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# THE TAMING OF THE PRECAUTIONARY PRINCIPLE

JOHN S. APPLGATE\*

At its core, the precautionary principle embodies two fundamental regulatory policies: anthropogenic harm to human health and the environment should be avoided or minimized through anticipatory, preventive regulatory controls; and, to accomplish this, activities and technologies whose environmental consequences are uncertain but potentially serious should be restricted until the uncertainty is largely resolved. It reflects the implicit judgment that, in the absence of some degree of *ex ante* regulatory review, new technologies will create novel, severe, and irreversible—but avoidable—harms to human health and the environment. It also reflects the value judgment that protection of human and environmental health trumps quantitative measures of risk and economic efficiency. The precautionary principle has become a fixture of formal expressions of international environmental law and policy. Principle 15 of the 1992 Rio Declaration of the United Nations Conference on Environment and Development (“UNCED”) provides,

[i]n order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.<sup>1</sup>

This text is the most authoritative formulation of the principle, by virtue of its widespread acceptance and the absence of credible challengers. Several more recent treaties have incorporated the Rio formulation by reference.<sup>2</sup>

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<sup>1</sup> Rio Declaration on Environment and Development, Annex 1, princ. 15, U.N. Doc. A/CONF.151/5/Rev. 1 (1992), *reprinted in* 31 I.L.M. 874, 879 [hereinafter Rio Declaration].

<sup>2</sup> *See, e.g.*, Plan of Implementation of the World Summit on Sustainable Development, Res.

Many other conventions and tribunals, even in a hostile forum like the World Trade Organization ("WTO"), have accepted the precautionary principle in some form,<sup>3</sup> to the extent that two commentators who have studied the question exhaustively regard the precautionary principle as a customary rule of international law.<sup>4</sup>

At some level of generality, precaution is undoubtedly a customary rule of international law.<sup>5</sup> At the level of specific words and provisions, however, there remains significant diversity in the meaning of the precautionary principle, and this diversity is both the product and target of considerable political maneuvering. There also remain some very important and powerful skeptics of the precautionary principle, principally the United

2, Annex, ¶ 22, at 19, U.N. Doc. A/CONF.199.20, U.N. Sales No. E.03.II.A.1 (2002), [http://www.johannesburg.org/html/documents/summit\\_docs/131302\\_wssd\\_report\\_reissue\\_d.pdf](http://www.johannesburg.org/html/documents/summit_docs/131302_wssd_report_reissue_d.pdf) [hereinafter Plan of Implementation]; Stockholm Convention on Persistent Organic Pollutants, U.N. Env't Prog., art. 1, U.N. Doc. UNEP/POPS/CONF/2 (2001), 40 I.L.M. 532 [hereinafter POPS Convention]; Cartagena Protocol on Biosafety to the Convention on Biological Diversity, Jan. 29, 2000, art. 1, 39 I.L.M. 1027 [hereinafter Cartagena Protocol]; Protocol to the 1979 Convention on Long-Range Transboundary Air Pollution on Persistent Organic Pollutants, *opened for signature* June 24, 1998, pmbl., [http://www.unece.org/env/lrtap/pops\\_h1.htm](http://www.unece.org/env/lrtap/pops_h1.htm) (last updated Dec. 5, 2002); and other conventions listed in ARIE TROUWBORST, *EVOLUTION AND STATUS OF THE PRECAUTIONARY PRINCIPLE IN INTERNATIONAL LAW* 320-27(2002).

<sup>3</sup> A recent comprehensive list is in TROUWBORST, *supra* note 2, at 303-47 (listing current to Sept. 1, 2001). See also HARALD HOHMANN, *PRECAUTIONARY LEGAL DUTIES AND PRINCIPLES OF MODERN INTERNATIONAL ENVIRONMENTAL LAW* (1994) (surveying international and domestic law).

<sup>4</sup> HOHMANN, *supra* note 3, at 335-45; TROUWBORST, *supra* note 2, at 244-45, 285. Other commentators are divided. See James Cameron & Juli Abouchar, *The Status of the Precautionary Principle in International Law*, in *THE PRECAUTIONARY PRINCIPLE AND INTERNATIONAL LAW: THE CHALLENGE OF IMPLEMENTATION* 36-50 (David Freestone & Ellen Hey, eds., 1996) [hereinafter *THE CHALLENGE OF IMPLEMENTATION*]; TROUWBORST, *supra* note 2, at 260-84 (reviewing findings of other commentators); Sonia Boutillon proposes that it be regarded as a "standard" which has a clear legal existence but gains legal force only in application. Sonia Boutillon, *The Precautionary Principle: Development of an International Standard*, 23 MICH. J. INT'L L. 429, 447, 469 (2002).

<sup>5</sup> Trouwborst's generalized version is, "in the face of a (whether or not 'significant') threat of environmental harm, preventive action ought to be taken even where relevant information on that threat and its probable effects is not conclusive." TROUWBORST, *supra* note 2, at 245.

States, the international trade community represented by the WTO, and national and transnational economic enterprises.<sup>6</sup> Within the United States, senior government officials and many prominent scholars vigorously oppose the precautionary principle, because they see it as a replacement for the risk-based, science-dominated, cost-sensitive regulatory structures that have come to characterize most of the world's sophisticated environmental regimes.<sup>7</sup> These regulatory regimes proceed from the view that economic expansion and technological innovation are to be encouraged because they increase overall social welfare, including improved human and environmental health. In this view, the precautionary principle offers an unwelcome and technically insupportable alternative. As a result, the precautionary principle, despite its enshrinement in many international agreements, is under constant pressure from opponents who accept the generality but vigorously seek to alter the specifics.

This Article argues that, even as the precautionary principle has found ever wider acceptance in international environmental policy, strong versions of the principle have been systematically tamed—reduced, as it were, from a tiger to a housecat. Part I demonstrates that the constituent elements of the precautionary principle have been altered over time to be less stringent or to

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<sup>6</sup> Thus, Trouwborst's talk of the "current *wholehearted* acceptance of the principle by the international community," *id.* at 285 (emphasis added), almost certainly overstates the enthusiasm with which the precautionary principle is regarded. David Vanderzwaag identifies three major environmental threats that have seen, in actual practice, "cautious approaches to precaution": climate change, hazardous chemicals, and overfishing. David Vanderzwaag, *The Precautionary Principle and Marine Environmental Protection: Slippery Shores, Rough Seas, and Rising Normative Tides*, 33 OCEAN DEV. & INT'L L. 165, 170-73 (2002) [hereinafter Vanderzwaag, *Slippery Shores*].

<sup>7</sup> See e.g., Frank B. Cross, *Paradoxical Perils of the Precautionary Principle*, 53 WASH. & LEE L. REV. 851 (1996); Christopher D. Stone, *Is There a Precautionary Principle?*, 31 Env'tl. L. Rep. (Env'tl. L. Inst.) 10,790 (2001); John D. Graham, *The Role of Precaution in Risk Assessment and Management: An American's View*, Address Before the The European Commission, the US Mission to the EU, the German Marshall Fund with the European Policy Centre and the Center for Environmental Solutions (Jan. 11-12, 2002), [www.whitehouse.gov/omb/inforeg/eu\\_speech.html](http://www.whitehouse.gov/omb/inforeg/eu_speech.html) ("As you know, the US government supports precautionary approaches to risk management but we do not recognize any universal precautionary principle. We consider it to be a mythical concept, perhaps like a unicorn.").

narrow the scope of the principle. In other words, those aspects of the principle that remain uncertain—"slippery" in Professor Vanderzwaag's words<sup>8</sup>—have been systematically pushed in the direction of a weaker principle. Part II reinforces this point by examining as a whole four key statements of the principle. At this level also, the precautionary principle shows a consistent pattern of being tamed. Specifically, the precautionary principle no longer reflects a hazard paradigm of environmental regulation; it now represents a very different risk paradigm.

At this summer's World Summit on Sustainable Development ("WSSD") in Johannesburg, the international community had an opportunity to evaluate this trend and to explore what, if anything, the precautionary principle adds to environmental policy and the role that it should play in sustainable development, the overarching environmental paradigm that was the focus of the Johannesburg discussions. The Johannesburg Summit, however, addressed other aspects of sustainable development, implicitly acquiescing in a compromised precautionary principle. Part III concludes the Article with a brief discussion of the roles that a revitalized precautionary principle might play in environmental law and policy.

## I. THE CHANGING ELEMENTS OF THE PRECAUTIONARY PRINCIPLE

One of the principal criticisms of the precautionary principle is its indefiniteness. There are many versions of it and none gives explicit direction for individual cases.<sup>9</sup> While the Rio version quoted above is as convenient

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<sup>8</sup> Vanderzwaag, *Slippery Shores*, *supra* note 6, at 166-70. See also David Vanderzwaag, *The Precautionary Principle in Environmental Law and Policy: Elusive Rhetoric and First Embraces*, 8 J. ENVTL. L. & PRAC. 355, 358 (1999) (suggesting a "spectrum of embraces" from passionate to cool) [hereinafter Vanderzwaag, *First Embraces*]. Both Trouwborst and Hohmann recognize the existence of significant variation. See HOHMANN, *supra* note 3, at 335-40 (describing "relativity" regarding form of the source of law, time, and region); Trouwborst, *supra* note 2, at 286; HOHMANN, *supra* note 3, at 335-40 (describing "relativity" regarding form of the source of law, time, and region).

<sup>9</sup> Even generally sympathetic commentators have noted this problem. Mark Geistfeld, *Implementing the Precautionary Principle*, 31 Env'tl. L. Rep (Env't. L. Inst.) 11,326, 11,326 (2001).

and authoritative a single text as there is, most international instruments develop their own unique language as the result of negotiation over the particular issue at hand. Arie Trouwborst's comprehensive study of the evolution and status of the precautionary principle in international law found references in fifty-three legally binding instruments and forty-five non-binding instruments, in addition to individual states', commentators', and nongovernmental organizations' statements of the principle.<sup>10</sup> Some recent treaties have either explicitly referenced or incorporated the Rio formulation, but it is too early to see a trend toward adoption of a single version. The precautionary principle is, and is likely to remain for some time, embodied in several different verbal expressions.

A. *Elements of the Precautionary Principle*

Notwithstanding a certain amount of American hand-wringing about the many versions of the precautionary principle,<sup>11</sup> it is perfectly possible to make sense out of the numerous formulations of the precautionary principle by breaking it down into elements and charting the variation within those elements. I count four:<sup>12</sup>

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<sup>10</sup> Many of these are collected in HOHMANN, *supra* note 3.

<sup>11</sup> This state of affairs is apparently very disconcerting for American critics of the precautionary principle, surprisingly so because this is exactly how the common law has developed in the fifty states. To take a familiar example, adverse possession has fifty different expressions in as many state courts, and yet property teachers have never had much difficulty distilling a number of key elements (entry and exclusive possession; open and notorious occupation; hostile occupation; and continuous, uninterrupted possession over the entire limitations period), which individual states either use or not and each of which they interpret in different ways. WILLIAM B. STOEBUCK & DALE A. WHITMAN, *THE LAW OF PROPERTY* 853-60 (3d ed. 2000). The Rule Against Perpetuities was presumably similarly diffuse until John Chipman Grey developed a generalized statement of the elements of the rule ("[n]o interest is good . . ."), which has over time come to dominate the field, *id.* at 118-25—just as the Rio formulation may one day.

<sup>12</sup> John S. Applegate, *The Prometheus Principle: Using the Precautionary Principle to Harmonize the Regulation of Genetically Modified Organisms*, 9 IND. J. GLOBAL LEGAL STUD. 207, 249-55 (2001) [hereinafter Applegate, *Prometheus Principle*]; John S. Applegate, *The Precautionary Preference: An American Perspective on the Precautionary Principle*,

- The *trigger* is the initial degree and certainty of future harm (i.e., the danger) that justifies a regulatory response. It incorporates two sub-elements: the seriousness of the anticipated harm, and the quantity and quality of the information on the basis of which harm is foreseen. Both of these, obviously, are susceptible of significant variation.
- The *timing* is the relationship between the initial understanding of the hazard (the trigger) and the taking of regulatory action. The temporal relationship tells regulators how to manage uncertainty, the defining characteristic of many environmental problems. It is designed to permit or require regulatory action before uncertainties are resolved, and it is the core purpose of the precautionary principle.<sup>13</sup> It goes beyond prevention of known risks (e.g., requiring

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6 HUM. & ECOL. RISK ASSESSMENT 413, 415-20 (2000) [hereinafter Applegate, *Precautionary Preference*]. Sandin identifies four "dimensions"—threat, uncertainty, action, and command—and he measures each dimension along a spectrum of precision and strength. Per Sandin, *Dimensions of the Precautionary Principle*, 5 HUM. & ECOL. RISK ASSESSMENT 889, 890-95 (1999). Vanderzwaag identifies seven areas in which the precautionary principle is "slippery," many of which overlap the elements proposed here. Vanderzwaag, *Slippery Shores*, *supra* note 6, at 166-70. Other efforts to identify and characterize elements of the precautionary principle include Boutillon *supra* note 4, at 447-51; Andrew Jordan & Timothy O'Riordan, *The Precautionary Principle in Contemporary Environmental Policy and Politics*, in PROTECTING PUBLIC HEALTH AND THE ENVIRONMENT: IMPLEMENTING THE PRECAUTIONARY PRINCIPLE 23-29 (Carolyn Raffensperger & Joel A. Tickner, eds., 1999) [hereinafter PROTECTING PUBLIC HEALTH]; Tim O'Riordan & James Cameron, *Introduction* to INTERPRETING THE PRECAUTIONARY PRINCIPLE, 17-18 (Tim O'Riordan & James Cameron, eds., 1994) [hereinafter INTERPRETING THE PRECAUTIONARY PRINCIPLE]; HOHMANN, *supra* note 3, at 189-203; Deborah Katz, *The Mismatch Between the Biosafety Protocol and the Precautionary Principle*, 13 GEO. INT'L ENVTL. L. REV. 949, 956-57 (2001). See also Juli Abouchar, *The Precautionary Principle in Canada: The First Decade*, 32 Env'tl. L. Rep. (Env'tl. L. Inst.) 11,407, 11,108 (2002) (describing the issues that arise in implementing the precautionary principle).

<sup>13</sup> David Freestone & Ellen Hey, *Origins and Development of the Precautionary Principle*, in THE CHALLENGE OF IMPLEMENTATION, *supra* note 4, at 12-13 [hereinafter Freestone & Hey, *Origins and Development*]. United Nations Secretary Annan's initiative for corporate responsibility, The Global Compact, includes "a precautionary approach to environmental challenges" and characterizes "prevention rather than cure" as the "key element of a

construction workers to wear hard hats) to anticipate as yet uncertain ones (e.g., endocrine disruption or the precise effects of climate change) where the causal relationship has yet to be firmly established.<sup>14</sup>

- Once the harm and uncertainty thresholds are met, the precautionary principle addresses the regulatory *response*.<sup>15</sup> The precautionary principle is frequently caricatured as requiring the regulator to ban or forgo an activity or technology altogether,<sup>16</sup> and sometimes it has been used to justify such action (for example, bans on genetically modified organisms (“GMO”s)). However, none of the texts speaks in such absolute terms. The precautionary principle embraces a range

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precautionary approach.” <http://65.214.34.30/un/gc/unweb.nsf/content/print.htm>.

<sup>14</sup> NICHOLAS DE SADELEER, ENVIRONMENTAL PRINCIPLES: FROM POLITICAL SLOGANS TO LEGAL RULES 91 (2002) (characterizing precaution as “a genuine paradigm stuff”); TROUWBORST, *supra* note 3, at 36–43 (distinguishing prevention and precaution). Professor Geistfeld reconceptualizes the relationship between uncertainty and regulatory action as less about timing than about the distribution of the error costs between actor and potential victim:

Cases of scientific uncertainty therefore pose a particular type of distributive problem. In such cases, regulatory errors are inevitable, and someone must bear the associated costs. A regulatory approach based on the precautionary principle places the cost on those who directly benefit from the potentially hazardous activity, while seeking to minimize the impacts of uncertainty on these parties who might be physically injured.

Geistfeld, *supra* note 9, at 11,331. Cf. Carl F. Cranor, *Asymmetric Information, the Precautionary Principle, and Burdens of Proof*, in PROTECTING PUBLIC HEALTH, *supra* note 12, at 77–82 (discussing the problem in terms of asymmetric information). From this perspective, the command of the precautionary principle is not to abjure the technocratic tools of risk assessment and cost-benefit analysis, but to apply those tools using the values that potential victims—as opposed to actors—would reasonably choose. Geistfeld, *supra* note 9, at 11,333. This allocates the costs of uncertainty across classes of persons, just as the temporal conception allocates it across time.

<sup>15</sup> Sandin emphasizes the “if . . . then” nature of the elements. Sandin, *supra* note 12, at 891.

<sup>16</sup> See e.g., Ronald Bailey, *Precautionary Tale*, REASON, Apr. 1999, at 37; see also Applegate, *Prometheus Principle*, *supra* note 12, at 252 (describing caricatures).



of regulatory responses, taking into account a variety of factors (severity, cost, risk trade-offs) and a flexible degree of risk aversion.<sup>17</sup>

- Finally, because the precautionary principle justifies regulatory action on the basis of present uncertainty, the precautionary principle anticipates *iteration*. Action taken on the basis of uncertainty is necessarily tentative, and the principle thus implies that some action will be taken by someone to reduce the uncertainty to levels appropriate for taking final regulatory action. Different versions of the precautionary principle take different positions on whether returning to the question is mandatory or not and where lies the burden of proof, that is, who is to produce the new information, when it is to be produced, and how persuasive it must be.

In the Rio formulation, the trigger is represented by the phrase “*threats of serious or irreversible damage*.” Timing is described as “*lack of full scientific certainty* shall not be used as a reason for *postponing . . . measures to prevent*.” The expected response is “*cost-effective measures to prevent environmental degradation*.” Iteration is implied in the idea of “*full scientific certainty*,” because there will never be full scientific certainty, but certainty can be progressively approached. The Rio formulation is silent on burden of proof.

Since each version of the precautionary principle contains all or most of these elements, division into elements can be used to make sense of the many verbal formulations of the principle. The elements can also be used to track variation and change in the precautionary principle. By comparing different verbal formulations of the same element, we can see how the

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<sup>17</sup> See David Freestone & Ellen Hey, *Implementing the Precautionary Principle: Challenges and Opportunities*, in THE CHALLENGE OF IMPLEMENTATION, *supra* note 4, at 250-53 [hereinafter Freestone & Hey, *Implementation*]; Les Levidow et al., *Genetically Modified Crops in the European Union: Regulatory Conflicts as Precautionary Opportunities*, 3(3) J. RISK RES. 189 (2000); André Noellkaemper, “What You Risk Reveals What You Value,” and Other Dilemmas Encountered in the Legal Assaults on Risks, in THE CHALLENGE OF IMPLEMENTATION, *supra* note 4, at 77-79.

precautionary principle has evolved. While there is some artificiality to this piecemeal approach<sup>18</sup> (remedied, it is hoped, in Part II), it is also the case that each different version of the precautionary principle was negotiated word by word and element by element. Thus, each element will show the conflicts and pressures that influence the principle as a whole.

### B. *Changing Elements*

It is indisputable that considerable variety exists among the verbal formulations of the precautionary principle, and commentators have suggested a number of factors to explain the variation and, in particular, the variation in strictness. Arguably stronger versions are associated with instruments that are merely hortatory,<sup>19</sup> that reflect regional agreements among relatively homogenous states,<sup>20</sup> or that address particularly disfavored activities.<sup>21</sup> There is truth in each of these observations. With respect to the binding nature of the instrument, for example, the Vienna Convention on the Protection of the Ozone Layer contains a strong precautionary command, but it is only stated in the preamble, and the overall treaty is merely a framework to be followed by mandatory reductions.<sup>22</sup> The Rio Declaration contains a fairly moderate version, but it is a statement of goals; Agenda 21, Rio's blueprint for action, is nearly silent on the precautionary principle.<sup>23</sup>

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<sup>18</sup> See Sandin, *supra* note 12, at 896-98.

<sup>19</sup> Katz, *supra* note 12, at 965; Jonathan B. Wiener, *Precaution in a Multi-Risk World*, in HUMAN AND ECOLOGICAL RISK: THEORY AND PRACTICE 1509, 1521-24 (Dennis D. Paustenbach ed., 2002).

<sup>20</sup> HOHMANN, *supra* note 3, at 339-40.

<sup>21</sup> Katz, *supra* note 12, at 958-61 (discussing hazardous waste).

<sup>22</sup> Vienna Convention for the Protection of the Ozone Layer, Mar. 22, pmbl., S. TREATY DOC. NO. 99-9 (1985), reprinted in 26 I.L.M. 1516, 1529.

<sup>23</sup> Agenda 21, U.N. Conference on Environment and Development, ¶ 17.21, U.N. Doc. A/CONF.151/PC/100/Add.1 (1992), <http://www.un.org/esa/sustdev/agenda21text.htm>, [hereinafter Agenda 21] (advocating a "precautionary and anticipatory rather than a reactive approach . . . to prevent the degradation of the marine environment"). See also ¶ 22.5(c) (mentioning precaution).

Turning to geographic reach, the very strong North Sea,<sup>24</sup> Nordic Council,<sup>25</sup> and Bergen<sup>26</sup> Declarations' statements of the precautionary principle all reflect agreement primarily among northern European nations. The agreements are advisory and address a broadly recognized problem, marine pollution. Likewise, the strong Bamako Convention on the Importation of Hazardous Waste into Africa<sup>27</sup> was a regional reaction to the weaker but globally applicable Basel Convention on the transportation of hazardous waste (which does not even mention the precautionary principle).<sup>28</sup> The Rio Declaration, a global consensus document, is less strong than these regional agreements. Indeed, it almost goes without saying (it is practically a tautology) that the identity of the parties drafting the precautionary principle in a given instrument will have a great deal to do with the way that it is expressed. African states have a different perspective than the Organization for Economic Cooperation and Development ("OECD")<sup>29</sup> or the WTO.<sup>30</sup> The European Commission has a different perspective from its individual member governments, as the Commission is primarily concerned with economic

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<sup>24</sup> Declaration of the Second International Conference on the Protection of the North Sea, Nov. 25, 1987, ¶¶ VII, XVI, 27 I.L.M. 835, 838, 840-845 (1998) [hereinafter North Sea Declaration].

<sup>25</sup> Declaration of the Nordic Council's International Conference on Pollution of the Seas, Oct. 18, 1989, reprinted in INTERPRETING THE PRECAUTIONARY PRINCIPLE, *supra* note 12, at 268 [hereinafter Nordic Council Declaration].

<sup>26</sup> *Bergen Ministerial Declaration on Sustainable Development in the ECE Region*, [1990] 1 Y.B. Int'l Envtl. L. 429, ¶ 7, U.N. Doc. A/CONF.151/PC/10 [hereinafter *Bergen Declaration*].

<sup>27</sup> Bamako Convention on the Ban of Import into Africa and the Control of Transboundary Movement and Management of Hazardous Wastes Within Africa, Jan. 29, 1991, art. 4, ¶ 3(f)-(h), 30 I.L.M. 773, 781-82 (1991) [hereinafter Bamako Convention].

<sup>28</sup> Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal, U.N. Doc. EP/IG.80/3 (1989), reprinted in 28 I.L.M. 657 [hereinafter Basel Convention].

<sup>29</sup> OECD Council Recommendation on Integrated Pollution Prevention and Control, Jan. 31, 1991, C(90)164 (final), excerpted in TROUWBORST, *supra* note 2, at 334.

<sup>30</sup> This is reflected in case law and in the Agreement on the Application of Sanitary and Phytosanitary Measures, Apr. 15, 1994, available at <http://www.wto.org/english/tratope/spse.htm> [hereinafter SPS Agreement].

integration and is only indirectly affected by the strong green presence in many European electorates.<sup>31</sup>

Examining subject matter, the strong version of precaution that can be found in the Bamako Convention and the Cartagena Protocol on GMOs<sup>32</sup> both regulate activities that have raised particular concern in the international community. Agreements designed to encourage trade, by contrast, adopt a considerably weaker version of the principle.<sup>33</sup> Deborah Katz demonstrated that treaties dealing with hazardous waste consistently score in the stronger range among the elements of the precautionary principle.<sup>34</sup>

This Article suggests that there is, in addition, chronological variation among versions of the precautionary principle, reflecting continuing pressure to adopt a less stringent principle. Earlier versions of the precautionary principle contain elements that tend to increase its stringency, while later versions tend to be less strict.<sup>35</sup> Not surprisingly, this pattern is not perfectly realized in practice. The period during which the change occurs is quite limited. A survey of the most important instruments suggests that, while it clearly had antecedents, the precautionary principle began to be a standard part of environmental treaties only in the late 1980s.<sup>36</sup> The 1992 Rio Declaration (and the other Earth Summit treaties, the United Nations Framework Convention on Climate Change and the Convention on

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<sup>31</sup> See generally Boutillon, *supra* note 4, at 465-67 (discussing the formalization of the precautionary principle by the European Commission).

<sup>32</sup> Bamako Convention, *supra* note 27, art. 4(3)(f)-(h); Cartagena Protocol, *supra* note 2, arts. 10(6), 11(8).

<sup>33</sup> E.g., SPS Agreement, *supra* note 30, art. 2(2).

<sup>34</sup> Katz, *supra* note 12, at 957.

<sup>35</sup> Here again, Sandin's work is invaluable in defining elements (or "dimensions") of the precautionary principle and describing the range of stringency of each element. Sandin, *supra* note 12, at 890-95. As noted above, his definitions of the elements differ somewhat from the ones adopted here. Sandin measures both "strength" and "precision." *Id.* at 895-98.

<sup>36</sup> For surveys, see David Freestone & Ellen Hey, *Origins and Development*, *supra* note 13, at 3-15; James E. Hickey, Jr. & Vern R. Walker, *Refining the Precautionary Principle in International Environmental Law*, 14 VA. ENVTL. L.J. 423, 432-38 (1995); HOHMANN, *supra* note 3; Peter H. Sand, *The Precautionary Principle: A European Perspective*, 6 HUM. & ECOL. RISK ASSESSMENT 445, 445-46 (2000); TROUWBORST, *supra* note 2, annexes A, B; Vanderzwaag, *First Embraces*, *supra* note 8, at 363-72.

Biological Diversity) represented something of a turning point.<sup>37</sup> The precautionary principle gained greater salience in the international environmental lexicon in 1992, but, as a result, statements of the precautionary principle came under increased scrutiny from its critics. Thus, after Rio—which was itself a carefully compromised text—there is a discernible trend toward less strict versions of the precautionary principle. The chronological shift, therefore, occurs over a fairly short time and there are examples of anticipation and lag among individual elements. The overall trend, however, is plain enough.

### 1. Trigger

Early statements of the precautionary principle did little to define the kinds of anticipated harm that would trigger the precautionary principle. The Nordic Council International Conference on the Pollution of the Sea (1989) spoke simply of “damage or harmful effects,”<sup>38</sup> and the North Sea Declaration (1987) of “possibly damaging effects.”<sup>39</sup> By the time of the Rio Declaration, the principle is limited to “serious or irreversible damage.”<sup>40</sup> The contemporaneous Helsinki Declaration on Transboundary Watercourses and the Biodiversity Convention speak, respectively, of “significant adverse effect[s]”<sup>41</sup> and of “significant reduction or loss of biological diversity.”<sup>42</sup> The much later European Commission Communication on the precautionary principle requires uncertainty to be affirmatively demonstrated before the

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<sup>37</sup> TROUWBORST, *supra* note 3, at 28 (describing a “breakthrough” of the precautionary principle into international law).

<sup>38</sup> Nordic Council Declaration, *supra* note 25.

<sup>39</sup> North Sea Declaration, *supra* note 24, ¶ VII.

<sup>40</sup> Rio Declaration, *supra* note 1, princ. 15. *See also* United Nations Framework Convention on Climate Change, May 9, 1992, S. TREATY DOC. NO. 102-38 (1992), 1771 U.N.T.S. 108, *reprinted in*, 31 I.L.M. 849, art. 3(3), also a product of the Earth Summit [hereinafter Climate Change Convention]; *Bergen Declaration*, *supra* note 26.

<sup>41</sup> Convention on the Protection and Use of Transboundary Watercourses and International Lakes, Mar. 17, 1992, art. 2(1), 2(5)(a), 31 I.L.M. 1312 [hereinafter Transboundary Lakes Convention].

<sup>42</sup> Nairobi Convention on Biological Diversity, May 22, 1992, pmbl., 31 I.L.M. 818 [hereinafter Biodiversity Convention].

principle may be relied upon, though it sets the seriousness trigger at any level above the member state's desired level of protection for its citizens.<sup>43</sup>

The threshold amount of information also changes over time. The 1987 North Sea Declaration speaks of "possibly damaging" activities,<sup>44</sup> the 1991 resolution of the parties to the London Dumping Convention of "reason to believe" that cause and effect are related,<sup>45</sup> and the 1991 Bamako Convention simply "may cause."<sup>46</sup> Transitional formulations in 1992 include "reasonable grounds for concern" in the Convention for the Protection of the Marine Environment of the North-East Atlantic ("OSPAR"),<sup>47</sup> and a shift in language at the Earth Summit to "threats" of harm,<sup>48</sup> suggesting both greater severity and likelihood. Other early statements, including the 1987 Montreal Protocol, clearly require that some amount of investigation precede invocation of the principle.<sup>49</sup> By contrast, the European Commission in 2000

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<sup>43</sup> Communication from the Commission on the Precautionary Principle, COM(00)1 final at 16-17, available at [http://europa.eu.int/eur-lex/en/com/cnc/2000/com\\_2000-0001en01.pdf](http://europa.eu.int/eur-lex/en/com/cnc/2000/com_2000-0001en01.pdf) (Feb. 2, 2000) [hereinafter Commission Communication]. The member state's ability to set this level is not unlimited; it must be, among other things, nondiscriminatory and consistent with other domestic risk levels. *Id.* at 18.

<sup>44</sup> North Sea Declaration, *supra* note 24, ¶ VII.

<sup>45</sup> Resolution LDC 44(14) on the Application of the Precautionary Approach to Environmental Protection within the Framework of the London Dumping Convention, Dec. 30, 1991, excerpted in TROUWBORST, *supra* note 2, at 308 [hereinafter London Dumping Convention Resolution]. For the London Dumping Convention, see Convention for the Prevention of Marine Pollution by Dumping of Wastes and Other Matter, adopted Dec. 29, 1972, 26 U.S.T. 2403, 1046 U.N.T.S. 120, <http://sedac.ciesin.org/pidb/texts/marine.pollution.dumping.of.wastes.1972.html> [hereinafter London Dumping Convention].

<sup>46</sup> Bamako Convention, *supra* note 27, art. 3(f).

<sup>47</sup> Convention for the Protection of the Marine Environment of the North-East Atlantic, Sept. 22, 1992, art. 2(2)(a), 32 I.L.M. 1069, 1076 (1993), reprinted in TROUWBORST, *supra* note 2, at 310-11 [hereinafter OSPAR].

<sup>48</sup> Rio Declaration, *supra* note 1, princ. 15; Climate Change Convention, *supra* note 40, art. 3(3). This terminology was anticipated in the Bergen Declaration, *supra* note 26, and the Ministerial Declaration of the Second World Climate Conference, Nov. 7, 1990, princ. 7, available in 1 Y.B. Int'l Env'tl. L. 473 (1990), excerpted in TROUWBORST, *supra* note 3, at 333.

<sup>49</sup> For example, the Montreal Protocol on Substances that Deplete the Ozone Layer, Sept. 16, 1987, pmbl., 26 I.L.M. 1541, 1550-51 (1987), states unequivocally that the parties are "[d]etermined to protect the ozone layer by taking precautionary measures" and also that

repeatedly emphasized the need to perform a traditional risk assessment based on available information—"Before the precautionary principle is invoked, the scientific data relevant to the risks must first be evaluated."<sup>50</sup>—and the European Union ("EU") Treaty's adoption of the precautionary principle is qualified by the parallel requirement to rely on "available scientific and technical data."<sup>51</sup> Most recently, the Cartagena Protocol "takes as its starting point a risk assessment."<sup>52</sup> The repeated use of the word "scientific" in the latter instruments is not accidental: the parties want to define both a quantum of preexisting evidence and appropriate methods of proof.<sup>53</sup> Most commentators are in agreement that current law requires a demonstrated scientific basis for anticipating harms.<sup>54</sup>

## 2. Timing

If environmental regulation is to prevent harm before it occurs, regulators will usually need to take action despite incomplete information or understanding, especially of the scientific issues relating to causation and

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"measures taken to protect the ozone layer from depletion should be based on relevant scientific knowledge, taking into account technical and economic considerations."

<sup>50</sup> Commission Communication, *supra* note 43, at 13-14. *See also id.* at 3 (stating that the precautionary principle is mainly relevant to risk *management*, which follows risk assessment).

<sup>51</sup> Treaty Establishing the European Community, Mar. 25, 1957, art. 174(2),(3), 298 U.N.T.S. 11, *as amended by* Treaty of Amsterdam, Oct. 2, 1997, 1997 O.J. (C 340) 1, *reprinted in* 37 I.L.M. 56.

<sup>52</sup> Aarti Gupta, *Governing Trade in Genetically Modified Organisms: The Cartagena Protocol on Biosafety*, 42(4) ENV'T 23, 30 (May 2000) [hereinafter Gupta, *Governing Trade*].

<sup>53</sup> *See* SPS Agreement, *supra* note 30; Commission Communication, *supra* note 43 (discussing scientific factors throughout the document).

<sup>54</sup> *See, e.g.,* Nollkaemper, *supra* note 17, at 73, 83-84; John S. Gray, *Integrating Precautionary Scientific Methods into Decision-Making*, in THE CHALLENGE OF IMPLEMENTATION, *supra* note 4, at 133, 135. Other authors assert that a different kind of science—that is, "precautionary science," which is not based on traditional, mechanistic proof of cause and effect and whose results are not necessarily quantitative—is an appropriate basis for action. *See* Katherine Barrett & Carolyn Raffensperger, *Precautionary Science*, in PROTECTING PUBLIC HEALTH, *supra* note 12, at 106, 109-12, 117-18.

risk. The *raison d'être* of the precautionary principle is its particular temporal relationship between scientific certainty and regulatory action: action precedes certainty.<sup>55</sup> Most versions of the precautionary principle simply assume that uncertainty will exist in any circumstance to which the principle applies. The 2000 European Commission statement, on the other hand, makes this a specific prerequisite to the application of the precautionary principle. If examination of the existing science reveals a well characterized risk, the precautionary principle is no longer "relevant," and a final regulatory decision should be reached on the basis of the existing information.<sup>56</sup>

The nature of the uncertainty is also an issue. Early versions applied the precautionary principle when there was inadequate proof of a causal link, that is, in situations in which, potentially, the cure would not affect the disease at all.<sup>57</sup> The emphasis on action in the absence of proof of a causal link is nearly universal in earlier versions of the principle.<sup>58</sup> The 1987 Second North Sea Declaration adopts precaution in the absence of "absolutely clear scientific evidence," a state of affairs which is more or less universal in environmental law, and so provides very little limitation on the scope of the precautionary principle.<sup>59</sup> Later versions, which tend to speak of "full

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<sup>55</sup> See Geistfeld, *supra* note 9, at 11,328; Jordan & O'Riordan, *supra* note 12, at 23-29.

<sup>56</sup> Commission Communication, *supra* note 43, at 13.

<sup>57</sup> North Sea Declaration, *supra* note 24, ¶ VII; Nordic Council Declaration, *supra* note 25; Ministerial Declaration of the Third International Conference on the Protection of the North Sea, pmbl., Mar. 8, 1990, available in 1 Y.B. Int'l Envtl. L. 658, 662-73 (1990), excerpted in TROUWBORST, *supra* note 2, at 332 [hereinafter Hague Declaration]; Paris Convention for the Prevention of Marine Pollution from Land-Based Sources, Feb. 21, 1974, arts. 4(4), 11, 13 I.L.M. 352 [hereinafter PARCOM].

<sup>58</sup> Precautionary Approach to Marine Pollution, Including Waste-Dumping at Sea, U.N. Environment Programme, 15th Sess., Decision 15/27, (1990), excerpted in TROUWBORST, *supra* note 2, at 331; Nordic Council Declaration, *supra* note 25; PARCOM, *supra* 57; Hague Declaration, *supra* note 57, pmbl.; London Dumping Convention, *supra* note 45; OSPAR, *supra* note 47, art. 2(2)(a); North Sea Declaration, *supra* note 24, ¶ VII. See also Wingspread Statement on the Precautionary Principle, Jan. 25, 1998, reprinted in PROTECTING PUBLIC HEALTH, *supra* note 12, at 353-54.

<sup>59</sup> North Sea Declaration, *supra* note 24, ¶ VII. Sandin characterizes this as a very weak form of the precautionary principle, but I read it differently. Sandin, *supra* note 12, at 901.



scientific certainty”<sup>60</sup> seem designed to limit the precautionary principle to the fairly narrow range between a sufficiently developed trigger (described above) and the impossible dream of truly complete certainty. The SPS Agreement of 1993 and Cartagena Protocol of 2000 contemplate inadequate information<sup>61</sup> or “lack of . . . certainty due to insufficient scientific information,”<sup>62</sup> suggesting that a practical regulatory meaning of complete information is contemplated. That is, if adequate information is within grasp—by doing more risk assessment studies, for example—then the precautionary principle would not be applicable.

Different formulations of precaution envision different relationships between the existence or finding of uncertainty and the obligation to take regulatory action.<sup>63</sup> Jonathan Wiener has identified three models.<sup>64</sup> The strongest *requires* restrictions in the face of uncertainty. That is, the overall burden of proving safety is on the risk creator. This is the defining characteristic of all licensing schemes (for example, for pesticides and pharmaceuticals),<sup>65</sup> but no actual version of the precautionary principle expressly requires it.<sup>66</sup> The middle-ground position is that uncertainty *justifies* regulatory action. This can be seen in the EU Treaty (“preventive

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<sup>60</sup> E.g., Rio Declaration, *supra* note 1, princ. 15; Bergen Declaration, *supra* note 26; Biodiversity Convention, *supra* note 42; Climate Change Convention, *supra* note 40, art. 3(3).

<sup>61</sup> SPS Agreement, *supra* note 33, art. 5(7).

<sup>62</sup> Cartagena Protocol, *supra* note 2, arts. 10(6), 11(8).

<sup>63</sup> Sandin calls this the “command dimension” and describes a spectrum from allowable, to justified, to recommended, to mandatory. Sandin, *supra* note 12, at 895.

<sup>64</sup> Wiener, *supra* note 19, at 1513-16.

<sup>65</sup> JOHN S. APPLGATE ET AL., THE REGULATION OF TOXIC SUBSTANCES AND HAZARDOUS WASTES 584-93 (2000).

<sup>66</sup> The North Sea Declaration, *supra* note 24, comes closest in referring to “a precautionary approach is necessary which may require action to control.” The introduction of “may,” however, makes it less than mandatory. Several commentators have advocated it, however. See, e.g., JOE THORNTON, PANDORA’S POISON: CHLORINE, HEALTH, AND NEW ENVIRONMENTAL STRATEGY 10, 246-49 (2000); David Santillo et al., *The Precautionary Principle in Practice: A Mandate for Anticipatory Preventative Action*, in PROTECTING PUBLIC HEALTH, *supra* note 12, at 47.

action *should* be taken”)<sup>67</sup> and, indirectly, in the Bamako Convention, which mandates “the precautionary principle to pollution prevention” rather than “a permissible emissions approach based on assimilative capacity assumptions.”<sup>68</sup> The most recent and by now best-established approach is that uncertainty does not justify *inaction*. This is the Rio formulation (“shall not be used as a reason for postponing” regulatory measures), and it also appears in the 1990 Bergen Declaration.<sup>69</sup> Perhaps the clearest statement of this position is the 2000 Cartagena Protocol, which holds that uncertainty “shall not prevent the Party from taking” regulatory action.<sup>70</sup>

### 3. Response

Critics of the precautionary principle often misrepresent its regulatory standard as unitary and draconian: to ban or forgo an activity or technology altogether. Neither the texts of the precautionary principle nor the writings of its advocates bear this out.<sup>71</sup> Bans may be appropriate in some cases, but in others it may mean process controls, field tests, limited periods of approval, pre-release testing, investigation of alternatives, or further research. Early versions of the precautionary principle did, however, look to eliminate or minimize potential threats to the environment,<sup>72</sup> much as the United States

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<sup>67</sup> Treaty Establishing the European Community, *supra* note 50, art. 174(2).

<sup>68</sup> Bamako Convention *supra* note 27, art. 4(3)(f).

<sup>69</sup> *Bergen Declaration*, *supra* note 26. See also Second World Climate Conference, *supra* note 48; Biodiversity Convention, *supra* note 42, pmbl.; Climate Change Convention, *supra* note 40, art. 3(3); Agreement for the Implementation of the Provisions of the United Nations Convention on the Law of the Sea of 10 December 1982 Relating to the Conservation and Management of Straddling Fish Stocks and Highly Migratory Fish Stocks, U.N. GAOR, 6th Sess., art 6(2), U.N. Doc. A/CONF.164/37 (1995), <http://ods-dds-ny.un.org/doc/UNDOC/GEN/N95/274/67/PDF/N9527467.pdf?OpenElement> (last visited Feb. 26, 2003).

<sup>70</sup> Cartagena Protocol, *supra* note 2, arts. 10.6, 11.8, 39 I.L.M. at 1031-32.

<sup>71</sup> See, e.g., Freestone & Hey, *Implementation*, *supra* note 17, at 250-59; Levidow et al., *supra* note 17; Noellkaemper, *supra* note 17, at 77-79; Jordan & O’Riordan, *supra* note 12, at 25-26, 30.

<sup>72</sup> Nordic Council Declaration, *supra* note 25 (1989); Montreal Protocol to the Vienna Convention on Substances that Deplete the Ozone Layer, Montreal, Sept. 16, 1987, pmbl., 30 I.L.M. 541; Vienna Convention, *supra* note 22, (1985); *World Charter for Nature*, U.N.

Clean Water Act speaks of a goal of eliminating water pollution<sup>73</sup> or the Resource Conservation and Recovery Act ("RCRA") speaks of "minimizing" threats to human health and the environment.<sup>74</sup> The minimization language appears in subsequent instruments as well, including the Earth Summit treaties<sup>75</sup> and even the very recent Cartagena Protocol.<sup>76</sup>

By 1992, however, the acceptance of some optimal level of risk, usually determined by reference to costs and benefits, became common. Severity, cost, and risk tradeoffs do not appear in early conventions.<sup>77</sup> In 1991, however, the OECD spoke of "mitigating risk," that is, lowering but not reducing it,<sup>78</sup> and the Rio Declaration speaks of "cost-effective" measures to prevent harm.<sup>79</sup> Other treaties specify measures "commensurate" to the risk presented.<sup>80</sup> The European Commission insisted that responses be "proportionate"—both in the sense of benefits and costs (broadly understood) and of the desired level of protection—to the threat, based on a preliminary cost-benefit analysis.<sup>81</sup> The use of the term "as appropriate" in the relevant section of the Cartagena Protocol also suggests proportionality.<sup>82</sup>

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GAOR, 37th Sess., Annex, Agenda Item 21, princ. 11, 22 I.L.M. 455.

<sup>73</sup> 33 U.S.C. §§1251(a)(6),(b), 1311(b)(2)(A) (2000). This was always a goal, never a mandate.

<sup>74</sup> 42 U.S.C. §6924(m)(1)(2000); *See Hazardous Waste Treatment Council v. EPA*, 886 F.2d 355, 361 (D.C. Cir. 1989) (holding that "minimize" refers to an even lower risk level than the "acceptable" level).

<sup>75</sup> Biodiversity Convention, *supra* note 42; Climate Change Convention, *supra* note 40.

<sup>76</sup> Cartagena Protocol, *supra* note 2, arts. 10.6, 11.8.

<sup>77</sup> *E.g.*, Transboundary Lakes Convention, *supra* note 41 (1992); Biodiversity Convention, *supra* note 42 (1992); OSPAR, *supra* note 47 (1992); Bamako Convention, *supra* note 27, (1991).

<sup>78</sup> OECD Council Recommendation, *supra* note 29.

<sup>79</sup> Rio Declaration, *supra* note 1, princ. 15. Agenda 21, *supra* note 23, the action plan appended to the Rio Declaration, speaks of response actions "which are justified in their own right." Presumably this is an oblique reference to the cost-effectiveness standard. *Id.* ¶ 35.3. Further, Rio acknowledged the relevance of development needs ("according to their capacities") as a limitation on the appropriate response. Rio Declaration, *supra* note 1, princ. 15. *See also* Second World Climate Conference, *supra* note 48.

<sup>80</sup> Climate Change Convention, *supra* note 48; Montreal Protocol, *supra* note 49.

<sup>81</sup> Commission Communication, *supra* note 43, at 4-5, 18-20.

<sup>82</sup> *See* Steve Charnovitz, *The Supervision of Health and Biosafety Regulation by World Trade*

#### 4. Iteration

Early versions of the precautionary principle were silent on the question whether, by taking action on the basis of present uncertainty, regulatory authorities are obliged to revisit their decisions as new information becomes available. The 1985 Vienna Convention for the Protection of the Ozone Layer is a notable, and interesting, exception.<sup>83</sup> A framework treaty that was structured to be progressively implemented by subsequent protocols, it very much looks to future regulatory action. Its preamble states that parties are,

determined to protect the ozone layer by taking precautionary measures . . . with the ultimate objective of their [i.e., ozone-depleting substances] elimination *on the basis of developments in scientific knowledge*, taking into account technical and economic considerations.<sup>84</sup>

The Convention clearly anticipates that increasing knowledge and technology will indicate further reductions (rather than increases) in ozone-depleting substances, as has in fact happened. To implement this expectation, the Convention anticipates regularly returning to the currently uncertain questions for further action.

Immediately subsequent versions of the precautionary principle did not follow this lead, presumably because they concentrate on the present, and the need to take regulatory action under uncertainty dominates the present. Since a core function of the precautionary principle is to justify regulatory action in the face present uncertainty, such action is necessarily somewhat

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*Rules*, 13 TUL. ENVTL. L.J. 271, 298-301 (2000).

<sup>83</sup> In addition, the OECD Council Recommendation on Water Resource Management Policies: Integration, Demand, Management, and Groundwater Protection, C(89)12 (final), pt. VII(19), *reprinted in*, BASIC DOCUMENTS OF INTERNATIONAL ENVIRONMENTAL LAW Doc. 30e, (Harold Hohmann ed. 1992), speaks of "interim protection measures to proceed concurrently with further research."

<sup>84</sup> Vienna Convention, *supra* note 22, pmbl. (emphasis added).

tentative, as further understanding may well reveal it to be too strict or too lenient.<sup>85</sup> Structurally, then, iteration has always been implicit in the precautionary principle. The post-Rio, trade-related SPS Agreement first made it explicit:

In cases where relevant scientific evidence is insufficient, a Member may *provisionally* adopt sanitary or phytosanitary measures on the basis of available pertinent information . . . . In such circumstances, Members *shall seek to obtain the additional information* necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly *within a reasonable period of time*.<sup>86</sup>

Likewise, the European Commission requires precautionary measures to be “periodically reviewed” in light of available scientific information. The recent Cartagena Protocol is similarly structured, but it does not use the term “provisional” and gives no indication of a time limit. The common feature of all of these variations is that the precautionary principle anticipates revisiting judgments based on it. Uncertainty may be unavoidable, but it is not desirable.<sup>87</sup>

The placement of the burden of proof in producing and evaluating the new information is a separate question. Many observers had inferred from the timing element that the proponent of an activity or technology bears the

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<sup>85</sup> Geistfeld calls these wrong guesses the error costs of regulating uncertainty, and the precautionary principle’s function is to allocate the error costs between risk creators and potential victims. Geistfeld, *supra* note 9, at 11,331.

<sup>86</sup> SPS Agreement, *supra* note 30, art. 5.7 (emphasis added).

<sup>87</sup> Two recent American studies of risk assessment and management have recommended an iterative or cycling process of investigation, regulation, and learning. 2 PRESIDENTIAL/CONG. COMM’N ON RISK ASSESSMENT AND MGMT., RISK ASSESSMENT AND RISK MANAGEMENT IN REGULATORY DECISION-MAKING 7, 32 (1997); NAT’L RESEARCH COUNCIL, UNDERSTANDING RISK: INFORMING DECISIONS IN A DEMOCRATIC SOCIETY 163-64. See also Bradley C. Karkkainen, *Toward a Smarter NEPA: Monitoring and Managing Government’s Environmental Performance*, 102 COLUM. L. REV. 903, 938-42 (2002) (advocating mandatory post-decision monitoring of environmental effects).

burden of proving its safety.<sup>88</sup> The more recent statements of the precautionary principle, however, take the opposite view. The SPS Agreement states that it is the regulator's responsibility to justify continued restrictions. The European Commission declares that precautionary measures themselves "may assign responsibility for producing the scientific evidence necessary for a comprehensive risk evaluation," thus retaining the preexisting burdens of proof, for instance, on manufacturers of drugs but not of industrial chemicals.<sup>89</sup>

## 5. Conclusion

By breaking the precautionary principle down into its constituent elements, we can better see how its requirements have changed over time. None of the factors that have been proposed to explain the variation in the precautionary principle—degree of obligation, geographic or political scope, type of activity, differing authors, chronology—explains all the data

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<sup>88</sup> The timing element in effect places the initial burden of demonstrating some degree of certainty on the proponent of the activity or technology, because without such a demonstration precautionary action may be taken. See Margo Brett Baender, *Pesticides and Precaution: The Bamako Convention as a Model For An International Convention on Pesticides Regulation*, 24 N.Y.U. J. INT'L L. & POL. 557, 588 (1991); Cranor, *supra* note 14, at 74, 86-96; PROTECTING PUBLIC HEALTH, *supra* note 12, 1-11; Jordan & O'Riordan, *supra* note 12, at 24-25; David Ozonoff, *The Precautionary Principle as a Screening Device*, in PROTECTING PUBLIC HEALTH, *supra* note 12, at 100, 101-04. See also HOHMANN, *supra* note 3, at 334-35 (burden shifting represents the "strong version" of the Precautionary principle). For arguments pro and con see TROUWBORST, *supra* note 3, 14-15 (2002). No serious advocate of the precautionary principle, however, suggests that the proponent of the activity must conclusively demonstrate a zero risk of harm. The European Commission, on the other hand, requires the regulator to demonstrate uncertainty as a prerequisite to application of the precautionary principle.

The silence on burden of proof in the Rio and most other formulations, as well as the idea that the precautionary principle operates as a "reason" for not "postponing" regulatory action, might suggest that the precautionary principle relates only to timing and that it otherwise functions within an existing framework of burdens of proof. It cannot be said, therefore, that reversal of the burden of proof is necessarily part of the precautionary principle as actually adopted.

<sup>89</sup> Commission Communication, *supra* note 43, at 20-22.

perfectly; there are counter-examples to each. Nevertheless, an examination of these factors demonstrates that the direction of the change is broadly consistent. In each element, strong requirements have been replaced by weaker ones which add prerequisites, that moderate responses, or require revisitation of regulation. Further, this change reflects a persistent, announced, and often successful effort by the United States and economic interests to tame what they regard as an unruly, unpredictable<sup>90</sup> standard which can be and has been used to justify inefficient, protectionist, misguided, and even perverse regulatory action.<sup>91</sup>

## II. FROM HAZARD TO RISK

If the first criticism of the precautionary principle is its indefiniteness, the second criticism is the supposed rigidity that leads to irrational and counterproductive results.<sup>92</sup> “When in doubt, ban it” is the repeated caricature, and commentators have asserted that its application would have doomed useful and life-saving products like penicillin. As we have seen, this *is* a caricature of the precautionary principle, though there are examples of the principle being deployed with little regard to its consequences, for example, in Zambia’s refusal to accept genetically modified crops to feed its starving population.<sup>93</sup> There is some tension between the two criticisms—if it is so undefined, how can it be so rigid? if there is nothing there, why is it such a dangerous idea?—but they are also related in an important way. The multiple versions of the precautionary principle bespeak considerable flexibility in expressing and interpreting it, and that flexibility can be exploited to moderate its effects. It is precisely because of its malleability that the

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<sup>90</sup> Aarti Gupta, *Advance Informed Agreement: A Shared Basis for Governing Trade in Genetically Modified Organisms?*, 9 IND. J. GLOBAL LEGAL STUD. 265, 265-66 (2001) [hereinafter Gupta, *Advance Informed Agreement*].

<sup>91</sup> E.g., Gail Charnley & E. Donald Elliott, *Risk Versus Precaution: Environmental Law and Public Health Protection*, [2002 Transfer Binder] 32 ENVTL. L. REP. (Envtl. L. Inst.) 10,363, 10,364-66; Cross, *supra* note 7; Graham, *supra* note 7; Wiener, *supra* note 19, at 1518-21.

<sup>92</sup> *Id.*

<sup>93</sup> 32 ENVTL. L. REP. (Envtl. L. Inst.) Update No. 25 (Sept. 9, 2002); Marc Lacey, *Engineering Food for Africans*, N.Y. TIMES, Sept. 8, 2002, [http://ipm.osu.edu/trans/092\\_081.htm](http://ipm.osu.edu/trans/092_081.htm).

precautionary principle finds itself in the position of being reinterpreted and tamed.

While the change has occurred at the elemental level, as we have seen, it also occurs, perhaps more importantly, at the level of complete statements of the principle. Per Sandin, who also analyzed the precautionary principle by dividing it into four elements, notes that weakness or imprecision in *one* element determines the *overall* weakness or imprecision of a particular formulation of the principle. It is thus a mistake, he warns, to look at each element in isolation; rather, one must look at the combination of all of the elements in a particular version of the principle.<sup>94</sup> Sandin's point is well taken, insofar as he is describing the overall effect of choices of wording for each element, and this Part adopts his recommended methodology. The holistic methodology has the added advantage of allowing us to see in the changes in the precautionary principle the reflection of a more fundamental change in the way that environmental dangers are regulated.

The nature of the fundamental change is familiar to students of environmental law. I will adopt Lakshman Guruswamy's labels—"hazard" *versus* "risk"—and his succinct description of the difference:

While used interchangeably in common parlance, "risk" and "hazard" have distinct meanings in the risk analysis literature. "Hazard" is the intrinsic potential of an agent to cause an adverse effect, whereas "risk" is the likelihood and magnitude of the adverse effect occurring under real-world exposure scenarios. While many earlier regulatory decisions were based on hazard identification, there has been increasing realization that a fuller characterization of risk usually provides a better basis for making regulatory decisions.<sup>95</sup>

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<sup>94</sup> Sandin, *supra* note 12, at 896-98.

<sup>95</sup> Lakshman D. Guruswamy, *Sustainable Agriculture: Do GMOs Imperil Biosafety?*, 9 IND. J. GLOBAL LEGAL STUD. 461, 484 (2002). Joe Thornton describes a Risk Paradigm and an Ecological Paradigm, which roughly correspond to the risk and hazard paradigms here. THORNTON, *supra* note 66, at 7-13.



Guruswamy's distinction is particularly useful because he developed it to describe international legal reactions to GMOs, an area dominated by the precautionary principle, or at least precautionary rhetoric. He also recognizes the general movement from hazard to risk in regulatory decision making. So, to use Guruswamy's terminology, this Article now traces the evolution of the precautionary principle from hazard to risk by examining four complete, influential expressions of the precautionary principle.

### A. *The Hazard Paradigm*

#### 1. Hazard-Based Precaution

Guruswamy observes that the precautionary principle, "at least as defended by some of its strongest proponents, would appear to be directed at hazard, as opposed to risk, by calling for precautionary measures once some indicia of hazard exist."<sup>96</sup> The hazard paradigm tends to view new technologies and large-scale human activities as derangements of the environmental status quo, with unforeseeable and frequently negative consequences for human health and the environment.<sup>97</sup> Accordingly, the hazard paradigm is determined to minimize, rather than optimize, environmental harm.<sup>98</sup> It represents a high degree of risk aversion<sup>99</sup> and rejects an approach that attempts to derive a "correct" or efficient level of harm from factors like costs, benefits, and comparison of other risks. The hazard paradigm does not aspire to a zero-risk world (a favorite accusation by its critics). That is impossible, of course, and many obviously desirable technologies—prescription drugs, for example—have associated risks.

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<sup>96</sup> Guruswamy, *supra* note 95, at 484. He characterizes this version of the precautionary principle as "a major leap backward." *Id.*

<sup>97</sup> *E.g.*, THORNTON, *supra* note 66, at 9-17, 343-49.

<sup>98</sup> HOHMANN, *supra* note 3, at 11. Skeptics of the precautionary principle urge just the reverse. *See e.g.*, Wiener, *supra* note 19, at 1524.

<sup>99</sup> Pearce, *The Precautionary Principle and Economic Analysis*, in INTERPRETING THE PRECAUTIONARY PRINCIPLE, *supra* note 12, at 132.

Rather, the goal is to keep technological risks to the lowest possible level, usually by avoiding the product or activity of concern.

The determination to minimize and avoid harm has two bases. The first and more important is the recognition of the limitations of present science and knowledge as they relate to environmental causes and effects. Professor Plater puts it this way:

Unless you are pretty sure that the background foundational equilibria will not be disrupted, or that the negative consequences will be foreseeable, minor, and mitigatable, you had better be sure that what you proposed to do is worth the potential costs; it is safer not to risk casually the escalating domino consequences that may follow. In this regard Carson showed that moving from a human-centered, master-of-nature perspective to the holistic, human-species-as-constituent-part-of-nature is not just an ethical idea, it is fundamentally practical and utilitarian as well.<sup>100</sup>

Theo Colborn, in her indictment of hormone-disrupting chemicals, explains:

This caution does not arise from any propensity for pessimism or dislike of technology. It arises from the very nature of our global experiment and from our inescapable ignorance, which makes it impossible to foresee consequences or guarantee safety. The dilemma is simply stated: the Earth did not come with a blueprint or an instruction book. When we conduct experiments on a global scale by releasing billions of pounds of synthetic chemicals, *we are tinkering with immensely complex systems that we will never fully comprehend*. If there is a lesson in the ozone hole and our experience with

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<sup>100</sup> Zygmunt J.B. Plater, *From the Beginning, A Fundamental Shift of Paradigms: A Theory and Short History of Environmental Law*, 27 LOY. L.A. L. REV. 981, 1000 (1994).

hormone-disrupting chemicals, it is this: as we speed toward the future, we are flying blind.<sup>101</sup>

Our basic understanding of the cause-and-effect relationships in the environment and human health is weak enough. Complexity and non-linear, unpredictable effects in a system in which everything is connected to everything else generate a fundamental, irreducible uncertainty.<sup>102</sup> It is a dangerous mistake, in this view, to attempt to "fine tune" regulatory measures to achieve optimally efficient or optimally risky levels of protection.<sup>103</sup> Whatever other faults such an approach might have,<sup>104</sup> its precision is illusory, and the process of elaborately considering costs, benefits, and countervailing risks is really the process of compromising human health and the environment.

The second reason for minimization and avoidance is a degree of technological pessimism,<sup>105</sup> Colborn's statement to the contrary notwithstanding. The enormous potency of twentieth century technologies—nuclear and fossil-fuel energy, ozone-depleting substances, synthetic organic pesticides—degraded the environment and threatened human health on a global scale. The effects cannot be easily or quickly reversed, and some, like nuclear waste, seem intractable. This is not some kind of neo-Luddism; it is simply *skepticism* of new technologies that have harmful potential.

It follows from the goal of minimizing harm and the recognition of uncertainty that hazard-based precaution accepts error on the side of

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<sup>101</sup> THEO COLBORN ET AL., OUR STOLEN FUTURE 242-43 (1997) (emphasis added). Aldo Leopold used a characteristically homely image: "To keep every cog and wheel as the first precaution of intelligent tinkering." *Id.* (emphasis added).

<sup>102</sup> O'Riordan & Cameron, *supra* note 12, at 5.

<sup>103</sup> Santillo et al., *supra* note 66, at 37-39; Malcolm MacGarvin, *Precaution, Science and the Sin of Hubris*, in INTERPRETING THE PRECAUTIONARY PRINCIPLE, *supra* note 12.

<sup>104</sup> And they are many. See Howard Latin, *Good Science, Bad Regulation, and Toxic Risk Assessment*, 5 YALE J. ON REG. 89 (1988); Howard Latin, *Ideal Versus Real Regulatory Efficiency: Implementation of Uniform Standards and "Fine-Tuning" Regulatory Reforms*, 37 STAN. L. REV. 1267 (1985).

<sup>105</sup> Applegate, *Prometheus Principle*, *supra* note 12, at 214-15.

overprotection as preferable to the reverse. It prefers the avoidance of new technologies and activities that have some likelihood of generating such harm.<sup>106</sup> Preventing harm before it occurs is also a practical justification for precaution—it's hard to get the toothpaste back into the tube, or the CFCs out of the stratosphere. As a result, the central principle of precautionary action is early regulatory action, in advance of scientific certainty, to restrict the proposed activity or to give it thorough consideration, or both. The strongest versions of the precautionary principle would place the burden of proof of safety on the proponent of a technology or activity. Under uncertainty, the advocate of endangering the status quo should demonstrate the wisdom of so doing.

The foregoing is a sketch of an approach that has been elaborated elsewhere in great detail. One qualification, therefore, needs to be repeated: the hazard paradigm does not reject all new technology regardless of large potential benefits (penicillin, an AIDS vaccine) or small potential risks. The world is full of technology and technological innovation, and life expectancy and quality of life are, in most (but not all) of the world, at levels that were inconceivable a century or two ago. Rather, the hazard paradigm casts a skeptical eye on new technologies with largely economic benefits and with a potential for serious, widespread damage. New technologies may be the savior or the scourge of the globe. Given plausible reasons for concern, the hazard paradigm asks for some assurance that it is the former before we are irretrievably committed to accepting the latter.

## 2. The Bamako Convention

The Bamako Convention on the Ban of Import into Africa and the Control of Transboundary Movement and Management of Hazardous Wastes within Africa<sup>107</sup> was signed in 1991 as a reaction to the perceived weakness of the earlier Basel Convention on the Control of Transboundary Movements

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<sup>106</sup> Thornton characterizes this as a "well-founded suspicion with a body of circumstantial evidence to back it up." THORNTON, *supra* note 66, at 113.

<sup>107</sup> Bamako Convention, *supra* note 27.

of Hazardous Wastes and their Disposal.<sup>108</sup> Many critics of the Basel Convention, which had widespread support among industrialized nations, thought that it in effect invited industrialized nations to export hazardous waste to less developed nations, because it only required prior informed consent. The Bamako Convention sought to remedy that weakness: "[A]ll Parties shall take appropriate legal, administrative, and other measures . . . to prohibit the import of all hazardous wastes, for any reason, into Africa from non-Contracting Parties. Such import shall be deemed illegal and a criminal act."<sup>109</sup>

The blanket prohibition on importation was followed by a precautionary approach to the management of existing waste:

Each Party shall strive to adopt and implement the preventive, precautionary approach to pollution problems which entails, inter-alia, preventing the release into the environment of substances which may cause harm to humans or the environment without waiting for scientific proof regarding such harm. The parties shall cooperate . . . to implement the precautionary principle to pollution prevention . . . rather than the pursuit of a permissible emissions approach based on assimilative capacity assumptions . . . .<sup>110</sup>

Even though it has not yet entered into force, the Bamako Convention is important because it represents a strongly protective environmental treaty that originated in the developing world. The exportation of hazardous waste from North to South is widely viewed—and universally viewed in the South—as a particularly egregious form of economic and environmental imperialism. Prohibited by their former colonies' independence from pillaging the former colonies' natural resources to enrich their own industries, the industrialized countries now use them as a low-cost resource for disposing of industrial wastes. In both cases, the North receives enormous economic benefit, and the

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<sup>108</sup> Basel Convention, *supra* note 28.

<sup>109</sup> Bamako Convention, *supra* note 27, art. 4(1)(f).

<sup>110</sup> *Id.* art. 4(3)(f).

South receives little benefit and much harm.<sup>111</sup> As a result, one can expect a South-sponsored treaty on this subject to be particularly aggressive.

Bamako invokes the hazard-based precautionary principle. Its trigger is the importation of hazardous wastes, "for any reason," into Africa.<sup>112</sup> Hazardous wastes are defined broadly by listing, characteristics, and national designation.<sup>113</sup> The convention triggers action against hazardous wastes *per se*, not in context. That is, it treats all such wastes as equally dangerous in themselves, rather than dangerous in different degrees or only under conditions of exposure to human beings at or above certain levels. Moreover, while there is some threshold of proof in the requirement that the substances be those which "*may cause harm* to humans or the environment,"<sup>114</sup> missing is the idea in weaker versions of the precautionary principle that regulatory action is justified only in advance of "full scientific certainty" (e.g., Rio Principle 15).<sup>115</sup> The "full certainty" language means that regulatory action will occur only when all that is missing is *full* certainty.<sup>116</sup> Because it does not contain this limitation, the Bamako version should be read to require a minimum of scientific evidence on which the timing decision is based, a further reflection of the hazard paradigm.

The timing requirement reinforces the hazard-based approach of the trigger. The language of Bamako's version of the precautionary principle speaks twice of prevention, that is, avoiding harm entirely before it is realized.<sup>117</sup> The temporal focus is further reflected in its particular formulation of the relationship between uncertainty and regulatory action:

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<sup>111</sup> Cheng Zheng-Kang, *Equity, Special Considerations, and the Third World*, 1 COLO. J. INT'L ENVTL. L. & POL'Y 57 (1990); Daniel Barstow Magraw, *The International Law Commission's Study of International Liability for Nonprohibited Acts as it Relates to Developing States*, 61 WASH. L. REV. 1041, 1049-51 (1986).

<sup>112</sup> Bamako Convention, *supra* note 27, art. 4(1).

<sup>113</sup> *Id.* art. 2.

<sup>114</sup> *Id.* art. 4(3)(f) (emphasis added).

<sup>115</sup> Rio Declaration *supra* note 1, princ. 15.

<sup>116</sup> The Rio version is thus quite weak in this respect, because "full scientific certainty" is a rarity in environmental regulation. Sandin *supra* note 12, at 892-94, 901.

<sup>117</sup> Bamako Convention, *supra* note 27, art. 4(3).

"without *waiting* for scientific proof."<sup>118</sup> The language, in other words, forcefully adopts the anticipatory approach that characterizes the strong version of the precautionary principle.<sup>119</sup>

The Bamako regulatory response is that the importation of hazardous waste into Africa is banned *period*. Indeed, it "shall be deemed illegal and a criminal act."<sup>120</sup> This, of course, is the strong form of the precautionary principle, based on the view that the only way to minimize the impact of hazardous waste is to avoid contact with it altogether. This view is reflected and underscored in Bamako's formal statement of the precautionary principle, which adopts "pollution prevention . . . rather than the pursuit of a permissible emissions approach based on assimilative capacity assumptions."<sup>121</sup> Minimization of harm is characteristic of the hazard paradigm, as is the clear rejection of an approach to risk that seeks to determine a particular level at which human beings and the environment can no longer tolerate additional exposure without unacceptable harmful effects.<sup>122</sup>

The convention does not entirely lend itself to the hazard-risk dichotomy. The response element is indeed strongly precautionary as it relates to importation of hazardous waste; however, the convention concerns itself equally with the management of hazardous waste generated in Africa. As to such wastes, the convention's standard is not an outright ban on generation, but rather a requirement that it be managed in an "environmentally sound" manner, meaning "taking all practicable steps to ensure" management "in a manner which will protect human health and the environment against the adverse effects which may result from such

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<sup>118</sup> *Id.* art. 4(3)(f) (emphasis added).

<sup>119</sup> Applegate, *Precautionary Preference*, *supra* note 12, at 417.

<sup>120</sup> Bamako Convention, *supra* note 27, art. 4(1). The treaty is open for membership only to members of the Organization for African Unity, arts. 22-23, so the absolute ban cannot be avoided by joining the convention, as in the Basel Convention.

<sup>121</sup> Bamako Convention, *supra* note 27, art. 4(3)(f).

<sup>122</sup> Ellen Hey, *The Precautionary Concept*, 4 GEO. INT'L ENVTL. L. REV. 303, 305 (1992) [hereinafter Hey, *Precautionary Concept*]; Santillo et al., *supra* note 66, at 37-38 (rejecting possibility that risks can be managed to precise "acceptable" levels).

wastes.”<sup>123</sup> While these are relatively strong statements (“effects which *may* result”), the practicability qualification is significant, especially in developing states where what is practicable may be extremely limited. Although it is still fair to regard the Bamako Convention, taken as a whole, as staking out the hazard-based approach to the precautionary principle, it is important to recognize that even here the precautionary principle represents less than absolute stringency. It is also noteworthy that the Bamako Convention has not yet entered into force, suggesting perhaps that enthusiasm for such strictness has waned over time.

The Bamako Convention is predictably silent on iteration, the relative newcomer to the precautionary principle. Iteration is an impossibility in connection with the importation ban, as the convention gives no suggestion that such a ban will be reconsidered at any time in the future, even if, for instance, a party were to develop the capacity to detoxify or store imported wastes in a demonstrably safe and secure manner. It can, however, be inferred from the familiar formulation, “without waiting for scientific proof regarding such harm,” in connection with waste management.<sup>124</sup> Amendments to the convention are expressly permitted, and the amendment provision strikingly parallels—or completes—this language in Bamako’s precautionary principle: “Such amendments shall take due account, *inter alia*, of relevant scientific, technical, environmental, and social considerations.”<sup>125</sup> This sentence implies, perhaps, an expectation that the main body of the treaty, as well as the annex listing specific wastes, will be revisited.<sup>126</sup> Moreover, even this version of the precautionary principle does not reject the idea of scientific proof; it is simply a rule about timing. By not rejecting the possibility of scientific proof either way, it leaves the door open for proof of safety. It is, however, open no more than a crack in the Bamako Convention, because the rejection of the assimilative capacity approach certainly suggests that the burden of proof lies with those who would demonstrate safety.

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<sup>123</sup> Bamako Convention, *supra* note 27, arts. 4(3)(d), 1(10) (definition).

<sup>124</sup> *Id.* art. 4(3)(f).

<sup>125</sup> *Id.* art. 17(1).

<sup>126</sup> Amendment of annexes is subject to article 17. *Id.* art. 18(2)(a).



The Bamako Convention, in sum, represents the hazard-based approach to the precautionary principle. In its absolute ban on the importation of hazardous waste into Africa and its rejection of the assimilative approach to management of hazardous waste generated in Africa, it embodies the view that hazards per se are to be avoided in order to minimize their effects on humans and the environment. The authorship and the pariah status of hazardous waste importation help to explain the adoption of a strong, hazard-based precautionary principle in the Bamako Convention.

### *B. The Risk Paradigm*

Risk-based precaution begins as a critique of the absolutism of the hazard paradigm, which creates "the potential for arbitrary, unfair, and inefficient regulations."<sup>127</sup> The growth of the risk paradigm has been traced in detail elsewhere,<sup>128</sup> so no more than highlights are presented here.

#### *1. The Rise of the Risk Paradigm*

The fundamental reason for the progressive replacement of the hazard paradigm by the risk paradigm was dissatisfaction with the hazard paradigm's bi-modal (on-off, safe-unsafe) approach to potential environmental harm. The recognition, for example, that many toxic chemicals have no discernible threshold at which they cease to have adverse effects led to the conclusion

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<sup>127</sup> Guruswamy, *supra* note 95, at 484. For sustained critiques of the precautionary principle along these lines, see sources cited in note 7, *supra*.

<sup>128</sup> DESADELEER, *supra* note 14, at 91 (tracing development from remedial action to prevention to precaution); SIDNEY A. SHAPIRO & ROBERT L. GLICKSMAN, RISK REGULATION AT RISK: RESTORING A PRAGMATIC APPROACH 3-13 (2003) [hereinafter SHAPIRO & GLICKSMAN]. John S. Applegate, *The Perils of Unreasonable Risk: Information, Regulatory Policy, and Toxic Substances Control*, 91 COLUM. L. REV. 261, 264-66 (1991) [hereinafter Applegate, *Perils*]; Donald T. Hornstein, *Reclaiming Environmental Law: A Normative Critique of Comparative Risk Analysis*, 92 COLUM. L. REV. 562, 565-84 (1992); Donald T. Hornstein, *Lessons from Federal Pesticide Regulation on the Paradigms and Politics of Environmental Law Reform*, 10 YALE J. ON REG. 369, 374-78 (1993) [hereinafter Hornstein, *Lessons*].

that a zero-risk standard was impossible to achieve in an industrial economy. In the United States, for example, Congress began to adopt legal standards that accept a greater-than-zero level of residual (i.e., post-regulation) risk, usually determined by considering social preferences, alternative risks, technical feasibility, and cost. As utilitarian-economic analysis increasingly came to dominate regulatory decision making, the overarching regulatory goal became achieving the most efficient (however defined) level of harm to humans and the environment. The hazard paradigm, in this view, deprives society of technologies and activities that have enormous net social value by simplistically abjuring anything that has dangers associated with it.

As Wiener argues in his contribution to this symposium, extreme risk aversion can be not only inefficient (we could put our resources to better effect elsewhere) but may also be perverse.<sup>129</sup> One need not accept all of Wiener's arguments to recognize the validity of his fundamental point that maintenance of the status quo itself involves risks to human health and the environment, and thus that both the choices to regulate and not to regulate create or accept certain risks.<sup>130</sup> To take the strongest case, the decision to approve a polio vaccine involves risks both ways, and so a no-risk goal is simply incoherent. Whether anyone other than a rhetorical straw man has ever actually imagined or advocated a risk-free world is doubtful, and the frequency of perverse results can be overstated. Nevertheless, it is clear, and the risk paradigm takes it as fundamental, that risk regulation cannot be reduced to simple, one-dimensional rules.

The risk paradigm is in this respect both a reaction against the hazard paradigm and a reflection of a strongly utilitarian (often economic) worldview.<sup>131</sup> The goal of the regulatory system is to *optimize*, rather than simply minimize, risk. As Professor Wiener puts it, one can observe in international environmental law "the move from the absolutist 'precautionary principle' toward a more pragmatic '*optimal precaution*' as precaution must

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<sup>129</sup> Wiener, *supra* note 19 at 1518-21. See also Cross, *supra* note 7.

<sup>130</sup> Wiener, *supra* note 19, at 1518-21. See also Cross, *supra* note 7.

<sup>131</sup> SHAPIRO & GLICKSMAN, *supra* note 128, at 8-11 ; John S. Applegate, *Worst Things First: Risk, Information, and Regulatory Structure in Toxic Substances Control*, 9 YALE J. ON REG. 277, 289-96 (1992).

confront the reality of a multi-risk world."<sup>132</sup> This starts with, but goes beyond, rejection of the zero-risk model. Some level of risk is to be *embraced* to achieve net social gains. Building tunnels and skyscrapers entail high degrees of risk, but on balance we are better off with than without them. Flexible plastic may pose carcinogenic and reproductive risks from the feed material and the plasticizer, respectively, but these plastics are essential for a myriad of useful purposes. There is little to be said for hazardous or radioactive waste as such, but they are the inevitable consequence of extremely useful activities that enhance wealth and well-being. Moreover, the case for optimizing risk can be made not only by comparing risk and wealth (quality of life) enhancement, but also in terms of risk reduction itself. The optimal level of risk is the lowest *net* risk, so even a fairly risky behavior is desirable if it reduces other risks even more. In this view, the cancer risks of chlorination by-products in drinking water, for example, are more than offset by the reduction in risks of bacterial infection (cholera, among others) from untreated water.<sup>133</sup>

The risk approach is undergirded by the utilitarian-economic view that decentralized, competitive markets are the best means of achieving these optimal solutions.<sup>134</sup> The commitment to market mechanisms may seem rather abstract, but in fact it is directly relevant. If the market determines and legitimates optimal risk choices, it follows that interference in the operation

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<sup>132</sup> Wiener, *supra* note 19, at 1524 (emphasis added).

<sup>133</sup> Susan W. Putnam & Jonathan Baert Wiener, *Seeking Safe Drinking Water*, in *RISK VS. RISK: TRADEOFFS IN PROTECTING HEALTH AND THE ENVIRONMENT*, 124-48 (John D. Graham & Jonathan Baert Weiner, eds. 1995). The same can be said of the DDT-malaria trade-off. Of course, these trade-offs can be—and often are—overdrawn. There may be—and often are—third alternatives (ozonation of drinking water, treated netting) that can avoid both risks. The existence of such alternatives is an empirical question in each case, and their desirability can also be measured by their net risk reduction. One purpose of the precautionary principle is to encourage the search for such alternatives. See Mary O'Brien, *Alternatives Assessment: Part of Operationalizing and Institutionalizing the Precautionary Principle*, in *PROTECTING PUBLIC HEALTH*, *supra* note 12, at 208-10; THORNTON, *supra* note 66, at 346-49.

<sup>134</sup> Hohmann argues that the original appearance of the precautionary principle represented the shift from an economic to an ecological basis of environmental law. HOHMANN, *supra* note 3, at 4-5, 10-12. In these terms, the principle is returning to the economic basis.

of the market should be minimized. The status quo of the risk paradigm is a market unencumbered by external regulation.<sup>135</sup> Regulation, not new technology, is the derangement, and so it is incumbent on such regulation to justify itself.<sup>136</sup> Moreover, when regulation is proposed, it must be tested by cost-benefit analysis to impose a kind of surrogate market discipline on regulators who are otherwise operating outside of the market. The goal is not, of course, to mimic the market for its own sake, but to pursue the general goal of efficient allocation of resources, measured in terms of satisfying individual wants.<sup>137</sup>

The risk paradigm also values a systematic approach to regulation that asks efficiency questions, generates data to answer them, and is ruled by such answers. A central element of this technocratic approach is what Donald Hornstein has called synopticism,<sup>138</sup> that is, examining all aspects of a problem thoroughly before reaching a decision that seeks to consider and make the best of all of its aspects. Such analysis, especially as it becomes more complex and fine-grained, requires the deployment of common metrics that quantify the relevant factors. Risk assessment and cost-benefit analysis, in fact, were developed to facilitate the shift from hazard-based regulation to risk-based regulation.<sup>139</sup> Likewise, the consideration of countervailing risks requires the identification and quantification of all intended and expected consequences (i.e., reduction of risk from the activity or product to be restricted), *as well as* second- and third-order consequences that may not be intuitively obvious or expected.

The risk approach, committed as it is to the market and to the tools of economic and risk analysis, is also founded on a strong technological

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<sup>135</sup> Steve Calandrillo, *Responsible Regulation: A Sensible Cost-Benefit, Risk Versus Risk Approach to Federal Health and Safety Regulation*, 81 B.U. L. Rev. 957, 970 (2001).

<sup>136</sup> *Id.* at 974.

<sup>137</sup> For a survey of economic definitions of efficiency and advocacy of a basic utilitarian approach, see Calandrillo, *supra* note 135, at 969-77, 980-86. For sustained critiques of economic/utilitarian efficiency as the goal of environmental regulation, see MARK SAGOFF, *THE ECONOMY OF THE EARTH* (1988), and SHAPIRO & GLICKSMAN, *supra* note 128.

<sup>138</sup> Hornstein, *Reclaiming*, *supra* note 128, at 580-84; Hornstein, *Lessons*, *supra* note 128, at 386-88. See also APPELGATE ET AL., *supra* note 65, at 165-72.

<sup>139</sup> Applegate, *Perils*, *supra* note 128, at 277.

optimism. Social welfare has demonstrably increased (in the aggregate, at least in the industrialized North), and our embrace of new technologies and their risks has everything to do with the increased welfare.<sup>140</sup> The risk approach is thus committed, also, to the scientific paradigm that has developed in western culture since the Renaissance and Enlightenment. The scientific method, with its preference for quantification and its insistence on the development of falsifiable hypotheses for rigorously testing knowledge, underlies our present technology-based prosperity; therefore, this method should also be used to understand the consequences of that technology.<sup>141</sup>

## 2. Risk-Based Precaution

The consequences of the risk paradigm for protective regulation are profound. Risk-based precaution does not limit itself to considering the inherent danger of an activity or product, but rather seeks to optimize the overall risks and benefits to society of the technology in its full context. Risks, costs, benefits, and alternative risks are essential to judging whether regulatory action is advisable and the nature and degree of such action. It follows that regulatory action should be based on prior, thorough consideration of the multitude of relevant considerations. "Regulate first, ask questions later" is anathema, because it invites arbitrary, subjective, and inefficient regulation. While risk-based precaution still accepts the basic idea of acting to prevent harm before it occurs—that is, *unacceptable levels* of harm—it is wary of anticipatory action in advance of proof of the existence of a risk in the first place.<sup>142</sup> The preference for market mechanisms in establishing environmental standards intensifies the concern about premature

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<sup>140</sup> Applegate, *Prometheus Principle*, *supra* note 12, at 222-26.

<sup>141</sup> There are alternative sciences or alternative approaches to science which emphasize induction from widespread observation (Colborn) and also de-emphasize quantification. These are described in Katherine Barrett & Carolyn Raffensperger, *Precautionary Science*, in PROTECTING PUBLIC HEALTH *supra* note 12; THORNTON, *supra* note 66, at 410. For a superb analysis of competing modes of science and their consequences, see SHELDON KRIMSKY, HORMONAL CHAOS: THE SCIENTIFIC AND SOCIAL ORIGINS OF THE ENVIRONMENTAL ENDOCRINE HYPOTHESIS 227-34 (2000).

<sup>142</sup> THORNTON, *supra* note 66, at 8.

action. Interference with the market ought to be exceptional and only undertaken with care. Therefore, the burden of justifying precautionary intervention appropriately lies with the regulator, as does the burden of justifying continuance of such restrictions over time.

Risk-based precaution employs the technocratic tools of risk assessment, cost-benefit analysis, and comparative risk assessment to consider as quantitatively and rigorously as possible all of the factors that might serve to make a precise determination.<sup>143</sup> Substantively, the risk paradigm holds that it is better to permit activities *up to* the point at which they do unacceptable harm, than to delay or refuse them altogether. In this respect, the risk-based approach is what the Bamako Convention aptly calls the assimilative capacity approach.<sup>144</sup> In line with the technocratic approach, regulation is justified by reference to “sound science,” that is, proof of cause and effect using the traditional scientific method.<sup>145</sup> Other sciences or nonquantitative methodologies are to be viewed with skepticism, if not hostility.<sup>146</sup> David Fidler, in fact, calls this approach the “science paradigm” for resolving disputes and making decisions.<sup>147</sup>

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<sup>143</sup> For example, in its challenge to EPA’s recent rulemaking under the Clean Air Act, industry repeatedly argued that EPA had failed “to quantify precisely” the relevant elements of its decision. *Am. Trucking Ass’n v. EPA*, 283 F.3d 355, 369, 378 (D.C. Cir. 2002). The court rejected these arguments; however, other courts in other settings have been more receptive. *See, e.g., Gulf South Insulation v. Consumer Prod. Safety Comm’n*, 701 F.2d 1137, 1146 (5th Cir. 1983) (“precise estimates”); *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201 (5th Cir. 1991).

<sup>144</sup> TROUWBORST, *supra* note 3, at 19. *See also* THORNTON, *supra* note 66, at 7. Geistfeld’s approach to the precautionary principle, which embraces risk and cost analysis, is unusual in that proponents usually reject these techniques. Geistfeld, however, would allow the potential victims to set the values that are plugged into these techniques, Geistfeld, *supra* note 9, at 11,333, a maneuver that proponents of the risk paradigm would undoubtedly reject as not “objective.”

<sup>145</sup> *See* Gupta, *Advance Informed Agreement*, *supra* note 90, at 272-80, for an excellent discussion of the ideology of science in the international regulation of GMOs.

<sup>146</sup> *See* KRIMSKY, *supra* note 141, at 190-94.

<sup>147</sup> David P. Fidler, *Challenges to Humanity’s Health: The Contributions of International Environmental Law to National and Global Public Health*, 31 *Envtl. L. Rep.* (Envtl. L. Inst.) 10,048, 10,070 (2001).

The risk paradigm regards the precautionary principle, being a response to uncertainty, as at best a temporary substitute for real analysis. Synoptic analysis does not cope well, either theoretically or practically, with uncertainty.<sup>148</sup> Uncertainty is a way station along the road to optimal policies, and the precautionary principle fills an awkward gap in an otherwise synoptic regulatory decision making process. Hence risk-based precaution emphasizes iteration, the fourth element of precautionary decision making. The regulator must continually update the available information, as the burden lies with it to justify continued restrictions. And, coming full circle, the implication for the first element (the trigger) is that the precautionary principle may be deployed only in well defined circumstances. Risk-based versions of the precautionary principle, for example, frequently limit its application to "irreversible" harm, that is, those effects which can *only* be addressed in advance.<sup>149</sup>

### 3. The SPS Agreement

The consequences of the risk paradigm for protective regulation are as apparent as they are profound in the Agreement on Sanitary and Phytosanitary Measures ("SPS Agreement"), adopted in 1993 as part of the suite of treaties governing the activities of the World Trade Organization ("WTO").<sup>150</sup> Free trade is the darling of the international community, or at

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<sup>148</sup> This is why Lindblom felt it was necessary to develop a coherent theory of incrementalism ("muddling through") to deal with situations of limited knowledge. For a fuller discussion of the problem of bounded rationality, see SHAPIRO & GLICKSMAN, *supra* note 128, at 22-25.

<sup>149</sup> See, e.g., Rio Declaration, *supra* note 1, princ. 15 ("serious or irreversible"). Commentators, too, have tended to favor an irreversibility threshold, as it most clearly justifies taking early regulatory action. See, e.g., Phillippe Sands, *The "Greening" of International Law: Emerging Principles and Rules*, 1 IND. J. GLOBAL LEGAL STUD. 293-323 (1994). Kiss speaks of the need to protect future generations from long-lasting, irreversible harms. Alexandre Kiss, *Rights and Interests of Future Generations*, in THE CHALLENGE OF IMPLEMENTATION, *supra* note 4, at 27. Christopher Stone, who is otherwise quite skeptical of the precautionary principle, recognizes the need to treat irreversible harms with particular care. Stone, *supra* note 7, at 10,797.

<sup>150</sup> SPS Agreement, *supra* note 30. The World Trade Organization is the "common

least of the economic international community as represented in trade negotiations. It is therefore not surprising that, on the basis of subject matter alone, the SPS Agreement takes a radically different view of the precautionary principle than the Bamako Convention does. Bamako seeks to end a particular kind of trade; the SPS Agreement seeks to facilitate trade generally. Politically, too, Bamako's sponsor, the Organization for African Unity, is one in which the influence of the United States and Northern economic powers is at a low ebb, while in trade negotiations it is at full flood. The SPS Agreement is Bamako's opposite number—a forum in which one can expect the precautionary principle to be expressed in its most limited form.

And it is. The version of the precautionary principle embodied in the SPS Agreement reads as follows:

[2.2.] Members shall ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles, and is not maintained without sufficient scientific evidence, except as provided [in article 5.7].

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[5.7.] In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent

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institutional framework for the conduct of trade relations among its Members." Agreement Establishing the World Trade Organization, Apr. 15, 1994, *reprinted in* 33 I.L.M. 1125 (1994). The substantive standards for trade relations are contained in separate conventions, most notably the General Agreement on Tariffs and Trade ("GATT"), Oct. 30, 1947, T.I.A.S. 1700, 55 U.N.T.S. 88 and the Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, Apr. 14, 1994, 33 I.L.M. 1145, and subsidiary agreements like the SPS Agreement. For a very helpful overview of the precautionary principle in WTO jurisprudence, see Jan Bohanes, *Risk Regulation in WTO Law: A Procedure-Based Approach to the Precautionary Principle*, 40 COLUM. J. TRANSNAT'L L. 323, 330-63 (2002).



information . . . . In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time.<sup>151</sup>

The trigger for application of the SPS precautionary principle is high. Article 2.2 states explicitly that the precautionary principle is the exception to the way that health and safety measures are to be justified and maintained. In fact, the precautionary principle is not only exceptional, it is the very negation of a scientific basis for justifying regulatory action: measures may be based *either* on science *or* on the precautionary principle.<sup>152</sup>

Having created a hostile environment in Article 2.2, the SPS Agreement in Article 5.7 requires some demonstration of actual uncertainty before the precautionary principle may be relied upon.<sup>153</sup> The precautionary principle only applies to "cases where relevant scientific evidence is insufficient," which clearly necessitates thorough prior consideration of such evidence by the would-be regulator and a finding of its insufficiency.<sup>154</sup> Moreover, the regulatory measure taken shall be based on "available pertinent information," again implying analysis before taking action.<sup>155</sup> These are, of course, not necessarily unreasonable demands of a regulatory system, but they reverse to a degree the temporal relationship between information and action that is at the core of the precautionary principle.

The timing explicitly mandated by the SPS Agreement likewise falls at the weak end of the spectrum. While the implied requirement for analysis in advance of regulation does not adopt the "full scientific certainty" language of the Rio version,<sup>156</sup> it comes to the same thing. It is expected that

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<sup>151</sup> SPS Agreement, *supra* note 30, arts. 2.2, 5.7.

<sup>152</sup> *Cf.* Charnovitz, *supra* note 82, at 280 (reporting a WTO decision that rejected an Australian restriction which justified action based on documented uncertainty rather than "science").

<sup>153</sup> SPS Agreement, *supra* note 30, art. 5.7.

<sup>154</sup> *Id.*

<sup>155</sup> *Id.*

<sup>156</sup> Rio Convention, *supra* note 1, pmbl.

the regulator will have acquired and analyzed a considerable amount of evidence before it takes action. The provision in Article 2.2 that all measures (whether based on the precautionary principle or “sufficient scientific evidence”) be applied “only to the extent necessary” underscores the need for a detailed prior analysis, in that such fine tuning cannot be estimated. Precautionary regulation cannot, in other words, take place as early under the SPS Agreement as it can under the Bamako Convention.

The SPS Agreement restricts responses, as just noted, to those “necessary to protect human, animal or plant life or health.”<sup>157</sup> Similarly, Article 3.3 requires specific, “scientific justification” of measures “which result in a level of . . . protection” greater than mandated by other international agreements.<sup>158</sup> The goal is to identify an optimal level of risk and to regulate no further than that. Cost and other economic factors, including the avoidance of undue trade restrictions, are also pertinent, either to the determination of what is “necessary” or as additional factors to be considered by the regulator.<sup>159</sup> Like other risk-based standards, the SPS Agreement balances health and safety considerations against other goals.

The SPS Agreement not only limits the substance of the response, but also the methods for determining the substance. The repeated references to science are supplemented in Article 5.7 by the specific identification of “objective assessment of risk” as the methodology to be used to justify the continuation of regulatory measures. Again, in the context of contemporary political rhetoric, it is impossible to see this as anything but a mandate for a quantitative risk assessment, with all that it entails.<sup>160</sup> Given the disjunctive

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<sup>157</sup> SPS Agreement, *supra* note 30, art. 3.2.

<sup>158</sup> *Id.* art. 3.3.

<sup>159</sup> *Id.* art. 2.1.

<sup>160</sup> Gupta, *Advance Informed Agreement*, *supra* note 90, at 271 (“The scientific validity of national health and safety measures is to be demonstrated through a formal risk assessment.”). The WTO Appellate Body in the beef hormones case took a broad view of what is meant by risk assessment, at least where there was a bona fide divergence of opinion within the scientific community. In such a case, the requirement for risk assessment does not preclude a member from choosing to credit, as a precaution, a minority view. Report from the Appellate Body, *WTO Appellate Body Opinion on EC Measures Concerning Meat and Meat Products Containing Growth Hormones*, WT/DS26/ & 48/AB/R, at ¶ 194, (Jan. 16,

treatment of science and precaution in Article 2.2, this is also potent rhetoric. By advocating application of the precautionary principle, one is *ipso facto* being unscientific.<sup>161</sup> The effect is exactly what a public relations firm recommended to the Chlorine Chemistry Council—"to mobilize science against the precautionary principle, . . . to [e]ngage a broad effort on risk assessment within the scientific community, [and] . . . to discredit the precautionary principle."<sup>162</sup> As Vanderzwaag has said, "institutional favoritism toward scientific rationality [is a way to] weaken and narrow the normative implications of precaution."<sup>163</sup>

Iteration, the final element, is an explicit, integral part of the SPS Agreement's precautionary principle. Measures based on precaution are only "provisionally adopt[ed]."<sup>164</sup> More important, "[m]embers shall seek to obtain the additional information . . . and review the . . . measure . . . within a reasonable period of time."<sup>165</sup> This passage expressly requires iteration; it allocates the burden of proof to the regulator, not the proponent of the activity or technology; it is mandatory ("shall"); and it even provides a deadline.<sup>166</sup> This is iteration with a vengeance, rendering all regulatory decisions that are supported by less than complete scientific information—which is most of

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1998) (Beef Hormones Case) (finding that the SPS Agreement "does not require that the risk assessment must necessarily embody only the view of a majority of the relevant scientific community"). For further discussion, see Geistfeld, *supra* note 9, at 11,332. Nevertheless, it is clearly expected that the regulator will undertake a thorough, searching inquiry into the relevant facts. See Bohanes, *supra* note 150, at 340-45 (discussing the nature of risk assessment under Article 5.1).

<sup>161</sup> See also KRIMSKY, *supra* note 141, at 194 (discussing the rhetorical use of sound science); THORNTON, *supra* note 66, at 410-20. Bohanes, *supra* note 150, at 361-63; Gupta, *Advance Informed Agreement*, *supra* note 90, at 272-80.

<sup>162</sup> THORNTON, *supra* note 66, at 344-45 (quoting the public relations firm report to the CCC).

<sup>163</sup> Vanderzwaag, *Slippery Shores*, *supra* note 6, at 173. Opponents of the precautionary principle acknowledge as much, though for the reason that, in their view, such channeling is necessary to avoid political and subjective application of the principle. *E.g.*, Charnley & Elliott, *supra* note 91, at 10,365-66.

<sup>164</sup> SPS Agreement, *supra* note 30, art 5.7.

<sup>165</sup> *Id.*

<sup>166</sup> *Id.*

them—unstable and subject to repeated challenge in trade tribunals. Indeed, the SPS Agreement begs the question whether it is a bona fide version of the precautionary principle, or whether it in effect substitutes what Wendy Wagner has called the “unprecautionary principle,” that is, permitting regulation only where risks (or even actual harm) have been proven.<sup>167</sup>

C. *European Apotheosis: Incorporation into the Risk Paradigm*

Institutionally, the European Union is divided on the precautionary principle. The Community's charter mandates it,<sup>168</sup> and many of the individual member states are politically committed to the principle, as is the European Parliament.<sup>169</sup> However, the executive branch (I use the term loosely) of the European Union, the Commission of the European Communities, has somewhat different motivations. Its *raison d'être* being the economic integration of Europe and the breaking down of barriers, its first instinct is to view the world much as the WTO does. Moreover, the Commission is a permanent bureaucracy of experts in all manner of governmental issues, so its general worldview tends toward the technocratic, favoring scientific methods and analysis.<sup>170</sup> The resulting tension between the Commission on the one side, and some member states' governments and the Parliament on the other, is on display in the controversy over GMOs. The Commission, finding little traditional scientific evidence for serious concern, has been relatively reluctant to impose severe restrictions on GMOs.<sup>171</sup> The

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<sup>167</sup> Wendy E. Wagner, *The Precautionary Principle and Chemical Regulation in the U.S.*, 6 HUM. & ECOL. RISK ASSESSMENT 459, 466-68 (2000).

<sup>168</sup> Treaty Establishing the European Community, *supra* note 51, art. 174.

<sup>169</sup> See Boutillon, *supra* note 4, at 464-68.

<sup>170</sup> PAUL CRAIG & GRÁINNE DE BÚRCA, EU LAW: TEXT, CASES, AND MATERIALS 53, 57 (2d ed. 1998).

<sup>171</sup> See Applegate, *Prometheus Principle*, *supra* note 12, at 228; Stephen Tromans, *Promise*,

governments and Parliament, on the other hand, have insisted on extremely restrictive measures, and they have by and large prevailed.<sup>172</sup>

The GMO debate is highly relevant to our current concerns. GMOs were surely the gorilla in the closet (together with beef hormones and "mad cow disease") when the Commission described its position on the precautionary principle in the Communication from the Commission on the Precautionary Principle in 2000. The Commission regards the precautionary principle as a "full-fledged and general principle of international law."<sup>173</sup> Interpreting it, however, the Commission steers a careful course between adoption of a limited version of the principle in accordance with its own predilections and an expansive version that would be acceptable to member governments and Parliament.<sup>174</sup> In so doing, the Commission manufactures a version of the precautionary principle that is a compromise of the different visions we have seen. And precisely because it is a compromise that seeks to elucidate a general principle of international law, the Commission Communication demonstrates how much the precautionary principle has changed.

First, the Communication offers a restatement of the principle:

When there are reasonable grounds for concern that potential hazards may affect the environment or human, animal or plant health, and when at the same time the available data preclude a detailed risk evaluation, the precautionary principle has

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*Peril, Precaution: The Environmental Regulation of Genetically Modified Organisms*, 9 IND. J. GLOBAL LEGAL STUD. 187, 195-99 (2001).

<sup>172</sup> Tromans, *supra* note 171, at 195-99.

<sup>173</sup> Commission Communication, *supra* note 43, at 11.

<sup>174</sup> The Canadian government recently adopted its own, unofficial position on the precautionary principle. Canadian society has some similar tensions on environmental issues, and the government statement parallels the Commission's very closely. GOVERNMENT OF CANADA, A CANADIAN PERSPECTIVE ON THE PRECAUTIONARY APPROACH/PRINCIPLE: PROPOSED GUIDING PRINCIPLES (2001).

been politically accepted as a risk management strategy in several fields.<sup>175</sup>

This is in many ways an unremarkable—if lukewarm—version of the precautionary principle, with the exception of the remark that the precautionary principle has been “*politically* accepted as a risk *management* strategy.”<sup>176</sup> Like the SPS Agreement, this statement deliberately relegates the precautionary principle to a rhetorical netherworld of non-science. The primary emphasis of the Communication, however, is a set of six guidelines for implementation. Regulatory measures taken pursuant to the precautionary principle are to be:

- proportional to the level of protection;
- nondiscriminatory in application;
- consistent with similar measures;
- based on examination of potential benefits and costs;
- subject to review in light of new scientific data;
- capable of assigning responsibility for producing scientific evidence.<sup>177</sup>

The Communication also addresses explicitly the “factors triggering recourse to the precautionary principle” and the “measures resulting from reliance” on it.<sup>178</sup>

To channel reliance on the precautionary principle, the Commission carefully defines what triggers its application. The general statement quoted above requires “reasonable grounds for concern.”<sup>179</sup> The Communication also requires specific identification of the adverse effects, the goal being to establish a “less theoretical and more concrete perception [i.e., in the sense

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<sup>175</sup> Commission Communication, *supra* note 43, at 8.

<sup>176</sup> *Id.* (emphasis added).

<sup>177</sup> *Id.* at 3.

<sup>178</sup> *See id.* at 15-16.

<sup>179</sup> *Id.* at 8.

of understanding] of the risk.”<sup>180</sup> Note in particular the use of the term risk: the Commission is not in fact limiting this preliminary investigation to the identification of effects, but rather expects at least a preliminary evaluation of their seriousness and likelihood, the two components of risk. This is confirmed by the insistence that identifying the adverse effects can only occur as the result of “[a] scientific evaluation . . . based on the available data,” which includes factors like severity, probability (“possibility of occurrence”), and irreversibility.<sup>181</sup> Indeed, the Commission regards the initial investigation as encompassing *all four* basic elements of risk assessment.<sup>182</sup> The Commission also treats the demonstrated existence of scientific uncertainty as a specific prerequisite for application of the precautionary principle.<sup>183</sup> As with the SPS Agreement, one cannot demonstrate uncertainty without a thorough analysis of what *is* known—and this is exactly what the Commission has in mind.

The Commission’s parameters for the timing element, as in the SPS Agreement, are heavily influenced by the trigger. Precipitant, *ad hoc* responses are in effect ruled out by the investigatory requirements of the trigger, such that regulatory action can only come later in the timeline between the earliest hints of an adverse effect and full characterization of the relationship between the cause and effect according to scientific methods. In addition, the Commission explicitly addresses the command point that most other versions leave unstated, and it takes a conservative position on it. Of the three timing positions that Wiener describes, the Commission takes the weakest, that uncertainty does not justify inaction.<sup>184</sup> This is the same position adopted by the otherwise inexplicably awkward language of the Rio Declaration (“shall not be used as a reason for postponing”).<sup>185</sup> Uncertainty, standing alone, does not justify regulatory action, and it certainly does not require it.

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<sup>180</sup> Commission Communication, *supra* note 43, at 13.

<sup>181</sup> *Id.*

<sup>182</sup> The elements are hazard identification, dose-response assessment, exposure assessment, and risk characterization. Commission Communication, *supra* note 43, at 13.

<sup>183</sup> *Id.* at 13-14.

<sup>184</sup> See Wiener, *supra* note 19, at 1514-15.

<sup>185</sup> Rio Declaration, *supra* note 1, princ. 15.

The Commission Communication specifies several important characteristics of appropriate responses. First, there is no limitation on the types of measures that can constitute appropriate responses. Bans, phase-outs, embargoes, and the like are not at all required, even when the precautionary principle is properly invoked. Indeed, "[t]he decision to do nothing may be a response in its own right."<sup>186</sup> Second, this flexibility must be used to assure that responses are proportional to the chosen level of protection.<sup>187</sup> Proportionality appears to have two aspects. One is a reasonable relationship between the seriousness of the risk presented and the measures adopted to reduce it to an acceptable level. Draconian responses to minor risks are not permitted. The other is the eschewing of a regulatory goal of zero risk. In this respect, among others, the Commission version of the precautionary principle explicitly embodies the risk paradigm.

Third, in achieving a proportionate response, the regulator must consider factors well beyond simple hazard. As we have seen, the analysis begins with the more complex concept of risk (hazard  $\times$  exposure), but it also embraces the benefits and costs of both action and the status quo.<sup>188</sup> It adopts the European trade principles of nondiscrimination, consistency with similar measures,<sup>189</sup> and consideration of less restrictive alternatives.<sup>190</sup> The principle is also not to be used as a "disguised form of protectionism."<sup>191</sup> From this perspective, the Commission's repeated reminders that the precautionary principle is part of risk management, and not assessment, emphasize that precaution is but one policy among many that risk managers apply in reaching risk decisions. Fourth, the consistency requirement has a function similar to the proportionality requirement, not in the sense of achieving a uniform acceptable risk level across all regulated activities (food, drinking water, driving, air pollution, etc.), but rather in restraining a regulator from using uncertainty *as such* to justify regulatory action. Instead, the regulator should

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<sup>186</sup> Commission Communication, *supra* note 43, at 15.

<sup>187</sup> *Id.* at 17-18.

<sup>188</sup> *Id.* at 18-19.

<sup>189</sup> *Id.*

<sup>190</sup> *Id.* at 17.

<sup>191</sup> *Id.* at 2.



follow comparable regulatory measures, rather than adopt excessively stringent ones.<sup>192</sup>

Fifth, the Commission specifically embraces the technocratic methodologies of risk assessment and "economic cost/benefit analysis" as the preferred ways to choose responses.<sup>193</sup> Finally, the Commission cautions that, while members have great flexibility in choosing responses, they may be subject to judicial review to ensure that they are not arbitrary.<sup>194</sup>

The last element of the precautionary principle, iteration, is also an explicit part of the Commission's version.<sup>195</sup> The Commission addresses both aspects of iteration. First, it declares that all measures relying on the precautionary principle are subject to reevaluation in the light of new information, which is the logical corollary of the uncertainty prerequisite. Once the uncertainty is removed, the precautionary principle no longer applies, and regulation based on it should be modified or abolished to reflect what is known with reasonable certainty.<sup>196</sup> The parallel to the SPS Agreement is obvious, and the Communication in fact makes specific reference to it. However, the Commission Communication—consistent with its general compromise position—carefully distinguishes itself from the SPS position.<sup>197</sup> The Commission Communication notes that different sectors of regulation may require different treatment; one precautionary principle does not necessarily fit all situations. In particular, the Commission rejects an arbitrary deadline within which precaution-based regulations must be abolished or modified. The appropriate time "is linked to the development of scientific knowledge rather than to a time factor," though excessive delays are not to be tolerated.<sup>198</sup> Second, the Communication rejects the clear allocation

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<sup>192</sup> To use the GMO example, which the Commission may or may not have had in mind, residual uncertainty about GMOs does not justify a total ban. Rather, the regulator should look for guidance from, for example, existing food safety standards.

<sup>193</sup> Commission Communication, *supra* note 43, at 17, 20.

<sup>194</sup> *See id.* at 15.

<sup>195</sup> *See id.* at 19-20.

<sup>196</sup> *Id.* at 19.

<sup>197</sup> *Id.* at 19-20.

<sup>198</sup> *See* Commission Communication, *supra* note 43, at 19-20.

of the burden of proof to the regulator.<sup>199</sup> It takes the middle ground position that the precautionary principle as such does not determine burden of proof. Rather, the burden of proof depends on the relevant preexisting regulatory structure. Drugs, for example, require preapproval, and the burden is on the manufacturer. Where no prior approval system applies, the burden is on the challenger to demonstrate the need for regulation.<sup>200</sup>

The overall, and explicit, thrust of the Communication is to fit the precautionary principle *into* the risk paradigm, rather than to offer it as an alternative to the risk paradigm, as many supporters of a strong precautionary principle would have it.<sup>201</sup> The Communication emphasizes repeatedly that the precautionary principle is a rule of risk management and not of risk assessment.<sup>202</sup> This move places the precautionary principle not only within the risk paradigm, but within one of the risk paradigm's preferred methodologies. At a technical level, compartmentalizing the precautionary principle in risk management prevents its application to the fact-gathering assessment phase, to which supporters of a strong version have sometimes applied it.<sup>203</sup> By keeping the precautionary principle out of risk assessment, the Commission Communication also signals its commitment to the traditional scientific basis of the risk paradigm. Throughout, regulatory decisions are legitimated by technical knowledge and the market, features of the risk paradigm.

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<sup>199</sup> *Id.* at 20.

<sup>200</sup> *Id.* at 20-21.

<sup>201</sup> Compare THORNTON, *supra* note 66, at 346-49 (advocating fundamental change); Hey, *Precautionary Concept*, *supra* note 122, at 305, with Charnley & Elliott, *supra* note 91, at 10,363-65 (criticizing the substitution of the precautionary principle for risk assessment). Cf. Rena I. Steinzor, "You Just Don't Understand" - *The Right and Left Conversation*, 32 *Env'tl. L. Rep.*, *Env'tl. L. Inst.* 11,109-11,112-13 (2002) ("The left views risk assessment as consistent with the precautionary principle. In operation, risk assessment must appropriately serve as a device for organizing the information that is then subject to the precautionary principle.").

<sup>202</sup> *E.g.*, Commission Communication, *supra* note 43, at 8, 9, 12.

<sup>203</sup> DOUGLAS CRAWFORD-BROWN, *RISK-BASED ENVIRONMENTAL DECISIONS: METHODS AND CULTURE* 126-27 (1999) (reporting a strong version of the precautionary principle that "whenever uncertainty exists about a risk, decisions should be based on the estimate of risk that is likely to lead to the greatest protection of health").

The Commission's compromise version of the precautionary principle tilts decisively in the direction of the risk paradigm and away from the hazard paradigm, and so toward the more recent, weaker versions of the precautionary principle and away from the earlier, stronger versions.<sup>204</sup> While this undoubtedly reflects to some degree the predilections of an institution like the Commission, it more importantly reflects the taming of the precautionary principle generally.

To gauge the extent of this tilt, it is interesting to compare the Commission position with that of the United States, which has sought to limit the scope and force of the precautionary principle at every opportunity.<sup>205</sup> The United States critique is encapsulated in a recent speech by John Graham, director of the Office of Information and Regulatory Affairs in the Office of Management and Budget.<sup>206</sup> Nearly all of his main concerns are shared by the Commission's Communication, as are most of his proposed remedies. Graham regards the precautionary principle as subjective and subject to abuse; it therefore requires scientific and procedural safeguards. The Communication recognizes the concern, particularly as it relates to trade, and so it hedges the precautionary principle around with threshold requirements and limitations on responses. It also, as we have seen, places the principle firmly within a risk-based decision making process. Graham believes that regulatory action should be preceded by full scientific and cost-benefit analyses of existing information; the Communication delivers precisely that. Graham urges acceptance of a wide range of precautionary responses; the Communication does him one better and expressly recognizes that non-action

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<sup>204</sup> The extent of this tilt will have to be reevaluated when the European Court of Justice rules on appeals from a pair of recent decisions by the Court of First Instance, *Pfizer Animal Health SA v. Council of the European Union*, Case T-13/99 (11 Sept. 2002), and *Alpharma Inc. v. Council of the European Union*, Case T-70/99 (11 Sept. 2002). Both cases upheld Council and Commission action to restrict certain antibiotics in animal feed, contrary to the recommendation of the Commission's science advisory committee, and based on the precautionary principle.

<sup>205</sup> Peter H. Sand, *The Precautionary Principle: A European Perspective*, 6 HUM. & ECOL. RISK ASSESSMENT 445, 447 (2000).

<sup>206</sup> Graham, *supra* note 7.

may be appropriate response in some circumstances. The “general principle of international law” offered by the Commission is, indeed, a tame one.

D. *A Note on the Cartagena Protocol*

The same evolution can be seen in the Cartagena Protocol to the Convention on Biological Diversity (“CBD”), signed in 2000.<sup>207</sup> The centerpiece of the Cartagena Protocol is prior informed consent (“PIC”), which requires an exporting state to inform the importing state, fully and in advance of shipment, of the nature and hazards of the product in question. Only certain classes of GMOs (or “living modified organisms,” in Cartagena’s parlance) are covered by the PIC (or “advance informed consent,” in Cartagena’s parlance) procedure.<sup>208</sup> For covered GMOs, the teeth of the Cartagena Protocol are in the importing country’s ability to refuse consent to importation, and that is where the precautionary principle comes in. The Cartagena Protocol as a whole was a remarkably successful compromise. It was signed by 103 countries and supported by both sides of the rancorous GMO debate.<sup>209</sup> The price of widespread acceptance by supporters of GM crops, however, was high.

To prevent PIC from becoming an excuse for discrimination or trade protectionism (sound familiar?),<sup>210</sup> the Cartagena Protocol describes in detail the permissible grounds for refusing consent. Like the SPS Agreement and the Commission Communication, it “takes as its starting point a risk assessment rather than the much feared nonscientific criteria for decision

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<sup>207</sup> Biodiversity Convention, *supra* note 42. The CBD was adopted at the Earth Summit in 1992. The United States has signed but not ratified the CBD, *available at* <http://www.biodiv.org/world/parties.asp> (last visited Oct. 2, 2001).

<sup>208</sup> Cartagena Protocol, *supra* note 2, arts. 7-10.

<sup>209</sup> The United States, because it has not ratified the underlying Convention on Biological Diversity, is not eligible to sign or ratify the Biosafety Protocol. Nevertheless, as the world’s largest producer of GMOs, the United States took a leading role in the negotiations and supported the outcome. *See Gupta, Governing Trade, supra* note 52, at 26.

<sup>210</sup> *See Holly Saigo, Note, Agricultural Biotechnology and the Negotiation of the Biosafety Protocol*, 12 GEO. INT’L ENVTL. L. Rev. 779, 811 (2000).

making.”<sup>211</sup> The decision to refuse consent “*shall* be in accordance with Article 15,”<sup>212</sup> and Article 15 (entitled “Risk Assessment”) requires that risk assessments “undertaken pursuant to this Protocol shall be carried out in a scientifically sound manner, in accordance with Annex III and taking into account recognized risk assessment techniques.”<sup>213</sup> Annex III sets out detailed protocols for such risk assessments. It is hard to imagine a stronger endorsement of the risk paradigm.

If the risk assessment shows an unacceptable level of risk, then the importing state may refuse entry, of course. If the risk assessment is inconclusive, however, the importer may nevertheless withhold consent, based on the Cartagena version of the precautionary principle:

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 on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of the living modified organism in question . . . in order to avoid or minimize such potential adverse effects.<sup>214</sup>

Again, like the Commission Communication, this version envisions primarily a technical decision: “relevant scientific information and knowledge” must refer, in light of Articles 10 and 15, to traditional risk assessments. The Cartagena Protocol is in fact indistinguishable from the SPS Agreement in

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<sup>211</sup> Gupta, *Governing Trade*, *supra* note 52, at 30; see also Gupta, *Advance Informed Agreement*, *supra* note 90, at 272-80 (describing role of science in Cartagena Protocol).

<sup>212</sup> Cartagena Protocol, *supra* note 2, art. 10(1) (emphasis added). See also *id.* art. 15(2) (mirroring art. 10).

<sup>213</sup> *Id.* art. 15(1).

<sup>214</sup> *Id.* art. 10(6). A parallel provision appears in Article 11(8).

this respect,<sup>215</sup> though it maintains a studied ambiguity about the exact relationship between the protocol and SPS.<sup>216</sup>

Turning to the elements, the Cartagena Protocol imposes a definite, science-based trigger. For timing, uncertainty “shall not prevent”—but does not require—a decision to ban importation. The response, on the other hand, is firm (refusing consent to import), though this is less a statement of principle than an artifact of the PIC procedure. Moreover, there is no restriction on conditioning consent,<sup>217</sup> which permits considerable flexibility in offering a response. Finally, Cartagena takes iteration to new heights by allowing *third parties*—including private parties—to request a state of import to review a decision to refuse consent.<sup>218</sup> The importing state must respond in writing, giving reasons, within ninety days<sup>219</sup>—far shorter than even the SPS Agreement allows.

The striking feature of the weak precautionary principle in the Cartagena Protocol is the huge unpopularity of GMOs in the international community generally. Subject matter usually has a strong influence on the content of the precautionary principle, as we have seen. If the importation of hazardous waste is a pariah in the South, GMOs are pariahs in both North and South. For example, Austria and France illegally continue to refuse importation of GMOs, and the President of Zambia has made news recently by rejecting genetically modified corn even to feed starving people because “there is no conclusive evidence that [GM corn] is safe.”<sup>220</sup> Moreover, opposition to GMOs is almost entirely based on the hazard paradigm,

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<sup>215</sup> See Charnovitz, *supra* note 82, at 298-301.

<sup>216</sup> The preamble to the Cartagena Protocol delivers deliberately conflicting messages. Gupta, *Governing Trade*, *supra* note 52, at 30-31.

<sup>217</sup> Cartagena Protocol, *supra* note 2, art. 10(3)(a).

<sup>218</sup> Cartagena Protocol Article 12(2) allows the “[p]arty of export or a notifier” to make a request for reconsideration. Under Article 8, an exporter may make notifications, and under article 3(d) an “exporter” includes “any legal or natural person.”

<sup>219</sup> Cartagena Protocol, *supra* note 2, art. 12(3).

<sup>220</sup> 32 Env'tl. L. Rep. (Env'tl. L. Inst.) Update No. 25, *supra* note 93. Zambia's action must be regarded as extreme, or worse. It is hard to imagine how one could ever justify permitting starvation on the basis of the very uncertain risks that GMOs pose.

regarding GMOs as dangerous in themselves.<sup>221</sup> And yet the version of the precautionary principle that emerged from Cartagena is firmly in the risk camp, even extending some features of the SPS Agreement model. This, too, is a measure of the extent to which the precautionary principle has been tamed.

### III. ACQUIESCENCE OF JOHANNESBURG

The recently completed World Summit on Sustainable Development in Johannesburg had little to say about the precautionary principle. The goal of the Johannesburg Summit was to revitalize—or, more accurately, reorient—the concept of sustainable development to focus on the situation of developing nations and the growing gap between North and South.<sup>222</sup> In this broad landscape, where basic sanitation, famine, and extreme poverty are the dominant features, the precautionary principle does not readily catch the eye. Moreover, the focus of the WSSD was implementation of the existing Rio framework, not renegotiation of its terms. As a result, the precautionary principle was not a focus of the Johannesburg meetings. However, it did not

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<sup>221</sup> In a previous article, I described this phenomenon in detail, though in somewhat different terms. Applegate, *Prometheus Principle*, *supra* note 12, at 211-22 (describing the “Frankenstein narrative”).

<sup>222</sup> The Johannesburg Declaration firmly redirects sustainable development in the direction of development rather than sustainability. This process began with the Rio Declaration in 1992, but more slowly and subtly. John S. Applegate & Alfred C. Aman, Jr., *Introduction: Syncopated Sustainable Development*, 9 IND. J. GLOBAL LEGAL STUD. 1, 2-4 (2001) (describing sustainable development as syncopated, with the emphasis on the second beat); Lakshman D. Guruswamy, *International Environmental Law: Boundaries, Landmarks, and Realities*, NAT. RESOURCES & ENV'T, Fall 1995, at 43, 45. The Johannesburg Declaration affirmed this change in paragraph 8, describing Rio as setting a “new agenda for sustainable development.” Johannesburg went further in Article 5 and identified three “pillars of sustainable development—economic development, social development and environmental protection,” formally relegating “sustainable” to minority partnership in sustainable development. Johannesburg Declaration on Sustainable Development, Res. 1, Annex, ¶¶ 5, 8, at 1, 2, U.N. Doc. A/CONF.199/20, U.N. Sales No. E.03.II.A.1 (2002), [http://www.johannesburg.org/html/documents/summit\\_docs/131302\\_wssd\\_report\\_reissued.pdf](http://www.johannesburg.org/html/documents/summit_docs/131302_wssd_report_reissued.pdf) (last visited Jan. 19, 2003) [hereinafter Johannesburg Declaration].

entirely escape the attention of the conference, and what it had to say about the principle is noteworthy.

A. *Precaution at Johannesburg*

Though the Johannesburg Declaration neither identifies nor refers to the precautionary principle, the companion Plan of Implementation mentions it twice.<sup>223</sup> The references in the Implementation Plan place the precautionary principle firmly in the science paradigm, much in the way that the Commission Communication does. Paragraph 22 adjures states to,

[aim] to achieve, by 2020, the use and production of chemicals in ways that lead to the minimization of significant adverse effects on human health and the environment, using transparent science-based risk assessment procedures and science-based management procedures, taking into account the precautionary approach, as set out in principle 15 of the Rio Declaration on Environment and Development . . . .<sup>224</sup>

Paragraph 109(f) similarly urges states to “[p]romote and improve science-based decision-making and reaffirm the precautionary approach as set out in principle 15 of the Rio Declaration on Environment and Development.”<sup>225</sup> By compartmentalizing the precautionary principle within “science-based risk management,”<sup>226</sup> the Summit tacitly acquiesced in the redefinition of the precautionary principle that this article has traced. At the very least, the Summit missed an opportunity to assess the steady erosion of

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<sup>223</sup> All WSSD documents are available at [www.johannesburgsummit.org](http://www.johannesburgsummit.org). The references in the Plan of Implementation are ¶¶ 23 and 109(f). The precautionary principle was mentioned in a number of the preparatory meetings, but only in passing. There was no suggestion that the precautionary principle would or should be a significant topic for consideration at the WSSD.

<sup>224</sup> Plan of Implementation, *supra* note 2, ¶ 23, at 19.

<sup>225</sup> *Id.* at ¶ 109(f).

<sup>226</sup> Whatever value “minimizing” may have in ¶ 23, it is largely taken away by the qualification to “significant adverse effects.” The two ideas are inconsistent. *Id.*



the precautionary principle and to reassert the core values that the principle was designed to vindicate. If instead the conference had acknowledged the change in the precautionary principle, it could have catalyzed discussion of its wisdom and desirability. Should the precautionary principle be strong or weak? Should it emphasize aggressive protection against unknown, unforeseen harms, or should it be a predictable standard that facilitates compliance by economic entities? Without a new consensus, the core functions of the precautionary principle will be lost, and it, like the toy poodle, will be domesticated to the point that its wild ancestors would not recognize it as kin.

## B. *Core Values*

If the international community accepts the changes in the precautionary principle as being for the better, it still makes sense to attempt to reach agreement on a new consensus position that stabilizes and reaffirms the principle as currently understood. Even a minimalist precautionary principle forms a bulwark against what Professor Wagner calls "unprecaution," that is, permitting new technologies to go forward, unabated and uncontrolled, until their harms are clearly demonstrated.<sup>227</sup> Even a minimalist precautionary principle can help to protect the core values described at the beginning of the article: minimizing harm and acting despite uncertainty.

### 1. *Minimizing Harm*

The precautionary principle seeks to avoid harm to human health and the environment wherever the opportunity to do so presents itself. Confronted with the choice, regulators should take the action that best assures that harm will be prevented. This seems a mere truism, but in fact it represents a fundamental choice, and that choice is exemplified by the ongoing efforts by economic entities in the United States to remake American environmental law. Taken as a whole, United States environmental law rejects economic

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<sup>227</sup> Wagner, *Chemical Regulation*, *supra* note 167, at 466-68.

efficiency as the sole, or even presumptive, measure of environmental protection. However, the same interests that challenge the precautionary principle have tried to impose a "supermandate" on all environmental, safety, and health regulation (but not on other forms of governmental action), which would subject it not only to cost-benefit analysis, but substantively require all regulations' calculated benefits to outweigh their calculated costs.<sup>228</sup>

A detailed analysis of regulatory standards by Sidney Shapiro and Robert Glicksman reveals that only a few federal statutes even adopt cost-benefit analysis as an analytical test and almost<sup>229</sup> none are governed by a requirement that benefits outweigh costs.<sup>230</sup> If there is a single theme that undergirds American environmental, health, and safety statutes, it is, as Thomas McGarity observed of the Occupational Safety and Health Administration ("OSHA"), "[i]f we cannot have a perfectly clean workplace and environment, then we shall do the best that we can."<sup>231</sup> Where it is "feasible" or technologically possible to avoid injuries, they are to be avoided; where it is not, technology must improve. Furthermore, environmental harm is not to be reduced to a technocratic calculation. In rejecting an effort to do just that, so as to "[promote] a rational allocation of society's assets," the D.C. Circuit observed:

This is nothing more or less than cost-benefit analysis:  
Interior's rule attempts to optimize social welfare by restoring

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<sup>228</sup> This legislation is described in Celia Campbell-Mohn & John S. Applegate, *Learning from NEPA: Guidelines for Responsible Risk Legislation*, 23 HARV. ENVTL. L. REV. 93, 137-38, and is advocated in Calandrillo, *supra* note 135, at 1013-16.

<sup>229</sup> The exception is a particularly obscure portion of the Safe Drinking Water Act, which permits EPA to override the general feasibility analysis with cost-benefit analysis. See 42 U.S.C. § 300g-1(b)(6)(A) (2000). It seems apparent that Congress and the supporters of this measure sought to hide this departure from the general minimization mandate.

<sup>230</sup> SHAPIRO & GLICKSMAN, *supra* note 128, at 31-45. President Reagan's Executive Order No. 12,291, 46 Fed. Reg. 13,193 (1981) (since replaced by President Clinton's No. 12,866, 58 Fed. Reg. 51,735 (1993)) instructed agencies to regulate only where benefits outweighed costs, but of course it had no authority to overturn statutory standards.

<sup>231</sup> Thomas O. McGarity, *Media-Quality, Technology, and Cost-Benefit Balancing Strategies for Health and Environmental Regulation*, 46(3) LAW & CONTEMP. PROBS. 159, 199 (Summer 1983) (quoting Indiana Senator Birch Bayh on the 1972 Clean Water Act).

an injured resource only when the diminution in the resource's value to society is greater in magnitude than the cost of restoring it . . . The fatal flaw of Interior's approach, however, is that it assumes that natural resources are fungible goods, just like any other, and that the value to society generated by a particular resource can be accurately measured in every case—assumptions that Congress apparently rejected. . . . [Congress'] repeated emphasis on the primacy of restoration rejected the underlying premise of Interior's rule, which is that restoration is wasteful if its cost exceeds—by even the slightest amount—the diminution in use value of the injured resource.<sup>232</sup>

Fundamentally, as the court recognized, the requirement to minimize environmental harm is a statement about values, not efficiency. Demonstrably perverse effects aside, even expensively or inefficiently avoided deaths and injuries are avoided deaths and injuries.

Minimizing harm also means assessing, and taking regulatory action, when indicated, in advance of harm occurring. The precautionary principle offers an opportunity to ask hard questions of new technologies. In the words of one advocate, it is a "speedbump"<sup>233</sup> that requires potential hazards to be studied and alternatives developed with an eye toward finding ways to prevent the harm altogether.<sup>234</sup> The information demands could be brief or extensive, standardized or ad hoc, depending on the setting. United States food and drug and pesticide laws insist on fairly rigorous proof of safety in advance of permission to distribute. Industrial chemicals, on the other hand, are subject to far weaker pre-market review,<sup>235</sup> resulting in extremely

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<sup>232</sup> *Ohio v. U.S. Dep't of the Interior*, 880 F.2d 432, 456-57 (D.C. Cir. 1989).

<sup>233</sup> Joel A. Tickner, *A Map Toward Precautionary Decision Making*, in *PROTECTING PUBLIC HEALTH*, *supra* note 12, at 163-64.

<sup>234</sup> *E.g.*, The Nuuk Declaration on Environment and Development in the Arctic, Sept. 16, 1993, princ. 8, 1993 WL 645202 [hereinafter Nuuk Declaration].

<sup>235</sup> Wagner, *Chemical Regulation*, *supra* note 167, at 466-68.

inconsistent and generally inadequate amounts of information to support any kind of assessment of risk.<sup>236</sup>

The United States National Environmental Policy Act ("NEPA") offers a practical example of prior assessment.<sup>237</sup> Substantively, NEPA requires the consideration of environmental effects in decision making, and it establishes several national policies that are consistent with the precautionary principle: protection of future generations, avoidance of "undesirable and unintended consequences" of human activities, and long-term sustainability of resources.<sup>238</sup> Procedurally, NEPA requires the preparation of detailed environmental impact statements that must take a hard look at the foreseeable consequences of the federal action.<sup>239</sup> Whether or not dire consequences are known or expected, both NEPA and the precautionary principle require the development of information about activities that might affect the environment *before* the activity can go forward. NEPA takes the view, also consistent with the precautionary principle, that it is better to delay action at the stage where harm can be anticipated and avoided or at least mitigated, than to attempt corrective action afterward.<sup>240</sup> It is not coincidental that both are triggered by serious or irreversible actions. Finally, NEPA offers invaluable experience with the question of how much information is enough before an activity can proceed.<sup>241</sup>

Minimizing environmental harm, and specifically minimizing environmental harm by taking anticipatory regulatory action to avoid or mitigate it, is a core value of the precautionary principle. It is also a core

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<sup>236</sup> David Roe, *Toxic Chemical Control Policy: Three Unabsorbed Facts*, 32 *Envtl. L. Rep.* (Envtl. L. Inst.) 10,232, 10,237 (2002) (describing basic testing batteries).

<sup>237</sup> See Campbell-Mohn & Applegate, *supra* note 228, at 125-34; SHAPIRO & GLICKSMAN, *supra* note 128, at 122-27; Dinah Shelton, *The Impact of Scientific Uncertainty on Environmental Law and Policy in the United States*, in *THE CHALLENGE OF IMPLEMENTATION*, *supra* note 4, at 214-18.

<sup>238</sup> 42 U.S.C. § 4331 (2000).

<sup>239</sup> 42 U.S.C. § 4332 (2000); *Calvert Cliffs Coord. Comm., Inc. v. U.S. Atomic Energy Comm'n*, 449 F.2d 1109, 1123 (D.C. Cir. 1971).

<sup>240</sup> See *Greene County Planning Bd. v. Board of Comm'rs*, 455 F.2d 412 (2d Cir. 1972).

<sup>241</sup> Campbell-Mohn & Applegate, *supra* note 228, at 133; Carla Matix & Kathleen Becker, *Scientific Uncertainty under the National Environmental Policy Act*, 54 *ADMIN. L. REV.* 1125, 1131 (2002); Shelton, *supra* note 237, at 214-18.

value of United States environmental law. Just as these values are under regular assault in the United States by economic interests, they are under regular assault in international fora. Even a limited precautionary principle would help to maintain the fundamental commitment to minimizing harm.

## 2. Acting Despite Uncertainty

The other core function of the precautionary principle might be characterized as negative: it is a bulwark against the reestablishment of the "unprecautionary principle" that dominated environmental law before the environmental decade from 1970 to 1980. Instead of taking early action to prevent harm, the unprecautionary principle demands a body count, as it were, before preventive action can be justified. Turning again to the United States for examples, regulatory decisions under uncertainty face an increasingly hostile Congress and federal judiciary. At the height of the environmental decade, the D.C. Circuit spoke of the "familiar choice" faced by a regulatory agency:

On one hand, it could regulate a substance whose properties were incompletely understood (less chlorinated PCBs) by relying, in major part, upon its knowledge about more familiar substances (more chlorinated PCBs), despite the uncertainties of extrapolation from one substance to another. On the other hand, it could delay regulation until science could more fully explore the risks of the new substance.<sup>242</sup>

The court strongly affirmed the agency's choice of the former tack.<sup>243</sup> Likewise, the decision to protect the ozone layer by severely restricting ozone-depleting substances was a truly precautionary choice. At the time of

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<sup>242</sup> *Envtl. Def. Fund v. EPA*, 598 F.2d 62, 79 (D.C. Cir. 1978).

<sup>243</sup> *Id.* at 89. *See also* *Ethyl Corp. v. EPA*, 541 F.2d 1, 2, 17, 19-20 (D.C. Cir. 1976) (*en banc*), cert. denied, 426 U.S. 941 (1976) (The Clean Air Act is to be "precautionary in nature," so the court will not "demand rigorous step-by-step proof of cause and effect." Such proof may be possible to obtain if the precautionary purpose of the statute is to be served.).

EPA's initial regulations, the thinning of stratospheric ozone was an unobserved hypothesis. Only after the new standards were established did further investigation permit actual observation of the "ozone hole" over the Antarctic.<sup>244</sup> In both of these examples, uncertainty was not regarded as a legitimate reason for withholding regulatory action.

This commitment, too, is under assault in the United States and around world. Federal courts have become increasingly aggressive in independently evaluating the scientific basis of agency decisions. If cases like *Gulf South* (reversing an agency decision that the court found was not based on "good science") and *Corrosion Proof Fittings* (rejecting what the court regarded as insufficiently detailed agency findings) are not yet the norm, there is talk of "Daubert-izing" agency review, that is, treating judges as scientific gatekeepers for agencies in the way that they are for civil juries.<sup>245</sup> In other cases, courts have set themselves up as arbiters of what constitutes the "best available evidence."<sup>246</sup> Congress has periodically supported legislation that would hold agencies to high standards of proof—mainly in terms of large amounts of risk and cost information—to justify regulation,<sup>247</sup> and the second Bush administration has markedly increased the role of the economists at the Office of Information and Regulatory Policy ("OIRA") in reviewing the basis of agency regulations before promulgation.<sup>248</sup> At the international level, the WTO repeatedly (and with legal justification, as we have seen) demands scientific justification for environmental protection measures and demands their removal when its tribunals find them wanting.<sup>249</sup> In unprecautionary

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<sup>244</sup> David Hurlbut, *Beyond the Montreal Protocol: Impact on Nonparty States and Lessons for Future Environmental Protection Regimes*, 4 COLO. J. INT'L ENVTL. L. & POL'Y 344, 351 n.21 (1993).

<sup>245</sup> See Wendy E. Wagner, "Bad Science" Fiction: *The Imaginary Crisis in Public Health and Environmental Regulation*, 66 LAW & CONTEMP. PROBS. (forthcoming) (manuscript at n.25, on file with author) (collecting examples and criticizing this development).

<sup>246</sup> See *Chlorine Chemistry Council v. EPA*, 206 F.3d 1286, 1291 (D.C. Cir. 2000).

<sup>247</sup> *Campbell-Mohn & Applegate*, *supra* note 228, at 106-07; *Calandrillo*, *supra* note 135, at 966.

<sup>248</sup> Rena Steinzor, "You Just Don't Understand": *The Left and Right in Conversation*, 32 ENVTL. L. REP. (Envtl. L. Inst.) 11,109, 11,109 n.4 (2002).

<sup>249</sup> For a critical overview of the WTO cases, see Lakshman D. Guruswamy, *The Promise of the United Nations Convention on the Law of the Sea (UNCLOS): Justice in Trade and*

fora, lack of full certainty is not just an excuse for doing nothing; it is a mandate for doing nothing.

A stable precautionary principle would resist further erosion of regulators' ability to act despite uncertainty by firmly rejecting the arguments, increasingly put forward, that a regulator needs full or nearly full information before acting. In a recent article, Gail Charnley and Donald Elliott make the remarkable assertion that the precautionary principle "challeng[es] a core premise of the American legal culture that requires an extensive factual record to justify government regulatory action."<sup>250</sup> Charnley and Elliott choose their words carefully. That an extensive record is a core premise of United States law is highly questionable,<sup>251</sup> but it is certain that economic interests would *like* to make that the case, and they have had some notable successes.<sup>252</sup> The adequacy of supporting information will always be debatable at the margin—the precautionary principle is no more vague than "arbitrary, capricious" in this regard—but its statement of a general goal or approach will guide regulators and tribunals in those marginal cases. Just as "substantial evidence" imparts a "mood" of skepticism in evaluating agency action,<sup>253</sup> the precautionary principle imparts a mood of caution in

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*Environmental Disputes*, 25 *ECOLOGY L.Q.* 189, 197-206 (1998). For a more complete (and more recent) overview, see STEVE CHARNOVITZ, *TRADE LAW AND GLOBAL GOVERNANCE* (2002).

<sup>250</sup> Charnley & Elliott, *supra* note 91, at 10,364.

<sup>251</sup> See, e.g., Steinzor, *supra* note 248, at 11,111-12. For example, the D.C. Circuit had this to say about the Clean Air Act as recently as this year:

As we discussed earlier, however, EPA has no obligation either to identify an accurate "safe level" of a pollutant or to quantify precisely the pollutant's risks prior to setting primary NAAQS. Rather, EPA must err on the side of caution, just as it did here—setting the NAAQS at whatever level it deems necessary and sufficient to protect the public health with an adequate margin of safety, taking into account both the available evidence and the inevitable scientific uncertainties.

*Am. Trucking Ass'n*, 283 F.3d at 378.

<sup>252</sup> Cases like *EDF v. EPA* and *Ethyl* are old. The post-Reagan judiciary has produced cases like *Corrosion Proof* and *Chlorine Chemistry*. On the other hand, most United States statutes are distinctly precautionary, though not uncompromisingly so. Applegate, *Precautionary Preference*, *supra* note 12, at 420-39.

<sup>253</sup> *Universal Camera Corp. v. NLRB*, 340 U.S. 474, 487 (1951) (Frankfurter, J.); see also

embracing new technologies, protecting the real core premise of American environmental culture.

The precautionary principle would, in other words, be a bulwark against what Hornstein has called “super synopticism,” the demand for more and more information to justify regulation. Super synopticism has a certain appeal because it is the logical extension of a system based on science.<sup>254</sup> But the demand for ever more information can be and has been used to insulate activities from regulation.<sup>255</sup> One of the great challenges for an information-based regulatory system is paralysis by analysis, the investment of so much effort in determining the need for and nature of regulatory intervention that no action is taken. This danger has, in fact, been exploited in numerous efforts to “reform” regulation in ways that would require massive expenditures of time and resources in providing an exacting basis for decisions.<sup>256</sup> The precautionary principle does not reject science or tools like risk assessment and cost-benefit analysis. Rather, it recognizes that the need for early detection and action is greater than the need for definition and quantification.<sup>257</sup> A precautionary principle that expressly permits regulation while a significant amount of uncertainty remains is, therefore, an important bulwark against endless demands for more information. As Geistfeld puts it, the precautionary principle stands for the proposition that lack of information should not disadvantage the potential victim.<sup>258</sup>

Whatever gross inefficiencies or perverse countervailing risks might be feared from such an approach can be remedied, within the terms of the precautionary principle, by the requirement of iteration. The iteration requirement makes early precautionary action more palatable and indeed

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Freestone & Hey, *supra* note 17, at 264 (“attitude of mind”).

<sup>254</sup> Hornstein, *Lessons*, *supra* note 128, at 387.

<sup>255</sup> Thomas O. McGarity, *Some Thoughts on “Deossifying” the Rulemaking Process*, 41 DUKE L.J. 1385, 1400-10. NEPA or NEPA-like requirements can be used in the same way, of course, to achieve opposite results. The practice under NEPA is therefore particularly valuable, because it seeks a balance between action and information.

<sup>256</sup> Campbell-Mohn & Applegate, *supra* note 228, at 121-23.

<sup>257</sup> See Santillo et al., *supra* note 66, at 45-46.

<sup>258</sup> Geistfeld, *supra* note 9, at 11,330-31.



more sensible.<sup>259</sup> As Christopher Shroeder explains, “[s]o long as precise information on risks and their effects remains unavailable or available only at substantial expense (in terms of both cost and regulatory delay), prophylactic rules will continue to be important regulatory tools, though the appropriate precision and detail of such rules for risks need further elucidation.”<sup>260</sup> Shapiro and Glicksman take this observation a step further and advocate a regulatory system built on initial, broadly precautionary action, to be followed by “back end adjustments”—deadline extensions, waivers, prosecutorial discretion, periodic review (i.e., iteration), etc.—as necessary.<sup>261</sup> Iteration allows regulators to take aggressively protective positions initially in the face of uncertainty, but to pull back when greater certainty yields greater confidence in our understanding of the nature and extent of the risk. The D.C. Circuit recently held that uncertainty was “an eminently rational reason to set the primary standard at a somewhat higher level, at least until additional studies became available.”<sup>262</sup> The National

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<sup>259</sup> Compare Steinzor, *supra* note 248, at 11,110, with Charnley & Elliott, *supra* note 91, at 10,363 (both approving generally an iterative system). Take the example of saccharine. It was initially banned because it was found to cause cancer in rodents. This is precautionary: rodents are not humans (so it is less than full certainty), but rodents are reasonably good predictors of other mammalian systems. The Congressional reaction, too, is a good example of the precautionary principle at work. Congress moderated the initial reaction (a ban) to require only labeling, but it also commissioned new research. Presumably, the saccharine industry also commissioned its own research. And when that research demonstrated that saccharine is apparently not a human carcinogen (though confirmed that it is a rodent carcinogen), the restrictions were lifted. This is exactly the course of events that an iterative precautionary approach to toxic substances anticipates. The whole process was longer and more convoluted than this *precis* suggests, but it shows caution being replaced by acceptance after a more thorough investigation. See APPLEGATE ET AL., *supra* note 65, at 390. Following the publication of the new National Toxicology Program position on saccharine, Congress repealed the saccharine labeling and study requirements at 21 U.S.C. §§ 343(o) and 343a. The name of the new legislation is a mouthful—Saccharin Warning Elimination via Environmental Testing Employing Science and Technology Act—but its acronym is positively saccharine: the SWEETEST Act (Pub. L. No. 106-554, § 518 (2000)).

<sup>260</sup> Christopher H. Schroeder, *Rights Against Risks*, 86 COLUM. L. REV. 495, 558 (1986).

<sup>261</sup> SHAPIRO & GLICKSMAN, *supra* note 128, at 158-76.

<sup>262</sup> Am. Trucking Ass'n, 283 F.3d at 379.

Academy of Sciences recommends this approach to conservative default assumptions in risk assessment.<sup>263</sup>

From this perspective, the requirement for iteration is a real strength of the precautionary principle, allowing it to fill “the silent interim” between initial concern and scientific certainty.<sup>264</sup> By providing a mechanism for regularly revisiting regulatory decisions, the precautionary principle permits early regulation in the absence of complete information because it can take another look later. It thus permits both regulation at the point when it will do most good, and correction when the initial restrictions seem too strict (or too lenient). The unprecautionary alternative, awaiting comprehensive analysis, will often mean that regulation will be imposed after it is too late, for individuals or for the earth.<sup>265</sup>

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The Johannesburg Summit should have debated, not acquiesced in, the erosion of the precautionary principle, because the precautionary principle safeguards some of the most important gains of the environmental movement in protecting human health and the environment from further injury by anthropogenic sources. No brief form of words can definitively describe the appropriate outcome of thousands of regulatory decisions in the widely varying situations to which precaution applies, nor need it. A principle can give general direction, it can set the tone, and most importantly it can provide a fundamental commitment to act aggressively in regulatory domains where scientific uncertainty is the norm.<sup>266</sup> Arrayed against this commitment are a host of economic interests whose claims to be free from stringent regulation

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<sup>263</sup> See generally NATIONAL RESEARCH COUNCIL, SCIENCE AND JUDGMENT IN RISK ASSESSMENT (1994). See also NATIONAL RESEARCH COUNCIL, UNDERSTANDING RISK: INFORMING DECISIONS IN A DEMOCRATIC SOCIETY (1994).

<sup>264</sup> Timothy Riley, *Redressing the Silent Interim: Precautionary Action and Short Term Tests in Toxicological Risk Assessment*, 12 RISK 281 (2001).

<sup>265</sup> See EUROPEAN ENVTL. AGENCY, ENVIRONMENTAL ISSUE REPORT NO. 22, LATE LESSONS FROM EARLY WARNINGS: THE PRECAUTIONARY PRINCIPLE 1896-2000 (2001).

<sup>266</sup> Bodansky, a critic of the vagueness of the precautionary principle, nevertheless recognizes its value in providing “a useful overall orientation.” Daniel Bodansky, *Comment*, 34 ENV’T 3,5 (1992). See also Nollkaemper, *supra* note 17, at 79-81 (value of PP as a principle); Konrad von Moltke, *The Relationship Between Policy, Science, Technology, Economics and Law in the Implementation of the Precautionary Principle*, in THE CHALLENGE OF IMPLEMENTATION, *supra* note 4, at 101, 106; Christensen, *Germany*, in O’Riordan & Cameron, *supra* note 12, at 53.

are politically and economically powerful. To defend our core commitment to protective standards, the environment needs a tiger, not a housecat.