

From General Policy to Legal Rule: Aspirations and Limitations of the Precautionary Principle

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The rapid spread of the precautionary principle (PP) demonstrates the need to explicitly address the role of precaution in environmental decision making. Unfortunately, the PP in its current form is limited by the vagueness of, and variations in, the many formulations of the PP. This ambiguity in the meaning of the PP would not be so serious if the PP were limited to a general aspirational policy, but in every jurisdiction that has adopted the PP it has been transformed rapidly into a binding legal rule. As a legal rule, the ambiguity of the PP results in arbitrary application by regulatory agencies and reviewing courts and limits the capability of reviewing courts to perform their function in overseeing agency actions. To improve the explicit application of precaution, we must go beyond the current form of the PP and attempt to define the factors that weigh in favor of more or less precaution for specific risks. *Key words:* environmental policy, law precautionary principle, risk management. *Environ Health Perspect* 111:1799–1803 (2003). doi:10.1289/ehp.6197 available via <http://dx.doi.org/> [Online 19 June 2003]

Few innovations in environmental policy have proliferated as quickly and widely as the precautionary principle (PP). Based on the maxim “better safe than sorry,” the PP seeks to formalize the application of precaution to regulatory decision making, even though no standard definition or wording of the principle has yet to emerge. Notwithstanding the lack of a definitive formulation, the PP in just the past decade has been included in over a dozen international environmental agreements, expressly incorporated into the legal framework of the European Union (EU), and adopted into the domestic laws of numerous nations. By any measure, this is an impressive record of success, and one that demonstrates that the PP is fulfilling a previously unmet need in environmental policy.

Notwithstanding its meteoric spread, the PP may be reaching its limitations, at least in its current form. The PP began as a general aspirational policy but in recent years has steadily been transformed into an obligatory legal requirement. It is in this latter context that the shortcomings of the PP become apparent. Specifically, the PP as currently cast fails to provide a workable guide to the application of precaution in specific regulatory decisions.

Need for Precaution

Precaution has always had an essential role in regulating environmental risks. Every risk involves some uncertainties, which must be bridged by precaution in making any decision to reduce risk. In other words, few if any regulatory decisions could be taken in the absence of some precaution. The United States and European nations have applied some degree of precaution in making health and environmental decisions for many years (Applegate 2000; Boehmer-Christiansen 1994; Ethyl Corp. v. U.S. Environmental

Protection Agency 1976). In the past, however, the application of precaution has often been implicit, whereas the PP makes the role of precaution explicit. By formalizing and bringing precaution to the forefront, the PP has the potential to make environmental decision making more deliberative, transparent, and coherent.

Yet, proponents of the PP do not seek merely to make the application of precaution more explicit. They also seek to apply more precaution than has been applied in the past. For example, a group of leading PP supporters gathered in January 1998 at the Wingspread Conference Center in Wisconsin and issued the Wingspread Statement, which states that “existing environmental regulations and other decisions, particularly those based on risk assessment, have failed to protect adequately human health and the environment” (Raffensperger and Tickner 1999).

Many examples can be cited of risks that were initially ignored or underestimated but that later turned out to be highly damaging. Examples include asbestos, leaded gasoline, mad cow disease, chlorofluorocarbons (CFCs), the drug diethylstilbestrol (DES), and methyl tertiary butyl ether in gasoline (Harremoës et al. 2002). Of course, other examples could also be cited where, in retrospect, perhaps too much precaution was applied to what turned out to be insignificant or nonexistent risks. Examples of excessive precaution might include saccharin, silicone breast implants, Bendectin, “ice minus” bacteria, the MMR (measles, mumps, and rubella) vaccine, swine flu, genetically modified (GM) *Bacillus thuringiensis* corn and the monarch butterfly, and the risk of pancreatic cancer from coffee consumption.

At least four observations can be made about these dueling laundry lists of past

examples showing too little or too much precaution. First, there will always be a trade-off between overregulation (false positives) and underregulation (false negatives) in *ex ante* regulation of uncertain risks (Stewart 2002; Wiener and Rogers 2002). The total number of false positives and false negatives can be reduced, although never eliminated, through the development of more accurate risk assessment methods and data. The relative balance between false positives and false negatives can also be shifted by applying more or less precaution but only at the cost of increasing one type of error by reducing the other. The more precaution that is applied, the more false negatives we will have avoided, but also the more often it will turn out that we have acted excessively (i.e., false positives) (Goldstein 1999). It should come as no surprise, therefore, that some examples of overregulation and underregulation can be identified after the fact, as there will always be some of both error types. The critical inquiry is whether the optimal balance between false positives and false negatives has been struck, a question that is difficult to examine empirically and likely to be highly contested.

A second preliminary observation is that many of the risks now cited as exemplars showing the need for greater precaution were not, and perhaps could not have been, foreseen at the time of initial product deployment. For example, the potential of asbestos to cause mesothelioma, CFCs to deplete stratospheric ozone, and DES to cause adenocarcinomas could not have been reasonably anticipated at the times those products were initially developed. To be sure, a strong case can be made that industry and government regulators moved too slowly in preventing additional harm once the evidence of such adverse effects was available, or that imposing stronger pre-market testing requirements on product manufacturers may have permitted earlier detection

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of product risks. But prior to that time, the problem was ignorance rather than uncertainty about risks that were outside the scope of foreseeable effects (Bodansky 1991; Hoffmann-Riem and Wynne 2002). It is difficult to see how the PP can help address risks for which we are ignorant rather than uncertain. As stated by Dovers and Handmer (1995), “[w]e cannot prevent the unanticipated: the PP still leaves us bound by present knowledge.”

A third observation is that any attempt to compare the number of historical false positives versus false negatives will be hampered by the asymmetry in verifying the two types of errors. It is easier to prove the existence of risk than the absence of risk (Hansson 1997). There is no serious doubt, for example, that asbestos causes mesothelioma or that DES caused adenocarcinomas, whereas any conclusion that a particular agent presents no significant risk is necessarily more tentative and qualified. For example, a new study could show tomorrow that the MMR vaccine does indeed cause autism, even though the data available to date indicate there is no such association (Madsen et al. 2002). In contrast, it is inconceivable that a new study could demonstrate, for instance, that asbestos does not cause mesothelioma. Thus, examples of false positives are likely to be more provisional (and perhaps then undercounted) than examples of false negatives.

Finally, although the false negatives may be easier to detect, they also generally involve more serious consequences than the false positives (Page 1978). The societal costs of unnecessary carcinogenicity warnings for saccharin or forcing apparently safe products such as silicone breast implants or Bendectin off the market may be substantial but pale in comparison to the consequences of many false negatives such as asbestos or mad cow disease. This asymmetry may not apply in all cases, such as when overly stringent regulation of one set of health risks may increase overall risk as a result of risk–risk trade-offs (Cross 1996; Graham and Wiener 1995). Other cases, however, will often involve balancing the health effects from potential underregulation (false negatives) versus the economic costs of potential overregulation (false positives). Our strong (although not infinite) preference for lives over dollars provides much of the justification for the PP (Geistfeld 2001).

Inherent Ambiguity of the Precautionary Principle

The PP is based on the common-sense adage that it is better to be safe than sorry. There is, however, no standard text for the PP. Each formulation of the PP shares the common prescription that scientific certainty is not required before taking preventive measures. In addition, most versions of the PP involve

some degree of burden shifting to the proponent of an activity or product to demonstrate the safety of its product. The many different versions of the PP have a common shortcoming, however, in that they fail to answer the critical question of how much precaution to apply in a given circumstance (Bodansky 1991; Marchant 2002).

Consider first the important differences between different versions of the PP. Sandin (1999) identified 19 different formulations of the PP that differ across four dimensions he described as threat, uncertainty, action, and command. Different versions of the PP vary, for example, in the level of the threat necessary to trigger the principle from “threats of serious or irreversible damage” to “possible risks,” a discrepancy of enormous policy importance. While some of the variations between different formulations of the principle are mostly semantic, other differences go to the core of the meaning and application of precaution.

Consider the important differences between two well-known formulations of the PP. The Rio Declaration produced by the 1992 United Nations Second Special Session on Environment and Development (United Nations Conference on Environment and Development 1992) endorsed the following PP formulation:

When there are threats of serious and irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.

The Wingspread Statement (1998) prepared by PP proponents defined the PP as follows:

When an activity raises threats of harms to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically.

These two PP formulations have critical discrepancies. The Rio Declaration applies only to “serious and reversible risks,” whereas the Wingspread Statement presumably applies to any risk. The Rio Declaration applies by its terms only to actions that would result in environmental degradation, whereas the Wingspread Statement is broader, applying to actions that would harm either the environment or human health. The Rio Declaration indicates that any regulatory actions undertaken should be cost effective, whereas the Wingspread Statement gives no consideration to costs. The Rio Declaration imposes no affirmative duty to act, but the Wingspread version is phrased in terms of a positive obligation to act. The combined effect of these differences could easily result in inconsistent regulatory outcomes in many cases. Given these and other important differences between various formulations of the PP,

it seems inappropriate to refer to “the” PP in the singular (Stone 2001).

In addition to the variations between PP formulations, any single formulation of the principle fails to specify an adequate decision-making rule. The EU has gone furthest in articulating the meaning of the PP in a 29-page communication issued in February 2000 (European Commission 2000), although neither that communication nor the legislation adopting the PP into the Treaty of Europe provides an actual definition of the PP. The communication makes some progress in clarifying the PP by, for example, specifying that the PP applies only to risk management and not risk assessment and is triggered only by risks identified by scientific risk assessment. Moreover, according to the communication, the PP incorporates the principle of proportionality, and “should include an economic cost-benefit analysis where this is appropriate and possible.”

Many PP proponents criticized the EU’s communication, especially its incorporation of cost-benefit analysis and scientific risk assessment. Many PP proponents reject the incorporation of economic considerations or risk assessment into the PP (Barrett and Raffensperger 2002; Santillo et al. 1998). This disagreement between the EU, the strongest governmental proponent of the PP, and many leading nongovernmental PP supporters further confirms the unsettled meaning of the PP.

More important, notwithstanding the impressive effort by the European Commission, its 29-page exposition of the PP still leaves many key questions about the meaning and application of the PP unanswered. For example, the communication fails to clearly articulate the factors that will determine when the PP applies and when it does not. At one point, the communication states that the PP only applies when it is “impossible to determine with sufficient certainty the risk in question” (European Commission 2000). But given that every risk involves some uncertainty, it is not clear when risk is “sufficiently” uncertain to justify application of the PP. The communication also states that a political decision is necessary to determine when a risk is “acceptable” but gives little guidance on how such acceptability determinations are to be made. Although the communication emphasizes the need to avoid misuse of the PP for arbitrary or protectionist purposes, it is not apparent how this will be accomplished, given the continuing vagueness of the PP. The U.S. government criticized the communication for, among other things, failing to ensure that the PP will not be applied in an arbitrary or discriminatory fashion, given that “a clear definition has not been provided and . . . political decisions will determine its use” (U.S. FDA/USDA 2000).

The EU and other supporters of the PP also fail to articulate when the proponent of a technology has met the burden of proof that is shifted to the proponent under most versions of the PP. Given the logical impossibility of proving a negative, along with the reality that nothing in this world presents zero risk, the PP surely cannot require a technology proponent to prove that its product has zero risk (Bodansky 1994). As the EU's communication states, "[m]easures based on the precautionary principle must not . . . aim at zero risk, something which rarely exists" (European Commission 2000). Other leading proponents of the PP likewise acknowledge that "we can never know with certainty whether a particular activity will cause harm" (Raffensperger and Tickner 1999). Given these realities, the burden of proof shifted to a product manufacturer under the PP must have some practical limitations, yet none are provided by any version of the PP.

The PP not only lacks any clear guidance on when and how it does apply but perhaps more importantly is devoid of any limitations of when it does not apply (Mossman and Marchant 2002). Without such limitations, the PP will be a vacuum that can consume any and all products and technologies, as some risk and uncertainty is associated with every human activity. Until PP proponents provide some clear, principled criteria for when the PP applies and when it does not, the PP will remain ill defined and subject to ad hoc advocacy and decision making.

Invitation for Arbitrariness

The ambiguity of the PP invites arbitrary application, both with respect to which risks it is applied to and what it requires when it does apply (Bodansky 1991; Marchant 2002). To be sure, the PP is not the only environmental policy instrument that has some ambiguity. Cost-benefit analysis, for example, has many potential ambiguities such as whether and how to quantify and monetize various benefits and costs, how to address benefits that cannot be quantified, whether and how to discount future costs and benefits, and how costbenefit analysis should be used in making a regulatory decision. Whenever costbenefit analysis is undertaken, however, these ambiguities have to be addressed, as it is not possible to conduct a costbenefit analysis without resolving those questions.

That is not the case with the PP. There is now a data set of hundreds of regulatory and judicial decisions in Europe and elsewhere that rely on the PP. Very few of these decisions provide any analysis of why the PP applies in that particular case (but not others), and why the PP requires the result reached in that specific case. Rather than articulating the meaning and applicability of the PP, those

decisions generally simply cite the PP to tip the balance in favor of the more protective action under consideration. Likewise, there are few decisions that discuss the PP in any depth and then conclude it should not apply (Commission of the European Communities *v.* French Republic 2001). Rather, what we have is a set of decisions, some of which deploy the PP as a trump card that determines the outcome, and others that make no mention of the PP. No criteria have been articulated by any agency or court that define when and when not the principle applies, and what it requires when it does apply. This empirical record certainly suggests the appearance, if not the reality, of resilient arbitrariness in the application and requirements of the PP.

To take a concrete example, the EU and some other nations have restricted GM foods based on the PP, an application strongly advocated by many supporters of organic foods. Yet, why is the PP being applied to GM foods but not organic foods? Various health and environmental risks have been hypothesized for GM foods, although to date no harm to human health or the environment have been demonstrated. Although significant uncertainties remain about GM foods, many safety tests have been conducted for each commercialized GM product. In contrast, there are known cases of human injury from organic foods, including contaminated organic lettuce, alfalfa sprouts, and apple juice (Belluck and Drew 1998). Other health and environmental risks from organic foods have been suggested, including cancer risks from increased mycotoxins in insect-damaged organic vegetables, toxicity from natural pesticides used on organic crops, and infections of *Escherichia coli* 0157 from the use of manure in organic farming (Leblanc et al. 2002; Trewavas 2001). Unlike GM foods, organic foods have generally not been subjected to any safety tests (Tierney 2000). Although substantial uncertainties exist about the risks hypothesized for both GM and organic foods, it would seem that the case for applying the PP is stronger for organic foods than GM foods. Organic foods have produced known injuries and have been tested less than GM foods, yet the PP is being used to restrict GM foods but not organic foods. There may be sound reasons for applying the PP to GM foods but not organic foods, but such reasons have yet to be articulated. In the absence of such criteria, the application of the PP appears to be governed primarily by arbitrary decisions based on individual and group self-interests and biases (Morris 2000).

Progression from General Policy to Legal Rule

Some proponents of the PP defend against its ambiguity by arguing that the principle is not

intended to provide a legal decision-making rule but rather provides only a general guiding policy that must be implemented through other means (Barrett and Raffensperger 2002; von Moltke 1996). The objections to the PP would be much more subdued if the principle were indeed confined to such a general policy role. Other commentators, however, argue that the PP will achieve its purpose only if it is applied as legal binding rule (Gullett 2000; Stein 2000).

The position that the PP must be applied as a legal rule is in the ascendancy, as the PP has evolved from a general policy preference to a legal instrument in every jurisdiction in which it has been adopted. In Europe and elsewhere, regulators and reviewing courts initially applied the PP cautiously, referring to the PP as at most supplementary support for a decision that was made and defended on other grounds. Over time, however, agencies and courts have gradually grown bolder in their use of the PP, and it is not uncommon for the PP to be outcome determinative for regulatory decisions that would likely have been decided differently in the absence of the PP (Leatch *v.* National Parks 1993; Pfizer Animal Health SA *v.* Council 2002). In other words, by mandating particular results, the PP is now being applied as an obligatory legal rule in the various jurisdictions that have adopted it, including Australia (Gullett 2000), New Zealand (Stein 2000), India (Razzaque 2002), Germany (de Sadeleer 2000), France (de Sadeleer 2000), and Belgium (Larmuseau 2000).

Just as national governments and courts are now applying the PP as a legal rule in their domestic regulatory system, so too do the most recent international environmental agreements treat the PP as a binding legal instrument. Whereas earlier international environmental agreements included the PP only in their preambles, more recent agreements such as the Cartagena Biosafety Protocol and the Stockholm Convention on Persistent Organic Pollutants include the PP as an operational requirement in the main body of the treaty text (Marchant 2002). Some international legal theorists argue that the PP has crystallized into a binding norm of customary international law as a result of its frequent inclusion in international environmental agreements and national regulatory decisions (Cameron and Abouchar 1996; McIntyre and Mosedale 1997). Indeed, the European Commission asserts that the PP is a "full-fledged and general principle of international law" (European Commission 2000).

Applying a concept as vague as the PP as a legal requirement creates two types of problems. First, it creates the opportunity for arbitrary and unpredictable decisions by agencies

and courts. Second, it makes it very difficult for courts to perform their responsibility to ensure the reasonableness of agency decisions.

Arbitrary and unpredictable decisions. The vagueness of the PP invites arbitrary or questionable decisions by regulatory agencies and courts. In the absence of any clear criteria governing the application or meaning of the PP, it can potentially be deployed as an outcome-determinative wild card at any time. Not surprisingly, it has produced some dubious outcomes that otherwise likely could not be justified. For example, the EU retroactively applied the PP to ban the import of North American beef from animals treated with hormones, even though its own scientific committees and subsequent World Trade Organization (WTO) arbitration panels found no scientific rationale for such a ban (Goldstein 2000; WTO 1998). The government of Norway recently invoked the PP to ban Kellogg's Corn Flakes fortified with vitamins because "the fortification in question might be a health hazard when eaten in uncontrollable and unforeseen amounts," although that decision was subsequently overturned by the European Free Trade Association (EFTA) court as an unjustified restraint of trade (EFTA Surveillance Authority *v.* Norway 2001). Zambia expressly cited the PP as the basis for its recent decision to reject food aid from the United States that contained GM corn kernels, even though the United Nations Food and Agriculture Organization concluded that the decision would leave 2.9 million citizens at risk of starvation (Bohannon 2002).

Courts too can use the PP to reach questionable results. One such example may be the decision of an Australian court to prohibit, based on the PP, a town from building a much-needed bridge because of its potential effect on the endangered Giant Burrowing Frog (Leach *v.* National Parks 1993). The problem was that the Giant Burrowing Frog had never been seen anywhere near the proposed bridge, having only been observed several kilometers away on two occasions some 20 years earlier and on another occasion was allegedly heard near the bridge site. Applying a similar standard in the United States would make it exceedingly difficult, if not impossible, to site most federal projects under the U.S. Endangered Species Act, which requires listing of endangered species to be based on objective scientific findings (National Research Council 1995).

Lack of meaningful judicial review. Louis L. Jaffe, one of the fathers of modern administrative law, once wrote that the availability of meaningful judicial review of regulatory agency decisions "is the necessary condition, psychologically if not logically, of a system of administrative power which purports to be legitimate, or legally valid" (Jaffe 1965). Regulatory

decisions made pursuant to the PP will make it difficult for courts to provide meaningful judicial review, given the almost unlimited discretion provided by the ambiguity and indeterminacy of the PP discussed above.

Several courts have already expressed concern about treating the PP as a legal instrument. An Australian court, when asked to apply the PP, rejoined that "the statement of the precautionary principle, while it may be framed appropriately for the purpose of a political aspiration, its implementation as a legal standard could have the potential to create interminable forensic argument. Taken literally in practice it might prove to be unworkable" (Nicholls *v.* Director 1994). A British court, after noting "the absence of any definition of the precautionary principle," found "quite remarkable the proposition that each state should be obliged to act alone on the basis of so general a statement of objectives and considerations" (*R. v. Secretary of State* 1994).

An EU court recently opined that "judicial review of the PP must be exercised with caution," in that courts can "only exercise minimal review" of decisions based on the PP given the "broad discretion" the PP gives to political authorities (National Farmers' Union *v.* Secretariat 2002). The court continued that

the precautionary principle has a future only to the extent that, far from opening the door wide to irrationality, it establishes itself as an aspect of the rational management of risks, designed not to achieve a zero risk, which everything suggests does not exist. . . .

Australian Justice Paul Stein, one of the leading advocates of applying the PP as a rule of law, nevertheless cautioned that the principle

. . . will fade as a principle of international environmental law unless given the teeth to enable it to be applied in the reality of a world environment subject to assaults on all sides. To achieve this, generalized and sometimes vague principles need to be refined and defined to avoid ambiguities, inconsistencies, and, dare I say it, uncertainties. (Stein 2000)

Given "the absence of legislative guidance," Justice Stein argues that "courts have an obligation to attempt to spell out the scope and application of the PP." In other words, reviewing courts may be forced to go beyond their traditional role of interpreting and enforcing the law and themselves take on the job of giving some substance to the PP.

The Future of Precaution

The PP is too vague and underspecified to serve as a legally binding decision-making rule. Yet, in every jurisdiction in which the PP has been enacted, it is increasingly assuming the status of a binding legal rule. Applying

the PP in this mode will result in real and perceived arbitrariness. Over the long run, the inevitable inconsistencies and unfairness that will result from the application of such a vague legal principle will result in growing dissatisfaction with the PP in its current form. As one legal commentator recently observed, the PP, both as conceived and as applied, is already in "disarray" (Stone 2001).

What is to be done? One option would be to abandon the PP altogether. This might result in a wasted opportunity to try to define a coherent and explicit legal framework for the application of precaution. The application of precaution is not new, but the PP is challenging us to deal explicitly with how we should apply precaution. It would be regrettable if we simply retreated to implicitly applying precaution as in the past.

Another option would be to limit the PP to a general policy objective rather than a legal decision-making instrument. As such, the PP would express a general objective of an agency, nation, or treaty but would not have a direct application to any specific regulatory decision. Unfortunately, the history of the PP suggests that such limits are unstable. Some actors will always be tempted to push to give the principle greater decision-making weight in specific circumstances, and the precedents established by these decisions will create a one-way ratchet toward greater legalization.

Yet another possibility would be to continue to apply the PP in its current vague form and hope that repeated application of the PP will eventually lead to the development of some consistent criteria for its application (Barrett and Raffensperger 2002). If a central premise of the PP is that uncertainty about risk is an inadequate reason to delay regulation, some PP proponents may likewise argue that uncertainty about the meaning of the PP is an inadequate reason for delaying its implementation. Such a strategy, however, risks many years of arbitrary and unfair regulatory decisions. Moreover, it is not clear that any consensus would ever develop on the meaning of the PP, given the fundamental disputes that exist today about the meaning of the PP and the diversity of risk scenarios to which it is being applied (Stone 2001). It may therefore be unrealistic to expect a consensus on the meaning of the PP to arise spontaneously through the experience of applying the principle. Rather, any progress toward agreement would likely come only through a deliberate and concerted effort to better define the PP.

This leads to the final policy option, which is to try to better define the appropriate application of precaution. In particular, it would be useful to define what factors argue for more or less precaution for a specific risk, given that some degree of precaution will be appropriate

for most risks. Attributes of individual risks that might affect the appropriate level of precaution may include irreversibility (itself not a simple concept to define coherently), the magnitude of possible consequences, the probability of occurrence, the amount and types of uncertainty associated with the risk, the societal benefits of the risk-creating activity, the difficulty and costs of reducing the risk, potential alternatives to the risk-creating activity, potential risk–risk trade-offs, and public perceptions of the risk. It will not be easy to reach agreement on how these factors should be weighed in determining the appropriate level of precaution in specific circumstances, given that many of these same issues have been debated without resolution in other contexts for decades. Nevertheless, addressing these issues explicitly will provide a more transparent and productive discourse on how we apply precaution than hoping we can somehow resolve these difficult issues with the alluring but ultimately contentless phrase “precautionary principle.” In the end, the most important and lasting legacy of the PP may be to focus the policy spotlight on the need to explicitly define the appropriate role of precaution in environmental decision making.

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