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ENVIRONMENTAL REGULATORY DECISIONMAKING UNDER UNCERTAINTY

Richard B. Stewart, **New York University**

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"[T]he public generally benefits from individual activity." Holmes, The Common Law

"When in doubt, don't pump it out!" Greenpeace

This essay examines the principles applicable to governmental decisions to regulate activities that may result in environmental harm when there is uncertainty regarding the probability and extent of any such harm. It analyzes and evaluates the precautionary principle ("PP"), which, in its weakest version, asserts that uncertainty regarding the adverse environmental effects of an activity should not automatically bar adoption of measures to prohibit or otherwise regulate the activity, and, in strong versions, further asserts that uncertainty provides an affirmative justification for regulating an activity or regulating it more stringently than in the absence of uncertainty. Strong versions of PP hold that regulators should adopt "worst case" presumptions regarding the harms of activities posing an uncertain potential for significant harm; should prohibit such activities or require them to adopt best available technology measures; that regulatory costs should be disregarded or downplayed in such decisions; and that the proponent of such activities should bear the burden of establishing their safety in order to avoid such regulatory controls. The essay also considers the relevance for regulatory decisions of uncertainties regarding the costs of regulating an activity as well as uncertainties regarding harms. It also considers the implications of the circumstance that regulatory decisions may be made sequentially over time and benefit from additional information developed in the interim between earlier and later decisions. The essay concludes that, while preventive regulation of uncertain risks is often appropriate and should incorporate precautionary elements where warranted, the strong versions of PP do not provide a conceptually sound or socially desirable prescription for regulation.

I. INTRODUCTION: ENVIRONMENTAL DECISION MAKING UNDER UNCERTAINTY AND THE PRECAUTIONARY PRINCIPLE

Examples of regulatory decisions involving uncertain risks include the following. In each case, consider whether a regulator should permit the potentially harmful activity to proceed or continue, or, alternatively, to prohibit or otherwise regulate it, and the implications of sequential regulatory decisionmaking and the opportunity to develop additional information to reduce uncertainties regarding the risks of harms posed by an activity and/or the costs of regulation.

Whether to prohibit the sale of meat products from cattle that have received bovine growth hormone injections.

Whether to prohibit the construction of an astronomic observatory atop Mt. Graham, in New Mexico, the only known habitat of the Mt. Graham Red Squirrel, a subspecies of the western red squirrel located only on Mt. Graham; other subspecies of the red squirrel are abundant in the Western United States.

Whether to prohibit field releases of crop plants that have been genetically modified through rDNA techniques.

Whether to adopt a National Ambient Air Quality Standard (NAAQS) to limit short-term (10-minute) exposures to elevated levels of sulfur dioxide (SO2). Several laboratory studies indicate that asthmatics exposed to higher short-term SO2 exposures experience airway resistance that makes breathing more difficult.

Whether to prohibit introduction of sucralose, an artificial beverage sweetener that has been touted as safer than saccharin or aspartame, the artificial sweeteners currently is use.

Whether to prohibit the dumping of any wastes of whatever sort at sea.

Whether to develop defenses against collisions with the earth by asteroids and other near earth objects.

Whether to eliminate use of chlorine to treat drinking water.

Whether to prohibit use of glyphosate ("Roundup®"), a broad-spectrum non-selective herbicide that is harmless to animals.

Whether to prohibit or tightly regulate conversion of rainforest to agricultural or other uses.

Whether to initiate immediately strict limits on greenhouse gas emissions in order to limit the potential adverse effects of climate changes attributable to such emissions.

In evaluating these and other environmental regulatory decisionmaking issues, available knowledge of the environmental harm that may be caused by the activity in question can be conceptually classified in three ideal type categories:

Type 1. The harm that the activity will cause is known and determinate. If, for example, the Mt.

Graham observatory is built, the Mt. Graham red squirrel population will be wiped out within 20 years.

Type 2. The harm is probabilistic in character but its probability distribution is well-characterized. For example, if the observatory is built, it is known that there is a 40% probability that the squirrel population will be wiped out within 20 years and a 60% probability that it will survive another 1000 years, in which it will become extinct from natural "background" causes. In this situation we deal with a risk of harm, but the risk (comprising both the probability of an adverse effect occurring and the magnitude of the adverse effect if it occurs) is more or less well-known.

Type 3. There is a risk of harm that is uncertain. Thus the probability of harm occurring, and/or the magnitude of the harm if it occurs, is not determinate and is subject to substantial uncertainty. To take the Mt. Graham example, it is may be uncertain, based on current knowledge, whether any adverse effect on the squirrels will occur. If any adverse effect does occur, its magnitude is uncertain. Thus, it may be uncertain what percentage of the population may be lost, whether any given level of loss will result in extinction of the subspecies, and when possible losses and extinction may occur.[1] The difference between Type 2 cases and Type 3 cases is obviously one of degree, but the distinction between the two ideal types is very useful for purposes of analysis.

Very many environmental problems are Type 3 cases, characterized by uncertainty regarding risks of harm, although the nature and degree of uncertainty varies widely from case to case. These uncertainties have many potential causes, including lack of data, limitations in scientific understanding of causal relationships, medical and ecosystem complexity, and "trans scientific" gaps in the capacities of science.[2] There may also be substantial uncertainties regarding the costs of prohibiting or otherwise regulating the activity in question. In many situations, such uncertainties can be reduced by the development of additional information and knowledge as discussed further below.

The common law traditionally awards damages only *ex post* for harm that has occurred and has been shown to have been caused by another's activity. It grants injunctive relief *ex ante* only if an activity poses an imminent and substantial likelihood of serious irreparable harm. Many environmental risks of types 2 and 3 would not qualify for an award of damages or prophylactic relief under this standard. In theory, *ex post* liability for harm caused could provide the requisite incentives for actors to manage their activities so as to prevent excessive risks of harm appropriately. In practice, however, these incentives have for a variety of reasons proven inadequate to prevent excessive environmental

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[1] There may also be cases where the type of harm, if any, that may occur is not known.

[2] For discussion of the various sources of uncertainty regarding environmental risks, see Tim O'Riordan, James Cameron, & Andrew Jordan, *The Evolution of the Precautionary Principle*, *in* Reinterpreting the Precautionary Principle (Tim O'Riordan James Cameron, & Andrew Jordan, eds) 1, 9, 23-24 (2001) (finding sources of uncertainty in the complexity and interdependency of natural phenomenon and the chaotic and discontinuous nature of many natural processes) [hereinafter Reinterpreting the Precautionary Principle].

harm from occurring.[3] Accordingly, administrative programs of preventive *ex ante* regulation have been widely adopted in the United States and other countries to regulate activities that pose substantial risks of harm, even in cases where it is not certain that harm will actually occur. International agreements, such as the Vienna Convention for the Protection of the Ozone Layer and the Framework Convention on Climate Change have also been adopted to address risks that, at the time of their adoption, were highly uncertain.

Preventive regulations have been adopted not only in cases where activities have been shown to cause harm, but also in cases involving risks of harm, including cases of substantial uncertainty in the risk of harm.[4] Quantitative risk analysis and cost-benefits analysis are increasingly being used in connection with the preventive approach to regulation.[5] Under most regulatory programs, regulators have the burden of establishing a significant risk of harm before imposing regulatory controls,[6] but under some programs, such as U.S. FDA new drug and food additive approvals and EPA registration of new pesticides, the applicant bears the burden of showing product safety.

In recent years, environmental advocates and many environmental law scholars, particularly in the field of international environmental law, have argued that environmental regulatory decisions and policies should follow a precautionary principle ("PP").[7] The focus of PP is on appropriate regulatory policy in Type 3 cases where the risks of harm posed by an activity are characterized by substantial uncertainty. PP advocates argue for a precautionary approach to regulation in the face of such uncertainty. They often critique prevailing preventive approaches to regulation on the grounds that they place the burden on regulators to show that an activity will cause serious harm or poses a high probability of serious harm before regulatory controls may be adopted, and that, given the lack of

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[3] These reasons include the circumstance that private actors may not have sufficient assets to pay for harms that they cause if the harms are large; the circumstance that private decisionmakers may have a higher rate of time discount or be less risk averse than is judged appropriate from a pubic policy perspective; the difficulties presented in resolving the issue of causal responsibility when a given harm may have a number of different causes; problems caused when harm is the product of activities by many actors; the circumstance that some private decisionmakers, including individuals and small business, may not have the knowledge or capacity to adjust their behavior so as to appropriately reduce risks of harm; and general public distrust of the reliability of *ex-post* incentive systems to prevent risks of serious harm.

[4] *See, e.g.*, Ethyl Corp. v. EPA, 541 F.2d 1 (D.C. Cir. 1976), *cert. denied*, 426 U.S. 941 (1976).

[5] *See* Richard Pildes & Cass Sunstein, *Reinventing The Regulatory State*, 62 U. Chi. L. Rev. 1 (1995).

[6] *See, e.g.*, Industrial Union Department, AFL-CIO v. American Petroleum Institute 448 U.S. 607 (1980).

[7] *See, e.g.*, Wingspread Statement on the Precautionary Principle, Jan. 25, 1998, *available at* http://www.gdrc.org/u-gov/precaution-3.html; Reinterpreting the Precautionary Principle, *supra* note 2; Perspectives on the Precautionary Principle (Ronnie Harding & Elizabeth Fisher eds., 1999); A. Charlotte De Fontaubert et al., *Biodiversity in the Seas: Implementing the Convention on Biological Diversity in Marine and Coastal Habitats*, 10 Geo. Int'l Envtl. L. Rev. (1998). The PP derives its intellectual heritage for the principle of Vorsorgenprinzip, adopted in Germany's domestic environmental law. *See* O'Riordan, Cameron, & Jordan, *supra* note 2 at 11.

scientific capacities to predict which activities will cause serious or irreversible harms, this approach results in seriously inadequate environmental protection.[8]

Various versions of PP, mostly weak ones, have been incorporated or invoked in a number of recent international environmental declarations and conventions, including, for example, the Framework Convention on Climate Change[9]; and in the EU Maastricht treaty.[10] These documents and the writings of PP advocates and of academics provide widely varying formulations of PP. It has been claimed that PP is already or is becoming established as a binding principle of customary international law.[11] PP critics have contended that the heterogeneity of PP formulations, many of which are quite vague and indeterminate, demonstrates that that there is no single or determinate PP.[12] Thus, they have concluded that the precautionary principle is a "composite of several value-laden notions and loose, qualitative descriptions" and that accordingly its "operational usefulness . . . is doubtful."[13] They also deny that PP

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[8] *See, e.g.*, Henrique Freire de Oliveira Souza, *Genetically Modified Plants: A Need for International Regulation*, 6 Ann. Surv. Int'l & Comp. L. 129, 173 (2000); Karen L. Smith, *Highly Migratory Fish Species: Can International and Domestic Law Save the North Atlantic Swordfish?*, 21 W. New Eng. L. Rev. 5, 35-39 (1999). *See also* Francois Ewald, *The Return of the Crafty Genius: An Outline of a Philosophy of Precaution*, 6 Conn. Ins. L.J. 47, 60-61 (1999) ("the precautionary principle does not target all risk situations, but only those marked by two principal features: a context of scientific uncertainty on one side, the possibility of serious and irreversible damage on the other.").

Some PP proponents contrast between a risk-based approach to regulation in the U.S. based on a "rationalist" weighing of probabilities and the costs and benefits of various alternatives, and a "political" model in Europe under which uncertainty is a normative principle that triggers precaution. *See* O'Riordan, Cameron & Jordan, *supra* note 2 at 27. To the extent that this distinction exists, however, it has not lead to adoption of more stringent regulation of uncertain environmental health and safety risks in Europe relative to the U.S. *See* Jonathan B. Wiener & Michael D. Rogers, Comparing Precaution in the United States and Europe, __ J. Pol'y Analysis & Mgmt. __ (forthcoming).

[9] *See, e.g.*, United Nations Conference on Environment and Development: Framework Convention on Climate Change, May 9, 1992, *in* Report of the Intergovernmental Negotiating Committee for a Framework Convention on Climate Change on the Work of the Second Part of Its Fifth Session, INC/FCCC, 5th Sess., 2d Part, at Annex I, U.N. Doc. A/AC.237/18 (Part II)/Add.1, *reprinted in* 31 I.L.M. 851. Any of the relevant texts are collected in James Cameron, *The Precautionary Principle in International Law*, *in* Reinterpreting the Precautionary Principle, *supra* note 2.

[10] Treaty on European Union and Final Act, Feb. 7, 1992, *reprinted in* 31 I.L.M. 247 (entered into force Nov. 1, 1993).

[11] *See generally* Owen McIntyre & Thomas Mosedale, *The Precautionary Principle as a Norm of Customary International Law*, 9 J. Envtl. L. 221. *See also* Communication on the Precautionary Principle, Communication from the Commission of the European Communities, COM (2000) 1 final (Feb. 2, 2000); Harald Hohmann, Precautionary Legal Duties and Principles of Modern International Environmental Law (1994); Russell Unger, Note, *Brandishing the Precautionary Principle Through the Alien Tort Claims Act*, 9 N.Y.U. Envtl. L.J. 638, 673-75 (2001).

[12] *See, e.g.*, David Freestone, *International Fisheries Law Since Rio: The Continued Rise of the Precautionary Principle, in* International Law and Sustainable Development: Past Achievements and Future Challenges 135-36 (Alan Boyle & David Freestone eds., 1999); Steve Charnovitz, *The Supervision of Health and Biosafety Regulation by World Trade Rules*, 13 Tul. Envtl. L.J. 271, 291-95 (2000); James E. Hickey, Jr. & Vern R. Walker, *Refining the Precautionary Principle in International Environmental Law*, 14 Va. Envtl. L.J. 423, 431-32 (1995).

[13] Stephen R. Dovers & John W. Harndmer, *Ignorance, Sustainability, and the Precautionary Principle: Towards*

has been established as customary international law.[14]

There is merit in criticisms of PP as indeterminate and conceptually fuzzy. With a very few exceptions, there is a remarkable lack of analytic care or rigor regarding the substance of and justification for PP by those who advocate or favor its adoption. One can, however, identify four different PP conceptions that have emerged in legal instruments, international and national governmental declarations, advocacy statements, and the academic literature that can serve as a useful basis for analysis and evaluation. These four versions of PP are as follows:

PP1. Scientific uncertainty should not automatically preclude regulation of activities that pose a potential risk of significant harm ("Non-Preclusion PP").

PP2. Regulatory controls should incorporate a margin of safety; activities should be limited below the level at which no adverse effect has been observed or predicted ("Margin of Safety PP").

PP3. Activities that present an uncertain potential for significant harm should be subject to best technology available requirements to minimize the risk of harm unless the proponent of the activity shows that they present no appreciable risk of harm ("BAT PP").[15]

PP4. Activities that present an uncertain potential for significant harm should be prohibited unless the proponent of the activity shows that it presents no appreciable risk of harm ("Prohibitory PP").

What unites these different formulations is a focus on uncertainty regarding risks as the key

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and Analytic Framework, *in* Perspectives on the Precautionary Principle, *supra* note 7 at 173.

[14] *See, e.g.*, Catherine Tinker, *State Responsibility and the Precautionary Principle*, *in* The Precautionary Principle and International Law: The Challenge of Implementation 3, 5 (David Freestone & Ellen Hey eds., 1996) ("it is difficult to conclude that the precautionary principle is customary international law at this time.").

[15] A modification of this version calls for the Best Available Technology Not Entailing Excessive Costs ("BATNEEC"). *See, e.g.*, Agreements on the Protection of the Rivers Scheldt and Meuse, Apr. 26, 1994, *reprinted in* 34 ILM 851 (1995) ("the Contracting Parties shall strive to use the best available technology…under economically acceptable conditions."). It is unclear whether this involves a cost-benefit analysis of the reduction achieved through a given technology, or simply rules out technologies that are judged "too costly." Other versions of PP also invoke vague cost considerations. *See, e.g.*, United Nations Rio Declaration on Environment and Development, June 13, 1992, principle 15, *reprinted in* 31 I.L.M. 874, 879 ("…lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation."). "Cost-effective measures" is a concept that makes little logical sense in this situation, since presumably the decision to regulate cannot be based upon a cost-benefit analysis. All this seems to require is that regulators not choose one measure that costs significantly more than another but achieves the same result. Most likely, it is intended to mitigate undue rigor in regulatory requirements and add some degree of flexibility to the application of PP. For additional commentary on cost-effective precautionary measures, see Gregory D. Fullem, Comment, *The Precautionary Principle: Environmental Protection in the Face of Scientific Uncertainty*, 31 Willamette L. Rev. 495, 505-08 (1995), Daniel Bodansky, *The United Nations Framework Convention on Climate Change: A Commentary*, 18 Yale J. Int'l L. 451, 456 (1993) and Donald M. Goldberg, *Negotiating the Framework Convention on Climate Change*, 4 Touro J. Transnat'l L. 149, 162 (1993).

factor in regulatory decisions. Some discussions of the PP blur the distinction between known (type 2 above) and uncertain risks (category 3), but the most careful commentators make clear that the precautionary principle is addressed to uncertain risks (type 3) as such.[16]

PP1 and PP2 are weak versions of precautionary approaches. Unlike the strong versions, PP3 and PP4, they do not mandate regulatory action and do not make uncertainty regarding risks an affirmative justification for such regulation.

Thus, PP1 is negative in character; it states that uncertainty should not preclude regulation but does not provide affirmative guidance as to when regulatory controls should be adopted or what form they should take. This is the approach that is most widely invoked in international treaties and declarations. While the exact wording may vary, this principle of non-preclusion always sets up a threshold, e.g. an uncertain risk of serious damage, and then makes the negative prescription that once that threshold has been triggered, regulators cannot rely on this fact alone to deny regulation. For example, the Bergen Ministerial Declaration states "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."[17] The Cartagena Protocol goes further by making clear that uncertainty can not, in and of itself, justify the decision not to regulate, nor, presumably the alternative conclusion to impose regulation:

> Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism shall not prevent [a] Party from taking a decision, as appropriate. Lack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk, or an acceptable risk.[18]

This principle of non-preclusion simply rejects the common law position that harm must be shown to have occurred or be imminent before legal liabilities or controls may be imposed. It also rejects the position, often asserted by industry, that significant uncertainty about risks should preclude imposition of preventive regulatory controls. Of all the formulations of the PP, this approach is the most often invoked and is most likely to be recognized as a part of customary international law; A general preventive

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[16] *See, e.g.*, Communication on the Precautionary Principle, *supra* note 11 ("[PP]is part of risk management, when scientific uncertainty precludes a full assessment of the risk"); Ewald, *supra* note 8 at 63 (1999) ("Precautionary logic does not cover risk (which is covered by prevention); it applies to what is uncertain - that is, to what one can apprehend without being able to assess.").

[17] Bergen Ministerial Declaration on Sustainable Development in the ECE Region, G.A. Prepatory Committee for the United Nations Conference on Environment and Development, 44th Sess., U.N. Doc., A/CONF.151/PC/10 (1990).

[18] Cartagena Protocol on Biosafety, Jan. 29, 2000, art. 10(6) & Annex III, *reprinted in* 39 I.L.M. 1027, 1045. *See also* Convention on the Protection and Use of Transboundary Watercourses and International Lakes, Mar. 17, 1992, art. 2(5), *reprinted in* 31 I.L.M. 1312, 1316; Communication on the Precautionary Principle, *supra* note 11; United Nations Framework Convention on Climate Change, *supra* note 9 at 854; United Nations Rio Declaration on Environment and Development, *supra* note 15 at 879.

approach to harm, even without full scientific certainty, is widely accepted.[19] Yet, PP1's very generality and lack of specific prescriptions may preclude it from being recognized as a binding norm.[20]

PP2 likewise fails to specify when or what form of regulation should be adopted, but instructs that, whenever regulation is adopted, it should incorporate a margin of safety. Unlike PP1, PP2 is operative only after regulators have made the determination to, in fact, regulate. Once this decision is made, regulators must first determine the maximum "safe" level of an activity, and then only allow the activity at some degree lower than that level (the "margin of safety"). This is a common approach in U.S. environmental law. An example is the Sustainable Fisheries Act of 1996, in which the optimum allowable yield from a fishery "is prescribed on the basis of the maximum sustainable yield from the fishery, as reduced by" relevant factors including "ecological" factors.[21] PP2 is consistent with many commentators' views that PP requires that regulators allow "large margins for error" in risk assessments.[22] It represents one formulation of the PP premise that: "Given scientific ignorance, prudent pessimism should be favoured over hazardous optimism."[23] PP2 is not explicitly set forth in any international agreements and declarations, but its approach is implicit in international agreements that require or provide for the adoption of precautionary measures.[24]

The weak versions of the PP are fully compatible with and are often reflected in many well-established regulatory programs that have been adopted at the domestic level by many countries and by international agreement over the past 30 years. These programs often authorize prophylactic regulation of uncertain risks in appropriate circumstances justified in the absence of a showing that harm will actually occur. In many cases they explicitly require a margin of safety in setting regulatory standards.[25] Thus the weak versions of PP do not represent or justify any basic change in the preventive approach to regulation that has generally prevailed over the past 30 years. They accordingly provide no basis for arguing that existing preventive regulatory programs are not sufficiently "precautionary" and need to be fundamentally changed in order to reflect precautionary principles. There are, however, important

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[19] *See* Communication on the Precautionary Principle, *supra* note 11.

[20] *See* Unger, *supra* note 11 at 677.

[21] Sustainable Fisheries Act of 1996 § 106(b), 16 U.S.C. § 1802(28) (2001). *See also* Mark Geistfeld, *Reconciling Cost-Benefit Analysis with the Principle that Safety Matters More than Money*, 76 N.Y.U.L. Rev. 114 (2001); George M. Gray, & John D. Graham, *Regulating Pesticides, in* Risk vs. Risk: Tradeoffs in Protecting Health and the Environment 173 (John D. Graham & Jonathan B. Wiener eds., 1995).

[22] Fullem, *supra* note 15 at 501.

[23] Michael Jacobs, The Green Economy: Environment, Sustainable Development and the Politics of the Future 100 (1991).

[24] *See* UNCED Text on Protection of Oceans, U.N. GAOR, 4th Sess., UN Doc. A/CONF. 151/PC/100/Add. 21 (1991).

[25] *See, e.g.*, Clean Air Act § 109, 42 U.S.C. § 7409(b)(1) (2001).

differences between established programs of preventive regulation and the strong versions of PP. Weak precautionary programs generally do not make the existence of uncertainty regarding risks as such a mandatory or distinct basis for imposing regulatory controls. PP3 and PP4, on the other hand, require regulators to regulate or regulate more stringently activities that pose risks that are more uncertain relative to risks that are less uncertain, and thus represent a significant change in regulatory concept and result.

Under PP3, when regulators determine that there is a serious but uncertain risk, they must impose BAT measures. For example, the Second International Conference on the Protection of the North Sea, calls for parties to:

> [R]educ[e] polluting emissions of substances that are persistent, toxic and liable to bioaccumulate at source by the use of the best available technology and other appropriate measures. This applies especially when there is reason to assume that certain damage or harmful effects on the living resources of the sea are likely to be caused by such substances, even where there is no scientific evidence to prove a causal link between emissions and effects ("the principle of precautionary action").[26]

Such a prescription does not appear to allow regulators to decide what sort of regulation is required, including no regulation: if there is an uncertain risk of serious harm, BAT measures should be imposed. However, some flexibility may remain under PP3 since the intensity of BAT controls may vary depending on the magnitude of the potential risk in accordance with a principle of proportionality.[27]

PP4 imposes an even more inflexible set of prescriptions upon regulators. Under this formulation, if there is an uncertain but serious risk of harm, the activity in question should not be undertaken at all until it is proven to be safe by the proponent of the activity. Thus, the Final Declaration of the First European "Seas at Risk" Conference provides that:

> The "burden of proof" is shifted from the regulator to the person or persons responsible for the potentially harmful activity, who will now have to demonstrate that their actions are not/will not cause harm to the environment. If the "worst case scenario" for a certain activity is serious enough then even a small amount of doubt as to safety of that activity is sufficient to stop it taking place.[28]

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[26] Second International Conference on the Protection of the North Sea, Nov. 25, 1987, art. XVI(1), *reprinted in* 27 I.L.M. 835, 840. *See also* Agreements on the Protection of the Rivers Meuse and Scheldt, *supra* note 15 at 855; Bamako Convention on Hazardous Wastes Within Africa, Jan. 30, 1991, art. 4(3), *reprinted in* 30 I.L.M. 773, 781 ("The Parties shall cooperate with each other in taking the appropriate measures to implement the precautionary principle to pollution prevention through the application of clean production methods....").

[27] *See* discussion *supra* note 15 on BATNEEC.

[28] Final Declaration of the First European "Seas at Risk" Conference, Annex I, Copenhagen, 1994, *available at* the

While this version of the PP presumably allows regulators some latitude to determine how serious an uncertain risk must be to invite regulation, it leaves them clear but very rigid instructions on what that regulation must be once the relevant risk threshold is met.

The strong versions of PP, PP3 and PP4, are the focus of this essay. Accordingly, unqualified references to PP in the discussion which follows should be understood as referring to the strong versions of PP. Unlike the weak versions of PP and the preventive approach to regulation generally, they make the existence of uncertain risks of significant harm both a sufficient and mandatory basis for imposing regulatory controls. We may term this the "uncertainty-based potential for harm" prescription for regulation. Different PP formulations incorporating this precept vary in the criteria for determining the potential for harm threshold that triggers the requirement of regulation, including how great the probability of harm must be and its character and magnitude. Some formulations, for example, stress that the probability of harm must be substantial and the harm that may eventuate must be "serious and irreversible."[29] Other formulations enunciate less demanding criteria.[30] In many strong PP formulations, once the applicable risk threshold is met, regulation is mandatory; regulatory compliance costs, including the social costs involved in forgoing the benefits of activities subject to regulatory prohibition or restriction, are not included as a factor to considered in the regulatory decision.[31] Some formulations allow for consideration of costs, but relegate them to a distinctly secondary role, while others introduce the principle of proportionality, tailoring the extent and character of the regulatory response adopted to

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Common Wadden Sea Secretariat, Virchowstraße 1, D-26382 Wilhelmshaven, Germany. *See also* Wingspread Statement on the Precautionary Principle, *supra* note 7; World Charter for Nature, GA Res. 37/7, Annex, para. 24, UN GAOR, 37th Sess., Supp. No. 51, at 17, UN Doc. A/37/51 (1982), *reprinted in* 22 I.L.M. 455, 455.

[29] *See, e.g.*, World Charter for Nature, *supra* note 28 at 455 ("Activities which are likely to cause irreversible damage to nature shall be avoided.").

[30] *See, e.g.*, Convention for the Protection of the Marine Environment of the North-East Atlantic, Sept. 22, 1992, art. 2, *reprinted in* 32 I.L.M. 1069, 1076 ("preventive measures are to be taken when there are reasonable grounds for concern that substances or energy introduced, directly or indirectly, into the marine environment may…harm living resources and marine ecosystems."); Hans-Joachim Priess & Christian Pitschas, *Protection of Public Health and the Role of the Precautionary Principle Under WTO Law: A Trojan Horse Before Geneva's Walls?*, 24 Fordham Int'l L.J. 519, 523 (2000) ("…'there can be no question but that the requirements of the protection of public health must take precedence over economic considerations.'" (quoting Alpharma Inc. v. Council of the European Union, Case T-70/99 R, [1999] E.C.R. II-2027)). *C.f.* Prue Taylor, *Heads in the Sand as the Tide Rises: Environmental Ethics and the Law on Climate Change*, 19 UCLA J. Envtl. L. & Pol'y 247, 257 (2000) ("Economic criteria and the operation of the market are notoriously ill equipped to cater to long-term objectives, such as the interests of future generations."); Lothar Gundling, *The Status in International Law of the Principle of Precautionary Action*, 5 Int'l J. Estuarine & Coastal L. 23, 26 (1990) ("[PP] requires reduction and prevention of environmental impacts irrespective of the existence of risks…and it also requires action even if risks are not yet certain but only probable, or, even less, not excluded.").

[31] *See, e.g.*, Convention for the Protection of the Marine Environment of the North-East Atlantic, *supra* note 30 ("preventive measures are to be taken when there are reasonable grounds for concern"); Brad L. Bacon, *Enforcement Mechanisms in International Wildlife Agreements and the United States: Wading Through the Murk*, 12 Geo. Int'l Envtl. L. Rev. 331, 331 (1999) ("uncertainties about the ability of a fish stock to sustain a harvest level must be resolved in favor of the fish.").

the gravity of the risk in question.[32] Under PP3, for example, the costs of BAT controls might be taken into account in determining whether a given technology is "available." It might be concluded that very costly technology controls are not as a practical matter "available." Under PP4, in cases where potential risks are judged less serious or where the social benefits of the activity are high, prohibitory controls might be adopted for only a limited initial period subject to "sunset" or reconsideration, or field trials may be permitted.[33]

Strong versions of the PP also often hold that the burden of resolving uncertainty should be borne by the proponent of an activity rather than by regulators or opponents of the activity.[34] Accordingly, in order to avoid or lift regulatory prohibitions or BAT requirements, the proponent of an activity bears the burden of demonstrating that it does not present a potential for significant harm. Proponents of regulation, however, bear some initial threshold burden of production and persuasion. They must establish that an activity poses uncertain risks of harm, including a potential for significant harm. Once that threshold burden is satisfied, however, the burden shifts to the activity proponent to resolve the uncertainty and show that that it does not have a potential for significant harm.[35]

The normative core of the strong versions of PP, which distinguish PP-based regulation from preventive regulation generally, is the principle that uncertainty regarding risks is an affirmative justification for adopting regulatory controls or adopting more stringent controls than would be appropriate in the case of activities posing more determinate risks. In the face of uncertainties regarding risk, decisionmakers should err on the side of precaution and environmental protection and, in effect, make "worst case" presumptions about the probability and magnitude of harm that an activity poses; precisely how "worst case" is defined ("reasonable worst case," etc.) varies in different PP

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[32] *See* Communication on the Precautionary Principle, *supra* note 11 at 18; Reinterpreting the Precautionary Principle, *supra* note 2.

[33] *See* Communication on the Precautionary Principle, *supra* note 11; Veerle Heyvaert, Uncertainty and the Role of Law: Towards a Sustainable Legal Framework for Health and Environmental Protection (Aug. 2000) (unpublished manuscript, on file with the author).

[34] *See, e.g.*, Final Declaration of the First European "Seas at Risk" Conference, *supra* note 28; Wingspread Statement on the Precautionary Principle, *supra* note 7 ("In this context the proponent of an activity, rather than the public bears the burden of proof."); Lawrence Juda, International Law and Ocean Use Management 287 (1996) ("…the burden of proof moved from those who seek to protect the environment to those who maintain that some ocean use or activity is not harmful.").

[35] The burden-shifting component of the strong PPs presents a number of intriguing problems. For example, how can proponents of regulation meet the threshold requirement of showing a potential for significant harm when the risks posed by an activity are highly uncertain and it may not be known what type of harm, if any, it might cause? Once the regulator has made an initial showing that the threshold requirement is satisfied, can the proponent of an activity escape regulatory controls by rebutting the regulators' prima facie case, or must it in all cases affirmatively carry the burden of establishing the activity's safety? These important issues have yet to be seriously addressed in the PP literature.

formulations.[36] The justifications advanced by PP proponents for adopting its prescriptions center around limitations in our ability to predict which activities will cause serious, irreversible environmental harms.[37] The predictive capacity of science is limited. For example, science has often been unable to predict, in timely fashion to support effective preventive action, the occurrence of serious environmental harms, such as asbestosis, stratospheric ozone depletion, or the ecological harms caused by DDT. Thus, a regulatory policy that requires regulators to demonstrate that an activity causes harm, or even a significant risk of harm before imposing controls will result in the occurrence of serious environmental harms. Some of these harms, such as biodiversity loss or highly disruptive changes in natural systems resulting from rapid global warming may be irreversible and seriously harm future generations. Accordingly, decisionmakers should err on the side of precaution and environmental protection of the planet by adopting PP-based regulatory controls on activities involving uncertain risks that pose a potential for significant harm.

The PP literature provides little in the way of helpful guidance on what regulators must show in order to establish a potential for harm that triggers PP.[38] While some PP proponents appear to assume that nature is inherently vulnerable and precarious rather than resilient, such a general presumption is not sufficient to show that a given activity triggers PP. The bovine growth hormone dispute suggests that a showing that a chemical product similar to the product in question can cause harm may be sufficient.[39] The BtCorn-Monarch butterfly controversy suggests that a report of a single experimental study, albeit one quite unrepresentative of field conditions, is enough to trigger PP controls if it is sufficiently widely publicized.[40]

Under strong versions of PP, once the risk posed by an activity satisfies the threshold that triggers a worst case presumption, regulators must then follow a set of relatively stringent regulatory prescriptions, including imposing prohibitory or BAT requirements on the activity, shifting the burden to the activity proponent to show that the activity is "safe" in order to avoid or lift these regulatory requirements; and disregard or downplaying of regulatory costs in implementing regulatory requirements. Thus, PP can be analyzed as containing two basic components: First, a worst case presumption for uncertain risks that

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[36] *See, e.g.*, Cartagena Protocol on Biosafety, *supra* note 18 at 1045 ("Lack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk."). *Compare, e.g.*, Tinker, *supra* note 14 at 779 ("…the precautionary principle should mandate a policy of 'no action.'").

[37] *See, e.g.*, Layla Hughes, Note, *Limiting the Jurisdiction of Dispute Settlement Panels: The WTO Appellate Body Beef Hormone Decision*, 10 Geo. Int'l Envtl. L. Rev. 915, 933 (1998). ("…[we must] appreciate the inability of science to predict environmental and physiological interactions."); O'Riordan, Cameron, & Jordan, *supra* note 2.

[38] *See* John S. Applegate, *The Precautionary Preference: An American Perspective on the Precautionary Principle*, 6 Hum. & Ecological Risk Assessment 413 (2000).

[39] *See* Appellate Body Report, GATT Doc. WT/DS26/AB/R (Jan. 16, 1998).

[40] *See* Paul Raeburn, *Clamor Over Genetically Modified Foods Comes to the United States*, 8 N.Y.U. Envtl. L.J. 610, 610-13 (2000).

meet a triggering threshold. Second, a set of regulatory decision rules that are mandatory once the presumption is triggered. These components can be analyzed separately. The potential justifications for the worst case presumption are examined in the remainder of this section and in Part III. The mandatory decision rules are considered in Part IV.

This essay concludes that the strong PP prescriptions for regulation suffer from two basic deficiencies. They lack a valid justifying principle. They also lead to socially undesirable outcomes.

Uncertainty regarding risks of harm as such does not provide valid grounds for mandating regulation of an activity, or for regulating it more stringently than risks that are determinate or less uncertain. The well-developed economics literature on decisionmaking under uncertainty, which is almost totally ignored in the legal literature on PP, focuses on two considerations that might justify a precautionary approach when regulating uncertain environmental risks. The first is with respect to the potential unavailability in the future of environmental resources that an individual might want to use or enjoy.[41] This essay concludes that this and other forms of risk aversion should play an appropriate role in regulatory decisions on activities that threaten very serious harm to society as a whole, but that, contrary to PP, risk aversion with respect to uncertainty as such is not a justifiable basis for regulation. The second consideration identified in the economic literature that might justify precaution in the face of uncertainty is the potential benefit from acquiring additional information about the risks posed by an activity before allowing tit to proceed.[42] As discussed below, this consideration may justify an initial decision to prohibit an activity or allow it to proceed only under certain limitations in order to gather information that will enable regulators to revisit the decision in the future with the benefit of the additional information. However, this justification is applicable only in certain circumstances and under certain conditions. This information-gathering rationale for precaution accordingly does not justify strong versions of PP, which do not include these qualifications.

In addition to lacking a valid conceptual foundation, PP-based regulation would be undesirable because it would secure less overall environmental protection and diminish societal welfare. PP-based regulation would systematically tend to allocate relatively more in the way of regulatory resources to risks that are highly uncertain relative to risks that are less uncertain or are known to result in harm. As a result, the PP, advocated in the name of environmental protection, in many cases provides less environmental protection. Further, the PP prescription is either perverse or useless as applied to the significant number of cases where regulation itself poses a potential for significant harm, creating a risk/risk tradeoff. Under PP, the regulatory agency must either disregard the environmental costs of regulation, or be required simultaneously to regulate and not regulate.[43] Also, the PP mandate that

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[41] *See* Part II.B, *infra*.

[42] *See* Part IV.B, *infra*.

[43] *See* Jonathan B. Wiener, *Precaution in a Multi-Risk World*, *in* The Risk Assessment of Environmental and Human Health Hazards (Dennis D. Paustenbach, ed., 2d ed. 2001) (forthcoming).

requires regulators to adopt specific types of regulatory measures -- prohibitory or BAT regulations -- whenever an uncertain potential for significant harm is presented, disregarding or downplaying regulatory costs, would lead to indiscriminately stringent and excessively costly regulation and to perverse strategies by regulators to avoid this result.

This essay contends that, contrary to PP, uncertain risks should be regulated under the same general decisional framework as risks that are well-characterized. In the face of uncertainty, regulators should resolve the uncertainty as best they can and treat the uncertain risk as the equivalent of a risk whose probability distribution is known. In resolving uncertainty, decisionmakers should make their best estimate of the probability distribution of an uncertain risk, relying on the available evidence, scientific theory, expert judgments, and guidance from analogous regulatory problems and experience with them. They should not proceed, as the PP requires, on the basis of "worst case" presumptions.

Having resolved uncertainty by estimating a probability distribution for a risk, regulators should follow an appropriate decision rule for preventive regulation. The most appropriate general rule, based on economic concepts and cost-benefit analysis, is to maximize expected value, balancing the expected value of the harm posed by the regulated activity against the expected costs of regulation, taking into account various regulatory alternatives including no action. In the case of risks that pose an appreciable risk of large harm from the viewpoint of society as a whole, risk aversion may justify adding a risk premium in determining the expected value of harm. A risk premium may likewise be appropriate in determining the expected value of regulatory costs where there is a substantial probability of very high costs from the viewpoint of society as a whole. While uncertainty regarding risks of harm (or cost) as such does not justify risk aversion in regulatory decisionmaking, extreme uncertainties may result in relatively flat probability distribution estimates that include significant probabilities of large harms (or costs). Such a probability distribution may justify the incorporation of societal risk aversion into the regulatory decision by adding a risk premium to the expected value of harm (or cost) and using the resulting enhanced value as the basis for regulatory decisionmaking.

Maximization of expected value after incorporating any appropriate risk premiums is not the only decision rule that might appropriately be followed for preventive regulation of risky activities. For example, PP2, which calls for regulation that incorporates a margin of safety below observed or predicted no-significant-effect levels, is an approach that has been widely followed in regulation of pollution and chemicals. This approach can be adjusted to take into account costs and benefits in determining what level of effect counts as significant and in determining the margins of safety. As discussed below, still other approaches may be appropriate.

Having evaluated an uncertain risk in accordance with these procedures, regulators should adopt the most appropriate type of regulatory instrument to deal with a given activity and risk. Contrary to PP, they should not be restricted to using only the prohibitory and BAT versions of command and control regulation. They should be free to consider adoption of other regulatory instruments, including command controls based on achieving environmental quality standards and total residuals loading targets and economic incentive systems such as environmental taxes and tradable pollution or resource-use quotas

and credits. They should select the instrument that will be most efficient and cost-effective in achieving regulatory goals for the type of activity and risk in question. The stringency of regulation should be established based on a balancing of social costs and benefits with the objective of maximizing net benefits.

Further, regulators should carefully consider that regulatory decisions typically do not have to be made once and for all, but generally can be made sequentially. Thus, a decision can be made at T1 either to regulate or not to regulate an activity. That decision can be revisited at T2, and again at T3, and so on. What considerations should be taken into account in deciding whether or not to regulate at T1 when the decision involves uncertainties and the decisionmaker can later reconsider its initial decision with the benefit of new information? The benefit of acquiring new information may in some circumstances justify precautionary decisions to impose regulatory controls on activities that pose uncertain but potentially irreversible risks of serious harm, provided that affirmative steps are taken to develop the new information so as to permit timely reconsideration of the regulatory decision with the benefit of such information. In some cases, however, developing the additional information may require and justify that the activity be allowed to proceed, perhaps in a limited and controlled manner, in order to take advantage of "learning by doing."[44] Some strong formulations of the prohibitory PP, however, exclude the possibility of such learning by doing; they accordingly can not be justified by information acquisition arguments for precaution. Greenpeace, for example, asserts that the uncertainties associated with the risks of GMO crops requires prohibition on their use, including prohibition of limited controlled field trials that provide the best means of resolving the uncertainties in question. This consequence provides an additional reason for rejecting such versions of PP.

In critiquing strong versions of PP, this essay does not argue that stringent preventive environmental regulation should never be adopted. Nor does the analytic framework that it advocates entail such an outcome. As society places a very high value on the environment and its protection, stringent preventive regulation of uncertain environmental risks is often justified and appropriate. Rejecting strong versions of PP does not mean that serious harm must be proved before regulatory controls may be adopted. Policies for preventive regulation must, however, be defined and implemented in a rational and therefore discriminating manner rather than through highly inflexible PP prescriptions.

II. DECISIONS TO REGULATE: THE ROLE OF UNCERTAINTY IN CHARACTERIZING AND VALUING ENVIRONMENTAL HARMS

This part of the essay considers the appropriate regulatory treatment of uncertainty in the risks of environmental harm posed by an activity in order to assess the validity and desirability of strong versions

[44] By the same token, as discussed below, learning by doing with respect to uncertain regulatory costs may in some circumstances justify initial imposition of regulatory controls.

of PP. The first section provides a general conceptual framework for preventive regulatory decsionmaking. It first considers the appropriate regulatory treatment of an activity known to cause a determinate harm. It then considers what additional considerations are presented when the activity poses a known risk of harm, i.e., it threatens harm that is probabilistic in character where the probability distribution is known. Finally, it considers what further additional considerations are presented when the risks of harm posed by an activity are uncertain. Using this framework, the second section considers the treatment of uncertain risks advocated by strong versions of PP and the justifications advanced for such treatment. The conclusion is that, contrary to strong versions of PP, uncertainty regarding risks as such does not justify greater precaution in regulation. This conclusion does not mean that strong preventive regulation of activities posing uncertain risks is not appropriate in some circumstances. Regulators should take into account societal risk aversion towards risks of very large harms. Regulators should also acknowledge and give due regard to the serious limitations in our ability to assess many environmental risks and predict which will cause serious harms. Neither of these considerations, however, justifies PP; there are more appropriately considered through the general framework for preventive regulatory decisionmaking. The section concludes that PP can not be justified by aversion to uncertainty, as such, and that the PP prescription for regulating uncertain risks leads to socially undesirable regulatory outcomes.

A. A Structure for Environmental Regulatory Decisionmaking

In order to provide a conceptual framework for analyzing and evaluating PP, this subsection presents a basic structure for preventive environmental regulatory decisionmaking. This structure, I believe, provides an appropriate standard or default approach for regulators to follow and captures the essential features of much regulatory practice, although I will not attempt to justify these propositions here. The structure has three components: a base case for regulatory decisions for known harms, a second stage for dealing with known risks of harm, and a third stage for dealing with uncertain risks. It involves the use, to the extent practicable, of quantitative and comparative risk assessment, and aims to maximize net social benefits, subject to relevant distributional and other constraints. As discussed below, this structure accommodates many of the important concerns of policy and principle that inform PP. At the same time, it highlights the character and operation of PP's distinctive prescriptions for regulatory decisionmaking and the reasons why those prescriptions are unsound and undesirable.

1. Known Determinate Harms: The Base Case

Assume that the environmental harms that will be caused by an activity are known and determinate (Type 1). The most persuasive general rule of regulatory decision for such activities is to decide so as

maximize net benefits to society, which requires a consideration of the benefits of regulation (in terms of harm avoided) and its costs. The mode and intensity of regulation should be selected so as to maximize the excess of social benefits over social costs. These costs include adverse environmental effects that will or may occur as a result of regulatory measures. Type 1 regulatory decisions may be presumptively regarded as the base case for regulatory decisionmaking. Decisions regarding activities that present risks of harm that are known and determinate and of activities that present uncertain risks of harms can, in most instances, appropriately be reduced to the type 1 base case decision framework. As discussed below, however, other approaches to regulating activities that pose a risk of harm may be appropriate in certain circumstances.

The decisional criterion of maximizing net societal benefits does not necessarily require that all benefits and costs be measured in a common metric such as money. A multi-attribute decisional analysis can potentially encompass a variety of different types of values, including market costs and benefits, non-market health benefits and costs, non-market ecological benefits and costs, the general social values associated with innovation and the growth of knowledge, and so on. These different types of values may have different weights. The prevention of certain types of environmental harms -- such as wide-scale losses of biodiversity or catastrophic consequences resulting from rapid global warming -- are justifiably regarded as enormously important. These harms should accordingly be given extremely strong weight. Further, the weighting of harms would reflect qualitative judgments by people of the character of different harms, giving greater weight to those harms viewed as unfamiliar, involuntary, or "dread."

For purposes of the analysis that follows, its is assumed that there exists a social decision process that assigns determinate weights to these various benefits and costs as basis for regulatory decisions. It is also assumed that there exists a social decision process to compare costs and benefits over different time periods. Determining the regulatory alternative (including no regulation) that will maximize net social benefit is, of course, very far from a mechanical exercise. Limitations in data and methodological conundrums require decisionmakers to exercise a large degree of judgment in implementing this criterion. Yet, as Cass Sunstein rightly points out in the context of regulatory standard stetting for arsenic concentrations in drinking water, "cost-benefit analysis, even with wide ranges, provides an important improvement over the 'intuitive toxicology' of ordinary people."[45]

Considerations of equity and justice also play a role in environmental regulatory decisions.[46] They

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[45] Cass Sunstein, The Arithmetic of Arsenic 2 (forthcoming).

[46] Issues of distributive justice may include what Mark Geistfeld calls a "safety principle," applicable to cases where one person imposes an unconsented risk of harm on another person and harm results. See Mark Geistfeld, Reconciling Cost-Benefit Analysis With the Principle That Safety Matters More than Money, 76 N.Y.U.L.Rev. 114 (2001). An overview of issues of risk, equity and distributive justice is provided in Jeremy D. Frailberg & Michael J. Trebilcock, *Risk Regulation: Technocratic and Democratic Tools for Regulatory Reform*, 43 McGll L.J. 835, 865-867 (1998).

include, for example, considerations of distributional justice, including justice to future generations, and, potentially, duties to other species and to nature. Structural norms, such as those based on the importance of diverse environments to human self-development and flourishing, are also relevant.[47] These considerations may be treated as additional values to be included and considered in a multi-attribute benefits maximization decision, or they may operate as absolute or weighted side constraints on such decisions. The analysis here assumes that these considerations can and are appropriately incorporated in the base case decisional framework.

Another very important consideration for regulators' decisions consists of the limitations imposed by the political process on their budgets and authority and on other regulatory resources (notably, the amount of societal resources that society is willing to devote to regulatory compliance), which in turn constrain the number of risks that they can regulate and the intensity of such regulation. These constraints require prioritization of risks in connection with application of the net benefits maximization principle. Much of the criticism of risk regulation focuses on wide disparities in the cost effectiveness of existing regulations: an example is the wide disparity among regulators in costs per life saved.[48] Comparative risk analyses should be performed by regulators not only when deciding the relative stringency of regulatory controls for different types of environmental harms, but also in connection with the threshold decision whether or not to regulate a given harm. Given resource constraints, a decision to regulate a given harm is necessarily also a decision not to regulate some other harms, which may or may not be more significant. These opportunity costs must be considered by regulators in making the benefit-benefit tradeoffs involved in setting regulatory priorities. One consequence of regulatory resource limitations is that regulators are likely to follow a general policy or practice of not regulating activities that cause *de minimis* harms.

2. Known Probabilistic Risks of Harm: The Second Case

Now assume that the harm caused by an activity is not determinate but instead characterized by a known probability distribution, determined, for example, by quantitative risk assessment (Type 2). Thus, the regulatory decisionmaker may know that the probability is 30% that an activity will cause a given harm and 70% that it will cause no harm at all. Or, it may be characterized by more complex probability distributions. How should the probabilistic character of the harm be handled in regulatory decisionmaking?

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[47] *See* Richard B. Stewart, *Regulation in a Liberal State: The Role of Non-Commodity Values*, 92 Yale L.J. 1537 (1983).

[48] *See, e.g.*, John D. Graham, *Making Sense of Risk: An Agenda for Congress, in* Robert W. Hahn, ed, Risks, Costs, and Lives Saved: Getting Better Results from Regulation 183 (1996).

The most appropriate general approach in deciding whether and how to regulate a type 2 risk is to take the expected value of the probability distribution, and proceed with regulatory decisionmaking as if the harm caused by an activity were determinate and equal to the expected value, using the base case decisional framework. Thus, if an activity poses a 30% probability of causing a harm valued at 100 and a 70% probability of no harm, the regulator should decide to regulate the activity on the assumption that the activity will cause a harm of 30. In accordance with the base case decision framework set forth above, the regulator should accordingly adopt a regulation that would eliminate the risk if the costs of regulations are 25 but not if the costs are 35.

It is often asserted, especially by PP proponents, that society should be risk adverse in dealing with significant environmental harms.[49] Accordingly, regulators should proceed as if the harm that the activity would cause is greater than 30 -- perhaps, at the extreme, close to 100. Risk aversion, however, is generally considered in the context of individual decisionmaking in relation to maximization of individual subjective utility. On the premises of declining marginal utility of wealth and starting point orientation, individuals place a greater disutility on a small risk of a large loss than a certain probability of a small loss with the same expected value. They will pay a risk premium to avoid the former risks (or demand such a premium for bearing them) rather than the latter. Risk averse individuals will accordingly purchase insurance against small probabilities of large losses even though the expected value of the risk of loss is less than the cost of insurance.

Just because individuals are risk averse in their individual decisions, it does not necessarily follow that society should be risk averse in its decisions, including environmental regulatory decisions. For one thing, societies have much greater ability to self-insure and engage in internal risk pooling than do individuals. To the extent that societal risk aversion is appropriate, regulatory decisionmakers should presumably be risk averse with respect only to those losses that are large relative to the well-being of society as a whole. Most environmental regulatory decisions -- for example, regarding most pollutants and wastes and the ecological effects of most development activities -- do not involve risks that are large in this sense. Thus, the appropriate decision rule in such cases is presumptively that discussed at the outset of this subsection: regulate each activity as if it will cause harm equal to its expected value. If the expected value of an activity is less than the *de minimis* threshold, it should not be regulated at all.

There may, however, be some activities that pose smallish probabilities of harms that society places a very high value on avoiding. Examples of such harms include fundamental alternation of the climate system that could cause catastrophic harms or the destruction of an especially rare, beautiful and revered natural resource that can be regarded as "unique" and irreplaceable, constituting an appreciable fraction of society's wealth. Societies also tend to place a higher value on losses that are "lumpy" and

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[49] *See* Fullem, *supra* note 15 at 498 ("…all current embodiments of the precautionary principle or approach implicitly reject risk neutrality."). *C.f.* Jeffrey J. Rachlinski, *The Psychology of Global Climate Change*, 2000 U. Ill. L. Rev. 299 (2000); John C. Dernbach, *Sustainable Development as a Framework for National Governance*, 49 Case W. Res. 1 (1998).

involve concentrated harms.[50] In such cases, it is plausible that regulators should be risk averse in valuing the risk for decisional purposes.[51] In such cases, regulators should add a risk premium to the expected value of harm generated by the probability distribution of the risk in question. Neither science nor economics, however, can answer the question of when regulators should be risk averse and the extent of risk premiums. That answer can only be provided, at a normative level, by a social welfare function, and, at a positive level, by politics.

To the extent that risk aversion is appropriate in valuing the risks of harms posed by activities and thereby determining the expected benefits of regulatory activities, the same principles of risk aversion should be applied to the costs of regulation. The appropriateness of this approach is apparent in risk/risk tradeoff situations, where the adoption of regulatory measures themselves pose a risk of environmental harm. Thus, if regulation creates a risk of potentially large health or ecological losses, regulators should follow the same principles of risk aversion in valuing such risks as they do with respect to risks caused by the activities subject to regulation. Thus, the framework for decision offered here can readily accommodate risk/risk tradeoffs. As previously discussed, strong versions of PP, at least as presently formulated, are incapable of dealing with such tradeoffs satisfactorily. The same general principles of risk aversion should also be applied to large regulatory costs, such as widespread unemployment, that do not consist (at least directly) of environmental harms.

Regulation, especially prohibitions on new products and activities, may also create a risk of large social costs in terms of the market and non-market benefits forgone from innovation and new investment. Such risks raise the issue whether society should be as risk averse to such harms as to harms to health and the environment. A potential argument in favor of being more risk averse with regard to large environmental losses is that such losses, (e.g., the destruction of an ecologically rare wilderness) are likely to be "lumpier" than large non-environmental losses, which tend to be more disaggregated (e.g., a general rise in oil prices resulting from a decision to ban drilling in a wilderness area).[52] However, some social costs of regulation -- for example, unemployment among Appalachian

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[50] For example, societies appear to weight harms that are concentrated in a given community and that injure identified individuals in that community much more heavily than the same harm when it is diffuse and harms individuals who can not be identified as victims. For example, the general public may regard an industrial accident that kills all 500 people in a town as much worse than widespread industrial pollution that is known, on the basis of epidemiologic studies to causes 500 excess deaths. This enhanced weighing probably cannot be explained by considerations of distributional equity or justice with regard to local communities.

[51] Alternatively, such a substantial probability of such harms may trigger justice-based or other structural constraints on benefits maximization, for example, undertaking activities that cause such harms may violate duties of justice to future generations.

[52] The counterargument is that the appropriate relative weight to be given to environmental harms on the one hand and to regulatory costs that do not consist of such harms on the other, has already been resolved in the base case analysis, and that there is no justification for revising such weights and placing a higher value on environmental harms simply because the harm is probabilistic in character rather than determinate. Thus, if the loss of a rare wilderness is of greater weight than a large rise in oil prices, that circumstance is appropriately taken into account in

coal miners due to greenhouse gas regulation -- may be lumpy, whereas many environmental harms, such as the adverse effects of widespread air pollution, may not be. Resolving this issue would require further inquiry into the appropriate grounds for societal risk aversion in connection with environmental regulatory decisions.

In sum, the general approach proposed for the preventive approach to regulating known environmental risks is that regulators should determine the expected value of the risks of harm that would be prevented by regulation and the expected value of regulatory costs, adjust the expected values by any applicable risk premiums, and decide in accordance with the base case criteria. There may, however be cases where an alternative approach to decisionmaking is appropriate.

For example, one potential alternative approach for regulatory decisionmaking is PP2, which calls for regulation that incorporates a margin of safety below observed or predicted no-significant-effect levels. This approach has been widely followed in regulation of pollution and chemicals. In such circumstances, there are often major uncertainties regarding the shape of the damage function for human exposure to such substances and their potency; it will accordingly be difficult to estimate a probability function for dose-response relations (in moving from step 3 to step 2) and also difficult to determine the appropriate risk premium for such an estimation (in moving from step 2 to step 1). Because of these difficulties, PP2 may serve as a useful shortcut to decisonmaking and be used in appropriate cases as a substitute for the general decision framework. This approach can take into account relevant social costs and benefits in determining what level of effect counts as significant and determining the margin of safety. Decision rules to prohibit activities that present sufficiently large risk (say, one in a million risk of 10,000 deaths from a nuclear plant accident), without engaging in cost/benefit balancing, represent another form of shortcut.[53] Of course, there is the danger that such rules-of-thumb will assume a life of their own and be excessively conservative (or excessively risky) regulatory decisions manipulated to produce undesirable results.

Another type of alternative decision rule for type 2 decisions may be especially appropriate for dealing with cases where a regulatory decisionmaker resolves uncertainty regarding a risk (type 3) by estimating a probability distribution for purposes of type 2 decision that is multi-peaked -- for example, a distribution with a significant probability of low harm and a significant probability of substantial harm. Such an estimation may be especially likely to result in cases in which the views of experts are sharply divided, for example on issues such as the ecological effects of widespread application of GMO crop plants.[54] In such circumstances it may be appropriate for the decisionmaker to conduct a sensitivity

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the base case analysis where the harm is determinate and known. There is no justification for an additional thumb on the scale in favor of the environment at the stage of second case analysis. At that stage, the same principles of risk aversion should apply to losses valued in the base case as "very large," whatever their character.

[53] *See* Frailberg & Trebilcock, *supra* note 46 at 877-78.

[54] *See* Richard D. Woodward & Richard C. Bishop, *How to Decide When Experts Disagree: Uncertainty-Based Choice Rules in Environmental Policy*, 73 Land Econ. 492 (1997) (discussing means of addressing expert

analysis, first examining the implications for base case decisionmaking if the harm is low, and secondly the implications if the risk is high, as well as examining the implications of regulation based on expected value. The decisionmaker may appropriately believe that to rely solely on expected value in deciding such cases would not be responsive to the structure of the risk, and conclude, based on the result of the sensitivity analysis, that a maximin strategy is appropriate for regulating this type of risk. If so, the decisionmaker would first evaluate the net benefits of a regulatory decision based on the assumption that harm will be low (the left-hand peak). In that case the criterion of maximizing net benefits may dictate not imposing any regulatory controls at all, or only modest controls. There is, however, the risk that society will suffer large losses if the harm turns out to be high (right-hand peak) and could have been prevented by more stringent regulation. The decisionmaker would then evaluate the net benefits of a regulatory decision based on the assumption that harm will be high. In that case net benefits would be maximized by more stringent regulation. But, there is the risk that the higher costs of stringent regulation will have been incurred unnecessarily if harm turns out to be low. Under maximin, the decisionmaker chooses the alternative that will maximize the minimum gain. This approach might lead to the adoption of more stringent regulation than under the standard framework.[55]

3. Uncertain Risks of Harm: The Third Case

The third and perhaps most common category of environmental regulatory cases involves activities that pose uncertain risks of harm; they threaten environmental harms that are characterized by a probability distribution that is uncertain (Type 3).[56] The degree of uncertainty of course varies, has a variety of causes, and can be characterized in many different ways. PP is directed at this category of harms. This subsection address the principles that should govern regulatory decisions of regulation of uncertain risks of harm, disregarding the possibility that such a decision does not have to be made once but can be revisited in the future when more information will be available. The additional issues presented by sequential regulatory decisionmaking are discussed in Part IV.

The fundamental question in third case decisions is what approach the regulatory decisionmaker should follow in characterizing an uncertain risk of harm when uncertainties are sufficiently great that

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disagreement in the context of climate policy). The sources of disagreements among experts are examined in Roger M. Cooke, Experts in Uncertainty: Opinions and Subjective Probability in Science (1991).

[55] For a discussion of other environmental regulatory problems for which a maximin approach might be appropriate, see Tim O'Riordan, *The Precautionary Principle and Civic Science, in* Reinterpreting the Precautionary Principle, *supra* note 2 at 103.

[56] The distinction between risk (type 2) and uncertainty (type 3), was systematically examined by Frank H. Knight, Risk, Uncertainty and Profit (1921).

probability estimations based upon long run frequencies in data and models validated by such data are of only limited utility. Bournelli's principle of the insufficiency of reason holds that, in the face of irreducible uncertainty (i.e., no additional information can be obtained to reduce the relevant uncertainty before a decision must be made), all risk probabilities should be deemed equal, which implies a perfectly flat probability distribution. The prevailing welfare economic approach, however, follows a Bayesian approach. Under this approach, individuals deciding a course of action in the face of significant uncertainty about outcomes should make their best judgment, based on their prior experience, in estimating the relevant probability distributions. They should then act, based on that estimation, so as to maximize their expected subjective utility. When faced with the same or similar decisions in the future, they should update and adjust their prior estimations giving appropriate weight to new information.[57] This approach to decisionmaking emphasizes the relevance and importance of sequential learning, taking into account multiple lines of evidence, analysis, and experience.[58] Accordingly, it is well adapted to environmental regulatory decisionmaking, as developed in Part IV.

What approach should regulators take with respect to uncertain risks? It would be infeasible and undesirable for regulators to attempt to aggregate the probability estimations and expected subjective utilities of all of the individuals in society as the basis for regulatory decisions in such cases. As a practical matter, individuals lack the information necessary to evaluate the myriad of environmental risks that are potentially subject to regulation and would not want to spend their lives acquiring and processing it. Regulators should therefore act as representatives of society as a whole. In order to promote accountability and transparency, regulators should make their best estimation of the probability distribution for the uncertain risk in question through a process that invites public and expert input and makes explicit and public the relevant uncertainties and the bases for the regulators' determinations. They should first seek to reduce uncertainty in the probability distribution to the extent that available information and science, including quantitative risk assessment, permit.[59] Because of limitations in data and scientific understanding, very substantial uncertainties are likely to remain in many cases. They should then exercise their best judgment in resolving the remaining uncertainty, estimating a probability distribution that they should then treat as if it were a known distribution for purposes of the later stages in the decisional process. In this way, third case decision problems are assimilated to second case

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[57] Bayes' Theorem provides that a person should asses the implications of new information for his pre-existing estimation of uncertain probabilities by multiplying his prior probability estimation by the ratio (1) of the probability that the new information would have been observed if his prior estimation were true with (2) the probability that the information would have been observed if the prior estimation were not true. For a discussion of Bayes' Theorem and Bayesian approaches to addressing uncertain probabilities in the context of the law of evidence, see Richard A. Posner, *An Economic Approach to the Law of Evidence*, 51 Stan. L. Rev. 1477 (1999) and Richard D. Friedman, *Presumption of Innocence, Not Even Odds*, 52 Stan. L. Rev. 873 (1999) (commenting on Posner).

[58] *See* W. David Montgomery & Anne Smith, *Global Climate Change and the Precautionary Principle*, 6 Hum. & Ecological Risk Assessment 399 (2000).

[59] I put to one side for present purpose the question of the weight, if any, that an informed regulatory decisionmaker should give to the much less informed risk estimations of members of the general public.

decision structures. Next, regulators should apply a recognized second stage decisional procedure to the estimation. The general procedure would be to determine the expected value of the harm, adjusting for any relevant risk premiums, and to make a regulatory decision in accordance with the base case rule of net benefit maximization, subject to relevant side constraints. In this way, the third case regulatory decision is ultimately reduced to a base case decision. Or, regulators may in appropriate cases follow an alternative second case procedure and decision rule such as those discussed in the previous subsection.

These decisions by regulators will, of course, be institutional rather than purely personal ones, although personal perspectives and judgments are inescapable. In estimating uncertain risks, empirical "hunches" and the attitudes and values of the decisionmakers, which, it is to be hoped, are in some way representative of the attitudes and values of the larger society, will necessarily play a large role. All of the problems of decisonmaking under uncertainty, including the influence of heuristics, framing effects, and other sources of potential bias and error, must be addressed.[60] Regulators' decisions will be complicated by the circumstance that in many regulatory proceedings, experts other than the ultimate decisionmakers may hold sharply opposed views as to the nature and extent of the uncertainty and how it should be resolved. In a highly adversarial regulatory process, such as found in the U.S., industry experts and environmental advocacy experts often assert such sharply opposed views. Even in less adversarial settings, experts from different disciplines and backgrounds often hold sharply opposed views. It must be emphasized, moreover, that there is no "correct" scientific or welfare economic way of making such estimations. Experience has shown that practicable and relatively robust methods for addressing uncertainty in the context of regulatory and other decisions can be developed through careful and systematic effort.[61] The application of best institutional judgment to resolve uncertainty, through an explicit, open process of decision with opportunity for a wide input of views from professionals and the public, is better than any other means for resolving the problem.

B. Regulatory Treatment of Risk and Uncertainty under PP

PP proponents advocate a different approach. They hold that in the case of uncertain risks that exceed a threshold of appreciable potential for serious harm, the decisionmaker should presume the worst and proceed as if the activity will in fact cause harms that approach the maximum severity that might potentially occur ("worst case"). In one PP formulation:

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[60] For a review of the relevant literature on these problems, see Mark J. Machina, *Choice Under Uncertainty: Problems Solved and Unsolved*, 1 J. Econ. Persp. 121 (1987).

[61] *See* Rex Brown, Using Soft Data to Make "Probabilistic Risk Assessments" Realistic (Discussion Paper, Institute of Public Policy, George Mason University, April 1999); Montgomery & Smith, *supra* note 58 at 399; Jean-Claude Pomerol, *Scenario Development and Practical Decisionmaking Under Uncertainty*, 31 Decision Support Sys. 31 (2001); Sunstein, The Arithmetic of Arsenic, *supra* note 45.

> Precautionary action requires reduction and prevention of environmental impacts irrespective of the existence of risks . . . The crucial point is that environmental impacts are reduced or prevented even before the threshold of risks is reached. This means that precautionary action must be taken . . . even if risks are not yet certain but even probable, or, even less, not excluded.[62]

As previously noted, there are significant questions that must be resolved in defining and applying the triggering PP threshold and the resulting presumption of harm. How great must the probability and severity of the risk of harm be in order to trigger the PP threshold? What sort of evidence can e used to establish that the threshold is met? How should the resulting presumption be defined? Do we assume the "absolute worst case"? The "reasonable worst case"? How are these concepts to be defined? But these problems need not concern us for purposes of the present discussion, which addresses the basic principle, not the details of its application.

If the PP consisted solely of requiring worst case presumptions in the face of uncertainty and did not include the mandatory PP regulatory rules discussed in Part III, it could be incorporated within the structure of decisionmaking set forth above. In the case 3 analysis of an uncertain risk, the uncertainty would be reduced, by virtue of the worst case presumption, to an estimate characterized by very high damage values. Under the general decisional rule for stage 2, that presumed distribution would be reduced to its expected value. Under the PP worst case presumption, the assumed probability distribution would be highly peaked and located at or near the upper end of the range of damage values. Such a distribution would allow little scope for the introduction of risk aversion and the need to add any risk premium to the expected value of the harm. The expected value of the distribution (plus any slight risk premium) would be used in the net social benefits maximization decision in the base case. Alternatively, if worst case is defined as a single outcome, the decisionmaker could directly use the value of the harm associated with that outcome in the base case decision.

The worst case presumption component of PP has two fundamental flaws. It lacks a sound theoretical foundation, and leads to bad regulatory outcomes.

PP proponents have failed to advance a persuasive justification for using a worst case approach to resolving uncertainty rather than having regulators make their best judgment of the probability distribution. PP advocates generally advance two related reasons for a worst case presumption.[63] First, they contend that it is very important to prevent certain types of serious environmental harms. Second, they contend that, due to serious limitations in data and scientific understanding, our ability to predict

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[62] L. Gundling, *The Status in International Law of the Principle of Precautionary Action*, 5 Int'l J. Estuarine & Coastal L. 23, 26 (1990), *quoted in* Ronnie Harding & Elizabeth Fisher, *Introducing the Precautionary Principle*, *in* Perspectives on the Precautionary Principle, *supra* note 7 at 11.

[63] *See*, *e.g.*, O'Riordan, Cameron & Jordan, *supra* note 2; De Fontaubert et. al., *supra* note 7 at 766; Fullem, *supra* note 15 at 499.

whether an activity will cause serious environmental harms is quite imperfect. PP advocates point to past instances where new technologies or other activities have been initiated without stringent regulatory controls because there was no evidence that they would cause serious harms, and where it is later discovered that they have caused and are causing serious harm. In addition, many PP proponents appear to assume that nature is inherently vulnerable rather than resilient. Accordingly, PP advocates argue, we should err on the side of caution and adopt a worst case presumption in order to prevent the occurrence of serious and perhaps irreversible harms.

These asserted justifications for PP are unconvincing. While the concerns adduced by PP proponents are legitimate, they do not require adoption of a worst case presumption, and can be appropriately accommodated within the decisional structure presented in the previous subsections. In presuming the worst, PP introduces deliberate and serious error into the assessment of risk in order to generate more conservative risk management decisions.[64] This tactic conflates risk assessment and risk management and prevents a sound and open approach both to the determination and to the appropriate regulatory treatment of uncertain risks. If avoidance of certain types of environmental harms is very important to society, then such harms will be weighted quite heavily in the base case. If it is appropriate that society be risk averse towards small possibilities of very serious environmental harms, that circumstance will appropriately be taken into account in the standard decisional process by adoption of a significant risk premium. And, if science has a poor track record in predicting environmental risks, or if nature is appropriately believed to be vulnerable rather than resilient, decisionmakers should take those circumstances into account in making their best judgment resolution of uncertainty in the third case analysis. To the extent that skepticism regarding our predictive capacities, a healthy respect for the potential for nasty surprises, and concerns about nature's vulnerability are warranted in particular types of cases, regulators will estimate a relatively flat probability distribution for uncertain risks. Such a distribution will produce a relatively high expected value of harm. Such a distribution will also include an appreciable probability of very large harm, which in appropriate cases will generate a significant risk premium that will be added on to an already high expected value. The high expected value plus risk premium will lead to a high harm value for the base case analysis, resulting in highly protective regulation. Thus, the decisional structure at each of these stages allows ample and appropriate scope for giving due weight to important environmental values, for risk aversion, for limitations in knowledge, and for concerns about ecosystem fragility.

Not all cases of uncertain risk, however, should be resolved in this way. Some uncertain risks can be better characterized. In many cases, the best estimate will be that it is highly probable that any harm that is caused will be insubstantial or modest; and not permanent; the possibility of more serious harm may not be entirely excluded, but the probabilities in many cases will be extremely small. Even assuming that some risk premium is appropriate in such cases, based on the small possibility of more serious harm, the total value of harm in the base case will be low. In other cases, the best estimate of an

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[64] *See* Aaron Wildavsky, *Trial and Error Versus Trial Without Error, in* Rethinking Risk and the Precautionary Principle 22, 33-34 (Julian Morris, ed. 2000).

uncertain risk will have a different shape and a will yield a higher value of harm. It is all a matter of context, of relevant evidence and knowledge, and of judgment. These variations, which are largely disregarded by strong versions of PP, are appropriately dealt with through the standard decisional framework and the "shortcut" alternatives to it, as previously discussed.

These conclusions are consistent with and supported by the economics learning regarding the concept of option value for environmental resources that are "irreplaceable" in the sense that they have no close substitutes.[65] It concludes that, under conditions of uncertainty, individuals will in some circumstances be willing, because of risk aversion, to pay a premium (option value) to preserve the opportunity to use a unique and highly valuable resource in the future, over and above the expected value (consumer surplus) to them of such use. Such a premium can be understood as the value of precaution. To the extent that individuals are willing to pay such a premium, regulators applying the criterion of net benefits maximization should take it into account in making decisions whether and how stringently to regulate activities that might destroy or harm such a resource and preclude its future use or enjoyment.

The discussion of this issue in the economic literature first focused on what might be called demand-side option value. It dealt with situations where an individual is uncertain whether she will use a resource in the future due to uncertainties about her future preferences and/or income.[66] The initial conclusion was that such an individual would normally be risk averse about losing the benefits that an irreplaceable resource would provide if it turned out that she wished to use the resource in the future, and that accordingly she would pay a premium over and above the expected value of future use in order to preserve the option of such use.[67] Later, however, it was shown that this option value might not be positive but rather might be negative (the individual would be willing to pay less than the expected use value for the option) or zero, depending on the individual's utility function and wealth.[68] An individual could be risk averse towards the possibility that the resource would not be available if it turned out that she wished to use it in the future, but she could at the same time be risk averse with regard to the opposite circumstance -- that she would pay for an option to preserve the resource and later find that

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[65] *See* Burton A. Weisbrod, *Collective Consumption Services of Individual Consumption Goods*, 77 Q. J. Econ. 71 (1964); Claude Henry, *Option Values in the Economics of Irreplaceable Assets*, 1974 Rev. Econ. Studies 89 (1974); **V.** Kerry Smith, *Option Value: A Conceptual Overview*, ____ (1982**)**; Richard C. Bishop, *Option Value: An Exposition and Extension*, 58 Land. Econ. 1 (1982). The analysis of option value for use values can be extended to include option value for non-use values, such as the value to an individual of preserving a resource even if he or she does not intend to ever visit or use it.

[66] This analysis could be extended to deal with cases where one is considering whether to preserve a resource for the benefit of future generations whose preferences and wealth are uncertain.

[67] *See* John V. Kutrilla, *Conservation Reconsidered*, 57 Am. Econ. Rev. 777 (1967); Charles J. Ciccetti & A. Myrick Freeman, *Option Demand and Consumer Surplus: Further Comment*, 85 Q. J. Econ. 85 (1971).

[68] *See* Richard Schmalensee, *Option Demand and Consumer's Surplus: Valuing Price Changes Under Uncertainty*, 62 Am. Econ. Rev. 62 (1972).

she didn't wish to use it.[69]

Subsequent analysis turned to the supply side aspect of the issue. It addressed the situation where an individual knows that he wants to use or enjoy a resource in the future, but it is uncertain whether or not an activity subject to regulation will destroy or seriously harm the resource and thereby deprive the individual of the use. Here the analysis has concluded that the option value is always positive, and that accordingly regulators should add an appropriate premium (likely to be small in most cases) to expected value in applying a criterion of net benefits maximization.[70] This analysis, however, did not consider uncertainties in regulatory costs and the possibility that they might generate some countervailing risk aversion. Notwithstanding this possibility, it seems quite likely that in many cases risk aversion towards the loss of an irreplaceable environmental resource that one wishes to use or enjoy in the future would generally justify the addition of some risk premium, over and above expected value, in regulatory decisions addressed to risks of potential harm. This "precaution premium" for unique or irreplaceable environmental resources and services however, can readily be accounted for in the standard framework for regulatory decisonmaking set forth above, through its treatment of risk aversion. Option value thus does not provide any justification for adopting strong version of PP, which would artificially inflate that value through inappropriate worst case presumptions.

Accordingly, uncertainty as such does not justify regulation, or more stringent regulation, of an uncertain risk just because it is uncertain. Only in specific circumstances, involving specific type of risks, is additional precaution justified, and then on grounds of risk aversion to large expected losses, not uncertainty as such. Pervasive, stringent regulation of all uncertain risks could be justified under the standard framework for regulatory decisionmaking, but only if one assumed an essentially flat distribution of risk in all cases of uncertain harm; such an assumption would require a quite radical, across-the-board epistemological skepticism that is wholly unwarranted. PP, however, goes even further than Bournelli. It assumes that an uncertain risk should always be treated as one posing a very high probability of enormous harm. Why does the mere fact of uncertainty in the risks of activity justify the automatic, across-the-board introduction of an additional and extreme degree of risk aversion in decisionmaking? I do not believe that the PP literature provides any coherent or sound answer to this question.[71]

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[69] *See* Smith, *supra* note 65.

[70] *See* Bishop, *supra* note 65; Smith, *supra* note 65.

[71] It might be thought that a potential justification could be found in Ellsberg's paradox and the notion of ambiguity aversion. Ellsberg found, based on experimental observations, that individual subjects did not regard the chances of drawing a black ball from an urn containing an unknown number of black and white balls as equivalent to the chances of drawing a black ball from an urn containing 50 black and 50 white balls. He further found that the subjects also did not regard the chances of drawing a white ball from the first urn as equivalent to the chances of drawing a white ball from the second urn; hence the paradox. *See* Daniel Ellsberg, *Risk, Ambiguity, and the Savage Axioms*, 75 Q. J. Econ. 643 (1961). The relevance for regulatory decisions of this "ambiguity" phenomenon on the part of untutored experimental subjects is at best unclear. Regulators are or can be educated about the issues presented by

In addition to lacking a sound justification in theory, the PP worst case presumption leads to bad regulatory outcomes that diminish social welfare and lead to less, rather than more, overall environmental protection. By virtue of its worse case presumption, PP would produce these bad outcomes even if the mandatory regulatory decision rules that form the second component of PP were disregarded. There are at least three reasons why PP leads to socially undesirable regulatory results.

First, and most obviously, the unrealistic worst case presumption leads to unnecessarily stringent and costly regulation in many cases -- the overwhelming majority -- where the worst case presumption is not justified and activities posing uncertain risks are extremely unlikely to cause serious harm.[72]

Second, PP leads to a disproportionate allocation of limited regulatory resources to those activities posing relatively more uncertainty because the worst case assumption inflates their harm value. Adoption of the PP leads to a sort of regulatory Gresham's Law, in which the regulation of more uncertain risks, which may never eventuate in significant harm, tends to drive out regulation of risks which are better known and more likely to cause harm. In short, PP prevents rational environmental regulatory priority-setting. In doing so, PP leads to a quite perverse regulatory paradox: the adoption of more precaution in the face of risk and uncertainty produces less environmental protection.[73]

Third, PP is incapable of dealing with risk-risk tradeoffs and setting intelligent regulatory priorities. It provides no guidance in dealing with the important class of regulatory problems where regulatory measures to reduce risks (target risks) themselves create risks (non-target risks). Should regulators simply disregard non-target risks because precaution demands strong measures to reduce or eliminate target risks? Or does PP prohibit the adoption of regulatory measures that would create a potential for serious harm? PP provides no answer to this dilemma.[74] PP also fails to provide any basis for setting regulatory priorities among different risks that meet the PP threshold or among uncertain risks and more determinate risks.

Fourth, PP is likely to lead to perverse efforts by regulators to avoid the draconian impacts of the PP prescription for regulation. Uncertain risks that meet the triggering PP threshold are subject to worst case presumptions and stringent regulatory controls that in many instances will be unjustified and disproportionately costly. Regulators, for a variety of reasons, will in many circumstances seek to avoid imposing such controls. In order to do so, they will seek to avoid making threshold determinations of potential risks that trigger PP, either by postponing decisions or applying the decisional criteria

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decisionmaking under uncertainty. PP proponents have not developed or relied on the concept of ambiguity to justify the PP prescriptions for regulatory decisionmaking.

[72] *See* Jonathan H. Adler, *More Sorry Than Safe: Assessing the Precautionary Principle and the Proposed International Biosafety Protocol*, 35 Tex. Int'l L.J. 173, 206 (2000); Ewald, *supra* note 8 at 78.

[73] *See* Frank B. Cross, *Paradoxical Perils of the Precautionary Principle*, 53 Wash & Lee L. Rev. 851, 908-15 (1996).

[74] *See id*.; Wiener, *supra* note 43.

inconsistently. This is the lesson of experience under Section 111 of the Clean Air Act before its amendment in 1990. As widely interpreted, the section mandated elimination of any risk from toxic air pollutants that were non-threshold in their effects, a requirement that would require widespread shutdowns of thousands of industrial facilities. In order to avoid this result, EPA dragged its feet in making decisions under Section 111 or otherwise sought to avoid its mandate. The lesson is that inflexible, draconian regulatory requirements that are not justified by the standard regulatory decisionmaking framework are likely to beget evasive tactics on the part of regulators that undermine the transparency and integrity of the regulatory process.[75] Strong versions of PP threaten precisely this result.

III. MANDATORY PRECAUTIONARY PRINCIPLE REGULATORY RULES

In addition to requiring worst case assumptions about harms, strong versions of PP also require regulators to follow specified regulatory rules for controlling activities posing uncertain risks that trigger the PP threshold potential for serious environmental harm. These mandatory rules include prohibiting the activity in question or requiring adoption of BAT measures; disregarding or downplaying regulatory compliance costs in imposing such controls; and shifting the burden of proof to the proponent of the activity to show that the activity is safe in order to avoid or lift these controls.[76] This section briefly discusses these rules, finding them unjustified as a general, mandatory prescription for regulation of uncertain risks that pose some potential for significant harm.

Given the premises of PP, these mandatory regulatory rules are logical complements to the worst case presumption. PP assumes that regulators applying the PP trigger threshold criteria are capable of distinguishing those uncertain risks that pose a potential for serious harm ("PP risks") from those that do not ("non-PP risks"). PP further assumes, however, that in many and perhaps most cases regulators lack the capacity to distinguish those PP risks that are more serious and more likely to cause serious

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[75] *See* John Dwyer, *The Pathologies of Symbolic Legislation*, 17 Ecology L. Q. 233 (1990). *See also* R. Shep Melnick, *Pollution Deadlines and the Coalition for Failure*, 75 Pub. Interest 123 (1984) (analyzing the perverse consequences of imposing unrealistic deadlines for achieving Clean Air Act air quality standards).

[76] *See, e.g.*, Final Declaration of the First European "Seas at Risk" Conference, *supra* note 28 ("The use of the 'economic availability' reservation in the application of precautionary measures…is inconsistent with [the requirement of precaution] and must be abandoned…If the 'worst case scenario' for a certain activity is serious enough then even a small amount of doubt as to safety of that activity is sufficient to stop it taking place."); Second International Conference on the Protection of the North Sea, *supra* note 26 at 840 ("…reduc[e] polluting emissions of substances that are persistent, toxic and liable to bioaccumulate at source by the use of the best available technology…"); Wingspread Statement on the Precautionary Principle, *supra* note 7 ("…the proponent of an activity, rather than the public bears the burden of proof.").

harm from those that are less serious. Because PP is highly risk averse with regard to uncertainty, it concludes that the worst case presumption should be applied to all PP risks. Accordingly, regulators should act as if all activities posing such risks will in fact cause serious and often irreversible harm to public health and the ecosystem. Given that assumption, it would be logical to regulate all PP risks quite stringently, as the mandatory PP regulatory rules require.

The most fundamental defect in the PP regulatory rules is the implausibility of the underlying epistemological assumptions. PP assumes a quite odd and highly implausible discontinuity in regulators' capacity to assess uncertain risks. Regulators are capable of applying the PP threshold criteria to distinguish PP from non-PP risks. But, thereafter, regulators' risk-assessment capacity largely disappears. They are consigned to ignorance regarding which PP risks are more serious and which less serious.[77] Experience, however, fails to establish that risk assessment capacities have the sharply discontinuous function assumed by PP. Instead, the ability to assess risk seems to display a more continuous variation, progressing by increments from a high degree of confidence to very considerable uncertainty, depending on the particular activity and type of risk in question. These circumstances call for a more flexible approach to regulation than PP, one that applies judgment in balancing the available evidence and knowledge of risk against the uncertainties, makes appropriate estimates of the likely probability and magnitude of harm, and tailors regulatory controls in accordance with those estimates. The framework for regulatory decisionmaking set forth in Part II.A, which operationalizes the principle of proportionality, provides just such an approach.

As shown in Part II, the PP worst case presumption, if applied to the standard risk regulatory decisionmaking framework, would result in excessively stringent and costly regulation even without the mandatory PP regulatory rules. PP, however, also requires regulators to impose a set of stringent regulatory controls for all risks that exceed a triggering threshold in the continuum of uncertain risks. Any selection of such a threshold will be arbitrary. Further, the mandatory package of controls triggered by the threshold will be inappropriately stringent for many of the risks that exceed that threshold unless the threshold is set at a very high level of risk. PP, however, is highly skeptical of regulators' ability to discriminate between more serious and less serious risks; accordingly, the logic of PP requires that the threshold be set at a substantially lower level. The result will be to require indiscriminate imposition of stringent regulatory controls on many risks for which they are inappropriate. Also, for reasons previously explained, the PP regulatory prescriptions will result in less overall environmental protection because they will allocate a disproportionate share of limited regulatory resources to those risks that are relatively uncertain relative to those known to cause harm. In order to avoid such outcomes, regulators will, as discussed in Part II.B, adopt various stratagems to avoid the PP threshold trigger.

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[77] Some of the more sophisticated PP literature does invoke a principle of proportionality, which includes considerations of cost-effectiveness of margins of error so that the selected degree of restraint is not unduly costly. This appears to offer regulators some degree of flexibility even after threshold criteria are met. However, any cost-benefit analysis that follows is intended to be weighted to favor regulation. *See* Communication on the Precautionary Principle, *supra* note 11..

Alternatively, PP's stringent regulatory prescriptions may be rooted in institutional rather than epistemological skepticism. The assumption might be that, even if regulators do have some ability to discriminate among uncertain risks of varying magnitude, they will fail to impose adequate regulatory requirements on activities that pose significant risks of harm as a result of institutional capacities and incentives, as well as political pressures.[78] PP's cure for distrust of administrative discretion is to mandate stringent controls for all uncertain risks that meet a relatively low risk threshold. Further, PP proponents may assume that, for similar institutional and political reasons, there will be an enormous degree of slippage in the actual implementation of the regulatory controls that are adopted. This assumption may be especially strong in the context of international environmental law.[79] PP's cure for these inevitable regulatory failures is to mandate stringent controls at the outset. Experience indicates, however, that a strategy of imposing draconian mandates and deadliness is generally a poor cure for perceived institutional failures, often producing perverse results.[80] If institutions are performing poorly, they will have to be improved. Imposing arbitrary mandates is likely to impede rather than advance the needed improvements.

The remainder of this Part considers the three basic elements in the strong PP package of regulatory controls.

Prohibitory or BAT Controls:

Strong versions of the PP require regulators to prohibit activities (PP4) or impose BAT controls (PP3) posing PP risks. Adoption of these categorical rules for all activities posing some uncertain potential for significant harm would lead to excessively stringent and costly regulation. By requiring regulators to either prohibit such activities or require them to adopt BAT controls, such rules would prevent regulators from using other available regulatory instruments that are often much more appropriate and cost-effective in dealing with many types of activities and risks. Further, PP requires regulators to disregard or mute considerations of regulatory costs in applying this narrow menu of

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[78] *See, e.g.*, Taylor, *supra* note 30 at 255-58 (arguing that property rights conceptions undermine the effectiveness of current regulatory programs); Dernbach, *supra* note 49 at 61 (arguing that the interest in economic development unduly influences current regulatory decisionmaking).

[79] *See generally* Daniel A. Farber, *Taking Slippage Seriously: Noncompliance and Creative Compliance in Environmental Law*, 23 Harv. Envtl. L. Rev. 297 (1999). *See also* O. Yoshida, *Soft Enforcement of Treaties: The Montreal Protocol's Noncompliance Procedure and the Functions of Internal International Institutions*, 10 Colo. J. Int'l Envtl. L. & Pol'y 95, 121-127 (1999); W. Kip Viscusi, *Regulating the Regulators*, 63 U. Chi. L. Rev. 1423, 1450 (1996).

[80] *See* R. Shep Melnick, Regulation and the Courts: The Case of the Clean Air Act (1993); Dwyer, *supra* note 75.

controls.[81] Regulators should be free to follow a more discriminating approach, tailoring the choice of regulatory instrument and its stringency to the particular type of activity and risk in question.

Under such an approach, categorical prohibitions of certain types of activities with uncertain risks of harm may be justified based on their significance and the potential for serious cumulative and/or irreversible harm, factoring in risk aversion where appropriate and also taking account of the social costs of the prohibition. The ban on disposal of radioactive wastes at sea is an example of such a strategy. In other instances, the potential for serious harm, the difficulties in applying pollutant-by-pollutant risk judgments, and scale economies may justify categorical BAT requirements for a class of risks. The BAT controls for toxic air pollutants mandated by Section 112 of the U.S. Clean Air Act as amended in 1990 is an example of this strategy.[82] Any such categorical regulatory requirements, however, must be devised and justified on a case-by-case basis for different types of activities and risks rather than mandated across the board for all uncertain risks with some potential for serious harm. Furthermore, there are many types of regulatory instruments other than prohibitions or BAT controls that regulators should be free to select. For example, some activities, including pollution and waste generation, may be addressed through controls based on environmental quality standards.[83] Where damage functions are approximately linear or are uncertain, measures to limit or gradually reduce total waste or pollutant loadings are often appropriate.[84] In many cases, the most efficient and cost-effective measures for accomplishing these objectives are economic incentive systems such as tradable quota or credit systems and environmental taxes.[85] Furthermore, economic incentive systems are often far better

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[81] *See* Adler, *supra* note 72 at 196-99; Cross, *supra* note 73 at 859-62. **ROB – THESE ARE CITES TO PP CRITICS. ANY CITES TO PP ADVOCATES FOR THIS PROPOSITION? – PROFESSOR STEWART – I CITED CRITICS BECAUSE IT SEEMS THAT MOST PROPNENTS SIMPLY IGNORE REGULATORY COSTS. THEY DON'T EXPLICITLY SAY TO OUTRIGHT DISREGARD THEM. THAT'S WHAT THESE TWO COMMENTATORS SAY.**

[82] *See* Clean Air Act § 112, 42 U.S.C. § 7412(i)(6)(A) (2001).

[83] PP proponents, however, generally disfavor use of such standards because such standards assume that there is a "safe" level of pollution exposure for humans or that the environment can safely assimilate a given level of pollution. Generally, such standards are based on evidence that contains no evidence that harm occurs at pollution concentrations below the standard. PP proponents, however, argue that there is generally no affirmative proof that such harm does not or will not occur, only evidence that harm has not yet been detected. As a result, it remains uncertain whether such harm exists. Accordingly, under the PP, regulatory requirements, such as prohibitions on pollution-generating activity or BAT requirements, should be adopted to address the risks associated with this uncertainty. *See, e.g.*, Bamako Convention on Hazardous Wastes Within Africa, *supra* note 26 at 781 ("…appropriate measures to implement the precautionary principle to pollution prevention [are] through the application of clean production methods, rather than the pursuit of a permissible emissions approach based on assimilative capacity assumptions....").

[84] *See* Richard B. Stewart, *Economic Incentives for Environmental Protection: Opportunities and Obstacles*, *in* Richard L. Revesz, Philippe Sands and Richard B. Stewart, eds., Environment, the Economy and Sustainable Development (2000).

[85] *See* Richard B. Stewart, *A New Generation of Environmental Regulation?*, 29 Cap. U. L. Rev. 21, 94-127 (2001).

suited for addressing environmental problems, such as climate change, involving significant uncertainties regarding harms or regulatory costs than are traditional command instruments.[86] The application of these different instruments should appropriately take into account the costs and benefits of different levels of regulatory stringency for different pollutants and activities.

Further, as discussed in Part IV, regulatory requirements should be adjusted in response to new information regarding relevant harms and control costs. Under PP's mandatory regulatory rules, such adjustments are impossible (in the case of prohibitions) or quite constrained (in the case of BAT controls). Other instruments, including case-by-case screening under an unreasonable risk standard and economic incentive systems, allow for much more flexibility.

Disregard of Regulatory Compliance Costs:

To the extent that the PP prescription for regulation disregards or slights regulatory compliance costs in imposing prohibitory or BAT controls on all PP risks, it will produce unduly stringent and excessively costly regulation.[87] PP regulation will also result in increases in other environmental risks that are not the direct target of the controls.[88] Sound regulatory policy, exemplified by the decision framework set forth in Part II.A, requires that the costs of regulation be explicitly taken into account and appropriately weighed against the risk of harm posed by an activity, with the objective of tailoring regulation of different activities and risks in order to maximize net social benefits, subject to any applicable structural, distributional, or other side constraints. Because of resource limitations and the many environmental risks that we must deal with, we can not devote all or even a large part of society's resources to reducing any given risk, however serious. Much less can we afford PP's injunction to disregard costs in regulating all PP risks. Efforts to pretend otherwise by prohibiting consideration of compliance costs in regulatory decisionmaking are inevitably evaded by one means or another. Candor is required in order to promote regulatory accountability. This does not, however, mean that we should do nothing in cases where the costs of reducing significantly serious risks of harm posed by current

[86] *See* Richard G. Newall & William A. Pizer, Regulating Stock Externalities Under Uncertainty (Resources for the Future Discussion Paper 99-10-REV 1999).

[87] There is a degree of flexibility in BAT requirements, which can be made more or less stringent depending on the level of cost and performance reliability invoked in determining whether a technology is "available." It is, however, often difficult to use this flexibility in order to achieve a more appropriate balance between regulatory costs and benefits because the BAT requirements are generally set for industry categories and the environmental benefits of different levels of control often vary substantially among different facilities (costs may vary substantially as well). But, to the extent that such flexibility is invoked, its exercise requires a more discriminating approach to the analysis of uncertainty and a more explicit balancing of regulatory costs and benefits than the precautionary principle allows.

[88] The inability of PP to deal satisfactorily with such tradeoffs is discussed *supra*.

activities are large. Such risks can be addressed through the use of regulatory instruments designed to stimulate the development of innovative, less costly means of reducing such risks. Economic instruments, including environmental taxes, tradable permit systems, deposit/refund systems, and market-based information systems are much more likely than PP's command prohibitions and BAT requirements to stimulate the necessary technological and institutional changes that will enable us to enhance overall environmental protection.[89]

Burden shifting rules:

A third component of the mandatory PP regulatory rules is shifting the burden of proof and persuasion regarding the uncertainties in the risks posed by an activity from the regulator to the regulated. In many environmental regulatory programs, the burden is on the regulator to show that an activity poses a significant risk of harm before imposing regulatory requirements.[90] Under PP, once the regulator shows that the risk posed by an activity triggers the PP threshold, the burden shifts to the proponent of the activity to show that it does not present significant risk of harm in order to avoid prohibitory or BAT controls.[91] Thus, the ultimate burden of resolving uncertainty regarding risk is placed on the proponent of the activity rather than the regulator.

PP's shift in the burden of proof on risk has sometimes been attacked by PP critics on the ground that it requires the activity proponent to prove a negative -- an absence of any appreciable risk -- which by its very nature is virtually impossible to carry.[92] This criticism is overbroad. If, as PP presumes, we were almost totally incapable of assessing the relative severity of different PP risks, then the burden of showing that an activity that triggers the PP threshold did not pose a significant risk would indeed be extremely difficult to carry; PP regulatory controls would in most cases remain applicable in perpetuity. As discussed above, however, such skepticism is unwarranted. The difficulty in carrying the burden of showing that an activity is "safe" depends on how safety and its proof is defined. There are regulatory programs, such as the U.S. FDA process for approval of new drugs or food additives and for EPA registration of new pesticides, that impose the ultimate burden of establishing safety on the manufacturer

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[89] *See* Stewart, *supra* note 85 at 94-95.

[90] *See, e.g.*, Industrial Union Department, AFL-CIO v. American Petroleum Institute 448 U.S. 607, 614-15 (1980).

[91] *See, e.g.*, Dernbach, *supra* note 49 at 61 ("…the precautionary principle would shift the burden of proof from those supporting natural systems to those supporting development."); Charmian Barton, Note, *The Status of the Precautionary Principle in Australia: Its Emergence in Legislation and as a Common Law Doctrine*, 22 Harv. Envtl. L. Rev. 509, 509 (1998) ("…places the burden of proof on proponents of change to show that their actions will not cause serious or irreversible environmental harm.").

[92] *See, e.g.*, Alex Milne, *The Perils of Green Pessimism*, New Scientist, June 12, 1993.

of the drug or pesticide and define the burden in a workable fashion that allows the burden to be carried in many cases.

Regardless of which party bears the ultimate proof burdens regarding safety, the standard of proof must be defined in a reasonable and workable fashion in order for a regulatory program to function successfully. Under some strong PP formulations, an activity may not proceed unless the proponent is able to negative almost any conceivable potential for significant harm.[93] Under such a decision rule, it will be extraordinarily difficult for the activity to proceed, no matter which party bears the burden.[94]

Assuming a sound decision rule, the most important question in allocating the proof burden is which party, the regulator or the regulated, is better able to generate and marshal the relevant data and analysis. As the new drug, food additive, and pesticide regulatory programs illustrate, in some instances the party regulated is better able to develop the relevant evidence. But in other instances, including those involving individuals or small-scale enterprises, the regulator often has the superior capacity. Thus, the burden shifting requirement of PP shares the same basic defect as the other PP regulatory requirements: it is overboard.[95] Once again, sound regulatory policy requires a more flexible and discriminating

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[93] *See, e.g.*, Naomi Roht-Arriaza, Book Review, 21 Colum. J. Envtl. L. 183, 196 (1996) (Harald Hohmann, Precautionary Legal Duties and Principles of Modern International Environmental Law (1994)) ("This burden shifting, according to Hohmann, runs along a spectrum, from weak obligations…[to a] not-yet-implemented total reversal of the burden of proof, requiring potential polluters to prove the safety of their activities before they can be permitted.").

[94] Such a decision rule will have a far greater impact on the regulatory outcome than the allocations of the production and persuasion burdens because it requires proof of facts that are inherently very difficult to establish by anyone. Take the example of the prohibitory PP. The decision rule makes it very easy for the regulatory agency to prohibit an activity, and very difficult for the agency to approve it. This is true regardless of how the burdens of production and persuasion are assigned. If, for example, the burden of production is on the regulator, it will be relatively easy for the regulator to introduce evidence of sufficient uncertainty regarding risk of harm such that the possibility of appreciable harm can not be excluded; once that production burden is satisfied, it also will be very difficult for the activity proponent to rebut the regulators' prima facie case. On the other hand (still assuming that the production burden is on the regulator) it will be very difficult for the regulator to make a prima facie case for approving an activity by introducing proof that excludes the possibility of harm from an activity where there is considerable uncertainty regarding risk. When the burden of production is on the activity proponent, it will also be very difficult for it to introduce such proof. Thus, whichever party bears the burdens of production and persuasion, it will be very difficult to make out a prima facie case for approval of the activity because of the stringency of the decisional rule for granting such approval; it will also be easy for the regulator to make out a prima facie case that it should be prohibited. For similar reasons, the allocation of the persuasion burden is also less significant than the decision rule. This is not to say that the allocation of the production burden (for example, in cases where expensive testing is required) or of the persuasion burden (where marginal uncertainty leaves the question whether the possibility of appreciable harm has been sufficiently excluded) may not have a significant impact on outcomes. But such impacts will be less significant than that of the underlying PP decision rule itself.

[95] If the burdens of producing evidence and of persuasion regarding risk are imposed on the regulator because it is better able to develop the necessary evidence, regulatory controls will not be imposed in cases of indeterminacy where the relevant risk threshold issue can not be resolved one way or another. If this consequence results in inadequate regulatory protection, there are ways to avoid that result other than by shifting the burden to the activity proponent even though it is generally less able to generate the relevant evidence. For example, the relevant risk

approach.

IV. SEQUENTIAL DECISIONMAKING, UNCERTAINTY, AND THE VALUE OF INFORMATION

Decisions whether or not to regulate seldom have to be made once and for all time. A decisionmaker can decide at T1 to regulate and then decide at T2 whether to continue the regulation, taking into account new information that has developed and other changes that may have occurred in the interim. Or, the decisionmaker can decide at T1 not to regulate, and then at T2 revisit the decision whether or not to initiate regulation, taking into account new information and developments. How should uncertainty regarding harms or costs affect a regulatory decisionmaker's decision at T1 whether or not to regulate, given the possibility of revisiting the decision later in the light of new information? Does such uncertainty justify a precautionary approach to regulation at T1, especially where the decision not to regulate an activity poses some uncertain risk of serious harm?

The economics literature, discussed further below, provides valuable insight in addressing this question. It shows that acquisition of additional information that will improve decisions by reducing uncertainty is often of considerable value. Assume that, as is often the case, time will be required to develop the information. Assume further that the regulator is faced with a decision now (T1) to approve or disapprove an activity that poses an uncertain risk of potentially serious harms. If the regulator approves the activity at T1, it will not have the benefit of the additional information that will allow the risk to be better characterized before deciding, and serious, irreversible harm may occur. This circumstance will eliminate or greatly reduce the value of any new information regarding the risk that is subsequently developed. Accordingly, overall welfare may be enhanced if the regulator declines to approve the activity at T1 and reconsiders the issue at T2 when the additional information is available. The value of additional information that will improve regulatory decisions regarding uncertain risks is thus a potential justification for some form of PP. This justification, however, is applicable only in certain circumstances, and only if the requisite steps are taken to develop the additional information in the interim. Strong versions of PP generally fail to respect these conditions, and impose controls far more broadly than would be justified by the value-of-information considerations.

In order to provide an analytical framework for exploring these questions, this part of the essay first considers sequential regulatory decisionmaking in cases where harms and costs are determinate and known or are characterized by a known probability distribution. It then considers the case of uncertain risks.

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threshold that the regulator is required to establish can be lowered.

A. Harms and Costs That Are Determinate and Known or Characterized by a Known Probability Distribution

When both harms and control costs are determinate or characterized by a known probability distribution, and where the harm caused by future activities will be greater than the harm caused by present activities and/or the costs of control will decrease in the future, it may be appropriate not to initiate regulation at T1 (because the costs of control outweigh the benefits) but to defer regulation until T2 (when the benefits of control outweigh the costs). Of course the harm that will be caused by deferring regulation must be considered in the analysis, including latent harms that are caused by activities conducted between T1 and T2 but that are not realized until after T2, and irreversible harms, such as the extinction of a species. Savings in regulatory costs, including compliance costs, that would be incurred in the interim between T1 and T2 if controls are not adopted at T1 must also be considered.[96]

Climate change is an example of an environmental problem where postponing regulation on such grounds is an important option. Significant reductions in greenhouse gas emissions will require major changes in the capital stock, especially in the energy and transportation sectors. Immediate scrapping and replacement of the capital stock will be much more costly than replacing capital stock with low-GHG technologies at the end of its useful life. Further, R&D and innovation may result in significant reductions in the costs of reducing GHG emissions in the future. Further, because GHGs are a stock pollutant, and annual flows are small relative to the stock, the harms associated with postponing regulation may be low relative to the savings achieved by postponing regulation.[97] There is, however, the

[96] This harm may be especially great in the case of latent harms that have a "long tail" and that can not be prevented by the subsequent adoption of regulation. Examples of such long tail harms include long-latency cancers caused by exposure to toxic substances, the adverse effects of climate change caused by emissions of greenhouse gases with long residence times in the atmosphere, and irreversible harms, such as the extinction of a species.

[97] Stock pollutants are those that can accumulate in the ecosystem and whose adverse effects are a consequence of the total stock, not the additions or subtractions from the stock at a given time. Examples include greenhouse gases and toxic substances that are emitted at relatively low levels but that bioaccumulate. Flow pollutants, such air pollutants like particulate matter or CO, do not reside in media for an extended period of time; their adverse effects are a function of the amounts emitted during a given time period. Stock pollutants have potentially distinctive implications for the decision to regulate uncertain risks now rather than deferring to later. If annual flows are small relative to the stock, postponing a decision whether to regulate will not result in large additions to the stock in the interim before the next decision and as a result may not pose a significant risk of harm if the damage function is approximately linear. Thus, in the face of considerable uncertainty, it may be preferable to postpone regulation until additional information about the extent of the risk and means for addressing it and their costs are developed. If the damage function is approximately linear, then irreversible harm will not occur. Also T1 regulatory "mistakes," in the form of a decision not to impose stringent regulatory limitations on GHG emissions when subsequent information shows that the harms from warming are serious and that more stringent controls should have been adopted, can be corrected by imposing more stringent controls later. On the other hand, there may be a risk of critical non-linear

counterargument that initiating regulation now will stimulate innovation that will reduce the costs of control, and that the harms caused by interim uncontrolled emissions may be substantial and long-tailed.

The analysis must also take into account lags in the implementation of regulation. A decision to initiate regulation at T1 rarely means that controls will become effective at or shortly after T1. The lag will be especially significant in the case of entirely new regulatory programs, and even greater in the case of a new international regulatory program such as that contained in the Kyoto protocol. There, entirely new international institutions must be developed, and policies and measures adopted at the international level, which must subsequently be implemented domestically.

A further practical consideration is the impact of administrative and political inertia. Experience indicates that once a regulatory program is undertaken, it becomes very difficult later to eliminate or relax the program even though it is no longer justified. Regulatory programs, like other government programs, create constituencies, both within and outside government, who benefit from their continuation and will strongly oppose their abolition. This problem can, however, be addressed to some degree by "sunset" provisions. On the other hand, it is possible that a decision not to initiate regulation at T1, thereby allowing a harm-causing activity to continue or even expand, will strengthen constituencies opposed to regulation, making it more difficult to adopt regulation in the future. This problem can to some degree be addressed by agenda-forcing provisions similar to the action-forcing provisions contained in the citizen suit provisions in the major federal environmental regulatory statutes.

B. Uncertain Harms and Costs

Where, the risk of harms and/or regulatory costs are uncertain, decisions and societal welfare can be improved, sometimes dramatically, by reducing uncertainty through the development of new information. Such information can improve societal welfare by reducing uncertainty, thereby ensuring that regulatory decisions are made on the basis of more accurate estimations of costs and benefits, which will in turn make it more likely that such decisions will enhance social welfare.[98]

In order to promote better regulatory decisionmaking, it is common practice to have a systematic process for gathering relevant information prior to a decision being made. Examples of such processes include notice and comment rulemaking, environmental impact statements, and procedures for the submission of evidence in licensing and other adjudicatory decisions. Depending on the underlying

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damage thresholds, such that a small addition to the stock will trigger the threshold and cause serious environmental harm. Rapid global warming resulting from increased GHG emissions poses some small uncertain risks of such harms. Also, it may be argued that additions to the stock should be immediately stopped or minimized so as to avoid imposing an additional control burden on future generations. *See* Charles D. Kolstad, *Learning and Stock Effects in Environmental Regulation: The Case of Greenhouse Gas Emissions*, 31 J. Envtl. Econ. & Mgmt. 1 (1996).

[98] See discussion and sources cited at pp.41-43 *infra*.

decision rule, the resulting lag in the timing of the regulatory decision can either impose regulatory costs or result in environmental harms, depending on legal rules defining the character of the status quo in the absence of decision. Thus, regulatory laws generally provide that a new plant or development project cannot be undertaken or a new drug or pesticide marketed until after regulatory approval is granted following an information gathering process. This delay imposes regulatory costs by postponing realization of the benefits that the activity would produce had it been allowed to begin earlier. On the other hand, an existing activity generally cannot be subjected to new or additional controls until after completion of a regulatory decisionmaking process in which information is gathered. In this case, delay may involve interim harm resulting from unregulated activity.[99] There are also hybrid procedures, as exemplified by TSCA, where manufacturers must submit basic information on new chemical products but may introduce them commercially within a short period following this submission unless EPA affirmatively takes action to require additional testing and study of potential environmental risk posed by such products.

Now consider the case where a regulatory decision involving uncertain risks of harm and/or uncertainty in regulatory costs need not be made once and for all, but can revisited one or more times in the future. In this situation, the decisionmaker must consider the value and the cost of information that could be gathered in the future, the possibility of an improved future decision based on that information, and the implications of such an improvement for the current regulatory decision.

The future development or collection of additional information can be undertaken or commissioned by the regulatory agency or other government authorities. In making these decisions, the government will have to consider the expected value and cost of the information that would be developed. Incentives can also be provided to the regulated industry and other non-governmental actors to obtain and develop new information. The regulated industry's interest in obtaining favorable regulatory decisions in the future is a powerful incentive to obtain and develop such information. The force of that incentive may be enhanced by imposing on the regulated industry the burden of production, the burden of persuasion, or both, in future regulatory proceedings. Further, regulators may be empowered to require the regulated industry to conduct research and report the results.

There are three categories of additional information that could be developed in the future: information generated by investment in research, information that results from learning-by-doing, and autonomous information that is produced by experience generally. Research includes theoretical and laboratory studies, simulations and small scale tests, and other direct investments in the generation of knowledge. Learning-by-doing consists of information developed as a result of carrying out an activity or imposing regulatory controls.[100]

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[99] The major federal environmental statutes, however, contain provisions granting general authority to the EPA or the Justice Department to take immediate enforcement action against activities that pose imminent and substantial risks of harm.

[100] See generally Wildavsky, supra note 64.

Learning-by-doing with respect to harms can occur when an activity posing uncertain risks of harm is allowed to proceed and monitoring of evidence of harm is conducted. For example, field releases of bioengineered crop plants presenting a potential risk of ecologically harmful transgenic transfers may be allowed and monitored for evidence of such harm. Learning-by-doing regarding regulatory costs can occur when regulatory controls are imposed and compliance costs and regulatory performance are monitored. For example, imposition of performance-based BAT controls on air emissions will lead the regulated industry and its suppliers to develop and install control technologies whose costs and performance can be monitored.

The value of the information produced by learning-by-doing will vary depending on the circumstances. If, for example, an activity has already been conducted for a substantial period of time and its effects have been monitored, the value of the additional information regarding harm that may be obtained as a result of continuing the activity may be far less than the information regarding harm obtained by allowing a new activity, such as field release of new bioengineered crops, to occur. The value of learning-by-doing regarding harms also depends on the extent to which adverse effects from an activity can be accurately detected. Thus, the health effects of very low level pollution exposures generated by certain industrial activities may be very difficult to detect through epidemiological studies; if so, the value of learning-by-doing with regard to harms by allowing these activities to continue may be quite low. The informational value of learning-by-doing regarding regulatory costs will also vary depending on the circumstances. If, for example, industry believes that regulatory controls adopted at T1 may be eliminated or relaxed at T2, or if it believes that such controls will be substantially tightened at T2, its response during the period T1-T2 is unlikely to be representative of its response if the controls were expected to be imposed on a long-term basis.

Against the background of these considerations, how should the value of additional information be taken into account in an initial regulatory decision? The discussion that follows assumes that the choice is between not regulating at all or imposing regulation of a given level of intensity. The same basic analysis can, however, be extended to cases where the choice is between more stringent and less stringent regulation.

Regulate:

The regulator can decide at T1 to regulate activity, and to reevaluate that decision at T2 on the basis of any new information developed in the interim, including the information about regulatory costs obtained through learning-by-doing. In doing so, the regulator forgoes the additional information regarding harm that might be obtained by allowing an activity to go forward without regulation.[101] The

[101] If the type of regulation (For example, BAT regulation) allows an activity to go forward and, e.g., pollute although

regulator also runs the error risk of imposing on society control costs that later prove to have been unwarranted because new information shows that the activity in question does not cause any significant harm.

Defer:

Alternatively, the regulator can decide not to regulate at T1 and to reconsider that decision at T2 taking into account the additional information obtained in the interim, including information about harm obtained by learning by doing by allowing the activity to go forward and monitoring its effects. In doing so, the regulator forgoes the information regarding regulatory costs that might be obtained by imposing regulatory controls. The regulator also runs the error risk of allowing the conduct of activities that cause harms that, in the light of new information, turn out to be both significant and unwarranted because they could have been prevented at reasonable cost by the adoption of regulatory controls at T1.

The decisionmaker at T1 will have to consider the nature and extent of these two different types of error risks and the costs associated with them in its decision whether or not to regulate. These risks will be characterized by significant uncertainties, which must be addressed using the decision analytical framework previously discussed. Because the relevant considerations will vary so widely from case to case, it seems very difficult to make any generalizations about which approach to follow.

The most stringent version of PP, however, asserts that the decisionmaker should always decide to regulate an activity and, further, that the regulation should take the form of a prohibition, whenever the risks posed by the activity are sufficiently uncertain that a possibility of appreciable harm can not be excluded. The previous discussion has established a number of reasons why this decision rule is unsound. The contribution to improved regulatory decisionmaking of new information potentially generated by learning-by-doing provides an additional consideration against adopting a PP requirement that new activities posing uncertain risks of potentially serious harm should be prohibited.[102] Such a rule precludes any learning-by-doing regarding the risks posed by such an activity. At the same time, prohibiting a new activity is unlikely to generate useful information about regulatory costs. In this circumstance, regulatory costs do not consist solely of compliance outlays, such as the costs of installing and operating pollution control equipment, but the opportunity costs of investments and innovations forgone as a result of the prohibition. Such costs are notoriously difficult to determine.[103] Thus the

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to a reduced degree, some learning-by-doing regarding harm may still be possible.

[102] *See* Wildavsky, *supra* note 64.

[103] *See* Richard B. Stewart, *Regulation, Innovation and Administrative Law: A Conceptual Framework*, 69 Calif. L. Rev. 1256 (1980).

prohibitory PP as applied to new activities deprives decisionmakers of any information benefits from learning-by-doing. Allowing the activity to proceed while monitoring it closely, however, can produce significant learning-by-doing information benefits. These benefits are likely to be especially pronounced when considered not in the isolated case of a single activity but new activities generally. Allowing various new activities to proceed while monitoring their effects can promote societal learning about which types of activities do not pose significant risks and which do. And, this knowledge may advance more general scientific and societal understanding of the origins and characteristics of risks and how best to respond to them, thereby enhancing societal resilience to risk.[104]

This is by no means to argue for an across-the-board rule allowing all new activities posing uncertain risks of harm to proceed, regardless of the circumstances. In some cases, the risk of serious harm may be sufficiently substantial to justify prohibiting the activity and develop new information through research rather than learning by doing. But considerations based on the informational value of learning-by-doing provide an additional strong counter argument to adoption of a prohibitory PP as applied to new activities. Such considerations are less weighty in the case of a prohibitory PP as applied to existing activities, where learning-by-doing regarding harm may have already occurred and where the benefits of the activity can be estimated as a basis for projecting the costs of prohibiting its continuation; and in the case of a BAT PP, whether applied to existing or new activities.

These conclusions are consistent with and supported by the insights of economic analysis. The importance of information value in connection with decisions regarding regulatory and management decisions for environmental resources involving uncertain risks of serious, potentially irreversible consequences was first analyzed by Kenneth J. Arrow and Anthony C. Fisher in 1974.[105] They pointed out that an irrevocable decision to develop a resource in such a way that might cause such harm would preclude the possibility of developing additional information to reduce the uncertainty and thereby allow a more informed decision to be made later. Such information has a positive economic value that would be lost if development proceeds. If the development proceeds without the benefit of additional information and has irreversible consequences, these can not be undone in the future, whereas an initial decision not to allow development can be reversed in the future if new information warrants. Hence, the loss of this information and of the associated opportunity for an improved decision in the future should be included and counted as a cost in the decision whether or not to allow development. In close cases where the benefits and other costs of development are fairly closely balanced, the inclusion of this cost in the analysis could result in a decision not to develop. In other words, considerations of information value tend to favor flexibility in the timing of development decisions, and should lead decisionmakers to err on the side of not allowing development when the effects may be irreversible. The applications to environmental regulatory decisions are apparent.

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[104] *See* Wildavsky, *supra* note 64.

[105] Kenneth J. Arrow & Anthony C. Fisher, *Environmental Preservation, Uncertainty, and Irreversibility*, 88 Q. J. Econ. 312 (1974).

The analytic framework pioneered by Arrow and Fisher has since been extended and applied to a range of decisional problems, including in particular decisions with respect to climate change.[106] This framework strongly supports a Bayesian approach to decisionmaking, in which initial judgments about uncertainties are continually revised in the light of new information.[107] It also provides an analytical structure for examining the benefits and costs of learning-by-doing strategies for reducing uncertainty within the context of a Bayesian approach.[108] For example, in the context of climate policy one study has concluded that the informational benefits of learning-by-doing with respect to the potential extent of warming support a decision not to impose stringent GHG controls in order to obtain valuable information on the warming effects of GHG emissions.[109]

Subsequent analysis has shown that the Arrow-Fisher framework is applicable to activities that threaten serious but remediable losses as well as to those that have irreversible consequences.[110] The subsequent literature also confirms that the value of information does not mean that a decision to undertake or allow activities that may cause serious or irreversible harms should always be postponed in order to have the benefit of new information. The value of new information depends on the circumstances and is only one factor to be balanced among other relevant costs and benefits, which in some cases justify an initial decision in favor of allowing a risky activity to proceed.[111] For example, one analysis has concluded that the probabilities of significant irreversibilities associated with global warming are too small to justify a decision to impose stringent controls on GHG emissions pending the development of further information on warming, especially where such controls would require large capital investments that could not be reversed if new information failed to show that they were justified.[112]

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[106] *See, e.g.*, Stephen G. Peck & Thomas J. Teisberg, *Global Warming Uncertainties and the Value of Information: An Analysis Using CETA*, 18 Resource & Energy Econ. 71 (1993) (stressing importance of resolving uncertainties about regulatory costs as well as harms); Montgomery & Smith, *supra* note 58 (rejecting appropriateness of strong PP presumptions and prescriptions for climate policy).

[107] *See* David L. Kelley and Charles D. Kolstad, *Bayesian Learning, Growth, and Pollution*, 23 J. Econ. Dynamics & Control 491 (1998); Jon R. Miller and Frank Lad, *Flexibility, Learning and Irrreversibility in Environmental Decisions: A Bayesian Approach*, 11 J. Envtl. Econ. & Mgmt. 161 (1984).

[108] *See* Sanford J. Grossman, Richard E. Kihlstrom, & Leonard J.Mirman, *A Bayesian Approach to the Production of Information and Learning by Doing*, 4 Rev. Econ. Studies 533 (1977).

[109] *See* Kelley & Kolstad, *supra* note 107.

[110] *See* Larry G. Epstein, *Decision Making and the Temporal Resolution of Uncertainty*, 21 Int'l Econ. Rev. 269 (1980); Miller & Lad, *supra* note 7.

[111] *See* W. Michael Haneman, *Information and the Concept of Option Value*, 16 J. Envt'l Econ. & Mgmt. 23 (1989).

[112] *See* Charles D. Kolstad, *Learning Effects in Environmental Regulation: The Case of Greenhouse Gas Emissions*, 31 J. Envtl. Econ. & Mgmt. 1 (1996).

The value of additional information and the consequent desirability of flexibility in regulatory decisionmaking can readily be incorporated into the standard framework for preventive regulatory decisionmaking developed in Part II.A. The loss of this information value should be accounted as a cost in decisions whether or not to regulate an activity posing a potentially significant risk of irreversible or otherwise serious harm and incorporated in the base case decision. Under this decisional framework, the benefit of acquiring new information may in some circumstances justify precautionary decisions to impose regulatory controls on activities that pose uncertain but potentially irreversible or otherwise serious risks of serious harm, provided that affirmative steps are taken to develop the new information so as to permit timely reconsideration of the regulatory decision with the benefit of such information. In other cases, however, developing the additional information may require and justify that the activity be allowed to proceed, perhaps in a limited and controlled manner, in order to take advantage of "learning-by-doing."[113] And, in still other cases, the social benefits of allowing an activity to proceed may so far outweigh the risks of harm that including considerations of information value would not affect a decision to allow the activity to proceed.

On the other hand, the economic analysis does not support strong versions of PP, which impose regulatory requirements on activities regardless of whether such requirements are justified by value-of-information considerations. For example, strong formulations of the prohibitory PP exclude altogether the possibility of learning by doing with respect to uncertain harms.[114] They accordingly can not be justified by information acquisition arguments for precaution. Greenpeace, for example, asserts that the uncertainties associated with the risks of GMO crops requires prohibition on their use, including prohibition of limited controlled field trials that provide the best means of resolving the uncertainties in question. This consequence provides an additional reason for rejecting such versions of PP.

Perhaps due to a perceived conflict of interest or goals between environmentalists and economists,[115] the value of additional information in the context of sequential regulatory decisionmaking is generally not discussed as a justification for a precautionary approach in the PP literature.[116] Yet, the underlying concept is sometimes acknowledged. The EC Communication on the Precautionary Principle, for example, provides that "Measures based on the precautionary principle shall be reexamined and if necessary modified depending on the results of the scientific research and the follow

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[113] By the same token, as discussed below, learning-by-doing with respect to uncertain regulatory costs may in some circumstances justify initial imposition of regulatory controls.

[114] *See* Wildavsky, *supra* note 64.

[115] *See* Survey of Economists and Ecologists. *See also* Richard L. Revesz, *Environmental Regulation, Cost-Benefit Analysis, and the Discounting of Human Lives*, 99 Colum. L. Rev. 941 (1999).

[116] The value of such information is discussed in Richard B. Howarth, *Sustainability Under Uncertainty: A Deontological Approach*, 71 Land Economics 417 (1995).

up of their impact."[117] This provision implicitly acknowledges the value and importance of continuing to gather and examine information throughout the regulatory process and take the result into account in subsequent regulatory decisions. Some international declarations contemplate broad adaptive approaches to managing environmental risks; such approaches could include the deliberate development of new information on risks and consideration of its implications for sequential regulatory decisions.[118]

Some students of PP commentators have proposed a "risk-oriented" or "procedural precautionary approach" to encourage the development of and then use valuable information obtained during a process of sequential regulatory decisionmaking.[119]. This "procedural" approach contemplates an adaptive process designed to encourage the development new information and continually reevaluate and appropriately modify previous regulatory decisions. These procedures function within an edict of precaution. Yet, the approach recognizes the drawbacks of rigid PP prescriptions and seeks to introduce flexibility. Flexibility can also be introduced by applying the principle of proportionality to precautionary regulation. For example, the EU Communication on the Precautionary Principle states that "The measures adopted presuppose examination of the benefits and costs of action and lack of action."[120] In various ways, these approaches are similar to attempts by scholars to bridge the perceived gap between PP and cost/benefit analysis.[121] They have the potential to creates a far more flexible and workable conception of PP that may not in substance be very different from the standard framework for preventive regulatory decisionmaking set forth in Part II.A.

V. CONCLUSION

This essay has examined two basic versions of the PP, weak and strong. The weak versions -- PP1 and PP2 -- enunciate principles that have been widely followed over the past thirty years in

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[117] Communication on the Precautionary Principle, *supra* note 11.

[118] For example, the UNCED Text on Protection of Oceans, *supra* note 24, provides for "*inter alia*, the adoption of precautionary measures, environmental impact assessments, clean production techniques, recycling, waste audits and minimization, construction and/or improvement of sewage treatment facilities, quality management criteria for the proper handling of hazardous substances, and a comprehensive approach to damaging impacts from air, land and water." While there is nothing among these measures that specifically calls for reevaluation of regulatory decisions in light of new information, they at least demonstrate a recognition that continued information gathering is an important part of any "comprehensive approach" to regulation.

[119] *See* Heyvaert, *supra* note 33. *See also* Harding & Fisher, *supra* note 62 at 11.

[120] Communication on the Precautionary Principle, *supra* note 11.

[121] *See* Geistfeld, *supra* note 21. *See also* Daniel A. Farber, Eco-Pragmatism (1998).

environmental regulatory programs in most industrialized nations, which generally follow a preventive strategy that includes regulation of uncertain risks. Many environmental regulatory programs in international agreements follow the same approach. Accordingly, the weak versions of PP propose nothing new. On the other hand, the strong versions of PP -- PP3 and PP4 -- would, if adopted, make important changes in the prevailing concept and substance of environmental regulatory law and practice at both the domestic and international levels. This essay concludes that the strong versions of PP lack a sound foundation in regulatory theory and would lead to undesirable regulatory outcomes, diminishing societal welfare and reducing overall environmental protection. They should accordingly be rejected. Instead, the valuable insights of PP, clarified through careful economic and legal analysis, should be integrated into the existing paradigm of preventive regulation. This essay offers one approach to accomplishing this integration.

PP proponents may complain that my characterization of strong versions of PP is too rigid and extreme, and that both the spirit and practice of PP would be more flexible and accommodating than my analysis has supposed. Any suggestion that this essay attacks a "straw man" version of PP would, however, be unwarranted. Of course one could, as some commenters have done,[122] interpret PP in a very "soft" fashion as a collection of general admonitions for regulators. Environmental protection is very important, especially if long term or irreversible harms are threatened. In assessing uncertain environmental risks, pay close attention to the limits to our ability to assess uncertain risks and the longer run and cumulative consequences of activities. Emphasize prevention. Be especially protective where very serious harms might occur, even if their probability is relatively small. Such admonitions, if followed with judgment and attention to context, are entirely appropriate. As discussed above, these admonitions of precaution, appropriately clarified and refined, can and should be incorporated within the net-benefits-maximization approach to preventive regulation.[123]

Proponents of strong versions of PP, however, advocate something quite different and more radical. They condemn the dominant approach to environmental regulation as seriously deficient and propose an entirely new paradigm targeted on risk uncertainty. PP proponents assert that a basic shift towards a far more precautionary approach in environmental regulation based on this paradigm is needed, requiring fundamental changes in the preventive approach to environmental regulation that has generally prevailed over the past 30 years.[124] The basic elements of PP3 and PP4 -- worst case presumptions, prohibitory or BAT regulatory controls, disregard or downplaying of compliance costs, and burden shifting -- would accomplish those changes. It is not unfair, indeed it would be disrespectful, not to take these arguments and proposals at face value and evaluate them as such. Of course, the

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[122] *See, e.g.*, Michele Territo, Note, *The Precautionary Principle in Marine Fisheries Conservation and the U.S. Sustainable Fisheries Act of 1996*, 24 Vt. L. Rev. 1351, 1352-53 (2000).

[123] *See* Part II, *supra*; Geistfeld, *supra* note 21.

[124] *See, e.g.*, Taylor, *supra* note 30; Wendy E. Wagner, *Innovations in Environmental Policy: The Triumph of Technology-Based Standards*, 2000 U. Ill. L. Rev. 83 (2000).

strong versions of PP will require judgment and a degree of flexibility in application to particular cases. But the strong PP prescriptions are regulatory rules that are to be applied across the board to all PP risks, which would include a potentially quite large array of human activities, including many existing, well-entrenched activities as well as new product and process technologies. It would be inconsistent with the basic premises of PP to suppose that the adverse consequences of such rules could be avoided by applying them selectively to the cases where they are most justified and carefully balancing regulatory burden against risk of harm. Selective application and balancing would require some means for distinguishing those uncertain risks most likely to pose serious harm from those that are less likely to do so. But, that would require epistemological and institutional capacities for resolving uncertainty that PP denies. It would also require significant discretion in regulatory decisionmaking, discretion that PP proponents seek to minimize. If there are indeed criteria, consistent with PP premises, to guide selective application of the PP regulatory prescriptions and a balancing approach so as to avoid unduly rigid and costly regulation, those criteria need to be identified and justified. Thus far, proponents of PP have failed to provide them.