

CHAPTER 19

The Legacy of the Precautionary Principle in US Law: The Rise of Cost-Benefit Analysis and Risk Assessment as Undermining Factors in Health, Safety and Environmental Protection

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INTRODUCTION

Over the last 35 years since the first appearance of federal health, safety and environmental laws in the US, public health and the environment continue to be adversely affected by development,¹ and limits to industrial growth are now clearly visible in the examples of global climate disruption, changes in the reproductive health of all species, and shortages of petroleum, freshwater and natural resources. Furthermore, the kinds of risks of concern, and the nature of scientific uncertainty, are changing. These developments have sparked new interest in the concepts of precaution and prevention in many environmental and public policy arenas.

Advances in the understanding of the causes of disease and new damage mechanisms include endocrine disruption² and other low-dose effects of chemical exposures;³ substances, such as nanoparticles, that can cross the blood–brain barrier; antibiotic, drug and pesticide resistance; climate disruption; and interactions between toxic chemicals, nutritional factors, infectious agents and genetics. Advances in scientific risk assessment include green chemistry, green engineering, predictive toxicology, structure activity relationships and rapid *in vitro* screens.⁴ Advances in technological approaches include sustainable technology, products and system design.

With advances in science and technology have come changes in the kinds of uncertainty facing government agencies mandated to protect health, safety and the environment. These include classical uncertainty (expressed as probability distributions of dose–response relationships and obscured by the lack of sufficiently definitive information, contradictory evidence, or a deficiency in the knowledge of causal mechanisms and pathways), indeterminacy (where we know what we don't know), and ignorance (where we don't know what we don't know).⁵ The general nature of uncertainty has shifted from classical uncertainty (which itself is now understood to be more complex than originally

envisioned and is difficult to apply in many areas of concern), towards indeterminacy (as in the case of the extent of global warming) and ignorance (e.g. of possible risks to ecosystems from deliberately released genetically modified (GM) crops).

Partly because of changing science and partly because of inadequate governmental response, the trust in both government regulators and industry has declined, with a corresponding increased demand for the participation of the public, consumers, non-governmental organizations (NGOs) and citizens in decision-making related to protection of health, safety and the environment. This increased demand for participation has resulted in a more critical look at the bases for governmental decisions.

Government has approached the problems of risky technologies and products by constructing a two-step exercise: risk assessment followed by risk management.⁶ Value judgments pervade both steps,⁷ and the precautionary principle could be applied in choosing the data and models to inform risk assessment and also in deciding whether, to what extent and how to provide protection.⁸

This chapter argues that in the US, the governmental responses to these changes are wrong-headed and hide behind misguided formulaic methodologies of cost-benefit analyses and quantitative risk assessments ostensibly offered to provide more sensible and rational solutions⁹ to guide approaches to health, safety and environmental problems, but in actuality motivated by desires to accommodate industrial and producer interests. Reflecting an increasingly anti-regulatory posture on the part of the federal government, the undemocratic use of these methodologies has seriously undermined health, safety and environmental protection in the US and (hopefully temporarily) rendered a precautionary approach to solving health and environmental problems to a historical relic. In the US, the undermining of protection is effectuated through:

- requiring regulations to be based on an increased level of scientific evidence or justification;
- allowing regulations to be delayed because of scientific uncertainty;
- allowing a *de minimis* risk to remain unprotected or requiring a 'significant risk' to be present before acting;¹⁰ and
- requiring that the benefits of regulating exceed, or justify, the imposition of costs.¹¹

These factors, of course, directly impact upon whether and to what extent the precautionary principle can be applied in the US.

The remainder of this chapter provides a brief history of the precautionary principle as developed in the US with comparisons to its evolution in Europe; a regulatory decision-making framework that agencies might follow, whether or not a precautionary approach is embraced; a brief account of the politics of the regulation of chemicals in the US; a capsule history of US chemical regulation and the use of the precautionary principle in US law; and suggestions for reclaiming health, safety and environmental protection through the creative use of the precautionary principle within the context of trade-off analysis: an alternative to cost-benefit analysis as a decision-making rationale that incorporates concerns for distributional effects (equity), accounts for technological change through the use of Technology Options Analysis, and otherwise avoids the biases of traditional cost-benefit analysis.¹² Contrary to the commonplace practice of both advocates and critics of the precautionary principle in placing risk assessment and the precautionary principle in

conflict, this chapter argues that risk assessment has a sensible place in implementing the precautionary principle and that it is cost-benefit analysis, and the use of risk assessment there, that conflicts with the principle.

A BRIEF HISTORY OF THE PRECAUTIONARY PRINCIPLE

The precautionary principle has two distinct formulations:¹³

- 1 Where there are possibilities of large or irreversible serious effects, scientific uncertainty *should not prevent* protective actions from being taken.
- 2 Where there are possibilities of large or irreversible serious effects, *action should be taken*, even if there is considerable scientific uncertainty.

The first formulation in the international context appears prominently in the Brundtland formulation agreed to in the United Nations Conference on Environment and Development (UNCED) held in Rio de Janeiro in 1992, and recurs in many multilateral environmental agreements.¹⁴ The second formulation appears in some multilateral agreements and in some European Union (EU) directives on environmental protection.¹⁵

In the US, a precautionary approach has been applied in various ways in decisions about health, safety and the environment for about 30 years, much longer than recent commentaries would have us believe, and earlier than the appearance of the precautionary principle in European law.¹⁶ In interpreting congressional legislation, the US courts have argued that federal regulatory agencies are permitted, and sometimes required, to protect workers even when the evidence is 'on the frontiers of scientific knowledge' and to protect public health from emissions to air with 'an ample or adequate margin of safety' by 'erring on the side of caution'. One scholar seeks to make a distinction between a precautionary approach and the precautionary principle, asserting that 'with rare exceptions, US law balances precaution against other considerations, most importantly costs' and, hence, is better described as a preference, rather than a principle.¹⁷ I find this distinction superficial, or at least unhelpful, if not often inaccurate; and when understood within the context of Roman/Napoleonic law-based European legal systems preferring 'codes' to court-based evolution of common law, this is a semantic rather than a real distinction.

In the US, in a series of industry challenges to regulations, courts acknowledged that even in the case where the scientific basis for a threat to health or the environment is not compelling, regulators have the discretion to 'err on the side of caution', often without laying down a specific requirement to do so, although the directive to do so is often found in the enabling legislation of various regulatory regimes. As we shall see in the section on 'The politics of regulating chemicals in the US', under *Chevron*,¹⁸ court deference to agency policy judgments initially not only allowed, but encouraged, agencies to take a precautionary approach under a myriad of legislation, partly by relegating questions of the sufficiency of scientific evidence to the province of discretionary policy-

making. In the early environmental decisions, rather than adopting stringent interpretations of statutory language requiring 'substantial evidence' in meeting the burden of proof for agencies to act, the courts adopted a deferential stance towards early environmental agency decisions, allowing them to relax the evidentiary showings in furtherance of protective public policy goals.

In the last decade or two, the precautionary inclinations of the American and Anglo-Saxon jurisprudential systems, as well as codified expressions of the precautionary principle in German law, for example, have found their way into multilateral environmental agreements and international law. Principle 15 of the Declaration of the 1992 UNCED (the Rio Declaration) states:

In order to protect the environment, the precautionary approach shall be widely used by States according to their capabilities. Where there are threats of serious and irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.

This is perhaps the best known, and often cited, statement of the precautionary principle. Note, especially, that the word 'approach' rather than 'principle' is used, and considerations of cost are certainly present in the phrases 'according to their capabilities' and 'cost-effective measures'. Nonetheless, it is acknowledged to be a principle – but one to be balanced in one way or another against other principles – no different than the situation in US law.¹⁹ Curiously, this statement of the principle is expressed in the negative – uncertainty should not be used to delay protection – rather than a statement that protection should be embraced deliberately even in the face of uncertainty (a subtle but important distinction), a formulation often more positively expressed in US case law.²⁰ The debate in Europe today is not whether the precautionary principle is a principle, but which formulation should be applied and whether it trumps other international law, particularly the manner in which risk assessment is addressed and is relevant to trade law involving the World Trade Organization (WTO).²¹

REGULATORY DECISION-MAKING FRAMEWORK

Whether taking a utilitarian approach that maximizes total welfare, ensuring that the costs and benefits are equal or commensurate, or seeking to protect certain beneficiaries with minimal considerations given to the costs of doing so in the face of scientific uncertainty, a regulatory agency responsible for protecting health, safety or the environment necessarily needs to answer *whether, where, when, how and to what extent* to intervene. Intervention could involve:

- notifying those (possibly) affected – for example, by warnings or labels;
- regulating exposure by limiting and controlling exposure or limiting production;
- eliminating production or use;
- treating those affected;
- compensating for harm.

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Answering these questions, in turn, requires asking:

- What are the criteria for deciding?
- Who has the burden of persuasion?
- What strength of evidence (burden of proof) triggers a requirement for what action?

This framework can be approached either through rational choice theory using cost-benefit analysis (see the following section on 'A capsule history of US chemical regulation and the use of the precautionary principle in US law') or by using a precautionary approach. Note that far from representing a binary approach (go, no go), the precautionary approach requires application at each juncture of decision-making – *whether, where, when, how, and to what extent* to intervene.²²

THE POLITICS OF REGULATING CHEMICALS IN THE US²³

The 1970s ushered in a period of intense environmental and workplace regulation. With the advent of the Reagan administration in 1980 and continuing more or less since then, the US beneficiaries have experienced a reversal of fortune in the decline of protection. In contrast, Europe began to take the lead in environmental health and safety regulation, 'trading places' with the US.²⁴ In the US, the decline of protection was effectuated through changes in:

- legislation;
- administrative practice by the executive branch through actions of the Office of Management and Budget (OMB);
- direct congressional intervention;
- agency policy/practices in standard-setting and subsequent judicial review by the appellate courts; and
- extra-legal (i.e. political) activities compromising the government's duty to protect.

This section addresses the first three and the last of these developments, while the next section discusses key health, safety and environmental decisions made by the regulatory agencies. In contrast to the EU, over the last few decades, the executive branch of government exercised much more control and direction over the practice of risk assessment and cost-benefit analysis than its EU counterparts.

Congressional legislation

During the 1990s, the US Congress turned its attention to the impacts of agency rule-making on the regulated community, and enacted a series of laws designed to reduce those impacts. The genesis of these laws was the 1994 election, when the Republican party regained control of both houses of Congress for the first time in several years. Led

by the then Speaker of the House Newt Gingrich, the Republicans brought with them an aggressive legislative agenda that they termed their 'Contract with America'. A chief plank in this agenda was 'regulatory reform,' which, broadly speaking, meant minimizing the costs and other burdens imposed by federal regulation on business and state and local government. A key goal of this reform movement was that all, or virtually all, federal regulation should be required to meet a cost-benefit criterion, which would have required a reduction in the stringency of those regulations whose costs were deemed not to be justified by the associated benefits. Although Congress came close to passing such sweeping legislation, it did not do so. However, Congress did enact two laws during this period that have had an impact on agency rule-making, especially in the areas of health, safety and the environment.

The first of these was the Unfunded Mandates Reform Act,²⁵ passed in 1995. This act requires that an agency prepare 'a qualitative and quantitative assessment of the anticipated costs and benefits' of any proposed 'major' rule (defined as a regulation whose aggregate impact is anticipated to be US\$100 million or more in any given year), unless the preparation of such an assessment 'is otherwise prohibited by law.'²⁶ The statute also specifies, in some detail, the contents of the required cost-benefit assessment. Since many federal rules will exceed the US\$100 million threshold, this law effectively imposes a cost-benefit 'overlay' on major federal regulation. It is important to note, however, that this law does not require an agency to abandon its particular statutory mandate in favour of balancing costs and benefits. That is, it does not impose cost benefit as a *substantive* decision-making criterion. Nonetheless, by requiring the agency to calculate the costs and benefits of major regulations, and to place this information into the administrative record, Congress clearly has elevated the importance of the cost-benefit criterion.

A year later, in 1996, Congress called for further review of agency decision-making with the passage of the Small Business Regulatory Enforcement Fairness Act.²⁷ A key aspect of this law was a series of amendments strengthening a 1980 statute known as the Regulatory Flexibility Act (RFA).²⁸ As amended, the RFA requires all agencies to publish a 'regulatory flexibility analysis' with any proposed or final rule likely to have a significant economic impact on a substantial number of small entities. The analysis published with a proposed rule is to include, among other things, 'a description of any significant alternatives to the proposed rule ... which minimize any significant impact of the proposed rule on small entities'.²⁹ The analysis published with a final rule, in turn, is to include 'a description of the steps the agency has taken to minimize the significant economic impact on small entities', and a statement of the 'factual, policy, and legal reasons' why the approach taken in the final rule was selected instead of the other regulatory alternatives considered.³⁰

The Unfunded Mandates Reform Act also imposes a substantive directive, albeit a 'soft' one, on major federal regulations. For any proposed regulation meeting the monetary threshold identified above, the agency must 'identify and consider a reasonable number of alternatives, and from those alternatives select the least costly, most cost-effective and least burdensome alternative that achieves the objectives of the rule'.³¹ The agency can avoid this requirement, however, if it publishes 'an explanation of why the least costly, most cost-effective or least burdensome method of achieving the objectives of the rule was not adopted', or if the requirement is 'inconsistent with law'.³² The focus of this latter exception would seem to be situations in which the agency's substantive

mandate requires it to prefer a certain regulatory result even if it is not the cheapest effective alternative. In general, however, the directive to select the most cost effective of those alternatives that will fulfil an agency's mandate should not, in itself, require the agency to compromise its substantive mandate.

During the mid 1990s, Congress also considered, but did not pass, legislation that would have required agencies to perform a detailed risk assessment, according to specified criteria, before promulgating health, safety and environmental regulation. While it did not pass broad legislation of this nature, however, Congress did include risk assessment provisions in its 1996 amendments to the Safe Drinking Water Act, the statute under which the US Environmental Protection Agency (EPA) establishes health criteria for public drinking water supplies. Under these new provisions, risk assessments conducted under the act must be based on 'the best available peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices', and on 'data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies the use of the data)'.³³ Such a requirement can be expected to have an impact on the substance of environmental regulation.

During 2000, in the waning days of the Clinton administration, Congress enacted the Information (Data) Quality Act, which added a short rider to an appropriations bill. The law, which was supported and largely written by business groups, directs the Office of Management and Budget to 'issue guidelines ... that provide policy and procedural guidance to federal agencies for ensuring and maximizing the quality, objectivity, utility and integrity of information (including statistical information) disseminated by federal agencies'.³⁴ Because it establishes guidelines for the 'quality, objectivity, utility and integrity' of scientific data used by federal agencies, and because it also affords interested parties the right to challenge an agency's adherence to those guidelines, the law can be expected to have a significant effect on agency rule-making if it is vigorously enforced.³⁵ The OMB has since issued detailed guidelines for good guidance practices performing cost-benefit analysis³⁶ and cost-effective analysis.³⁷ The EPA has issued guidelines for carcinogenic risk assessment.³⁸ Together, these guidance documents influence the course and tenor of regulatory rule-making.

Unless there is a concomitant increase in agency resources, legislation that expands the responsibilities that an agency must fulfil before issuing its regulations – such as by requiring a cost-benefit analysis or a complicated risk assessment – will tend to reduce the number of regulations that the agency can promulgate because of the substantial burdens placed on regulatory agency resources. It also adds a chilling effect on agencies promulgating stringent regulations because of conservative constraints placed upon the actual undertaking of risk assessments.

Additional executive branch influence through the Office of Management and Budget

Administrative agencies sit within the executive branch. Accordingly, the executive also exercises considerable control over agency decision-making. Much of the executive's influence over the direction of an agency stems from the president's control of the

appointment process. Most statutes that create an administrative agency also permit the president to appoint the agency's top decision-makers (the so-called political appointments), subject to the approval of the US Senate. The power to appoint includes the power to remove from office, along with all of the more subtle means of persuasion that lie between the two. The underlying theory, presumably, is that each new administration should be free, within the bounds of the applicable statutory mandates, to chart the direction of the agencies that operate within its purview. However, this approach often entails an inherent conflict because the direction favoured by the administration frequently differs from that favoured by Congress. This appears to be an accepted part of the political process.

The executive branch also wields considerable influence over the agencies through the budget process. Although final approval of the national budget rests with Congress, the budget is shaped, in large part, by the proposed budget submitted to Congress by the president. Even more directly than Congress, then, the executive branch can use its grip on the national purse strings to expand the size of those regulatory programmes that it favours and to contract the size of those it does not. Furthermore, since 1980, the president has used the Office of Management and Budget (OMB) to oversee an economic analysis of all proposed major regulations. This has had a significant effect on the regulatory initiatives proposed by the EPA, the Occupational Safety and Health Administration (OSHA) and the Food and Drug Administration (FDA).

President Reagan's 1981 Executive Order 12291 (the core substance of which remains in effect under a 1993 executive order issued by President Clinton) required the OMB to review significant new regulatory actions to ensure that the potential benefits to society outweigh the potential costs, with such benefits and costs to be quantified in monetary terms. In essence, this order imposed the cost-benefit criterion as a prerequisite to promulgation of federal regulations. The OMB has used the review authority granted by this order to delay the promulgation of several regulations. A precursor to this executive order was President Ford's 1974 Executive Order 11821, which required that all regulations issued by executive branch agencies should be accompanied by an inflationary impact statement, where 'inflationary' was defined by the Council on Wage and Price Stability as a situation in which the costs of the regulation exceeded the benefits. However, it did not require that the regulation should not be inflationary, but only that the inflationary impacts should be evaluated. Similarly, President Carter's Executive Order 12044 required federal agencies to analyse the economic consequences of significant regulations and their alternatives, though it imposed no cost-benefit requirement. Although President Clinton's 1993 executive order expressly revokes President Reagan's order,³⁹ it incorporates many of its basic concepts and retains the cost-benefit review as a key part of the OMB's role.

The Clinton order requires agencies to submit detailed information on anticipated costs and benefits for OMB review before they take any 'significant regulatory action', which is defined as an action that is likely to result in a rule that may have 'an annual effect on the economy of US\$100 million or more', that may 'adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local, or tribal governments or communities', or that may meet another of the criteria enumerated therein. The cost-and-benefit information submitted is to be quantified 'to the extent feasible'.⁴⁰ The OMB, in turn, is

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directed to 'provide meaningful guidance and oversight so that each agency's regulatory actions are consistent with applicable law, the president's priorities and the principles set forth in the executive order'.⁴¹ The cost-benefit criterion is incorporated within the following Principle of Regulation stated in the order:

*Each agency shall assess both the costs and benefits of the intended regulation and, recognizing that some costs and benefits are difficult to quantify, propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs.*⁴²

The OMB has sought to impose the cost-benefit criterion on agency decision-making even when the underlying statute has required that the regulation be promulgated according to criteria other than cost-benefit balancing. It uses this criterion in its review of workplace health regulations proposed by the OSHA, for example, even though the Supreme Court has held that such regulations are to be set according to technological and economic feasibility, and not according to a weighing of costs and benefits.⁴³ This approach contravenes the executive order's directive that the OMB endeavour to ensure that agency regulation is 'consistent with applicable law'.

The philosophical tension between Congress and the president on the cost-benefit issue would appear to have been lessened by the former's embrace of the cost-benefit criterion in the Unfunded Mandates Reform Act of 1995. As discussed earlier, however, this law applies to a more limited class of 'major' regulations and does not require that the benefits of a regulation outweigh its costs.

The OMB has a limited, *congressionally delegated* authority to influence the content of agency regulations under the Paperwork Reduction Act (PRA).⁴⁴ The general purpose of the PRA is to reduce the public and private burdens incident to government data-gathering activities, and the act directs the OMB to oversee the work of other agencies in order to achieve this objective.

Direct congressional intervention in agency rules

A second key aspect of the Small Business Regulatory Enforcement Fairness Act discussed above was the creation of the Congressional Review Act (CRA).⁴⁵ As its name suggests, the CRA was designed to facilitate congressional review of agency rule-making. It requires that, before a final rule takes effect, the promulgating agency provides a report to Congress that includes, among other things, 'a complete copy of the cost-benefit analysis of the rule, if any', and the regulatory flexibility analyses prepared under the Regulatory Flexibility Act. If the regulation is a 'major' rule under the Unfunded Mandates Reform Act, it does not take effect until 60 days after this report has been submitted, unless the president determines that the rule should take effect immediately because one of four designated criteria has been satisfied.⁴⁶ This is intended to give the members of Congress time to review the regulation and, if they choose, to debate its merits. Moreover, Congress may (subject to a potential presidential veto) nullify any rule submitted under the CRA and prevent it from taking effect by passing a 'joint resolution of disapproval'.⁴⁷ Congress did exactly this when it repealed an OSHA standard on ergonomics in 2001.

Extra-legal activities compromising protection of health, safety and the environment

Aside from legislative and executive policy initiatives that have the effect of reducing protection of health, safety and the environment by imposing a cost-benefit calculus and formalistic risk assessment conventions upon regulatory agencies, two other areas of activity have seriously reversed earlier trends towards a precautionary approach: the political purging of agency science advisory boards and the selective removal of environmental scientists from study sections that review research grants by the agencies,⁴⁸ and the gradual replacement of members of the judiciary, at both the circuit court and Supreme Court level, with anti-regulatory ideologues.⁴⁹

A CAPSULE HISTORY OF US CHEMICAL REGULATION AND THE USE OF THE PRECAUTIONARY PRINCIPLE IN US LAW

The history of the use of the precautionary approach in US law contrasts with that in the EU. Whereas in the EU, the precautionary principle appears first in food safety and then moves slowly to develop in environmental regulations and is yet to find full expression in the regulation of occupational health and safety, in the US, it begins strongly and emphatically in worker health and safety, then in the environment, and is weakly expressed in food safety law. In fact, interpretations of what constitutes sufficient scientific evidence and how precautionary agencies should be are given their strongest expression in occupational health and safety law,⁵⁰ which profoundly affects the development of these considerations in the environmental area.

The Occupational Safety and Health Act of 1970⁵¹

The Occupational Safety and Health Act (OSHAct) of 1970 specifically addresses the subject of toxic substances. It states, under Section 6(b)(5) of the act, that the secretary of labour, through the Occupational Safety and Health Administration (OSHA), in promulgating permanent standards dealing with toxic materials or harmful physical agents, shall set the standard that:

... most adequately assures, to the extent feasible, on the basis of the best available evidence that no employee will suffer material impairment of health or functional capacity, even if such employee has a regular exposure to the hazard dealt with by such standard for the period of his working life [emphasis added].⁵²

Standards promulgated under this section of the act are reviewable by the circuit courts of appeal; the standard of judicial review is 'substantial evidence on the record as a whole'.⁵³

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The case *Industrial Union Department, AFL-CIO v Hodgson*,⁵⁴ promulgated a more stringent regulation for asbestos – at the time regarded as a lung toxin causing asbestosis, but not a carcinogen – and the industry challenged the standard, arguing that there was insufficient evidence to justify lowering the permissible exposure limit. In deferring to the agency's determination that a more protective level was needed, the DC Court of Appeals held that:

Some of the questions involved in the promulgation of these standards are on the frontiers of scientific knowledge, and consequently ... insufficient data is presently available to make a fully informed factual determination ... it rests, in the final analysis, on an essentially legislative policy judgment, rather than a factual determination, concerning the relative risks of under-protection as opposed to overprotection.

One might regard this as an articulation of the permissive use of the precautionary principle.

In a subsequent case, *The Society of Plastics Industry, Inc v Occupational Safety and Health Administration*,⁵⁵ concerning an industry challenge to a very stringent OSHA standard of allowing no more than 1 part per million (ppm) exposure over an eight-hour period to the carcinogen vinyl chloride, the Second Circuit Court of Appeals reiterated the rationale in *Industrial Union* above, adding: 'Under the command of OSHA, it remains the duty of the secretary to act to protect the working man, and to act where existing methodology or research is deficient.' Here, applying a precautionary approach appears to be mandatory, rather than permissible, even under industry protests that achieving the standard was not technologically feasible.

These cases profoundly influenced the extent to which the Environmental Protection Agency regulated air pollutants under the 1970 Clean Air Act (amended in 1977 and 1990) and attempted to regulate toxic substances under the 1976 Toxic Substances Control Act.

After industry testing revealed formaldehyde to be an animal carcinogen in 1979, during the 1980s, under President Reagan, the OSHA initially did nothing to follow up on the prior Carter administration's intent to regulate it.⁵⁶ Regulatory agency decisions 'not to act', while technically reviewable by appellate courts, are notoriously difficult to counter. Ultimately, in 1992, 13 years after the animal study, the OSHA was forced to regulate formaldehyde, but chose to place the most minimal restrictions possible on allowable exposure, permitting lifetime risks of greater than 10^{-3} following the directives emanating from the Supreme Court benzene case discussed immediately below.

In a 1980 case involving the industry challenge to an OSHA regulation of the carcinogen benzene at 1 ppm over an eight-hour period, the appellate process reached the Supreme Court. In *Industrial Union Department v American Petroleum Institute*,⁵⁷ the Supreme Court added a requirement, with dubious legal justification, to the OSHAct that only 'significant risks' could be regulated under the toxic substances provision of the OSHAct. The court remanded the standard to OSHA to determine whether benzene exposure at 1 ppm was 'significant', offering guidance that 'significance' should lie somewhere between a lifetime risk of 10^{-3} (a clearly significant risk) and 10^{-9} (a clearly insignificant risk). The OSHA, under President Reagan, chose the 'bright line' at the least permissibly protective level of 10^{-3} . This heralded the end of the precautionary era

in toxic substances regulation. Although President Clinton subsequently could have drawn the line differently, he did not change it.

The OSHA can also administratively and immediately establish 'temporary emergency standards' under the OSHAct; but much discretion is left to the OSHA to determine whether the requirements of a 'necessity to prevent grave danger' prevails in a particular case.⁵⁸ In addition, there is a provision in the OSHAct that authorizes the OSHA to go to a federal district court (a court of first instance) to restrain or halt an industrial operation in the case of imminent dangers.⁵⁹

In addition to complying with specific standards, employers are also under a 'general duty' to provide workplaces and work free from 'recognized hazards likely to cause death or serious bodily harm'.⁶⁰ Again, defining what constitutes a 'recognized hazard' is left to the discretion of the OSHA.

Thus, what first appears as an emerging mandatory requirement to apply the precautionary principle for worker protection disappears after the benzene case into the abyss of agency discretion dominated by industry interests.

The 1970 Clean Air Act (CAA) (and amendments of 1977 and 1990)^{61, 62}

The 1970 Clean Air Act (CAA) regulated both criteria pollutants (carbon monoxide, sulphur dioxide, nitrogen oxides, particulates, ozone and lead) under CAA Section 109,⁶³ and so-called hazardous pollutants under CAA Section 112.⁶⁴ Federal ambient air quality (concentration) standards were established for the former, and federal emission standards were to be established for the latter. The standard of judicial review in the DC Circuit Court of Appeals is 'arbitrary or capricious'. The ambient air quality standards were to be set by the EPA to protect public health 'with an adequate margin of safety' without consideration of economic costs; they were to be achieved through state-imposed emission levels in state permits on existing sources and through state-enforced federal emission limitations on new sources,⁶⁵ the latter taking economic burdens into account while permitting the standards to be 'technology forcing' in stringency.

The leading case interpreting standard-setting for criteria pollutants, *Lead Industries Association, Inc v Environmental Protection Agency*, addressed a new standard for airborne lead compound particulates.⁶⁶ There, the DC Circuit Court of Appeals agreed with the EPA that 'Congress directed the administrator to *err on the side of caution* in making the necessary decisions' (emphasis added). Furthermore, the court agreed with the EPA that:

- Congress made it abundantly clear that considerations of economic or technological feasibility are to be subordinated to the goal of protecting the public health by prohibiting any consideration of such factors.
- [I]t specified that the air quality standards must also protect individuals who are particularly sensitive to the effects of pollution.
- [I]t required that the standards be set at a level at which there is 'an absence of adverse effect' on these sensitive individuals.
- [I]t specifically directed the Administrator to allow an adequate margin of safety in setting primary air quality standards in order to provide some protection against effects that research has not yet uncovered.

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It is hard to imagine a stronger endorsement of the precautionary principle. Note the absence of any specific reference to irreversibility of damage or persistence or biomagnification of the pollutant in the environment or the human body. But do note the specific concern for sensitive individuals, the explicit rejection of cost-benefit balancing, and the endorsement of action 'against effects that research has not yet uncovered'. But the precautionary approach was not long lived in the agency. Ronald Reagan won a two-term presidency in 1980 and 1984 and dramatically changed the landscape of US environmental regulation.

For hazardous air pollutants, the 1970 CAA similarly directed the EPA to set emission standards 'at the level which, in his judgment, provides an ample margin of safety to protect the public health'.⁶⁷ Departing from the rationale in *Lead Industries*, in an industry challenge to the EPA proposed emission standard for vinyl chloride, writing for a three-judge panel of the DC Circuit Court of Appeals, Judge Robert Bork in *Natural Resources Defense Council, Inc v Environmental Protection Agency*⁶⁸ opined:

We find that the congressional mandate to provide 'an ample margin of safety' 'to protect the public health' requires the Administrator to make an initial determination of what is 'safe ... [T]he administrator's decision does not require a finding that 'safe' means 'risk free' or a finding that the determination is free from uncertainty. Instead, we find only that the Administrator's decision must be based upon an expert judgment with regard to the level of emission that will result in an 'acceptable' risk to health... This determination must be based solely upon the risk to health. The Administrator cannot under any circumstances consider cost and technological feasibility at this stage of the analysis ...

Congress, however, recognized in Section 112 that the determination of what is 'safe' will always be marked by scientific uncertainty and thus exhorted the administrator to set emission standards that will provide an 'ample margin' of safety. This language permits the administrator to take into account scientific uncertainty and to use expert discretion to determine what action should be taken in light of that uncertainty. Congress authorized and, indeed, required EPA to protect against dangers before their extent is conclusively ascertained. Under the 'ample margin of safety' directive, EPA's standards must protect against incompletely understood dangers to public health and the environment, in addition to well-known risks ...

We wish to reiterate the limited nature of our holding in this case because it is not the court's intention to bind the administrator to any specific method of determining what is 'safe' or what constitutes an 'ample margin'. We hold only that the administrator cannot consider cost and technological feasibility in determining what is 'safe'.

Unable to shake the clear congressional intent in Section 112 to require standards to be set in the face of considerable scientific uncertainty and without regard to economic or technological feasibility, the three-judge panel of the DC Circuit invented a *de minimis* risk requirement to soften the blow. This case prompted Congress to amend Section 112 of the CAA in the 1990 CAA amendments to allow a technology-based approach to be used, directing the EPA to set technology-based emission standards (based on maximum

achievable control technology) established on the level achievable by the 'average' performance of the top 12 per cent of the industry.⁶⁹ The EPA could establish more stringent emission standards for new sources.⁷⁰ Where technology-based standards were not practical, the EPA could resort to a health-based approach, protecting the public health with an ample margin of safety,⁷¹ the original mandate of the 1970 CAA. Congress expressly provided that, ultimately, carcinogenic chemicals cannot present a risk greater than a 10^{-6} lifetime risk.⁷²

In a later challenge to the EPA's revised standards for the criteria pollutants ozone and particulates, in *Environmental Protection Agency v American Trucking Associations, Inc.*,⁷³ the Supreme Court reinforced the correctness of the lead case criteria, with concurring Justice Stephen Breyer echoing Judge Bork's rationale that protecting public health with an 'adequate margin of safety' does not mean a world that is 'free of all risk'.

Appellate court deference to the agencies as to what constitutes tolerable *de minimis* risks or significant risks that must be demonstrated in order to be regulated is a 'back door' pathway to reducing a precautionary approach by allowing risk assessments that do not clearly show calculable significant risks to justify non-action. Furthermore, by compromising the independence of agency science advisory boards and by eliminating research grants to scientists who do not think 'the right way', the federal government has greatly compromised the independence and integrity of science in the political process.⁷⁴

The 1976 Toxic Substances Control Act (TSCA)⁷⁵

Under the 1976 Toxics Substances Control Act (TSCA), the EPA must set standards for substances that present or will present 'unreasonable risks to health or the environment',⁷⁶ taking into account costs, effects on health and the environment, technological innovation and substitutes.⁷⁷ The EPA requires industry to test chemicals⁷⁸ if there is insufficient data and the substance 'may present unreasonable risks to health or the environment' or if there is a substantial quantity produced or exposure is deemed to be significant. If there may be a reasonable basis to conclude that a chemical presents (or will present) a 'significant' risk of cancer, mutation or birth defects, the EPA must either regulate or explain why it has chosen not to – that is, why the risk is not 'unreasonable'.⁷⁹ Upon challenge, any federal court of appeal can examine the standards to ensure that they are based on 'substantial evidence on the record as a whole' (the same standard of judicial review found in the OSHAct).⁸⁰ As with the OSHAct, the TSCA provides for emergency measures⁸¹ and imminent hazards.⁸² Under the TSCA, the EPA also requires industry to report 'significant adverse reactions' and information about their products' toxicity.⁸³

Asbestos, the most notorious carcinogen known in the context of workplace, consumer and environmental exposure, did receive EPA attention during the 1980s. The EPA decided to ban the substance under the TSCA for many uses; but the standard was remanded to the agency for reconsideration by the Fifth Circuit Court of Appeals in *Corrosion Proof Fittings v EPA*.⁸⁴ As stated above, the TSCA requires the EPA to consider, along with the toxic effects on human health and the environment, 'the benefits of such substance[s] and mixture[s] and the *availability* of substitutes for such uses' (emphasis

added). Because the EPA did not explore regulatory options other than a ban, and, more specifically, because the EPA did not evaluate the toxicity (and costs) of likely substitute products⁸⁵ in a search for 'least burdensome requirements', the court vacated the proposed standard and remanded it to the EPA for further proceedings. While, arguably, the court incorrectly interpreted the TSCA's requirements regarding mandating substitutes' toxicity (and cost) comparisons (the TSCA mentions only that the 'availability' of substitutes must be considered) and could have sought to establish regulation in another circuit court to give a more favourable result concerning what criteria need to be met in order to regulate, the EPA chose not to reinstate the asbestos ban, primarily because of the likely extensive burden on agency resources to perform extensive risk and economic assessments for substitutes. For all intents and purposes, the EPA regards the TSCA as a 'dead letter'.⁸⁶ The analytic burdens placed by the Fifth Circuit Court of Appeals effectively emasculated the TSCA regulation in the US.

RECLAIMING HEALTH, SAFETY AND ENVIRONMENTAL PROTECTION

The precautionary principle has been criticized as being both too vague and too arbitrary to form a basis for rational decision-making. The assumption underlying this criticism is that any scheme not based on cost-benefit analysis and risk assessment is both irrational and without secure foundation in either science or economics. This section contests that view and makes explicit the rational tenets of the precautionary principle within an analytical framework – trade-off analysis – which is as rigorous as uncertainties permit, and one that mirrors democratic values embodied in regulatory, compensatory and common law. It offers an approach to making decisions within an analytic framework, based on equity and justice, to replace the economic paradigm of utilitarian cost-benefit analysis. As will be seen, the strength of trade-off analysis is that it explicitly takes into account who bears the costs and who reaps the benefits.⁸⁷ This feature of trade-off analysis mirrors the increasing EU tendency to balance 'interests' rather than costs and benefits.⁸⁸

The limits of cost-benefit analysis in addressing distributional concerns

During the past two decades, cost-benefit analysis has become the dominant method used by policy-makers to evaluate government intervention in the areas of health, safety and the environment. In theory, cost-benefit analysis of a policy option enumerates all possible consequences, both positive and negative; estimates the probability of each; estimates the benefit or loss to society should each occur, expressed in monetary terms; computes the expected social benefit or loss from each consequence by multiplying the amount of the associated benefit or loss by its probability of occurrence; and computes the net expected social benefit or loss associated with the government policy by summing over the various possible consequences.⁸⁹ The reference point for these calculations is the state of the economy in the absence of the government policy, termed the 'baseline'.

The mechanics of constructing a cost-benefit analysis can be seen with reference to Table 19.1, which presents a relatively disaggregated matrix of the various positive and negative consequences of a government policy for a variety of actors. The consequences are first separated into economic, health and safety, and environmental effects, and those affected are organized into policy-relevant groups of actors, such as producers, workers, consumers and 'others'. Initially, the consequences are represented in their natural units: economic effects are expressed in monetary units; health and safety effects are expressed in mortality and morbidity terms; and environmental effects are expressed in damage to ecosystems, etc. Economic analysis is used to evaluate monetary costs and benefits related to economic effects. Health and environmental risk assessments inform the entries in the last two columns of the matrix.

All of the consequences of a candidate policy (or regulation) are described fully in terms of the times during which they occur. What traditional cost-benefit analysis does is translate all of these consequences into 'equivalent' monetary units. This poses two problems. One is the difficulty, even arbitrariness, of placing a monetary value on human life, health and safety and a healthy environment. Another is that by translating all of these consequences into equivalent monetary units, discounting each to current value (since a US\$/Euro invested now is expected to earn interest over time), and aggregating them into a single US\$/Euro value intended to express the net social effect of the government policy, the effects on the economy from investing now in future health, safety and environmental benefits are weighted far more heavily than those benefits that occur in the future, including those to future generations.

As a decision-making tool, cost-benefit analysis offers several compelling advantages. It clarifies choices among alternatives by evaluating consequences systematically. It professes to foster an open and fair policy-making process by making explicit the estimates of costs and benefits and the assumptions upon which those estimates are based. And by expressing all gains and losses in monetary terms, cost-benefit analysis permits the total impact of a policy to be summarized in a single US\$/Euro figure (cost-effectiveness analysis relies on a benefit-to-cost ratio, rather than a net benefit calculus, but otherwise shares the other weaknesses of a cost-benefit approach).

Table 19.1 *Matrix of policy consequences for different actors*

| Group | Economic effects | Health/safety effects | Environmental effects |
|-----------|------------------|-----------------------|-----------------------|
| Producers | C_s | | |
| Workers | C_s | $B_{H/S}$ | |
| Consumers | C_s | $B_{H/S}$ | |
| Others | C_s | $B_{H/S}$ | $B_{Environment}$ |

This final step, however, may be stretching analytic techniques one step too far. An alternative approach, called trade-off analysis, begins in the same way as does cost-benefit analysis, but does not aggregate like effects into a single benefit or cost stream, and it stops short of assigning monetary values to non-monetary consequences. Instead, all effects are described in their natural units. The time period in which each effect is experienced is fully revealed; but future effects are not discounted to present value. All kinds of uncertainties are fully described: risk, probability distributions and indeterminacy. It is not possible to know what we don't know (ignorance), but confidence that we have fully described the world is a proxy for a belief that ignorance is not likely to be a problem. Trade-offs between worker health or environmental improvements and costs to producers and consumers are made apparent because the different cost and benefit elements are not aggregated.

Using trade-off analysis, politically accountable decision-makers could make policy choices in a transparent manner. Who bears the costs and who reaps the benefits from a policy option would not be hidden in a single aggregate US\$/Euro figure. Decisions would be based on accountability rather than accounting. Note that while cost benefit is formulaic – that is, a single figure of merit is sought for a policy/regulation, such as the 'net benefit' or a 'benefit-to-cost ratio' – trade-off analysis seeks to 'bound the set of not clearly incorrect – that is, unfair – decisions'. This has important implications for policy choices. Under a cost-benefit framework, one can easily demand prioritization of risk-reduction options based on the ranking of net benefits or cost-benefit ratios – with choices representing violations of the ranking being allegedly inconsistent or irrational. However, where large uncertainties exist, and the distributions of risks and benefits are of concern, there is no uniquely correct prioritization scheme or metric demanding 'consistency'. Advances in risk assessment techniques and economic analysis that takes technological innovation into account through the deliberate undertaking of Technology Options Analysis (see below) can narrow the uncertainties, but can never provide a unique best answer. That process, ultimately, has to reflect political, social and value judgments – preferably informed by public participation/stakeholder processes and transparent for all to see. Taking care to include concerns for effects, their uncertainties and their distributional consequences – that is, exercising precaution – in order to make responsible, accountable decisions is possible using trade-off analysis, but not cost-benefit analysis.

Promoting rational technology choices

One important element often left out of the traditional cost-benefit matrix has been the consideration of technological alternatives.⁹⁰ Regulatory agencies have a mixed history in making information about cleaner and safer technologies available and promoting their adoption. Agencies could help to prevent pollution and accidents by helping firms to think about their technological options in a more formal and systematic fashion.

Options for technological change must be considered according to a variety of criteria, including economic, environmental, and health and safety factors. Identifying these options and comparing them against the technology in use is called Technology Options Analysis.⁹¹ Unlike traditional technology assessment, Technology Options

Analysis does not require absolute quantification of all of the variables: one has only to demonstrate, in a *comparative* manner, that one technology is better or worse than another in performance, health, safety, ecological effects and so forth. It is likely to be less sensitive to initial assumptions than, for example, cost-benefit analysis, and would enable industry and government to identify more creative cost-effective solutions. Government might require industries to undertake Technology Options Analysis instead of traditional technology assessment focusing on technologies already existing within, or easily accessible to, the firm or industry. The latter would likely address only the technologies that industry puts forward; it may thus miss the opportunity of identifying and subsequently influencing the adoption or development of superior technological options.⁹²

Once superior existing technologies – or technologies within easy reach – are identified, industries may be motivated to change their technology out of economic self-interest or in order to avoid future liability. On the other hand, government might either force the adoption or development of new technology, or provide technical or financial assistance. Requiring firms to change technology can itself be a risky venture. Adopting a technology new to a firm or industry introduces new uncertainties and financial risks. If this is done, policy should allow for error and accommodate industry for failures in *bona fide* attempts to develop new technologies – for example, by allowing more time or sharing the financial risk. Developing a new technology may often not be possible for the incumbent polluting or dangerous firm. New entrants displacing the dominant or prevailing technology may be required. To adopt environmental, health or safety requirements in this case takes considerable political courage; but the options of doing so should not be ignored.⁹³

Whichever route government takes, the precautionary principle requires the investigation of technology options for developing and adopting cleaner and inherently safer (sustainable) technologies.

Which errors are worse?

Policy-makers must address both uncertainty about the nature and extent of health, safety or environmental risks, and about the performance of an alternative technology. First, they must choose whether to err on the side of caution or risk. With regard to the first type of uncertainty – scientific uncertainty – two mistakes can be made. A ‘type I’ error is committed if society regulates an activity that appears to be hazardous, but turns out later to be harmless (a ‘false positive’ in the parlance of experimental findings) and resources are needlessly expended. Another error, a ‘type II’ error is committed if society fails to regulate an activity because the evidence is not initially thought to be strong enough, but that finally turns out to be harmful (a ‘false negative’).⁹⁴

A ‘type III’ error is said to occur when one provides an accurate (or precise) answer to the wrong problem.⁹⁵ Not taking into account opportunities to change technology restricts the decision-maker to ‘static solutions’ and thus gives rise to the further error of considering options within ‘bounded rationality’.

Where uncertainty exists on the technology side, type I errors can be said to be committed when society mandates the development or adoption of a technology that

turns out to be much more expensive or less able to reduce risks than anticipated, and when resources are needlessly or foolishly expended. Type II errors might be said to be committed when, because of insufficient commitment of resources or political will, a significant missed opportunity is created by which society fails to force or stimulate significant risk-reducing technology.⁹⁶ An important distinction between a cost-benefit approach and one based on precaution is that the former is 'risk neutral' in the balancing of costs and benefits with their attendant uncertainties, and the latter reflects 'risk averseness' for some kinds of errors.

Value judgments clearly affect decisions on whether to tolerate type I or type II errors with regard to *both* risk and technology choices. This is because the cost of being wrong in one instance may be vastly different from the cost of being wrong in another. For example, banning a chemical essential to a beneficial activity, such as the use of radio nuclides in medicine, has potentially more drastic consequences than banning a non-essential chemical for which there is a close, cost-comparable substitute. It may be perfectly appropriate to rely on 'most likely estimates' of risk in the first case and on 'worst-case analysis' in the second. A type II error on the technology choice side was committed in the case of the Montreal Protocol banning chlorofluorocarbons (CFCs) by creating a scheme through which DuPont and ICI, the producers of CFCs, were allowed to promote the use of their own substitute, hydrochlorofluorocarbons (HCFCs), rather than adopt a more stringent protocol that would have stimulated still better substitutes.

Evaluating errors and deciding which way to lean is not a precise science. However, making those evaluations and valuations explicit within a trade-off analysis that acknowledges distributional effects, accounts for uncertainties in risk assessments and considers opportunities for technological change will reveal the preferences upon which policies are based and may suggest priorities.

CONCLUSIONS

The application and discussion of the precautionary principle have focused on action to prevent or refrain from contributing to possible serious irreversible harm to health and the environment – whether on an individual basis or in terms of widespread environmental or health consequences. In particular, the precautionary principle has become embodied in regulations directed towards persistent and/or bioaccumulative toxic substances.⁹⁷ Lately, the principle has been applied to problems attended by indeterminacy and ignorance.

Here it is worth reviewing the fact that the nature of uncertainty in the problems that now concern health, safety and environmental regulators and advocates is changing. Formerly, concentrating on the magnitude of risks and their uncertainties – in a probabilistic sense – consumed the attention of the decision-maker. Since better science would be expected to yield a better basis for decisions, it could be argued that risk management decisions should await its arrival. Today, problems of indeterminacy and ignorance increasingly characterize the risks we face. It is no longer a question of waiting for the science to be developed. The limitations of 'knowing with greater accuracy' and 'not knowing what we don't know' attend – and will continue to attend in the foreseeable

future – modern day risks and confound so-called rational approaches to dealing with these hazards. The social concern with genetically modified organisms (GMOs) or with bioterrorism are examples. The proponents of GMOs deride social attempts to exercise caution over risks we cannot estimate or imagine; but who is arguing that taking precaution against terrorism is ‘irrational’? Ought we to expect ‘consistency’ in the management of highly uncertain (that is, indeterminable or unknowable), possibly catastrophic, risks? Clearly, a different theoretical framework is needed – one outside of deterministic rational choice theory.

I have argued elsewhere that the precautionary principle need not be restricted to cases of irreversibility or large uncertainty of effect.⁹⁸ If it is, as I contend, an alternative to cost-benefit analysis, it can be used wherever that approach gives an objectionable outcome. For example, it might also be applied to mitigate a harm that is ultimately reversible – if reversing the damage could be more costly than preventing it. And what of the cases in which there are no uncertainties – for example, when we know that future generations will be harmed? Cost-benefit analysis is biased against investing heavily in the present to prevent such future harm because of the use of discounting cost and benefit streams over time. And there are many situations in which we are aware of our ignorance: for example, we know that only a very small percentage of all chemicals in commerce have been tested for toxic effects.⁹⁹ In these cases, too, precaution is appropriate.

However, it is not the precautionary principle *per se* that is amenable to replacing cost-benefit analysis as a ‘decision rule’ for action. Nor does the precautionary principle replace risk assessment. Attempts to establish a threshold of harm above which the precautionary principle is triggered, for example, have been less than satisfactory.¹⁰⁰ Instead, a precautionary approach or principle is most useful in guiding the selection of policies, and aiding in the establishment of priorities, in an attempt to deliver justice and fairness within a more appropriate framework than cost-benefit analysis. Precaution rightly focuses on uncertainty and irreversibility as two important factors; but others must be considered as well, particularly technology alternatives. A complete list of the important elements must include:

- the *seriousness and irreversibility* of the harm addressed;
- the *societal distribution of possible costs and benefits* of policies and technologies;
- the *technological options* for preventing, arresting, reversing or mitigating possible harm – and the opportunity costs of selecting a given policy option;.
- *society’s inclinations* regarding erring on the side of caution and erring on the side of laxity;
- the *nature of the uncertainty encountered*: classical uncertainty, indeterminacy or ignorance?

Nothing substitutes for a transparent and accessible decision-making framework in which the values and assumptions are clearly articulated and compared to alternative approaches. Trade-off analysis makes this possible, but also offers the opportunity to operationalize the precautionary principle by:

- *Minimizing uncertainty* through:
 - refinement of (comparative) risk analysis; and
 - undertaking (comparative) Technology Options Analysis.

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- *Reflecting societal preferences for error avoidance* regarding:
 - risk avoidance (type I versus type II errors regarding requirements for the *reduction of risk*); and
 - cost avoidance (type I versus type II errors regarding requirements for *changes in technology*).
- *Changing the burden of proof* through:
 - consideration of creating a *sliding scale* for the burden of proof – that is, the strength of data/information needed to justify taking (or stopping) action, depending upon the hazard, extent of protection desired and action taken (notification, regulation, compensation, etc.); this means *linking causality to level of desired protection*.

Much of the discussion of the precautionary principle focuses on cause-and-effect relationships for which a high statistical confidence level (usually expressed as having a p value of ≤ 0.05 – that is, a small chance of the association being spurious or random) or a high strength of association is traditionally required in scientific publications. It should be remembered that the convention of requiring a p value no higher than 0.05 was an arbitrary historical choice. Critics of those wishing to invoke the precautionary principle by reducing the strength of causal proof would do well to remember this. In addition, other ways of knowing besides statistical correlations might be pursued.¹⁰¹

Other standards (burdens) of proof commonly invoked in public policy determinations include, in decreasing order of stringency, ‘strict liability for harm’ (in the area of compensation, the polluter pays principle is sometimes invoked in statutory language or by the courts in fashioning equitable relief to victims); ‘clear and convincing evidence’; ‘more probable than not’ or ‘preponderance of the evidence’; ‘substantial cause or factor’; and ‘contributing factor’. This sliding scale of evidentiary strength can be thought of as invoking the precautionary principle by expanding the ‘allowable possible error’ in factual determinations. An alternative to shifting the burden of proof that lessens the burden of proof required to trigger an intervention to prevent or mitigate harm to health, safety or the environment is to shift the *burden of persuasion* to another party.

Presumptions and shifts in the burden of persuasion

Part of the perceived fairness of the process involves the burden of persuasion – that is, the designation of which party has the burden of demonstrating or refuting a presumed fact. This is distinct from the burden or standard of proof – a term referring to the strength of the evidence (data and information) needed to justify taking action. Both terms are relevant in formulating the precautionary principle.

Much discussion has focused on cause-and-effect relationships between exposure/other events and harmful effects for which a high statistical confidence level or strength of association is traditionally required. To escape the rigors of these requirements, some proponents of the precautionary principle argue that the burden of persuasion should be shifted to the proponents of a potentially harmful technology. Opponents argue against so radical a shift, pointing out that negatives are harder to prove.

Sometimes ignored by many commentators is the fact that burdens of persuasion often shift in the course of fact-finding. Thus, depending upon the nature of the intervention (notification, control, banning, treatment, compensation, etc.), even if it is necessary for the regulator or potential victim initially to prove a (potential) harm, that proof is sometimes not a very high burden. A presumed fact (though a rebuttable presumption) might even be established by statute on showing certain other factual elements, such as the very existence of harm. Then, the burden of persuasion shifts to the intended regulated industry or alleged (potential) wrong-doer to refute the presumed or initially established fact, often with a higher burden of proof. Legal injunctions against potentially harmful action are granted by the courts as equitable remedies. The commentators on the precautionary principle have often ignored a rich and important set of policy interventions or actions that are informed, but not dictated, by factual determinations. Regulatory agencies themselves – depending upon their statutory mandates – are not bound by traditional burdens of proof. Furthermore, reviewing courts usually give deference to factual findings by the agencies as long as they stay within the ‘zone of reasonableness’ defined by those mandates.

NOTES

- 1 This is not to say that some improvements have not also occurred; but the magnitude of problems in other areas has increased, and the nature of risks has also changed.
- 2 Colborn, T., Dumanowski, D. and Myers, J. P. (1996) *Our Stolen Future*, Dutton Press, New York.
- 3 Ashford, N. A. and Miller, C. (1998) *Chemical Exposures: Low Levels and High Stakes*, second edition, John Wiley Press, New York.
- 4 Hoefer, T., Gerner, I., Gundert-Remy, U., Liebsch, M., Schulte, A., Spielmann, H., Vogel, R. and Wettig, K. (2004) ‘Animal testing and alternative approaches for the human health risk assessment under the proposed new European Chemicals Regulation’, *Archives of Toxicology*, vol 78, pp549–564.
- 5 Wynne, B. (1992) ‘Uncertainty and environmental learning’, *Global Environmental Change*, vol 2, pp111–127.
- 6 National Academy of Sciences (1983) *Risk Assessment in the Federal Government: Managing the Process*, National Academy Press, Washington, DC.
- 7 Ashford, N. A. (1988) ‘Science and values in the regulatory process’, *Statistical Science*, vol 3, no 3, pp377–383.
- 8 See de Sadeleer, N. (2006) ‘The precautionary principle in EC health and environmental law: Sword or shield for the Nordic countries?’ – Chapter 2 in this volume.
- 9 Indeed, the offered methodologies are based in so-called ‘rational-choice’ theory pioneered by the University of Chicago School of Law and Economics. See Ashford, N. and Caldart, C. (2007) ‘Economics and the environment’, in *Environmental Law, Policy, and Economics: Reclaiming the Environmental Agenda*, Cambridge, MIT Press, Chapter 3.
- 10 Rather than focusing on requiring minimum certainty before acting, agencies sometimes formulate their defence of no regulation by arguing that (conservative) risk assessments yield risks that are too small to justify action – that is, the risks are *de minimis*. See the discussion in the section on ‘The politics of regulating chemicals in the US’. In the context of genetically modified foods, the then Food and Drug Administration (FDA) Commissioner David Kessler

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- stated that those foods were 'substantially equivalent' to foods produced by traditional production, thus glossing over small but possibly important differences vis-à-vis food safety. See Kessler, D. (1984) 'Food safety: Revising the statute', *Science*, vol 223, pp1034–1040.
- 11 There is the increasing tendency of the EU to balance 'conflicting interests' rather than costs and benefits. See Chapter 2 in this volume. This turns out to be a major feature of trade-off analysis rather than cost-benefit analysis, as discussed in the section on 'A capsule history of US chemical regulation and the use of the precautionary principle in US law'.
 - 12 Ashford, N. A. (2005) 'Implementing the precautionary principle: Incorporating science, technology, fairness and accountability in environmental, health and safety decisions', *International Journal of Risk Assessment and Management*, vol 5, no 2/3/4, pp112–124. Based on an article written by Ashford, N. A. (2004) 'Incorporating science, technology, fairness, and accountability in environmental, health, and safety decisions', *International Journal of Occupational Medicine and Environmental Health*, vol 17, no 1, pp59–67, and reprinted in *Human and Ecological Risk Assessment*, vol 11, no 1, pp85–96.
 - 13 For an extensive discussion of these two formulations, see Chapter 2 in this volume. See also de Sadeleer, N. (2002) *Environmental Principles: From Political Slogans to Legal Rules*, Oxford University Press, Oxford.
 - 14 See Chapter 2 in this volume for an in-depth discussion.
 - 15 See Chapter 2 in this volume for an in-depth discussion.
 - 16 de Sadeleer, N. (2000) *Two Approaches of Precaution: A Comparative Review of EU and US Theory and Practice of the Precautionary Principle*, Centre d'Étude du Droit de l'Environnement, Brussels. See also de Sadeleer, N. (2002) *Environmental Principles: From Political Slogans to Legal Rules*, Oxford University Press, Oxford, p139.
 - 17 Applegate, J. S. (2000) 'The precautionary preference: An American perspective on the precautionary principle', *Human and Ecological Risk Assessment*, vol 6, no 3, pp413–443.
 - 18 *Chevron, USA*, v *NRDC*, 467 US 837 (1984).
 - 19 Attempts to distinguish 'approaches' from 'principles' by arguing that the approaches are flexible, whereas principles are not, fails a logical test. Principles in the law are not without their limits, and they are sometimes in direct conflict. For example, the freedom of speech can be said to be a fundamental principle of US law, but it is not absolute and may be compromised in favour of public safety: 'No one has the right to yell fire in a crowded theatre.'
 - 20 See Hornstein, D. (1992) 'Reclaiming environmental law: A normative critique of comparative risk analysis', *Columbia Law Review*, vol 92, pp562–633.
 - 21 See Chapter 2 in this volume; See also several papers by Majone, G. (2001) *The Precautionary Principle and Regulatory Impact Analysis*, Manuscript, described as an expanded version of a paper submitted at the International Seminar on Regulatory Impact Analysis organized by Progetto AIR, Rome, 15 June 2001; Majone, G. (2002) 'What price safety? The precautionary principle and its policy implications', *Journal of Common Market Studies*, vol 40, pp89–106; and Majone, G. and Everson, M. (2001) 'Institutional reform: Independent agencies, oversight, coordination and procedural control', in De Schutter, O., Lebessis, N. and Paterson, J. (eds) *Governance in the European Union*, Office for the Official Publications of the European Communities, Luxembourg, pp129–168.
 - 22 In Chapter 2 in this volume, de Sadeleer emphasizes this point in observing that the precautionary principle applies to both risk assessment and risk management decisions and is not the province of risk management alone.
 - 23 This section draws heavily on Ashford, N. and Caldart, C. (2007) 'Administrative law', in *Environmental Law, Policy and Economics: Reclaiming the Environmental Agenda*, MIT Press, Cambridge, MIT Press, Chapter 5.
 - 24 See Vogel, D. (2003) 'The hare and the tortoise revisited: The new politics of consumer and environmental regulation in Europe', *British Journal of Political Science*, vol 33, pp557–580.

- 25 2 U.S.C. §§551–559, 701–706.
- 26 See 2 U.S.C. §1532.
- 27 Public Law 104–121, 26 March 1996.
- 28 5 U.S.C. §§601–612.
- 29 See 5 U.S.C. §603(c).
- 30 See 5 U.S.C. §603(a)(5).
- 31 See 2 U.S.C. §1535(a).
- 32 See 2 U.S.C. §1535(b).
- 33 See 42 U.S.C. §300g–1(b)(3)(A).
- 34 See Section 515 of the Treasury, Postal Service and General Government Appropriations Act for Fiscal Year 2001, enacted on 21 December 2000 as part of an omnibus spending bill. See Consolidated Appropriations FY 2001 of 2000, Pub. L. No 106–554, 114 Stat. 2763A–153 to 2763A–154.
- 35 See, generally, Revkin, A. L. (2002) ‘Law revises standards for scientific study: Agencies face challenges on health and environment research’, *The New York Times*, 21 March 2002, pA24.
- 36 See www.whitehouse.gov/omb/inforeg/.
- 37 See www.nap.edu/catalog/11534.html?send.
- 38 See www.pubs.acs.org/cen/news/83/i14/8314guidelines.html.
- 39 Executive Order 12866, 58 FR 51735 (30 September 1993).
- 40 See Executive Order 12866, Sections 3(f) and 6(a)(3)(B).
- 41 See Executive Order 12866, Section 6(b).
- 42 See Executive Order 12866, Section 1(b)(6).
- 43 See *American Textile Manufacturers Institute v Donovan*, 452 U.S. 490 (1981).
- 44 44 U.S.C. §3501–3520.
- 45 5 U.S.C. §§801–808.
- 46 See 5 U.S.C. §§801(a)(3) and 801(c).
- 47 See 5 U.S.C. §802.
- 48 See Steinbrook, R. (2003) ‘Science, politics and federal advisory committees’, *New England Journal of Medicine*, vol 350, no 14, pp1454–1460.
- 49 The effect is seen in the Supreme Court benzene decision, discussed in the following section on ‘Congressional legislation’, where more or less out of thin air, the court fashioned a ‘significant risk’ requirement for application of the OSHAct in clear contravention of the congressional mandate to the secretary of labour to set standards ‘which more adequately [ensures], to the extent feasible, on the basis of the best available evidence, that *no employee* suffer material impairment of health or functional capacity’ (emphasis added), 29 U.S.C. §655(b)(5). But also see the discussion of the vinyl chloride decision of Judge Robert Bork, in the section on ‘Additional executive branch influence through the Office of Management and Budget’, who argued that the congressional mandate in Section 112 of the 1970 Clean Air Act to protect public health ‘with an ample margin of safety’ did not require the EPA to establish a level that was ‘risk free’. Both a ‘significant risk’ (unacceptable risk) requirement and exclusion of ‘*de minimis* risks’ (acceptable risks) from protection permitted and encouraged regulatory agencies, under conservative reviewing courts, to provide modest levels of protection under their statutes.
- 50 See Ashford, N. and Caldart, C. (1996) *Technology, Law and the Working Environment*, second edition, Island Press, Washington, DC.
- 51 29 U.S.C. §651–683.
- 52 29 U.S.C. §655(b)(5).
- 53 29 U.S.C §660.
- 54 499 F2d 467 (DC Cir. 1974).
- 55 509 F2d 1301 (2nd Cir 1975).

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- 56 Ashford, N. A., Ryan, W. C. and Caldart, C. C. (1983) 'Law and science policy in federal regulation of formaldehyde', *Science*, vol 222, pp894–900, and Ashford, N. A, Ryan, W. C., and Caldart, C. C. (1983) 'A hard look at federal regulation of formaldehyde: A departure from reasoned decision-making', *Harvard Environmental Law Review*, vol 7, pp297–370. See also Rest, K. and Ashford, N. A. (1988) 'Regulation and technology options: The case of occupational exposure to formaldehyde', *Harvard Journal of Law and Technology*, vol 1, pp63–96.
- 57 448 U.S. 607 (1980).
- 58 Temporary emergency standards, which allow the OSHA to put into play immediate restrictions lasting six months without engaging in the long procedural process of promulgating permanent standards, might be compared to the 'safeguard principle' in EC environmental law, whereby EU member states reserve the right to address emergency situations without recourse to EC restrictions. Temporary emergency standards also implicitly incorporate the concept of proportionality through the requirement that these standards are 'necessary'. See Chapter 2 in this volume.
- 59 29 U.S.C. §662.
- 60 29 U.S.C. §654.
- 61 42 U.S.C. §7401–7671.
- 62 See Ashford, N. and Caldart, C. (2007) 'Limiting exposure to outdoor air contaminants: The Clean Air Act', in *Environmental Law, Policy, and Economics: Reclaiming the Environmental Agenda*, MIT Press, Cambridge, Chapter 7.
- 63 42 U.S.C. §7409.
- 64 42 U.S.C. §7412, otherwise known as Section 112 of the CAA.
- 65 42 U.S.C. §7411. A current controversy involves the EPA's relaxation of new source requirements for installing new pollution control equipment where there have been updates to coal-fired power plants. An additional concern is that the EPA now proposes to replace the mercury hazardous substance emission standard under Section 112 and to establish a cap and trade provision allowing mercury emissions from power plants (and other sources) be traded, thus creating 'hot spots'.
- 66 647 F.2d 1130 (DC Cir. 1980).
- 67 §7412(b)(1)(B).
- 68 824 F.2d 1146 (DC Cir. 1987).
- 69 §7412(d)(3).
- 70 §7412(d)(3).
- 71 §7412(d)(4).
- 72 §7412(f)(2).
- 73 531 U.S. 457 (2001).
- 74 On 18 February 2004, over 60 leading scientists – Nobel laureates, leading medical experts, former federal agency directors, and university chairs and presidents – following up on an initiative organized by the Union of Concerned Scientists (UCS), signed a statement voicing their concern over the misuse of science by the Bush administration. See the UCS website: www.ucsusa.org/scientific_integrity/.
- 75 15 U.S.C. §2601–2629.
- 76 15 U.S.C. §2605a.
- 77 15 U.S.C. §2605c.
- 78 15 U.S.C. §2603.
- 79 15 U.S.C. §2603f. As with OSHA reluctance to take action on formaldehyde, the EPA dragged its feet on formaldehyde, refusing to 'either act or explain' as required by this section of the TSCA. For a history of formaldehyde regulation, see Rest, K. and Ashford, N. A. (1988) 'Regulation and technology options: The case of occupational exposure to formaldehyde', *Harvard Journal of Law and Technology*, vol 1, pp63–96; and Ashford, N. and Caldart, C. (1996)

- 'The Toxics Substances Control Act', in *Technology, Law and the Working Environment*, revised edition, Island Press, Washington, DC, Chapter 4.
- 80 15 U.S.C. §2618.
- 81 15 U.S.C. §2605d.
- 82 15 U.S.C. §2606.
- 83 15 U.S.C. §2607.
- 84 947 F.2d 1201 (fifth Cir.1991).
- 85 Note the contrast with the result reached in the WTO panel's rejection of Canada's argument that France was obligated to assess likely substitutes for asbestos before it should be permitted to ban Canadian asbestos imports under Section XX of the General Agreement on Tariffs and Trade (GATT). Articles 8.218 to 8.223, *European Communities – Measures Affecting Asbestos and Asbestos-Containing Products*, Report of the Panel, WT/DS135/R, 12 March 2001 (00–3353).
- 86 There is a danger that REACH could suffer the same fate, with the result that regulation (authorization and restrictions) is not often vigorously pursued. Note, as discussed earlier, that comparative assessment of risks and costs are not nearly as burdensome as conducting separate risk and cost assessments. Whether using comparative assessment could circumvent the hurdle that the EPA needs to overcome to satisfy the requirements laid out in *Corrosion Proof Fittings v EPA* (note 84, *supra*) needs to be explored. Because the issue of alternatives needs to be considered in formulating regulations under the TSCA, this may well be possible. In contrast, because risk assessment seems to drive the REACH process, and because the consideration of alternatives seems to come in later, whether the use of comparative analysis in the context of REACH can circumvent the need for extensive risk analyses is unclear. See Koch, L. and Ashford, N. A. (2006) *Journal of Cleaner Production*, vol 14, no 1, pp31–46.
- 87 Criticisms of traditional cost benefit, of course, are not new. See Mishan, E. J. (1981) *Introduction to Normative Economics*, Oxford University Press, New York, and Fischhoff, B. (1977) 'Cost-benefit analysis and the art of motorcycle maintenance', *Policy Sciences*, vol 8, pp177–202.
- 88 See Chapter 2 in this volume.
- 89 Ashford, N. A. (1981) 'Alternatives to cost-benefit analysis in regulatory decisions', *Annals of the New York Academy of Sciences*, vol 363, pp129–137. See also Ashford, N. A. and Caldart, Charles C. (1996) 'Economic issues in occupational health and safety', in *Technology, Law and the Working Environment*, revised edition, Island Press, Washington, DC, Chapter 5.
- 90 Ashford, N. A. (1998) 'The importance of taking technological innovation into account in estimating the costs and benefits of worker health and safety regulation', in *Proceedings of the European Conference on Costs and Benefits of Occupational Health and Safety*, The Hague, Holland, 28–30 May 1997, pp69–78. See also O'Brien, M. (2000) *Making Better Environmental Decisions*, MIT Press, Cambridge.
- 91 Ashford, N. A. (2002) 'An innovation-based strategy for a sustainable environment', in Hemmelskamp, J., Rennings, K. and Leone, F. (eds) *Innovation-Oriented Environmental Regulation: Theoretical Approach and Empirical Analysis*, ZEW Economic Studies, Springer Verlag, Heidelberg and New York, pp67–107 (Proceedings of the International Conference of the European Commission Joint Research Centre, Potsdam, Germany, 27–29 May 1999).
- 92 This has direct relevance to the concerns for 'proportionality' in EU law. Assessing the 'necessity' of restrictive measures should ideally take into account not only the *regulatory* alternatives, but also the likely technological alternatives that could arise in the face of stringent regulatory options. Technology options analysis assists in the latter evaluation. Failure to fully investigate or plan for the stimulation of new technological solutions gives rise to 'technology' errors as important as the 'scientific' errors associated with inadequate, incorrect or incomplete risk assessments. See especially the discussion in the following section.

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- 93 Ashford, N. A. (2002) 'Government and innovation in Europe And North America', in Sonnenfeld, D. and Mol, A. (eds) *American Behavioral Scientist: Special Issue on Ecological Modernization*, vol 45, no 9, pp1417–1434.
- 94 Ashford, N. A. (1988) 'Science and values in the regulatory process', in *Statistical Science*, vol 3, no 3, pp377–383.
- 95 Schwartz, S. and Carpenter K. (1999) 'The right answer for the wrong question: Consequences of type III error for public health research', *American Journal of Public Health*, vol 89, pp1175–1180.
- 96 One glaring error is committed when, under pressure from cost constraints, standards are not as stringent as health or environmental concerns might justify. Lax standards may not stimulate serious changes in technology, while stringent standards would. Stringent standards may actually be more economically beneficial for the society than lax standards, although there may be winners and losers within the industrial or product sectors. See the discussion of the Porter hypothesis and stimulating technological change through regulation in Ashford, N. A. (2002) 'Government and innovation in Europe And North America', in Sonnenfeld, D. and Mol, A. (eds) *American Behavioral Scientist: Special Issue on Ecological Modernization*, vol 45, no 9, pp1417–1434.
- 97 Aarhus Protocol on Persistent Organic Pollutants to LRTAP Convention, 1998.
- 98 Ashford, N. A. (2005) 'Implementing the precautionary principle: Incorporating science, technology, fairness and accountability in environmental, health and safety decisions', *International Journal of Risk Assessment and Management*, vol 5, no 2/3/4, pp112–124. Based on an article found in Ashford (2004), note 12, *supra*.
- 99 Indeed, the EU REACH Directive has been proposed to address these uncertainties, which could be resolved, in principle, if enough resources were devoted to researching toxicity. But see Koch, L. and Ashford, N. A. (2006) *Journal of Cleaner Production*, vol 14, no 1, pp31–46, for an argument that efforts to find safer technologies could be more cost effective and safer than reducing toxicological uncertainty.
- 100 See Chapter 2 in this volume.
- 101 Josephson, J. R. and Josephson, S. G. (1996) *Abductive Inference*, Cambridge University Press, Cambridge, UK.