

**Precaution in International
Environmental Policy and
United States Law and Practice**

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October 2002

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I. INTRODUCTION

The concept of precautionary decision making has received considerable attention in the context of such global environmental issues as stratospheric ozone depletion, climate change, and biotechnology. Those debates, having reached a relatively high level of sophistication and refinement, of late have tended to crystallize around discrete questions that are both highly controversial and occasionally somewhat remote from real-world considerations. One relatively esoteric concern is the status of precaution in customary international law, a question about which there is an apparent lack of consensus, but one whose resolution either way is likely to have relatively little concrete impact. Even the terminology employed, such as references to a “precautionary principle” as opposed to “precautionary approaches,” can be an occasion for vociferous disagreements.

Stepping back somewhat from some of the international dissension, precaution is an inherent part of day-to-day life in decisions that are made by individuals and governments alike. Everyone is familiar with the concept of making decisions under conditions of uncertainty or incomplete information, whether expressly labeled “precautionary” or not. For example, a recent report of the US General Accounting Office¹ found no conclusive evidence that radio frequency energy emitted by cellular telephones poses a health risk. On the other hand, the report noted that “the findings of some studies have raised questions about cancer and other health problems that require further study” and that “there is not yet enough information to conclude that they pose no risk.” Similarly, the Royal Society, an independent scientific academy in the United Kingdom, has been unable to give conclusive answers as to the presence or absence of health risks to armed forces personnel from depleted uranium in armor-piercing shells used in the Persian Gulf and Kosovo. Its most recent report² concludes that “radiological risks from

1. US General Accounting Office, *Telecommunications: Research and Regulatory Efforts on Mobile Phone Health Issues* (Report no. GAO-01-545, 7 May 2001) (available at web site <<http://frwebgate.access.gpo.gov/cgi-bin/useftp.cgi?IPAddress=162.140.64.88&filename=d01545.txt&directory=/diskb/wais/data/gao>>).
2. Royal Society, *The Health Hazards of Depleted Uranium Munitions*, Part I, at 8 (22 May 2001) (available at web site <<http://www.royalsoc.ac.uk/templates/search/websearch.cfm?mainpage=/policy/reports.htm>>).

the use of [depleted uranium] are for the most part low, but that for small numbers of soldiers there might be circumstances in which risks are higher, and it is for this reason that further work should be undertaken to clarify their extent.”

Most individuals, institutions and governments are also familiar with the need on occasion to act even when risks are uncertain or incompletely characterized. For instance, in June 2001 and effective later this year, the American Red Cross, a private organization, voluntarily tightened its restrictions beyond the good practice standard established by guidelines issued by the US Food and Drug Administration (FDA)³ on blood donations from travelers who had been to Europe because of concerns about bovine spongiform encephalopathy (BSE). Likewise, US FDA has proposed prohibiting at least one drug and scrutinizing others for use in animal feeds because of concerns about the transfer of resistance to human pathogens, despite a lack of consensus about the potential harm from their continued use.⁴

This paper examines the role of a regulatory philosophy of precautionary decision making in United States law and policy. Because of the high level of multilateral activity with potentially significant implications for national and international policies, the paper first identifies international authorities articulating the need for precaution. Next, the paper analyzes variations in those formulations and evaluates their significance. The paper then goes on to consider precaution as it might be understood from the perspective of the role of science in the regulatory process.

3. See Royal Society, *The Health Hazards of Depleted Uranium Munitions and BSE* (6 June 2001) (available at web site <<http://www.redcross.org/services/biomed/blood/supply/tse/bsepolicy.html>>). See also American Red Cross Urges Tightened Restrictions on Blood Donors Who Reside in Europe: Red Cross President and CEO Describes Policy As “Prudent, Cautious” (18 January 2001) (available at web site <<http://www.redcross.org/services/biomed/blood/supply/1%2D18%2D01b.html>>) (Red Cross urges FDA further to tighten restrictions on blood donations).
4. See 65 Fed. Reg. 64,954 (31 October 2000) (notice of opportunity for hearing concerning FDA’s proposed withdrawal of approval of new animal drug application for use of fluoroquinolone enrofloxacin in poultry). See also FDA Center for Veterinary Medicine, *An Approach for Establishing Thresholds in Association With the Use of Antimicrobial Drugs in Food-Producing Animals* (19 December 2000) (available at web site <<http://www.fda.gov/cvm/antimicrobial/threshold21.pdf>>); Use of Antimicrobial Drugs in Food Animals and the Establishment of Regulatory Thresholds on Antimicrobial Resistance (available on web site <<http://www.fda.gov/cvm>>) (transcripts of public meeting, held 22-24 January 2001, on issues identified in previous document).

The second major portion of the paper scrutinizes precautionary theories as interpreted in the United States. Federal legislation is assessed, case studies involving the application of federal statutory mandates are presented, and judicial opinions interpreting federal law are evaluated. The paper concludes with an examination of selected examples of precaution as applied by subnational entities, such as the constituent states of the United States.

II. ANALYTICAL METHODOLOGIES FOR IMPLEMENTING PRECAUTION

A large number of international instruments of a normative nature, both non-binding and legally binding, now articulate expectations for precautionary decision making. All those instruments identify circumstances under which it is desirable for governmental decisions to reflect a preference for precaution under conditions of uncertainty. To understand how precautionary decision making might work in practice, it is consequently helpful to have a perspective on both the regulatory process and theories of uncertainty. Accordingly, this section first surveys international norms for precaution and then addresses approaches to regulation and the scientific treatment of uncertainty or error.

A. International Formulations of Norms for Precaution

Although they have roots in domestic approaches such as the German *Vorsorgeprinzip*, precautionary methodologies have rapidly become the subject of a wide variety of international exhortations and obligations. Because the products from multilateral deliberations are driving so much of the debate over precautionary perspectives on governmental decision making, this section examines some of the salient international contexts in which precaution has been articulated as an approach to formulating public policy.

As the focus of this paper is United States law and policy, the authorities analyzed are confined to those in which the United States Government participated in negotiations and which do or might apply to the United States. Many of these same instruments could or do apply to Canada and Mexico as well. The following compilation is intended to be illustrative as opposed to exhaustive.

1. *Non-binding Statements*

Non-binding instruments may serve a number of purposes. One important function of “soft” law is consciously to establish normative

expectations, which often function as standards of good practice for states and governments. The texts of non-binding instruments are typically phrased in terms of “shoulds” rather than the obligatory “shalls” characteristic of binding obligations, which are more frequently found in the “hard” law created by treaties and international agreements. While not creating formal international legal obligations, these advisory instruments can nonetheless establish widely accepted criteria for desirable or sound state practice. Adjectives typically applied to this category of instruments include “hortatory,” “precatory,” and “aspirational.” Many of the non-binding exhortations encouraging states to take measures based on a theory of precaution also apply generally, in contrast to the typically more discrete subject matter areas addressed by treaty obligations, as discussed in section II.A.2 below.

a. *Rio Declaration*

The most generally applicable exhortation to apply precautionary governmental decision-making processes appears in Principle 15 of the Rio Declaration on Environment and Development,⁵ a non-binding recommendation adopted at the United Nations Conference on Environment and Development (UNCED), attended by over a hundred heads of state or government in 1992. The text of that instrument provides as follows:

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.

This statement, while not legally binding, is not confined to a particular subject matter area and is therefore quite broad in application.

The desirability of public policies based on precaution is also identified in the Bergen Ministerial Declaration on Sustainable Development in the ECE Region,⁶ the final statement from a preparatory meeting of European states, the United States and Canada that preceded UNCED.

5. 14 June 1992, UN Doc. A/Conf.151/5/Rev. 1 (1992), 31 *ILM* 876 (1992).

6. 16 May 1990, para. 7, 20 *Environmental Policy and Law* 100 (1990) (“In order to achieve sustainable development, policies must be based on the precautionary principle. Environmental measures must anticipate, prevent and attack the causes of environmental degradation. Where there are threats of serious or irreversible damage, lack of full scientific certainty should not be used as a reason for postponing measures to prevent environmental degradation.”)

Agenda 21, the action plan for the future adopted at UNCED, also contains references to precaution.⁷

b. Other Non-binding Instruments

The final communiqué of the G-8 summit held in Okinawa in 2000,⁸ in paragraph 56 under the heading of "Biotechnology/Food Safety," endorses the Codex Alimentarius Commission's "efforts...to achieve greater global consensus on how precaution should be applied to food safety in circumstances where available scientific information is incomplete or contradictory."

More generally, the Houston Economic Summit Declaration⁹ from the G-7's 1990 meeting, in paragraph 62, states that "...in the face of threats of irreversible environmental damage, lack of full scientific certainty is no excuse to postpone actions which are justified in their own right."

The 1992 summit declaration of the Conference for Security and Cooperation in Europe (CSCE)¹⁰ stated that "the use of economic and fiscal instruments in addition to regulatory instruments is important in order to implement, at national level, the 'polluter-pays' principle, as well as the precautionary approach."

7. Paragraph 17.21 of Agenda 21, UN Doc. A/Conf./151/4 (1992), reprinted in *The Earth Summit: The United Nations Conference on Environment and Development (UNCED)* 125 (Stanley P. Johnson, ed., 1993), provides as follows:

A precautionary and anticipatory rather than a reactive approach is necessary to prevent the degradation of the marine environment. This requires, inter alia, the adoption of precautionary measures, environmental impact assessment, clean production techniques, recycling, waste audits and minimisation, construction and/or improvement of sewage treatment facilities, quality management criteria for handling of hazardous substances, and a comprehensive approach to damage impact from air, land and water. Any management framework must include the improvement of coastal human settlements and the integrated management and development of coastal areas.

Paragraph 35.2 states:

In the face of threats of irreversible environmental damage, lack of full scientific understanding should not be an excuse for postponing actions which are justified in their own right. The precautionary approach should provide a basis for policies relating to complex systems that are not yet fully understood and whose consequences and disturbances cannot yet be predicted.

8. 23 July 2000 (available at web site <<http://www.g7.utoronto.ca/g7/summit/2000okinawa/finalcom.htm>>).

9. 11 July 1990 (available at web site <<http://www.g7.utoronto.ca/g7/summit/1990houston/communique/environment.html>>).

10. Helsinki Summit Declaration, 10 July 1992, pt. VIII, para. 3, 31 *ILM* 1389 (1992).

A number of non-binding recommendations adopted by the Organization for Economic Cooperation and Development (OECD) contain references to precaution. Among those is a 1990 recommendation on integrated pollution prevention and control,¹¹ which in an appendix entitled “Guidance on integrated pollution prevention and control” contains the following language under the heading “Essential Policy Aspects:”

Certain policies, common to all aspects of environmental protection, are essential to an effective integrated approach. These include that...

d) the absence of complete information should not preclude precautionary action to mitigate the risk of significant harm to the environment.

2. Treaties

In contrast to the Rio Declaration and other non-binding instruments, statements concerning precautionary decision making in treaties are legally binding. Treaty obligations, in contrast to the “soft,” non-binding instruments identified in the previous section, in principle are legally enforceable under international law. However, binding obligations of treaty origin also have some limitations in scope. As treaties in international law are formed on a consensual theory similar to that of contracts in municipal legal systems, their obligations apply only to those states party to the treaty in question. Second, such statements, like the treaties in which they are embedded, tend to be confined to relatively discrete subject matter areas. Consequently, the language dealing with precaution in a particular treaty is likely to be specific to the subject matter covered by the agreement, and is not necessarily generally applicable to all regulatory decision making. The number of treaty references to precautionary decision making is now quite large. This section identifies some of the more significant examples.¹²

11. OECD Doc. C(90)164.

12. Another possible source of binding or “hard” law is custom, which arises from a pattern and practice of states motivated by a sense of legal obligation (*opinio juris*). In contrast to “soft” instruments such as the Rio Declaration, which do not articulate legally enforceable obligations, and treaties, which do so only for those states that have given their express consent, a requirement to implement precaution as a matter of customary law in principle could bind states that had not affirmatively indicated their intent to accept the obligation. There does not appear to be international agreement as to whether the conditions for the existence of customary international standards for precaution have been satisfied.

a. *Persistent Organic Pollutants (POPs)*

The most recent articulation of precaution as a public policy is contained in the Stockholm Convention on Persistent Organic Pollutants,¹³ adopted at a diplomatic conference on 23 May 2001. In the preamble¹⁴ to that instrument, the parties declare that they are

Acknowledging that precaution underlies the concerns of all Parties and is embedded in this Convention.

Operative Article 1, entitled "Objective," provides as follows:

Mindful of the precautionary approach as set forth in Principle 15 of the Rio Declaration on Environment and Development, the objective of this Convention is to protect human health and the environment from persistent organic pollutants.

Article 8, addressing the listing of additional chemicals governed by the agreement at the initiative of one of the parties, states in paragraph 9 that the Conference of the Parties shall act on such a proposal "in a precautionary manner." Annex C, part V, directs parties in considering best available techniques for preventing or reducing releases of chemicals regulated by the agreement, to take into account considerations of "precaution and prevention."

b. *Climate*

The 1992 United Nations Framework Convention on Climate Change¹⁵ in article 3, paragraph 2 states that:

The Parties should take precautionary measures to anticipate, prevent or minimize the causes of climate change and mitigate its adverse effects.

13. Available at web site <http://www.chem.unep.ch/pops/POPs_Inc/dipcon/meetingdocs/conf-2/en/conf-2e.pdf>. The United States signed this agreement, which has not yet entered into force.

14. The preamble to a treaty is generally considered to establish its contextual setting as opposed to containing substantive obligations. See Vienna Convention on the Law of Treaties, 22 May 1969, art. 31, para. 2, 8 *ILM* 679 (1969) (identifying elements of context of treaty as "the text, including [the treaty's] preamble and annexes"). Hence, the identification of precaution in preambular language, depending on its phraseology, may have a different legal significance from that in the operative text. The Vienna Convention on the Law of Treaties, although not in force for the United States, has been accepted by the Executive Branch as a codification of customary international law regarding international agreements. See S. Exec. Doc. L, S. Exec. Doc. L, 92d Cong., 1st Sess. (1971), at 1; *Restatement (Third) of the Foreign Relations Law of the United States* pt. III, introductory note (1987).

15. 9 May 1992, 31 *ILM* 851 (1992). The United States is a party to this instrument.

Where there are threats of serious or irreversible damage, lack of full scientific certainty should not be used as a reason for postponing such measures, taking into account that policies and measures to deal with climate change should be cost-effective so as to ensure global benefits at the lowest possible cost.

The 1990 Ministerial Declaration on the Second World Climate Conference, an important non-binding precursor to the Convention, also contains a reference to precaution.¹⁶

c. Biodiversity

While not mentioning precaution by name, the United Nations Convention on Biological Diversity (Biodiversity Convention)¹⁷ contains the following preambular language:

Noting also that where there is a threat of significant reduction or loss of biological diversity, lack of full scientific certainty should not be used as a reason for postponing measures to avoid or minimize such a threat[.]

The Cartagena Protocol on Biosafety,¹⁸ an ancillary agreement to the Biodiversity Convention, specifies in article 1, entitled "Objective," as follows:

In accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development, the objective of this Protocol is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects

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16. 7 November 1990, para. 7, 20 *Environmental Policy and Law* 220 (1990) ("In order to achieve sustainable development in all countries and to meet the needs of present and future generations, precautionary measures to meet the climate challenge must anticipate, attack, or minimize the causes of, and mitigate the adverse consequences of, environmental degradation that might result from climate change. Where there are threats of serious or irreversible damage, lack of full scientific certainty should not be used as a reason for postponing cost-effective measures to prevent such environmental degradation. The measures adopted should take into account different socio-economic contexts.").
17. 22 May 1992, 31 *ILM* 822 (1992). The United States has signed but not ratified this agreement. Article 18 of the Vienna Convention on the Law of Treaties, *supra*, note 14, provides that "[a] State is obliged to refrain from acts which would defeat the object and purpose of a treaty when... it has signed the treaty or has exchanged instruments constituting the treaty subject to ratification, acceptance or approval, until it shall have made its intention clear not to become a party to the treaty..."
18. 29 January 2000 (available at web site <<http://www.biodiv.org/biosafety/protocol.asp>>). The United States has not signed this instrument, which has not yet entered into force.

on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements.

This instrument also contains a preambular reference “reaffirming the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development.”

d. Long-range Transboundary Air Pollution

The second sulfur protocol of 1994¹⁹ to the Convention on Long-Range Transboundary Air Pollution (LRTAP),²⁰ negotiated under the auspices of the UN Economic Commission for Europe, contains two preambular paragraphs in which the parties to the instrument declare that they are

Resolved to take precautionary measures to anticipate, prevent or minimize emissions of air pollutants and mitigate their adverse effects, [and]

Convinced that where there are threats of serious or irreversible damage, lack of full scientific certainty should not be used as a reason for postponing such measures, taking into account that such precautionary measures to deal with emissions of air pollutants should be cost-effective[.]

Similarly, in preambular language to the Aarhus Protocol on Persistent Organic Pollutants to the Convention on Long-Range Transboundary Air Pollution,²¹ the parties to that instrument declare themselves:

Resolved to take measures to anticipate, prevent or minimize emissions of persistent organic pollutants, taking into account the application of the precautionary approach, as set forth in principle 15 of the Rio Declaration on Environment and Development[.]

e. Marine Environment

Once it enters into force, the Protocol to the Convention on the Prevention of Marine Pollution by Dumping of Wastes and other Matter

19. Oslo Protocol to the 1979 Convention on Long-Range Transboundary Air Pollution, on Further Reductions of Sulfur Emissions, 14 June 1994, 33 *ILM* 1540 (1994). Although the United States is a party to the LRTAP Convention, it is not a party to the Oslo Protocol, which entered into force in 1998.
20. Convention on Long-Range Transboundary Air Pollution (LRTAP), 13 November 1979, 18 *ILM* 1442 (1979).
21. 24 June 1998, 37 *ILM* 505 (1998). The United States has signed but not ratified this agreement, which has not yet entered into force.

(London Dumping Convention)²² will supersede the existing 1972 instrument for parties to both agreements.²³ Article 3, paragraph 1 of the Protocol specifies that

In implementing this Protocol, Contracting Parties shall apply a precautionary approach to environmental protection from dumping of wastes or other matter whereby appropriate preventive measures are taken when there is reason to believe that wastes or other matter introduced into the marine environment are likely to cause harm even when there is no conclusive evidence to prove a causal relation between inputs and their effects.

This language is virtually identical to a provision in a 1991 resolution adopted by the parties to the London Dumping Convention.²⁴

Another instrument adopted under the auspices of the International Maritime Organization (IMO), the International Convention on Oil Preparedness, Response and Co-operation,²⁵ refers in preambular language to “the importance of precautionary measures and prevention in avoiding oil pollution in the first instance...”

f. Fisheries

Article 5, entitled “General Principles,” of the UN straddling stocks agreement adopted in 1995,²⁶ specifies

In order to conserve and manage straddling fish stocks and highly migratory fish stocks, coastal States and States fishing on the high seas shall, in giving effect to their duty to co-operate in accordance with the Convention...

(c) apply the precautionary principle in accordance with Article 6[.]

22. 7 November 1996, 36 *ILM* 1 (1997). The United States has signed the Protocol, which has not yet entered into force.

23. Convention on the Prevention of Marine Pollution by Dumping of Wastes and Other Matter, 13 November 1972, 11 *ILM* 1294 (1972).

24. IMO Doc. *LDC* 44(14).

25. 30 November 1990, 30 *ILM* 735 (1991). The United States has signed but not ratified this instrument, which entered into force in 1995.

26. Agreement for the Implementation of the Provisions of the United Nations Convention on the Law of the Sea of 10 December 1982 Relating to the Conservation and Management of Straddling Fish Stocks and Highly Migratory Fish Stocks, 4 August 1995, 34 *ILM* 1547 (1995). The United States has ratified this agreement, which has not yet entered into force.

Article 6, entitled "Application of the Precautionary Approach," is devoted in its entirety to principles of precaution. That provision provides in part:

1. States shall apply the precautionary approach widely in conservation, management and exploitation of straddling fish stocks and highly migratory fish stocks in order to protect the living marine resources and preserve the marine environment.
2. States shall be more cautious when information is uncertain, unreliable or inadequate. The absence of scientific information shall not be used as a reason for postponing or failing to take conservation and management measures.

An annex to the agreement consists of guidelines for application of precautionary reference points in conservation and management of straddling fish stocks.

g. Transboundary Watercourses

According to the 1992 ECE convention on transboundary watercourses,²⁷ in the operative language of article 2, paragraph 5,

...the Parties shall be guided by the following principles:

- (a) The precautionary principle, by virtue of which action to avoid the potential transboundary impact of the release of hazardous substances shall not be postponed on the ground that scientific research has not fully proved a causal link between those substances on the one hand, and the potential transboundary impact on the other hand.

B. A Typology of Precautionary Decision Making

Precautionary precepts apply a heuristic approach along the lines of the adage "better safe than sorry." A precautionary perspective would urge governmental decision makers to err on the side of anticipating and preventing uncertain harm. The texts contained in the international instruments identified in section II.A above take a variety of approaches in applying precaution to governmental decision-making processes. Moreover, some issues necessarily encountered in applying precautionary methodologies are barely alluded to in the international

27. Convention on the Law of the Non-navigational Uses of International Watercourses, 17 March 1992, 36 *ILM* 700 (1997). The United States is not a party to this agreement, which entered into force in 1996.

texts. After analyzing the variety of international approaches, this section undertakes to articulate a comprehensive approach to precautionary decision making that reflects these considerations.

A helpful framework in which to analyze precautionary exhortations, and one which is frequently employed in debates over precaution in a variety of domestic and international settings in the United States and abroad, bifurcates the regulatory process into two phases: “risk assessment,” which in principle establishes the strictly scientific basis for regulatory action, and “risk management,” which is the multidisciplinary process of choosing regulatory measures.²⁸ In this two-stage methodology, scientific questions are isolated and addressed in an objective manner through risk assessment methodologies at the beginning of the regulatory process. Pure policy choices are supposedly confined to the second phase, risk management. At this stage, science may

28. As described by a former Administrator of the US Environmental Protection Agency:

Risk assessment is an exercise that combines available data on a substance's potency in causing adverse health effects with information about likely human exposure, and through the use of plausible assumptions, it generates an estimate of human health risk. Risk management is the process by which a protective agency decides what action to take in the face of such estimates. Ideally the action is based on such factors as the goals of public health and environmental protection, relevant legislation, legal precedent, and application of social, economic, and political values.

William D. Ruckelshaus, *Risk, Science, and Democracy, Issues in Sci. & Tech.*, Spring 1985, at 19, 28. Another influential publication has described the distinction as follows:

We use *risk assessment* to mean the characterization of the potential adverse health effects of human exposures to environmental hazards. Risk assessments include several elements: description of the potential adverse health effects based on an evaluation of results of epidemiologic, clinical, toxicologic, and environmental research; extrapolation from those results to predict the type and estimate the extent of health effects in humans under given conditions of exposure; judgments as to the number and characteristics of persons exposed at various intensities and durations; and summary judgments on the existence and overall magnitude of the public-health problem. Risk assessment also includes characterization of the uncertainties inherent in the process of inferring risk.

The term *risk assessment* is often given narrower and broader meanings than we have adopted here. For some observers, the term is synonymous with *quantitative risk assessment* and emphasizes reliance on numerical results. Our broader definition includes quantification, but also includes qualitative expressions of risk. Quantitative estimates of risk are not always feasible, and they may be eschewed by agencies for policy reasons. Broader uses of the term than ours also embrace analysis of perceived risks, comparisons of risks associated with different regulatory strategies, and occasionally analysis of the economic and social implications of regulatory decisions—functions that we assign to risk management.

Committee on the Institutional Means for Assessment of Risks to Public Health, Commission on Life Sciences, National Research Council, *Risk Assessment in the Federal Government: Managing the Process* 18 (1983) (emphasis in original).

be relevant for such tasks as evaluating technical options. Risk management decisions, however, also engage other considerations, most notably social values.²⁹

Within the framework of the risk assessment/risk management duality, there appears to be agreement that precautionary approaches are relevant, if at all, at the risk management phase.³⁰ There is less of a consensus about the role of precautionary elements in the risk assessment process. In particular, there has been concern that some formulations of precautionary approaches to risk assessment might allow governments to use cultural preferences and other nonscientific factors in making risk management decisions. The United States in particular has identified the potential for governmental measures based on precautionary rationales to serve as trade barriers.³¹

1. *Variations in International Formulations for Precaution*

International authorities generally identify the following features common to precautionary decision making: (1) an indication of a potential for harm; (2) uncertainty in the data set that might lead to a conclusion of a potential for harm; and (3) the desirability of a public policy response to reduce that potential at an early juncture. Within this general framework, as demonstrated by the texts quoted below, there is some variability in multilateral formulations of precautionary methodologies.

a. *Lack of Certainty*

As with any normative approach, binding or not, most formulations of precautionary norms for governmental decision making identify the universe of actions to which those tests will apply. A central

29. “[R]isk management... describes the process of evaluating alternative regulatory actions and selecting among them. Risk management, which is carried out by regulatory agencies under various legislative mandates, is an agency decision-making process that entails consideration of political, social, economic, and engineering information with risk-related information to develop, analyze, and compare regulatory options and to select the appropriate regulatory response to a potential chronic health hazard. The selection process necessarily requires the use of value judgments on such issues as the acceptability of risk and the reasonableness of the costs of control.” National Research Council, *supra*, note 28, at 18-19 (emphasis in original).

30. See, e.g., *Communication from the Commission on the Precautionary Principle*, summary para. 4, EU Doc. COM (2000) 1 (2 February 2000) (<http://europa.eu.int/eur-lex/en/com/cnc/2000/com2000_0001en01.pdf>)(“The precautionary principle is particularly relevant to the management of risk.”)

31. See, e.g., White House Policy Declaration on Environment and Trade, *infra*, note 45.

component of precautionary heuristics is their application to situations involving uncertainty, which can be regarded as one element of the “trigger” or condition precedent for invoking precautionary methodologies. This aspect of precaution, concerning at least in part the scientific predicate for governmental action, is best understood as an element of the risk-assessment phase of regulatory decision making.³²

Principle 15 of the Rio Declaration is typical in specifying its application to situations characterized by “lack of full scientific certainty.” Other instruments using this identical formulation include the Bergen Ministerial Declaration, the 1990 G-7 Houston summit communiqué, the UN Climate Convention, the Second World Climate Conference declaration, the UN Biodiversity Convention, and the second sulfur protocol to the LRTAP Convention. The numerous references to Principle 15 of the Rio Declaration by name implicitly incorporate this normative prescription by reference.

The Okinawa G-8 summit declaration applies to biotechnology and food safety issues “where available scientific information is incomplete or contradictory.” The 1990 OECD recommendation on integrated pollution prevention refers to “the absence of complete information.” Agenda 21 refers to “policies relating to complex systems that are not yet fully understood and whose consequences and disturbances cannot yet be predicted.” The protocol amending the London Dumping Convention refers to situations in which “there is no conclusive evidence to prove a causal relation between inputs and their effects.” The straddling stocks agreement takes as its reference point “information [that] is

32. In this context, “risk assessment” does not necessarily imply only a quantitative risk assessment, which would arguably restrict the application of precautionary methodologies. For example, in the dispute settlement proceedings initiated by the United States and Canada in the World Trade Organization (WTO) against the European Union over hormone-treated beef, the WTO Appellate Body expressly recognized that a “risk assessment” need not necessarily be quantitative in nature. *European Communities-Measures Concerning Meat and Meat Products*, WTO Doc. No. WT/DS26/AB/R & WT/DS48/AB/R, paras 186-87 (16 January 1998): “the imposition of... a quantitative requirement finds no basis in the [Uruguay Round Agreement on the Application of Sanitary and Phytosanitary Standards, whose interpretation was at issue in the dispute]... [T]o the extent that the Panel purports to exclude from the scope of a risk assessment... all matters not susceptible of quantitative analysis by the empirical or experimental laboratory methods commonly associated with the physical sciences, we believe that the Panel is in error”. This conclusion is particularly compelling because the Appellate Body found that a precautionary principle, as asserted by the European Union, did *not* control the interpretation of the Uruguay Round SPS Agreement. *Id.* at para. 125. Consequently, there would be, if anything, *less* of a need for quantification of risk in situations, such as those which are the subject of this paper, in which precautionary methodologies would be applicable.

uncertain, unreliable or inadequate” and refers to “[t]he absence of scientific information.” The ECE Convention on transboundary water-courses applies in instances in which “scientific research has not fully proved a causal link between those substances on the one hand, and the potential transboundary impact on the other hand.”

Particularly in light of current approaches to processing scientific uncertainty discussed in section II.B.2.a below, the variability in textual formulations among some of the sources probably has little, if any, significance. In light of the current international debate over precaution, one variation that might have some significance is the presence or absence of the qualifier “scientific” or its equivalent in describing the information base against which precautionary precepts should or must be applied. Among the instruments surveyed, only the 1990 OECD recommendation, Agenda 21, and the protocol amending the London Dumping Convention fail to identify the factual predicate for action as “scientific” in nature. Those authorities, moreover, certainly do not exclude scientific considerations. Based on these texts, it consequently would appear to be reasonable to expect, as a general matter, that the factual predicate for the exercise of precaution would be based on scientific data.

b. Likelihood and Severity of Harm

The Rio Declaration is typical of many of the instruments examined in specifying that precautionary approaches apply to situations involving “threats of serious or irreversible damage.” Again, those instruments that allude to Principle 15 by name would be assumed to incorporate this criterion by reference. Additionally, the UN Climate Convention, the second sulfur protocol to the LRTAP Convention, and the Bergen Ministerial Declaration include the identical textual formulation.

The Houston Summit communiqué is confined to “threats of irreversible damage.” The 1990 OECD recommendation on integrated pollution prevention speaks of “the risk of significant harm to the environment.” The formulation in the UN Biodiversity Convention addresses “a threat of significant reduction or loss of biological diversity,” a test which is clearly unique to the subject matter of that agreement. The protocol amending the London Dumping Convention covers situations in which “there is reason to believe that [ocean dumping is] likely to cause harm.” The ECE Convention on Transboundary Water-courses speaks of “potential transboundary impact.”

While the precise wording varies among the instruments surveyed, all either explicitly or implicitly incorporate the notion of probability of adverse consequences within their scope of applicability. Most of the formulations expressly utilize either the word “threat” or “risk” to embody this concept. In light of the purpose of public policies based on precaution—to assure early intervention in the face of uncertainty—the choice of one or the other term probably should not be regarded as carrying any particular significance.³³

Similarly, the language addressing the magnitude or severity of harm that will qualify for the application of precaution varies among the different instruments. The various formulations identify a variety of thresholds of likelihood of effects, which can be considered to lie at various points on a spectrum. At one end of this continuum are “threats of serious or irreversible damage.” At the other end is at least one example speaking of “impact[s]” without qualification, with other tests such as “significant harm” lying between the two. In contrast to the criterion related to likelihood of harm, these different formulations do appear to convey disparities in underlying intent. This suggests that, with respect to the factor of severity of harm qualifying for the application of precautionary decision making, there would be a need to identify which instruments or authorities apply to a given situation with some particularity.

c. Policy Responses

Given the apparently wide agreement, as discussed in section II.B above, on the treatment of precaution as a risk management response, the authorities surveyed in this paper have remarkably little to say about the purpose, from a public policy point of view, of the measures contemplated as a result of the application of precautionary methodologies. Although the Rio Declaration, as discussed in the next section, includes a cost-effectiveness criterion, it otherwise speaks only of “measures.”

Among those instruments that specifically address this question, the policy goals are related to specific contexts, and even those tend to be general rather than specific. The UN Climate Convention states that precautionary measures should “anticipate, prevent or minimize the causes of climate change and mitigate its adverse effects,” and the Second World Climate conference declaration includes similar language. The Biodiversity Convention identifies the need to “avoid or minimize” threats to biodiversity. The second ECE sulfur protocol identifies the need to “anticipate, prevent or minimize emissions of air pollutants and mitigate their adverse effects.”

33. With respect to the need for quantification of risks or threats, see note 32 *supra*.

d. *Cost-effectiveness*

Among the instruments surveyed, a number specify that the risk-management measures contemplated should be “cost-effective.” These include the Rio Declaration, the Ministerial Declaration from the Second World Climate Conference, and the second ECE sulfur protocol. As before, it would probably be most appropriate to interpret those instruments that reference the Rio Declaration consistently with this criterion. The UN Climate Convention further reinforces the need for cost-effective measures by adding that the purpose of this criterion is “to ensure global benefits at the lowest possible cost.” As indicated by this last example, cost-effectiveness implies a choice of measure with the lowest cost that still leads to a result consistent with precepts of precaution.³⁴ Again, just as the inclusion of a cost-effectiveness criterion in some of the instruments is an indication of the intent of their drafters, the absence of such a test in those that omit it would also have interpretive significance.

e. *Differential Criteria*

The Rio Declaration qualifies its exhortation for states to apply a precautionary approach with the phrase “according to their capabilities.” This appears to be an indication of a graduated or differential test whose application is intended to be different for countries at various stages of economic development. While several of the instruments identified above have differential substantive obligations for developing countries, none of the other formulations of precautionary norms contain a similar qualification. Once again, however, this factor would also be relevant to those instruments that reference the Rio Declaration.

2. *Kinds of Scientific Uncertainty*

While referring to “uncertainty,” the formulations of criteria for precautionary decision making surveyed for this paper have remark-

34. Particularly by reference to the purpose of precautionary approaches, the concept of cost-effectiveness should be contrasted with a cost-benefit test. A criterion of cost-effectiveness implies the identification of a precautionary goal, with the subsequent choice of risk-management measures that achieve that goal with the lowest cost. By contrast, a cost-benefit test could imply that an otherwise precautionary outcome might be precluded if the overall benefits of the action did not exceed the costs. See, e.g., Richard D. Morgenstern, “Conducting an Economic Analysis: Rationale, Issues, and Requirements”, in *Economic Analyses at EPA: Assessing Regulatory Impact* 26 (Richard D. Morgenstern, ed. 1997). Significantly, none of the instruments surveyed articulate a cost-benefit test. Cf. section III.A.2.d *infra* (discussing US domestic legal instruments containing cost-benefit requirements).

ably little to say in elaborating the concept. While perhaps not the last word on the matter in a public policy setting, there is a reasonably well developed literature addressed to the nature of scientific uncertainty, both as applied in public policy contexts and otherwise.³⁵

a. *Quantifiable Uncertainties*

Although it may sound paradoxical, certain kinds of uncertainties are “knowable” in a meaningful sense because their outer bounds can be identified. Uncertainties in this sense can be expressed as a level of confidence in an experimental observation, a calculated result, or an inference from empirical data. Theories of scientific uncertainty in this sense have been well developed for a considerable time and include such elements as statistical treatment of data sets, criteria for determining the range of possible values indicating the reliability with which a measured or calculated value is appropriately reported, and procedures addressing the “propagation of error” resulting from a calculation based on two or more measured quantities, each characterized by their own error factors.³⁶

(1) Measurement Uncertainties

From a scientific perspective, the concept of “error” probably tracks most closely at least a portion of the concept intended to be captured in the term “uncertainty” as used in normative formulations for precautionary public policies. “Error” does not in general refer to outright computational mistakes. Rather, the scientific concept of error describes uncertainties in human capacity to observe and describe the natural world through experiment. Experimental errors, or measurement uncertainties, generally fall into two categories: random and systematic. Both arise because of imperfections in the measuring process.

(a) *Random errors*

Random errors manifest themselves in the scatter observed when empirically measured values diverge from one another on repeated iter-

35. See, e.g., Vern R. Walker, “Risk Regulation and the “Faces” of Uncertainty”, 9 *Risk: Health, Safety & Environment* 27 (1998); Vern R. Walker, “The Siren Songs of Science: Toward a Taxonomy of Scientific Uncertainty for Decisionmakers”, 23 *Conn. L. Rev.* 567 (1991).

36. See, e.g., Yardley Beers, *Introduction to the Theory of Error* (1953); Philip R. Bevington, *Data Reduction and Error Analysis for the Physical Sciences* (1969).

ations of the measurement process. Random experimental error can arise because of fluctuating conditions in variables intended to be held constant, such as the temperature of a laboratory. Alternatively, random errors can arise because of small disturbances to the measurement apparatus. Random errors of this sort are characteristic of most if not all experiments, no matter how carefully designed. Random error is generally expressed by a range around a measured or calculated value. The reliability of the measurement is indicated by the expressed range of uncertainty; the smaller the range of observed measurements, the higher the precision of the measurement method.

(b) *Systematic errors*

In contrast to random errors, which can be expected to produce a data set clustering around the “true” value, systematic errors result in a deviation by a constant amount. Systematic errors can arise because of the nature of experimental design or technique, errors in calibration of instrumentation, or deviations in experimental conditions from those for which the experiment was calibrated. In some cases, systematic errors can be removed through the application of suitable corrections to compensate for the error. As in the case of random errors, scientific theory and practice in this area are reasonably well developed.

(2) *Sampling Uncertainties*

Uncertainty in measurements may be enhanced or reduced depending on the number of data points collected. This “sampling error” may result in imprecise inferences arising from potential errors or defects in sampling techniques, as in a toxicological study of the effects of a chemical on mice.³⁷ As a general matter, the larger the sample size the smaller the error. At the same time, economic or other factors may require inferences about large populations from relatively small samples. For example, this kind of uncertainty accounts for the confidence ranges typically reported in public opinion or political polling data. Sampling error can be processed quantitatively through the application of statistical methods, as expressed in such tests as statistical significance and confidence intervals.

37. For reasons such as this, the US National Academy of Science has urged the Environmental Protection Agency to discontinue the practice of precisely defining “point estimates” of risk, and instead to offer a range of risks commensurate with the integrity of the underlying data set. See National Research Council, *Science and Judgment in Risk Assessment* (1994).

(3) Modeling Uncertainties

Uncertainties can also arise from the use of mathematical models that are frequently used to predict the behavior of natural systems with particular relevance to environmental problems such as stratospheric ozone depletion and global warming. In some cases, the predictive power of computer models can be quantified by identifying the correlation between the independent and dependent variables. Precautionary considerations can be taken into account in the selection of a model, as well as in the choice of model inputs and default values. For example, a precautionary perspective might counsel applying conservative assumptions in the absence of empirical data, as in assessing low-dose cancer risks. Uncertainties in scientific models can also arise, however, from more fundamental limitations in human capacity to model natural systems, in which case attempts to quantify uncertainties may fail to capture limits on the utility of the model.

b. Fundamental or Irreducible Uncertainties

An entirely different kind of uncertainty arises not from limitations on the capacity to observe natural systems accurately or precisely, but from a more fundamental limitation in observers' capacity to understand them. Various writers have identified different kinds of uncertainty in this category. For example, "concept uncertainty" arises from an inappropriate choice of variables for observation. "Causal uncertainty" can result from flawed reasoning from empirical data about mechanistic relationships. "Epistemic uncertainty" appears in situations of cumulative or additive exposures whose interactions may be poorly understood. These types of uncertainty are difficult or perhaps impossible to quantify.

Precaution as a public policy appears to be directed primarily to these categories of fundamental or irreducible uncertainty to a much greater extent than "traditional" scientific errors. So, for instance, precautionary decision-making methodologies as articulated in the instruments surveyed in this paper are arguably addressed to something more fundamental than choosing the upper as opposed to the lower bound identified by a risk assessment as a basis for risk management measures. Rather, at least one interpretation of a precautionary methodology addresses not uncertainties in the underlying data but in the inferences to be drawn from them.

For example, quantitative risk assessments include both "traditional" uncertainties, arising from the integrity of the underlying data

set, and “concept” uncertainties, related to assumptions concerning extrapolations from animals to humans or high to low doses. While both kinds of uncertainties are addressed by precautionary approaches, the intent seems to be specifically to include the latter in the “trigger” factor, or the determination that a precautionary approach ought to apply. So, for example, a precautionary perspective might be taken to counsel more aggressive risk management measures than suggested by a risk assessment applying even conservative assumptions in the estimation of low-dose cancer risks.

At the same time, science has relatively less to say about these kinds of fundamental or irreducible uncertainties, at least from a quantitative point of view. Indeed, it is very likely impossible to imagine a numerical calculus for such a purpose. Carried to its logical conclusion, a precautionary heuristic attempts to provide a public policy response designed to anticipate the unexpected or unpredictable.

There is no doubt that such situations exist, with potentially profound public policy implications. For example, notwithstanding an appreciation of the process by which chlorofluorocarbons deplete stratospheric ozone, computer models failed to predict the existence of the Antarctic ozone hole before its discovery in 1985.³⁸ As suggested by that example, there is no purely scientific methodology for addressing such uncertainties, in this case resulting from limits in human capacity to model natural systems.

Precautionary approaches appear to be designed to fill this gap. In the case of stratospheric ozone before the discovery of the Antarctic ozone hole, an application of the precautionary approach set out in Principle 15 of the Rio Declaration might have proceeded as follows: Scientific data in the early 1980s were interpreted as demonstrating the potential for some loss of stratospheric ozone.³⁹ The potential for larger losses could be catastrophic, satisfying the textual test of a “threat[] of serious or irreversible damage.” While the likelihood of such an outcome was poorly defined, it was nonetheless a possibility, satisfying Principle 15’s test of a “lack of full scientific certainty.” The remainder of the text would then counsel the earlier rather than later adoption of “cost-effective measures to prevent environmental degradation” from loss of stratospheric ozone.

38. See, e.g., Richard Elliott Benedick, *Ozone Diplomacy: New Directions in Safeguarding the Planet* 19 (enlarged edition, 1998).

39. See, e.g., 45 Fed. Reg. 66,726 (7 October 1980) (US Environmental Protection Agency advance notice of proposed rulemaking concerning chlorofluorocarbons).

3. *Science in the Public Policy Process*

Scientists often disagree among themselves, especially on issues at the cutting edge of regulatory policy that may involve considerable scientific uncertainty.⁴⁰ Even the supposedly strictly technical process of risk assessment involves the exercise of judgments reflecting underlying public policy biases.⁴¹ Social value choices necessarily intrude into the analysis of physical phenomena by means of risk assessment methodologies through the selection of inferences and assumptions. Consequently, there is unlikely to be a single, unique way to analyze even the purely scientific significance of much empirical data in a public policy setting. As a result, in a regulatory context science may be relatively unhelpful when there is a genuine scientific dispute.

The scientific peer review process operating in a regulatory context can reduce disagreement, identify gaps and holes, and articulate the need for further investigation. Scientific peer review involves a sometimes protracted give and take among experts. Significantly, peer review does not anticipate the sort of bipolar “yes or no” result contemplated by an adjudicatory process. Instead, peer review is responsive to a characterization of science as an ongoing search for knowledge against a constantly shifting and evolving background that by its very nature is always operating at new frontiers. On the other hand, peer review in a

40. As a former Administrator of the US Environmental Protection Agency has noted: Science is only orderly after the fact; in process, and especially at the advancing edge of some field, it is chaotic and fiercely controversial. Thus, the expectation built into environmental law, that science can provide definitive answers to the kinds of questions that policymakers are obliged to ask under the terms of that law, will be disappointed to the degree that such answers derive from the forward edge of research . . .

Nor can we order a consensus in the areas of greatest interest to environmental policy: pollutant exposure and effects. Policymakers, including me, have often deplored the tendency of scientific panels to engage in interminable debate rather than reach the agreement that was clearly indicated on the invitation. *Of course* scientists will disagree on issues involving the advancing edge of research; that is what they do for a living. And even if we could somehow get a group of scientists to endorse a consensus position, it would be, in the first place, only tentative and subject to revision with the arrival of new discoveries; and in the second place, it may be entirely wrong.

In science, the majority does not rule, as the history of science amply demonstrates. Ruckelshaus, *supra*, note 28, at 24 (emphasis in original).

41. “[S]ome people in the regulated community believe that the structure of risk assessment inherently exaggerates risk, while many environmentalists believe that it will not capture all the risk that may actually exist....[T]his disagreement is not resolvable in the short run through recourse to science. Risk assessment is necessarily dependent on choices made among a host of assumptions, and these choices will inevitably be affected by the values of the choosers, whether they be scientists, civil servants, or politicians.” *Id.* at 28.

regulatory setting may also engage disputed, value-laden questions of science policy and may be unresponsive to the development of new scientific methodologies that, while lacking general acceptance, may nonetheless be reliable.

Against this background, a precautionary approach can be taken to be one that gives particular credence to minority or dissenting scientific opinions that plausibly suggest the existence of a risk, notwithstanding some uncertainty, conceptual or otherwise. At an absolute minimum, precaution would tend to affirm the capacity of a government to regulate on the basis of minority or uncertain science, should it choose to do so.⁴²

4. *Range of Policy Responses*

As discussed in section II.B.1.c above, multilateral formulations of precautionary theories of regulation give relatively little attention to the choice of measure after a determination has been made that a precau-

42. The US cases interpreting precautionary legislation, discussed in section III.B *infra*, imply a similar conclusion, based on a theory of deference to the judgment of a technically expert agency.

The question of deference to domestic regulation based on minority or uncertain science arose particularly pointedly during negotiations over trade-based disciplines on food safety measures in the context of the Uruguay Round of Multilateral Negotiations in GATT and the North American Free Trade Agreement. The Executive Branch of the United States Government, which negotiated those agreements, explained that

It is clear that the requirement in the [Uruguay Round SPS] Agreement that measures be based on scientific principles and not be maintained "without sufficient scientific evidence" would *not* authorize a dispute settlement panel to substitute its scientific judgment for that of the government maintaining the sanitary or phytosanitary measure. For example, by requiring that a measure be based on scientific principles (rather than, for instance, requiring that a measure be based on the "best" science) and not to be maintained without sufficient scientific evidence (rather than, for instance, requiring an examination of the "weight of the evidence"), the [SPS] Agreement recognizes the fact that scientific certainty is rare and many scientific determinations require a judgment among differing scientific views. The [SPS] Agreement preserves the ability of governments to make such judgments.

Uruguay Round Agreements Act, Statement of Administrative Action, H.R. Doc. No. 103-316, 103d Cong., 2d Sess. 656, 746, reprinted in *1994 US Code Cong. & Ad. News* 4040, 4105 (emphasis in original). See also Office of the United States Trade Representative, *Report on US Food Safety and the Uruguay Round: Protecting Consumers and Promoting US Export* 5 (June 1994) (same). Cf. *North American Free Trade Agreement Implementation Act, Statement of Administrative Action*, H.R. Doc. No. 103-159, 103d Cong., 1st Sess. 450, 542 (1993) ("[t]he question is... *not* whether the measure was based on the 'best' science or the 'preponderance' of science or whether there was conflicting science. The question is only whether the government maintaining the measure has a scientific basis for it" [emphasis in original]).

tionary perspective is appropriate. United States legislation, as discussed in section III.A.2 below, articulates a variety of approaches to the relationship between risk on the one hand and risk management options on the other, and no single overarching principle can readily be discerned.⁴³

As a general matter, however, one can identify a variety of public policy responses to a risk or threat once a precautionary methodology has been determined to be appropriate. Indeed, one of the principal recommendations of advocates of more extensive use of precaution is the desirability or necessity of a systematic examination of a range of policy responses.⁴⁴ Among the precautionary public policy measures that might be appropriate, depending on the circumstances, are the following:

- labeling or other risk communication strategies, which might be particularly appropriate in situations in which it is considered fitting for individual workers or members of the public to make determinations about their own exposures to risk;
- technical standards establishing manufacturing or processing specifications so as to reduce exposures to consumers, workers, or the environment;
- production or manufacturing limitations, or limitations for particular uses, for toxic substances with environmental and/or health effects;
- limitations on exposures, such as to pesticides in food or contaminants in drinking water or food;
- requirements for disposal for substances or wastes that may have adverse environmental effects;
- limitations on emissions of environmental pollutants to air, water and soil;

43. By contrast, the European Union purports to have a relatively strict requirement for proportionality for all risk management measures, including those motivated by precautionary concerns. See *Communication from the Commission on the Precautionary Principle*, *supra*, note 30.

44. See, e.g., Wingspread Statement on the Precautionary Principle, 25 January 1998, reprinted in *Protecting Public Health and the Environment: Implementing the Precautionary Principle* 353 (Carolyn Raffensperger & Joel Tickner, eds. 1999 (“The process of applying the Precautionary Principle... must... involve an examination of the full range of alternatives, including no action”).

- taxes or fees on use or emission of substances with adverse environmental or public health effects;
- requirements for prior governmental approval for substances such as pesticides or pharmaceuticals where risks may be significant and the need for a prior demonstration of safety is paramount; and
- bans or absolute prohibitions, either because of the hazardous nature of the substance or process concerned, the availability of less hazardous alternatives, or the need to create incentives for the development of alternatives.

III. UNITED STATES FEDERAL LAW

Elements of precaution are found throughout US law—in the broad sense of legislation enacted by the Congress, regulations adopted by federal agencies, and judicial decisions and interpretations by US courts—addressing environment and public health. As noted in the White House Policy Declaration on Environment and Trade, a statement of the Executive Branch of government charged with implementing federal law:

Precaution is an essential element of the US regulatory system given that regulators often have to act on the frontiers of knowledge and in the absence of full scientific certainty. We believe that this precautionary element is fully consistent with WTO rules, which make clear that a regulatory agency may take precautionary action where there is a rational basis for concern based upon available pertinent information. We will insist that this ability to take precautionary action be maintained in order to achieve our environmental objectives.

At the same time, precaution must be exercised as part of a science-based approach to regulation, not a substitute for such an approach. In this connection, the term precaution must not be used as a guise for trade protectionist measures as this would have the effect of casting doubt upon, and even undermining, environmental as well as trade policy objectives.⁴⁵

A. Legislation

While precaution may be integral to much of US regulation on environment, health, safety, and the conservation of natural resources, the legislation in these areas has been adopted over a considerable

45. White House policy declaration on environment and trade, 16 November 1999 (available at web site <<http://ustr.gov/environment/finpol.html>>).

period of time, now on the order of a century, often to address discrete problems. There is no single overarching regulatory philosophy that can be identified in a body of statutory enactments which is neither systematic nor comprehensive. While elements of precaution appear throughout US environmental regulation, the statutes governing this field must consequently be examined individually to identify the precautionary elements.⁴⁶

US federal legislation on environment, public health, worker safety, and natural resources is organized by discrete statutes, often addressing a single medium such as air or water, or a specific problem, such as hazardous wastes. In the interest of drawing larger inferences from this now quite massive compendium of statutory enactments, the following analysis does not address each statute individually. Rather, the treatment below is intended to identify precautionary themes in regulatory approaches that are common to a variety of legislative enactments.

Federal regulatory approaches that articulate precautionary policies can be divided into two broad classes: (1) procedural mechanisms, in which the structural form of the governmental decision-making process facilitates precautionary outcomes; and (2) substantive mandates, which establish outcome-oriented tests against which the results of governmental decision-making processes are intended to be measured.

1. Procedural Tools Facilitating Precaution

One common element of precautionary exhortations or directives, as discussed above, is a policy preference for identifying risks and anticipating and preventing adverse effects, in contrast to reacting to environmental harms after they have been suffered. United States law facilitates governmental decision making that is precautionary in this procedural sense by specifying certain requirements for governmental approval as a condition for entry into commerce, for advance notification of new substances or new uses, and for analysis preceding implementation of proposed governmental activities.

46. Because the discussion of precaution as a public policy is most frequently encountered and most highly developed in the fields of environment and public health, the examples that follow are drawn from those areas. However, precaution as a regulatory philosophy can and has influenced legislative requirements relating to other subject matter, such as consumer protection, public safety, transportation, and securities, banking and insurance regulation.

a. *Requirements for Prior Approval*

Requirements for prior governmental approval serve a gate-keeping function by shifting the burden onto the proponent of a product, substance or activity to justify the approval sought, usually by reference to a predetermined test or criterion. Before or pending approval, the action for which the approval must be granted is ordinarily prohibited. For that reason, requirements for prior governmental approval are regulatory tools for expressing a conclusive public policy preference for erring on the side of caution, and are consequently inherently precautionary. If a product, substance or activity for which approval is required may present risks, those risks will not be experienced until the approval is granted.

United States law requires prior approval by the federal Environmental Protection Agency (EPA) before pesticides may be sold,⁴⁷ and by the federal Food and Drug Administration (FDA) before food additives, human and animal drugs, and medical devices⁴⁸ may be marketed. Although the terminology and procedural details differ somewhat, each of these authorities requires the submission of a request to a federal regulatory authority supported by appropriate studies, review of that request by the governmental entity, and affirmative approval by the regulatory authority concerned. These requirements can be interpreted as a concrete mechanism for assuring precautionary decision-making.

In the case of pesticides, for example, any pesticide residue on food presumptively “shall be deemed unsafe”⁴⁹ absent the establishment of a tolerance (maximum residue limitation) or tolerance exemption. This means that the federal Environmental Protection Agency, in approving a pesticide, must simultaneously assure the safety of the product for use on those food crops for which it is intended. Similarly, a food additive “shall, with respect to any particular use or intended use of such additives, be deemed to be unsafe”⁵⁰ absent affirmative approval of a food additive petition by the federal Food and Drug Administration.

Permitting requirements are regulatory tools similar to requirements for prior approval, applied particularly to certain sources of air⁵¹

47. *Federal Insecticide, Fungicide, and Rodenticide Act*, 7 USC §§ 136-136y [hereinafter FIFRA].

48. *Federal Food, Drug, and Cosmetic Act*, 21 USC §§ 301-397 (hereinafter FDCA).

49. FDCA § 408(a)(1), 21 USC § 346a(a)(1).

50. *Id.* § 409(a), 21 USC § 348(a).

51. *Clean Air Act*, 42 USC § 7401-7671q.

and water⁵² pollution and for hazardous waste facilities.⁵³ All these schemes specify that a regulated entity may not engage in an identified activity—discharge of pollution into the air or water, or treatment, storage or disposal of hazardous wastes, as the case may be—without a permit. A prospective permittee must submit an application to a governmental permitting authority, which then must give its affirmative approval before the regulated activity may commence. Similar requirements apply to the licensing of nuclear power plants.⁵⁴

b. Requirements for Prior Notification

With the exception of identifiable subcategories such as pesticides and hazardous wastes which are regulated under specific statutory mandates, toxic substances in general are not subject to requirements for prior approval under federal legislation in the United States. A notable exception applies to private parties proposing to manufacture a new chemical substance, or proposing to process an existing chemical substance for a significant new use. Those persons must notify the federal Environmental Protection Agency at least 90 days in advance, providing data that the submitter believes demonstrates that the chemical will not present an unreasonable risk.⁵⁵ Although not so aggressive as affirmative advance regulatory approval schemes, notification requirements such as this create a temporal window during which governmental authorities may act in a prophylactic or precautionary manner.

c. Requirements for Prior Study

Prior study is yet another approach that is useful for facilitating public policies stressing prevention and precaution. The principal legislative vehicle in the United States is the *National Environmental Policy Act* (NEPA),⁵⁶ which is the US version of the methodology known internationally as “environmental impact assessment.” NEPA establishes requirements for the analysis of the potential effects of anticipated “major Federal actions significantly affecting the quality of the human environment” in a formal document known as an environmental impact statement (EIS). Implementing regulations and a considerable body of case law establish that an EIS must contain the following elements: (1) a

52. *Clean Water Act (Federal Water Pollution Control Act)*, 33 USC §§ 1251-1387.

53. *Resource Conservation and Recovery Act*, 42 USC §§ 6901-6992k.

54. *Atomic Energy Act of 1954*, 42 USC §§ 2011-2282.

55. *Toxic Substances Control Act*, § 5, 15 USC § 2604 (hereinafter TSCA).

56. *National Environmental Policy Act of 1969*, 42 USC §§ 4321-4370 (hereinafter NEPA).

description of the proposed action; (2) an analysis of the potentially affected environment; (3) a description of the direct and indirect potential impacts on that environment resulting from the proposed action; (4) a consideration of alternatives, including the alternative of no action, and the potential impacts of those alternatives; and (5) an analysis of mitigating measures. Federal agencies are directed to commence consideration of the nature and extent of potential environmental impacts of a proposed activity at an early stage through a process known as “scoping.” Many states of the United States have adopted similar enactments, sometimes known as “little NEPAs.”

NEPA’s mandate for prior study before a proposed action may be undertaken and its public participation requirements, on occasion as enforced through judicial action, have frequently empowered federal agencies to identify and either avoid or mitigate adverse environmental effects at an early stage in the process of project identification and implementation.⁵⁷ One of NEPA’s strengths is its across-the-board application to all federal actions and agencies, including those that do not have an affirmative environmental mandate. Consistent with a precautionary perspective, NEPA’s implementing regulations specifically direct agencies preparing an EIS to identify and evaluate incomplete or unavailable information.⁵⁸ On the other hand, although the statute requires the identification and analysis of alternatives, it does not require the selection of environmentally preferable options. Moreover, its scope—in contrast to similar requirements in some other countries—is limited to projects that are initiated by or require the approval of public authorities, thereby potentially exempting certain strictly private undertakings from scrutiny under the statute.

2. *Substantive Mandates*

United States federal legislation includes a wide variety of substantive directives that govern the outcomes of governmental decision-making processes, as distinct from the processes by which those decisions are taken. Some of these formulations are more precautionary than others. This section identifies a number of the tests found in US federal environmental legislation by reference to a precautionary imperative to err on the side of caution in situations characterized by uncertainty.

57. Under certain circumstances, NEPA’s mandate for prior study and analysis may augment the efficacy of other regulatory tools, such as permitting requirements. See, e.g., *Roosevelt Campobello International Part Commission v. EPA*, 684 F.2d 1041 (1st Cir. 1982) (interaction of NEPA, *Clean Water Act*, and *Endangered Species Act*).

58. 40 CFR § 1502.22 (incomplete or unavailable information).

a. *Zero Tolerance*

Almost by definition, the most precautionary policies would be those that tolerate absolutely no risk. The so-called “Delaney Clauses,”⁵⁹ which ban the addition of demonstrated cancer-causing food colorings, additives, and animal drugs in any amount to food, are probably the best-known examples of this approach in United States law. The Delaney Clauses, which articulate a “zero risk” threshold generally regarded as the most demanding in federal law, are nonetheless subject to a “de minimis” exception⁶⁰ and have on occasion been criticized on both scientific and policy grounds.⁶¹ Moreover, there is a certain amount of discretion inherent in the determination whether a substance causes cancer and is therefore subject to the statutory prohibition. The requirement for prior approval of a food additive petition⁶² enhances the precautionary nature of this substantive directive.

Another policy close to a “zero tolerance” philosophy is found in the *Endangered Species Act*, which requires the federal government to assure that each of its actions “is not likely to jeopardize the continued existence” of any listed endangered or threatened species. Although the terms “likely” and “jeopardize” suggest a relative determination based on risk, this passage has been interpreted as a blanket prohibition on federal actions that may harm endangered species.⁶³ As is the case with NEPA, this portion of the statute is limited to governmentally-sponsored activities and does not in general govern the behavior of private parties.

The *Clean Water Act* articulates a policy goal “that the discharge of pollutants into the navigable waters [of the United States] be eliminated by 1985.”⁶⁴ The vigor of this mandate is somewhat attenuated by its identification as a broad-gauge policy goal. Even now, well after the target date of 1985, permits continue to be granted for discharges of pollutants under the substantive portion of the statute.⁶⁵

59. FFDCA §§ 409(c)(3)(A), 512(d)(1)(H) & 721(b)(5)(B), 21 USC §§ 348(c)(3)(A), 360b(d)(1)(H) & 379e(b)(5)(B). Congress recently specified that the first of these provisions no longer applies to pesticide residues in food. *Food Quality Protection Act of 1996*, Pub. L. No. 104-170, 110 Stat. 1489 (1996).

60. See, e.g., *Monsanto Co. v. Kennedy*, 613 F.2d 947 (DC Cir. 1979).

61. See, e.g., Richard A. Merrill, “FDA’s Implementation of the Delaney Clause: Repudiation of Congressional Choice or Reasoned Adaptation to Scientific Progress?”, 5 *Yale J. Reg.* 1, 75-76 (1988) (“the large gaps in Delaney’s wall favor old additives and disfavor new ones[.]... revealing the law’s inequity and documenting its perversity, for newer technologies are often safer than older ones”).

62. See section III.A.1.a *supra*.

63. See, e.g., *Tennessee Valley Authority v. Hill*, 437 US 153 (1978).

64. *Clean Water Act*, § 101(a)(1), 33 USC § 1251(a)(1).

65. See section III.A.1.a *supra*.

b. Health- and Safety-based Criteria

Several US statutory authorities direct federal agencies to act in a precautionary manner by reference to tests designed to protect human health or the environment. The *Clean Air Act* instructs the federal Environmental Protection Agency to establish primary ambient air quality standards for criteria pollutants such as particulates, sulfur dioxide, carbon monoxide, nitrogen oxides, ozone, and lead which, “allowing an adequate margin of safety, are requisite to protect the public health.”⁶⁶ This language precludes the consideration of economic factors in determining the appropriate requirements.⁶⁷

The *Occupational Health and Safety Act* authorizes regulations limiting workers’ exposure to toxic substances that “most adequately assure[], to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity...”⁶⁸ This language requires the implementing agency, the Occupational Safety and Health Administration (OSHA), to document the presence of a significant risk to justify the need for regulatory intervention,⁶⁹ but does not require the consideration of cost-benefit balancing.⁷⁰

As discussed above, US law categorically prohibits the approval of carcinogenic food and color additives. Non-cancer-causing additives must nonetheless be “safe,”⁷¹ a term that appears without qualification in the statutory mandate known as the “general safety clause.” “Safe means that there is convincing evidence that establishes with reasonable certainty that no harm will result from the intended use of the color additive.”⁷² Similarly, the Environmental Protection Agency may grant an exemption from the need for a pesticide tolerance (maximum residue limitation) only if “there is a reasonable certainty that no harm will result

66. *Clean Air Act*, § 109(b)(1), 42 USC § 7409(b)(1). Cf. *Ethyl Corp. v. EPA*, 541 F.2d 541 F.2d 1, 14 (DC Cir.) (en banc), cert. denied sub nom. *E. I. Du Pont de Nemours & Co. v. EPA*, 426 US 941 (1976) (noting that risk assessment phase preceding risk management measure “is not a precautionary statute at all” because it “demand[s] a threshold determination that the pollutant causes actual harm”).

67. *Whitman v. American Trucking Associations*, 531 US 457 (2001); *Lead Industries Association v. EPA*, 647 F.2d 1130, 1148 (DC Cir. 1980).

68. *Occupational Safety and Health Act*, § 6(b)(5), 29 USC § 655(b)(5).

69. *Industrial Union Department v. American Petroleum Institute*, 448 US 607 (1980).

70. *American Textile Manufacturers Institute, Inc. v. Donovan*, 452 US 490 (1981).

71. FFDC § 409(c)(3)(A) & 721(b)(4), 21 USC §§ 348(c)(3)(A) & 379e(b)(4).

72. 20 CFR § 70.3. This definition was implicitly approved in *Simpson v. Young*, 854 F.2d 1429 (DC Cir. 1988). Responses to individual color additive petitions under the general safety clause as applied, however, may at least arguably be based on a risk assessment. See, e.g., *Scott v. FDA*, 728 F.2d 322 (6th Cir. 1984).

from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposure and all other exposure for which there is reliable information,”⁷³ including a determination that “there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue.”⁷⁴

c. *Risk-based Tests*

Despite the extensive use of risk assessments and the prevalence of risk-based policy making in the Executive Branch and federal agencies, statutory mandates addressing environment, public health, and natural resources include relatively few that expressly require risk assessments by name or contain risk-based tests explicitly identified as such.

As modified by amendments in 1990, section 112 of the *Clean Air Act* is one prominent example. The Environmental Protection Agency is directed to establish technology-based controls on a list of 189 chemicals pursuant to a statutorily-specified schedule. Within eight years after the promulgation of a standard, the Agency must review it to determine whether it provides “an ample margin of safety to protect human health.”⁷⁵ In the case of carcinogens, revisions to the standards are required to the extent that they “do not reduce lifetime excess cancer risks to the individual most exposed to emissions from a source in the category or subcategory to less than one in one million.”⁷⁶

The *Food Quality Protection Act of 1996* eliminated the Delaney Clause’s zero-tolerance requirement for carcinogenic pesticides in processed foods⁷⁷ and replaced it with a requirement that all pesticide tolerances be “safe,” defined as “a reasonable certainty that no harm will result from aggregate exposure to the pesticide... residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.”⁷⁸ In the case of pesticides for which there is no threshold effect—i.e., for carcinogens—this test is generally regarded as reflecting a one-in-a-million risk as determined by a quantitative risk assessment. The statute expressly requires consideration of particular sensitivity and exposure to pesticides by infants and children and directs EPA to establish an additional safety factor of up to tenfold to ensure that tolerances are safe for infants and children.⁷⁹

73. FFDCA § 408(c)(2)(A)(ii), 21 USC §§ 346a(c)(2)(A)(ii).

74. *Id.* § 408(b)(2)(C)(ii), 21 USC § 346a(b)(2)(C)(ii).

75. *Clean Air Act*, § 112(e)(2)(A), 42 USC § 7412(e)(2)(A).

76. *Ibid.*

77. See section III.A.2.a *supra*.

78. See section III.A.2.b *supra*.

79. FFDCA § 408(b)(2)(B)(iv), 21 USC §346a(b)(2)(B)(iv).

Another instance of a statutory directive for risk-based decision making is found in the so-called Superfund statute, designed to assure the identification and cleanup of hazardous waste sites. This authority requires the preparation of health assessments to assist in the reduction of exposure to hazardous substances from Superfund sites.⁸⁰

The *Safe Drinking Water Act* directs the Environmental Protection Agency to establish drinking water regulations designed to protect against "adverse effect[s] on the health of persons."⁸¹ In amendments enacted in 1996, Congress recognized that "in considering the appropriate level of regulation for contaminants in drinking water, risk assessment, based on sound and objective science, and benefit-cost analysis are important analytical tools for improving the efficiency and effectiveness of drinking water regulations to protect human health."⁸²

d. Technology-based and Cost-benefit Requirements

A number of US statutes, including those addressing air and water pollution and hazardous waste facilities, make extensive use of technology-based approaches, in which the stated goal of controlling releases or concentrations of a regulated substance are defined, and limited, by the technical capability of specified pollution control systems or production process changes.

Technology-based approaches, whatever else their utility may be, would not ordinarily be considered to articulate a public policy based on precaution. There is no necessary congruence between what may be judged technically achievable and a desirable risk management outcome from a public policy perspective, particularly one that emphasizes anticipation and prevention of harm in the face of uncertainties concerning risks. A precautionary perspective would counsel that if available technologies, or even strongly encouraged developments in technology through the creation of regulatory incentives, are inadequate to reduce risks to the extent considered desirable from other perspectives, then further actions, such as limits on production or specific use, should be available to policy makers.

Risk-benefit balancing is yet another regulatory philosophy that has played a significant role in federal environmental law. The principal

80. *Comprehensive Environmental Response, Compensation, and Liability Act of 1980*, § 104(i), 42 USC § 9604(i) (response authorities for hazardous waste disposal sites).

81. 42 USC § 300g-1(b)(1)(A)(i).

82. *Safe Drinking Water Act*, Amendments of 1996, Pub. L. No. 104-182, § 2, 110 Stat. 1614 (1996).

authority governing the approval of pesticides⁸³ and a major statutory enactment on toxic substances both require cost-benefit analyses.⁸⁴

A risk-benefit test might be precautionary as applied to certain situations, such as large risks for which the cost of elimination or reduction is low. As a general matter, however, the balance of costs and benefits does not necessarily correlate with a policy of anticipating and preventing risks. It is not infrequently the case, moreover, that harms to the environment, public health, or natural resources are poorly characterized. Difficulty in evaluating or quantifying the benefits of regulation, defined as risks ameliorated or abated, in valuing those benefits, or in accurately estimating costs of risk reduction may further attenuate the utility of risk-benefit approaches by reference to a precautionary endpoint. There are also significant methodological limitations in monetizing such environmental amenities as visibility, wilderness preservation, or endangered species.

In the case of pesticides, the requirement for prior regulatory approval provides a procedural tool that tends to offset the effect of a substantive mandate that is arguably less than precautionary. However, for toxic substances more generally, as discussed in section III.A.1.b above, there is no analogous requirement. The rigor required for the necessary finding of “unreasonable risk” prior to regulation under the *Toxic Substances Control Act*,⁸⁵ defined by reference to a risk-benefit balancing approach in a statute that contains no requirement for prior governmental approval of toxic substances, has arguably limited the law’s effectiveness as a precautionary instrument of public policy.⁸⁶

B. Judicial Decisions

Precautionary precepts have also been articulated by federal courts in the United States, primarily in interpreting statutory authorities of the kind described in section III.A above to lawsuits seeking to set

83. FIFRA § 3(c)(5), 7 USC § 136a(c)(5). See *Save Our Ecosystems v. Clark*, 747 F.2d 1240, 1248 (9th Cir. 1984) (“FIFRA registration is a cost-benefit analysis that no unreasonable risk exists to man or the environment taking into account the economic, social and environmental costs and benefits of the use of any pesticide.”)

84. TSCA § 6, 15 USC § 2605 (“unreasonable risk” as test for regulation by reference to cost-benefit analysis).

85. 15 USC §§ 2601-29.

86. See, e.g., *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201, 1214, 1230 (5th Cir. 1991) (setting aside EPA’s final rule banning the manufacture, importation, processing, and distribution in commerce of most asbestos-containing products, promulgated under authority of *Toxic Substances Control Act*, despite ten years of agency work on regulation and hundreds of studies on the effects of asbestos).

aside specific agency actions, such as regulations. With one exception, all the judicial opinions in this section were rendered in cases seeking judicial review of administrative action, a legal institution whose purpose is to provide a private party with an opportunity to contest the legality or adequacy of governmental action implementing a regulatory statute through a comparison of official conduct in a particular case with specified legal mandates.

To that extent, suits seeking judicial review of agency action create an opportunity for citizens, corporations, non-profit organizations, and other private actors to challenge the legality of governmental action through appeals to a neutral third party, namely a court. Accordingly, the institution of judicial review is frequently viewed as an important source of legitimacy in US administrative law. In evaluating the legality of the challenged action—which in the environmental field is frequently a regulation or rule promulgated by an administrative agency—the reviewing court will typically apply a legal test of statutory origin. The principal, although not the only, sources of such criteria are substantive environmental laws, some of which are summarized above. Consequently, judicial opinions in suits seeking judicial review contain interpretations of statutory authorities and analyses of the extent to which the agency's action which is challenged complies with the statutory test as interpreted by the court.

Cases involving precautionary decision making usually involve the processing of some underlying data, often of a scientific nature, by a technically expert agency. The agency's conclusions resulting from analysis of those data are reflected in the challenged action, such as an environmental regulation. One basic principle of US administrative law asserts that an agency must identify the data on which it relied and explain the reasoning by which the agency proceeded from that data set to its action.⁸⁷ Another fundamental principle of administrative law involves the concept of "standard of review," with scientific determinations customarily receiving a high level of deference.⁸⁸

Because the mandate for precaution (or not, as the case may be) comes from the statutory authority concerned, it is most useful to group and analyze the cases by statute. That is, a substance might be treated differently under one statute governing air emissions from under a dif-

87. E.g., *United States v. Nova Scotia Food Products*, 568 F.2d 240 (2d Cir. 1977).

88. See, e.g., *Baltimore Gas & Electric Co. v. Natural Resources Defense Council*, 462 US 87, 103 (1983) ("a reviewing court must remember that the [expert administrative agency] is making predictions, within its area of expertise, at the frontiers of science. When examining this kind of scientific determination, as opposed to simple findings of fact, a reviewing court must generally be at its most deferential.")

ferent statute governing pollution of waterways by the same substance. This section describes and analyzes federal cases often relied upon under the rubric of precaution in the United States.

1. *The Ethyl Case*

The clearest and most frequently cited case articulating a precautionary philosophy toward regulatory action is *Ethyl Corp. v. EPA*,⁸⁹ which dealt with the question of lead in gasoline. At issue in this case were regulations promulgated by the federal Environmental Protection Agency requiring a scheduled phasedown in the lead content of leaded gasoline. The statute required the Agency to demonstrate that the additive, tetraethyl lead, “will endanger the public health or welfare”⁹⁰ before regulating it. The Agency had relied on a number of studies that suggested, but did not conclusively prove, the deleterious character of lead originating from gasoline, particularly to children. The lead additive manufacturers who challenged the regulation claimed that the Agency lacked proof of actual harm and that the regulation was therefore legally defective by reference to the “will endanger” test.

In reviewing the regulation, the United States Court of Appeals for the District of Columbia Circuit concluded that the threshold for action did not require a demonstration of actual harm. The court emphasized that the concept of “endanger” relates to threats and implies no necessity for a finding of actual harm. Accordingly, the court approved the Agency’s interpretation of the “will endanger” mandate to mean “presents a significant risk of harm.”⁹¹ The court also observed that “the magnitude of risk sufficient to justify regulation is inversely proportional to the harm to be avoided.”⁹²

With respect to the question of scientific uncertainty and the potentially disparate inferences that could be drawn from the data on which the Agency relied, the court opined as follows:

Questions involving the environment are particularly prone to uncertainty. Technological man has altered his world in ways never before experienced or anticipated. The health effects of such alterations are often unknown, sometimes unknowable. While a concerned Congress has passed legislation providing for protection of the public health against

89. 541 F.2d 1 (DC Cir.) (en banc), cert. denied sub nom. *E. I. Du Pont de Nemours & Co. v. EPA*, 426 US 941 (1976).

90. *Clean Air Act*, § 211(c)(1)(A), 42 USC § 1857f-6c(c)(1)(A).

91. 541 F.2d at 13.

92. *Id.* at 19.

gross environmental modifications, the regulators entrusted with the enforcement of such laws have not thereby been endowed with a pre-science that removes all doubt from their decision making. Rather, speculation, conflicts in evidence, and theoretical extrapolation typify their every action. How else can they act, given a mandate to protect the public health but only a slight or nonexistent database upon which to draw?... Sometimes, of course, relatively certain proof of danger or harm... can be readily found. But, more commonly, “reasonable medical concerns” and theory long precede certainty. Yet the statutes—and common sense—demand regulatory action to prevent harm, even if the regulator is less than certain that harm is otherwise inevitable.

Undoubtedly, certainty is the scientific ideal—to the extent that even science can be certain of its truth. But certainty in the complexities of environmental medicine may be achievable only after the fact, when scientists have the opportunity for leisurely and isolated scrutiny of an entire mechanism. Awaiting certainty will often allow for only reactive, not preventive, regulation.⁹³

In the most frequently quoted language in the opinion, the court summarized as follows:

Where a statute is precautionary in nature, the evidence difficult to come by, uncertain, or conflicting because it is on the frontiers of scientific knowledge, the regulations designed to protect the public health, and the decision that of an expert administrator, we will not demand rigorous step-by-step proof of cause and effect. Such proof may be impossible to obtain if the precautionary purpose of the statute is to be served.⁹⁴

2. OSHA Cases

The question of the federal government’s capacity to employ precautionary approaches to governmental decision making has arisen a number of times in cases decided under the *Occupational Safety and Health Act’s* (OSHA’s) provisions that apply to toxic substances in the workplace. The statutory standard, as set out in section III.A.2.b above, requires that permissible exposure limits (PELs) promulgated under the statute be those that “most adequately assure[], to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity...”⁹⁵ Like the *Ethyl* case, interpreting a different statutory test, the judicial opinions interpreting this provision have tended to emphasize that the intent of the

93. *Id.* at 24-25 (footnotes omitted).

94. *Id.* at 28 (footnotes omitted).

95. *Occupational Safety and Health Act*, § 6(b)(5), 29 USC § 655(b)(5).

legislation is to protect against risks to workers, and that to demand a rigorous demonstration of cause and effect would be contrary to that prophylactic purpose.

In a leading case interpreting this provision of OSHA as applied to a PEL limiting worker exposure to asbestos fibers, the DC Circuit observed that

...some of the questions involved in the promulgation of these standards are on the frontiers of scientific knowledge, and consequently as to them insufficient data is presently available to make a fully informed factual determination. Decision making must in that circumstance depend to a greater extent upon policy judgments and less upon purely factual analysis. Thus, in addition to currently unresolved factual issues, the formulation of standards involves choices that by their nature require basic policy determinations rather than resolution of factual controversies.⁹⁶

In a footnote, the court went on to state that

Where existing methodology or research in a new area of regulation is deficient, the agency necessarily enjoys broad discretion to attempt to formulate a solution to the best of its ability on the basis of available information.⁹⁷

In a challenge to a PEL for vinyl chloride, a carcinogen, the United States Court of Appeals for the Second Circuit also adopted this interpretation of the statute, citing these passages in the earlier case with approval.⁹⁸ A challenge to a standard for lead in the workplace prompted the DC Circuit to reaffirm its earlier interpretations, restating that “in an area of scientific uncertainty [OSHA] has broad discretion to form the best *possible* solution.”⁹⁹

In a case involving review of a standard for ethylene oxide, which the expert agency had concluded presents a significant risk of cancer in humans, the DC Circuit elaborated its earlier views, opining that

While some of OSHA’s evidence suffers from shortcomings, such incomplete proof is inevitable when the Agency regulates on the frontiers of scientific knowledge...

96. *Industrial Union Department v. Hodgson*, 499 F.2d 467, 474 (DC Cir. 1974).

97. *Id.* at 474 n. 18.

98. *Society of the Plastics Industry, Inc. v. Occupational Safety and Health Administration*, 509 F.2d 1301, 1304, 1308 (2d Cir.), cert. denied sub nom. *Firestone Plastics Co. v. Department of Labor*, 421 US 992 (1975).

99. *United Steelworkers of America v. Marshall*, 647 F.2d 1189, 1259 (DC Cir. 1980), cert. denied sub nom. *Lead Industries Association v. Donovan*, 453 US 913 (1981) (emphasis in original).

The scientific evidence in the instant case is incomplete but what evidence we have paints a striking portrait of serious danger to workers exposed to the chemical. When the evidence can be reasonably interpreted as supporting the need for regulation, we must affirm the agency's conclusion, despite the fact that the same evidence is susceptible of another interpretation.¹⁰⁰

In a later passage, the court observed that "requiring strict proof would fatally cripple all of OSHA's regulatory efforts."¹⁰¹

3. *Testing of Chemicals*

As discussed in section III.A.2.d above, section 6 of the *Toxic Substances Control Act* (TSCA)¹⁰² authorizes the Environmental Protection Agency (EPA) to promulgate regulations ranging from labeling to total bans for a chemical that "presents or will present an unreasonable risk of injury to health or the environment," a formulation which implies the need for a cost-benefit analysis. Section 4 of the statute sets out a framework for EPA to require testing of suspect chemicals that "may present an unreasonable risk of injury to health or the environment."¹⁰³

In cases in which industry interests challenged regulations requiring testing of 2-ethylhexanoic acid¹⁰⁴ and certain fluoroalkenes,¹⁰⁵ two federal courts of appeal have held that the statutory formulations "present or will present an unreasonable risk" on the one hand and "may present an unreasonable risk" on the other have different meanings, related to the statutory purpose. In particular, the threshold of scientific certainty for testing chemicals is lower than that for a substantive regulation, such as a production limitation. This interpretation is consistent with the statutory purpose and structure, which is designed to identify a universe of chemicals about which additional information is required—those that "may present" an unreasonable risk—to determine which of those substances require regulation, based on test data and other information that show which of those tested "present[] or will present an unreasonable risk."

At a higher level of generality, these judicial opinions address the relationship between the threshold for action and an appropriate public policy response. A low or relaxed threshold for action is arguably appro-

100. *Public Citizen Health Research Group v. Tyson*, 796 F.2d 1479, 1495 (DC Cir. 1986).

101. *Id.* at 1499.

102. 15 USC § 2605(a).

103. 15 USC § 2603(a)(1)(A)(i) (emphasis supplied).

104. *Chemical Manufacturers Association v. EPA*, 859 F.2d 977 (DC Cir. 1988).

105. *Ausimont USA., Inc. v. EPA*, 838 F.2d 93 (3d Cir. 1988).

priate if the risk management strategy is the collection of additional information, as in the TSCA section 4 test rule cases.

4. *Reserve Mining Co. v. EPA*

*Reserve Mining Co. v. EPA*¹⁰⁶ is often mentioned in tandem with the *Ethyl* opinion as a leading case on the interpretation and application of precaution in US environmental jurisprudence. *Reserve Mining* was a situation in which a particular company was discharging taconite tailings containing asbestiform fibers similar to those regulated by OSHA, as described above, because of their capacity to cause disease in occupational settings. It was, however, uncertain whether discharges into water and the ambient air presented similar risks.

In affirming the trial court's award of an injunction after a finding that the air and water discharges "substantially endanger[]" the local population, the United States Court of Appeals for the Eighth Circuit observed as follows:

...the medical and scientific conclusions here in dispute clearly lie "on the frontiers of scientific knowledge." ...The trial court, not having any proof of actual harm, was faced with a consideration of 1) the probabilities of any health harm and 2) the consequences, if any, should the harm actually occur....

These concepts of potential harm, whether they be assessed as "probabilities and consequences" or "risk and harm," necessarily must apply in a determination of whether any relief should be given in cases of this kind in which proof with certainty is impossible. The district court, although not following a precise probabilities-consequences analysis, did consider the medical and scientific evidence bearing on both the probability of harm and the consequences should the hypothesis advanced by the plaintiffs prove to be valid.

In assessing probabilities in this case, it cannot be said that the probability of harm is more likely than not. Moreover, the level of probability does not readily convert into a prediction of consequences. On this record it cannot be forecast that the rates of cancer will increase from drinking Lake Superior water or breathing Silver Bay air. The best that can be said is that the existence of this asbestos contaminant in air and water gives rise to a reasonable medical concern for the public health. The public's exposure to asbestos fibers in air and water creates some health risk. Such a contaminant should be removed.

106. 514 F.2d 492 (8th Cir. 1975) (en banc).

...the existence of this risk to the public justifies an injunction decree requiring abatement of the health hazard on reasonable terms as a precautionary and preventive measure to protect the public health.¹⁰⁷

Reserve Mining differs from all the other cases cited in this paper in that it was an enforcement action against a particular firm initiated by the federal government, several states of the United States, and a number of environmental groups. Because it was not a suit for judicial review, the court of appeals in *Reserve Mining* concluded that the trial court had both identified a suitably precautionary perspective and that the judicial authority had directly applied that test appropriately to the evidence, absent prior evaluation by a regulatory agency. By contrast, in a suit for judicial review, the reviewing court articulates the legal standard, as to which the courts as a general matter have the final word, and evaluates the application of that standard to the factual data set identified by the agency. With respect to this second step, the courts are guided by standards of review involving deference to the expert agency's presumptively appropriate analysis of the underlying scientific data set.

It is also worthwhile to note that all the cases cited here are ones in which an agency—or, in the case of *Reserve Mining*, a lower court—has taken the initiative to act in a proactive and precautionary manner. It does not necessarily follow that, if the agency (or the lower court, as the case may be) had decided to refrain from acting, the reviewing court would necessarily have compelled or ordered precautionary action when presented with an analysis of conflicting evidence supporting inaction as opposed to action.¹⁰⁸

IV. EXAMPLES OF US STATE AND LOCAL INITIATIVES

In a federal system such as that of the United States, not only the federal government, but also sub-national governmental units, may have legislative authority. The exercise of this authority can, on occasion, provide useful insights into precautionary approaches that may augment or supplement federal initiatives. Precautionary legislation in the United States has been enacted not only at the federal level, but also by subnational units within the US federal system—by the quasi-sovereign constituent states, as well as by local municipalities. This section describes two examples of each.

107. *Id.* at 519-20.

108. Additionally, a court may set aside precautionary agency action if not authorized by the relevant statutory authority. See, e.g., *Corrosion Proof Fittings*, *supra*, note 86 (setting aside arguably precautionary ban on most asbestos-containing products as exceeding statutory authority under *Toxic Substances Control Act*).

A. California Proposition 65

California's Proposition 65,¹⁰⁹ approved by voter referendum in that state in 1986, prohibits the discharge into sources of drinking water of any chemical that is a carcinogen or reproductive toxin except in amounts that the discharger can demonstrate "will not cause any significant amount of the discharged or released chemical to enter any source of drinking water." This aspect of the statute is a discharge limitation, together with a burden-shifting component that places the onus on the discharger to demonstrate the absence of significant exposure. Second, the statute prohibits exposing the public to carcinogens or reproductive toxins, as in consumer products or food, without warning unless the risk of a lifetime of exposure is insignificant. This requirement relies upon a risk management theory based on risk communication, but again with a presumption that labels are required unless demonstrated to be unnecessary.

The burden-shifting requirements of Proposition 65 can be regarded as a precautionary approach to regulation because they require the entity creating an exposure to demonstrate the absence of an adverse consequence. The statute also demonstrates the variety of risk management strategies to which precaution can be applied, including risk communication, which is generally regarded as among the less intrusive and least burdensome forms of regulation. Perhaps not coincidentally, the statute has generally been considered a success story, in particular because its burden-shifting has created an incentive for industry to support the promulgation of regulations, in the absence of which the presumption of the statute's application would apply. Further, because of the "California effect" resulting from the size of the market in that state, Proposition 65 has had a nationwide impact on manufacturers that have had an incentive to reformulate all their products to avoid the labeling requirements in California.

B. Massachusetts Toxic Use Reduction Act

The Massachusetts *Toxic Use Reduction Act of 1989* (TURA)¹¹⁰ is another effort at implementing precautionary perspectives at the state level. The overall strategy is one of pollution prevention focused on the use of toxic chemicals and the generation of wastes in the manufacturing

109. *Safe Drinking Water and Toxic Enforcement Act of 1986*, Cal. Health & Safety Code §§ 25249.5-25249.13.

110. *Mass. Gen. L.*, ch. 21I, §§ 1-23.

process. The statute does not regulate based on risk or "safe" levels of exposure or emission, but instead encourages reductions in use.

TURA identifies a statewide goal of reducing toxic waste generated by fifty per cent by the year 1997, through a toxics use reduction strategy as the preferred means for compliance with state and federal laws governing toxics production and use, hazardous waste, industrial hygiene, worker safety, public exposure to toxics, or releases of toxics into the environment and for minimizing the risks associated with the use of toxic or hazardous substances and the production of toxic or hazardous substances or hazardous wastes. The law requires businesses in Massachusetts which manufacture or use more than 25,000 pounds, or otherwise use more than 10,000 pounds annually, of about 1400 industrial chemicals to prepare a Toxics Use Reduction Plan every two years.

These plans examine the ways in which toxics are utilized in the facility and must include an assessment of alternatives, including such toxics-use reduction strategies as input substitution, product reformulation, production unit redesign or modification, production unit modernization, improved operation and maintenance, and recycling, reuse, or extended use of toxics. In contrast to federal reporting requirements, which are based on releases, firms governed by the Act must also report the quantities of toxic chemicals used, generated as waste, and shipped in and out as product. The reports, which are annually filed by about 500 firms, are publicly available.

Adjusted for changes in production during that period, firms governed by the statute decreased their toxic chemical use by 33 % between 1990 and 1997, generated 48 % less byproduct or waste per unit of product, and reduced releases of reportable chemicals by 83 %. Quantities of chemicals shipped in product showed a production-adjusted reduction of 23 % between 1990 and 1997.¹¹¹

*New Jersey's Pollution Prevention Act*¹¹² and its implementing regulations¹¹³ establish a program similar to that of Massachusetts, consisting of the development of plans and the submission of reports by individual facilities.¹¹⁴

111. See Toxics Use Reduction Institute, Success Stories (available at web site <<http://www.turi.org/turadata/Success/ResultsToDate.html>>).

112. *NJ Stat. Ann.*, §§ 13:1B-1 et seq.

113. NJ Admin. Code tit. 7, §§ 1K-1.1 to 12.11 (available at web site <<http://www.state.nj.us/dep/opppc/docforms/document.htm>>).

114. See generally New Jersey Technical Assistance Program for Industrial Pollution Prevention, *The New Jersey Pollution Prevention Act* (available at web site <<http://www.cees.njit.edu/njtap/njppa.htm>>).

C. Bay Area Dioxin Phaseout

Several municipal governments in the San Francisco Bay area—the cities of San Francisco, Oakland, and Berkeley, and Marin County—have coordinated actions over the past two years with the goal of eliminating dioxin emissions.¹¹⁵ These resolutions have given rise to an initiative under the auspices of the Association of Bay Area Governments (ABAG) to develop a menu of dioxin pollution reduction projects from which local governments can select to reduce their contributions to dioxin loadings. A consultant was hired to elaborate these options, resulting in a report¹¹⁶ which has been made available for public comment and is now awaiting revision and finalization. There is some possibility that this initiative will lead to a binding ordinance adopted by the city of San Francisco requiring specified actions with respect to dioxins.

D. Los Angeles School District Integrated Pest Management Program

The Los Angeles Unified School District has adopted an integrated pest management (IPM) program that is expressly based on a theory of precaution. The policy states that “no pesticide product is free from risk or threat to human health.” The program “give[s] non-chemical methods first consideration when selecting appropriate pest control techniques” and “strive[s] to ultimately eliminate the use of all chemical controls.”

The program establishes a Pest Management Team, consisting of 15 members, including two parents of students in the system, two community members, two environmental representatives, one teacher, and a medical practitioner. The Pest Management Team is directed to review and approve pesticide product use. The program also provides for a professional IPM coordinator.¹¹⁷

115. The resolution adopted by the San Francisco Commission on the Environment is available at web site <<http://www.sfgov.org/sfenvcomm/resolutions/021-98.htm>>.

116. Screening Evaluation of Dioxins Pollution Prevention Options (draft available at web site <<http://dioxin.abag.ca.gov/pdf/ReportText.pdf>>).

117. A description of the program does not appear to be posted on the Internet. An overview of pest management policies, programs, and practices in California can be found at <<http://www.cdpr.ca.gov/docs/dprdocs/schools/text.htm>>.