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## NEWS & ANALYSIS

### Risk Versus Precaution: Environmental Law and Public Health Protection

by Gail Charnley and E. Donald Elliott

**E**nvironmental regulation in the United States has been characterized by short-term decisions with unknown or unanticipated long-term public health consequences. Some propose to use our inability to predict possible long-term consequences of environmental health regulation as a justification for replacing risk assessment with the “precautionary principle” as the dominant paradigm for making regulatory decisions. The precautionary principle is based on the idea that it is better to be safe than sorry; that is, precaution reflects the need to take action in the face of potentially serious risks without awaiting the results of scientific research that establishes cause-and-effect relationships with full scientific certainty.<sup>1</sup> In contrast, U.S. law reflects a traditional suspicion of government regulation, requiring extensive factual records proving “significant risks” to justify regulation aimed at protecting public health from environmental contaminants. This fundamental norm of the U.S. legal culture, sometimes called the “principal of legality,” makes precautionary environmental health regulation difficult because government must assemble a factual record to support its actions.

Support for the precautionary principle is motivated in part by a desire for a more agile legal system that does not use incomplete science as a reason to postpone regulating. But the long-term consequences of substituting precaution for risk-based decisions could undermine the already somewhat meager scientific basis for regulatory actions unless we develop improved mechanisms to revisit decisions as better scientific information develops. Meanwhile, huge investments continue to be made in complying with regulation of chemical contaminants despite our limited ability to demonstrate the impact of that investment on improving public health. In that sense, environmental health regulation in the United States already implements the precautionary principle on a grand scale. This Dialogue argues that applying a combination of both risk assessment and the precautionary principle in environmental regulation, along with an improved environmental health infrastructure, are needed to protect public health and the environment more effectively.

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1. See Christopher D. Stone, *Is There a Precautionary Principle?*, 31 ELR 10790 (July 2001).

#### Risk Management Decisionmaking

Today, with our expanding knowledge of how human activities affect the environment, we have no choice but to attempt to manage them because postponing or avoiding a decision is in itself a decision.<sup>2</sup> Unfortunately, there is no magic algorithm to define precisely how much analysis or how much information is sufficient to enable us to make wise decisions. There is a constantly shifting balance between the costs and benefits of deciding now as opposed to waiting until we have better information.<sup>3</sup> This issue of how much science is needed before governments regulate has recently come to the forefront in international debates about environmental health policy as a result of increasing emphasis in Europe and in the United States on the “precautionary principle.”<sup>4</sup>

Over the last two decades, quantitative risk assessment has emerged as the dominant paradigm in the United States for including science in regulatory decisionmaking as the best way to manage threats to public health and the environment. Risk assessment is a way to organize scientific information in a form that is meant to provide useful input—both qualitative and quantitative—to risk management decisionmaking. Because scientific information is generally incomplete, however, health risk assessment relies on science-based policy and expert judgment as well as on data.

The preeminent role of risk assessment in U.S. regulation emerged from the U.S. Supreme Court’s decision in *Industrial Union Department, AFL-CIO v. American Petroleum Institute*,<sup>5</sup> commonly known as the *Benzene* decision, which established the requirement for factual support in the administrative record for deciding that a risk to health is “significant” enough to merit regulation. In practice, this record-building requirement has generally been satisfied by quantitative risk assessment.<sup>6</sup> The significance test, by conceiving of risk assessment as fundamentally an issue of fact, subordinates policy considerations to “facts” in the assess-

2. E. Donald Elliott, *Against Ludditism: An Essay on the Perils of the (Mis)use of Historical Analogies in Technology Assessment*, 65 S. CAL. L. REV. 279 (1991).

3. E. Donald Elliott, *Global Climate Change and Regulatory Uncertainty*, 9 ARIZ. J. INT’L & COMP. L. 259 (1992).

4. Andrew Jordan & Timothy O’Riordan, *The Precautionary Principle in Contemporary Environmental Policy and Politics*, in PROTECTING PUBLIC HEALTH AND THE ENVIRONMENT: IMPLEMENTING THE PRECAUTIONARY PRINCIPLE 15-35 (Carolyn Raffensperger & Joel Tickner eds., Island Press 1999).

5. 448 U.S. 607, 10 ELR 20489 (1980).

6. See John Martonik et al., *The History of OSHA’s Asbestos Rulemakings and Some Distinctive Approaches That They Introduced for Regulating Occupational Exposure to Toxic Substances*, 62 AM. INDUS. HEALTH ASS’N J. 208, 213 (2001).

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ment of public health risk (although not necessarily from decisions about how best to manage risks or decide they are “significant”). By overemphasizing the factual component of risk assessment, U.S. appellate courts misunderstand the nature of risk assessment and undervalue expert judgment and policy considerations.<sup>7</sup> Implementation of the recent European Commission Communication on the precautionary principle, however, would not require the same high level of factual evidence to support decisions about managing potential risks.<sup>8</sup> The rise of the precautionary principle can be viewed as an objection to the U.S. legal tradition of extensive administrative law requirements and court review of the factual basis of government decisions about environmental risks.

### Managing Public Health Consequences: Risk, Precaution, and the Law

The precautionary principle guided regulatory decisionmaking on public health risks in the United States for many years. For example, in the 1950s the Delaney Clause required the Food and Drug Administration to ban outright food and color additives that had been shown to produce tumors in humans or laboratory animals, whether or not they posed a risk to public health.<sup>9</sup> In the 1970s, a legal basis for the precautionary principle was established by the *Ethyl Corp. v. U.S. Environmental Protection Agency*<sup>10</sup> decision, which involved the ban of leaded gasoline. At the time there was great debate about the wisdom of taking such a radical step when the benefits of doing so were unclear. But the U.S. Court of Appeals for the D.C. Circuit upheld the U.S. Environmental Protection Agency’s (EPA’s) decision to take a precautionary approach and ban lead anyway, even in the absence of scientific evidence adequate to demonstrate exactly what the risks from the lead were or what the benefits of removing it would be. As it turned out, banning leaded gasoline was the single most important contributor to the virtual elimination of lead from air and from most children’s blood.

In 1980, however, the Supreme Court’s *Benzene* decision turned away from the precautionary policy basis of the *Ethyl* decision and substituted a fact-based principle focusing on the extent of risk.<sup>11</sup> The *Benzene* decision struck down a workplace standard for benzene exposure that was based on a policy of trying to reduce concentrations of benzene as far as technologically possible without considering whether existing concentrations posed a “significant risk” to health. The Supreme Court decided that benzene could be regulated only if it posed a “significant risk of material health impairment.”<sup>12</sup> Although the Court did not define “significant risk

of material health impairment” and stressed that the magnitude of the risk need not be determined precisely, the decision strongly implied that some form of quantitative risk assessment is necessary as a basis for deciding if a risk is large enough to deserve regulation.<sup>13</sup>

To a large extent, the body of U.S. statutory law that seeks to ensure public health safety—or at least mitigate public health risk—from chemical or other contaminant exposures was established before quantitative risk assessment was a well-recognized and codified discipline. Most of the methodology of risk assessment was developed in reaction to the calls by these laws to define limits on exposure that will protect the public health “with an adequate margin of safety”<sup>14</sup> or similar precautionary language. That is, in passing the laws, the U.S. Congress called on the regulatory agencies to develop means to assess risks so as to define exposure levels that would achieve the stated qualitative goals of health protection.<sup>15</sup>

Thus, the United States has had a long history of applying the precautionary principle in regulation but has moved gradually away from doing so as we learn more about risk assessment and its underlying scientific basis. To a great extent and on a more global scale, the re-emergence of the precautionary principle is a reaction against the U.S. legal tradition that requires extensive proceedings to establish a factual basis for regulation as a precondition to government action.<sup>16</sup> Regulatory decisions in the United States generally have to be justified by an extensive factual record that is subject to judicial review.<sup>17</sup> It has been estimated that only about 10% of EPA’s analysis of scientific data is necessary to reach a decision; the other 90% is required to build the record for court review.<sup>18</sup> When Europeans today call for decisions based on “the precautionary principle” in international forums, they are challenging a core premise of the American legal culture that requires an extensive factual record to justify government regulatory action.

U.S. tradition holds the deep belief that the risks of arbitrary government action are so great that it is better to pay the costs of procedural delay and elaborate legality than to run the risk of unjustified government actions. That is not the case in Europe or in most industrialized nations, including Canada, where governmental regulatory decisions are not subject to judicial challenges to nearly the same degree as they are in the United States. As a consequence, outside the United States, the necessary procedures for marshaling and analyzing scientific evidence before a decision can be made are nowhere near as great. For example, in Europe,

13. See, e.g., *id.* at 646, 10 ELR at 20499.

14. 42 U.S.C. §7409(b)(1), ELR STAT. CAA §109(b)(1) (Clean Air Act).

15. Lorenzo R. Rhomberg, *A Survey of Methods for Chemical Health Risk Assessment Among Federal Regulatory Agencies*, 3 HUM. ECOL. RISK ASSESSMENT 1029-196 (1997). See also David Schoenbrod, *Goal Statutes or Rules Statutes: The Case of the Clean Air Act*, 30 UCLA L. REV. 201 (1983).

16. E. Donald Elliott, *Environmental TOM: A Pollution Control Program That Works!*, 92 MICH. L. REV. 1840, 1844-48 (1994); Douglas Costle, *Brave New Chemical: The Future Regulatory History of Phlogisten*, 33 ADMIN. L. REV. 195 (1981).

17. 5 U.S.C. §706, available in ELR STAT. ADMIN. PROC. (Administrative Procedure Act).

18. Personal communication with Michael Shapiro, Deputy Ass’t Administrator, EPA (2000). See also Martonik et al., *supra* note 6, at 215-16 (time period from notice of proposed rulemaking to final rule went from six months in 1972 to four years in most recent asbestos rulemaking).

7. See, e.g., *AFL-CIO v. OSHA*, 965 F.2d 962, 22 ELR 21229 (11th Cir. 1992) (overturning 428 workplace standards based on consensus expert judgment for the lack of factual support).

8. Commission of the European Communities, Communication from the Commission on the Precautionary Principle, COM(2000) final at 1.

9. Federal Food, Drug, and Cosmetic Act, 21 U.S.C.A. §§409(c)(3)(A), 706(b)(5)(B), and 512(d)(1)(H).

10. 541 F.2d 1, 6 ELR 20267 (D.C. Cir.), cert. denied, 426 U.S. 941 (1976).

11. 448 U.S. at 607, 10 ELR at 20489. See also *id.* at 655 n.62, 10 ELR at 20501 n.62.

12. *Id.* at 639, 10 ELR at 20497.

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standards limiting exposure to chemicals in the workplace are routinely set based on a consensus of expert judgment. In contrast, U.S. courts have held that the expert consensus approach is *not* a sufficient factual basis for regulation.<sup>19</sup>

One solution to this problem is to synthesize U.S. and European approaches. For example, temporary regulation could be based on reduced evidentiary requirements while specifying informational needs and future reconsideration. U.S. courts have traditionally been willing to enter temporary remedies to preserve the status quo and protect the public interest based on less of a factual showing than would be necessary to support a permanent final judgment. By analogy, temporary regulations might be adopted to run for a few years' duration while more definitive scientific research is conducted. There are already some precedents for this approach in U.S. law. For example, EPA may "conditionally register" a pesticide while additional scientific studies are completed if it determines that doing so will not run a significant risk of an unreasonable adverse effect on public health or the environment.<sup>20</sup>

The precautionary principle is not a substitute for risk-based decisionmaking. And while there are major differences between the background legal norms in the United States and the rest of the world, the alleged choice between risk assessment and the precautionary principle is a false opposition. Risk assessment provides just part of the information used to protect public health and the environment. The extent to which the precautionary principle is applied in regulatory decisionmaking depends partly on the confidence that can be placed in a risk assessment as well as on the nature and severity of the risk of concern, the likelihood that new data would change a risk management decision, the effectiveness and feasibility of the risk management action under consideration, and a wide variety of other considerations such as politics, public health, economics, and the law. There is a danger that if applied in the extreme, the precautionary principle will be used as a license to ignore these other elements of risk management decisionmaking.

### **Risk, Precaution, and Transparent Public Health Decisions**

Environmental health regulation is path-dependent: actions taken now affect the nature of actions taken later. Governments may not be able to "roll back" citizen protections in the face of charges from environmental advocates even if the original actions turn out to have been unnecessary or ineffective. There are few examples in U.S. history of environmental chemical regulation becoming less stringent. Thus, regulating on a precautionary basis before adequate data are available requires a better mechanism for revising decisions later in light of new evidence. Proponents of the precautionary principle have yet to clarify how regulation based on precaution in the absence of adequate science can be revisited and changed when better science becomes available. For example, if regulation based on precaution establishes a set of standards for limiting chemical exposures based on procedures that are more political than scientific—on the premise that there is insufficient information to do otherwise—some means is necessary to communicate

that policy, not science, underlies those standards. It must also be possible to change those standards when more science becomes available.

One approach that might help scientists and regulators communicate about their confidence in the science underlying a particular standard would be a classification system that indicates where on the spectrum of science versus policy the basis for that standard lies. The categories might be "adequate," "preliminary," or "insufficient" science. This classification system differs from that used to indicate whether chemicals are "known," "probable," "possible," or "unclassifiable" human carcinogens because it does not make a statement about the likelihood that a chemical is or is not a particular type of toxicant. The classification system does not indicate whether a chemical is or is not "toxic." As any toxicologist will tell you, all chemicals are toxic at some level of exposure (but all chemicals do not necessarily pose risks to public health). The proposed system would allow regulators to be transparent about the science and policy basis for a standard when—for whatever reason—a standard is set. Such a classification system does not convey the likelihood of risk nor does it dictate how risks from chemicals in different categories should be managed. It is solely a means of communicating how confident regulators are in the scientific basis of a particular standard. EPA does this to a limited extent already when it classifies its confidence in the quality of the data supporting the development of chemical-specific reference doses and reference concentrations as high, medium, or low.<sup>21</sup>

A classification approach need not be restricted to chemical-specific standards. It is applicable to risk management actions of all types. For example, actions taken to restrict children's exposure to lead could be classified as based on "adequate" science because the adverse impacts of lead on children's health are well known. Regulatory or trade-restricting actions taken as a result of concerns about particular genetically modified organisms could be classified as based on "preliminary" science if there is some science suggesting a basis for concern, but the actions are based mostly on policy. Similar actions taken as a result of concerns about bovine spongiform encephalopathy in beef could be classified as based on "insufficient" science to clarify that they are based primarily on a reaction to public concern about a dreaded risk and not on strong scientific evidence of a public health risk. The goals of such classifications would be twofold: improving transparency about risk management and providing a basis for changing classifications and risk management actions as the quality of the science changes.

### **Public Health Consequences of Environmental Decisions**

In the United States, some \$100 to \$150 billion are devoted annually to environmental regulatory protection and compliance, but we have very little by which to judge the impact of this tremendous investment on public health protection and improvement.<sup>22</sup> Eliminating lead in gasoline and installing air pollution controls have clearly played critical roles in greatly reducing childhood lead exposure and respi-

19. *AFL-CIO v. OSHA*, 965 F.2d 962, 22 ELR 21229 (11th Cir. 1992).

20. 7 U.S.C. §136a(c)(7), ELR STAT. FIFRA §3(c)(7) (Federal Insecticide, Fungicide, and Rodenticide Act).

21. See U.S. EPA, *Integrated Risk Information System*, at <http://www.epa.gov/ncea/iris.htm> (last modified July 31, 2001).

22. Robert W. Hahn & John A. Hird, *The Costs and Benefits of Regulation: Review and Synthesis*, 8 *YALE J. ON REG.* 233 (1991).

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ratory disease morbidity in the United States. Beyond those two examples, however, we have little rigorous analysis documenting a relationship between environmental health regulation of chemical contaminants and public health improvement. In fact, studies have found that in places where the parameters we use to characterize the environment have shown improvement—public reporting of industrial chemical releases, air quality indices, water quality indices—the quality of public health is often dismal.<sup>23</sup> In one sense, then, the entire trillion dollar U.S. environmental effort is an application of the precautionary principle writ large.

To a great extent, advocates of the precautionary principle have focused on our chemical-by-chemical regulatory process at the expense of the larger public health context. This focus reflects frustration with the ossified regulatory process in the United States but ignores the manner in which that process diverts attention from public health. In many cases, the public health foundation of environmental health protection has been obscured by legalistic, technical, and centralized decisionmaking processes that are often unresponsive to the important public health problems faced by communities.<sup>24</sup> A greater focus on the goal of public health protection and improvement would better serve the environmental health objectives of our regulatory statutes, although it is the specificity of the dictates of those statutes that often pose impediments to a focus on public health.<sup>25</sup> One way to empower communities to focus resources on local priorities is to permit trading among risks.<sup>26</sup> Con-

tinuing the environmental improvements of the last 25 years will require moving beyond the current chemical-by-chemical, medium-by-medium, risk-by-risk approach dictated by existing statutes as well as a public health approach to refocus our priorities.<sup>27</sup>

## Conclusion

The effectiveness of how our risk management resources are targeted must be questioned if little impact on public health can be measured. To target our resources more effectively into the new century, we are going to have to demonstrate that they are having an impact—that they are, in fact, improving public health. Doing so will require more than relying on the precautionary principle. It ultimately will require an environmental health infrastructure that includes a national disease surveillance network and the ability to track environmental exposures so we can start to make meaningful connections between environmental exposures and public health outcomes. Until then, risk management requires reliance on risk assessment as a means to use science effectively to understand, describe, and help us set priorities and make decisions about protecting public health and the environment.

To maximize the long-term effectiveness of environmental decisionmaking today, we must balance science and precaution intelligently. Relying entirely on science can lead to paralysis by analysis. Relying entirely on precaution holds science hostage to interest group politics.

23. REGION III, U.S. EPA, SOUTH AND SOUTHWEST PHILADELPHIA ENVIRONMENTAL HEALTH CHARACTERIZATION STUDY (1997).

24. William D. Ruckelshaus, *Stepping Stones*, ENVTL. F., Mar./Apr. 1998, at 30-36.

25. Gilbert S. Omenn, *Putting Environmental Risks in a Public Health Context*, 111 PUB. HEALTH PERSP. 514-16 (1996).

26. E. Donald Elliott & Gail Charnley, *Toward Bigger Bubbles: From Environmental Protection Agency to Environmental Accounting*

*Agency: Why Inter-Pollutant and Inter-Risk Trading Are a Good Idea and How We Get There From Here*, 13 FORUM FOR APPLIED RES. & PUB. POL'Y 48-54 (1998).

27. Gail Charnley & Bernard D. Goldstein, *A Public Health Context for Residual Risk Assessment and Risk Management Under the Clean Air Act*, 106 ENVTL. HEALTH PERSP. 519-21 (1998).