Foreword

Missing Information: The Scientific Data Gap in Conservation and Chemical Regulation

JOHN S. APPLEGATE[*] & ROBERT L. FISCHMAN[**]

Scientific information has become a central rationale for environmental regulation, and scientific uncertainty is viewed as a major obstacle in developing, justifying, and enforcing environmental laws and policies. In the context of environmental regulation, scientific information may be analyzed as subject to both supply and demand. A regulatory system that supplies more scientific information than it demands can operate effectively to impose protective regulation. By contrast, a system that demands more information than it supplies will face a "data gap" and will fail to accomplish its protective goals. The data gap can be addressed by applying regulatory techniques that increase the supply of data by providing more information ("filling" the gap) or that reduce the demand by permitting regulation to proceed despite uncertainty and incomplete information ("bridging" the gap).

Environmental law is also structured by the divide between pollution control and chemical regulation on the one hand, and resource management on the other. In addressing the data gap, therefore, it is necessary to distinguish not only between supply and demand, but also between chemical and conservation issues. The existence of a data gap between the scientific information necessary for effective environmental regulation and the information available to regulators and the public presents an opportunity to study the causes and extent of the differences in the chemical and conservation regulatory systems.

Environmental regulation is science-based regulation.[1] The federal agencies that adopt environmental regulations rarely justify them by reference to economic goals or to social or moral values, though these clearly play an important role. Rather, for reasons having to do with regulatory effectiveness, administrative professionalism, historical development, and political manipulation, scientific information has become the indispensable—if not always the true or only[2]—rationale for environmental

---

* Executive Associate Dean for Academic Affairs and Walter W. Foskett Professor of Law, Indiana University School of Law–Bloomington. Applegate is also a member-scholar of the Center for Progressive Reform, which co-sponsored this symposium. Thanks to Jay Hamilton and Wendy Wagner for very helpful ideas.

** Professor of Law and Ira C. Batman Faculty Fellow, Indiana University School of Law–Bloomington. The authors thank the Indiana University School of Law–Bloomington and the Center for Progressive Reform for co-sponsoring this symposium.

1. "Science," for these purposes, refers to the physical, including the health, sciences.

2. *See* Cary Coglianese & Gary E. Marchant, *Shifting Sands: The Limits of Science in Setting Risk Standards*, 152 U. PA. L. REV. 1255 (2004) (detailing a regulatory action in which the authors argue that such a charade occurred); Holly Doremus, *Science Plays Defense: Natural Resource Management in the Bush Administration*, 32 ECOLOGY L.Q. 249 (2005); Wendy E. Wagner, *The Science Charade in Toxic Risk Regulation*, 95 COLUM. L. REV. 1613 (1995) (suggesting that non-scientific considerations are often at work, despite the nominal reliance on scientific rationales).

regulations.[3] As a result, the discussion of scientific uncertainty is an element of nearly every text on environmental law. Scientific uncertainty is viewed, quite correctly, as one of the obstacles, if not *the* obstacle, that environmental regulators must overcome in developing sensible and effective laws and policies, in justifying them before the courts and the political branches of government, and in enforcing them.

Some scientific uncertainty is intractable. Because of limitations in our understanding of the physical world around us or the vast resources that would be required to obtain such an understanding, we will rarely know precise answers in advance of taking regulatory action to protect human health and the environment. Therefore, we must either accept uncertainty, not regulate at all (or regulate only with the consent of the regulated, which amounts to the same thing), or tolerate a number of regulatory pathologies designed to obfuscate the lack of scientific certainty.[4] The intractable form of scientific uncertainty—"knowledge uncertainty," as Professor Howard Latin put it[5]—is most frequently what the environmental law texts refer to, because intractability establishes uncertainty as a central, inherent characteristic of environmental regulation, which environmental law and policy must somehow manage.[6] Thus, for example, the increasingly influential precautionary principle in international environmental law is a forthright effort to acknowledge uncertainty without forgoing environmental protection, by permitting regulatory action in advance of full information.[7]

---

3. John S. Applegate, *Introduction* to 1 THE INTERNATIONAL LIBRARY OF ESSAYS IN ENVIRONMENTAL LAW: ENVIRONMENTAL RISK (John S. Applegate, ed. 2004), at xiii–xxiv; *see also* Holly Doremus & A. Dan Tarlock, *Science, Judgment, and Controversy in Natural Resource Regulation*, 26 PUB. LAND & RESOURCES L. REV. 1, 1 (2005) ("Science has been seen both as the justification for environmental law and as the means for fairly administering it."); Donald T. Hornstein, *Reclaiming Environmental Law: A Normative Critique of Comparative Risk Analysis*, 92 COLUM. L. REV. 562, 569–75 (1992) (describing the "allure" of science).

4. These are most frequently referred to by Professor Wendy Wagner's felicitous phrase, the "science charade." *See* Wagner, *supra* note 2. Other examples are collected in Stephanie Tai, *Three Asymmetries of Informed Environmental Decisionmaking*, 78 TEMP. L. REV. 659, 661 n.7, 682–84 (2005).

5. Howard A. Latin, *The "Significance" of Toxic Health Risks: An Essay on Legal Decisionmaking Under Uncertainty*, 10 ECOLOGY L.Q. 339, 356–57 (1982).

6. This has been a continuing theme throughout the history of environmental law. *See, e.g.*, Richard J. Lazarus, *Restoring What's Environmental About Environmental Law in the Supreme Court*, 47 UCLA L. REV. 703, 745–47 (2000) (listing "uncertainty and risk," as well as other characteristics that also contribute to uncertainty such as physically and temporally distant injury); Talbot Page, *A Generic View of Toxic Chemicals and Similar Risks*, 7 ECOLOGY L.Q. 207, 208–09 (1978) (describing "ignorance of mechanism" as exemplifying "the uncertainties surrounding environmental risk decisionmaking").

7. The most common formulation of the precautionary principle can be found in the Rio Declaration: "In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation." United Nations Conference on Environment and Development [UNCED], Rio de Janeiro, Braz., June 3–14, 1992, *Rio Declaration on Environment and Development*, princ. 15, U.N. Doc. A/CONF.151/5/Rev. 1 (June 14, 1992), *reprinted in* 31 I.L.M. 874, 879; *see also* John S. Applegate, *The Taming of the Precautionary Principle*, 27 WM. & MARY ENVTL. L. & POL'Y REV. 13 (2002) (providing

There is another, equally important kind of scientific uncertainty, however. It is the absence of scientific data which could feasibly (which is not to say cheaply or rapidly) be obtained. Latin calls this "information uncertainty," and it is a distinctly tractable problem.[8] It affects, for example, basic toxicology information, chemical exposure pathways, and observational data of many kinds. Since such data are available or could feasibly be generated, their absence must be accounted a *choice*, rather than an inherent quality, of environmental law. This information is absent because environmental law has, for a variety of reasons, established a regulatory regime in which the information needs of regulation outstrip the available information.

The absence of such information—the "data gap"—in the environmental regulation of chemicals was the subject of considerable academic discussion in the early 1990s.[9] Interest in this problem has recently intensified[10] as a consequence of two recent developments. First, in connection with the adoption of the new European Union legislation to regulate industrial chemicals, a great deal of attention has focused on studies in Europe and the United States that demonstrate, remarkably uniformly, that there is a large deficit of even basic toxicity information about most commercial chemicals.[11] Second, in the last few years, Congress has adopted legislation designed, more or less transparently, to restrict the information available to support environmental regulation without at the same time moderating the information requirements for regulatory action.[12] This legislation, the Data Access Act and the Information Quality Act, offers regulated entities additional and more extensive opportunities than ever before to challenge or cast doubt on the scientific basis for agency action, indeed, on practically any science publicly used by any federal agency. In contrast, the procedures and results of cost-benefit analysis, for example, are not covered by this legislation. The legislation further intensifies the indispensability of science in the environmental regulatory process both directly, by adding substantial

---

commentary on the purposes and elements of the precautionary principle).

8. Latin, *supra* note 5, at 356 (emphasis omitted); *see also* Wendy E. Wagner, *Choosing Ignorance in the Manufacture of Toxic Products*, 82 CORNELL L. REV. 773, 777–90 (1997) (discussing "preventable scientific uncertainties").

9. *See, e.g.*, John S. Applegate, *The Perils of Unreasonable Risk: Information, Regulatory Policy, and Toxic Substances Control*, 91 COLUM. L. REV. 261 (1991); Mary Lyndon, *Information Economics and Chemical Toxicity: Designing Laws to Produce and Use Data*, 87 MICH. L. REV. 1795 (1989).

10. *See, e.g.*, RESCUING SCIENCE FROM POLITICS (Wendy Wagner & Rena Steinzor eds., 2006); David Roe, *Toxic Chemical Control Policy: Three Unabsorbed Facts*, 32 ENVTL. L. RPTR. (Envtl. Law Inst.) 10232 (2002); Wendy E. Wagner, *Commons Ignorance: The Failure of Environmental Law to Produce Needed Information on Health and the Environment*, 53 DUKE L.J. 1619 (2004) [hereinafter Wagner, *Commons Ignorance*].

11. *See* John S. Applegate, *The Government Role in Scientific Research: Who Should Bridge the Data Gap in Chemical Regulation?*, *in* RESCUING SCIENCE FROM POLITICS, *supra* note 10, at 255, 263–64. A different perspective, emphasizing the amount of information that *is* available, can be found in James W. Conrad, Jr., *Open Secrets: The Widespread Availability of Information About the Health and Environmental Effects of Chemicals*, 69 LAW & CONTEMP. PROBS. 141 (2006).

12. *See, e.g.*, Data Access Act, Pub. L. No. 105-277, 112 Stat. 2681, 2681-495 (1998) (enacted as a rider to the Omnibus Consolidated and Emergency Supplemental Appropriations Act, 1999; also known as the Shelby Amendment); Information Quality Act, Pub. L. No. 106-554, § 515, 114 Stat. 2763, 2763A-153–54 (2000) (enacted as a rider to the Treasury and General Government Appropriations Act, 2001).

time and process to the technical analysis of regulatory action, and indirectly, by reinforcing the centrality of scientific information to the regulatory enterprise. The information legislation confirms, as never before, that the existence and extent of scientific information is often the most difficult hurdle that a robust program of protective environmental legislation must surmount. Therefore, explicit attention to the use of scientific information in environmental law and policy is of critical importance.

In the context of an environmental regulatory system, scientific information can be analyzed as subject to both supply and demand. Some aspects of regulatory regimes demand information to support governmental action, and other aspects supply information to the regulator. For example, the "substantial evidence" of a chemical's carcinogenic potency under the Toxic Substances Control Act (TSCA)[13] imposes substantial demands for scientific information, which TSCA's testing and adverse effect reporting provisions only partially supply. As presently structured, therefore, TSCA's information needs outstrip the information available to the agency, creating a data gap, and resulting in a seemingly dormant program of chemical regulation. Generalizing from the TSCA example, an environmental regulatory program can be described by its balance of demand for and supply of scientific information. Moreover, the individual regulatory choices or techniques that constitute regulatory programs can be characterized by their contributions to the supply and demand of scientific information, as follows[14]:

Demand	**Supply**
Increases demand	*Decreases supply*
Risk-based regulation	Declining public R&D funding
Aggressively skeptical judicial review	"Sound science" demands
Burden of proof on government	Data Quality Act
OMB intervention	Politicized peer review
	Legal incentives for ignorance
Decreases demand	*Increases supply*
Technology-based standards	Increased R&D funding
Burden of proof on polluters	Coherent, targeted R&D plans
Hazard-based regulation (Prop. 65)	Collections of data
Legislative listing of chemicals	Licensing, burden of proof on polluters
Precautionary principle	Test rules and testing requirements

A regulatory system that supplies more than it demands will be able to operate effectively to impose protective regulation. A system that demands more than it supplies will encounter a data gap, as does TSCA, and will fail to accomplish its protective goals.

The above schema illustrates not only the potential gap between supply and demand, but also the potential devices for addressing the data gap. To extend the "gap" metaphor, the data gap can be either "filled" or "bridged" by applying regulatory techniques. Filling involves increasing the supply of data by providing more information, while bridging refers to reducing the demand by permitting regulation to

13. 15 U.S.C. §§ 2601–2692 (2000); *see* Applegate, *supra* note 9; Wendy E. Wagner, *The Precautionary Principle and Chemical Regulation in the U.S.*, 6 HUM. & ECOLOGICAL RISK ASSESSMENT 459 (2000) (suggesting that TSCA embodies an "unprecautionary principle").

14. *See* Applegate, *supra* note 11, at 261–75.

proceed despite residual uncertainty. TSCA adopts a filling strategy: "It is the policy of the United States that … adequate data should be developed with respect to the effect of chemical substances and mixtures on health and the environment,"[15] and other provisions of the statute provide some tools to implement that strategy.[16] In other statutes, a licensing requirement, as for prescription drugs or pesticides, is intended to generate sufficient information to make a safety determination concerning the object of regulation.[17]

By comparison, statutes that mandate bans or phase-outs (for example, TSCA's treatment of PCBs[18]) or technology-based regulatory standards (for example, the post-1990 system for hazardous air pollutants[19]) adopt a bridging strategy. Because they select standards that can be translated into regulatory restrictions with relatively little new information, the precautionary principle is a bridging strategy, which "can be defended as a pragmatic decisionmaking heuristic that is particularly well-suited to the task of fostering consideration of how best to safeguard life and the environment under conditions of uncertainty and ignorance."[20] That is, the precautionary principle permits restrictions to go forward with less than complete information.[21]

In addition to the choice of regulatory devices, the differences between scientific and regulatory-legal norms of knowledge exacerbate the data gap in environmental policy.[22] The scientific model of endless questioning has served our society extraordinarily well as an engine for advancing knowledge, but this model is ill suited—and was not intended—to be the engine for protecting human health and the environment in the face of an extremely complex and imperfectly understood reality. By failing (mistakenly or manipulatively) to recognize the distinct purposes of scientific inquiry, opponents of protective regulation can encourage a regulatory system whose demands for scientific information are nearly infinite while the supply remains static. In other words, the level of importance of scientific information in supporting environmental regulation is not, as anti-regulatory rhetoric of the "sound

---

15. 15 U.S.C. § 2601(b)(1). The policy continues, "and that the development of such data should be the responsibility of those who manufacture . . . such chemical[s] . . . ." *Id.*

16. For example, the EPA is authorized to issue "test rules" that require manufacturers to generate test data. § 2603. Also, manufacturers must report adverse effects data. § 2607; *see* Applegate, *supra* note 9, at 315; Conrad, *supra* note 11, at 143–46. The effectiveness of these devices has been questioned, however. *See supra* note 11 and accompanying text.

17. *See* Applegate, *supra* note 9, at 308–12 (comparing data availability for licensing and non-licensing systems).

18. 15 U.S.C. § 2605(e). TSCA was enacted shortly after it was learned that PCBs—polychlorinated biphenyls, fire retardant chemicals frequently used in large electrical equipment—were potential carcinogens.

19. 42 U.S.C. § 7412(d) (2000).

20. Douglas A. Kysar, *It Might Have Been: Risk, Precaution, and Opportunity Costs*, 22 J. LAND USE & ENVTL. L. 1, 14 (2007).

21. Some versions of the precautionary principle require that the authority invoking the principle will continue to seek to reduce the uncertainty, which muddies the classification somewhat. *See, e.g.*, *Communication from the Commission on the Precautionary Principle*, at 20–21, COM (2000) 1 final (Feb. 2, 2000).

22. *See, e.g.*, Doremus, *supra* note 2, at 253–57; Doremus & Tarlock, *supra* note 3, at 17–20; Howard Latin, *Good Science, Bad Regulation, and Toxic Risk Assessment*, 5 YALE J. ON REG. 89 (1988); Tai, *supra* note 4, at 666–69.

science" variety would have it,[23] a self-evident matter of truth and justice. Instead, the role of science is the direct result of legislative, administrative, and judicial choices that mandate the demand for and supply of scientific information.

Moreover, these choices are necessarily overlaid on patterns of asymmetric access to reliable scientific information and the ability to generate that information. As Professors Wagner, Tai, and others have demonstrated, "privately held information can constitute a costly barrier—sometimes an insurmountable one—to regulating product and related industrial risks."[24] Thus, information provisions that are relatively ineffective at obtaining or generating such information perpetuate an asymmetry which frustrates effective regulation. While it is possible that the information requirements in environmental statutes have been enacted without regard to their effect on these asymmetries, it has been widely recognized since the "McNollgast" papers that political actors quite deliberately exploit procedural requirements to assure or frustrate particular decisions by regulatory agencies:

> [B]ecause policy decisions depend on what information is available to the agency, structure and process determine the quantity, quality, and completeness of available information and the extent to which policy decisions must be supported by this information. Political principals can control the influence of a constituency by using structure and process to affect the dependence of the agency on information the constituency supplies.
>
> An agency that has sufficient resources to generate its own information about the consequences of its decisions, available funds to subsidize the participation in its processes of various poorly organized interests, and a relatively lenient standard for judicial review of its actions (for example, arbitrary and capricious), will be far less dependent on highly organized, well-represented interests than an agency that lacks resources and faces a high standard for upholding its decisions in court.[25]

Information requirements are thus not only choices, but choices with substantial and predictable practical consequences.[26] In sum, information policies and requirements

---

23. Some scholars offer trenchant critiques of "sound science" rhetoric. *See, e.g.*, Thomas O. McGarity, *Our Science Is Sound Science and Their Science Is Junk Science: Science-Based Strategies for Avoiding Accountability and Responsibility for Risk-Producing Products and Activities*, 52 U. KAN. L. REV. 897 (2004).

24. Wendy Wagner, *When All Else Fails: Regulating Risky Products Through Tort Litigation*, 95 GEO. L.J. 693, 697 (2007); *see also* Tai, *supra* note 4, at 686–98; Wagner, *Commons Ignorance*, *supra* note 10.

25. Matthew D. McCubbins, Roger G. Noll & Barry R. Weingast, *Structure and Process, Politics and Policy: Administrative Arrangements and the Political Control of Agencies*, 75 VA. L. REV. 431, 440–41 (1989); *see also id.* at 469 ("More elaborate procedures are generally regarded as favorable to regulated industries. Because industries possess much of the information relevant to regulatory decisions, elaborate processes give them more power by increasing the importance of that information."); Matthew D. McCubbins, Roger G. Noll & Barry R. Weingast, *Administrative Procedures as Instruments of Political Control*, 3 J. L. ECON. & ORG. 243, 268–69 (1987) (offering TSCA as an example); Tai, *supra* note 4, at 698–709 (criticizing the Information Quality Act).

26. *See* Holly Doremus, *The Purposes, Effects, and Future of the Endangered Species Act's*

have the capacity to further or to frustrate the protection of human health and the environment as implemented by environmental regulation.

Along with scientific uncertainty, the divide in environmental law between pollution control and resource management is a pervasive attribute of the standard structuring of the field. It is commonplace for teachers of environmental law courses and authors of environmental law casebooks to separate the conservation (endangered species, ecosystem management, and land and resource use) and the chemical (air and water pollution, toxic substances and hazardous wastes) aspects of environmental law. Indeed, the two areas are routinely confined to different courses and books. As both a cause and effect of this division, the conservation and chemical aspects of environmental law have surprisingly few points of intersection and are analytically very separate.[27]

The division is not, of course, simply arbitrary; there are real differences. The most obvious is scale: conservation regulation generally concerns itself with ecosystems and the wildlife within them; chemical regulation concerns itself primarily with health and the threats posed to it, often at the cellular and molecular level, by chemical agents of various kinds. A further difference is the object of statutory concern: for conservation regulation, it is primarily non-human species, and even inanimate objects like land forms; for chemical regulation, it is overwhelmingly human health, usually with only a perfunctory nod at other aspects of the environment. Moreover, while both chemical and conservation law focus on harm avoidance (to human health and ecosystems, respectively) primarily through negative commands, only conservation regulation focuses on the *management* of resources, through positive commands, to enhance their value.

While the data gap, as such, has most frequently been observed and theorized in the chemical setting, it is by no means limited to chemicals. It is a fundamental problem on the conservation side of the house, as well.[28] Indeed, one need go no further than Aldo Leopold's germinal work on conservation to find concern with the data gap for species, ecosystems, and habitats. Lack of scientific knowledge about ecosystems led to Leopold's famous aphorism, "To keep every cog and wheel is the first precaution of intelligent tinkering."[29] Thus, in thinking about information needs, we must distinguish not only between supply and demand, scientific and regulatory-legal norms, and asymmetric access to information, but also between chemical and conservation issues. The information needs of land management are as likely to be distinct from the needs of regulation, as ecosystems are distinct from chemicals—or so we hypothesize. The contributors to this symposium will assess these differences in their articles.

The symposium that follows thus explores two familiar but insufficiently analyzed aspects of environmental regulation: the needs for scientific information that are created and satisfied by regulatory systems, and the disjunction between the regulatory

---

Best Available Science Mandate, 34 ENVTL. L. 397 (2004).

27. *See, e.g.*, Robert L. Fischman, *The Problem of Statutory Detail in National Park Establishment Legislation and its Relationship to Pollution Control Law*, 74 DENV. U.L. REV. 779 (1997); Robert L. Glicksman, *Pollution on the Federal Lands I: Air Pollution Law*, 12 UCLA J. ENVTL. L. & POL'Y 1 (1993). *But see* Lazarus, *supra* note 6, (describing characteristics common to all of environmental law).

28. *See* Kristin Carden, Note, *Bridging the Divide: The Role of Science in Species Conservation Law*, 30 HARV. ENVTL. L. REV. 165 (2006); Doremus, *supra* note 26.

29. ALDO LEOPOLD, ROUND RIVER 147 (Luna B. Leopold ed., 1953).

systems for the chemical and conservation areas of environmental law. The continuing existence of a severe data gap between the scientific information required for effective regulation and the information available to regulators and the public provides a valuable opportunity to uncover the causes and extent of the respective data gaps. The data gap also permits us to study in a concrete setting the differences between chemical and conservation regulatory regimes, and to use insights from each area to improve regulation in both. The objectives of the symposium, therefore, are to bring together established experts in the conservation and chemical areas of environmental regulation to describe the nature, sources, and extent of the data gaps in their respective areas; to seek commonalities among areas; and, by learning from both areas, to propose regulatory reforms to fill or bridge the data gap.

The contributions to the symposium are organized into three overlapping groups. The first considers supply and addresses several key questions: How does the law generate the information that it requires? What legal tools are available, and how well are they deployed? What institutional capacities exist for generating information? Where is the relevant scientific expertise located? These articles include those of Professor Holly Doremus on the "information pipeline" in natural resource management, Professor Robert Glicksman on the use of models in U.S. Forest Service planning, and U.S. Fish and Wildlife Service experts Teresa Woods and Steve Morey on the Endangered Species Act.

The demand group includes articles by Professor Alyson Flournoy on wetlands permitting under section 404 of the Clean Water Act, and by Professor William Buzbee on "adjudicatory triggers" in the context of the ill-fated Westway project in New York City. They ask: How does the law create the need for scientific information? What are the statutory/legal objectives (harm avoidance, value enhancement) of the various types of environmental protection? What are the uncertainties that each form of environmental protection encounters? How do legal and scientific information needs differ?

The last group of articles considers information regulation and legal systems that address data needs directly. How have generally applicable requirements like the Information Quality Act been used in the chemical and conservation areas of environmental protection? Have information requirements had an important impact on substantive implementation of environmental law? How should we measure whether an information demand is constructive or counter-productive in environmental law? Professor Carl Cranor describes the informational consequences of California's landmark antitoxics referendum, Proposition 65, and Professor Wendy Wagner is concerned with the use of private parties to regulate the quality of information used in public environmental regulation. Finally, Professor Fischman explores other dimensions besides subject matter (i.e., pollution control or resource management) along which to divide environmental law. This reveals certain information policy affinities otherwise obscured by the subject matter divide. He illustrates this point by showing how the EPA pollution control permit programs can offer a model for improving the implementation of section 9 of the Endangered Species Act, which prohibits significant habitat modification under certain circumstances.

We invite you to consider these articles, both individually as contributions to an important and ongoing debate on the importance of information in environmental regulation, and collectively as a serious effort to illuminate the commonalities and differences in conservation and chemical environmental law.