https://doi.org/10.1017/S0265052509090281 Published online by Cambridge University Press

UNDERSTANDING THE PRECAUTIONARY PRINCIPLE AND ITS THREAT TO HUMAN WELFARE

By H. Sterling Burnett

I. Introduction

Over the past three decades, the precautionary principle (PP) has become popular in discussions of public policy, especially in relation to health and environmental policy. There is, in fact, no single formulation of the precautionary principle in universal use. Indeed, an article by Robert Hahn and Cass Sunstein notes no less than nineteen different versions of the principle.[1] John D. Graham, founder and (until 2001) director of the Harvard Center for Risk Analysis, offers a very strong version of the principle: "No human technology should be used or introduced into the environment until it can be shown to pose no threat of harm to humans or the environment."[2] Proponents of using the PP when shaping public policy argue that it is grounded in such common-sense adages or proverbs as "Better safe than sorry," "Look before you leap," and "Haste makes waste."

In Section II, I describe certain core elements common to the different versions of the PP and then show how these elements apply to what has become one of the most commonly cited or popular versions of the PP. In Section III, I briefly review some laws and treaties that have incorporated the PP and examine the differences between Europe and the United States concerning how they incorporate precaution, both in theory and in practice, with particular focus on its application to agricultural biotechnology. In Section IV, I examine objections that critics have raised against the PP. In Section V, I examine an attempt to reframe the PP in an effort to salvage it for use in public policy. In Section VI, I argue that the PP is ultimately unworkable, because it offers no clear guidance for action, and because of the threat it poses to human welfare. Section VII offers some concluding remarks.

[1] Robert W. Hahn and Cass R. Sunstein, "The Precautionary Principle as a Basis for Decision Making," *The Economists' Voice* 6, no. 2 (2005): 1–9. Hahn is cofounder and executive director of the American Enterprise Institute–Brookings Joint Center for Regulatory Studies. Sunstein is Karl N. Llewellyn Distinguished Service Professor in the Law School and Department of Political Science at the University of Chicago.

[2] John D. Graham, "Making Sense of the Precautionary Principle," *Risk in Perspective* 7, no. 6 (September 1999): 1, 5. In 2001, Graham accepted the position of Administrator, Office of Information and Regulatory Affairs, United States Office of Management and Budget, where he served until 2005.

doi:10.1017/S0265052509090281

© 2009 Social Philosophy & Policy Foundation. Printed in the USA.

II. Defining the Precautionary Principle

In this section, I briefly note a concept that preceded and served as an early progenitor of the PP. I then discuss certain core elements common to the variety of statements of the PP found in the academic literature and in public policies that incorporate the principle. Finally, I describe perhaps the most commonly cited statement of the PP and the concerns upon which it is based.

The PP arose out of an earlier German concept or principle known as *Vorsorgeprinzip*, literally "foresight-planning," which was the basis for much of German environmental policy in the 1970s.[3] *Vorsorgeprinzip* requires intervention to prevent harm in any area where human action may result in harm. It requires government to act prospectively to prevent future harms or risks of harm imposed on the public by human actions. The PP is similarly forward looking and interventionist in nature. As Tim O'Riordan and James Cameron state,

> precaution is an interventionist measure, a justification of state involvement in the day to day lives of its . . . citizenry in the name of good government. Social planning in the economy, in technology, in morality and in social initiatives can be justified by a loose and open-ended interpretation of precaution.[4]

At their core, *Vorsorgeprinzip* and its current incarnation, the precautionary principle, are concerned with (1) the wrongness of imposing harms on uninformed, unwilling persons (including future generations) and the environment, (2) the inadequacy of science in judging the possibility, nature, and extent of harms from proposed actions or the introduction of new or novel technologies and techniques, and, thus, (3) the inadequacy of cost-benefit analysis as a policy tool for assessing whether or not proposed actions should be allowed to proceed. The latter two points seem to go beyond the fear that present decision-making is not supported by the best available scientific knowledge to the concern that, at any point in time, the state of scientific knowledge concerning all possible harms that might arise from any new human endeavor is inadequate to judge and thus prevent harm.

[3] See for instance, Julian Morris, "Defining the Precautionary Principle," in Julian Morris, ed., *Rethinking Risk and the Precautionary Principle* (Oxford: Butterworth-Heinemann, 2000): 1–21; Matthias Kaiser, "Introduction to the Special Issue on the Precautionary Principle," *Journal of Agricultural and Environmental Ethics* 15, no. 1 (2002): 2; and Tim O'Riordan and James Cameron, "The History and Contemporary Significance of the Precautionary Principle," in O'Riordan and Cameron, eds., *Interpreting the Precautionary Principle* (London: Earthscan, 1994), 16.

[4] O'Riordan and Cameron, "The History and Contemporary Significance of the Precautionary Principle," 16–17.

https://doi.org/10.1017/S0265052509090281 Published online by Cambridge University Press

https://doi.org/10.1017/S0265052509090281 Published online by Cambridge University Press

A. Understanding the structure of the precautionary principle

Neil Manson, assistant professor of philosophy at the University of Mississippi, argues that all versions of the PP share a core structure or have certain generic elements in common: a damage condition, a knowledge condition, and a remedy condition.[5] The damage condition characterizes a negative effect from a specific activity by virtue of which precautionary measures should be considered. The knowledge condition specifies the state of knowledge regarding the causal connection between the activity and the negative effect. The remedy condition specifies the remedy policymakers should undertake in response to the activity. Manson argues that each version of the PP has the following conditional structure: "if the e-activity meets the damage condition and if the link between the e-activity and the e-effect meets the knowledge condition, then decision makers ought to enact the specified e-remedy."[6]

Manson's tripartite structuring of the PP provides a useful framework for analyzing how it is being applied under current laws and how its proponents have posited that it should be applied. For instance, Manson notes that a range of damage conditions have been cited for invoking the PP, including the following: if an activity is harmful to humans; if an activity has potentially catastrophic consequences; and if an activity poses the risk of irreversible harm to humans, other species, or the environment. Manson also explores a range of knowledge conditions that have been suggested to invoke the PP—from the mere possibility that an e-activity could result in some negative e-effect, to an actual suspicion that an e-activity will produce an as yet unidentified e-effect, to its being reasonable to think, based on precedent, that the e-activity in question could result in a negative e-effect.

Manson's essay notes a number of arguments that lead many to claim that strict precautionary measures are always justified. For instance, many argue for the damage condition of "irreversibility" as the benchmark against which to judge whether or not a given activity merits precautionary limits. But there is a problem. Manson notes that what is meant by irreversibility is left undefined or vague by those who wish to use it as a damage condition for instituting precautionary measures. He argues that,

[5] Neil A. Manson, "Formulating the Precautionary Principle," *Environmental Ethics* 24 (2002): 263–74. Susan Carr, "Ethical and Value-Based Aspects of the European Commission's Precautionary Principle," *Journal of Agricultural and Environmental Ethics* 15, no. 1 (2002): 31–38, also argues for three stages of precaution: the trigger stage; the decision stage; and the application stage. These correspond closely to Manson's tripartite structuring of the PP.

[6] Manson, "Formulating the Precautionary Principle," 265. For the sake of brevity, Manson refers to "e-activities," "e-effects," and "e-remedies." As examples of e-activities, he cites such things as commercial fishing and the commercial release of genetically modified foods. E-effects are outcomes from e-activities, such as the depletion of fish stocks or a severe allergic reaction to a genetically modified organism that has entered the food supply. E-remedies include a range of measures from an outright ban on an activity to further study of the activity and its effects.

https://doi.org/10.1017/S0265052509090281 Published online by Cambridge University Press

at a minimum, proponents of the PP must define what they mean by irreversibility more clearly; otherwise, they risk having the PP be ignored because it is both too vague and too all-encompassing to be taken seriously as a guide to policy. After all, Manson notes that, by definition, each and every change is irreversible in the sense that the precise conditions of the world that obtained before the act was undertaken can never come into being again.[7] On this view, no activity open to policy prescriptions is beyond the realm of the precautionary principle.[8]

As Manson notes, even if one rejects this view of irreversibility (or similar damage conditions) as too all-encompassing, the same restrictive policy claims can be (and are) made by proponents of a strong PP based on a sufficiently weak knowledge condition. One can argue that the burden of proving "no harm" should be shifted from government regulators to industrialists or potential polluters. Alternatively, before a new technology is introduced, one could maintain the regulator's burden of showing harm, but set the knowledge conditions so low that the burden is easily satisfied based on the mere assertion that a harm might be possible, or based on a mere hunch, casting aside the idea that there ought to be reasonable grounds for believing that an e-activity might lead to a harmful e-effect. As Manson puts it, "From the perspective of an advocate of precautionary action, whether it is better to place a high burden of proof on those who would engage in the e-activity rather than a low burden of proof on those who would regulate the e-activity is entirely a matter of pragmatics rather than principles."[9]

Finally, Manson points out that under most versions of the precautionary principle, the e-remedy is simply the prohibition of the suspect activity.

Manson, among other theorists, argues for graduated levels of precaution, ranging from further research being warranted, to searching for ways to diminish the harm, to a temporary moratorium, to an outright ban—based upon the potential severity of the harm, the relative likelihood that the act or technology in question might result in the harm, and the potential that further research or knowledge might bring greater certainty regarding the causal relationship between the purported harm and the supposed cause.

[7] Ibid., 266, 268. This brings to mind Heraclitus's view of change: "You cannot step into the same river twice."

[8] Julian Morris, director of the Environment and Technology Program at the Institute of Economic Affairs in London, is among those who criticize the use of the vague notion of "irreversibility" that justifies precautionary policies: "[A]ll change (and hence all damage) is irreversible in the strict sense that the precise structure of the world that pertained before cannot once again come into being. . . . This ultimately negates the utility of including 'irreversible' as a criterion distinct from 'serious.' " Julian Morris, "Defining the Precautionary Principle," in Morris, ed., *Rethinking Risk and the Precautionary Principle,* 14.

[9] Manson, "Formulating the Precautionary Principle," 269.

B. A popular definition of the precautionary principle

While the PP has evolved over time, a gathering of environmentalists, scientists, lawyers, and philosophers at a 1998 conference at the Johnson Foundation's Wingspread Conference Center in Racine, Wisconsin, produced a popular formulation of the principle in its "Wingspread Declaration": "When an activity raises threats of harm to human health or to the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically."[10] This is one of the most widely cited versions of the PP, and I will refer to it throughout this essay.[11]

The full text of the Wingspread Declaration lays out key attributes shared by most, if not all, versions of the PP. First, existing public policies and regulations are formulated on the basis of inadequate risk assessments. Science is unable to fully assess the range of future harm from novel innovations or applications of modern technology. Second, especially where there is a risk or threat of serious and/or irreversible harms to humans or the environment, the government is not only justified but obligated to act to prevent the harm or at least reduce the risk of harm. The government should do this by acting to improve our understanding of the nature and scope of potential risks of technologies and by disseminating information to those parties potentially affected by the use of the technology. In addition, the government should restrict the use of new technologies or novel applications of established technologies until the activity is shown to be safe. For most proponents of the PP, this latter point leads them to advocate a shift in the traditional burden of proof.[12] Abandoning the old maxim "innocent until proven guilty" for the new standard "guilty until proven innocent" (as I will explore in more detail below), most versions of the PP require (for instance) that when indus-

[10] See the Wingspread Statement on the Precautionary Principle, http://www.sehn.org/wing.html. The 1998 conference was cosponsored by the Science and Environmental Health Network.

[11] Morris calls the Wingspread PP the "international standard definition," noting that an internet search lists literally hundreds of references to it. Morris, "Defining the Precautionary Principle," 5–6.

[12] Wingspread Statement on the Precautionary Principle. See also Henk van den Belt and Bart Gremmen, "Between Precautionary Principle and 'Sound Science': Distributing the Burdens of Proof," *Journal of Agricultural and Environmental Ethics* 15, no. 1 (2002): 103–22; and John Lemons, Kristin Shrader-Frechette, and Carl Cranor, "The Precautionary Principle: Scientific Uncertainty and Type I and Type II Errors," *Foundations of Science* 2 (1997): 207–36. As I will discuss in Section III, some precaution has been built into U.S. and European laws, particularly laws concerning medicines and chemicals, for many years. For instance, using scientific risk analysis, prescription drug manufacturers and pesticide manufacturers have had to do extensive testing on the efficacy and safety of their products before their products were allowed onto the market. However, proponents of the PP argue that standard risk analyses are inadequate in the light of scientific uncertainty. Based on this view, they have been successful, in Europe, in placing a much higher burden of proof on the manufacturers of chemicals, pesticides, and medicines, especially in relation to genetically modified organisms or biotech creations.

https://doi.org/10.1017/S0265052509090281 Published online by Cambridge University Press

https://doi.org/10.1017/S0265052509090281 Published online by Cambridge University Press

tries propose to make use of new technologies or technologies which raise suspicions that harm could result, those proposing to undertake the activity must show that no harm would result before proceeding.

Clearly, the Wingspread version of the PP contains each of Manson's three elements: a damage condition, a knowledge condition, and a remedy condition. The damage condition is met when an activity, such as the use of a newly created technology, threatens harm to humans or the environment. The knowledge condition is met when anyone raises the issue of whether some harm might occur from using the technology, even if the cause-and-effect relationships between the activity and the threatened harm have yet to be fully established. Finally, the remedy condition includes government and corporate action to improve our understanding of the technology and the potential harms that it may pose, and the condition also includes wide dissemination of that knowledge to all potentially affected parties. In the interim, until the risks posed by a new technology can be adequately assessed and judged benign, government must restrict or ban its use.

III. The Precautionary Principle in Practice

The PP has been influential. In one form or another, the PP has been incorporated in domestic legislation in Europe and America and in a number of international treaties. For instance, as noted by the legal scholar Jonathan Adler, the 1987 Ministerial Declaration of the Second Conference on the Protection of the North Sea includes the assumption that

> in order to protect the North Sea from possible damaging effects of the most dangerous substances, a precautionary approach is necessary which may require action to control inputs of such substances even before a causal link has been established by absolutely clear scientific evidence.[13]

The 1992 Convention on Biological Diversity states: "Where there is a threat of significant reduction or loss of biological diversity, lack of full scientific certainty should not be used as a reason for postponing measures to avoid or minimize such a threat."[14]

The 1990 Bergen Ministerial Declaration on Sustainable Development in the European Common Economic Region incorporates the PP as follows: "In order to achieve sustainable development, policies must be

[13] For ease of reference, the precautionary language in this variety of laws and treaties can be found in Jonathan Adler, "The Precautionary Principle's Challenge to Progress," in Ronald Bailey, ed., *Global Warming and Other Eco-Myths* (Roseville, CA: Prima Lifestyles, 2002), 278–80. Morris also notes the wide adoption of the precautionary principle ("Defining the Precautionary Principle," 2–7).

[14] Adler, "The Precautionary Principle's Challenge to Progress," 279.

based on a precautionary principle. . . . Where there are threats of serious or irreversible damage, lack of full scientific certainty should not be used as a reason for postponing measures to prevent environmental degradation."[15] Using much the same language, the 1992 Rio Declaration on Environment and Development states: "In order to protect the environment, the precautionary approach shall be widely applied by States. . . . 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."[16]

The 2000 Cartagena Protocol on Biosafety, an addendum to the 1992 Convention on Biological Diversity, reinforces the signatory countries' commitment to the PP specifically with regard to genetically modified living organisms:

> 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 the risks to human health, shall not prevent that Party from making a decision, as appropriate, with regard to the import of that living modified organism intended for direct use as food or feed, or for processing, in order to avoid or minimize such potential adverse effects.[17]

The extent to which the PP has become fundamental to policy within the European Union cannot be overstated. Indeed, the PP is part of the founding document of the EU. With the signing of the 1992 Maastricht Treaty, the European Union was officially created as a union of nations with a common currency (the euro) and open borders between the member states. Concerning environmental policy, the treaty says, "Community policy on the environment . . . shall be based on the precautionary principle and on the [principle] that preventive actions should be taken. . . ."[18]

Certainly, the PP, as a formal principle, has found more widespread acceptance (both intellectually and in the law) in Europe than in America. The United States has refused to ratify a number of the multilateral agreements and international treaties (many negotiated under the auspices of the United Nations) that have contained the PP as a part—in some instances specifically citing the PP as a significant problem. By contrast, the European Union has fought for the inclusion of the PP in each of these agree-

[15] Ibid., 278.
[16] Ibid., 279.
[17] Ibid., 280.
[18] Ibid., 279–80.

https://doi.org/10.1017/S0265052509090281 Published online by Cambridge University Press

https://doi.org/10.1017/S0265052509090281 Published online by Cambridge University Press

ments and has adopted each one. For instance, the United States has not adopted either the Convention on Biological Diversity or its addendum, the Cartagena Protocol. Indeed, in 2003 the United States, Canada, and Argentina filed a grievance with the World Trade Organization arguing that the European Union was illegitimately applying the Cartagena Protocol (to which none of the countries filing the grievance was a party) and the PP it contained, in order to block the licensing and sale of agricultural biotechnology products.[19] As further evidence that the PP has more widespread acceptance in Europe than in the United States, a search of the term "precautionary principle" in the archives of the U.S. journal *Environmental Ethics* yielded just two articles discussing the topic, with a third discussing precaution in the face of uncertainty without directly relating it to the precautionary principle. By contrast, entire issues of European journals are devoted to the topic.[20]

To say that the PP has not had the profound influence in the United States that it has had in Europe is not to say that the U.S. does not incorporate some degree of precaution in its laws. For example, in 1976, Congress passed the Toxic Substances Control Act (TSCA), authorizing the Environmental Protection Agency (EPA) to regulate chemicals that pose an unreasonable risk to human health or the environment.[21] TSCA requires the EPA to review new chemicals that are manufactured, imported, processed, distributed in commerce, used, or disposed of in the United States before they enter commerce, and it allows the EPA to review those already in commerce.[22]

For existing chemicals, if the EPA conducts a review and finds that a reasonable basis exists to conclude that a chemical presents or will present an unreasonable risk to human health or the environment, the EPA may impose regulatory requirements ranging from labeling the chemical as hazardous and specifying allowable uses to banning the chemical. However, the EPA must consider the costs of any proposed action in evaluat-

[19] For a discussion of this case, see Institute for Agriculture and Trade Policy, "U.S. v. EC Biotech Products Case: WTO Dispute Backgrounder," http://www.tradeobservatory.org/library.cfm?refid=76644. Though the WTO ruled for the plaintiff countries in 2006, as of 2008, member countries of the European Union have yet to comply with the ruling by removing their bans. See "Europe's Biotech Bans in WTO Firing Line" (February 2006; updated May 2007), http://www.euractiv.com/en/trade/europe-biotech-bans-wto-firing-line/article-152393, and "Commission Hesitant to Approve More GM Crops" (May 8, 2008), http://www.euractiv.com/en/environment/commission-hesitant-approve-gm-crops/article-172209.

[20] See, e.g., *Journal of Agricultural and Environmental Ethics* 15, no. 1 (2002), and *Foundations of Science* 2 (1997).

[21] The description of how the TSCA works in the U.S. is taken from a Government Accountability Office report to the Senate, "Chemical Regulation: Approaches in the United States, Canada, and the European Union," http://www.gao.gov/new.items/d06217r.pdf.

[22] TSCA excludes certain chemical substances, including, among other things, pesticides that are regulated under the 1947 Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and food, food additives, drugs, cosmetics, or devices that are regulated under the 1938 Federal Food, Drug, and Cosmetic Act (FFDCA).

ing what risks are unreasonable and must apply the least burdensome regulatory requirement available to adequately protect against a chemical's risk.

For new chemicals, the TSCA generally requires chemical companies to notify the EPA at least ninety days before beginning production or use by submitting a premanufacture notice. Such notices are to provide information on the chemical's identity, production process, anticipated production volume, intended uses, potential exposure and release levels, disposal, and by-products. In addition, companies are required to provide to the EPA any test data that they possess or control related to the chemical's effects on health or the environment. The EPA has ninety days to review the chemical information in the premanufacture notice and identify the chemical's potential risks. It is notable that chemical companies generally do not have such data at the time they submit the chemical to the EPA for review.

On the basis of this review, the EPA makes a decision to either (1) take no action; (2) require controls on the use, manufacture, processing, distribution in commerce, or disposal of the chemical pending development of test data; or (3) ban or otherwise regulate the chemical pending the receipt and evaluation of test studies performed by the chemical's manufacturer.

If the EPA determines that there is insufficient information available to permit a reasoned evaluation of the health and environmental effects of a chemical and that, in the absence of such information, the chemical itself, or the volume to which people will likely be exposed, may present an unreasonable risk of injury to health or the environment, it can issue a proposed order or seek a court injunction to prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of the chemical. In proceeding, the EPA must still choose the least burdensome requirement that will adequately protect against the risk. This presents a high evidentiary burden for the EPA in regulating chemicals. The EPA must prove both that a given chemical does pose an unreasonable risk, and that the regulatory response chosen is the least burdensome response that is necessary to protect against that risk. Unless the EPA asks for further review or challenges a chemical use, companies can proceed to use the chemical. No explicit prior authorization is required.

Under this regulatory regime—which has not changed since the PP's rise to prominence—between 1979 and 2005 the EPA reviewed 32,000 new and 200 existing chemicals, requiring companies to act to one degree or another to reduce the risk of 3,500 of these chemicals.[23]

In contrast to the United States, in 2007, the European Union adopted a new, much more precautionary, regulatory regime for chemicals:

[23] See Government Accountability Office, "Chemical Regulation."

https://doi.org/10.1017/S0265052509090281 Published online by Cambridge University Press

https://doi.org/10.1017/S0265052509090281 Published online by Cambridge University Press

REACH.[24] When it is fully phased in, in 2018, the REACH regime will provide standardized rules for chemical testing and regulation throughout the European Union, replacing state-by-state regulation and registration.

REACH does not distinguish between chemicals in present use and new chemicals. Rather, existing and new chemicals will be treated alike and the companies manufacturing, importing, exporting, using, or selling them will be required to have prior approval for continued use (in the case of existing chemicals) or introduction (in the case of new chemicals). The companies will be required to develop and provide information on the physical properties of each chemical, along with information on the chemical's production process, anticipated production volume, intended uses, potential exposure and release levels, disposal, and by-products. In addition, the companies will have to test chemicals for toxicity and mutagenicity[25] and provide that data to the EU Chemicals Agency. The Chemicals Agency is required to prioritize all chemicals for further review and testing based on a risk assessment of how hazardous the chemical is, what its potential pathways are for exposure (and in what amounts), and how much will be produced. The company registering the chemical must then submit plans (which may include animal testing) for addressing whatever concerns the Chemicals Agency may have. All of this is done at the company's expense. Under the REACH regime, companies bear the burden of proving the chemical is safe prior to using (or continuing to use) the chemical, and, if concerns about previously unrecognized or unanticipated risks to humans or the environment are raised at a later date, companies are responsible for undertaking more testing and providing more information, subject to the requirements of the Chemical Agency.

There is a similar disparity between the United States and Europe concerning the use and regulation of biotechnological products or genetically modified organisms. According to the United States Regulatory Agencies Unified Biotechnology Web site, the United States uses health and safety laws written prior to the advent of modern biotechnology to review genetically engineered products.[26] To date, the United States has not issued any new legislation for these products. Rather, different biotech products are regulated by different agencies depending upon their use, not the method of their creation. In other words, pesticides are regulated by the EPA under authority granted to it by the 1947 Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA),[27] and food products

[24] The European Commission's Environment Web site describes REACH in detail; see http://ec.europa.eu/environment/chemicals/reach/reach_intro.htm.

[25] Mutagenicity is the ability and tendency of a chemical or other agent to induce or increase the frequency of mutation in an organism.

[26] This discussion is based on material from the United States Regulatory Agencies Unified Biotechnology Web site; see http://usbiotechreg.nbii.gov/index.asp.

[27] As amended in 1972, 1988, and 1996.

https://doi.org/10.1017/S0265052509090281 Published online by Cambridge University Press

are regulated by the Food and Drug Administration (FDA) under the Federal Food, Drug, and Cosmetic Act (FFDCA) of 1938.[28]

What this means is that the regulations for any particular genetically modified (GM) food may fall under the authority of the EPA, the FDA, or the U.S. Department of Agriculture (USDA), or any combination of the three, depending upon the type of modification. If the biotech modification was done to enhance nutrition, plant hardiness, or appearance, regulation would fall under the FDA, but if the modification involved improving the plant's pesticide resistance, authority for regulation would fall to the EPA.

For the purposes of this essay, the details of the regulations are not important. What is important is that U.S. regulation of any biotech product does not stem from its being produced through the modification of an organism at a genetic level; rather, regulation is based on the reason for or the type of modification. As a study by the Pew Trust Initiative on Food and Biotechnology points out:

> [F]ederal requirements for [food products] apply regardless of how the food is produced, such as through mechanical or genetic methods (e.g., product formulation, modern biotechnology techniques, or other means). Thus, rice that has been genetically enhanced to provide beta carotene is subject to basically the same statutory and regulatory framework as rice to which beta carotene is added through product formulation.[29]

As I have noted, Europe has incorporated the PP into its founding law, and REACH is a product of that law. The European Commission (EC) has also set out guidelines for how the EU's precautionary policy would apply to GM products.[30] On paper, at least, as Susan Carr of the United Kingdom's Open University Biotechnology Policy Group[31] describes the

[28] This act has been amended numerous times, most recently in 2007. However, none of the amendments (for registration, regulation, or testing) treat GM foods differently based on their origin (as GM foods as opposed to conventionally modified foods).

[29] Pew Initiative on Food and Biotechnology, *Application of Biotechnology for Functional Foods* (Washington, DC: Pew Initiative on Food and Biotechnology, 2007), 37. Available online at http://www.pewtrusts.org/uploadedFiles/wwwpewtrustsorg/News/Press_Releases/Food_and_Biotechnology/PIFB_Functional_Foods.pdf.

[30] The European Commission is the executive branch of the European Union. It is made up of twenty-seven members, one proposed from each member state, who are supposed to represent the interests of Europe as a whole rather than the parochial interests of their home state. The commission has four main roles: to propose legislation to the European Parliament and Council; to administer and implement European Community policies; to enforce Community law; and to negotiate international agreements (mainly those relating to trade and commercial cooperation). See the European Commission Web site, http://ec.europa.eu/index_en.htm.

[31] The Biotechnology Policy Group conducts research that relates biotechnology to the broader issues of agriculture, sustainability, regulation, and technological change. Most of the group's projects have focused on the development of genetically modified organisms

https://doi.org/10.1017/S0265052509090281 Published online by Cambridge University Press

EC's rules pertaining to GM organisms and products, they seem to follow the framework of graduated levels of precaution described by Manson.[32] The EC laid out a series of what it characterized as objective, science-based guidelines for its selection of precautionary measures. These guidelines specify that (1) the precautionary measures should be proportional to the chosen level of protection; (2) the measures should be nondiscriminatory (i.e., the measures should be comparable to those imposed in similar situations); (3) the measures should be consistent with similar measures already taken in equivalent areas in which all scientific data are available; (4) the measures should be based upon an examination of the benefits and the costs of action and inaction with the goal of reducing risks to an acceptable level; and (5) the measures should be subject to review in light of new scientific data—with regular monitoring required in order to review, modify, or remove precautionary measures.[33]

As Carr notes, however, though graduated levels of precaution are part and parcel of Europe's GM regulations, in practice the restrictions have gotten stricter the closer a particular product has come to widespread or commercial use.[34] In theory, European GM regulations were based on the premise that initially strong restrictions would be relaxed as more experience with GM products was gained, first in the laboratory, then in field trials. European politicians assumed that initial uncertainties concerning the potential harms (and their likelihood) would be clarified and resolved before the products (usually crops) became commercially viable.

Yet, in practice, from the outset the European Commission arguably violated its own guidelines for choosing and applying precautionary measures. For instance, critics of the EC argued that the restrictions it ultimately placed on GM products violated both the second and third guidelines described above. Critics argued, first, that GM crops and foodstuffs were no different with regard to the risks they posed than food and products developed through conventional breeding, yet bans on the field testing and sale of GM crops were not also applied to conventionally developed foods. Second, critics argued that no additional precautionary

(GMOs) designed for agricultural uses. For more information, see the Biotechnology Policy Group's Web site, http://technology.open.ac.uk/cts/bpg.htm.

[32] Carr, "Ethical and Value-Based Aspects of the European Commission's Precautionary Principle," 31–38.

[33] Ibid., 36–37. Points 2 and 3 seem very similar, and Carr's discussion does not illuminate the precise difference between the two. However, it seems that guideline 2 concerns value judgments regarding whether one technology is comparable to another; if so, then regulatory measures should not discriminate between the two. Guideline 3 concerns the difference in our knowledge about the risks posed by new technologies versus existing technologies. Technologies for which there is less scientific understanding of the risks involved in their introduction or use merit greater scrutiny than technologies within similar policy areas (say, agriculture) for which we have greater understanding of their impact.

[34] See Marian Deblonde and Patrick du Jardin, "Deepening a Precautionary European Policy," *Journal of Agricultural and Environmental Ethics* 15, no. 1 (2002): 319–43. The article's authors laud the increasing stringency of European precautionary regulatory policies and, indeed, argue for the need to make laws and regulations even more restrictive.

measures were justified for GM crops beyond standard safety tests, because such precautions are not imposed on conventional crops and foodstuffs even though they are known to have some adverse impacts.

Worse still, from the perspective of the EC's acting consistently with its own principles, as more knowledge of GM products was gained and no harms were found during the testing stage, precautions were tightened rather than relaxed as the products approached the commercial stage. Furthermore, in response to objections from environmental pressure groups, the media, and the general public, new precautionary measures were introduced.

Beyond the EC and its tightening rules on biotech plants, there is another precautionary legal hurdle that GM foods must overcome before they can be used throughout Europe. European Union member states can invoke a "national safeguard clause" to keep bans on products in place even if the EC has approved their production, import, and use. Under this clause, if a member state has lingering concerns about a GM crop's effects on human health or the environment, even if the EC has found the product safe and approved it for use, the member state can temporarily ban the product within its borders on precautionary grounds while the EC reviews its findings.[35] Eight member states have repeatedly invoked this clause to keep bans on GM products in place. When the EC has confronted these countries' bans and required them to follow its directives, the countries have ignored the EC's orders. Other EU member states that lack individual bans themselves have backed the objecting member states in this confrontation.

The EC's restrictions, combined with the national safeguard clause, offer further confirmation that the precautionary principle is keeping the EU from allowing the introduction of novel technologies—even when the technologies are safe and their approval would seem to be required by the EC's own rules and by international agreements to which the EU is a party. As evidence, Europe has only approved one GM crop for use—a GM maize variety approved in 1998. Since then, not a single new biotech crop has been allowed to reach the marketplace.[36] The European Food Safety Authority (EFSA) has never given a negative recommendation regarding a GM product.[37] Following the EFSA's recommendations, the EC has authorized the import of sixteen GM products since 2005, yet none of these products have reached the marketplace because member nations refuse to change their domestic laws to allow their production, use, or import. The EC has not forced the matter and enforced its own decisions

[35] "Europe's Biotech Bans in WTO Firing Line" (see note 19 above).

[36] "Commission Hesitant to Approve More GM Crops" (see note 19 above); "Europe's Biotech Bans in WTO Firing Line."

[37] The European Food Safety Authority is a body of scientists established in 2002 and mandated to conduct a scientific assessment of GM foods and to report their findings to the EC.

https://doi.org/10.1017/S0265052509090281 Published online by Cambridge University Press

upon recalcitrant countries.[38] By contrast, since 1998, twenty-three new GM crops and more than 120 GM products have become available to farmers (and thus have been consumed or used by consumers) elsewhere in the world.

In Europe, public opinion (as measured by opinion polls) and interest group pressure has substituted for a rational, science-based assessment of remaining risks when deciding whether to allow the introduction of new GM organisms, tying the European Commission's hands.

Fear of new technologies and novel industrial processes certainly drives many environmental interest groups to embrace and advocate the imposition of a strong version of the precautionary principle. Their efforts have been successful in shaping public opinion—especially in Europe, but also to a more limited degree elsewhere—and public opinion and the potential political costs of ignoring it account for the PP's influence on policy. The public's opposition to GM products, and the policy responses this opposition has engendered, are based in an intellectual argument often raised in support of a strong PP. Some have labeled this the argument from prudence, and others have called it the argument from catastrophe or disaster.

For Matthias Kaiser, Director of the National Committee for Research Ethics in Science and Technology in Norway, precautionary bans are justified in areas of scientific uncertainty where failure to anticipate a future harm may lead to disaster.[39] Neil Manson argues that a "catastrophe principle" is relied upon by many advocates of the PP who favor particularly restrictive regulations.[40] The catastrophe principle is defined as a situation in which there is a possibility, however remote, that an activity under consideration could lead to catastrophic results.

The catastrophe or disaster arguments for a strong PP are similar to the argument made by the seventeenth-century French philosopher Blaise Pascal in his famous work *Pensées*, in which he argues that rational self-interest leads one to believe in God so long as the possibility that He exists is not zero, since the rewards of doing so are so great (and the

[38] Some may say that I am being too hard on the EC. After all, it has approved some GM products, and how can it be blamed if member states won't follow its directives? But this misses the point. The EC has the authority to penalize member countries that violate its rulings on commercial matters, and it has failed to do so. The EC has ordered countries to allow, at a minimum, the GM crops it has approved and to follow the WTO ruling, but none of the eight countries with national bans has lifted them, nor have they or the EU as a whole followed the WTO's ruling and modified their approval procedures for GM crops.

[39] Matthias Kaiser, "Introduction to the Special Issue on the Precautionary Principle," *Journal of Agricultural and Environmental Ethics* 15, no. 1 (2002): 1–5.

[40] Manson, "Formulating the Precautionary Principle," 270. U.S. federal judge and noted legal scholar Richard Posner has written a book concerning the need for governments to take precautionary actions in response to the threat posed by extremely unlikely but possible catastrophes: Richard Posner, *Catastrophe: Risk and Response* (Oxford: Oxford University Press, 2004). Unlike proponents of the PP, however, Posner extends his argument for precautionary policies to natural as well as human-induced potential catastrophes.

https://doi.org/10.1017/S0265052509090281 Published online by Cambridge University Press

potential punishment for not doing so is so horrible).[41] Perhaps the clearest exposition of this link is made by contemporary philosopher Stephen Haller of Wilfrid Laurier University in Canada.[42]

For Haller, claims that a range of human activities threaten global systems with catastrophic collapse, however unlikely or uncertain, justify strong precautionary action. He believes that we have an ethical obligation to avoid catastrophe whatever the practical costs. Recognizing that some may not share his ethical intuition, he argues that there are overwhelming prudential reasons for precaution that should convince even those not persuaded by ethical arguments. Haller argues that a number of environmental problems are "zero-infinity" dilemmas: problems with a near-zero probability of occurring, but having catastrophic consequences if they do. In these situations, policymakers confront problems for which the costs in terms of resources and lost opportunities will be very high. Though Pascal's zero-infinity dilemma dealt with the loss of infinite rewards, not catastrophic harms, the reasoning governing the selection of options in the two situations is the same: even if the costs of precautionary action are high, they are nothing compared to the "infinite negative value of a catastrophe." As a result, for Haller, we don't just need regulatory reform for new technologies; rather, we may need to "restructure society . . . [and] . . . live a lower technology lifestyle," up to and including controls on the growth of population.[43]

Keeping in mind Haller's argument for precaution and its implications for public policy, I will now explore a number of theoretical and practical failings which undermine the usefulness of the PP, as most often formulated and proposed, as an integral part of public policy.

IV. Problems with Precaution: Theoretical and Practical

The PP as popularly understood suffers from a number of fundamental defects. In this section, I will address some theoretical problems that advocates of the PP should have to confront before their views are enshrined in law. I will then look at the practical threat that the PP has posed when applied to the development and use of genetically modified crops.

[41] Blaise Pascal, *Pensées,* trans. Martin Turnell (London: Harvill Press, 1962), 202–3. Numerous scholars have noted the similarity in reasoning between the catastrophe or disaster arguments for a strong PP and Pascal's famous wager. See, for instance, Henk van den Belt, "Debating the Precautionary Principle: 'Guilty until Proven Innocent' or 'Innocent until Proven Guilty'?" *Plant Physiology* 132 (2003): 1122–26; Manson, "Formulating the Precautionary Principle," 272; and Julian Morris, "Defining the Precautionary Principle," in Julian Morris, ed., *Rethinking Risk and the Precautionary Principle* (Oxford: Butterworth-Heinemann, 2000), 7.

[42] Stephen Haller, "A Prudential Argument for Precaution under Uncertainty and High Risk," *Ethics and the Environment* 5, no. 2 (2000): 175–89.

[43] Ibid., 185.

https://doi.org/10.1017/S0265052509090281 Published online by Cambridge University Press

https://doi.org/10.1017/S0265052509090281 Published online by Cambridge University Press

A. General theoretical problems with the precautionary principle

Elsewhere I have argued that while the PP may sound reasonable in theory, it threatens greater harms than it prevents when embodied in law.[44] The PP requires one to do the impossible: prove a negative. As Henk van den Belt and Bart Gremmen put it, "The application of the Precautionary Principle . . . tends to impose an impossible burden of proof on proponents of new technologies. In the name of absolute safety they are asked nothing less than to demonstrate conclusively that the new technologies they advocate offer no possible harm. This is a formidable, perhaps even logically impossible task."[45]

In addition, proponents of the PP hold a distinct but undefended bias toward natural (or at least currently existing) technologies, products, and goods, even if they are known to be harmful or to pose a significant risk of harm for some portion of the population that new technologies might reduce.

Every food (including organic foods), product, and tool poses some risk of harm. Without the use of fire, automobiles, antibiotics, coffee, water, salt, and chlorine—just to name a few natural and man-made tools and products—human life, to paraphrase the philosopher Thomas Hobbes, would be nasty, poor, brutish, and short. Yet, arguably, none of these items would satisfy the standard set by the precautionary principle.

This focus on human technological alterations of "natural" goods or the development of completely new chemicals ignores the significant risks from so-called natural products, and how these risks might be reduced through human efforts. For instance, scientists Bruce N. Ames and Lois Swirsky Gold cite an array of studies which show that 99.9 percent of the chemicals humans ingest are natural, and that the amounts of synthetic chemicals (including pesticide residues) in food plants are insignificant compared to the amount of natural pesticides produced by plants themselves.[46]

[44] H. Sterling Burnett, "Progress at Risk: Using the Precautionary Principle as a Standard for Regulatory Policy," in Laura Jones, ed., *Safe Enough? Managing Risk and Regulation* (Vancouver: The Fraser Institute, 2000), 155–64.

[45] Van den Belt is Assistant Professor with the Applied Philosophy Group, and Gremmen is Professor of Ethical and Societal Aspects of Genomics at the Center for Society and Genomics, both at Wageningen University in the Netherlands. Van den Belt and Gremmen, "Between Precautionary Principle and 'Sound Science'," 107. Van den Belt and Gremmen note others who have made the same point: for instance, Aaron Wildavsky observed that the only way to prove a negative is an impossibility theorem demonstrating that the contemplated action is contrary to the laws of nature. Aynsley Kellow made the point more graphically: "Demanding that a negative be proved is the logical equivalent of asking people to prove that they are not witches." See Aaron Wildavsky, *But Is It True? A Citizen's Guide to Environmental Health and Safety Issues* (Cambridge, MA: Harvard University Press, 1995); and Aynsley Kellow, "Risk Assessment and Decision-Making for Genetically Modified Foods," IPA Policy Backgrounder, Melbourne: Institute for Public Affairs, 1999.

[46] Bruce N. Ames and Lois Swirsky Gold, *Misconceptions about Environmental Pollution, Pesticides, and the Causes of Cancer* (Dallas: National Center for Policy Analysis, Policy Report No. 214, 1998). The study can be found online at http://www.ncpa.org/studies/s214.html.

These natural pesticides that humans eat are chemicals produced by plants to defend themselves against fungi, insects, and other animal predators. On average, Americans ingest five to ten thousand different natural pesticides and their breakdown products over a lifetime—about 1,500 milligrams of natural pesticides per person per day—ten thousand times more than they consume of synthetic pesticide residues.[47] By contrast, the residues of two hundred synthetic chemicals measured by the FDA, including the synthetic pesticides thought to pose the greatest risk, average only about 0.09 milligrams per person per day. For example, the natural chemicals that are *known* rodent carcinogens in a single cup of coffee are about equal in weight to a year's worth of synthetic pesticide residues consumed by the average person in the U.S. that are known rodent carcinogens, even though only 3 percent of the natural chemicals in roasted coffee have been adequately tested for carcinogenicity.[48]

Indeed, only a small proportion of natural pesticides have been tested for carcinogenicity, but of the sixty-three that have been tested, more than 50 percent (thirty-five) are rodent carcinogens. Naturally occurring pesticides that are rodent carcinogens are ubiquitous in fruits, vegetables, herbs, and spices. About 50 percent of all chemicals—whether natural or synthetic—that have been tested in standard, high-dose, animal cancer tests are rodent carcinogens.

In the face of the evidence of the carcinogenicity of foods (both conventionally bred and organic), one can only assume that proponents of the PP cling to Barry Commoner's third law of ecology, "nature knows best," as a ground for their advocacy of a strong PP.[49] In fairness, Commoner's claim is not a metaphysical one concerning nature as a conscious entity, though a few environmentalists may hold such a view. Rather, it is a normative claim representing the view common among many environmentalists that the workings of nature absent human technological interventions are to be preferred or are "right" when compared to the world as shaped or affected by human actions. This view has no basis in science, and, in reality, is rejected as a guide for living by all but perhaps the most extreme environmental radicals in their own lives. Few if any proponents of the PP live in caves or refuse lifesaving medical interventions for themselves or their families.

As I have noted, proponents of the PP commonly argue that the use of some new technology, chemical, procedure, or product could result in disaster or catastrophe. Even if the possibility is remote, they argue, it cannot be ignored and should be avoided at all costs. This is the PP version of Pascal's wager.

[47] Ibid.
[48] Ibid.
[49] Commoner is a biologist and, in 1980, was the U.S. presidential candidate of the Citizens Party. Barry Commoner, *The Closing Circle: Nature, Man, and Technology* (New York: Alfred A. Knopf, 1971). For an excerpt from Commoner's book setting out his four laws of ecology, see http://www3.niu.edu/~td0raf1/history261/nov1910.htm.

https://doi.org/10.1017/S0265052509090281 Published online by Cambridge University Press

https://doi.org/10.1017/S0265052509090281 Published online by Cambridge University Press

Yet a strong theoretical response to Pascal's wager has been known for years and is just as telling against arguments for the PP: the "many gods" objection. Suppose that in addition to (or instead of) Pascal's God, there is another god, say Odin, and he is also jealous and willing to punish those who don't believe in him. In that case, one would have equal reason not to believe in Pascal's God, since one would risk incurring Odin's wrath and thus paying an infinite price for one's transgression. How this applies to the catastrophe argument for the PP should be clear. Proponents of the PP only focus on the potential harm to be prevented by using the PP, but they ignore the fact that any particular action or inaction has benefits as well as costs. It's not just, as many critics of the precautionary principle claim, that the benefits of a new e-activity (to borrow Manson's phrase) outweigh the costs, or even that the harms prevented by the proposed e-activity would be greater than any harms that might result from it. Rather, one cannot ignore the possibility that banning a particular e-activity could result in catastrophe as well.

Consider the case of GM foods. We can imagine that a new type of genetically engineered rice could provide many benefits. For instance, biotech modifications might create a rice variety—let's call it "Super Rice"—that needs much less water to grow and contains the recommended daily allowances of various micronutrients that people in rice-dependent countries commonly lack. Super Rice could come to dominate the market. If it did, proponents of the catastrophe argument for a strong PP could argue that disaster might result. It's possible, they might argue, that an Armageddon cult could create a virus that is easily dispersed and could destroy this rice variety within twenty-four hours. If this occurred, widespread famine and starvation could result, killing hundreds of millions of people. If one takes seriously the catastrophe argument, must one prevent the development and commercialization of Super Rice on precautionary grounds?

No. Not if one takes seriously the fact that such a Super Rice variety could save millions of lives, and that preventing it from being developed or commercialized could result in far worse (and arguably more likely) harms than allowing its production. The world's population is expected to increase to more than nine billion during this century. In addition, some scientists argue that widespread drought and water shortages could occur due to natural or human-induced climate change, such that conventionally bred rice, corn, and other crops could fail with some regularity. If this occurs, then far more people could starve due, in part, to the banning of Super Rice. In short, the catastrophe argument cuts both ways. One cannot, in principle, show that the widespread use of the PP in shaping regulatory policy will not result in an irreversible calamity of untold proportions.

Those advocating greater use of the PP when shaping laws and regulations show a distinct bias toward preventing what are known as type II

errors to the exclusion of preventing type I errors.[50] A type II error occurs when an analysis concludes that there is no effect from an action or a policy, when in fact an effect exists. So, for instance, a regulatory agency with responsibility for approving chemicals before they enter the market would commit a type II error if it concluded that a chemical it approved had no negative effect on human health or the environment when, in fact, the chemical did have harmful effects. A type I error, by contrast, occurs when an analysis concludes that there is an effect where one does not exist. For instance, the same agency might conclude that a chemical would harm humans or the environment when, in fact, the chemical in question has no harmful effects. Though PP proponents do not state it as such, their view seems to be that preventing hypothetical, speculative, and/or minuscule threats of future harm should take precedence in regulatory policy over acting to reduce existing dangers or problems, some with known catastrophic consequences in the present.[51]

The late Aaron Wildavsky, a political scientist and former president of the American Political Science Association, argued that there can be no safety without risks. Yet the PP is promoted as a policy guide as if human and environmental health can be assured at virtually no cost whatsoever if we just don't do anything new. In addition, advocates of the PP seem to operate on the false assumption that bans and regulations have no adverse health effects of their own.[52] Every particular action and inaction has benefits as well as costs, and often the benefits of a particular e-activity outweigh the costs, or the harms prevented by the proposed e-activity are greater than any harms that might result from it. As Van den Belt and Gremmen argue: "The maxims 'Safety first!' and 'Better safe than sorry' do not point the way to a safe, risk-free world, for such a world is not to be had."[53] They might have added: the pursuit of such a world comes with substantial costs in terms of human welfare.

B. Problems in practice: The precautionary principle and GM foods

Numerous industries and activities have come under sustained attack by proponents of the PP, including energy and chemical production and use. For instance, in December 1999, citing the PP, environmentalists fought

[50] See, for instance, Joel Tickner, "Precautionary Principle," *The Networker: The Newsletter of the Science and Environmental Health Net,* May 1997, http://www.safe2use.com/data/precaut1.htm; and Lemons, Shrader-Frechette, and Cranor, "The Precautionary Principle: Scientific Uncertainty and Type I and Type II Errors."

[51] For critical comments concerning the regulatory bias of PP proponents in relation to type I versus type II errors, see, for example, Frank B. Cross, "Paradoxical Perils of the Precautionary Principle," *Washington and Lee Law Review* 53, no. 3 (1996); Van den Belt, "Debating the Precautionary Principle"; and Van den Belt and Gremmen, "Between Precautionary Principle and 'Sound Science'."

[52] Aaron Wildavsky, *Searching for Safety* (New Brunswick, NJ: Transaction Books, 1988).

[53] Van den Belt and Gremmen, "Between Precautionary Principle and 'Sound Science'."

https://doi.org/10.1017/S0265052509090281 Published online by Cambridge University Press

https://doi.org/10.1017/S0265052509090281 Published online by Cambridge University Press

successfully to have Europe ban a group of six chemicals, called phthalates, that are used as softeners to make vinyl flexibile. In addition, citing the PP, many environmental organizations, including Greenpeace and the Natural Resources Defense Council, have argued that the government should end the use of chlorine in plastics, pesticides, and as a disinfectant in water. Their efforts to ban chlorine have thus far proven unsuccessful, perhaps because it occurs naturally and is ubiquitous, and perhaps because the chemical has proven spectacularly useful, saving lives and helping make food more abundant, and in long use has demonstrated few if any detrimental health effects.

No human use of technology, however, has come under as much scrutiny and criticism from backers of the PP as the use of genetic engineering to modify plants for agriculture. This is important because nothing is arguably more vital to the continued improvement of the human condition than the availability and abundant supply of nutritious food.

Agricultural economist Dennis Avery has pointed out that approximately eight hundred million people do not currently have nutritionally adequate diets.[54] Four hundred million people currently suffer from vitamin A deficiency, including 500,000 children who go blind each year. The human population is growing, especially in countries where people are already malnourished, and global population will probably plateau sometime in this century at between eight and nine billion people.[55]

With approximately six million square miles under cultivation—an amount of land equal in size to the United States and Europe—the world currently produces more than enough food to feed the earth's six billion people.[56] Avery argues that populations in most countries are beginning to demand and actively strive for standards of living similar to what they see in the West. However, he calculates that feeding nine billion people (and their pets) diets similar to those currently enjoyed by people in industrialized countries will require the production of approximately three times more food by 2050. Avery further calculates that if all of the world's farmers adopted the best modern farming practices with high inputs of fertilizers and pesticides, it might be possible to double current crop yields on the same amount of land—but we need to triple yields to feed the coming generations.[57]

Alternatively, according to Avery, if we went totally "organic," eschewing the use of artificial fertilizers, pesticides, and biotechnologies, we would have to double the amount of land under active cultivation. This would be

[54] Dennis Avery, "Biotechnology: Trade Crisis or Path to Future?" *Global Food Quarterly,* Summer 1999, pp. 1, 3; see also Dennis Avery, *Saving the Planet with Pesticides and Plastic: The Environmental Triumph of High Yield Farming* (Indianapolis: Hudson Institute, 2000), 33.

[55] Patrick Moore, "How to Fight Childhood Blindness," *The American: A Magazine of Ideas* (October 12, 2007), http://www.american.com/archive/2007/october-10-07/how-to-fight-childhood-blindness. Population estimates are from the United Nations, http://esa.un.org/unpp/p2k0data.asp.

[56] Avery, "Biotechnology," 3.

[57] Ibid.

disastrous for wildlife and native plants, as the lands most likely to be converted to agriculture are forests, rangelands, and other wildlands. Massive biodiversity losses from land conversion for organic food production are especially likely since the relatively undeveloped tropics, the most biodiverse region on Earth, is also where population growth is occurring and where hunger and malnutrition are most prominent.[58]

Avery presents a third option: the judicious use of biotechnology, being quick to regulate or end the use of products that are shown to cause harm. Bioengineered or GM crops are already in widespread use (and this use is growing), and, as of yet, there is very little evidence to show that bioengineered crops pose a threat to human health or the environment. Between 1995 (when the first bioengineered crops were licensed for use) and 2007, farmers have continued to plant more biotech crops every year. As of 2007, more than 114.3 million hectares (282.4 million acres) have been planted in biotech crops in twenty-three different countries (twelve developing countries and eleven industrialized countries).[59]

In 2007, the United States, Argentina, Brazil, Canada, India, and China were the principal adopters of biotech crops globally, with the U.S. retaining its top world ranking with 57.7 million hectares (50 percent of global biotech area). In the same year, the number of small and resource-poor farmers planting biotech crops in developing countries exceeded ten million for the first time (of the total twelve million farmers using biotech). Thus, more than 90 percent of the farmers using biotech crops were small and resource-poor farmers from developing countries.[60]

This continued growth has occurred, in large part, because of the efforts of the United States. (Indeed, as noted above, there is a virtual ban on biotech crop production or use within the European Union.) For instance, the U.S. has led the charge against ongoing efforts to have the PP incorporated into various rules and principles developed by Codex Alimentarius. The Codex Alimentarius Commission was created in 1963 by the United Nations Food and Agriculture Organization (FAO) and the World Health Organization (WHO) to develop food standards, guidelines, and related texts, such as codes of practice, under the Joint FAO/WHO Food Standards Program. The main purposes of the Food Standards Program are protecting the health of consumers, ensuring fair trade practices in the food trade, and promoting coordination of all food-standards work undertaken by international governmental and nongovernmental organizations.

In mid-2007, despite intense lobbying from environmental nongovernmental organizations (NGOs) and European Union member governments, Codex excluded the precautionary principle from its "Working Principles for Risk Analysis for Food Safety for Application by Govern-

[58] Ibid.

[59] *Global Status of Commercialized Biotech/GM Crops: 2007,* International Service for the Acquisition of Agri-Biotech Applications, ISAAA Brief 37 (2007), http://www.isaaa.org/resources/publications/briefs/37/executivesummary/default.html.

[60] Ibid.

https://doi.org/10.1017/S0265052509090281 Published online by Cambridge University Press

https://doi.org/10.1017/S0265052509090281 Published online by Cambridge University Press

ments."[61] Codex ultimately accepted the U.S. argument that "regulatory oversight and risk assessment should focus on the characteristics of the product rather than the molecular or cellular techniques used to produce it."[62] Scientifically, there is largely a consensus that the scope of oversight should be based on the risk-related characteristics of products, whether they are inert or living organisms and whether they are organic, conventionally bred, or genetically modified.

In the United States, genetic modifications have made tomatoes more resistant to cold, and soybeans, cotton, and corn immune to selected herbicides used to control weeds. More than 50 percent of the U.S. soybean crop—parts of which end up in more than 60 percent of processed foods—has been genetically modified since 1995.

Usually unacknowledged by those who would use the PP to suppress the introduction of biotech crops is the fact that they are already providing benefits to millions of people worldwide. For instance, the Rockefeller Foundation reports that golden rice—rice genetically altered to contain beta-carotene (which readily converts to vitamin A) and new genes to overcome iron deficiency—is preventing thousands of cases of childhood blindness and reducing the amount of anemia suffered by more than two billion women in rice-dependent countries.[63]

Despite the fact that numerous studies and thirteen years of commercial experience (1995–2008) attest to the safety of GM foods, precautionary critics of GM crops have raised a number of objections to the development, commercialization, and dispersion of GM crops.[64] These critics argue that there are risks posed by unintended gene transfer from GM plants to wild relatives. They also argue that GM crops could spur the evolution of super-weeds or super-bugs with immunity to the GM crops.[65] An additional fear raised by critics of GM foods is that the transfer of genes from one plant type to another might result in crops uniquely toxic to humans or animals, or that the transfer of genes from one plant type to

[61] See "Working Principles for Risk Analysis for Food Safety for Application by Governments," http://www.codexalimentarius.net/web/more_info.jsp?id_sta=10751.

[62] Henry I. Miller and Gregory Conko, "Genetically Modified Fear and the International Regulation of Biotechnology," in Morris, ed., *Rethinking Risk and the Precautionary Principle,* 84–104.

[63] Avery, "Biotechnology," 1, 3.

[64] One report discusses more than 150 government and industry-financed studies: Committee on Identifying and Assessing Unintended Effects of Genetically Engineered Foods on Human Health, *Safety of Genetically Engineered Foods: Approaches to Assessing Unintended Health Effects* (Washington, DC: The National Academies Press, 2004). Another report discusses more than forty-seven peer-reviewed articles published in scientific journals: Christopher Preston, "Peer Reviewed Publications on the Safety of GM Foods," http://www.agbioworld.org/biotech-info/articles/biotech-art/peer-reviewed-pubs.html. The studies reviewed have found little or no evidence of harm from GM foods.

[65] The fear is that weeds or insects targeted by GM crops (crops that have been modified, for instance, with resistance to a particular pesticide) will either be cross-hybridized (in the case of the plants) or evolve immunity not only to the pesticide contained in the GM plant but to other pesticides as well.

another might result in a plant that would induce an allergic reaction in persons allergic to a chemical in the donor plant.[66]

The genetic modification of crops could, in theory, result in any or all of the above risks (or others that PP proponents cite). But thirteen years of history show that the fears of critics are unlikely to be borne out in fact, and that, when they are borne out, the risks are not that different from the risks posed by crops developed through conventional cross-breeding techniques. For instance, corn was the first plant to be genetically altered to contain the *Bacillus thuringiensis* bacteria (Bt-corn). Bt-corn was developed to control the European corn-borer, an insect that causes millions of dollars of losses to corn growers each year.[67] Bt-corn effectively prevents corn-borer infestation, reducing the need for costly pesticide applications. These characteristics made it increasingly popular among corn growers.

However, in 1999, laboratory studies found that should the pollen from Bt-corn drift out of the fields in sufficient amounts and fall onto milkweed plants on which Monarch butterflies lay their eggs, and upon which newly hatched Monarch caterpillars feed, the caterpillars die at a rate far above average.[68] This was enough to start a media frenzy driven by environmental NGOs and designed to end the use of Bt-corn and to place the creation of other biotech crops on hold. The reaction from the food industry was quick and affected more GM foods than Bt-corn. Fearing a consumer boycott (which was threatened by the Sierra Club and the U.S. Public Interest Research Group), baby food manufacturers Gerber and Heinz announced that they would stop using GM crops in their products. Frito-Lay told its farmers that it does not want Bt-corn for use in its chips. Seagram said that its wines and spirits would be free of biotech crops.[69]

However, Professor John Losey of Cornell University, the lead scientist involved in the research, admonished that it was far too soon to say whether Bt-corn posed a real threat to butterflies or other beneficial insects, much less humans. Losey stated: "Our study was conducted in a laboratory and, while it raises an important issue, it would be inappropriate to draw any conclusions about the risk to Monarch populations in the field based solely on these initial results."[70] His caution was merited: later field experiments failed to show that Bt-corn posed a threat to Monarchs. It seems Monarchs avoid laying eggs on milkweed plants surrounded by corn (whether genetically modified or not). In addition, on

[66] Anne Ingeborg Myhr and Terje Traavik, "The Precautionary Principle: Scientific Uncertainty and Omitted Research in the Context of GMO Use and Release," *Journal of Agricultural and Environmental Ethics* 15, no. 1 (2002): 73–86; Sue Mayer and Andy Stirling, "Finding a Precautionary Approach to Technological Developments—Lessons for the Evaluation of GM Crops," *Journal of Agricultural and Environmental Ethics* 15, no. 1 (2002): 57–71.

[67] *Bacillus thuringiensis* was later proved so successful in corn that it was tested in other plants, where it proved to be effective in controlling other insects as well.

[68] Susan Milius, "New Studies Clarify Monarch Worries," *Science News* 156 (December 18 and 25, 1999): 391.

[69] Jim Ritter, "Genetic Food Fallout," Associated Press Wire, February 28, 2000.

[70] Steven J. Milloy, "The Greens' Ear-ie Ad," *Washington Times,* December 10, 1999: 21.

https://doi.org/10.1017/S0265052509090281 Published online by Cambridge University Press

https://doi.org/10.1017/S0265052509090281 Published online by Cambridge University Press

milkweed plants in areas adjoining cornfields, Monarchs prefer to lay their eggs on the upper leaves of plants rather than the lower leaves where corn pollen builds up. Finally, the levels of corn pollen found on milkweed plants along the immediate edge of cornfields was less than half of those levels that produced caterpillar deaths in the laboratory, and these levels fell to between one ninth and one one-hundredth of the amount shown to cause harm just ten meters from the cornfield edge.[71]

After the Bt scare blew over, the bacteria was eventually introduced into other crops with the result that crops with the Bt modification are the fastest-growing group of GM crops in the world. Indeed, most of the twelve million farmers in the world that farm GM crops are raising crops that use the Bt modification: 7.1 million in China (Bt-cotton), 3.8 million in India (Bt-cotton), and the balance in the Philippines (biotech maize), South Africa (biotech cotton, maize, and soybeans often grown by subsistence women farmers), and the other eight developing countries that grew biotech crops in 2007. Even Poland, in PP-dominated Europe, now grows Bt-corn.[72]

Another example of the threats posed by GM crops cited by environmentalists is the case of the GM soybean hybrid developed by Pioneer Hi-Bred. Pioneer transferred genes from the Brazil nut into soybeans in an effort to improve the nutritional quality of animal feed. However, before commercial introduction, research by the company into the possible allergenic properties of the product revealed that the gene that made the soybeans higher in protein also carried an allergenic trait that could produce immunological reactions (ranging from severe to mild) in people suffering from Brazil nut allergies.[73] But what this example shows, if anything, is that thus far, at least, the current regulatory regime and the common commercial practice of testing agricultural innovations before commercial introduction has been adequate to protect the public and the environment from harm caused by bioengineered crops.

It is important to note that none of the risks feared by PP backers are unique to genetically modified plants. For instance, Henry Miller and Gregory Conko have pointed out that in recent years conventional breeding, of the trial-and-error variety, has resulted in the production of varieties of squash, potatoes, and celery that contained dangerous levels of toxins.[74]

The risks posed by genetic modification of crops are not unique, because GM is simply a targeted, more focused extension of conventional breed-

[71] Milius, "New Studies Clarify Monarch Worries," 391.

[72] *Global Status of Commercialized Biotech/GM Crops: 2007* (see note 59 above).

[73] Julie A. Nordlee, Steve L. Taylor, Jeffrey A. Townsend, Laurie A. Thomas, and Robert K. Bush, "Identification of a Brazil-Nut Allergen in Transgenic Soybeans," *New England Journal of Medicine* 334, no. 11 (March 14, 1996): 688–92.

[74] Henry I. Miller and Gregory Conko, "The Toxic Politics of Biotech," *Tech Central Station,* October 6, 2004, http://cei.org/gencon/019%2C04249.cfm. Miller was founding director of the U.S. Food and Drug Administration's Office of Biotechnology in 1989 and is currently a senior research fellow at Stanford University's Hoover Institution. Conko is director of Food Safety Policy at the Competitive Enterprise Institute.

ing. Crops naturally evolve; genetic changes occur. Through conventional breeding techniques—cross-breeding to select for specific traits—humans have increased the flow and modification of genotypes and phenotypes. Most of the major food crops have been so altered through conventional breeding that they hardly resemble in appearance, fecundity, or nutritional quality the wild ancestors from which they arose.[75] This view was reinforced by the National Research Council (NRC), which wrote that "there is no evidence suggesting [genetically modified food] is unsafe to eat." The NRC went on to report that there is "no strict distinction between the health and environmental risks posed by plants genetically engineered through modern molecular techniques and those modified by conventional breeding practices."[76]

Indeed, because it can target specific genes, biotechnology should often reduce the risk of the spread of unwanted traits that is common with conventional cross-breeding. The NRC also concluded that any negative impact on nontarget species, such as beneficial insects, is likely to be smaller than that from chemical pesticides.[77] Genetic modification should also reduce the amount of time it takes to create a new variety of plant with selected (even multiple) desirable characteristics.

Concerning the threat of super weeds or pests: as with pests that become resistant to the traditional pesticides used on non-GM crops, if the targeted insects or plants develop immunity to the transferred GM trait, farmers can resort to other pesticides to kill them. In the end, as one commentator wrote recently, "biotechnology might go awry in 105 unexpected ways, but the result would be a nuisance rather than a catastrophe."[78] As importantly, biotech crops go through greater regulatory scrutiny, even in the United States, than newly created conventionally bred varieties, and the evidence indicates that the current testing regime is capable of finding any but the most remote potential problems before they result in substantial or irreversible harms to humans or the environment.

V. Can the Precautionary Principle Be Salvaged?

The problems noted above have caused many scholars, commentators, and policymakers to question the utility of the PP as a guide to shaping policy. This section will discuss an attempt to answer some of the criticisms leveled at the PP above, and thus provide a PP that can be used to guide public policies.

[75] Alan McHughen, *Biotechnology and Food* (New York: American Council on Science and Health, 2000).

[76] Associated Press, "Study Says Bio-engineered Foods Safe, But More Tests, Monitoring Urged," *Dallas Morning News,* April 6, 2000: 5A.

[77] Ibid.

[78] Holman W. Jenkins, Jr., "Fun Facts to Know and Tell about Biotechnology," *Wall Street Journal,* November 17, 1999: A23.

https://doi.org/10.1017/S0265052509090281 Published online by Cambridge University Press

https://doi.org/10.1017/S0265052509090281 Published online by Cambridge University Press

Indur Goklany, assistant director of science and technology in the U.S. Department of the Interior's office of program analysis, finds the precautionary principle—the idea of not acting precipitously or recklessly—too intuitively attractive to dismiss out of hand.[79] For Goklany, however, the goal of using a PP should be to help identify policies that would most reduce overall risks.

Most policies reduce some public health and environmental risks while increasing or prolonging others. Accordingly, Goklany argues that the only truly precautionary policy for each proposed restriction on some e-activity is to compare the risks of adopting the e-activity against the risks of the status quo; in instances where a policy reduces risks both to human health and to the environment, all other things being equal, we should adopt the policy.

A. A properly focused precautionary principle and a framework for applying it

Goklany develops a framework for applying the PP in situations where a particular policy will result in both positive and negative outcomes and where, moreover, both sets of outcomes are uncertain. The framework allows risks to be compared based on their nature, severity, magnitude, certainty, immediacy, and other characteristics.

For Goklany, mortal threats to humans outweigh similar threats to other species. Indeed, even nonmortal threats to humans should, in most instances, take precedence over threats to other parts of the environment.[80] These anthropocentric criteria allow policymakers to account for necessary trade-offs in situations where a policy's net effect on environmental risks is in the opposite direction from its net effect on health.

However, relatively few policy issues present clear conflicts between human life and health and harm to other species. Most actions under review for regulation result in both potential benefits and potential harms for public health (and welfare), and bring with them both positive and negative environmental consequences unrelated to public health. Accordingly, Goklany proposes that, all else being equal, more immediate threats and threats of harm that have a higher probability of occurring should be

[79] Indur M. Goklany, *The Precautionary Principle: A Critical Appraisal of Environmental Risk Assessment* (Washington, DC: Cato Institute, 2001). Unless otherwise noted, the material in this section comes from this book.

[80] I would add that, in a liberal polity in which one of the primary responsibilities of government is respecting and protecting individuals' liberty and rights, this criterion should be expanded to threats to individual rights. Goklany does not extend his principles in this manner, perhaps because his views are founded not on a rights-based liberalism, but rather on a liberalism based on utilitarian calculations. Based on e-mail exchanges, Goklany's view seems to be that individual liberty has no (or at best limited) independent value apart from its tendency to generally promote well-being, defined as macroeconomic progress; beyond the ethical criteria, policies are worth enacting, or at least worth serious consideration, if they promote overall net social benefits.

given priority over threats that could occur later or those that are less certain, provided the potential consequences are of equivalent severity.[81] In addition, in instances where there are threats to human mortality, human health, or the environment that are equally certain, precedence should be given to those that have a higher expectation value. For instance, actions (or policies) that would result in fewer expected deaths or that present lesser threats to biodiversity should be preferred over those that result in a larger number of expected deaths or greater risks to biodiversity.

In many situations, there are technologies available to adapt to or cope with adverse consequences of an action (or a policy, including a policy of inaction). In such situations, the impact can be discounted to the extent that the threatened harm can be counteracted. Finally, Goklany argues that priority should be given to preventing outcomes that are irreversible or likely to be more persistently harmful, rather than to harms or costs that are temporary in nature.

B. Applying Goklany's precautionary principle

Among the policy issues to which Goklany applies his version of the PP in order to demonstrate how it should work in practice is the development and use of GM crops.

Even without the human health criterion, applying this framework to evaluate whether a precautionary global ban on GM crops is justified leads Goklany to conclude that a ban would, in fact, increase net global risks to both health and the environment. Thus, contrary to conventional environmental wisdom, the precautionary principle should require the use of GM crops, provided that due caution is exercised prior to commercialization of individual GM crops.

Annually, hunger and malnutrition kill over six million children worldwide.[82] Preventing and reducing the future toll of hunger and malnutrition in the face of increasing global population requires enhancing the quantity and nutritional quality of food. The faster this occurs, the fewer the casualties. In addition, no other human activity has a greater impact on the environment than agriculture. Agriculture accounts for 38 percent of global land use, 66 percent of the world's water withdrawals, and 85 percent of consumptive use worldwide.[83] Landscapes, ecosystems, waterways, and watersheds have been entirely reshaped, with profound effects on biodiversity, as lands have been brought under the plow.

[81] Ibid., 9–10. All further criteria are also found on page 10.

[82] World Health Organization, *Malnutrition Worldwide (1999),* www.who.int/nut/malnutrition_worldwide.htm.

[83] Land use numbers come from the Food and Agriculture Organization, FAOSTAT Database, http://www.apps.fao.org (2001). Water use numbers come from Igor A. Shiklomanov, "Appraisal and Assessment of World Water Resources," *Water International* 25, no. 1 (March 2000): 11–32. "Consumptive use" means withdrawing water from its source for human uses—for example, water used for drinking, cleaning persons or property, or irrigation. Nonconsumptive use would include recreational or commercial fishing, for example.

https://doi.org/10.1017/S0265052509090281 Published online by Cambridge University Press

https://doi.org/10.1017/S0265052509090281 Published online by Cambridge University Press

The U.S. experience since the broad introduction of GM crops in 1996 clearly indicates that the health effects of ingesting GM crops have so far been undetectable, if they exist at all. Goklany notes that GM crops are already proving that, when allowed, they can appreciably increase the quantity and nutritional quality of food supplies faster than conventional crops.[84] Therefore, banning GM crops would, by retarding reductions in global hunger, malnutrition, and nutrition-related diseases, raise mortality and morbidity rates worldwide higher than they would be otherwise.

With respect to environmental risks, environmental pressures can be reduced more rapidly (and more certainly) with GM crops than with conventional crops because GM crops are more likely to increase agricultural productivity per area of land and volume of water, increase it faster, and do so with fewer or lower inputs of toxic chemicals.

In conclusion, Goklany's formulation of the PP is arguably a sophisticated version of a cost-benefit analysis. It argues for taking into account what is known about the risks and benefits of proposed actions, and it weighs the likelihood of their occurring and when they may occur, giving extra weight to risks to human health and interests. Goklany's reformulation of the PP may answer the concerns of some critics of conventional versions of the PP—as defined, for example, in the Wingspread Declaration. However, it is unlikely to be accepted by those who argue for wider adoption of the PP as conventionally defined in law.

The application of Goklany's version of the PP may, in practice, result in policies identical or at least largely similar to those touted by some critics of the PP. For instance, while Robert Hahn, Cass Sunstein, and Gary Marchant provide a long list of criticisms of conventional versions of the PP, as noted above, their most persistent criticisms are twofold: (1) conventional versions of the PP are inherently vague or ambiguous and thus do not provide useful guidelines for policymakers concerning when and how much to regulate; and (2) conventional versions of the PP only look at the potential harms or costs from a proposed action, ignoring both the potential benefits from the action and the harms that might result (or continue) from inaction.[85] With regard to the first point, on their view, the Wingspread version of the PP is a recipe for policy paralysis at worst and for inconsistent or arbitrary actions and court rulings at best.[86] In contrast to conventional versions of the PP, however, Goklany's version clearly

[84] See, for example, Goklany, *The Precautionary Principle*, 29–56.

[85] Hahn and Sunstein, "The Precautionary Principle as a Basis for Decision Making"; Gary Marchant, "From General Policy to Legal Rule: Aspirations and Limitations of the Precautionary Principle," *Environmental Health Perspectives* 111, no. 14 (2003). Marchant is a law professor with Center for the Study of Law, Science, and Technology at Arizona State University.

[86] On the PP as a recipe for policy paralysis, Hahn and Sunstein write: "A key problem with strong versions of the precautionary principle is that they are logically inconsistent. They would frequently eliminate all policies from consideration—including the status quo—because almost all policies impose risks of one kind or another." Hahn and Sunstein, "The Precautionary Principle as a Basis for Decision Making," 2. On the ambiguity and arbitrariness of the PP, see Marchant, "From General Policy to Legal Rule," 1800–1801.

accounts for both the harms threatened and the rewards possible from proposed actions and provides clear principles for when to apply the PP, what criteria to apply when considering regulation of a proposed activity, and how to weigh the relative risks and rewards. In short, Goklany attempts, as Marchant suggests, to "better define the appropriate application of precaution. In particular . . . 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." [87]

Proponents of conventional versions of the PP, such as that found in the Wingspread Declaration, would reject a reformulated version because it defeats the theoretical purpose of using the PP: preventing potentially catastrophic harms for which traditional risk analysis cannot adequately account. For proponents of the Wingspread Declaration and PP proponents like Stephen Haller, Goklany's reformulated PP is simply an updated version of traditional cost-benefit analysis with its inadequate accounting for the depth of scientific uncertainties, its inability to deal properly with potentially catastrophic risks, and its bias against future generations and environmental harms (when compared to human desires for economic progress). On this latter point, many traditionalists who call for a more holistic environmental ethic would reject Goklany's reformulated PP's explicit anthropocentrism.[88] Others would argue that it treats future generations unfairly—that is, it too deeply discounts the needs of future generations when compared to present generations.[89]

VI. Giving Up on the Precautionary Principle Does Not Mean Throwing Precaution to the Wind

In an earlier essay on this topic, I noted that whatever utility the PP has stems from applying it to itself.[90] As the Social Issues Research Center in Oxford, England, has stated, "If we apply the precautionary principle to

[87] Marchant, "From General Policy to Legal Rule," 1802–3.

[88] See, e.g., Laura Westra, "Post-Normal Science, the Precautionary Principle, and the Ethics of Integrity," *Foundations of Science* 2 (1997): 237–62; Hugo Fjelsted Alroe and Erik Steen Kristensen, "Toward a Systemic Ethic: In Search of an Ethical Basis for Sustainability and Precaution," *Environmental Ethics* 25 (Spring 2003): 59–78; and Robin Attfield, "The Precautionary Principle and Moral Values," in O'Riordan and Cameron, eds., *Interpreting the Precautionary Principle,* 152–64.

[89] Edith Brown-Weiss, *In Fairness to Future Generations: International Law, Common Patrimony, and Intergenerational Equity* (New York: Transaction Publishers, 1989); see also Haller, "A Prudential Argument for Precaution under Uncertainty and High Risk." See also Ernest Partridge, ed., *Responsibilities to Future Generations* (New York: Prometheus Books, 1981), for numerous arguments both for and against the notion that present generations have obligations to future generations. Some of these arguments are tied to the precautionary principle, as noted in Wilfred Beckerman, "The Precautionary Principle and Our Obligation to Future Generations," in Morris, ed., *Rethinking Risk and the Precautionary Principle,* 46–59.

[90] Burnett, "Progress at Risk" (*supra* note 44).

https://doi.org/10.1017/S0265052509090281 Published online by Cambridge University Press

https://doi.org/10.1017/S0265052509090281 Published online by Cambridge University Press

itself—ask what are the possible dangers of using this principle—we would be forced to abandon it very quickly."[91]

I would argue that this still holds true. The wholesale adoption of the PP would, as its proponents maintain, be a radical break with the principles and practices that have shaped public policy and regulations in the past. Therefore, I would argue that before adopting the PP as a guide for public policy, the burden should be on its proponents to show: (1) that current policies aimed at reducing risk and preventing harm to public health and the environment are inadequate; and (2) that the PP is workable in practice and would prevent more harm than current policies.

With regard to the first point, proponents of the PP have failed to make a convincing case that current regulations consistently fail to protect public health. As in every other area of life, in regulations perfection is not an option. It is certainly true that, on occasion, technologies and products have reached the market that later proved to cause unanticipated harms. However, as law professor Gary Marchant notes: "[M]any 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. . . . [In these cases] the problem was ignorance rather than uncertainty about risks that were outside the scope of forseeable effects."[92]

Since we are not omniscient and cannot prevent unanticipated effects, it is difficult to see how the PP would be better than current policies at addressing risks and harms of which we are ignorant rather than merely uncertain. In addition, Marchant notes that if we begin to substitute the PP as a legal rule in place of current risk-assessment policies in order to prevent type II errors, this will almost certainly result in an increase in type I errors. It is hardly clear that such a result would be an improvement over current practice.

If we consider the case of GM foods, we can observe that none of the risks or harms stemming from the use of such foods that have been raised by PP proponents have come to pass. This fact surely ought to count against the claim that present regulations have failed to protect the public and thus need reform with the PP as a basis. Under current regulatory regimes, all the GM foods that have been commercialized to date have gone through extensive safety testing, and no harm to human health or the environment has ever been demonstrated. There have been rare instances where the possibility of the type of harm predicted by proponents of the PP did seem to appear, but even then the current regulatory regime (and common commercial practices) proved adequate to assess and respond to the risk. In the case of Bt-corn and its purported threat to Monarch butterflies, for instance, further research proved that the threat, if not entirely nonexistent, is at least substantially overstated. In another

[91] Social Issues Research Center, "Beware the Precautionary Principle," 1999, http://www.sirc.org/articles/beware.html.

[92] Marchant, "From General Policy to Legal Rule," 1799.

case, that of Pioneer Hi-Bred soybeans, the risk of allergic reaction was discovered in the testing stage, with the result that the product was never commercialized.

While it is not clear that the principles out of which the current regulatory regime have developed (or the resulting regulations themselves) are inadequate to protect public health when compared to the PP, there are indications that the PP, as it is incorporated into public policies and international laws, does pose a threat to public health. To the extent that proponents of the PP, and nations or multinational organizations, are effective at restricting or limiting the use of existing GM crops or the creation and dissemination of new biotech foods, untold harm is likely to result. Indeed, harms driven by the precautionary principle may already be occurring. Marchant provides the example of Zambia, which cited the PP as its reason for rejecting food aid from the United States that contained GM corn, even though the corn has not proven harmful and the UN Food and Agriculture Organization concluded that the decision would leave 2.9 million citizens at risk of starvation.[93]

How many people, if any, died as a result of this decision? We may never know, and that is another factor that weighs against giving legal standing to the PP. Environmental harms, or human illnesses or deaths, that result because a product or technology was not allowed to enter the marketplace are likely to be underreported or go unaccounted for and thus not be taken into account when considering expanding the use of the PP in law. Deaths from products—such as medicines—that are allowed to enter the market are much clearer or easier to trace than deaths from illnesses that might have been prevented had a novel product been allowed into the market.[94]

As a basis for law, the PP is too ambiguous to provide consistent guidance for policymakers. One source of the PP's ambiguity is the fact that so many different versions are in popular use, each specifying different levels of risk and uncertainty as triggers for precautionary action. Ambiguity also results from the fact that every version of the PP fails to articulate what factors will determine when the PP applies and when it does not. Formulations of the PP also fail to provide a clear answer regarding how much precaution to apply in a given circumstance. While shifting the burden of proof to those who would introduce new products or technologies into the marketplace, proponents of the PP fail to specify when that burden of proof is met—except for strong versions of the PP which specify that the burden is met when those introducing the technology can prove it poses no threat of harm.

Marchant argues that the lack of specificity or the inherent ambiguity of the PP invites arbitrary applications in law and legal rulings concerning

[93] Ibid., 1802.

[94] Marchant makes this same point, arguing that it is inherently more difficult to verify false positives (what I refer to as "type I errors") than false negatives. See ibid., 1800.

https://doi.org/10.1017/S0265052509090281 Published online by Cambridge University Press

https://doi.org/10.1017/S0265052509090281 Published online by Cambridge University Press

when the PP applies and what it requires when it applies.[95] He notes that there have been hundreds of regulatory and judicial decisions in Europe and elsewhere that rely on the PP, but few of the decisions provide any analysis of why the PP applies in the particular case at issue but not in others, or why the PP requires the particular finding reached in the specific case. Rather, the decisions generally cite the PP and then adopt the most restrictive protective action under consideration.

Europe's response to GM foods is a clear example of this phenomenon. The EU applies the precautionary principle to GM foods but not to organic foods. Yet every GM food has undergone extensive testing, and none has ever been proven harmful to human health or the environment. By contrast, organic foods are typically not tested before commercialization, and contaminated organic foods have resulted in known instances of human illness. Quite aside from instances of contamination, scientists have identified a range of possible risks from organic foods, including increased toxicity from the natural pesticides used on organic crops and *E. coli* infections from the manure used as fertilizer in organic farming.[96] If anything, current evidence suggests that on a strictly precautionary basis, organic foods merit more scrutiny than GM foods, yet the opposite is the case, and the EU has offered no justification for this disparate treatment.

The PP invites arbitrary decisions from governments and agencies as they formulate regulations and make decisions under those regulations. As I noted in Section III, even though the EC (following the recommendations of its scientific advisory body) ruled that member nations should allow the use of select GM crops that it had approved, the countries have refused to comply, citing the precautionary "national safeguard clause" in EU law. To take another example, the EU used the PP as a basis for retroactively banning the import of North American beef from animals treated with growth hormones, even though the European Food Safety Authority and World Trade Organization panels found no scientific rationale for the ban.[97]

Depending upon a particular court's disposition (and the particular case), the PP either limits the judiciary's effectiveness as it attempts to exercise its responsibility for ensuring the legality and reasonableness of agency decisions, or invites arbitrary decisions. Concerning the latter point, as I have noted, courts have routinely cited the PP as a basis for choosing to use the more stringent of possible protective actions, without articulating why the principle applies or why it requires the result specified. Concerning the former point, because the PP is so vague, it gives regulators a great deal of discretion or latitude when determining whether or not (or the extent to which) an action merits precautionary restrictions.

[95] Ibid., 1801.

[96] See, for example, Anthony J. Trewavas, "Urban Myths of Organic Farming," *Nature* 410 (March 22, 2001): 409–10; or John Tierney, "Is Food Safe Just Because It's Organic?" *New York Times,* August 25, 2000: B1.

[97] Marchant, "From General Policy to Legal Rule," 1802.

Because of this, some judges have questioned whether the PP allows for meaningful judicial review or oversight of agency actions. For instance, as Marchant notes, one EU court has written 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 discretions' the PP gives to political authorities."[98] If the PP undermines the ability of courts to exercise regulatory oversight, it has a serious defect, since meaningful judicial review is arguably a necessary component of any legal system that wants to claim legitimacy for the actions of its legislature, administration, and administrative agencies.

VII. Conclusion

In this essay, I have examined the precautionary principle. I pointed out that in one version or another, the PP is having a growing influence on public policy and international law. I discussed arguments made for adoption of the PP and found them lacking both in the light of theoretical criticisms of the justifications offered for the PP, and the practical effects that widespread adoption of the PP would have for human welfare—in particular with regard to the development and use of GM foods. I looked at an attempt to develop a less objectionable version of the PP and found that, while it answers some of the criticisms raised against the PP, in principle, it differs only modestly from the types of risk analyses that are conducted under present U.S. law.

In conclusion, the PP offers no clear improvement over the current regulatory regime, based in scientific risk-benefit analysis. Indeed, the PP is inherently ambiguous and provides little clear guidance for policymakers. Ultimately, precaution as an aspiration may be worthwhile, and certainly some level of precaution is built into present laws; however, the PP has little merit as a basis for law or regulatory policy.[99]

Environmental Policy, National Center for Policy Analysis

[98] Ibid.

[99] Some critics argue that present law already contains too much precaution, resulting in unnecessary harms. For them, rather than adopting the PP as an explicit basis for future laws and regulations, many of the present precautionary aspects of the law should be reduced or eliminated. See, for instance, Adler's discussion of the drug approval process and restrictions on the use of DDT, in Adler, "The Precautionary Principle's Challenge to Progress," 285–88. Though I share that view, that is a case to be made at another time in another essay.

https://doi.org/10.1017/S0265052509090281 Published online by Cambridge University Press