOOD REGULATION IN THE UNITED KINGDOM, 1875-1938 (2000); *see also Government White Paper on the Food Standards Agency, The Food Standards Agency: A Force for Change*, Cm. 3830 (Jan. 14, 1998); CHRISTOPHER ANSELL & DAVID VOGEL, WHAT'S THE BEEF?: THE CONTESTED GOVERNANCE OF EUROPEAN FOOD SAFETY (2006).

[2] *See generally* INGEBORG PAULUS, THE SEARCH FOR PURE FOOD: A SOCIOLOGY OF LEGISLATION IN BRITAIN (1974); JOHN HARVEY YOUNG, PURE FOOD: SECURING THE FEDERAL FOOD AND DRUGS ACT OF 1906 (1989).

[3] *See* MARIA LEE, EU REGULATIONS OF GMOS: LAW AND DECISION MAKING FOR A NEW TECHNOLOGY (Han Somsen ed., 2008); PATRICK VAN ZWANENBERG & ERIK MILLSTONE, BSE: RISK, SCIENCE AND GOVERNANCE (2005).

[4] CLAYTON A. COPPIN & JACK HIGH, THE POLITICS OF PURITY: HARVEY WASHINGTON WILEY AND THE ORIGINS OF FEDERAL FOOD POLICY (1999); *see* FRENCH & PHILLIPS, *supra* note 1, at 191-92.

[5] Peter Barton Hutt, *Recent Developments: The State of Science at the Food and Drug Administration*, 60 ADMIN. L. REV. 431 (2008).

nate.[6] Any particular crisis is understood as an example, for that commentator at least, of the wrong input dominating.

In this article, I argue not only that this is an incorrect characterisation of food safety crises and food safety regulation, but also that this characterisation creates a massive "blindspot"[7] which results in decision-makers and scholars failing to learn as much as they can, and should, from any particular controversy. In particular, the characterisation of food safety decision-making in such binary terms results in a failure to see that food safety decision-making is *administrative* in nature. Moreover, food safety crises are essentially controversies over what constitutes legitimate administrative decision-making. Crises are controversies over how to constitute, limit, and hold public administration to account so as to ensure that any regulatory decision is reasonable. In essence, these are debates over "administrative constitutionalism" in that they are normative debates over the different roles that law can, and should, play in constituting and limiting public administration.[8] By understanding a food safety crisis in these terms there is far more that scholars and law makers can learn about the nature of the crisis and the possible responses to it.

This article illustrates the value of viewing food safety controversies through the lens of administrative constitutionalism with two case studies. The first examines the litigation concerning whether the United States Food and Drug Administration (FDA) had the power under the Food and Drug and Cosmetic Act (FDCA) to regulate tobacco.[9] The second case study examines why the United Kingdom (UK) government relied on a short and guarded report of an ad hoc committee, the Southwood Working Party, in asserting that bovine spongiform encephalopathy (BSE) posed no risks to human health.[10] That decision, and all other aspects of what has become

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[6] *See* Les Levidow, *Precautionary Uncertainty: Regulating GM Crops in Europe*, 31 SOC. STUD. SCI. 842 (2001); FOOD SAFETY REGULATION IN EUROPE: A COMPARATIVE INSTITUTIONAL ANALYSIS (Ellen Vos & Frank Wendler eds., 2006).

[7] For a discussion about blindspots, see Elizabeth Fisher & Patrick Schmidt, *Seeing the Blindspots in Administrative Law: Theory, Practice, and Rulemaking Settlements in the United States*, 30 COMMON L. WORLD REV. 272 (2001); Jim Rossi, *Bargaining in the Shadow of Administrative Procedure: The Public Interest in Rulemaking Settlement*, 51 DUKE L.J. 1015 (2001).

[8] ELIZABETH FISHER, RISK REGULATION AND ADMINISTRATIVE CONSTITUTIONALISM 22-26 (2007).

[9] *See* Coyne Beahm, Inc. v. FDA, 966 F. Supp. 1374 (M.D.N.C 1997); Brown & Williamson Tobacco Corp., v. FDA, 153 F.3d 155 (4th Cir. 1998).

[10] DEP'T OF HEALTH, MINISTRY OF AGRIC., FISHERIES & FOOD, REPORT OF THE WORKING PARTY ON BOVINE SPONGIFORM ENCEPHALOPATHY 21 (1989) [hereinafter WORKING PARTY REPORT ON BOVINE SPONGIFORM ENCEPHALOPATHY].

known as the 'BSE crisis' was the subject of a three year independent inquiry set up by the incoming Labour government in 1997.[11] The Inquiry is known as the BSE Inquiry and was chaired by a member of the judiciary, Lord Justice Phillips. This article draws on the oral and written evidence submitted at that Inquiry.

These controversies are very different, as are the legal cultures in which they operate, but both highlight the importance of administrative constitutionalism for framing and directing food safety crises. Moreover, these case studies highlight how administrative constitutionalism opens up a series of important lines of inquiry for scholars and policy-makers thinking about food safety crises.

This article is divided into three parts. In Part One, I first examine how scholars and decision-makers have understood food safety crises in terms of requiring a choice between whether science or politics should dominate food safety decision-making and the limits of this way of characterising these controversies. I then examine the concept of administrative constitutionalism and introduce the two paradigms of administrative constitutionalism which have dominated food safety regulation – the rational instrumental paradigm and the deliberative-constitutive paradigm. In Part Two, I present the two case studies described above. Both examine very different aspects of food and drug safety issues, but both highlight the power of administrative constitutionalism as an explanatory lens. In Part Three, I conclude by considering the implications for scholars and decision-makers of thinking about food safety issues in terms of administrative constitutionalism.

Two points should be made before starting. First, it should be noted that the arguments about administrative constitutionalism presented in this article are made at greater length in a recent book which also considers an analysis of administrative constitutionalism in U.S. environmental and occupational health and safety law.[12] Second, the human health risks from food that this article focuses on are primarily technological risks. That is, they are risks that arise, often inadvertently, from human activity. Technological risks are notable for being scientifically uncertain, complex, and often the focus of socio-political

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[11] The BSE Inquiry, *The Inquiry into BSE and Variant CJD in the United Kingdom* (2000), *available at* http://www.webarchive.org.uk/wayback/archive/20060308232515/http://www.bseinquiry.gov.uk/index.html (last visited Mar. 18, 2010).

[12] *See generally* FISHER, *supra* note 8.

debate.[13] The food and drug safety risks discussed in this article are no exception.[14]

I. MAKING SENSE OF A FOOD SAFETY CRISIS

The theme of crisis and controversy pervades food safety regulation.[15] My concern in this article is not the question of whether a crisis exists or whether controversy is valid – in nearly all cases where the language of crisis and controversy is used, a regulatory regime is understood to have failed and thus in need of reform.[16] Rather, my concern, and this article's focus, is why a regime is understood to have failed and what form the reform should take. My argument is that the predominant way in which food safety crises have been conceptualised has created a "blindspot" which severely limits the capacity of scholars, decision-makers, and policy-makers to learn from a food safety crisis.

A. How *Not* to Think About a Food Safety Crisis: The Science/Democracy Binary Choice

The predominant orthodoxy in scholarship and policy is to understand the development of frameworks for food safety and other forms of risk regulation decision-making and food safety decision-making as requiring a choice between grounding decisions on primarily a democratic *or* a scientific basis.[17] Thus food safety decisions are understood as requiring a binary choice between allowing one of these

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[13] *Id.* at 7-11.

[14] ROBERT RABIN & STEPHEN SUGARMAN (EDS), REGULATING TOBACCO (2001); Sheila Jasanoff, *Civilization and Madness: The Great BSE Scare of 1996, in* PUBLIC UNDERSTANDING OF SCIENCE 221 (1997).

[15] This is most obvious in the UK and EU context. *See* Roman Gerodimos, *The UK BSE Crisis as a Failure of Government*, 84 PUB. ADMIN. 911 (2004); THE MAD COW CRISIS: HEALTH AND THE PUBLIC GOOD (Scott C. Ratzan ed., 1998); Giandomenico Majone, *The Credibility Crisis of Community Regulation*, 38 J. COMMON MKT. STUD. 273, 274, 281-83 (2000); RICHARD LACEY, UNFIT FOR HUMAN CONSUMPTION: FOOD IN CRISIS – CONSEQUENCES OF PUTTING PROFIT BEFORE SAFETY (1992).

[16] *See* ANSELL & VOGEL, *supra* note 1.

[17] *See* LEE, *supra* note 3, at 72-89; Mikhail Kritikos, *Traditional Risk Analysis and Releases of GMOs into the European Union: Space for Non-Scientific Factors?* 34 EUR. L. REV. 405 (2009); James T. O'Reilly, *Losing Deference in the FDA's Second Century: Judicial Review, Politics, and a Diminished Legacy of Expertise*, 93 CORNELL L. REV. 939 (2008); ORTWIN RENN, RISK GOVERNANCE: COPING WITH UNCERTAINTY IN A COMPLEX WORLD (2008); Erik Millstone, *Can Food Safety Policy-Making Be Both Scientifically and Democratically Legitimated? If So, How?*, 20 J. AGRIC. ENVTL. ETHICS 483, 497 (2007).

inputs to dominate. There are many different versions of this choice. And it can be characterised as a choice between: participatory discourse and expert opinion; interest group politics and scientific objectivity; irrational fear and scientific analysis. In each of these circumstances, the non-dominating factor still has a role to play but it is only marginal.[18]

Furthermore, food safety crises are primarily understood by commentators as resulting from decision-makers and legislators getting the choice wrong. Thus poor decisions are understood as a product of favouring the wrong type of input into decision-making.[19] However, different commentators have different views over whether scientific or democratic inputs should dominate.[20]

Besides the vagueness and malleability inherent in the concepts of science and democracy, three main problems plague this understanding of food safety crises. The first problem is that this characterisation of food safety controversies suggests that disputes over food safety are fundamentally conflicts between facts on one side and values on the other. But opponents in food safety crises usually simultaneously disagree about the relevant science and the relevant values.[21] The second problem with this characterisation is that science and democracy are treated as different realms of public life, but there is little discussion of the institutional contexts in which they operate and of how those contexts might shape understandings of scientific or democratic inputs. In particular, the focus on science and democracy overlooks the fact that food safety decision-making is primarily the province of the unelected *administrative* decision-makers and thus can never be truly scientific or truly democratic.[22] Food safety decision-making cannot be democratic due to the fact that food decision-makers are not elected and cannot be subject to direct rule. Likewise, they cannot be truly scientific because their decisions are not only

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[18] FISHER, *supra* note 8, at 11-14.

[19] *See* LEE, *supra* note 3, at 72-89; Jacqueline Peel, *Risk Regulation Under the WTO SPS Agreement: Science as an International Normative Yardstick?* 7 (Jean Monnet Program, Working Paper No. 02/04, 2004), *available at* http://www.jeanmonnetprogram.org/papers/04/040201.pdf; Hutt, *supra* note 5.

[20] ERIK MILLSTONE ET AL., SCIENCE IN TRADE DISPUTE RELATED TO POTENTIAL RISKS: COMPARATIVE CASE STUDIES (2004), *available at* http://epub.oeaw.ac.at/0xc1aa500d_0x0010b251.pdf.

[21] *See generally* Flue-Cured Tobacco Co-op v. EPA, 4 F. Supp. 2d 435 (M.D.N.C. 1998); Panel Report, *E C Measures Concerning Meat and Meat Products (Hormones)*, WT/DS26/R/USA (Aug. 18, 1997); Director of Animal and Plant Quarantine v. Australian Pork Ltd. (2005) 206 F.C.R 1; *see also* Case T-13/99, Pfizer Animal Health SA v. Council of the European Union, 2002 E.C.R. II-3305.

[22] *See* FISHER, *supra* note 8, at 16-18.

based on science but also policy, law, and other factors. Moreover, the administrative context directs, frames, and limits action. The third problem is that the present depiction of food safety crises and controversies tends to sideline the role of legal discourse. Law is understood to be an instrument to promote either a more scientific or democratic approach.[23] However, food safety is a fiendishly complex area of law, and food safety crises often have a significant legal dimension and frequently results in legal reform.[24]

The sketch above may seem to some as too unsophisticated and unfair a depiction of present commentary about food safety. Yet my point is that the invidious nature of this dichotomy has blinded commentators to the realities of food safety decision making. Controversies are oversimplified and understood to be solely a product of crude politics where either more science or more participation is proposed as the perfect answer. The administrative nature of food safety decision-making is overlooked, as is the importance of law to food safety regulation.

B. How to Think About a Food Safety Crisis: Administrative Constitutionalism

Saying all this is not to say that there is not a role for politics, participation, values, science, and information in food safety decision-making. All these elements are incorporated into food safety decision-making, although, as we shall see, they can be defined and incorporated in fundamentally different ways. My argument is that far more analysis must be done on the *context* in which that decision-making occurs, and that context is *administrative*. By focusing on this context, a more subtle and nuanced picture can be gained of what disputes in food safety are really about.

The significance of the administrative context is that, in a liberal democracy, public administration suffers from a legitimacy deficit because of unelected and unelectable nature of public administra-

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[23] For a discussion of the instrumental understanding of law in the legislative context see John Applegate, *A Beginning Not an End In Itself: The Role of Risk Assessment in Environmental Decision Making*, 63 U. CIN. L. REV. 1643 (1995). For a more general discussion, see Jeremy Fraiberg & Michael Trebilock, *Risk Regulation: Technocratic or Democratic Tools for Regulatory Reform*, 43 MCGILL L.J. 835 (1998).

[24] *See generally* Ralph F. Fuchs, *The Formulation and Review of Regulations Under the Food, Drug, and Cosmetic Act*, 6 LAW & CONTEMP. PROBS. 43 (1939); R. HAMILTON, *Rulemaking on a Record by the Food and Drug Administration*, 50 TEX. L. REV. 1132 (1972); PETER B. HUTT & RICHARD A. MERRILL, FOOD AND DRUG LAW: CASES AND MATERIALS (2nd ed. 1991).

tion.[25] That legitimacy deficit is particularly acute in the public administration of food safety because the uncertain and highly technical nature of food safety issues makes decision-making particularly opaque.[26] In these circumstances, divergent groups of legal and policy actors have fundamentally divergent understandings about what is, and what should be, the role and nature of public administration. This conflict is best described as a conflict over "administrative constitutionalism" in that disagreement arises over what form public administration should take so as to ensure principled and constitutional government. Those disagreements have both descriptive and normative aspects in that they are disagreements over how to conceptualise what public administration actually *is* doing, and what it *should* do.

There are three particularly important features of administrative constitutionalism to appreciate. First, administrative constitutionalism is an "essentially contested" [27] concept and there will nearly always be debate over the nature and role of public administration just as there is always debate over concepts such as the rule of law and democracy.[28] Second, and most significantly for lawyers, administrative constitutionalism is part of legal culture because debate and discourse invariably concerns the role of law in constituting, limiting and holding public administration accountable.[29] Third, debates over administrative constitutionalism are most likely to take place as part of the process of holding a decision maker to account.[30] Those processes include legal processes such as judicial review and more political processes such as official inquiries. Most significantly, a focus on administrative constitutionalism highlights that the process of holding a decision maker to account is the process of challenging what is legitimate public administration. Thus a litigant seeking judicial review is

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[25] BRIAN COOK, BUREAUCRACY AND SELF GOVERNMENT: RECONSIDERING THE ROLE OF PUBLIC ADMINISTRATION IN AMERICAN GOVERNMENT 3 (1996); *see* FISHER, *supra* note 8, at 16-18.

[26] *Cf.* HENRY S. RICHARDSON, DEMOCRATIC AUTONOMY: PUBLIC REASONING ABOUT THE ENDS OF POLICY 3 (2002).

[27] W.B. Gallie, *Essentially Contested Concepts*, 56 PROC. ARISTOTELIAN SOC'Y 167, 168 (1956).

[28] *See* FISHER, *supra* note 8, at 22-26.

[29] For a lengthy discussion of the concept of legal culture, see id. at 35-39. For a discussion on studies that map the difference between legal cultures, see generally David Nelken, *Disclosing/Invoking Legal Culture: An Introduction*, 4 SOC. & LEGAL STUD. 435 (1995) (highlighting several different ways of conceptualizing legal culture and discussing the inherent conceptual difficulties involved).

[30] *See* FISHER, *supra* note 8, at 24-25.

often arguing that a decision maker misunderstood their role and the proper basis for decision-making.[31]

Despite significant variations between legal cultures there are also enduring normative understandings about the role of public administration. Broadly speaking, in the context of food safety decision-making, two different paradigms of administrative constitutionalism have dominated thinking – the rational-instrumental (RI) and the deliberative constitutive (DC).[32] According to the RI paradigm of administrative constitutionalism, public administration is a Weberian bureaucracy,[33] a "transmission belt"[34] that applies facts to specific legislative commands. Facts include information rigorously policed by scientific and social scientific methodologies and preferences voiced through a fair pluralist participatory process.[35] Reasonable RI administrative action carries out this process of application in the most efficient and effective manner possible.[36] RI administration is understood as legitimate because the food safety problems that RI administration deals with are understood to be inherently manageable by analytical techniques and rigorous participatory processes.[37]

In contrast, DC public administration is understood as a substantive institution engaging in ongoing problem solving through the exercise of flexible discretion based on deliberation and analysis.[38] Analysis is understood to be a flexible tool that must be adapted to different problems.[39] Deliberation is understood to be a transformative process that is more than just a trade off between different value

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[31] For a study of this phenomena in U.S. administrative law, see id. at 89-124.

[32] For a far more detailed account of these two paradigms, see id. at 26-35. These paradigms are also reflected in earlier administrative law works. MARTIN SHAPIRO, WHO GUARDS THE GUARDIANS? JUDICIAL CONTROL OF ADMINISTRATION (1988); COOK, *supra* note 25, at 5-6; THOMAS O. MCGARITY, REINVENTING RATIONALITY: THE ROLE OF REGULATORY ANALYSIS IN THE FEDERAL BUREAUCRACY 5-16 (1991); CAROL HARLOW & RICHARD RAWLINGS, LAW AND ADMINISTRATION (3rd ed. 2009).

[33] FROM MAX WEBER: ESSAYS IN SOCIOLOGY (H.H. Gerth & C. Wright Mills eds. and trans., Routledge 1991) (1948).

[34] Richard Stewart, *The Reformation of American Administrative Law*, 88 HARV. L. REV. 1667, 1684 (1975).

[35] *See* FISHER, *supra* note 8, at 28-30.

[36] *Id.* at 29.

[37] *See* CASS R. SUNSTEIN, RISK AND REASON: SAFETY, LAW, AND THE ENVIRONMENT (2002).

[38] *See* FISHER, *supra* note 8, at 30-32; *see also* Mark Seidenfeld, *A Civic Republican Justification for the Bureaucratic State*, 105 HARV. L. REV. 1511 (1992).

[39] *See* FISHER, *supra* note 8, at 30-31.

preferences.[40] The legitimacy of DC administration is derived from its substantive role in addressing complex problems in the democratic public interest.

These two different paradigms are represented in the table below:

Table One: The Rational Instrumental and Deliberative-Constitutive Paradigms of Administrative Constitutionalism

	Rational-Instrumental	Deliberative-Constitutive
	Food Safety Problems	
Nature of Problems	Objective and quantifiable Scientific uncertainty as manageable	Complex socio-political disputes involving values and epistemological problems
Nature of Regulatory Decision-Making	Value laden aspects limited to those identified in legislation. Scientific analysis constrained by methodological frameworks. Participation through interest representation.	Values inherent in all aspects of decisionmaking and scientific analysis adapted to the problem at hand. Participation through deliberation.
	Public Administration and Law	
Relationship with Primary Law Maker	Principal/Agent	Constitutive ongoing authority granted by primary lawmaker
Limits on Discretion	Legislation Analytical methodology Interest representation	Constitutive structure Deliberative process
Accountability	Policing the methodology of decision-making and ensuring that decision makers have kept within legislative limits.	Requires those reviewing the decisions to engage in a substantive review of decision-making.

As can be seen from the table, each paradigm of administrative constitutionalism prescribes a very different role not only for public administration but also for the law in constituting, limiting, and holding public administration to account. Moreover, each paradigm also conceptualises the nature of food safety problems differently.[41] For

[40] *See generally* Cass R. Sunstein, *Factions, Self-Interest, and the APA: Four Lessons Since 1946*, 72 VA. L. REV. 271 (1986); Robert B. Reich, *Public Administration and Public Deliberation: An Interpretative Essay*, 94 YALE L.J. 1617 (1985).

[41] *See generally* David Winickoff et al., *Adjudicating the GM Food Wars: Science, Risk and Democracy in World Trade Law*, 30 YALE J. INT'L L. 81, 94 (2005); Brian Wynne, *Seasick on the Third Wave? Subverting the Hegemony of Propositionalism: Response to Collins & Evans (2002)*, 33 SOC. STUD. SCI. 401 (2003); SHELIA JASANOFF, DESIGNS ON NATURE: SCIENCE AND DEMOCRACY IN EUROPE AND THE

the RI paradigm to be logical, food safety issues are understood to be manageable. In contrast, under the DC paradigm, the wide-ranging discretion of public administrators is justified on the basis of the complexity and uncertainty that pervades food safety issues.[42] Likewise, both the RI and DC paradigms mobilise science and participation but define and utilise them in different ways. Science under the RI paradigm is largely defined in terms of methodologies which can be strictly applied.[43] In contrast, science under the DC paradigm has a broader definition which also encapsulates scientific judgment and expertise.[44] Likewise, participation under the RI paradigm is a bargaining process whereby public administrators play an "umpire role."[45] In contrast, under the DC paradigm, participation is deliberative in nature and requires public administration to take a more significant leadership role.[46]

Neither paradigm offers up a perfect model of public administration in the food safety context. The RI paradigm addresses the problem of the legitimacy of public administration by ensuring that it is limited and controlled and has no authority except that derived from the legislature. In that sense, it is the classic model for lawyers. Likewise, it offers a means of assessing the success of a risk regulation regime by seeing whether certain legislative commands were followed through,[47] particularly if food safety issues are understood in quantitative terms. Yet at the same time, the RI model does not adequately address the complex nature of technological risk.[48] The focus in the RI paradigm on control of public administration means that the actual addressing of the problems administration was set up to address is overlooked. Indeed, RI public administration is often seen as the

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UNITED STATES 23-26 (2005).

[42] *See generally* NAT'L RESEARCH COUNCIL, UNDERSTANDING RISK: INFORMING DECISIONS IN A DEMOCRATIC SOCIETY (1996).

[43] The strict application of methodologies is discussed in CASS R. SUNSTEIN, LAWS OF FEAR: BEYOND THE PRECAUTIONARY PRINCIPLE 129-48 (2005); Elizabeth Fisher, *Risk and Environmental Law: A Beginner's Guide*, *in* ENVIRONMENTAL LAW FOR SUSTAINABILITY 97, 101-08 (Benjamin J. Richardson & Stepan Wood eds., 2006).

[44] *See* STEPHEN BREYER, BREAKING THE VICIOUS CIRCLE: TOWARD EFFECTIVE RISK REGULATION (1993).

[45] *See* Stewart, *supra* note 34, at 1711, 1722, 1760, 1790.

[46] *See generally* Michael Dorf & Charles Sabel, *A Constitution of Democratic Experimentalism*, 98 COLUM. L. REV. (1998); NAT'L RESEARCH COUNCIL, *supra* note 42.

[47] CASS R. SUNSTEIN, THE COST-BENEFIT STATE: THE FUTURE OF REGULATORY PROTECTION 27-31 (2002).

[48] *See* Thomas O. McGarity, *A Cost-Benefit State*, 50 ADMIN. L. REV. 7, 13-15 (1998).

cause of many technological risk controversies for exactly this reason.[49]

In contrast, the DC paradigm starts with the messiness of technological risk problems and acknowledges that those problems require a flexible institutional response. As such, public administration is recognised as a permanent feature of the democratic landscape and is given wide discretion. While such an institutional structure may provide an appropriate framework for decision-making, it also threatens to usurp the legislature. Thus, for lawyers, it is a more difficult model to conceptualise and accept, even though, as shall be shown, numerous regimes have been built on the DC paradigm. Public administration has its own internal authority, but it is difficult to provide a justification for it other than necessity. Likewise, the process of holding a decision maker to account is not an easy one. If a decision is said to be the product of complex deliberation and the judgment of the public administration, then it is difficult to know when a decision maker got it right and when a decision maker got it wrong.

II. ADMINISTRATIVE CONSTITUTIONALISM IN ACTION: TWO EXAMPLES

The discussion so far has been frustratingly abstract. In this second part, I illustrate the power of the lens of administrative constitutionalism by considering two recent controversies in terms of the RI and DC paradigms. The first example involves a series of cases dealing with the issue of whether the U.S. Food and Drug Administration (FDA) had the power to regulate tobacco under the Food Drug and Cosmetic Act.[50] The second example concerns why the UK government relied heavily on a single report of an ad hoc Working Party in asserting there was no human health risk from BSE.[51]

At first blush, the selection of these two case studies to sit side by side may appear very odd. Yet, as Gerhard Danneman has noted, "there is no point in comparing what is identical, and little point in comparing what has nothing in common."[52] These two examples are

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[49] ULRICH BECK, RISK SOCIETY: TOWARDS A NEW MODERNITY (Mark Ritter trans., 1992); *see also* Brian Wynne, *Uncertainty and Environmental Learning: Reconceiving Science and Policy in the Preventive Paradigm*, 2 GLOBAL ENVTL. CHANGE 111 (1992).

[50] *See* Coyne Beahm, Inc. v. U.S. Food FDA, 966 F. Supp. 1374 (M.D.N.C 1997); Brown & Williamson Tobacco Corp., v. FDA, 153 F.3d 155 (4th Cir. 1998).

[51] For a lengthier analysis, see FISHER, *supra* note 8, at 59-88.

[52] Gerhard Dannemann, *Comparative Law: Study of Similarities or Differences?*, *in* THE OXFORD HANDBOOK OF COMPARATIVE LAW 384 (Mathias Reimann & Reinhard Zimmermann eds., 2006).

clearly not identical. The first involves an isolated doctrinal point about statutory interpretation, and the second concerns the institutional role of expert advice in UK public administration. Moreover, both case studies reflect the very different legal cultures operating in the United States and United Kingdom, which have resulted in two very different discourses about administrative constitutionalism.[53] In the United States, administrative constitutionalism has been a discourse carried out primarily in judicial and legislative terms. This is particularly true in the judicial arena because of the way in which "adversarial legalism" is an inherent feature of U.S. legal culture.[54] In the United Kingdom, administrative constitutionalism is a blurring of law, policy, political theory, ideology, and convention.[55] Moreover, it is a product of a "language of normative discussion, the set of historical reference points, the range of solutions proposed in the past, the institutional norms taken for granted, given a particular context of repeated social interaction."[56] Indeed, UK administrative law is profoundly pluralistic in its legal forms.[57]

Nevertheless, these examples do have something in common in that they are both examples of highly politicised controversies that have been largely understood in terms of requiring decisions to be either based on science or democracy. In particular, both controversies have largely been understood as examples of crude interest group politics – an explanation which provides very little in the way of constructive reform beyond injecting more "objectivity" or greater "genuine participation" in the process. By viewing these two disputes through the lens of administrative constitutionalism, a very different set of issues are highlighted – a set of issues intimately tied to questions about the legitimacy of public administration and the role of law.

A. Defining Tobacco in the FDA

The litigation concerning whether the FDA could regulate tobacco under the FDCA did not deal directly with a food safety crisis. Rather, it concerned one of the most significant controversies in which the FDA was involved (in recent decades).[58] This controversy is

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[53] For a more in-depth discussion of this point, see FISHER, *supra* note 8.

[54] *See* ROBERT A. KAGAN, ADVERSARIAL LEGALISM: THE AMERICAN WAY OF LAW (2001).

[55] HARLOW & RAWLINGS, *supra* note 32.

[56] Jeremy Webber, *Culture, Legal Culture, and Legal Reasoning: A Comment on Nelken*, 29 AUSTL. J. LEGAL PHILOSOPHY 27, 32 (2004).

[57] *See* H. W. Arthurs, *Rethinking Administrative Law: A Slightly Dicey Business*, 17 OSGOODE HALL L.J. 1 (1979); HARLOW & RAWLINGS, *supra* note 32.

[58] *See* DAVID KESSLER, A QUESTION OF INTENT: A GREAT AMERICAN BATTLE

usually understood as the product of politics[59] – an explanation which completely sidelines the fact that the case was really about the nature of the FDA. In particular, it overlooks the fact that while there was little disagreement over the relevant legal precedents or principles of statutory interpretation in the case,[60] the way in which those legal principles were understood to limit the FDA were conceptualised very differently. Indeed, as the majority in the Court of Appeals for the Fourth Circuit noted, "at its core, this case is about who has the power to make this type of major policy decision."[61] In particular, it was about whether the FDA should be understood in RI or DC terms.

In 1996, the FDA passed a regulation that restricted the sale and distribution of cigarettes and smokeless tobacco to children and adolescents.[62] Tobacco was not mentioned in the FDCA, so whether the FDA had the legislative authority largely depended on whether, as a matter of statutory interpretation, tobacco products fell within one of the classes of products that the FDA possessed the authority to regulate. The FDCA states that the FDA can regulate "combination products," which are defined as products that "constitute a combination of a drug, device, or biologic product."[63] A "drug" is defined under that Act as "articles (other than food) intended to affect the structure or the function of the body."[64] The FDA's authority thus rested not on the existence of a serious health hazard but rather on the "objective intent" of the manufacturers.[65] In light of new evidence about the addictive effects of nicotine and of tobacco manufacturers' manipulation of tar and nicotine levels in cigarettes, the FDA felt that it could establish

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WITH A DEADLY INDUSTRY 51, 83, 266-67 (2001); M. Gillhooley, *Tobacco Unregulated: Why the FDA Failed and What To Do Now*, 111 YALE L. J. 1179 (2002).

[59] Jonathan Turley, *A Crisis of Faith: Tobacco and the Madisonian Democracy*, 37 HARV. J. LEGIS. 433 (2000); ALLAN BRANDT, THE CIGARETTE CENTURY 242 (2007).

[60] The relevant legal authority setting forth the principles for judicial review of an agency's construction of the statute which it administers is *Chevron, U.S.A. Inc., v. Nat'l Res. Def. Council, Inc.*, 467 U.S. 837, 842-43 (1984).

[61] Brown & Williamson Tobacco Corp., v. FDA, 153 F.3d 155, 176 (4th Cir. 1998).

[62] Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 61 Fed. Reg. 44,396 (Aug. 28, 1996). The regulation later was repealed in 2000, following the Supreme Court decision in *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000), which held that Congress had not given FDA the authority to regulate tobacco products as customarily marketed.

[63] 21 U.S.C.A. § 353(g)(1) (West 2006).

[64] 21 U.S.C.A. § 321(g)(1)(C) (West 2006).

[65] See FDA Commissioner's arguments in *Action on Smoking & Health v. Harris*, 655 F.2d 236, 238-39 (D.C. Cir. 1980).

that nicotine "affected the structure and function of the body" and that manufacturers intended for that to occur.[66] The FDCA required the FDA to provide "reasonable assurance of the safety and effectiveness of the device"[67] once regulated, and while this would suggest the need to ban cigarettes, the FDA felt that this was not acceptable as it would lead to a black market.[68] In light of the fact that eighty percent of people started smoking at, or before, the age of sixteen,[69] a regulation banning sale of tobacco cigarettes to minors would provide a far more "reasonable assurance." Thus from a purely textual perspective, it could be argued that the FDA could be found to have authority over tobacco products.[70]

Yet the series of judgments in these cases were not concerned with the purely literal perspective. The courts in reviewing these cases were bound by administrative law doctrine, and in particular, the two-step test for statutory interpretation set out in *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*[71] Under the first step, if the "intent of Congress" was clear, both the court and an administrative body should abide by that intent. If the intent was ambiguous, then the agency's interpretation should stand unless it was unreasonable.[72] Yet while the *Chevron* test has become the "ubiquitous formula governing court-agency relations"[73] and has been applied in thousands of cases,[74] it can be applied in a number of different ways.[75] As a result, the *Chevron* test provides very little directive guidance.

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[66] Nicotine in Cigarettes and Smokeless Tobacco is a Drug and These Products are Nicotine Delivery Devices Under the Federal Food, Drug, & Cosmetic Act: Jurisdictional Determination, 61 Fed. Reg. 44,619 (Aug. 28, 1996).

[67] *E.g.*, 21 U.S.C.A. § 360c(a)(1)(A)(i) (West 2006).

[68] As discussed in *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 139 (2000).

[69] Cass R. Sunstein, *Is Tobacco A Drug? Administrative Agencies as Common Law Courts*, 47 DUKE L.J. 1013, 1021 (1998); *see* 42 U.S.C. § 300x-26(a)(1) (2008). It is also interesting to note that the Synar Amendment (passed in 1992) makes it a precondition of Federal grants to States that those states ban the sale of tobacco products to minors and as such the rule already exists in all states.

[70] Sunstein, *supra* note 69, at 1017.

[71] 467 U.S. 837 (1984).

[72] *Id.* at 842-44.

[73] Thomas Merrill & Kristin Hickman, *Chevron's Domain*, 89 GEO. L.J. 833, 834 (2001); *see* Cynthia R. Farina, *Statutory Interpretation and the Balance of Power in the Administrative State*, 89 COLUM. L. REV. 452, 456 (1989); *see also* Mark Seidenfeld, *A Syncopated Chevron: Emphasizing Reasoned Decision Making in Reviewing Agency Interpretations of Statutes*, 73 TEX. L. REV. 83 (1994) (applying deliberative democracy to modify the *Chevron* test for interpreting statutes).

[74] *E.g.*, Peter Schuck & E. Donald Elliott, *To the* Chevron *Station: An Empirical Study of Federal Administrative Law*, 39 DUKE L.J. 984, 989 n.13 (1990).

[75] *See* Thomas W. Merrill, *Textualism and the Future of the* Chevron *Doc-*

Instead, whether a judge found that the FDA had jurisdiction largely depended on his or her understanding about the FDA's role and the nature of its relationship to Congress. Most judges in these cases started with those understandings, which subsequently dictated the outcomes. In particular, in line with step one of the *Chevron* test, the point of departure was *what* Congress was assumed to have delegated to the FDA. If that delegation was construed in RI terms as limited to a set of specific tasks, then the FDA could not act on its own initiative to regulate tobacco because that would be exercising power it did not have. If, however, it was understood that the FDA had been entrusted with DC powers to address the general problem of food and drug safety, then the FDA's assertion of authority jurisdiction over tobacco products was lawful. In other words, the issue of the FDA's power was not simply ideological but was directly concerned with the ways in which law and legal culture had constructed the FDA's power.

That exercise of construction of the FDA's power did not occur in a vacuum. The answer to the question of what is and should be the FDA's role should ideally be derived from a history of the FDA and FDCA and from broader administrative law principles. Yet, as with all risk regulation, those principles and that history did not present a definitive answer. As already seen, the *Chevron* doctrine was ambiguous, and the FDCA and the FDA had developed in a piecemeal fashion mainly in response to a variety of crises and developments in administrative law.[76] On the one hand, the original logic behind the FDCA was a very limited RI one, concerned with a specific task – the proper labelling of foods.[77] Later amendments, such as the Delaney clause,[78] were also consistent with the RI paradigm, in that they gave very little discretion to the FDA.[79] However, these amendments were interspersed with other legislative and administrative reforms that granted greater rulemaking discretion to the FDA. The most dramatic metamorphosis occurred as part of the second wave of New Deal leg-

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trine, 72 WASH. U. L.Q. 351, 366-69 (1994); *see also* Michael P. Healy, *Textualism's Limits on the Administrative State: Of Isolated Waters, Barking Dogs, and* Chevron, 31 ENVTL. L. REP. 10,928 (2001).

[76] For a history see generally YOUNG, *supra* note 2; David F. Cavers, *The Food, Drug and Cosmetic Act of 1938: Its Legislative History and Its Substantive Contents*, 6 L. & CONTEMPORARY PROBLEMS 2 (1939); *see also* CHARLES O. JACKSON, FOOD AND DRUG LEGISLATION IN THE NEW DEAL (1970).

[77] *See* United States v. Johnson, 221 U.S. 488, 496-98 (1911).

[78] The Delaney Clause stated "that no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal." 21 U.S.C. § 348(c)(3)(A) (West 2006).

[79] Pub. Citizen v. Young, 831 F.2d 1108 (D.C. Cir. 1987).

islation with the Food Drug and Cosmetic Act of 1938.[80] The FDA was thus a body whose purpose and nature had evolved with new Presidents, new Commissioners, and with legislative amendments.[81]

The judges, in these cases in ruling on the matter of agency authority, were required to make a decision about the appropriate model of administrative constitutionalism in this shifting context. Judge Osteen in the District Court embraced a DC approach. He noted that the intentionally broad definition of "drug," along with other amendments, was intended to "amplify and strengthen the FDCA so as to ensure that the consumer was protected against 'a multiplicity of abuses not subject to the present law.'"[82] Likewise, Judge Osteen drew attention to the expertise and discretion of the FDA.[83] As such, the issue was whether it was obvious that Congress had *not* intended the FDA to regulate tobacco, and held there was no such intent (except in regard to the provisions that limited advertising and promotion);[84] therefore, the FDA did have authority.

The Court of Appeals for the Fourth Circuit reversed the district court's decision, stating that Judge Osteen had proceeded on a "fundamental misconception" that "unavoidably skewed the remainder of [his] analysis."[85] This sharp disagreement was due to the fact that the RI paradigm underpinning the majority's approach and the majority's choice to construe the FDA as a "servant" of Congress. The real question, the majority argued was "whether Congress intended to *delegate* such jurisdiction to the FDA or, in other words, whether the FDA had explicit authorisation.[86] Thus they stated that "[w]e begin with the basic proposition that agency power is not the power to make law. Rather it is the power to adopt regulations to carry into effect the will of Congress as expressed by the statute."[87] This was indeed a fundamentally different question than that posed by the district court. On the majority's analysis, Congress had not explicitly authorised the FDA to regulate tobacco. First, they argued that, while tobacco fell literally under the definition of "drug," to find that it did so was large-

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[80] *See* Fuchs, *supra* note 24.

[81] *See generally* Lars Noah, *The Little Agency That Could (Act With Indifference to Constitutional and Statutory Strictures)*, 93 CORNELL L. REV. 901 (2008).

[82] *See* Coyne Beahm, Inc. v. FDA, 966 F. Supp. 1374, 1380-81 (M.D.N.C 1997) (quoting from the Congressional Record).

[83] *Id.* at 1396.

[84] *Id.* at 1397.

[85] Brown & Williamson Tobacco Corp., v. FDA, 153 F.3d 155, 161 (4th Cir. 1998).

[86] *Id.*

[87] *Id.* at 161 (quoting Ernst & Ernst v. Hochfelder, 425 U.S. 185, 213-14 (1976)) (internal citations omitted).

ly contrary to the statute.[88] In particular, if tobacco did fall under the FDA's authority, their failure to ban it would amount to an abuse of discretion.[89] Second, the FDA had constantly stated that it did not have the authority to regulate tobacco and that Congress's action in the face of such statements was proof of acquiescence to the FDA.[90] Furthermore, and following on from this, Congress developed its own regulatory regime for tobacco by passing a number of statutes from 1965 onwards, suggesting that Congress did not delegate tobacco regulation to the FDA.[91] Moreover, the Fourth Circuit noted that any decision "involving countervailing national policy concerns" should be left to Congress.[92] Indeed, the majority took a hard-line RI approach – the FDA as a rational-instrumental body had little discretion to take initiative on this issue.

This judgment, however, was accompanied by a strong dissent from Circuit Judge Hall that reprised and strengthened the DC line of analysis. Indeed, Hall's judgment is an exemplar of DC reasoning, particularly in the way in which his reasoning encompasses the different aspects of the FDA's power. The FDA, for him, was an institution that was set up to address a series of problems. He stated "[t]he FDCA delegates to the FDA the duty of promulgating and enforcing regulations aimed at protecting the nation's citizens from misbranded and unsafe drugs and food."[93] Moreover, Judge Hall noted the importance of understanding the FDCA in broad purposive terms.[94] This was particularly important with regard to the FDA's change of position on its authority to regulate tobacco. For Judge Hall, Congress did not intend to delegate the power to regulate tobacco specifically. Rather, Judge Hall noted "[t]he operative congressional intent at the outset was simply to confer broad discretionary powers on the FDA to regulate 'drugs' and 'devices.' The FDCA was written broadly enough to accommodate both new products and evolving knowledge about existing ones, and it was written that way on purpose."[95]

From the DC perspective, explicit authorisation was not needed. Likewise, Judge Hall described the FDA's change in stance growing out of the rulemaking process and the administrative record, and as

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[88] *See id.* at 163-64.
[89] *Id.* at 167.
[90] *See id.* at 168-70.
[91] *See id.* at 171-75.
[92] *Id.* at 164.
[93] *Id.* at 176 (Hall J., dissenting).
[94] *See id.* at 179.
[95] *Id.*

such, out of the active exercise of discretion of the FDA.[96] The FDA acted quite legitimately in changing its mind because of the analysis and deliberation inherent in that rulemaking process. Judge Hall also noted, that the majority's holding that tobacco could not fall under the Act (because if it did it must be banned), confused the issue of *how* the FDA regulated with *whether* it regulated.[97] This collapsing of the question of how an agency should regulate into the question of whether an agency can regulate is a common feature of the RI paradigm because as very little discretion should be left to the administrator.

The decision was ultimately appealed to the U.S. Supreme Court where a five to four majority upheld the Fourth Circuit's decision.[98] The Supreme Court majority favoured an RI approach to the question by emphasising the first step of the *Chevron* test and characterising it as whether Congress had explicitly authorised the delegation. Justice O'Connor, writing for the majority, stated:

> [W]e are confident that Congress could not have intended to delegate a decision of such economic and political significance to an agency in so cryptic a fashion. To find that the FDA has the authority to regulate tobacco products, one must not only adopt an extremely strained understanding of "safety" as it is used throughout the Act – a concept central to the FDCA's regulatory scheme – but also ignore the plain implication of Congress' subsequent tobacco-specific legislation.[99]

The Supreme Court majority, like the Fourth Circuit, understood the FDCA's objective as ensuring that FDA regulated products were "safe" and "effective" as particularly important.[100] The fact that FDA's proposals to regulate tobacco would not result in safety would thus obviate Congressional intent because Congress had granted no remedial discretion under the Act.[101] Likewise, the existence of tobacco specific legislation not only ratified the FDA's previous view but also showed that Congress had developed a specific legislative response to the issue.[102]

In a dissenting opinion, Justice Breyer took a very DC approach, and his starting point was to note the constitutive nature of the FDCA:

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[96] *See id.*
[97] *See id.*
[98] FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120 (2000).
[99] *Id.* at 160.
[100] *Id.* at 133.
[101] *See id.* at 134-36.
[102] *See id.* at 156-57.

> After studying the FDCA's history, experts have written that the statute "is a purposefully broad delegation of discretionary powers by Congress," . . . and that, in a sense, the FDCA "must be regarded as a constitution" that "establish[es] general principles" and "permit[s] implementation within broad parameters" so that the FDA can "implement these objectives through the most effective and efficient controls that can be devised."[103]

Indeed for Justice Breyer, the FDA should be largely understood as a product of the New Deal and the FDCA was passed because such bodies as the FDA "need[ed] broad authority and would exercise that authority wisely."[104] A narrow reading of the statute would contravene the statute's overall purpose of protecting health.[105] Accordingly, more tobacco-specific legislation did not override the authority of the FDA. For Breyer, the FDA is an institution founded on DC principles and should be held accountable as such.

At first glance, this line of cases may appear to some to have nothing to do with the choice required between science and democracy as described as in Part I. Yet as noted above, this line of cases has usually been understood in purely ideological terms, and the outcome of the case primarily being due to the unique place of the tobacco industry.[106] Even those scholars who have focused on the application of the *Chevron* doctrine have understood that doctrine as finding a balance between the democratic accountability of the legislature and the expertise of public administration.[107] What the analysis above reveals is that the way in which the *Chevron* doctrine was applied in the above cases was less about that choice between democracy and expertise but far more about how the actual nature and power of the FDA was characterised as an institution. That process of characterisation was shaped not only by different judges' normative understandings about what is, and should be, the nature of the administrative state, but also by doctrine and institutional history. Indeed, the analysis above begins to hint at the richness of administrative constitutionalism as a form of legal culture.

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[103] *Id.* at 165 (Breyer, J., dissenting) (citations omitted).

[104] *See id.* at 165-66; *see also* BREYER, *supra* note 44.

[105] FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 168 (2000).

[106] Turley, *supra* note 59, at 437.

[107] Sunstein, *supra* note 69, at 1058.

B. The Southwood Working Party and the UK BSE Crisis

The role and significance of administrative constitutionalism can also be seen in the context of the next case study. In contrast to the case law discourse charted above, the UK BSE crisis has less of a substantive legal dimension – a fact reflecting the nature of administrative law culture and administrative constitutionalism in the United Kingdom. The non-legal nature of UK administrative constitutionalism is reflected in the fact that there was no significant challenge to UK government decision-making in a UK court but there was a major independent three year Inquiry.[108]

The BSE crisis is a multi-faceted controversy,[109] but one of its most significant and controversial aspects was the UK government's reliance on a short report published in 1989 by a committee, the Southwood Working Party, on the issue of whether BSE presented a human health risk.[110] That report concluded "[f]rom present evidence, it is likely that cattle will prove to be a 'dead-end host' for the disease agent and most unlikely that BSE will have any implications for human health. Nevertheless, if our assessments of these likelihoods are incorrect, the implications would be extremely serious."[111]

This conclusion was treated by government decision-makers as authority for the proposition that BSE did not present a human health risk despite: (1) the caveat; (2) the Working Party's small nature; (3) the fact that the Working Party only met a few times; (4) the report's brevity; and (5) the discussions regarding the report's uncertainties. Not until 20 March 1996, did another expert committee, the Spongiform Encephalopathy Advisory Committee (SEAC), advise that the "most likely explanation" for the appearance of a new and fatal disease in humans – variant Creutzfeldt-Jakob disease (v-CJD) – was an individual's exposure to BSE through direct beef consumption and the use of beef products in other products such as cosmetics.[112]

The conventional explanation of this event is nearly always in terms of the science/democracy dichotomy.[113] The reliance on the

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[108] The BSE Inquiry, *supra* note 11.

[109] *See generally id.* at vol. 1 (2000), http://www.webarchive.org.uk/wayback/archive/20060308232515/http://www.bseinquiry.gov.uk/report/volume1/toc.htm (last accessed 18 March 2010).

[110] WORKING PARTY REPORT ON BOVINE SPONGIFORM ENCEPHALOPATHY, *supra* note 10.

[111] *Id.* at § 9.2.

[112] *Hansard*, HC Deb, vol. 275, col. 375 (20 March 1996).

[113] VAN ZWANENBERG & MILLSTONE, *supra* note 3; *see also* Merle Jacob & Tomas Hellstrom, *Policy Understanding of Science, Public Trust and the BSE-CJD Crisis* 78 J. HAZARDOUS MATERIALS 303, 307-10 (2000).

Southwood Working Party is either understood as due to the dominance of political interests or as due to a naive faith in objectivity.[114] As this is the case, the solutions to the problems encountered in the BSE crisis are thus understood to lie in greater transparency, objectivity, and the promotion of communication between science and politics.[115]

Viewing the creation, operation, and reception of the Southwood Working Party through the lens of administrative constitutionalism yields a very different narrative however. That narrative suggests that the inappropriate reliance on the Working Party's report stemmed from debates over the role and nature of legitimate public administration being carried on in the United Kingdom at that time. These debates should be understood as debates over administrative constitutionalism and the Southwood Working Party can be understood to have operated itself on the basis of the DC paradigm but was created and received in terms of the RI paradigm.

Broadly speaking, for much of the twentieth century, the DC paradigm dominated the British administrative state. This dominance can be seen in the institutional structure in the mid-1980s of the two main administrative institutions involved in making decisions about BSE – the Ministry of Agriculture Food and Fisheries (MAFF) and the Department of Health (DH).[116] Both departments were organised along DC lines. Food safety was only one of a number of responsibilities of these large sprawling departments, which had a three-prong role of providing advice, formulating policy, and implementing that policy.[117] Such departments were also responsible for an array of different matters. MAFF, for example, was concerned both with the protection of health and the promotion of interests of the agricultural sector.[118] Though many have viewed this combination as leading to a direct conflict of interest,[119] from a DC perspective, the combination was not problematic because of the deliberation's ability to diffuse the power of self interest.[120]

These departments were statutorily vested with administrative powers, which were in very broad DC terms. Ministers and their

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[114] VAN ZWANENBERG & MILLSTONE, *supra* note 3, at 102.

[115] *Id.* at 229-78; *see* Gavin Little, *BSE and the Regulation of Risk*, 64 MOD. L. REV. 730, 754-56 (2001); The BSE Inquiry, *supra* note 11, at vol. 1.

[116] The BSE Inquiry, *supra* note 11, at vol. 15.

[117] *See id.* at 5, 91 (2000).

[118] *Id.*; VAN ZWANENBERG & MILLSTONE, *supra* note 3, at 50.

[119] VAN ZWANENBERG & MILLSTONE, *supra* note 3, at 50-54.

[120] See Section III.B in Chapter One; Cass R. Sunstein, *Interest Groups in American Public Law*, 38 STAN. L. REV. 29, 31-32 (1985).

departments were entrusted with wide-ranging powers to deal with complex problems as they arose. Most legislation granted significant powers to pass secondary legislation to address issues with few procedural constraints on how such legislation should be passed.[121] Thus, for example, under section 13(1) of the Food Act 1984:

> The Ministers may make such regulations as appear to them expedient for securing the observance of sanitary and cleanly conditions and practices in connection with –
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> a) the sale of food for human consumption, or
> b) the importation, preparation, transport, storage, packaging, wrapping, exposure for sale, service or delivery of food intended for sale or sold for human consumption,
>
> or otherwise for the protection of the public health in connection with those matters.

Subsection 2 of the Act listed illustrative examples of the types of regulations which might be passed under this provision but did not limit the power of the Minister. The Act could also be amended by Ministers acting in their executive capacity, via what is known as a Henry VIII clause so long as there was a consultation process, albeit a limited one.[122]

Furthermore, the DC paradigm permeated MAFF and DH through the general culture of the permanent civil service and its guiding principles of impartiality, integrity, and objectivity (in its non-scientific sense).[123] While the central government departments implemented government policy, these departments were not simply the instruments of the governing party. Personnel did not change with the change of government, and civil servants understood their primary duty as to serve the public interest, rather than a particular political party's interest.[124] The emphasis on generalist administrators reflected a recognition of the complexity of governing, and civil servants were expected to be imaginative, responsive to change, and humane.[125] Decisions and delegated legislation were understood to be

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[121] VAN ZWANENBERG & MILLSTONE, *supra* note 3, at 50-54.

[122] Section 118 of the Food Act 1984.

[123] For an interesting discussion of this, see DIANA WOODHOUSE, IN PURSUIT OF GOOD ADMINISTRATION: MINISTERS, CIVIL SERVANTS AND JUDGES 27-39 (1997).

[124] *Id.* at 32-34.

[125] WILLIAM ARMSTRONG BARON, THE ROLE AND CHARACTER OF THE CIVIL SERVICE 1 (1970).

the product of a "long and tortuous process" in which the emphasis was on deliberation and the putting across of a number of different points of view.[126] As one MAFF official put it, policy decisions required "a build-up of available information, discussion amongst officials either orally or through correspondence, perhaps preliminary discussion with Ministers, [written] submissions to Ministers with argument and options, discussion with Ministers, further discussion between Ministers, decisions and an action timetable."[127] The aim was for a frank and wide-ranging consideration of issues with input from numerous different sources, albeit that conversation only involved a small group.[128]

By the late 1970s, however, the dominance of the DC paradigm was being challenged. In particular, the deliberative capacities and the public interest of the permanent civil service were starting to be doubted. Decisions were now being understood by commentators and political actors as less a product of wise judgment and more as a product of "fudge and smudge, a quagmire of intellectual fuzziness . . . and administrative laxity."[129] Moreover, there was an increasing perception, particularly among Members of Parliament, that the civil service should serve the ruling government, and the 1980s' Conservative government introduced administrative, management and financial reforms, including regulatory impact analysis (as part of the Deregulation Initiative), to encourage this shift to RI thinking.[130] Thus, by the late 1980s, a more RI understanding of the role of the civil service was becoming apparent, and civil servants began to see that their giving of advice was less in line with the tradition of the permanent civil service and more the provision of information the Minister wanted to hear.[131] The civil service was transforming from a permanent DC institution to a RI agent of the ruling party.

This set of changes can be seen particularly in relation to the role and nature of expertise and information. As noted in Part One, exper-

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[126] *See* The BSE Inquiry, *supra* note 11, at vol. 15.

[127] *Id.*

[128] *Id.* at 10; *see also id.* at vol. 3.

[129] Andrew Jordan, *The Impact on UK Environmental Administration*, *in* 1 BRITISH ENVIRONMENTAL POLICY AND EUROPE 183 (Philip Lowe & Stephen Ward eds., 1998); *see also* Barbara Castle, *Mandarin Power*, *in* THE WHITEHALL READER 61 (Peter Barberis ed., 1996); WOODHOUSE, *supra* note 123, at 37-38. FULTON COMMITTEE, THE CIVIL SERVICE - VOLUME ONE (Cmnd 3638, 1968).

[130] Cabinet Office, *The Armstrong Memorandum*, *in* THE WHITEHALL READER 114 (Peter Barberis ed., 1996); The BSE Inquiry, *supra* note 11, at vol. 15, at 62-67, 136.

[131] *Id.* at 10.

tise is understood to have a role under both the DC and RI paradigms, but that role is understood in different ways.

From a DC perspective, the role and nature of expertise in public administration was understood as one input into decision-making rather than its source of authority.[132] Both the MAFF and DH found it important to have both generalist and specialist administrators working together in a "cooperative" problem solving process in which the role of each would depend on the nature of the problem.[133] Heads of the specialist branches also saw themselves in DC terms.[134] Scientific advice to these government departments was largely provided by ad hoc expert committees set up to consider specific issues.[135] That expertise was defined in broad, deliberative terms, and the expertise of the official scientific advisor lay not in a "monopoly of scientific wisdom" but rather "in a practical experience of the way the machine of government works."[136]

Expertise was thus broad-based and not simply confined to the methodologies of a discipline. Experts participated in policy-making, which was understood to be a multidisciplinary exercise.[137] Moreover, during the early years of the BSE crisis, quantitative methodologies were not seen as necessary in the risk evaluation process.[138] While such methods were seen as relevant to areas where knowledge allowed their use, such tools were limited in areas where considerable scientific uncertainties existed.[139] The concepts of reasonableness and proportionality were preferred as broad guiding principles, as was general precautionary thinking.[140] Likewise the concept of "best practicable means," developed in the nineteenth century, continued to be the basis for action and also gave rise to associated qualitative concepts such as "as low as reasonably practicable"(ALARP).[141] Historically, the application of these concepts did not require the precise quantification of risk but rather required the application of as safe standards as feasibly possible. This was understood primarily as a matter of practical judgment and one in which mathematical concepts

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[132] *Id.* at 23.

[133] *Id.* at 30, 32; DEREK H. ANDREWS, STATEMENT OF EVIDENCE TO THE BSE INQUIRY, NO. 281 ¶ 19 (Nov. 10, 1998).

[134] The BSE Inquiry, *supra* note 11, at vol. 15.

[135] *Id.* at 23-40.

[136] SOLLY ZUCKERMAN, ADVICE AND RESPONSIBILITY: ROMANES LECTURE FOR 1975 33 (1975).

[137] The BSE Inquiry, *supra* note 11, at vol. 15, at 33-34.

[138] *Id.* at 45.

[139] *Id.* at 46, 50-51.

[140] *Id.* at 46, 48.

[141] *Id.* at 42.

of risks did not significantly figure.[142] These ideas flowed from an understanding that technological risk problems were complex and thus would not yield easily to strict methodological approaches.[143]

Simultaneously, the role and nature of expertise changed from being understood in DC terms to being grounded in a RI understanding of public administration. Not only was the role of scientific advice being understood more in terms of a customer-contractor relationship but also in government policy and administrative arrangements an increasing emphasis was placed on the use of risk assessment methodologies and on ensuring that decisions were based on analytical evidence.[144] These changes only began at the time that the Southwood Working Party operated, and hence the Working Party was operating in a context in which both DC and RI conceptions of expertise were at work.

The first case of BSE was identified by the MAFF-run Central Veterinary Laboratory (CVL) in 1986, but MAFF Ministers were informed about BSE in June 1987.[145] The discourse among the senior civil servants after this memorandum was a DC nature. First, these civil servants focused upon the possibility that health risks might have arisen from BSE.[146] This small group deliberated about the nature of the uncertainties involved and how one would go about establishing whether there was a health risk.[147] They planned a programme of research[148] but also saw their role as taking precautionary action, even if such a risk could not be strictly proved.[149] An options paper was circulated among MAFF officials in early 1988, which reflected wide-ranging deliberations.[150] Very little in that paper focused on issues of evidence, even though BSE remained a poorly understood disease. In February 1988, senior officials proposed to the MAFF Minister, John MacGregor, the action to be taken in relation to BSE. In that submis-

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[142] HEALTH AND SAFETY EXECUTIVE, REDUCING RISKS, PROTECTING PEOPLE (1999).

[143] *Id.*; Elizabeth Fisher, *Drowning by Numbers: Standard Setting in Risk Regulation and the Pursuit of Accountable Public Administration*, 20 OXFORD J. LEGAL STUD. 109 (2000).

[144] The BSE Inquiry, *supra* note 11, at vol. 2; *id.* at vol. 5, at 49.

[145] *Id.* at vol. 5, at 10.

[146] *Id.* at 124.

[147] *Id.* at 121, 123, 125-27.

[148] *Id.* at 26, 121.

[149] ANDREWS, *supra* note 133, at ¶ 34; The BSE Inquiry, *supra* note 11, at vol. 5, at 121, 124; *see* Lawrence, *BSE: Meeting 9AM on 8 Jan in CVO: Room*, BSE INQUIRY EVIDENCE, Y.B. 1988, 88\01.04\2.1-2.4 (1988), *available at* http://www.webarchive.org.uk/wayback/archive/20060308232515/http://www.bseinquiry.gov.uk/evidence/yb/index.htm.

[150] The BSE Inquiry, *supra* note 11, at vol. 5, at 125.

sion, senior officials recognised the considerable scientific uncertainties involved, others related concerns such as welfare and trade, and MAFF's responsibility in relation to human health.[151] Before that submission was given to the Minister, it was circulated among MAFF officials with a cover note, stating:

> We do not know where this disease came from, we do not know how it is spread and we do not know whether it can be passed to humans. The last point seems to me to be the most worrying aspect of the problem. There is no evidence that people can be infected but we cannot say that there is no risk.[152]

Even though this was the case, the submission recommended precautionary action through a slaughter and compensation scheme.[153] This scheme was controversial however, because it conflicted with the policy then in operation to recover costs from industry.[154] Moreover, if compensation was to be paid, MAFF would need to show that such expenditure would yield benefits – a difficult thing to do in circumstances of scientific uncertainty, but logical in a context in which the Treasury was attempting to control the administrative state.[155]

The submission was put to the relevant Minister, John MacGregor, with accompanying advice from the Permanent Secretary which stated:

> I do not see how you could defend taking no action now unless you had the support of the Chief Medical Officer [CMO]. But, on the face of it, it seems unlikely that he would feel able to endorse a wholly reassuring statement of the likely risks of transmission of this disease to man until we have much more information available.[156]

However, MacGregor made clear that action would not be taken without seeking the advice of the CMO.[157] This stance was due to MacGregor's understanding of reasonable administrative action in RI terms and that any decision should be based on firm evidence.[158]

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[151] *Id.* at 127.
[152] *Id.* at 126-27.
[153] *Id.* at 128.
[154] *Id.* at 128-29; RICHARD PACKER, THE POLITICS OF BSE 37-38 (2006).
[155] The BSE Inquiry, *supra* note 11, at vol. 5, at 128.
[156] *Id.* at 129.
[157] PACKER, *supra* note 154, at 37.
[158] John MacGregor, *Statement of Evidence to the BSE Inquiry*, NO. 302 ¶¶ 6,

MacGregor's reasons for taking this stance were that it was consistent with the RI paradigm, which was being promoted by the Treasury's budgetary policies, by the Deregulation Initiative, and by the perception that evidence was needed to withstand any judicial review challenges.[159] Moreover, MacGregor saw a direct analogy between BSE and rhizomania in sugar beet[160] and was concerned that compensation for the former would require compensation to the latter.[161] This simplistic understanding of both problems ignored the serious health implications of BSE.[162]

The CMO, on being informed, recognised the problems of assessing the potential health risks, the need to investigate the issue further, and the need to seriously consider regulatory action. He recommended setting up an expert committee to advise on the matter.[163] In evidence to the BSE Inquiry, the CMO explained that there were a number of reasons for this recommendation. These included: the scientific uncertainty that existed concerning the health risks, the inappropriateness of the CMO giving such advice "off the cuff," and the need for expert advice to justify a slaughter and compensation scheme to the Treasury.[164] In other words, a committee was needed for both DC and RI reasons.[165] The Committee that was set up was the Southwood Working Party.

The group first met on 20 June 1988, and it produced its final report in February 1989. Before the first meeting, MAFF had banned the use of ruminants in ruminant feed and made BSE a notifiable disease that was to be reported to the CVL.[166] Immediately following its first meeting, the Working Party made interim recommendations. Specifically, the Working Party suggested a compulsory slaughter and compensation scheme for infected animals be introduced and that a research committee be set up to investigate the animal and human

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19 (Dec. 2, 1998), *available at* http://www.webarchive.org.uk/wayback/archive/20060308232515/http://www.bseinquiry.gov.uk/evidence/ws/wsalpha4.htm; VAN ZWANENBERG & MILLSTONE, *supra* note 3, at 88.

[159] *See* The BSE Inquiry, *supra* note 11, at vol. 6, at 115; *see also id.* at vol. 5, at 130.

[160] *Id.* at vol. 5, at 154-55.

[161] *Id.* at 130.

[162] *See id.* at 154.

[163] *Id.* at 133.

[164] *Id.* at 150, 161.

[165] See Lord Phillips questioning of Sir Derek Andrews in relation to issue of whether different reasons for setting up expert committees may exist. The BSE Inquiry, Transcript of Oral Hearing Day 81 (Nov. 10, 1998), at 10:18 – 12:23, *available at* http://www.webarchive.org.uk/wayback/archive/20060308232515/http://www.bseinquiry.gov.uk/evidence/trans/transcripts.htm.

[166] Bovine Spongiform Encephalopathy Order, 1988, S.I. 1988/1039 (U.K.).

health risks of BSE. The government accepted both these recommendations in its final report, the Working Party recommended that the regulatory authorities address the possible health risks from medicines and occupational exposure and ban the use of thymus and offal in baby food.[167] As shall be illustrated below, the thymus and offal ban in baby food made no obvious sense.

My concern is not with what the Working Party recommended however, but with what was understood to be its role and nature in the risk evaluation process. As can be seen above, the Working Party operated in a context in which both the DC and RI paradigms were at play, and thus, what was understood as the role and nature of such an expert body was bifurcated. The Working Party was created mainly because of a perception among senior civil servants that regulatory action could not be taken without evidence and/or expert advice. This RI understanding of reasonable administrative action diverged from traditional DC ideas, but the actual establishment and operation of the Working Party was along DC lines. This can be seen in what was understood to be the expertise of the Working Party, how it operated, and what it perceived as its role in risk evaluation.

In regards to the first issue, the Working Party's expertise was initially understood by those on it in very broad terms. As the academic Jasanoff has put it, the committee was staffed by the "great and the good," whose authority derived not from individuals' specific disciplinary expertise but from their ability to exercise "caution, empiricism, and constraint."[168] The Working Party consisted of four eminent research scientists who lacked particular expertise in transmissible spongiform encephalopathies (TSEs) but rather had more general expertise in the area.[169] This was seen as desirable by those appointing the members of the Working Party because it was felt that those who had direct expertise in TSEs would be "too close to the front line to take the slightly broader view needed."[170] In asking Sir Richard Southwood to chair the Party, the CMO told Southwood that he was the appropriate choice because "it is an ecological food chain problem [Southwood's area of expertise] and because I know you are an independent chap."[171] In oral evidence to the BSE Inquiry,

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[167] WORKING PARTY REPORT ON BOVINE SPONGIFORM ENCEPHALOPATHY, *supra* note 10, at §§ 5.3.5, 8.2, 8.3.

[168] Sheila Jasanoff, *Civilization and Madness: The Great BSE Scare of 1996*, 6 PUB. UNDERSTANDING SCI. 221, 227-28 (1997).

[169] The BSE Inquiry, *supra* note 11, at vol. 4, at 2-3.

[170] *Id.* at 3.

[171] Statement of Sir Richard Southwood to the BSE Inquiry, *available at* http://www.webarchive.org.uk/wayback/archive/20060308232515/http://www.bse

Southwood said he did not see the Working Party as "experts in the narrow sense of carrying out research into BSE," and it was for this reason that the committee was called a Working Party.[172] This is not to say that the Working Party ignored those with expertise in TSEs, but rather only consulted them, particularly those who had long experience in the area.[173] The breadth of the Working Party's expertise extended beyond the scientific and most of those on the Working Party had experience on other government committees and thus understood their task in broad public interest terms.[174] In particular, these experienced members saw that their deliberations, while taking account of the policy context, should not be influenced by specific interests.[175] These views were consistent with the DC ideals of the civil service and with an appreciation that technological risks are not easily manageable.

The second way in which the expertise of the Working Party accorded with the DC paradigm is in the deliberative way that the Working Party conducted itself. The Committee saw itself as a "scoping committee" that needed to see what "pointers they could discover" about BSE.[176] As this was the case, the fact that the Members of the Working Party did not have a grasp on all issues was not necessarily problematic. Moreover, the members viewed themselves as the first, not the last, word on the problem and that their role was to identify what the issues were through a wide scoping analysis. Because of their need to "scope" the committee felt that very broad terms of reference were important because "one could not have been restricted and operated properly."[177] The Working Party needed an expansive perspective on BSE and all the problems it might create. Indeed, the Working Party's inquiries and deliberations covered a range of issues including: the nature of the disease itself; problems inherent in ruminant feed; health risks to animals; and human health risks arising from medicines, food, and occupational exposure.[178] As a result, the

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inquiry.gov.uk/evidence/ws/index.htm.

[172] The BSE Inquiry, Transcript of Oral Hearing Day 3 (Mar. 11, 1998), at 6:4-15, *available at* http://www.webarchive.org.uk/wayback/archive/20060308232515/http://www.bseinquiry.gov.uk/evidence/trans/transcripts.htm.

[173] The BSE Inquiry, *supra* note 11, at vol. 4, at 3-4.

[174] *See* Statement of Sir Richard Southwood, *supra* note 171; THE BSE INQUIRY, *supra* note 169, at 3-4.

[175] *See* Statement of Sir Richard Southwood, *supra* note 171.

[176] The BSE Inquiry, Transcript of Oral Hearing Day 3, at 12 (Mar. 11, 1998), *available at* http://www.webarchive.org.uk/wayback/archive/20060308232515/http://www.bseinquiry.gov.uk/evidence/trans/transcripts.htm.

[177] *Id.* at 14:4-5; *see also* The BSE Inquiry, *supra* note 11, at vol. 4, at 2.

[178] The BSE Inquiry, *supra* note 11, at vol. 4, at 8-11.

Working Party members were acutely aware that they were operating in the context of many scientific and behavioural uncertainties.[179] Thus, for example, Southwood, in discussing these issues with MacGregor, the MAFF Minister, stressed that the Working Party was operating in "uncharted waters."[180] The Working Party consulted formally and informally with an array of people, albeit within a reasonably small circle.[181] Deliberations were supported by advice and information resources from DH and MAFF.[182] The Working Party did not carry out quantitative risk assessments but operated on the ALARP principle, although not in a systematic way.[183] Instead, they deliberated on the scientific issues in light of general principles of proportionality and reasonableness.

The third way that those of the Working Party saw themselves in DC terms is that they saw their report not as an authoritative basis for action but as one input into the deliberative process. Indeed, the bulk of the report was less than twenty pages long (thirty-five pages with appendices), and while a good overview of the state of knowledge about BSE at that time, it contained little in-depth analysis of data. Most of its analysis was in qualitative terms, and the report was not heavily footnoted. Moreover, as already noted in the introduction, the conclusions in the report contained an important caveat regarding uncertainties about the effects on human health.[184] Throughout the report, the authors stressed the problems of scientific uncertainty,[185] problems created by the long incubation of the disease,[186] and the need to do more research.[187] The scientific and evidentiary issues were discussed in terms of theories, assumptions and hypotheses.[188] The report reads as a preliminary judgment on the available information rather than as an exercise in proving risks. Indeed, in evidence to the Inquiry, those on the Working Party stressed that their conclusions were based on judgment and that "good and wise men and women

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[179] *Id.* at 20; *see also* The BSE Inquiry, Transcript of Oral Hearing Day 3, at 13 (Mar. 11, 1998), *available at* http://www.webarchive.org.uk/wayback/archive/20060308232515/http://www.bseinquiry.gov.uk/evidence/trans/transcripts.htm.

[180] The BSE Inquiry, *supra* note 11, at vol. 4, at 20.

[181] *Id.* at 11, 17.

[182] *Id.* at 6-7.

[183] *Id.* at 48-49.

[184] WORKING PARTY REPORT ON BOVINE SPONGIFORM ENCEPHALOPATHY, *supra* note 10, at § 9.2.

[185] §§ 1.1, 3.1, 3.4, 4.2.5, 5.3.1, 5.3.6.

[186] § 3.4.

[187] § 5.2.3.

[188] §§ 2.6, 4.1.3-4.1.4, 4.2.5, 4.2.9, 5.2.2, 5.3.3, 5.3.6.

may reach different sorts of conclusions."[189] Moreover, the members hoped that due to the progress in research that their report would soon be out of date.[190] That was because those on the Working Party did not see themselves as research scientists but rather as providing an account of the issues at a particular point in time. As Sir Anthony Epstein, one of the members of the Working Party stated:

> [W]e were simply asked to alert them to the implications, and that is what we did. They had their army of civil servants and Government scientists. It was for them to take over at that stage, and decide what policy should be followed by government. It was not the remit of the Working Party to enter into that at all.[191]

Moreover, some of the Working Parties' conclusions regarding BSE coincided with what MAFF officials had already concluded. In fact, in the words of the BSE Inquiry, these conclusions would have been "shared by any scientists, or indeed intelligent layman" informed of the issues.[192]

The problem however, was that the Southwood Working Party's report was not treated as one input into an ongoing process of risk evaluation. Rather, it was treated by those in MAFF and DH as if it "contained definitive conclusions based on an evaluation of adequate data by expert scientists in relation to the extent both of the risk and of the precautionary measures necessary to counter that risk."[193]

This interpretation of the report, while entirely at odds with a DC understanding of the role and nature of expertise, was very consistent with the concept of expertise embodied in the RI paradigm of administrative constitutionalism. Because public administration should only act when rigorous analysis has established a factual basis, the Working Party's report was interpreted as such to meet that end.

First, the Report was interpreted as an authoritative risk evaluation, concluding that the human health risks from BSE were remote. Until the Working Party's statement on 20 March 1996, the UK government consistently stated that beef was safe to eat and preventative measures reflected this belief. Such BSE statements repeatedly focused on the scientific evidence. The Inquiry was replete with phrases such as "[t]here is no scientific justification to avoid eating British

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[189] The BSE Inquiry, *supra* note 11, at vol. 4, at 67.
[190] *Id.* at 67.
[191] *Id.* at 69.
[192] *Id.* at 42.
[193] *Id.* at 1.

beef"[194] and "there is *no* scientific evidence of a casual link between BSE in cattle and CJD in humans"[195] were common phrases.[196] Emphasis was placed on measures being "based on the best scientific expertise available"[197] and on the most "eminent and distinguished scientists"[198] having found no such risk. The assumption was that the Working Party's conclusions could not be revisited unless new evidence or an improved risk evaluation appeared.[199] As such, government expert committees also relied heavily on the Report until the evidence warranted a new risk evaluation.[200]

Second, the government treated the advice of the Working Party as the primary basis for carrying out administrative and regulatory action. As one MAFF Minister noted, it was a "bible"[201] and others saw it as "the foundation of government policy."[202] As a practical consequence of this view, all regulatory action needed to be justified by officials in terms of the Working Party's report, and any action that went beyond that advice needed to be strictly justified.[203] The main regulatory initiatives that the UK government took in relation to human health – the slaughter and compensation policy and the specified offal ban – were both a direct product of the advice of the Working Party as were other more minor regulatory actions.[204]

Moreover, administrators, even specialist administrators, did not see it as their task to question the report. In a statement to the BSE Inquiry, the Chief Veterinary Officer (CVO) at the time of the Southwood Report stated that:

> [T]the Southwood Working Party had considered the then available scientific evidence (from work on scrapie), had conducted a risk assessment and had concluded that any risk of transmission of BSE to humans was remote. I had no reason to question that conclusion and *nor did I have responsibility*

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[194] The BSE Inquiry, *supra* note 11.

[195] *Id.* at 531.

[196] *Id.* at 348, 365, 368, 372-73.

[197] *Id.* at 369.

[198] *Id.* at 377.

[199] *E.g.*, *id.* at 120-21, 136, 143.

[200] PACKER, *supra* note 154, at 46.

[201] The BSE Inquiry, *supra* note 11, at vol. 4, at 67.

[202] *Id.* at vol. 11, at 1.

[203] *Id.* at 1-2.

[204] For example, the ban on milk from cattle suspected of being infected with BSE. WORKING PARTY REPORT ON BOVINE SPONGIFORM ENCEPHALOPATHY, *supra* note 10, at § 10.4; The Bovine Spongiform Encephalopathy (No. 2) Order, 1988, S.I. 1988/2299, art. 9 (U.K.).

> *to do so.* Similarly, I believe that my colleagues and Ministers did not question the conclusion that the risk was remote[205]

The CVO saw his task as acting on the basis of evidence. The CVO understood his *responsibility* as a conduit for information and expertise rather than as a deliberating official. Moreover, the CVO understood the role and nature of the Working Party, in rationalistic terms, as providing the relevant methodological analysis of evidence. Thus, the CVO described the Working Party as carrying out a "risk assessment," even though the Working Party never used that language itself or purported to carry out any formal risk assessment.

This stance on the role of expertise is very different from that seen under the DC paradigm where expert input was understood as the starting point for deliberation rather than the closure of it. Neither the MAFF nor DH made significant attempts to formally review the Working Party's report, even though it was obvious among MAFF and DH officials that the report's advice was problematic.[206] For example, it became increasingly clear that the Working Party had not taken into account slaughterhouse practices, an issue which was important in thinking about how any regulations were to apply.[207]

More significantly, however, one of the report's recommendations was quickly found to be not well thought out. In the body of the report, the Working Party recommended that manufacturers refrain from using ruminant offal and thymus in baby food.[208] This recommendation was based on the assumption that these parts of cattle may be infective in subclinical animals, and if so, babies would be particularly vulnerable in being exposed to BSE.[209]

There were a number of problems with this recommendation. First, thymus was not used in baby food, and ruminant offal's meaning was open to different interpretations.[210] It quickly became apparent to officials that the recommendation had not been based on a thorough analysis of the issue. MAFF and DH responded to this problem by asking Sir Richard Southwood for clarification rather than using the recommendation as a starting point for deliberation.[211] Second, a number of officials saw a disjunction between the suggested action to

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[205] The BSE Inquiry, *supra* note 11, at vol. 5, at 145 (emphasis added).

[206] *Id.* at 99, 103.

[207] PACKER, *supra* note 154, at 42.

[208] WORKING PARTY REPORT ON BOVINE SPONGIFORM ENCEPHALOPATHY, *supra* note 10, at § 5.3.5.

[209] The BSE Inquiry, *supra* note 11, at vol. 4, at 50.

[210] *Id.* at vol. 5, at 84, 91.

[211] *Id.* at 91.

be taken to protect babies and the lack of similar action in relation to children and adults. While babies were clearly more susceptible to TSEs, it did not follow that a risk to babies precluded a risk to adults.[212] Third, the Working Party had recommended a slaughter and owner compensation policy for those animals obviously suffering from BSE, a policy based on the assumption that such animals should not be consumed by humans. However, considering the long incubation period of the disease and the fact that it could be infective in subclinical animals, the lack of precautions in relation to cattle not diagnosed with BSE but which might be infected with it seemed odd.[213] MAFF and DH officials deliberated and discussed these issues. While many in MAFF and DH were experts on disease notification, the Working Party's expert advice was still viewed as the only legitimate basis for discussing the possibilities of regulatory action.[214]

Ultimately, the recommendation regarding baby food transformed into a wider ban on certain specified offal being using in products consumed by humans.[215] Such a ban turned out to be eminently sensible and entirely consistent with the application of the traditional DC principle of ALARP.[216] The ban, however, was not justified in DC terms. Rather, the ban was seen by most in MAFF and DH as an application of the Working Party's expert advice, the ban's wider nature being explained as due to the technicalities of the legal system, which meant it was the only way to implement that advice.[217] Deliberations that had occurred in MAFF and DH were not seen as the legitimate basis for administrative action, and many did not believe the ban was necessary because there was no basis in the scientific advice for it.[218]

III. IMPLICATIONS OF ADMINISTRATIVE CONSTITUTIONALISM FOR THINKING ABOUT FOOD SAFETY CRISES

The two case studies above are remarkably different. The interpretation of the FDCA by three courts is an exercise in legally constrained doctrinal analysis, the sort with which U.S. lawyers will be well acquainted. The role of the Southwood Working Party will strike U.S. lawyers as peculiarly strange. There was no legislated rulemak-

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[212] *Id.* at 105, 118-19.
[213] *See id.* at 103.
[214] *Id.*
[215] Bovine Offal (Prohibition) Regulations, 1989, S.I. 1989/2061 (U.K.).
[216] *See* The BSE Inquiry, *supra* note 11, at vol. 6, at 84, 91.
[217] *Id.* at 85, 198-99.
[218] *Id.* at vol. 1, at 45.

ing process for either MAFF or DH, no need for the compilation of a record, and no judicial review (although the threat of it existed). Both case studies highlight that food safety crises do not operate in a vacuum and do not simply require striking the right balance between science and democracy, or objectivity and values. Rather both controversies focus on the legitimacy of public administration and what is understood as good administrative decision-making. Thus, the perceived scope of the FDCA largely turned on what judges understood to be the role and nature of the FDA. Likewise, what significance and interpretation was given to the Southwood Working Party's report by officials depended on what was understood to be the larger role for public administration and expertise. Moreover, the two cases highlight that the issue of legitimacy of public administration has many different dimensions.

Three major implications of analysing food safety crises in terms of administrative constitutionalism arise. The first is that public administration and administrative constitutionalism becomes the central focus of these crises. Recognising this does not require a dramatic rewriting of the whole field, but rather, it provides a more accurate starting point for understanding these debates. Assumptions about what is good public administration drive the administrative and judicial responses to issues. Thus, in the tobacco case, competing conceptions of the role and nature of the FDA transcended simplistic pro- and anti-regulatory ideology. Likewise, the reliance on the Southwood Working Party's report had more to do with a naive pursuit of good public administration than a product of scheming political interest. Indeed, what can be seen from these two brief examples is that a focus on public administration and administrative constitutionalism results in a more nuanced account of food safety crises in which different institutions, doctrines, frameworks, policies, and ideals are all seen to have a role to play. That nuance highlights that reform should often be more subtle and sophisticated than it currently is. Thus for example, reform should not be about more science or more participation but rather about developing particular types of science and participation for the issue at hand.[219]

The second implication of the studies above is that there are no utopian solutions to food safety crises. Put another way, food safety crises are inevitable because no perfect paradigm of administrative constitutionalism exists in the food safety context. Food safety issues are simply too uncertain, complex, and socio-politically ambiguous,

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[219] ORTWIN RENN, RISK GOVERNANCE: COPING WITH UNCERTAINTY IN A COMPLEX WORLD (2008).

and both the RI and DC paradigms have their strengths and their weaknesses. The DC paradigm emphasises the need for public administration to wield considerable discretion so as to aid their ability to solve problems effectively, but the granting of considerable discretion to public administration makes it more difficult to hold DC public administration to account. This dilemma is particularly evident in the UK context where historically public administration has acted within few constraints. The RI paradigm promises accountability and control but does so at the cost of effective problem solving. Thus in the tobacco case, the FDA was powerless in the face of a significant public health issue. Appreciating the intractability of food safety problems may be depressing for some, but such an appreciation is important. In particular, it helps direct reform by avoiding a fruitless search for the perfect model of food safety regulation. Rather, by those involved in reform appreciating intractability, a far more pragmatic debate about how to find a negotiated compromise between different paradigms of administrative constitutionalism can be developed.

The third implication of these two studies is to highlight the particular importance of legal culture. Legal culture is not just an instrument. In the tobacco cases, the dispute was not only a legal one but was occurring in a legal arena in legal terms using legal authorities. Likewise, the Southwood Working Party was embedded deeply within UK administrative constitutionalism with all its ideals, policies, institutions, and structures. A study of food safety crises thus needs to be a study of everything from basic facts about a legal system to "more nebulous aspects of ideas, values, aspirations and mentalities."[220] Legal culture is not a static ideal but constantly evolving due to changes in arguments and ideas. Moreover, legal culture is not simply an instrument of other disciplines – it is a "thick" cultural phenomenon that is both complex and substantive in nature.[221] The "thickness" of legal culture is in part due to it operating at the point of contact between "sociological description and normative assessment."[222]

Highlighting the importance of legal culture is particularly important in an era in which issues of food safety have become closely intertwined with issues of globalisation.[223] In particular, food safety standards have become the focus of World Trade Organisation (WTO)

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[220] David Nelken, *Using the Concept of Legal Culture*, 29 AUSTL. J. LEGAL PHIL. 1, 1 (2004).

[221] CLIFFORD GEERTZ, LOCAL KNOWLEDGE 214 (1993).

[222] Webber, *supra* note 56, at 36.

[223] CATHERINE BUTTON, THE POWER TO PROTECT: TRADE, HEALTH AND UNCERTAINTY IN THE WTO (2004).

settlement proceedings, and these disputes have been understood primarily in terms of the science/democracy dichotomy.[224] Disputes between two jurisdictions are thus usually understood as disputes over whether science or values should be the basis of food safety decision-making.[225] Yet if food safety is shaped and framed by administrative constitutionalism then this analysis is no longer valid. Not only can disputes between jurisdictions not be oversimplified this way, but such disputes must themselves be understood as forums for debating and sharing discourses of administrative constitutionalism.[226] This process of sharing and debating is not a straightforward one, and highlighting it underscores some difficult legal questions about globalisation.[227]

CONCLUSION

The theme of this Symposium is rethinking food safety crises. The rethinking that has been argued for in this article has been dramatic – the need to view food safety regulation and controversies through a very different lens – that of administrative constitutionalism. The nature of that rethinking was illustrated with two case studies both of which highlight the multidimensional and culturally bound notion of administrative constitutionalism.

The implications of this rethinking are also significant. Crises can no longer be explained in glib one-liners. Reform needs to be understood in more subtle terms, and is unlikely to lead to a perfect solution. All of that is sobering for the scholar and decision maker, as it is obvious that far more attention must be paid to legal culture and legal detail. Moreover, this rethinking highlights the fact there are unlikely to be any perfect solutions to the problems of food safety and that globalisation brings with it some difficult challenges.

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[224] Elizabeth Fisher, *Beyond the Science/Democracy Dichotomy: The World Trade Organisation Sanitary and Phytosanitary Agreement and Administrative Constitutionalism*, *in* CONSTITUTIONALISM, MULTILEVEL TRADE GOVERNANCE AND SOCIAL REGULATION 327, 349 (Christian Joerges & Ernst-Ulrich Petersmann eds., 2006); *see* FISHER, *supra* note 8, at 173-206.

[225] Howard Chang, *Risk Regulation, Endogenous Public Concerns, and the Hormones Dispute: Nothing to Fear but Fear Itself?*, 77 S. CAL. L. REV. 744, 745-46 (2004); Vern R. Walker, Keeping the WTO from Becoming the "World Trans-Science Organization": Scientific Uncertainty, Science Policy, and Factfinding in the Growth Hormones Dispute, 31 CORNELL INT'L L.J. 251, 252 (1998); Jonathan B. Wiener & Michael D. Rogers, *Comparing Precaution in the United States and Europe*, 5 J. RISK RES. 317, 320 (2002).

[226] *See* FISHER, *supra* note 8, at 173-206.

[227] *See id.* at 207-41.