Governing through Controversy: The Challenge of New Toxicological Methodologies

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Abstract

Building institutional and procedural bridges between science and policy is a vital role for law. Fundamental to the success of this work is the development of more sophisticated, nuanced understandings of scientific knowledge production than those which are current in legal and policy spheres. In this paper, I consider scientific controversies that have emerged in the field of human and environmental health impacts of endocrine disrupting chemicals (EDCs), notably around methodological approaches to identifying such chemicals and analysing the risks they pose. Building on literatures in the philosophy and sociology of science, I identify bases on which bridge-building between science and policy could proceed and discuss the role that legal normativity can play in those processes.

Keywords: Chemical risk, environmental policy, science policy, science studies

Résumé

La construction de ponts institutionnels et procéduraux entre la science et les politiques publiques est un rôle vital que joue le droit. Pour s'assurer du succès d'une telle construction, le développement d'une compréhension plus raffinée et plus nuancée de la production de connaissances scientifiques, comparativement à celle qui sont présentement en cours dans les sphères juridiques et politiques, est toutefois nécessaire. Dans cet article, j'examine les controverses scientifiques qui ont émergé dans la recherche portant sur les impacts des perturbateurs endocriniens sur la santé humaine et environnementale. Un intérêt particulier est accordé aux controverses entourant les approches méthodologiques utilisées pour identifier de tels produits chimiques et analyser les risques qu'ils présentent. En m'appuyant sur des écrits en philosophie et en sociologie des sciences, j'identifie les bases sur lesquelles la construction de ponts entre la science et la politique pourrait s'ériger, et je discute du rôle que la normativité juridique peut jouer dans un tel processus.

Mots clés: Risque chimique, politique environnementale, politique scientifique, *Science studies*

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I. Introduction

Political decisions and legal judgments regarding environmental and health risks posed by chemical substances depend heavily on inputs of scientific knowledge, yet the objectives and logics of politics, law, and science are different, and one cannot hope to bring them together seamlessly without significant investment in translation. Such processes of translation do not simply involve the movement of meaning from one system—science—to others—law and politics—but rather the reconstitution of meaning produced in one setting, and for one set of purposes, to another setting serving different purposes.[1] These processes are essential to all areas of policy, notably environmental and human health, that depend on inputs of expertise.

Regulatory toxicology is an excellent illustration of these processes of translation. Regulatory toxicology was developed with the need to provide policy-makers with scientific insights into the impacts of exposure to chemicals squarely in mind.[2] In addition to high-quality, reliable scientific findings based on well-accepted testing methodologies, policy-makers require a high degree of consistency across scientific studies.[3] This consistency is important for a range of policy objectives, many of which are relevant to the rule of law and legality, including like treatment of like cases, which fosters stability and predictability; even-handedness in reaching conclusions, which fosters fairness; and a degree of procedural transparency, which contributes to the legitimation of policy and regulatory decisions.

By the early 1990s, there was growing concern among scientists regarding the impacts of a range of substances (endocrine disrupting chemicals, or EDCs) on the endocrine systems of human and non-human animals.[4] As knowledge of these substances and their impacts grew, some scientists began to express concern about the suitability of conventional methodological approaches to detect endocrine-disrupting properties in chemicals and to understand their impacts on humans and ecosystems.[5] Among the various matters at stake in these debates is a raft of alternative approaches to toxicity testing developed over the past decades and

1 J. Ellis, "The Role of Translation in Transnational Governance," *Tilburg Law Review* 22 (2017): 165–84. Gunther Teubner's conception of "productive misreading" is particularly helpful in contemplating the ways in which meaning from one discipline or social system can be reconstructed in another, even if it must be acknowledged that the respective meanings are quite different: G. Teubner, "The Two Faces of Janus: Rethinking Legal Pluralism," *Cardozo Law Review* 13 (1991): 1443–62 at 1447, 1453ff.

2 H. Greim, "Aims and Mission of *Regulatory Toxicology*," in *Regulatory Toxicology*, ed. F.-X. Reichl and M. Schwenk (Cham: Springer, 2021), 3–22 at 3, 4–5.

3 K.-M. Wollin, S. Harston, and W. Lilenblum, "Quality Assurance in Toxicology," in *Regulatory Toxicology*, ed. F.-X. Reichl and M. Schwenk (Cham: Springer, 2021), 59–67 at 62ff; M. Mondou et al., "Factors Affecting the Perception of New Approach Methodologies (NAMs) in the Ecotoxicology Community," *Integrated Environmental Assessment and Management* 16 (2020): 269–81 at 269.

4 T. Colborn and C. Clement, *Chemically-induced Alterations in Sexual and Functional Development: The Wildlife/Human Connection* (Princeton: Princeton Scientific, 1992). See also World Health Organization, "Global Assessment of the State-of-the-Science of Endocrine Disruptors" (2002) (accessed 28 May 2022) and World Health Organization, *State of the Science of Endocrine Disrupting Chemicals* (2012).

5 L. N. Vandenberg, M. V. Maffini, C. Sonnenschein, B. S. Rubin, and A. M. Soto, "Bisphenol-A and the Great Divide: A Review of Controversies in the Field of Endocrine Disruption," *Endocrine Reviews* 30 (2009): 75–95.

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enjoying a period of rapid evolution, collectively referred to as New Approach Methodologies (NAMs). The relative novelty of many of these approaches means that scientists, regulatory agencies, and other stakeholders are often less familiar and therefore less comfortable with them than with the time-honoured conventional approaches involving the administration of large doses of substances to laboratory animals and extrapolation of results to environmental exposures in humans.

This is a fascinating, and fraught, moment in the science and governance of toxicity. Some observers argue that we are witnessing a paradigm shift à la Thomas Kuhn as NAMs gain increasing recognition as an acceptable—some would argue superior—means of gaining insight into the health and environmental risks posed by chemicals.[6] As scientific consensus begins to coalesce around a range of NAMs, and as the advantages of these methodologies become more apparent to regulators, the process of political acceptance of these methodologies enters the spotlight. Scientific acceptance is less likely today to generate political, let alone broader public, acceptance on its own, particularly in situations such as this in which there is a good deal of dissensus within the scientific community. The processes of scientific and political validation of NAMs therefore present opportunities for scientists and political authorities to develop new, potentially more robust approaches to building political and public confidence and trust in scientific inputs to the policy process, and for policy and legal scholars to examine these processes in action.

In this paper, I focus on two dimensions of the broad and complex process of bridge-building between science and policy which I believe are of particular relevance to jurists. First, there is a need to develop more nuanced and sophisticated understandings of the production of scientific knowledge among regulatory authorities and members of the public, understandings that reflect the need for scientists to exercise professional judgment. Second, certain of the practices, standards, and procedures on which scientists rely when making and justifying such judgments may have the capacity to travel beyond communities of scientists and provide regulatory authorities, stakeholders, and members of the public with a basis for developing confidence in the scientific inputs into regulatory processes.[7] Law has a range of potentially important roles to play in these bridge-building processes. First, in some instances, standards that scientific findings must meet in order to be deemed relevant to regulation may be inscribed in regulations. Jurists ought to think carefully about whether, and how, to legislate such standards: as the experience with regulation of EDCs indicates, elaborate and strictly applied standards may impede rather than foster interactions between scientists and regulators.

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6 M. E. Andersen and D. Krewski, "Toxicity Testing in the 21st Century: Bringing the Vision to Life," *Toxicological Sciences* 107 (2008): 324–30; E. J. Calabrese and L. A. Baldwin, "Toxicology Rethinks its Central Belief," *Nature* 421 (2003): 691–92; T. Hartung, "From Alternative Methods to a New Toxicology," *European Journal of Pharmaceutics and Biopharmaceutics* 77 (2011): 338–49 at 341; B. J. Blaauboer and M. E. Andersen, "The Need for a New Toxicity Testing and Risk Analysis Paradigm to Implement REACH or any other Large Scale Testing Initiative," *Archives of Toxicology* 81 (2007): 385–87 at 386.

7 W. Rehg, *Cogent Science in Context: The Science Wars, Argumentation Theory, and Habermas* (Cambridge, Mass.: MIT Press, 2009).

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Second, interactions between science and policy require attention to the procedural and institutional frameworks within which these interactions occur; once again, these are issues with which jurists have valuable experience and insight. Third, there are a number of features of robust and fruitful science–policy interactions that resonate with concepts of legality: as noted above, these include transparency, accountability, fairness, and due process.

II. Breaking New Ground: Canadian Regulation of Bisphenol-A

A key tenet of toxicology is the principle that substances that are harmless at low doses may be harmful at high doses. Toxicology is designed to provide insights into the thresholds beyond which exposure presents health and environmental risks and on which regulation of chemicals is based. This principle, in layperson's terms, is "the dose makes the poison."[8] However, some scientists argue that impacts on the endocrine system may be brought about by exposure to low doses.[9] Fundamental to toxicology is the *in vivo* study, involving the administration of high doses of substances to laboratory animals to roughly mimic human exposure to smaller doses over longer periods of time.[10] One of the advantages of such studies, as opposed to a cell culture or tissue sample, is that they generate insights into the impact on the whole organism of exposure to the substance under consideration.[11] However, many scientists point to problems and limitations, including the resources consumed by toxicological studies, the long time periods required to produce results, ethical concerns with the use of animals, and the limited insights derived from these studies regarding the manner in which the substance being tested causes the observed effects.[12] The huge numbers of chemicals in circulation and the rapid development of new chemical substances generate enormous information requirements: regulatory authorities need high-quality, reliable information on the impacts of these chemicals, but the time and expense of generating such information can be prohibitive. For these and other reasons, concerted efforts have been made to introduce alternative testing methodologies into regulatory decision-making processes. Some of these methodologies have been in use by scientists, and to some extent by regulatory authorities as well, for some time; others are novel, and their strengths and weaknesses are less well understood. While many scientists believe that these methods hold great promise for identifying and analyzing EDCs, and that they may in fact pose significant advantages over conventional toxicology

8 J. S. Bus and R. A. Becker, "Toxicity Testing in the 21st Century: A View from the Chemical Industry," *Toxicological Sciences* 112 (2009): 297–302 at 301; J. P. Myers, R. T. Zoeller, and F. S. vom Saal, "A Clash of Old and New Scientific Concepts in Toxicity, with Important Implications for Public Health," *Environmental Health Perspectives* 117 (2009): 1652–55.

9 D. Eaton and T. Vandivort, "General Overview of Toxicology," in *Comprehensive Toxicology*, ed. C. A. McQueen (Amsterdam: Elsevier, 2018), 1–38 at 8ff; S. Edge and J. Eyles, "Message in a Bottle: Claims Disputes and the Reconciliation of Precaution and Weight-of-Evidence in the Regulation of Risks from Bisphenol A in Canada," *Health, Risk & Society* 15 (2013): 432–48; Myers, Zoeller, and Saal, "A Clash."

10 Eaton and Vandivort, "General Overview," 32.

11 Greim, "Aims and Mission," 12.

12 T. Hartung, "Food for Thought… On Animal Tests," *ALTEX-Alternatives to Animal Experimentation* 25 (2008): 3–16; S. Scholz *et al.*, "A European Perspective on Alternatives to Animal Testing for Environmental Hazard Identification and Risk Assessment," *Regulatory Toxicology and Pharmacology* 67 (2013): 506–30.

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for public policy purposes,[13] other scientists defend conventional methods and cast doubt on novel approaches.[14]

Scientists are not without tools to address debates over methodology such as these. There is consensus regarding the criteria and standards that testing methodologies should meet, and on the considerations that guide the choice of methodology.[15] Because these choices are of great moment for regulatory decisions, governments, as well as intergovernmental organisations such as the Organisation for Economic Cooperation and Development (OECD), have also developed procedures and criteria for the recognition and acceptance of testing methodologies.[16] As we will see below, scientific consensus on these matters remains somewhat elusive, and the processes within and across regulatory agencies to validate additional testing methodologies and approaches can be long and painstaking. Nevertheless, as a brief discussion of the Canadian decision to ban one suspected EDC, bisphenol-A (BPA) in infant feeding bottles and certain other products will illustrate, regulatory agencies have found ways to move EDC policy forward.

Bisphenol-A is described by regulatory agencies as a high-volume chemical[17] to which humans are exposed mainly through food packaging.[18] It is bioavailable, meaning that it can accumulate in tissue, though most scientific data indicate that it has low potential to bioaccumulate and can be metabolized. The decision of the Canadian federal government to regulate the use of BPA in baby bottles and certain other products was taken in 2010,[19] by which time debates about methodology were already lively. Canada's regulatory decision broke new ground, being the first to restrict BPA. The decision was itself the product of a policy innovation, Canada's Chemicals Management Plan (CMP), introduced in 2006 with the object of

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13 Calabrese and Baldwin, "Toxicology Rethinks"; Myers, Zoeller, and Saal, "A Clash," 1652.

14 A. C. Gore *et al.*, "Policy Decisions on Endocrine Disruptors Should be Based on Science across Disciplines: A Response to Dietrich et al.," *Endocrinology* 154 (2013): 3957–60.

15 J. Bressler, A. Maertens, and P. Locke, "Alternative Testing Models for Testing Chemical Toxicity," in *Comprehensive Toxicology*, ed. C. A. McQueen (Amsterdam: Elsevier, 2018), 119–26 at 120ff.

16 P. Browne, L. Van Der Wal, and A. Gourmelon, "OECD Approaches and Considerations for Regulatory Evaluation of Endocrine Disruptors," *Molecular and Cellular Endocrinology* 504 (2020): 110675.

17 Environment Canada (as it was then known) and Health Canada estimated global production at four billion kilograms in 2006, with an estimated 12 million kilograms manufactured, imported, or in commerce in Canada in 1986: Environment Canada and Health Canada, *Screening Assessment for the Challenge: Phenol, 4,4" -(1-methylethylidene)bis- (Bisphenol A)* (2008), 5–6.

18 BPA is found in plastics used in drinking bottles, including infant feeding bottles, and other food contact materials: Government of Canada, *Bisphenol A (BPA)*, https://www.canada.ca/en/health-canada/services/home-garden-safety/bisphenol-bpa.html, last modified 29 July 2020, accessed 21 May 2022. BPA is listed by the European Chemical Agency (ECHA) as a substance of very high concern due to endocrine disrupting properties: European Chemicals Agency, *Assessment of Regulatory Needs for Bisphenols* (2021). Infant exposure is particularly high, and data indicate that fetuses and infants may be particularly vulnerable to BPA's effects (Environment Canada and Health Canada, *Screening Assessment for the Challenge: Phenol, 4,4" -(1-methylethylidene)bis-(Bisphenol A)*, ii.

19 *Hazardous Products Act* (RSC 1985, c H-3); Hazardous Products Regulations (SOR/2015-17); Order Amending Schedule I to the Hazardous Products Act (bisphenol A) 2010 (*Canada Gazette*, Part II). The European Union followed with its own ban on BPA in infant feeding bottles (Commission Directive 2011/8/EU of 28 January 2011), followed by regulations on BPA in all food contact materials (Commission Regulation (EU) 2018/213 of 12 February 2018) and restrictions on permitted concentrations in thermal paper (Commission Regulation (EU) 2016/2235 of 12 December 2016).

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meeting the obligation set out in the *Canadian Environmental Protection Act* to evaluate all substances in circulation in Canada for toxicity. Bisphenol-A was one of the substances prioritized for screening under the Challenge programme due to their potentially persistent, bioaccumulative, and/or toxic nature and likelihood of human exposure.[20] Maguire and Hardy note that the process launched by the CMP, involving the screening and categorizing of all chemical substances present within Canada in quantities above identified thresholds, represented a novel and highly ambitious approach, and this created certain challenges around justifying the decision to regulate BPA. They argue that communication about this decision included a series of activities which appear to normalize the processes through which BPA was assessed and eventually regulated, stressing continuity with long-standing processes of assessing and managing chemical risk.[21] However, the innovative nature of the CMP meant that the time-honoured way of doing things had also to be problematized, a process which Maguire and Hardy describe as involving "the reflexive acknowledgment of potential inadequacies in knowledge, discontinuity in organizational activities, and the use of open-ended deliberations as a basis for action." More specifically, in government communications and publications, certain substances are particularised, or singled out, for different treatment; reference is made to the innovative nature of risk assessment and management activities and approaches; questions are posed, with some being answered but others left open, gesturing sometimes in the direction of certainty and sometimes uncertainty; and the importance of plural points of view of a variety of stakeholders is acknowledged.[22] The Government of Canada made explicit reference to the innovative approach to risk assessment and the need for the development of methodologies to assess poorly understood substances.[23] It responded to criticisms that it was sacrificing rigour for politics in its interpretation of texts "not by denying that [the interpretations] were value-driven, but on grounds that they were—and *ought to be*—value-driven."[24] The government's weight-of-evidence approach led it to include a wide range of studies and data, including a number with various types of limitations that critics argued should have been excluded for lack of scientific rigour. These criticisms were addressed in a few

[20] C. Hardy and S. Maguire, "Organizations, Risk Translation, and the Ecology of Risks: The Discursive Construction of a Novel Risk," *Academy of Management Journal* 63 (2020): 685–716 at 696ff; M. Meek and V. Armstrong, "The Assessment and Management of Industrial Chemicals in Canada," in *Risk Assessment of Chemicals: An Introduction*, ed. C. J. van Leeuwen and T. G. Vermeire (New York: Springer, 2007), 591–621; Edge and Eyles, "Message in a Bottle," 434ff; Environment Canada and Health Canada, *Screening Assessment for the Challenge: Phenol, 4,4" -(1-methylethylidene)bis- (Bisphenol A)*, 1. BPA was of concern because of high levels of exposure and because it had been identified by the European Commission as having potential effects on reproduction: Environment Canada and Health Canada, *Screening Assessment for the Challenge: Phenol, 4,4" -(1-methylethylidene)bis- (Bisphenol A)*, 1.

[21] S. Maguire and C. Hardy, "Organizing Processes and the Construction of Risk: A Discursive Approach," *Academy of Management Journal* 56 (2013): 231–55 at 239ff.

[22] Maguire and Hardy, "Organizing Processes," 240ff.

[23] Government of Canada, *Summary of Public Comments Received on the Government of Canada's Draft Screening Assessment Report and Risk Management Scope on Bisphenol A (CAS RN 80-05-7)* (2008); cited in Maguire and Hardy, "Organizing Processes."

[24] Maguire and Hardy, "Organizing Processes," 247.

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different ways: by noting that the weight-of-evidence approach[25] was designed to account for the limitations of particular sources; by emphasizing the rigour and validity of other sources given greater weight in the overall assessment; and by drawing attention to the input of scientists with appropriate expertise.[26] There are, in short, dimensions of the government's communication that indicate that it was meeting the controversy head on. The regulatory decision was taken, as is permitted by the *Canadian Environmental Protection Act*,[27] on a precautionary basis, potentially giving the government a degree of cover in the event that scientific and societal consensus did not end up coalescing around low-dose effects of BPA and other EDCs.

III. Debates over New Approach Methodologies (NAMs)

The Canadian CMP highlights another difficulty that regulatory agencies face, namely the need to assess large numbers of chemical substances for toxic properties.[28] The scale and pace at which assessment of the risks posed by these chemicals must take place draw attention to further limitations that conventional toxicological methodologies present.[29] As a result of these concerns, scientists and political authorities have invested in the development of a suite of new methodologies, collectively referred to as NAMs.[30] The novelty of these methods means that scientists, regulatory agencies, and stakeholders tend to have much less experience or familiarity with them than with conventional toxicology, with implications for levels of confidence in them.

The debate between proponents and opponents of the proposition that EDCs can have effects at low doses has at times become quite bitter, drawing a modest

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[25] The weight-of-evidence approach will be familiar to jurists. It involves analysis of a wide range of studies and data, including those in which reviewers have relatively low levels of confidence, for example because the sample size is very small, or the methodology has limitations. Evaluations are made of the weight that different pieces of evidence should have, and the overall assessment takes these relative weights into account.

Health Canada defines weight of evidence as

> [a] qualitative measure that takes into account the nature and quality of scientific studies intended to examine the risk of an agent. Uncertainties that result from the incompleteness and unavailability of scientific data frequently require scientists to make inferences, assumptions, and judgements in order to characterize a risk. Making judgements about risk based on scientific information is called "evaluating the weight of evidence." (Health Canada, *Decision-Making Framework for Identifying, Assessing, and Managing Health Risks* (2000), 74)

For an overview of the use of weight of evidence by Health Canada, see T. Tao et al., *Weight of Evidence: General Principles and Current Applications at Health Canada* (Ottawa: Health Canada, 2019).

[26] Government of Canada, *Summary of Public Comments Received on the Government of Canada's Draft Screening Assessment Report and Risk Management Scope on Bisphenol A (CAS RN 80-05-7)*; cited in Maguire and Hardy, "Organizing Processes."

[27] *Canadian Environmental Protection Act, 1999*, SC 1999, c 33, preamble and s 2(1)(a).

[28] Hartung, "From Alternative Methods to a New Toxicology," 341.

[29] Mondou et al., "Factors Affecting," 269; N. Basu, D. Crump, J. Head, G. Hickey, N. Hogan, S. Maguire, J. Xia, and M. Hecker, "EcoToxChip: A Next-Generation Toxicogenomics Tool for Chemical Prioritization and Environmental Management," *Environmental Toxicology and Chemistry* 38 (2019): 279–88 at 280; Andersen and Krewski, "Toxicity Testing," 324; Blaauboer and Andersen, "New Toxicity Testing and Risk Analysis Paradigm," 386.

[30] Mondou et al., "Factors Affecting."

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amount of media attention.[31] The seriousness with which the objects of dispute were taken and the pains taken to reinforce the beliefs of one's own camp while criticizing those of the other may be due in part to perceptions on the part of scientists involved that their own reputations, the status of their work, and the perceived legitimacy of their theoretical and methodological approaches were at risk.[32] Another possible contributing factor is sets of assumptions, among scientists and non-scientists alike, regarding the nature of scientific knowledge. For instance, some contributions to scientific debates over EDC methodologies indicate that participants do not see disagreements as the result of different perspectives or interpretations, but as matters of right and wrong. Their own conclusions are portrayed as unproblematic, a natural consequence of adopting the appropriate theory or framework, whereas those reaching different conclusions or espousing different positions are described as lacking knowledge, understanding, or competence.[33] Diverging opinions are "traced back to the action of various 'non-scientific' factors, such as undue commitment to [a different model], a defensive attitude, prejudice, dislike and failure to put in enough effort." The account of the speaker's belief is "organized to show that the speakers' theoretical conclusions were a simple, unmediated response to the evidence, whereas those of their opponent were influenced by extraneous or non-cognitive considerations."[34]

These asymmetrical accounts of one's own and others' beliefs is in evidence in the rhetorical strategies used in an exchange between two groups of scientists referred to as the "Dietrich v. Gore letters."[35] The methodology employed by the other camp is not merely described as having limitations or weaknesses; it is treated as inadequate for the phenomenon under investigation or even unscientific.[36] Studies cited in support of a proposition do not simply contain limitations or flaws; they are deemed worthless or irrelevant.[37] Arguments or conclusions are not insufficiently supported; they are said to be without foundation.[38] The accusation is levelled by one group of scientists that members of the other group have missed important developments in scientific knowledge, do not understand contrary positions, or have no knowledge of relevant disciplines or sub-disciplines.[39] Certain

[31] P. Basken, "In Chemical Regulatory Fight, Journal Editorials Are New Battleground," *Chronicle of Higher Education* (September 18, 2013); J. Girling, "The Junk-Science Threat to Free Trade," *Wall Street Journal* (January 23, 2014).

[32] Hardy and Maguire, "Organizations," 692ff.

[33] Mulkay and Gilbert argue that this is a pattern detected in scientific accounts of disagreement: M. Mulkay and G. N. Gilbert, "Accounting for Error: How Scientists Construct Their Social World When They Account for Correct and Incorrect Belief," *Sociology* 16 (1982): 165–83 at 167ff.

[34] Mulkay and Gilbert, "Accounting for Error," 168.

[35] Gore et al., "Policy Decisions,"; D. R. Dietrich, S. von Aulock, H. Marquardt, B. Blaauboer, W. Dekant, J. Kehrer, J. Hengstler, A. Collier, G. Batta Gori, O. Pelkonen, F. Lang, F. A. Barile, F. P. Nijkamp, K. Stemmer, A. Li, K. Savolainen, A. W. Hayes, N. Gooderham, and A. Harvey, "Editorial: Scientifically Unfounded Precaution Drives European Commission's Recommendations on EDC Regulation, While Defying Common Sense, Well-Established Science and Risk Assessment Principles," *Food and Chemical Toxicology* 62 (2013): A1–4; Mondou et al., "Factors Affecting," 278.

[36] Hardy and Maguire, "Organizations," 693.

[37] Dietrich et al., "Editorial: Scientifically Unfounded Precaution," A1.

[38] Gore et al., "Policy Decisions," 3957.

[39] Dietrich et al., "Editorial: Scientifically Unfounded Precaution," A1. This text was published in a different journal as an open letter to the European Commission: D. Dietrich et al., "Open letter to

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scientists have also criticized colleagues for allowing politics to get in the way of science.[40] Indeed, some have even accused political authorities of doing so when making regulatory decisions.[41] In short, rival beliefs were often not understood as flowing from the very nature of the scientific enterprise, but as resulting from psychological or cultural distortions.[42]

These kinds of controversies over policy-relevant scientific knowledge are profoundly unsettling to members of the public, particularly in light of certain received notions about the nature of scientific knowledge production. At crucial moments such as this one, the nature of popular conceptions of scientific knowledge can pose significant challenges for trust-building across scientific and non-scientific communities. All scientific methodologies demand that scientists reach decisions and make judgments, interpret and infer, but if members of the public generally view science as an objective process of representing reality and producing facts, public discussion of these exercises of professional judgment and of disagreement over them may foster conclusions that some scientists are not behaving in the appropriate, impersonal disinterested manner. The impact of these perceptions will be heightened if other scientists assert that they themselves are *not* exercising judgment but simply making objective observations to which they are led through rigorous application of "the" scientific method.

As Mondou et al. observe, regulatory (as distinct from scientific) acceptance of NAMs as an appropriate means to assess toxicity is fostered by perceptions that a given methodology is relevant, meaning that it answers the questions that regulatory agencies need to address and generally advances regulators' mandated objectives, and is reliable. Reliability is mainly a matter for scientific validation, but perceptions of reliability may be increased by the availability of documentation providing instructions and guidance for the correct execution of the methodology.[43] However, the authors also refer to a series of organizational and institutional factors that may facilitate or weaken acceptance of NAMs.[44] In an investigation into the role of various such factors, the authors found that familiarity with particular methodologies was associated with favourable perceptions of their viability.[45] In this regard, the authors pointed to statistically significant differences in perceptions between academics and non-academics of certain categories of NAMs. Non-academics, working in industry and government, were more comfortable with a

the European Commission: Scientifically Unfounded Precaution Drives European Commission's Recommendations on EDC Regulation, While Defying Common Sense, Well-Established Science and Risk Assessment Principles," *Archives of Toxicology* 87 (2013): 1739–41.

40 Maguire and Hardy, "Organizing Processes," 693ff.

41 Dietrich et al., "Open Letter to the European Commission"; Dietrich et al., "Editorial: Scientifically Unfounded Precaution."

42 S. Yearley, *Making Sense of Science: Understanding the Social Study of Science* (London: SAGE, 2005), chapter 6; G. N. Gilbert and M. J. Mulkay, *Opening Pandora's Box: A Sociological Analysis of Scientists' Discourse* (Cambridge: Cambridge University Press, 1984); Mulkay and Gilbert, "Accounting for Error."

43 Mondou et al., "Factors Affecting," 270; R. J. Kavlock, T. Bahadori, T. S. Barton-Maclaren, M. R. Gwinn, M. Rasenberg, and R. S. Thomas, "Accelerating the Pace of Chemical Risk Assessment," *Chemical Research in Toxicology* 31 (2018): 287–90.

44 Mondou et al., "Factors Affecting," 270.

45 Mondou et al., "Factors Affecting," 275.

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particular category of NAMs known as quantitative structure-activity relationship (QSAR) models,[46] which are being used more frequently in industry and government in Europe and have long been used in those contexts in North America. Furthermore, QSAR models are supported by the Organization for Economic Cooperation and Development (OECD). Another set of NAMs known collectively as omics[47] have received a good deal of attention in academic literature. Omics are well adapted to the hypothesis-driven approach in academic science in which a main objective is the advancement of knowledge—they permit inquiry into the impacts of chemical substances of complex biological systems—but their openness to complexity may pose problems in a regulatory context. Regulatory decision-making must attend to procedural fairness: decisions ought to be "consistent, predictable, and explainable." This is difficult to achieve with omics-based approaches.[48]

Generally supporting these findings are further findings on the impact of cohort on perceptions of the viability of NAMs: recent graduates are more accepting than those having graduated earlier, which could be explained by greater exposure during degree programs to certain NAMs for more recent graduates, given that NAMs tend to be developed in academic research environments. Older scientists would have been less likely to have been exposed to them during their studies and would be unlikely to have had much exposure in the context of professional careers in industry or government. Overall, in the words of the authors, "[t]he findings demonstrated strong support for the expectation that the more knowledgeable an individual was regarding a given test method, the more she or he found such a test method viable, again reinforcing the 'pattern of familiarity' interpretation."[49]

Lack of familiarity with a testing method creates problems on a pragmatic level that have implications for the kinds of errors that professionals are likely to commit. Conventional methods having been around for a very long time, professionals have personal and institutional experience with them and are in a better position to exercise with confidence their professional judgment in the face of uncertainty or ambiguity. As the authors note, "[t]hese social and reputational dynamics, along with concern for error cost, generate inertia in regulatory science [and] exert pressure toward the perpetuation of status quo."[50]

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46 Quantitative Structure-Activity Relationship (QSAR) approaches are methodologies that identify substances of similar structure to known toxins and thus permit predictions of toxicity based on the physicochemical properties of substances. QSARs make use of computer programs and can integrate machine learning to permit the rapid processing of large amounts of data: National Research Council (NRC), *Toxicity Testing in the 21st Century: A Vision and a Strategy* (Washington, D.C.: National Academies Press, 2007), 69.

47 Omics technologies are molecular testing methods that permit the analysis of large numbers of genes, proteins, and metabolites. They provide information on the mechanisms through which substances affect organisms, going beyond the type of information that whole animal experiments reveal, namely a health outcome such as cancer or reproductive problems: M. Kroeger, "How Omics Technologies Can Contribute to the "3R" Principles by Introducing New Strategies in Animal Testing," *Trends in Biotechnology* 24 (2006): 343–46 at 345.

48 Mondou et al., "Factors Affecting," 276.

49 Mondou et al., "Factors Affecting," 276–78.

50 Mondou et al., "Factors Affecting," 276-8.

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Of particular interest is the authors' finding that "paradigmatic beliefs about environmental toxicology" do not appear to have much influence over perception of NAMs. The authors sought to investigate these beliefs through questions about the accuracy, appropriateness, or truth of a series of propositions regarding toxicology. It had been predicted that adherence to principles and maxims of conventional toxicology would correlate to scepticism about NAMs, but this did not appear to be the case.[51] In light of the bitterness to which the debate has at times descended, this suggests that the impasse between camps drawn from toxicology and endocrinology may either resolve itself or pose less of an obstacle over time to scientific and regulatory change.

IV. New Approach Methodologies: Addressing Science-Policy Communication Gaps

In addition to the need for scientific validation of these methods, trust and confidence on the part of political authorities and stakeholders must be established. Some scientists refer to this process as "post-validation," arguing that it is more difficult to manage than validation within scientific communities.[52] Because of the different languages, logics, and objectives of science and policy, communication about the merits of these methodologies must be structured in ways that differ significantly from those used for validation of methodologies among scientists. The exercise amounts to one of trust-building across communities. One possible basis of trust in science could be a belief that scientists have the means to get at the truth; when they deploy their methodologies properly and honestly, they are, quite simply, right. Another basis relates not to truth but to procedure: rigorous procedures scrupulously followed might produce results in which we may have confidence because adherence to those procedures creates assurances that the scientists have not followed their own inclinations and preferences in reaching results. These two bases of trust correspond to two of the many possible meanings of objectivity, namely absolute—objectivity as truth—and procedural—objectivity as the impersonal production of knowledge.

Science being a human enterprise, it cannot provide us with universally valid truth, but scientists and non-scientists alike require means for ensuring, and receiving assurance, that high standards are adhered to in the production of scientific knowledge. What exactly those standards should be will depend on the objectives of those who rely on scientific evidence. These objectives will virtually always require scientific knowledge to be objective, in the sense of impersonal or disinterested, which in turn will require adherence to certain procedures and standards in the production of that knowledge. These standards will in turn depend

[51] Three such hypotheses were: "'Whole animal studies are the best way to understand the integrated way in which biological systems work;' 'The maxim "the dose makes the poison" is an accurate guide for testing all chemicals;' [and] 'All adverse outcomes originate from a molecular-level event:'"; Mondou et al., "Factors Affecting."

[52] A. A. Bottini *et al.*, "Optimisation of the Post-Validation Process: The Report and Recommendations of ECVAM Workshop 67," *ATLA: Alternatives to Laboratory Animals* 36 (2008): 353–66 at 361.

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on the confidence that stakeholders place in them. Individual scientists and scientific teams must exercise judgment at multiple points in their investigations, and other scientists must then reach judgment on the validity and reliability of the resulting conclusions and findings. As William Rehg argues, the practices, procedures, and standards on which scientists rely in reaching conclusions about the cogency of scientific findings can inform the building of bridges between scientific communities and bodies that rely on scientific inputs, notably regulatory authorities.[53]

Building these bridges requires a degree of insight among non-scientists, including regulatory authorities and members of the public, into the nature of scientific knowledge and the processes through which that knowledge is constituted. The objective is not to transform everyone into a proto-scientist but, rather, to foster a more nuanced perspective of scientific knowledge, one that acknowledges and accepts the role played by professional judgments at every stage of the scientific enterprise. The significance of judgment problematizes commonly held conceptions of science as comprised of objective knowledge of the world as it "really" is, and of scientists as mere observers and reporters of that reality rather than as constitutors and creators of scientific knowledge. This problematization can be destabilizing, potentially sowing doubts about the solidity and reliability of science. However, awareness of the role of judgment in the constitution of scientific knowledge also has the potential to foster awareness of the strong connections between scientific knowledge and other forms of knowledge and of the potential for fruitful interactions among those forms of knowledge. The practices, norms, and standards used by scientists to structure their exercises of judgment and to promote confidence within scientific communities in the findings and conclusions that issue from those judgments provide promising foundations for bridge-building between science and politics. Legal normativity has a vital role to play in structuring and organizing interactions between science and policy. Good laboratory practice (GLP), which involves highly structured methodology subject to detailed guidelines rigorously respected, is an example of a standard that serves to build bridges between science and policy.[54] Strict implementation of GLP produces highly consistent results across studies and laboratories, but it may produce the impression that the point of such standards is to reduce to a strict minimum the scope for scientists to exercise judgment. Opinion will certainly differ on the matter, but GLP has been criticized for placing too much emphasis on the standardized production of highly replicable results at the expense of robust and far-reaching assessment of health and environmental hazards.

The conception of science that, in the opinion of many observers, stands to be problematized bears a number of features. As noted above, at its heart is an assumption that scientists report on an objective reality that they observe.[55] To

[53] Rehg, *Cogent Science in Context*, 163ff.

[54] OECD, Principles of Good Laboratory Practice (GLP) and GLP Compliance Monitoring, https://www.oecd.org/chemicalsafety/testing/overview-of-good-laboratory-practice.htm (accessed 16 July 2002).

[55] P. Frank, "The Variety of Reasons for the Acceptance of Scientific Theories," in *The Validation of Scientific Theories*, ed. P. Frank (Boston: Beacon Press, 1956), 13–26 at 21–22.

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be objective in this manner is to proceed without reference to values or, more precisely, to make reference only to a certain category of epistemic values, designed to ensure rigour. These epistemic values are seen to be distinct from social or ethical values, which, according to this conception of science, should be kept carefully at bay.[56] Separating the production of scientific knowledge from the rest of society aims in particular to protect science from politics,[57] an obviously difficult task in fields such as endocrinology and toxicology that provide vital insights into health and environmental risks. One means to this end is to defer altogether to scientists in the establishment of standards for the production of high-quality scientific knowledge. This imperative follows of necessity if one views scientific research as distinct from other forms of human knowledge, since non-scientists would generally have nothing of value to say on the identification and selection of such standards. This sharp separation between science and society and dedication to the maintenance of scientific freedom and independence are cornerstones of the post-war science policy of the United States federal government, proposed by Vannevar Bush, Director of the Office of Scientific Research and Development, in the mid-1940s.[58] This approach is presented by Bruno Latour as based on two constitutions, one structuring and organizing the domain of scientific research and the other the political domain. Essential to this arrangement is a kind of bargain between science and politics: the political sphere guarantees independence and financial and other resources, and the scientific sphere produces both material benefits and facts upon which public policy can be built.[59] Isolation of science from the rest of society was key to this approach, permitting non-scientists, including political authorities, to view the "facts" that the scientific community threw over the wall into the social and political spheres as unproblematic.[60]

Heather Douglas describes debates among science policy experts and philosophers of science on the status of science as value-free, noting that this position was not particularly well-accepted in the 1940s and only came to be the object of consensus in the 1960s.[61] In the immediate post-war period, there was a good deal of support for the contention that the production of scientific knowledge is shaped and conditioned by social values and, moreover, that the promotion of those values within the broader society is important to their promotion within scientific communities.[62] On this conception, standards and guidelines governing the production of scientific knowledge could readily be negotiated between scientists and

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56 I. Levi, "Must the Scientist Make Value Judgments?" *Journal of Philosophy* 57 (1960): 345–57; H. E. Douglas, *Science, Policy, and the Value-Free Ideal* (Pittsburgh: University of Pittsburgh Press, 2009), 55ff.

57 Douglas, *Science, Policy, and the Value-Free Ideal*, 44ff.

58 V. Bush, *Science – The Endless Frontier: A Report to the President on a Program for Postwar Scientific Research* (1945; repr. Alexandria, Va.: National Science Foundation, 1990), 32ff.

59 B. Latour, *Nous n'avons jamais été modernes : Essai d'anthropologie* (Paris: La Découverte, 2006), 23ff.

60 Douglas, *Science, Policy, and the Value-Free Ideal*, 46; Latour, *Nous n'avons jamais été modernes.*

61 Douglas, *Science, Policy, and the Value-Free Ideal*, chapter 3.

62 This was the view held by the highly influential sociologist of science, Robert K. Merton: "The Normative Structure of Science" (1942), reprinted in R. K. Merton, *The Sociology of Science: Theoretical and Empirical Investigations* (Chicago: University of Chicago Press, 1973), 270; Douglas, *Science, Policy, and the Value-Free Ideal*, 46ff.

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policy-makers, with one eye on the production of high-quality, reliable, and rigorous scientific knowledge and the other on the needs of policy-makers and, by extension, those of their constituents. Before taking a closer look at these standards, we turn to the concept of objectivity, addressing the question of whether scientific knowledge production not carefully protected from the effect of ethical and social values can be considered objective, and therefore a suitable basis for the crafting of health and environmental law and policy.

Two contending ways of understanding objectivity will be considered here: absolute and procedural.[63] Absolute objectivity is often understood to mean representing things as they really are, but given the inaccessibility of a view from nowhere, is better understood as a representation of things as they really are that meet rigorous criteria of validity. Allan Megill describes absolute objectivity as "present[ing] itself as absolute not in its certitude or infallibility, but rather in the hold that it ought to have on us as rational beings."[64] Procedural (or impersonal) objectivity, by contrast, is defined not so much in alignment with truth as with rule-following. Knowledge derived through the application of procedural, notably methodological, standards is not subjective, that is, not dependent on the vicissitudes of individual preferences, interests, and blind spots.[65] Helen Longino makes a similar distinction between these two meanings of objectivity, describing the second sense as relating to modes of inquiry, flowing from the claim that "the view provided by science is one achieved by reliance upon nonarbitrary and nonsubjective criteria for developing, accepting, and rejecting the hypothesis and theories that make up the view."[66] These criteria are important for scientists as they reach conclusions and make assessments of one another's work, but criteria of this general nature are important in public policy as well, since regulatory decisions drawing on scientific insight have immense implications for regulated actors and members of the public generally.

Michael Porter argues that there is a close relationship between the motivations behind the use of standardized, carefully defined scientific methodologies, on one hand, and rule of law, on the other. Rigorous adherence to protocols provides

[63] A. Megill, "Introduction: Four Senses of Objectivity," in *Rethinking Objectivity*, ed. A. Megill (Durham, N.C.: Duke University Press, 1994), 1–20 at 1. The two that will not be considered in detail here, but which are nevertheless relevant, are disciplinary objectivity, referring to a consensus among members of research communities; and dialectical objectivity, which addresses interplay between subject and object and thus leaves scope for the subjectivity of the observer: Megill, "Introduction," 1. See also T. M. Porter, *Trust in Numbers: The Pursuit of Objectivity in Science and Public Life* (Princeton: Princeton University Press, 2001), 74., who refers to the two meanings of particular interest here as objectivity as truth and objectivity as impersonality.

Procedural objectivity is referred to by Porter as impersonal objectivity. This is a useful term as it well represents what this form of objectivity aims to achieve; however, because my focus here is on the use of conventions and standards in the production of scientific knowledge, placing heavy emphasis on procedure, I will use the term procedural objectivity. See also H. Douglas, "Rejecting the Ideal of Value-Free Science," in *Value-Free Science? Ideals and Illusions*, ed. H. Kincaid, John Durpré and Alison Wylie (Oxford: Oxford University Press, 2007).

[64] Megill, "Introduction," 2–3.

[65] T. M. Porter, "Objectivity as Standardization: The Rhetoric of Impersonality in Measurement, Statistics, and Cost-Benefit Analysis," in *Rethinking Objectivity*, ed. A. Megill (Durham, N.C.: Duke University Press, 1994), 197–237 at 197–98.

[66] H. E. Longino, *Science as Social Knowledge: Values and Objectivity in Scientific Inquiry* (Princeton: Princeton University Press, 1990), 63.

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assurances that results are not driven by the researcher's personal preferences. Reducing the scope for discretion in the making of decisions, particularly in the field of public policy, is associated as well with democratic principles: as Porter puts it, "[i]neffable judgment is a highly undemocratic form of expertise."[67] The trust that an official bestows on the judgment of experts may depend on the strength of the personal relationship between expert and official, and decisions based on judgment derive some of their authority from that of the judging agent or body. If an expert enjoys the personal trust of those she is advising, or if the authority of a decision-making body is firmly grounded and highly respected, a broad measure of discretion may be granted; where, however, personal trust is not present or where authority is not granted blindly, means to hold experts and decision-makers to account are sought.[68] One such means is to subject exercises of data-gathering and data-analysis to guidelines and standards, such that exercises of discretion and making judgments are disciplined and structured to some extent. However, these standards can come to be relied on too heavily, influenced by the "ideal [of] a withdrawal of human agency,…avoid[ing] the responsibility created by active intervention." The development of highly structured procedures and methodologies of risk analysis is presented as an example of a research specialty created to provide "an especially rigorous and objective form of knowledge." In this context, great deference is paid to experts and expertise, but what is expected is not that experts shall exercise professional judgment but that they should follow rules. Porter acknowledges that the objective is not actually to eliminate judgment from regulatory decision-making; however, "there is a strong incentive to systematize [value judgments], so they will be applied uniformly, and to isolate them so they do not corrupt the process of establishing scientific facts."[69] The argument made by many scientists is that the standards and norms that structure conventional toxicology tip the balance too far. Strict adherence to GLP may create the impression that scientific conclusions are produced not so much by scientists as by methods and protocols, but arguably those conclusions are based on methodologies that are so narrowly constructed that they do not permit appropriate examination of the phenomena they were created to analyze. The incorporation of a wider range of data and findings, including those produced by novel or non-conventional methodologies, would provide regulatory agencies with more insights into the potential risks of EDCs, but it also requires renewed investment in bridge-building between science and policy in order to foster confidence in the robustness and reliability of scientific inputs and the validity of policy and regulatory decisions.

These kinds of trade-offs between getting closer to the truth and ensuring procedural rigour will be familiar to jurists. The standard of proof in civil liability, the balance of probabilities, is indicative of a fairly high tolerance for false positives, or type II error, corrected to some extent by devices such as legal causation and the duty of care. The rather large chances of error can be justified in a number of ways. For example, depending on practical rather than scientific reasoning in

[67] Porter, *Trust in Numbers*, 80.
[68] Porter, *Trust in Numbers*, 81.
[69] Porter, *Trust in Numbers*, 195–97.

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demonstrating causation means that decisions about causation may be made by finders of fact without deferring excessively to experts whose testimony is difficult for laypersons to evaluate. This is arguably appropriate, in that turning questions of causation into scientific rather than legal matters would make it more difficult for causation to be viewed through a normative lens, with the result that legal causation may lose its mooring in normatively-tinged questions of responsibility and the appropriateness of shifting burdens of loss from plaintiffs to defendants. Another factor, however, has to do with the even-handedness of the application of legal principles: all civil liability cases are meant to be handled in the same way, and all parties are supposed to face the same risks of error. Further elimination of error must be balanced against the even-handedness, fairness, and procedural objectivity of the process, which require interpretation, discretion, and judgment rather than simply mechanical rule-following.

There is some evidence that judges are uncomfortable with the exercise of individual judgment, even in contexts in which the flexibility of opting for greater latitude for the exercise of judgment would produce better outcomes than reliance on a mechanical solution or strict procedure. As Cooter and Porat argue, "[t]echnology is sometimes more effective than manpower in avoiding accidents, and sometimes the opposite is true. In either case, courts are more likely to find fault when humans lapse than when machines that are reasonably maintained fail." Similarly, Cooter and Porat note that organizations that promote standardization over discretion are less likely to be found liable for accidents, even if accidents tend under those circumstances to be more frequent.[70] This is not dissimilar to the tendency for regulatory agencies to prefer tried-and-true methodologies over less familiar ones that promise to produce more relevant information about health and environmental risks. Rules and standards can reduce error up to a certain point, but beyond that point, they may actually increase the chances of error. In complex contexts, the best way to reduce error further may well be to allow those executing tasks to exercise a degree of discretion. Discretion increases the opportunity for lapses in judgment or execution and increases the likelihood of variation in decisions and actions. Therefore, the balance to be struck between standardization and discretion will depend to a great extent on assessments of the value of different overall outcomes. Standardization produces greater consistency in decision and execution but, beyond a certain point, may promote superficial investigations and reasoning.

An important desideratum of proponents of value-free science is an account of the process of confirming or refuting hypotheses that is rational, logical, and objective. William Rehg describes the efforts of philosophers of science to reconstruct this process in formal-logical terms, notably by devising quantitative models that would determine the degree of confirmation of a hypothesis. Rehg describes their objective as an account of confirmation or refutation that would be objective, not dependent on an individual scientist's intuition.[71] Thomas Kuhn focused

[70] Porter, *Trust in Numbers*, 68–70.
[71] Rehg, *Cogent Science in Context*, 39–40.

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instead on the practice of science itself. This approach created a gap between, "on the one side, analyses of cogent argument in terms of formal or substantive properties of the product of argumentation; on the other, a focus on the social-institutional contexts and process from which cogent arguments emerge."[72] The focus on the social-institutional context could be analyzed in a prescriptive sense, seeking to identify practices, standards, and norms that govern or guide the production of scientific knowledge, or that analysis could be purely descriptive. If the latter, there would be no basis on which an observer could distinguish between good or better arguments. Differences of opinion between proponents of conventional toxicological methodology and proponents of NAMs could be described and analyzed, but such analysis would be unlikely to help regulatory authorities or other non-scientists make assessments of the relative merits of these positions. Kuhn himself supported a prescriptive approach, which, on the one hand, allowed that scientists rely on certain epistemic values, such as accuracy, consistency, explanatory scope, simplicity, and fruitfulness,[73] but, on the other hand, left the identification and implementation of such values to the scientific community: "[t]he community [of scientists] as a *socially organized whole* provides the argumentative norm for good science" (emphasis in original). If, as many have argued, debates over appropriate methodological approaches for identifying and analysing EDCs are in fact debates over Kuhnian paradigms, then regulatory authorities may be obliged to simply wait until the dust settles and a consensus emerges.[74] Alternatively, one could look, as Rehg does, for means to extend the standards and norms on the basis of which the cogency of scientific arguments is assessed from scientific to policy spheres or, perhaps more accurately, to reconstruct these standards for regulatory purposes. Unlike Kuhn, Rehg argues that the epistemic values on which scientists rely have the capacity to travel beyond the scientific community. This is because the assessment of the cogency of a scientific finding is not only a logical but a dialectical process: "cogent arguments should stand up to critical challenges in open debate." Because collaborating scientists bring different expertise to their projects, they rely not only on their own assessments of one another's work but on the procedures that were followed:[75] this is essential if scientific findings are to be justifiable not only locally, among the members of a specialized sub-discipline, but to a broader audience. However, Rehg notes, the procedures relied on to provide assurance of the cogency of scientific conclusions and their justifications cannot be fixed and permanent; rather, they take different shapes depending on the context.[76] This is another reason to seek to identify epistemic values that not only resonate with non-scientific audiences but can be constituted within networks whose members include scientists, regulatory authorities, regulated actors, and members of the public. For this to occur, however,

[72] Rehg, *Cogent Science in Context*, 53.
[73] T. S. Kuhn, *The Essential Tension: Selected Studies in Scientific Tradition and Change* (Chicago: University of Chicago Press, 1977), 321–22.
[74] Rehg, *Cogent Science in Context*, 49ff.
[75] Rehg, *Cogent Science in Context*, 182.
[76] Rehg, *Cogent Science in Context*, 225–26, 231.

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both scientists and non-scientists will need to accept a conception of scientific knowledge and its production that makes room for the exercise of professional judgment, which in turn takes into account not only narrowly defined epistemic values but also broader social values.

Recent research by teams of scientists and social scientists on acceptance of NAMs highlights the importance of non-epistemic factors in fostering this acceptance. For example, familiarity may foster confidence. Observers have argued that this process could be accelerated by policies aimed at introducing NAMs into regulatory decision-making without making the outcomes of decision-making processes depend heavily on them. QSAR and other NAMs are very useful in screening processes to establish lists of substances to be prioritized for more careful scrutiny.[77] A range of initiatives have been proposed to promote acceptance of NAMs by both scientists and regulatory authorities, including the identification of barriers to acceptance,[78] workshops and similar events to share knowledge and educate participants,[79] and mandating the use of NAMs in regulatory decision-making processes, even if very little reliance on their results may initially be present.[80]

Efforts on the part of governmental and intergovernmental organizations, notably the United States National Research Council[81] and the OECD,[82] to develop and promote new approaches to testing for endocrine activity have a variety of aims, one of which is to promote understanding of and confidence in NAMs.[83] Part of this effort involves scientific validation, but research indicates that confidence is not generated on the basis of scientific acceptance alone. Mondou and colleagues argue that, beyond information about EDCs and NAMs, researchers and regulators need to develop a common language. They call for "a network of trust and cooperation…creating links where validity and measurement are communicated and transferred." Importantly, they argue that this network must incorporate not only scientists, both in academia and in regulatory agencies, but also regulatory agencies, regulated actors—including firms that produce and use chemicals—and members of the public.[84]

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77 V. Zaunbrecher, E. Beryt, D. Parodi, D. Telesca, J. Doherty, T. Malloy, and P. Allard, "Has Toxicity Testing Moved into the 21st century? A Survey and Analysis of Perceptions in the Field of Toxicology," *Environmental Health Perspectives* 125 (2017): 087024 at 8.

78 Zaunbrecher et al., "Toxicity Testing"; Kavlock et al., "Accelerating the Pace"; Mondou et al., "Factors Affecting."

79 Mondou et al., "Factors Affecting," 279; Kavlock et al., "Accelerating the Pace," 288ff.

80 Zaunbrecher et al., "Toxicity Testing."

81 The National Research Council's innovative and highly influential approach involves a more structured, organized means of generating data and integrating it into a framework for analysis: NRC, *Toxicity Testing in the 21st Century*; Andersen and Krewski, "Toxicity Testing."

82 The OECD established a Special Activity on Endocrine Disrupter Testing and Assessment in 1996 with the objective of promoting the development of test guidelines for endocrine activity: OECD, *Detailed Review Paper on the State of the Science on Novel* In Virtro *and* In Vivo *Screening and Testing Methods and Endpoints for Evaluating Endocrine Disruptors,* ENV/JM/MONO(2012)23, 21 August 2012 at 33.

83 M. Mondou, S. Maguire, G. Pain, D. Crump, M. Hecker, N. Basu, and G. M. Hickey, "Envisioning an International Validation Process for New Approach Methodologies in Chemical Hazard and Risk Assessment," *Environmental Advances* 4 (2021): 100061 at 2.

84 Mondou et al., "Envisioning an International Validation Process," 8–10.

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V. Concluding Remarks: Why This Matters for Law

Received wisdom on the production of scientific knowledge assumes that rule-following, in the form of scrupulous adherence to approved method, is central to the process. Similarly, received wisdom on the production of legal conclusions tends to place much greater emphasis on the syllogistic application of rules to facts than on the process of judgment. In each case, processes of weighing evidence and evaluating and assessing possible conclusions are in fact much more complex. In both law and science, rule-following is an important part of the process of generating conclusions, but the exercise of judgment cannot be avoided; indeed, it is necessary in order to bring about an appropriate adaptation and application of the rules to a particular case. Other means must therefore be found to promote confidence in the soundness of reasoning and conclusions. Objectivity as impersonality is an important dimension of this confidence-generating process. Strict adherence to detailed rules may be one way to promote such objectivity, but, as we have seen, it generates costs as well: more sophisticated approaches that provide richer and more detailed information and are better adapted to individual problems cannot be applied without the exercise of professional judgment. Furthermore, proceduralization and standardization are not the only means to foster objectivity as independence. In law, reason-giving is an important approach, but the reasons operate in logical *and* rhetorical ways to persuade interlocutors.

Jurists with expertise in the regulation of toxic substances will be among the actors exercising influence on the opinions, attitudes, and approaches of regulatory authorities and stakeholders to NAMs, and it is therefore important to promote sophisticated understandings of the relative strengths and merits of conventional toxicology and NAMs, as well as more nuanced approaches to the nature of scientific contributions to public policy and regulation. Jurists will also be particularly well-positioned to propose potential contributions of law to structuring and shaping the processes of communication and trust-building between law and policy, as well as the decision-making processes through which scientific and policy considerations are brought together.

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