CAST® Issue Paper
Number 52
June 2013

Impact of the Precautionary Principle on Feeding Current and Future Generations

The Goldilocks Strategy may be the most appropriate when striving for a balanced and deliberate approach to precaution. (Photos from Shutterstock.)

Abstract

After a research-based analysis and peer-reviewed process, the authors of this CAST Issue Paper make it clear: "The precautionary principle may well be the most innovative, pervasive, and significant new concept in environmental policy over the past quarter century. It may also be the most reckless, arbitrary, and ill-advised." Using data, specific examples, and case studies, the task force members conclude with allusions to a literary paradox, a child's fairy tale, and a futuristic axiom to make their points.

The paper first looks at the history of the precautionary principle (PP) and then examines problems of ambiguity, arbitrary application, and bias against new technologies. Because the publication is especially focused on the need to feed a growing population, the case studies center on agricultural issues such as chemical use and genetically modified foods. They use a quote to illuminate their Catch-22 concern: "A ban on genetic engineering of food is literally dangerous to people who have a great deal to gain from genetic modification. The precautionary principle forbids genetic modification of food because it gives rise to risk, but the precautionary principle also forbids forbidding of genetic engineering of food because forbidding genetic engineering of food gives rise to risk" (Sunstein 2006b).

The authors give examples of the PP's failure to offer a credible and reasoned framework for the application of risk management. They describe inconsistencies and suggest that the PP will be increasingly controversial, marginalized, and ignored in the future. They acknowledge the importance of safety and give credit to the general concept that sparked the PP, but they indicate it has become unworkable and counterproductive. A passage in the conclusion illustrates this: "As with many things in life, the Goldilocks strategy may be most appropriate—not too little precaution, not too much, but just the right amount is needed. If the PP helps us to more consciously strive for such a deliberate and balanced approach to precaution, that might be its most positive legacy."

The PP has played an important part in bringing attention to appropriate risk management. If it is applied in its more stringent formulations, however, the PP will suppress innovation, to the detriment of both the economy and human health. For example, a precautionary approach to managing the risks associated with food irradiation sends a message

This material is based upon work supported by the U.S. Department of Agriculture's (USDA) National Institute for Food and Agriculture (NIFA) Grant No. 2010-38902-20899. Any opinions, findings, conclusions, or recommendations expressed in this publication are those of the author(s) and do not necessarily reflect the views of USDA–NIFA, any other USDA agency, or the USDA.

CAST Issue Paper 52 Task Force Members

Authors

Gary Marchant (Chair), Sandra Day O'Connor College of Law, Arizona State University, Tempe

Linda Abbott, Office of Risk Assessment and Cost-Benefit Analysis, U.S. Department of Agriculture, Washington, D.C.

Allan Felsot, Department of Entomology and School of the Environment, Washington State University, Richland

Robert L. Griffin, Plant Epidemiology and Risk Analysis Laboratory, U.S. Department of Agriculture, Raleigh, North Carolina

Reviewers

Richard Crowder, Department of Agricultural and Applied Economics, Virginia Tech, Blacksburg

Leen Hordijk, Joint Research Centre, European Commission, Brussels, Belgium (retired)

Andrew LaVigne, American Seed Trade Association, Alexandria, Virginia

CAST Liaison

Thomas P. Redick, Global Environmental Ethics Counsel, Clayton, Missouri

that the technology is more dangerous than the benefits. This assumption that acting to protect cannot result in damage has led to a reluctance to use a technology that could actually be a great benefit to food safety.

In many respects, the PP does more harm than good. Of course, commonsense safety practices are necessary, and these findings do not advocate reckless abandon. But the future involves a mission to feed "a population of 9.1 billion by 2050." The PP has failed as an overall risk management strategy, and it is time to move past it.

Introduction

Managing risks has become a central focus of modern society. Indeed, the term "risk society" is often used to describe modern life (Beck 1992). Successful management of risk presents difficult challenges and requires careful balance. On one hand, as our society becomes wealthier, healthier, and longer-lived, we are less tolerant to risks that could prematurely shorten or diminish the enjoyment of our new prosperity. The development of powerful new technologies that have the potential to create new and, in some cases, potentially irreversible risks further enhances the need to better manage risks. On the other hand, overly restrictive *risk management* will suppress innovation and impede new technologies that may lessen future risks as well as provide important benefits. It is a general (although not universal) observation that new technologies tend to be safer than the older technologies they replace (Huber 1983). Thus insufficient precaution would allow unacceptable existing and new risks to occur, whereas excessive precaution is likely to make us less safe and prosperous by restricting beneficial new technologies. Finding the delicate balance between these undesirable outcomes from too little or too much precaution is the goal of effective risk management.

Perhaps no risks—real or potential—have created more concern, debate, and controversy than those relating to food. Food is obviously a basic requirement for human survival. In recent years, food has also become a central focus of risk management. Highly publicized incidents of deaths or illnesses resulting from contaminated foods in North America, Europe, and China have increased public sensitivity about food safety. New technologies applied to food, such as food irradiation, genetic modification, and nanotechnology, have resulted in new disputes about food safety. Trends toward organic, "natural," and even unpasteurized food products evince not only social and philosophical concerns but also worries of food safety and new food technologies by vocal segments of the populations of developed nations.

At the same time, without adoption of new technologies and other drivers of productivity growth in food and agriculture, food production will not keep up with global food demand expansion that is being driven by income and population growth. The global population is projected to exceed 9 billion by 2050. Global food demand is projected to double in that same time period, which will require significant increases in agricultural productivity in all regions of the world (FAO 2009; Global Harvest Initiative 2012). New technologies, in combination with economic, social, and political advances, will be critical to meeting this growing food demand.

In this highly polarized and contested field of managing the risks of food, the concept known as the "*precautionary principle*" (PP) emerged some 20+ years ago. Originating primarily in Europe, the PP has encountered a much more skeptical reception in the United States and elsewhere, although it has its supporters even in those areas. These different national perspectives on the PP are causing enormous disruptions in international trade and markets at this time by producing inconsistent regulations on food technologies such as genetically modified crops, antimicrobial treatments in processing, chemical feed additives in meat, and pesticides that are resulting in unjustified and harmful trade restrictions. Almost every new agricultural and food technology being developed for the future is likely

to face similar restrictions if the PP continues to block new technologies. These and other PP-related controversies threaten to derail the new free trade agreement that is being negotiated between the European Union (EU) and the United States. As the German Foreign Minister, Guido Westerwelle, recently warned, the "treaty cannot fail because of chlorinated chickens this time" (Pauly and Schult 2013). There has thus never been a more urgent need or time to clarify the role of, and resolve the controversies over, the PP.

This Issue Paper seeks to understand and evaluate the PP, especially as it applies to food. The paper first summarizes the history, objectives, and limitations of the PP, then considers three case studies in which the PP has been applied to food, and concludes with some recommendations on how the controversy over the PP might be resolved.

The Precautionary Principle: History and Objectives

The PP concept has received increasing attention around the globe, stirring both support and controversy in each jurisdiction and context in which it has been adopted or proposed. This section describes the tumultuous rise and spread of the PP (see Textbox 1), the arguments supporting its rapid proliferation, and the growing resistance and declining momentum the PP is now facing.

History of the Precautionary Principle

The PP emerged in the latter decades of the 20th century as an overarching philosophy of prudent caution in the environmental programs of nations such as Germany and Sweden. After then being incorporated into several relatively unknown regional and international treaties primarily relating to marine protection and being proposed for others (Freestone and Hey 1996; Lofstedt, Fischhoff, and Fischhoff 2002), the PP jumped into international prominence with two important developments in 1992. First, the United Nations Conference on Environment and Development (UNCED) endorsed a relatively weak version of the PP, which remains the only version supported by the United States to this date (UNCED 1992). Second, the EU adopted the PP into the 1992 amendments to the Treaty of Rome, the foundational treaty of the EU, making it a binding principle of EU environmental law. Subsequent interpretations of this provision by the European Commission and the European Court of Justice expanded the scope of the PP to apply to all environmental, health, and safety regulatory decisions in the EU.

The EU did not define or explain the PP when it adopted it as a mandatory legal requirement, simply stating that "the precautionary principle" shall apply. Eight years after adopting the PP, the European Commission published the most extensive official explanation of the principle to date in its 2000 "Communication" on the PP (Commission of the European Communities 2000). The Communication expressly stated that the PP applies in the risk management rather than *risk assessment* stage of decision making, to be applied only after the fullest possible scientific assessment of risks. The Communication also set forth criteria for application of the PP, including that actions taken pursuant to the PP must be "*proportional* to the chosen level of protection; *non-discriminatory* in their application; *consistent* with similar measures already taken; *based on an examination of the potential benefits and costs* of action or lack of action (including, where appropriate and feasible, an economic cost/benefit analysis); *subject to review* in the light of new scientific data; and *capable of assigning responsibility for producing the scientific evidence*" (Commission of the European Communities 2000).

Although advancing understanding of the PP, the Commission's Communication did not define it and avoided answering critical questions about its application, such as what quantum of evidence of risk is needed to trigger the PP or what level of risk is acceptable under the PP. The Commission explained that such questions were "political questions" to be decided on an ad hoc basis by politicians or regulators. The Commission's construction of the PP in its Communication, such as its requirement that the application of the PP be based on cost-benefit balancing, was vociferously opposed by many proponents of the PP in the EU Parliament, by numerous environmental and citizens' groups, and elsewhere (ENDS Europe 2000; Lofstedt 2004). After facing so much opposition and controversy to its initial attempt to explain and operationalize the PP, the Commission has refrained from any further concerted attempts to elucidate it.

While the EU has been the global leader in adopting and promoting the PP, other nations have also adopted it by legislative action or judicial opinion, including Australia, Canada, India, Japan, and New Zealand. The PP has also been incorporated into more than 60 international environmental agreements (Trouwborst 2007). More recently, a small number

Textbox 1. Some factors explaining rise of the PP.

- Record of past risk management failures
- Growing mistrust of government and industry
- Rapid development of many new "exotic" technologies (e.g., genetically modified organisms [GMOs], nanotechnology, synbio)
- Increased uncertainty about new risks
- Outdated laws and risk regulatory approaches
- Increased role for nongovernmental organizations (NGOs) on scientific and risk issues
- Can be used as a protectionist trade tool

of U.S. municipal governments, including San Francisco and Seattle, have adopted the PP into their local laws. As was the case with the EU, none of the legal adoptions of the PP include a specific definition of it.

Rationales for the Precautionary Principle

The PP is based on the everyday aphorism that it is better to be safe than sorry and that some degree of precaution is appropriate, indeed essential, for any meaningful regulatory program. Given the inevitable scientific uncertainty that surrounds most environmental, health, and safety risks, it would be unacceptable to require regulators to wait for absolute certainty of harm before undertaking any protective measures, including delaying a potentially dangerous technology or product until additional safety data are produced. Indeed, every regulatory system necessarily has exercised some degree of precaution. The U.S. government, for example, has taken the position that it applies a "*precautionary approach*" in making regulatory decisions. In the words of one U.S. government official, "the US government supports precautionary approaches to risk management, but we do not recognize any universal precautionary principle. We consider it to be a mythical concept, perhaps like a unicorn" (Graham 2002).

The PP, as adopted by the EU, purports to go beyond the precautionary approach employed by the United States to apply precaution more definitively and aggressively (see Textbox 2). The PP changes two things: first, it tries to make explicit the typically implicit application of precaution, a largely unobjectionable goal; and second, and more controversially, it seeks to increase the amount of precaution applied.

The PP's call for greater precaution is premised on the history of previously suspected hazards that were not regulated until extensive harm to human health and the environment had been inflicted (Harremoës et al. 2001). Frequently cited examples include asbestos, lead, and polychlorinated biphenyls or PCBs. The PP seeks to reverse the fallacy that absence of evidence of hazard is evidence of absence of hazard (Grandjean 2005). A number of other factors (see Textbox 1), relating both to the nature of scientific uncertainty and the perceived inadequate regulatory response to many technological risks, have also contributed to the rise of the PP (Ashford 2007; Lofstedt, Fischhoff, and Fischhoff 2002).

Textbox 2. Precaution terminology.

Precaution: As defined by Webster's dictionary, "a measure taken beforehand against possible danger."

Precautionary Approach: A regulatory approach, such as that applied by the United States, that seeks to err on the side of safety by applying precaution informally and implicitly in regulatory decisions.

Precautionary Principle: A legal requirement, such as that enacted by the EU, that mandates the formal and explicit application of precaution in regulatory decisions.

Growing Resistance and Flagging Momentum

Although the PP has experienced a swift rise over the past two decades since its breakthrough in 1992, its expansion and acceptance has stalled in recent years (Lofstedt 2004). It is increasingly encountering criticisms that it is antiscientific and economically damaging. Despite concerted efforts by the EU and advocacy organizations, the United States has steadfastly refused to accept the PP as a formal requirement at the federal level under both Republican and Democratic administrations. Likewise, the PP has made only minor progress in being adopted at the state and local levels. The World Trade Organization has rejected the EU's attempted reliance on the PP to justify restrictions on genetically modified (GM) food exports from nations such as the United States, Canada, and Argentina (WTO 2006).[1]

Even the EU has moderated its application of the PP (Lofstedt 2004), recognizing that in "the real world of multiple risks, the PP must be qualified by the recognition that there are real costs of excessive precaution: False positives, cost, inhibited innovation, and the countervailing risks of regulatory interventions" (Wiener 2002). The EU courts are increasingly reining in the PP, requiring its application to be preconditioned on a scientific risk assessment, the very requirement that most nongovernmental proponents of the PP sought to replace with the PP (Stokes 2008). The EU has recently launched several major new regulatory process initiatives referred to as its "Better/Smart Government" and "evidence-based policy" agendas that appear to at least implicitly diminish and de-emphasize the role of the PP. For example, in its 2004 Communication titled *Towards a European Strategy for Nanotechnology*, a critical document that set forth the European regulatory approach to nanotechnology, the EU Commission rejected calls for a moratorium on nanotechnology and made very little reference to the PP, other than to state that the "Precautionary Principle, as used up to now, could be applied in the event that realistic and serious risks are identified" (Commission of the European Communities 2004). The PP should not be necessary to regulate "realistic and serious risks"—they should and likely would be addressed under any regulatory system.[2]

Moreover, attempts by nations

[1] The World Trade Organization held that world trade law does not sanction GM food trade restrictions based on the PP. Because these nations are not parties to the *Cartagena Protocol on Biosafety*, they are also not subject to the precautionary approach to trade in GM products imposed on parties under that protocol.

[2] The European Parliament has recently advocated more restrictive policies on nanotechnology in products such as food and cosmetics based on the PP.

such as France and Italy to adopt precautionary policies that prohibit GM products approved by the EU have been consistently rejected by the European Court of Justice (ECJ 2012). The United Kingdom House of Commons Science and Technology Committee recommended that the use of the term "precautionary principle" should cease because of its persistent ambiguity (United Kingdom House of Commons Science and Technology Committee 2006). Or, as one of the leading and most respected EU experts on administrative law, Gianomenico Majone, recently wrote, the EU's regulatory actions "such as the strenuous advocacy of the precautionary principle—appear to be manifestations of an infantile disorder of risk regulation rather than progressive moves" (Majone 2010). Although the meteoric rise of the PP appears to have stalled and may even be retreating, the PP is still having an enormous impact on regulatory decisions, international trade, and technological innovation. Unfortunately, for reasons discussed later, these impacts of the PP are mostly negative.

Problems with the Precautionary Principle

A number of criticisms have been leveled against the PP, the three most common being (1) the ambiguity and lack of definition of the PP; (2) the arbitrariness and unprincipled ways in which the PP has been applied; and (3) a bias against new technologies.

Ambiguity

Although many jurisdictions, led by the EU, have adopted the PP as a legal requirement, none have officially defined it. There are many semiofficial and unofficial definitions that have been offered, but these differ in significant ways, even if they seem roughly similar on first impression (see Textbox 3). For example, compare the 1992 UNCED definition with that adopted by a workshop of leading nongovernmental PP proponents gathered at a conference center in Wingspread, Wisconsin, in 1998 ("Wingspread definition"; see Textbox 3). The UNCED definition, described as "wimpy" by one PP proponent (Cranor 2004), is stated in permissive language, applies only to serious and irreversible risks, requires any precautionary action to be "cost effective," and is addressed to risks where there is a "lack of full scientific certainty." In contrast, the Wingspread definition is stated in affirmative and mandatory language, applies to any risk whether serious and irreversible or not, contains no requirement that actions be cost effective, and applies "even if some cause and effect relationships are not fully established scientifically." An even more extreme version of the PP is provided in the 1982 *World Charter for Nature*, which requires that "where potential adverse effects are not fully understood, the activities should not proceed" (United Nations General Assembly 1982). Because the "potential adverse effects" of no technology or product are "fully understood," this version of the PP would seemingly ban anything to which it is applied (Foster, Vecchia, and Repacholi 2000).

Textbox 3. Disparate definitions of the PP.

United Nations Conference on Environment and Development (UNCED 1992)

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

Wingspread Definition (Raffensperger and Tickner 1999)

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

World Charter for Nature (United Nations General Assembly 1982)

Activities which are likely to pose a significant risk to nature shall be preceded by an exhaustive examination; their proponents shall demonstrate that expected benefits outweigh potential damage to nature, and where potential adverse effects are not fully understood, the activities should not proceed . . .

In fact, there are dozens of versions of the PP, differing significantly in multiple dimensions (Sandin 1999). One level of ambiguity of the PP, therefore, is the lack of an official definition and the important variations in the many unofficial versions, none of which have any application precedence. A regulator could choose to apply any of the existing versions, without even stipulating which version is being applied. Indeed, regulators routinely state they are applying "the" PP, but there is no "the" PP—there is only a multitude of different unofficial versions with critical variations in wording, meaning, and application.

A second level of ambiguity of the PP is that none of the many unofficial definitions answer essential questions that are critical to rational risk regulation. For example, none of the PP versions answer questions such as the following (Bodansky 1991; Marchant 2003): (1) What level and types of evidence are needed to trigger the PP? (2) What level of risk is acceptable under the PP? (3) How should the costs (including opportunity costs) of risk reduction or risk avoidance be factored into the decision, if at all? (4) How should "risk-risk" trade-offs or the risks from not adopting a new technology be factored in and managed? (5) What type of action does the PP require?

A third level of ambiguity concerns differences in the understanding of the intended purpose and status of the PP. Depending on the source, the PP is sometimes construed as a general philosophy, a rhetorical statement, an informal rule of thumb, a risk management decision rule, or a legally

binding requirement (Marchant 2003; Starr 2003; Weed 2002).

Some proponents, including the EU, contend that the PP is only to be applied at the risk management stage after a scientific risk assessment (Chapman 1999; Commission of the European Communities 2000), whereas other proponents of the PP state that it should also apply to risk assessment (Cranor 2004; Santillo et al. 1998). More broadly, some argue that the PP is complementary and should be part of the traditional risk assessment/risk management framework that has been used for decades by regulatory agencies (Commission of the European Communities 2000; Goldstein and Carruth 2004), whereas others contend that the PP is antagonistic to the traditional risk assessment/risk management framework and is an alternative to that framework (Cranor 2004; Kriebel and Tickner 2001). Some proponents argue that the PP shifts the burden of proof to the manufacturer of a product (Raffensperger and deFur 1999), whereas others argue that such a shift is infeasible (Trouwborst 2007). Some contend that the PP should only apply to irreversible or catastrophic risks (Sunstein 2006a), whereas others respond that the PP should not be so limited (Ashford 2005). Some argue that the PP implicitly incorporates cost-benefit analysis (Commission of the European Communities 2000; Farrow 2004); others argue that it is an alternative to cost-benefit analysis (Ashford 2007; ENDS Europe 2000).

The inherent ambiguity of the PP has been known and criticized for many years (Bodansky 1991). Other regulatory principles (e.g., cost-benefit analysis) also involve some ambiguity but are gradually defined and implemented through the development of more detailed criteria and guidelines. The PP is unique in that there has been no official attempt to "operationalize" it through adoption of criteria or guidance—other than some initial steps by the EU Commission with its "Communication" that resulted in widespread disagreement among PP proponents—and it appears that any further official attempts to define or refine the PP officially have been abandoned.

Arbitrary Application

Given the ambiguity in the definition, meaning, and application of the PP, it is not surprising that the PP has been applied arbitrarily (Marchant and Mossman 2004). To be sure, the PP is cited in many regulatory decisions that are relatively uncontroversial and likely would have been made with or without the PP. But in other cases, political factors appear to be the only explanation for why the PP is applied to some risks but not others (see Table 1). At least some government officials recognize this potential for mischief in the PP. For example, the EU Commissioner for Health and Consumer Protection, David Byrne, stated in 2004, "I am no fan of the indiscriminate use of precaution. Precaution in this sense can be a thinly disguised trade protection measure, not to mention a badge of political cowardice," and he cautioned that the PP is not intended to be "a joker or wild card that can be played at any moment as a pretext for unjustified measures" (Byrne 2004). Notwithstanding such warnings, some EU entities have used the PP for inappropriate or unjustified restrictions on products and technologies.

For example, the PP is sometimes used to justify protectionist policies. Thus the PP was invoked by Norway and the Netherlands to ban Kellogg's Corn Flakes® allegedly because the added vitamins could potentially harm susceptible individuals, and Denmark relied on the PP to ban Ocean Spray Cranberry® drinks because the added vitamin C could also potentially harm susceptible individuals (Marchant and Mossman 2004). Both decisions had the effect of excluding an American product from European markets to the benefit of domestic competing products. Both decisions were subsequently struck down by courts as thinly disguised protectionist measures that lacked any scientific support (Marchant and Mossman 2004). In other cases, the protectionist intent may be harder to demonstrate but can nevertheless have enormously destructive consequences for the economy and human health (Goldstein and Carruth 2004).

Another important factor influencing application of the PP is the actions of NGOs that target certain products that they politically oppose for special treatment under the PP. For example, there is strong pressure to apply the PP to restrict GM foods but not food manipulated in similar, though non-*genetic engineering*, ways. As a case in point, herbicide-resistant crops created by genetic engineering and non-genetic engineering techniques exhibit similar environmental and health risks, but the PP is selectively being applied only to the GM versions

Table 1. Some dubious applications of the precautionary principle

Jurisdiction	Action Based on PP	Rationale
Norway	Banned cornflakes fortified with vitamins	Vitamins may harm susceptible individuals (*EFTA Surveillance Authority v. Norway* 2001)
France	Banned caffeinated energy drinks	Pregnant women may consume too much caffeine (*Commission v. France* 2004)
Denmark	Banned cranberry juice drinks with extra vitamin C	Some individuals may be susceptible to vitamin C (*Commission v. Denmark* 2003)
EU	Justifying subsidization of coal extraction	None given (European Union 2001)
Zambia	Rejection of U.S. food aid during famine	U.S. corn may contain genetically modified kernels (Bohannon 2002)

(Morris 2007). Similarly, many foods are created by nuclear or chemical mutagenesis, producing greater numbers of unknown mutations than the more precise GM methods (Batista et al. 2008), yet they escape calls for application of the PP.

As a general matter, the PP is often applied selectively to "exotic" new technologies, such as genetic modification, nanotechnology, and synthetic biology, that are often sensationalized (both the risks and benefits) in the news media. Research on public perceptions of risk demonstrates that the public is more concerned about and tends to inflate the risks of technologies that are unfamiliar and uncertain, triggering "dread" responses (Slovic 1987). The extent to which public perceptions should govern application of the PP is one of the most important and controversial aspects of the PP, especially when public perceptions are inconsistent with scientific assessments of risk. Some governments seek to reassure the public about new technologies by invoking the PP to apply precautionary measures, but empirical studies show that such applications of the PP backfire and have the effect of increasing rather than calming public fears about a technology (Wiedemann and Schütz 2005).

There are other examples of arbitrary application of the PP that are only possible because of the lack of any coherent definition or criteria for application of the PP (Marchant and Mossman 2004) (see Table 1). For example, the EU inexplicably justified subsidization of the coal industry based on the PP (Trouwborst 2007), and the government of Zaire denied its own starving population U.S. food aid based on the PP because of the potential for trace amounts of GM corn kernels, something the U.S. population had been consuming for many years (Goldstein and Carruth 2004; Mallaby 2002).

Bias against New Technologies

The PP is applied disproportionately to new technologies and products, which is not surprising given that the primary orientation of the PP is prevention of new risks when there is significant uncertainty (Weiss 2003). A generic focus on new products is problematic because they often present lower risks than the older products they are intended to replace (Huber 1983; Marchant, Sylvester, and Abbott 2009; Sunstein 2005), and failing to adopt new products can increase risks. Regardless of whether the subject is automobiles, pharmaceuticals, pesticides, factories, or a myriad of other products, new technologies are generally safer than the older versions. By imposing a barrier to the introduction of newer technologies, the PP favors the status quo, which could often mean higher risks (Sunstein 2005).

There is another problem concerning how the PP treats new technologies. Many emerging technologies, such as biotechnology, nanotechnology, and synthetic biology, are prime targets of the PP because unfamiliarity increases uncertainty. Thus, political opposition by NGOs is facilitated by invoking the strong PP. Yet these emerging technologies present potential environmental and health benefits in addition to possible risks. It is therefore not obvious whether restricting such a technology under the PP will increase or decrease net risks (Goklany 2001). The PP is thus incoherent. For example, a "ban on genetic engineering of food is literally dangerous to people who have a great deal to gain from genetic modification. So … the precautionary principle forbids genetic modification of food because it gives rise to risk, but the precautionary principle also forbids forbidding of genetic engineering of food because forbidding genetic engineering of food gives rise to risk" (Sunstein 2006b).

Another example of the incoherency of the PP is the use of nanotechnology to develop important cancer therapies and other medical interventions, new environmental remediation approaches, and components in most clean energy technologies (Marchant et al. 2012). It is therefore quite possible, if not probable, that the calls to put a moratorium on all nanotechnology products based on the PP would do more harm than good to public health and the environment. Regulators applying the PP rarely consider the risk-reducing potential of new technologies and instead focus solely on the risk-creating potential, thus resulting in a skewed and potentially self-defeating decision (Miller and Conko 2001; Morris 2002).

The PP may also do more harm than good by placing an impossible or highly burdensome impediment in the pathway of the development of new technologies. As two scholars noted (Holm and Harris 2000):

> As a principle of rational choice, the PP will leave us paralysed. In the case of genetically modified (GM) plants, for example, the greatest uncertainty about their possible harmfulness existed before anybody had yet produced one. The PP would have instructed us not to proceed any further, and the data to show whether there are real risks would never have been produced. The same is true for every subsequent step in the process of introducing GM plants. The PP will tell us not to proceed, because there is some threat of harm that cannot be conclusively ruled out, based on evidence from the preceding step. The PP will block the development of any technology if there is the slightest theoretical possibility of harm.

In other words, if taken and applied in its more stringent formulations, the PP will suppress innovation, to the detriment of both the economy and human health. "Because risks are everywhere, the Precautionary Principle forbids action, inaction and everything in between. It is therefore paralyzing; it bans the very steps that it mandates" (Sunstein 2004). Moreover, the more stringently the PP is applied,

the more likely such application is to create countervailing risks: "as we try to squeeze out more and more risk, the pressure leading to side effects may grow" (Graham and Wiener 1995). Given the many potential negative consequences that the PP is likely to have on human health and the environment, it fails its own test at least in its present undefined and ambiguous status, as it cannot demonstrate that it will not cause any adverse impacts and therefore, according to its own dictates, should be prohibited. As Michael Crichton wrote in *State of Fear*, the "'precautionary principle,' properly applied, forbids the precautionary principle" (Crichton 2004).

Food Case Studies: Precautionary Principle Doing More Harm Than Good?

In this section, three case studies involving the application of the PP to food-related risks are evaluated. These three studies are (1) agricultural chemicals, (2) genetically modified foods, and (3) food irradiation. The studies permit a real-world assessment of the pros and cons of the PP for managing food-related risks.

Agricultural Chemicals

Although the United States does not explicitly apply the PP in regulating pesticides, it does apply a precautionary approach, particularly since statutory changes were adopted in 1996. This case study demonstrates some of the problems of applying an overly stringent and narrow precautionary approach. As a backdrop to evaluating the consequences of a precautionary approach in the evaluation of pesticides, consider several projections of world population growth and food demand. By 2050, feeding a world population of 9.1 billion people will require raising current levels of food production by approximately 70% (FAO 2009). Improving crop yield at a rate similar to the global growth in food demand will require significant reductions in current *yield gaps*,[3] the gap between the average and potential crop yield (Lobell, Cassman, and Field 2009). Losses due to insects, diseases, and weeds contribute to this yield gap. Current estimates of average yield gaps throughout the world range from 20% to 80% of the potential yields (Lobell, Cassman, and Field 2009).

Pesticides have played a significant role in increasing crop yields. Since World War II, food production and demand have kept pace with one another largely because of innovation in science and technology, including agrochemicals (Godfrey et al. 2010). The percentage contribution of pesticides in decreasing global potential yield losses was estimated in 1993 at 35 to 38% for rice, wheat, and maize, and at 43% for soybeans and potatoes (Oerke and Dehne 1997). Even as Earth's climate changes, it is expected that further crop yield increases are likely in some areas because of improved climates for plant growth, but also in other areas through a combination of plant breeding and the continued availability of control techniques for pests, diseases, and weeds (see, for example, Jaggard, Qi, and Ober 2010).

By 2050, there will not only be an increased demand for food but also a change in dietary composition, fueled by a demand for more energy-rich foods like meat (Godfrey et al. 2010; Seufert, Ramankutty, and Foley 2012). Animal production also benefits from pesticide technology because higher yields for feed crops and the control of disease vectors lower the costs of production and decrease the prevalence of animal disease. In short, pesticides will continue to be necessary as the burgeoning world population and income growth increase the demand for food.

[3] Italicized terms (except genus/species names, published material titles, legal case names, and quoted material) are defined in the Glossary.

Now consider the regulatory approach facing pesticide development and use in the United States. It can be argued that a precautionary approach flows through the procedural requirements for U.S. pesticide registration (Applegate 2000). All pesticides sold, distributed, or used in the United States are required to have a valid registration prior to entering the marketplace (United States Code, Title 7, Section 136a [a]). Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the Environmental Protection Agency (EPA) has the sole authority to grant such registrations. Risks to human health and the environment are evaluated before new products are registered.

In 1996, the Food Quality Protection Act (FQPA) added a new periodic review for all pesticides. Even those pesticides with valid registrations when the FQPA was enacted must be reexamined under the act's new risk-based registration approach (United States Code, Section 136a [b] [2] [B] [v]). The FQPA also requires examination of potential impacts of pesticides on vulnerable subpopulations, such as infants and children. During registration, the EPA must ensure that the pesticide will cause no unreasonable adverse effect on human health or the environment once the product is registered and used according to label directions. Registrants must submit data from a battery of required tests (Code of Federal Regulations, Title 40, Section 158) prior to registration. The default condition in absence of satisfying the data requirements is prohibition of sale of the product as a pesticide.

Pesticide registration in the United States also exhibits a precautionary approach to risk management, more evident after the passage of the FQPA. New science policy guidance was created to implement the FQPA's requirement allowing residues on food only if "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide residue,

including all anticipated dietary exposures and all other exposures for which there is reliable information" (United States Code, Title 21, Section 346a [b] [2] [A] [ii]). Precaution is evident in pesticide risk assessment and risk management not only from adherence to formal risk assessment guidelines but also from the discretionary judgment exercised by the assessors (Brock et al. 2003). The uncertainty associated with the numerous choices, both small and large, that assessors make is not often systematically identified, and their combined effect is not evaluated.

Between 1999 and 2006, the EPA reassessed 99% of the tolerances on food, modifying 12% and revoking 33% (USEPA 2012a). Although the FQPA decreased exposure to pesticide residues (USEPA 2012b), it also impacted registration. The influence on registration can be coarsely examined by comparing the rate of product removal from and entry to the market since implementation of the FQPA. Of the 16,952 products that have completed reregistration, 4,742 were reregistered, 10,571 were cancelled or suspended, and 1,639 were amended (USEPA 2012c). New active ingredients and new uses have been registered, but it appears not to be at the same rate at which products were cancelled or suspended. Between 2005 and 2007, 4,065 pesticide registration actions were completed. These included 156 new active ingredients and 457 new uses for previously registered active ingredients (USEPA 2008). The data on reregistered formulated products and new decisions are not reported using the same metrics or over the same time period, making this comparison inexact.

Quantitative examination of regulatory thresholds used in risk management reveals an additional precautionary approach resulting from the discretionary choices made by assessors (Gray 2004). European countries are generally considered to embrace the PP more vigorously than the United States, although analysis reveals that differences in relative precaution depend more on the issue-specific context of the risk than on broad differences in national regulatory regimes (Wiener and Rogers 2002). In one of the few empirical treatments of precaution in risk management, a comparison between the United States and the World Health Organization (WHO) standards—reference doses and acceptable daily intakes used to establish negligible risk levels in food—suggests that the U.S. regulatory approach is more stringent than the WHO policy (Gray 2004). Regulatory thresholds for the same pesticide, based on the same input data, were lower in the United States. Lower reference doses may translate into fewer allowable dietary uses for the pesticide or decreased application rates. If precaution can be measured as regulatory stringency, then U.S. pesticide tolerances appear to be more precautionary than the comparable international (WHO) standards (Brock et al. 2003).

As a specific example, the proposed revocation of sulfuryl fluoride tolerances in 2012 (USEPA 2012d) illustrates an unintended consequence of the new risk-based requirements of the FQPA. Reevaluation of the toxicological endpoint for fluoride resulted in a reassessment of the cumulative and aggregate risks from fluoride-containing pesticides. The total fluoride exposure from all sources (water, food, toothpaste, soil, and pesticides) exceeded the new reference dose, causing the proposed revocation of tolerances for sulfuryl fluoride. Sulfuryl fluoride is a stored product fumigant that has increased in agricultural importance as methyl bromide uses have been curtailed to decrease risk of stratospheric ozone depletion. The reasonable certainty of no-harm test in the FQPA required revocation of sulfuryl fluoride, even though all other fluoride sources contribute more than 97% of total fluoride exposure; revoking sulfuryl fluoride tolerances will not appreciably decrease risk and will likely result in disruption to commodity markets where no fumigant other than sulfuryl fluoride is available or economically feasible to use.

The cost of registration may prevent some products from being manufactured. Food uses are limited by a maximum dietary exposure for all uses no greater than the reference dose. Registering a pesticide with food uses may cost more than $9,000,000 to comply with the tests required (USEPA 2011). The registration process may be too time consuming and costly for registrants to support pesticides for uses with small markets not likely to generate enough revenue to justify the cost of registration. Pesticide registrations are crop or use specific; each crop constitutes a separate use as well as a separate market. There is a real possibility of not having products to protect important agricultural sectors against certain types of pests. Specialty crops (fruits and vegetables) appear to have disproportionately lost registrations relative to larger commodities such as corn or wheat (USEPA 2012e).

As this discussion demonstrates, pesticide registration in the United States incorporates a precautionary approach with respect to the environmental and human health risks from pesticide use. Yet the U.S. regulatory system does not examine risks of not using the pesticide with the same degree of rigor. Precautionary approaches that focus only on the "target" risk—here, the risks due to pesticide use—are prone to neglect adverse effects related to decreasing the target risk on other aspects of the system or "system neglect" (Sunstein 2003). Uncontrolled pests and diseases may threaten human health, the environment, or food security. Pesticides may decrease the disease risk to animals, plants, and humans through vector control or disinfection. Pesticides eradicate or suppress invasive species that impact native species, change the species composition of environments they occupy, and alter normal functioning of the ecosystem. As noted in the Office of Management

and Budget's (OMB's) memorandum on risk analysis principles, agencies should seek to offer the greatest net improvement in welfare and account for a broad range of social and economic considerations when choosing among alternative approaches to decreasing risk (OMB/OSTP 2007). "Welfare" is defined by the OMB to include considerations "such as equity, quality of life, individual preferences, and the magnitude and distribution of benefits and costs (both direct and indirect, both quantifiable and non-quantifiable)."

Organic agriculture is often cited as a solution for feeding an increasing global population (Seufert, Ramankutty, and Foley 2012). Crop yields are, on average, 25% lower for organic systems compared to similar conventional agriculture systems, although local differences vary considerably depending upon the agroecosystem type. Yield differences may be as high as 34% for the most comparable organic and conventional systems. Differences in pest pressure between the systems could not be directly examined but may have contributed to the yield differences (Seufert, Ramankutty, and Foley 2012).

Many different agricultural techniques, including both organic and conventional as well as possible hybrids of the two systems, will be required to produce food for future generations at affordable prices and decrease environmental agricultural costs. Applying a highly precautionary regulatory approach on a pesticide-by-pesticide basis or within a common mechanism of action group does not provide an efficient framework for evaluating the risk to agriculture of not having a robust set of pest management products to control pests or diseases.

Genetically Modified Foods

The success of modern agriculture thus far can be rightfully attributed to plant breeding and the creation of cultivars that perform very well in the context of different environments. Although inputs (fertilizer, pesticides, cultivation) to support the world's crops are important, the *genome* of the cultivars is critical to yield potential. Prior to the new techniques of *transgenic engineering* (i.e., specific transfer of a gene from one species into another species accompanied by stable expression), not much attention was paid to environmental or social consequences of plant breeding.

Yet the ongoing mystery of DNA (deoxyribonucleic acid) biochemistry in the mind of the general public and misunderstanding of basic scientific principles have surely contributed to feelings of uncertainty and unease concerning the new breeding techniques of agricultural biotechnology. This uneasiness has influenced government policy in many parts of the world to invoke the PP in making decisions about commercialization of transgenic crop plants. In the case of the EU, this application of the PP has resulted in severe restrictions on approval and availability of GM crops, food, and feed. A variety of social and economic factors underlie the EU's resistance to GM crops and foods, including public concerns about the risks of GM foods, the recent history of risk management fiascos involving foods (e.g., mad cow disease), distrust in regulatory institutions for food safety, and protectionist sentiments on behalf of EU farmers.

The concern among advocates for agricultural biotechnology as the breeding paradigm of the future is that society ruled by the PP will be missing many of the benefits of a proven technology. This fear raises four pertinent questions discussed later: (1) Are the details of genetic modification using recombinant DNA technology understood as necessary before any type of regulatory approach is implemented? (2) How are GMOs regulated under application of the PP and a risk-based system using the EU and the United States as the respective standard bearers for these regulatory stances? (3) If the PP is strictly and/or loosely applied, will it affect the future adoption of the technology and will there be lost benefits or negative consequences? (4) From an examination of the spread of transgenic crop technology, has the PP really affected introduction of the new crops?

The Nature of Crop Biotechnology

Before addressing pertinent questions about GMOs and regulation under the perspective of the PP, the technology of genetic engineering needs some explication. Concisely defined (Ronald 2011), genetic engineering of crops is distinguished operationally from conventional breeding methods. Genetic engineering is a method allowing the introduction of one or a few well-characterized genes from just about any species into a host plant. In contrast, conventional breeding methods create new varieties of plants by mutating or introducing many uncharacterized genes into the same species (Ronald 2011). Indeed, recent research shows that conventional breeding methods probably cause more mutations in a new cultivar's genome than breeding by focused genetic engineering (Batista et al. 2008; Ricroch, Berge, and Kuntz 2011). Furthermore, environmental conditions influence genetic expression and compositional differences more than the process of genetic engineering itself (Frank et al. 2012).

Because the philosophy embedded in the PP seems singularly applied only to genetically engineered crops and not to conventional breeding techniques (Morris 2007), advocates seem to assume that something very new or perhaps unnatural has been invented and thus uncertainty about its hazards is high—i.e., the potential for catastrophic consequences is inferred. This premise is misinformed. For example, special pieces of a plant's own DNA called *transposons* are known to periodically move from one chromosomal location to another (Fedoroff 1989). The resulting effects on the observed phenotype of plants have been well studied in conventional breeding and do not differ in any biologically meaningful way when specific transgenes are inserted (Bradford et

al. 2005).

Transfer of genes across species is also a natural phenomenon. Bacteria are able to transfer genes to unrelated bacterial species and, in some cases, plants via a mechanism known as *horizontal gene transfer*. Indeed both bacterial and viral gene sequences are commonly detected in various conventional plant cultivars (Bradford et al. 2005). Whether the inserted "new" DNA functions or not depends on the specific regions of a host organism's genome at which the complementary interactions occur. Most insertions will not be functional, but a small percentage will be transcribed and expressed.

This process of gene insertion and the phenomenon of horizontal gene flow have been noted to occur comparatively frequently in nature and are now considered a contributing driver of evolution (Keeling and Palmer 2008). So insertion of a new coding sequence of DNA into a plant genome using recombinant DNA technology is not inherently new or as uncertain as the PP as applied supposes. Rather we have learned to speed up a naturally occurring biochemical mechanism to more quickly and precisely breed new characters into plants and animals. To be sure, modern biotechnology permits the transfer of genetic information between different species in ways that are unlikely to occur in nature, but any risks that result from such transfers will be due to the specific construct created and the environment into which it is released rather than to the simple fact that genetic recombination and transfer was involved. The focus of any precautionary regulatory approach should therefore be shifted from breeding mechanics to trait functionality in the context of its environment and use.

Contrasting Regulations in the United States and the European Union

In the United States, new crop cultivars produced using DNA recombinant technology are regulated differently than in Europe. A contrast between the regulatory approaches of the two jurisdictions provides instruction about the contrasting approaches of the PP and risk assessment. The United States has relied on the 1986 Coordinated Framework for Regulating Biotechnology (OSTP 1986). In this framework, three agencies—the U.S. Department of Agriculture, specifically the Animal and Plant Health Inspection Service; the Food and Drug Administration; and the EPA—share primary responsibility for regulating the introduction and assessing the safety of GMOs (McGinnis, Meyer, and Smith 2012; McHughen and Smyth 2008). While more specific regulations have been written over the last decade to enhance regulation, largely in response to scientific scrutiny and public input, new statutes were not created to deal with agricultural biotechnology.

Although the reliance on existing statutory authority under the Coordinated Framework has resulted in some gaps and overlaps in the oversight of GMOs (Mandel 2004), the Coordinated Framework has generally worked fairly well to regulate GMOs and there has been little pressure or need to try a different regulatory approach (McHughen and Smyth 2008; Pew Initiative on Food and Biotechnology 2004). All of these agencies have fulfilled their legislative mandate under a risk assessment paradigm. While safety is ultimately the goal of regulatory action, a precautionary approach is not stated explicitly, although some degree of precaution is inherently applied.

In contrast to the U.S. regulatory system, the EU starts from a philosophical premise of the PP. In part, this approach to managing risk is consistent with principles of precaution mapped out in the *Cartagena Protocol on Biosafety* (Convention on Biological Diversity 2000). Most PP proponents identify the central core of the principle to be that a technology should be prevented from commercialization if it is suspected of being harmful even without a scientifically backed proof of hazards. Thus, the PP introduces the concept of uncertainty as a consideration when regulating GMOs. The novelty and potential for harm conceived for a comparatively new technology first led to a moratorium on new approvals of genetically engineered crops and foods and then, following its end in 2004, a case-by-case, albeit slow, process of approval.

European Union regulation of GM crops is mandated in three different interacting directives or regulations: "Deliberate release into the environment of genetically modified organisms" (Directive 2001/18/EC); "Genetically modified food and feed" (Regulation 1829/2003); "Concerning the traceability and labeling of genetically modified organisms, and the traceability of food and feed products produced from genetically modified organisms" (Regulation 1830/2003). The latter two of these mention the requirement for a precautionary approach but are written more as philosophical directives. The actual regulations require a risk assessment, and the requirements for carrying out this mandate are detailed within the regulations. In this sense, the European laws are not unlike requirements in the United States. The European laws require that the entity wishing to introduce into the food chain or release into the environment take primary responsibility to submit the data needed for risk assessment.

The European regulations developed specifically for GM products and the U.S. Coordinated Framework, as well as specific responsibilities and jurisdiction of each federal agency as applied to GM products, do not differ in the essential need for some form of premarket risk assessment. Necessary risk management follows from the findings of the risk assessment. The PP comes into play with the EU regulations in the mandate for GM product traceability and labeling (medicines exempted) and the requirement for postmarketing surveillance (Heinemann and Ell-Kawy 2012). In

the United States, however, registrants of GM crops containing gene coding for plant-incorporated protectants (PIPs) are required under FIFRA section 6(a)(2) to submit adverse effects information regarding their products. This regulatory requirement suggests that postmarket monitoring also has been built into U.S. regulations for at least some GM crops when they contain PIPs.

The EU expressly relies on the PP to require traceability and labeling of GM foods (Regulation 1830/2003, preamble [3]), which is perhaps the most distinguishing feature of the EU GM regulations compared to the requirements of U.S. law. The EU traceability and labeling regulation is not absolute, however, notwithstanding its precautionary justification, because it does not require labeling for foods containing GM ingredients below the regulatory threshold of 0.9% presence of inadvertent authorized GM ingredients in any food or feed that would trigger mandatory labeling.

Ironically, the perception of a more precautious system that requires traceability and labeling has not prevented exposure of many European consumers to GM foods. For example, one study of putatively GM-free foods showed that 40% of sampled items contained detectable levels of GM soy, albeit below the 0.9% EU threshold that would trigger labeling (Partridge and Murphy 2004). A study of German processed foods showed that 75% of GM soy detections were less than the mandatory labeling threshold (Greiner, Konietzny, and Villavicencio 2005). Thus, European consumers are exposed to GM foods if one considers the possibility that many foods originating from GM crops may fall below the labeling threshold.

On the other hand, lack of labeling in the United States does not necessarily mean that U.S. consumers are exposed to higher levels of GM crop-derived foods than European residents. For example, a study using an analytical detection limit of 0.5% reported that <30% of sampled foods processed with U.S. corn had detectable GM traits (Kim et al. 2010), suggesting that nearly ubiquitous use of GM corn and soy in the United States does not mean that all processed foods would exceed the EU's labeling threshold. Considering that most GM crops are grains and few are directly consumed but rather dispersed, diluted, and/or degraded during food processing, the EU's application of the PP to require mandatory traceability and labeling of GM foods may not necessarily result in appreciable differences in exposures to GM food ingredients.

Adoption of Genetically Modified Technology and Potential for Lost Benefits

Shortly after the United States commercialized GM crops, efforts to export them to Europe faced severe opposition, leading to a de facto moratorium that was not lifted until 2004. Arguably, this moratorium represents application of the strong PP, i.e., rejection of a technology when definitive proof of safety is absent (a standard few, if any, technologies or products could satisfy). If the PP is applied to reject GM foods more generally, one could speculate on what benefits might be lost, especially if the technology is reasonably certain to pose no harm (an often-used U.S. regulatory standard). Three cases discussed later are: (1) how the PP could affect benefits accrued by growers and extending to those in rural areas; (2) how the PP could affect future development of nonproprietary crop seed development; and (3) how the PP can impact health improvement by slowing a decentralized solution.

Benefits to Farmers and Their Communities

Enough time has passed since the introduction of GM crops for measurement in economic trends around the world. Studies suggest that, more often than not, yields are greater when GM crops are compared to conventional cultivars and gross margins of return are better (Carpenter 2010; Qiam 2009; Raney 2006). How much gross margins benefit, however, is likely to be related to their home country. For example, the benefits of growing Bt (*Bacillus thuringiensis*) cotton are much higher in India than in China, but for all countries pesticide costs are lower with the adoption of GM technology (Finger et al. 2011). Evidence of foregone loss of income from increased input costs to farmers owing to the restrictive regulatory policies of the EU was estimated to range up to $1.2 billion per year (Park et al. 2011).

The role of PP advocates who deem genetically engineered plants too hazardous and uncertain has essentially killed or at least seriously delayed introduction of Bt brinjal (also known as eggplant) into Indian agriculture (Kathage and Qaim 2012; Padmanaban 2009). This crop is widely consumed and reputed to have medicinal properties. It is, however, quite vulnerable to insect damage. A Bt variety was developed in an Indian company that had partnered with Monsanto. Field trials indicated steep reductions in insecticide use. Estimated economic returns were hundreds of dollars per acre (Shelton 2010). The Genetic Engineering Approval Committee of India had approved its commercialization after required testing confirmed that it met safety standards. Following a coordinated effort by NGOs to invoke the extreme version of the PP, however, the Minister of Environment and Forests banned cultivation. Thus, the Bt brinjal case is but one glaring example of how advocacy groups, under cover of the PP, can influence government policy against a technology that poses no problems for human consumption or the environment when appropriately scrutinized using risk assessment.

Introduction of New Nonproprietary Genetically Modified Traits

Ironically, advocates of a strict precautionary approach in lieu of product (i.e., phenotype) risk

assessment have strengthened the hand of proprietary GM seed holders. The extra layers of regulation for a well-understood plant breeding method have led to a situation in which universities or other nonprofit entities cannot afford to bring their nonproprietary cultivars to commercial status (Lotter 2009). Holders of proprietary seeds with substantial commercial potential are essentially the only entities that can afford the myriad of regulations. Such is the result of the precautionary focus on the process of plant breeding rather than the product. Yet, when considering developing countries and populations in poverty, an urgent need exists to either develop a "homegrown" seed industry and GM crop technology or perform greater public research on plant varieties that will provide food security and speed economic development (Pingali and Traxler 2002; Spielman 2007).

In addition to nutritional attributes, much nonprofit research is focused on improved biofuel crops and processes as well as crops that can withstand drought and temperature extremes (Vinocur and Altman 2005; Wang, Vinocur, and Altman 2003). Indeed, the latter traits are conferred at one time by simple gene insertion, and the cultivars are already developed. They still, however, have not been commercialized several years after their reported development and functionality testing owing to prohibitive regulatory costs (Wang and Brummer 2012).

Introduction of Traits Beneficial to Consumers

Biofortification of foods, defined simply as production of cultivars with enhanced nutrient content, has long been a goal for plant breeders (Khush et al. 2012). Presently, research and development of such cultivars seems more prevalent in public institutions than in private industry. Despite successful progress, commercialization of seed with value-added traits for nutrition enhancement seems mired in the advocacy of precautionary resistance that has forced regulatory policy toward a proliferation of tests that perhaps seem unnecessary. The case of golden rice has become the poster child for a technology designed to help nutrient-deficient populations gain adequate nutrients from their own food supply that has been delayed by opponents relying on the PP.

Specifically, golden rice is a popularized name for a rice cultivar that has been transformed by genetic modification with two genes that allow the seed endosperm to synthesize carotenoids (Beyer et al. 2002). Present rice cultivars lack sufficient enzymatic activity to carry out this synthesis. Carotenoids are microbially transformed by human gut microbiota to vitamin A. A significant population of children is deficient in vitamin A and does not have access to the typical remedies available in the economically developed countries, such as more leafy green vegetables like spinach, carotenoid-rich root crops like carrots, or vitamin supplements.

The slow, drawn-out regulatory morass holding up dissemination of golden rice varieties, despite numerous studies vouching for its safety, is partly due to regulatory requirements (Potrykus 2010). The initial and ongoing strong push against the cultivar from advocacy groups based on the PP, however, has also arguably contributed to the lack of introduction at this time.

In addition to golden rice, concerns have been expressed that the introduction of needed nutritionally improved cassava will be slowed (Adenle et al. 2012). The recalcitrance of some advocacy groups to accept the process of genetic engineering despite repeated safety testing shows the flaw of a regulatory policy that focuses on process (the PP) rather than product (typical risk assessment and management paradigm). Moreover, the selective application of precaution under the PP to look only at the potential risks presented by a new technology while not also looking at the existing risks lessened by that technology, skews risk decision making and may result in decisions that do more harm than good to human health and the environment (Goklany 2001).

The Global Spread of Genetically Modified Organisms

The global spread of GM crops proves a very rapid expansive adoption of the technology in many countries beyond the United States (Khush 2012). The 2011 data show production of these crops on nearly 420 million acres among 30 countries (James 2012). The numbers themselves speak to a global farmer population wanting new technologies that are perceived to benefit them.

Thus, with or without attention to the PP, the technology has, and is likely to continue to, spread. Nevertheless, because nongovernmental advocacy organizations have gained voice and have proven to wield significant influence on governmental policy (Falkner 2007; Seifert 2011), these forces will continue to demand that the PP be implemented. If governments do not themselves restrict GM products directly based on the PP, the experience in Europe of NGO advocacy groups directly pressuring retailers to not carry GM-labeled products on their shelves will also continue to exert scientifically unjustified negative pressure against biotechnology-derived crops.

Food Irradiation

Access to sufficient, safe, and nutritious food is central to the concept of food security (CFS 2012). Ionizing radiation that is used as a food-processing technology has two benefits that could contribute substantially to food security: the destruction of certain foodborne pathogens, thus making the food safer; and prolongation of the shelf life of food by killing pests and delaying the deterioration process, thus increasing food supply. Independent studies spanning decades have consistently shown ionizing radiation to be an effective, safe, and feasible technology for food processing, but precautionary perceptions and policies have severely limited the

contribution this technology can make to food security.

Ionizing radiation occurs naturally in the environment and may also be artificially produced using x-ray tubes, electron beam accelerators, or gamma sources such as cobalt-60. Exposing food to high doses (greater than 20 *kilograys* [kGys]) of ionizing radiation can destroy harmful microorganisms such as *E. coli* and *Salmonella*. This makes irradiation an important strategy for decreasing foodborne illness and waste. Low-dose treatments (below 1 kGy) effectively inhibit sprouting (e.g., potato, onion, garlic) and can also increase the shelf life of many fresh commodities by delaying ripening, improving quality factors such as juice yield and hydration, and killing or sterilizing invasive insects such as fruit flies (Urbain 1986). All foods are not suitable for treatment with ionizing radiation, just as all foods are not suitable for canning, freezing, drying, and other food-processing technologies.

Food irradiation is sometimes referred to as "cold pasteurization" because the effect of irradiation is similar to pasteurization without heating the product or significantly changing its physical or sensory characteristics. Contrary to many popular perceptions, irradiated food does not become radioactive. In the same way that a microwave oven does not make food radioactive, the energy from ionizing radiation is not retained in treated food. Ionizing radiation only has sufficient energy to remove electrons from atoms, creating short-lived ions (free radicals) that damage the cells of contaminating organisms. The formation of free radicals and any resulting radiolytic products raises concerns about possible health hazards, even though free radicals are also formed in much higher concentrations when food is barbequed, fried, or baked and they disappear within a fraction of a second (Taub 1984).

In 1981, a joint FAO (Food and Agriculture Organization of the United Nations)/IAEA (International Atomic Energy Agency)/WHO committee of experts found that irradiated foods are safe and wholesome after reviewing extensive chemistry and animal-feeding studies from several independent laboratories (WHO 1981). The committee concluded that no special nutritional or microbiological problems were associated with the irradiation of any food commodity with an overall average dose of up to 10 kGy. In 1992, the WHO issued a policy statement reaffirming that "[i]rradiated food produced under established Good Manufacturing Practices is to be considered safe and nutritionally adequate" (WHO 1994). In 2003, the Codex Alimentarius standard was revised to indicate that the maximum absorbed dose could exceed 10 kGy when necessary to achieve a legitimate technological purpose (Codex Alimentarius Commission 1983).

The American Medical Association endorses food irradiation as "a safe and effective process that increases the safety of food when applied according to governing regulations" (Marsden 1994). An *E. coli* O157:H7 Consensus Development Conference sponsored by the American Gastroenterological Association Foundation concluded that "[p]rotection of the public's health requires the immediate implementation of currently recognized scientific technology for ensuring food safety. An emphasis should be placed on science-based monitoring and verification of the nation's slaughter plant operations. The current inspection-based system should be replaced by a science-based risk assessment process with government verification." The conference recommended that "[i]rradiation pasteurization is a safe and effective intervention strategy, especially in ground beef and should be implemented as soon as possible" (Gallager and Kwittken 1994).

Numerous other studies spanning more than four decades have resulted in similar conclusions regarding the efficacy, safety, and wholesomeness of irradiated food without any significant evidence to the contrary. Regulatory authorities in many countries nevertheless continue to be reluctant to create a regulatory environment that would facilitate the broader use of food irradiation and enhance its contribution to food security now and in the future. For example, since 1999 the EU only has allowed for the treatment of dried aromatic herbs, spices, and vegetable seasonings (EC 1999). Adding authorizations, including grandfathering authorizations that existed previously in the EU, requires that member states submit a petition to the European Food Safety Authority with individual studies on the toxicology of each food and for each of the proposed dose ranges requested.

An item-by-item, dose-by-dose toxicological review, followed by an extended political approval process, is difficult to justify in the face of a plethora of scientific findings and internationally agreed policies regarding the safety of food irradiation and the lack of contradictory evidence that would argue for greater uncertainty. Such cumbersome bureaucratic requirements and strict controls severely stifle implementation of the technology under the auspices of demonstrating precaution in matters of consumer safety where large amounts of sound, consistent scientific findings supported by international consensus are politically inadequate to offset real or imagined uncertainties.

Part of the problem is the general perception that nuclear technologies are intrinsically dangerous and that the consequences of miscalculations are catastrophic. Another problem is that, based on the declaration made by the Joint FAO/IAEA/WHO Expert Committee on Food Irradiation in Rome in 1964, irradiation was defined as an additive rather than a process (WHO 1966). These issues contribute to regulatory foot dragging by casting a negative light on the public perception of food irradiation, even though other consumer products, ranging from bandages to medical instruments

to tampons, are irradiated in the same way and have no such stigma attached to them.

Opponents of food irradiation say the preferred alternative is increased government regulation and inspection; however, inspectors cannot see harmful microorganisms and it is not currently feasible to perform routine laboratory analysis on huge commercial quantities of raw products (Fumento 1994). An argument frequently raised by critics is that the technology benefits sellers, not producers, because inferior quality products can be safely marketed. The same could be argued for any other form of food processing, but by focusing this argument on food irradiation, such claims contribute to greater doubt in the minds of regulators and the general public regarding the wisdom of endorsing and applying food irradiation as part of a broader strategy to promote food security either locally or globally.

A precautionary approach to managing the risks associated with food irradiation sends a signal that food processed with this technology is more dangerous, and food security, trade, and other benefits that may be derived from using the technology do not outweigh the risks. This is a classic example of an important weakness in the PP—the assumption that acting to protect cannot result in damage.

In the case of food irradiation, the barriers to implementation that auspiciously serve to protect public health limit the use of the technology not only to protect public health, but also to provide broader benefits associated with food security and trade. It is, therefore, a simple question not only of protection that is gained but also of protection that is lost, other benefits that will be lost, and the repercussions of both scenarios. Because there are risks from using the technology and also risks from not using it, precaution cannot be increased on one side of the question without decreasing itself on the other. This nonsensical argument points to a fundamental flaw in the PP.

A further weakness in this situation is the lack of clarity regarding the type, quantity, and quality of evidence (scientific or otherwise) that is required to overcome the uncertainties that are the causes for concern with food irradiation. In other words, an arbitrary and nontransparent threshold for reasonable certainty has been established by adopting a precautionary approach. The problem is compounded if a judgment regarding the degree of uncertainty becomes the basis for not doing a risk assessment. Any credible scientist will agree that uncertainty is ubiquitous. Uncertainty may be associated with error or variability, and usually both—but it is always present at some level. The challenge in risk assessment is recognizing and characterizing the uncertainty. The absence of such an analysis makes it impossible to understand a strategy for mitigating uncertainty.

The challenge for risk managers is responding appropriately to risk, recognizing that zero risk does not exist. A precautionary approach is one type of response to risk that, by virtue of its reflection in decision making, sets a bar for research that becomes an unjustified barrier if it is not transparent and based on rational criteria. A century ago, the pasteurization of milk was banned from commercial use because of irrational fears. Today, most consumers would consider unpasteurized milk to be the greater risk. The same transition has yet to occur with food irradiation.

Summary and Conclusion

An empirical analysis of the PP in practice concluded that the "precautionary principle may well be the most innovative, pervasive, and significant new concept in environmental policy over the past quarter century. It may also be the most reckless, arbitrary, and ill-advised" (Marchant and Mossman 2004). Notwithstanding its swift rise in the international arena, the PP has serious shortcomings and does not, at least in its current form, provide a coherent, rational, and defensible basis for risk management decisions. As the record and case studies summarized earlier demonstrate, the PP is flawed. Without a workable definition and agreed-upon criteria for its application, the PP's employment to date, including in the food context, has been dictated more by political influences than scientific factors. For example, governments have exploited the PP's ambiguity and arbitrariness to adopt protectionist policies, and activist groups have used the PP to apply a double standard of higher scrutiny and demands for certain technologies of which they disapprove. Moreover, in many cases the PP has been applied or proposed to be applied in ways that may have the net effect of increasing overall health and environmental risks by impeding safety-enhancing technologies. Given these failures, it is not surprising that the momentum behind the PP is fading, and it has become clear that the PP will never achieve the consensus that its proponents had once envisioned.

The failure and decline of the PP does not mean that appropriate risk management is not essential. It is in the joint interests of government, industry, NGOs, and the general public to ensure appropriate risk management is applied with all technologies to minimize unreasonable risks and injury. The PP can be credited for bringing attention to the need to better define the appropriate level and form of risk management that should be applied in various situations. To date, however, the PP's solution to the question of appropriate risk management is blunderbuss rather than nuanced, extreme rather than reasoned, biased rather than balanced, and arbitrary rather than principled. Its failure to offer a credible and reasoned framework for the application of risk management suggests that the PP will be increasingly controversial, marginalized, and ignored in the future.

Where should we go from here? After twenty years of being at the forefront of the debate on risk management, there has not been any

progress on further refining and operationalizing the PP to provide a sensible, predictable, and reasonable decision rule. Some individual scholars have put forward promising proposals to better rationalize and structure the PP (e.g., Farrow 2004; Goklany 2001; Sandin and Hansson 2002), but these proposals have received no political traction. It is becoming increasingly apparent that the PP is not going to be better defined and operationalized because it cannot be—there is no consensus even among the proponents of the PP as to what it should mean or require. Two PP supporters recognized that the PP may be too amorphous to be captured by definitions or operational criteria, noting that "the application of precaution will remain politically potent so long as it continues to be tantalizingly ill-defined and imperfectly translatable into codes of conduct, while capturing the emotions of misgiving and guilt" (Jordan and O'Riordan 1999).

The PP thus has superficial appeal on initial impression, which explains much of its political popularity, but when put to the test actually lacks the substance and content necessary to guide realistic risk decision making. Some supporters of the PP are now retreating from applying it as a legal obligation (such as adopted by the EU) or a specific decision rule, but rather are recasting the PP as a general philosophical approach or ethical principle. Such a formulation is less objectionable, although still subject to criticism if it is construed as tilting too heavily against innovation. The problems with the PP are imposing real harms on society—by delaying beneficial technologies; disrupting world trade; and perhaps most importantly impeding economic, social, nutritional, and safety progress in developing nations. Indeed the PP, as has often been pointed out, fails its own test of being better safe than sorry. As with many things in life, the Goldilocks strategy may be most appropriate—not too little precaution, not too much, but just the right amount is needed. If the PP helps us to more consciously strive for such a deliberate and balanced approach to precaution, that might be its most positive legacy.

But for the millions of people who are lacking adequate nutrition today, and the many millions more who will suffer as a result of the growing food demand-supply gap projected over the next few decades, the PP does more harm than good. New technologies of many different types that can produce safer, more abundant foods, and wider distribution of those technologies, are crucial to decreasing the number of hungry and under-nourished people in the world now and in the future. The evidence summarized in this Issue Paper has demonstrated that the PP holds back technology, innovation, incomes, environmental improvements, and health benefits, while increasing trade disruptions, risks, and human suffering. The PP has been tried but has failed as a risk management strategy. It is time to move beyond it.

Glossary

Genetic engineering. A method that allows the introduction of one or a few well-characterized genes from just about any species into a host plant.

Genome. The genetic material of an organism.

Horizontal gene transfer. A mechanism by which bacteria are able to transfer genes to unrelated bacterial species and, in some cases, plants.

Kilogray. Dose measurement unit of absorbed radiation.

Precaution. A measure taken beforehand against possible danger.

Precautionary approach. A regulatory approach, such as that applied by the United States, that seeks to err on the side of safety by applying precaution informally and implicitly in regulatory decisions.

Precautionary principle. A legal requirement, such as that enacted by the EU, that mandates the formal and explicit application of precaution in regulatory decisions.

Risk assessment. The estimation and characterization of a risk, often quantified.

Risk management. A policy decision on what to do about a risk.

Transgenic engineering. The specific transfer of a gene from one species into another species accompanied by stable expression.

Transposon. A transposable element containing genetic material controlling functions other than those related to its relocation.

Yield gap. The gap between the average and potential crop yield.

Literature Cited

Adenle, A. A., O. C. Aworh, R. Akromah, and G. Parayil. 2012. Developing GM super cassava for improved health and food security: Future challenges in Africa. *Agr Food Sec* 1:1–15.

Applegate, J. 2000. Precautionary preference: An American perspective on the precautionary principle. *Hum Ecol Risk Assess* 6 (3): 413–443.

Ashford, N. A. 2005. Implementing the precautionary principle: Incorporating science, technology, fairness and accountability in environmental, health and safety decisions. *Int J Risk Assess Manage* 5:112–124.

Ashford, N. A. 2007. The legacy of the precautionary principle in U.S. law: The rise of cost-benefit analysis and risk assessment as undermining factors in health, safety and environmental protection. In N. de Sadeleer (ed.). *Implementing the Precautionary Principle: Approaches from the Nordic Countries, the EU and the United States*. Earthscan, London.

Batista, R., N. Saibo, T. Lourenco, and M. M. Oliveira. 2008. Microarray analyses reveal that plant mutagenesis may induce more transcriptomic changes than transgene insertion. *P Natl Acad Sci* 105 (9): 3640–3645.

Beck, U. 1992. *Risk Society: Towards a New Modernity*. Sage Publications Limited, London.

Beyer, P., S. Al-Babili, X. Ye, P. Lucca, P. Schaub, R. Welsch, and I. Potrykus. 2002. Golden rice: Introducing the β-carotene biosynthesis pathway into

rice endosperm by genetic engineering to defeat vitamin A deficiency. *J Nutr* 132 (3): 506S–510S.

Bodansky, D. 1991. Scientific uncertainty and the precautionary principle. *Environment* 33 (7): 4–5.

Bohannon, J. 2002. Zambia rejects GM corn on scientists' advice. *Science* 298:1153.

Bradford, K. J., A. V. Deynze, N. Gutterson, W. Parrott, and S. H. Strauss. 2005. Regulating transgenic crops sensibility: Lessons from plant breeding, biotechnology and genomics. *Nat Biotechnol* 23 (4): 439–444.

Brock, W. J., J. V. Rodricks, A. Rulis, V. L. Dellarco, G. M. Gray, and R. W. Lane. 2003. Food safety: Risk assessment and decision-making criteria. *Int J Toxicol* 22:435–451.

Byrne, D. 2004. "The Regulation of Food Safety and the Use of Traceability/Tracing in the EU and USA: Convergence or Divergence?" Speech to Food Safety Conference, Washington, D.C., March 19, 2004.

Carpenter, J. 2010. Peer-reviewed surveys indicate positive impact of commercialized GM. *Nat Biotechnol* 28 (4): 319–321.

Chapman, P. M. 1999. Risk assessment and the precautionary principle: A time and a place. *Mar Pollut Bull* 38:944–947.

Codex Alimentarius Commission. 1983. *Codex General Standard for Irradiated Food and Recommended International Code of Practice for the Operation of Irradiation Facilities Used for the Treatment of Foods*. Vol. 15. Food and Agriculture Organization of the United Nations—World Health Organization, Rome, Italy (rev. 2003).

Commission of the European Communities. 2000. *Communication from the Commission on the Precautionary Principle*. Brussels, 02.02.2000, COM (2000) 1.

Commission of the European Communities. 2004. *Communication from the Commission: Towards a European Strategy for Nanotechnology*. Brussels, 12.5.2004, COM(2004) 338 final.

Commission v. Denmark, Case C-192/01 (Advocate General 2003).

Commission v. France, Case C-24/00 (ECJ 2004).

Committee on World Food Security (CFS). 2012. *Global Strategic Framework for Food Security and Nutrition*, http://www.fao.org/fileadmin/templates/cfs/Docs1112/WGs/GSF/MD976E_GSF_Draft_Two.pdf (14 September 2012)

Convention on Biological Diversity. 2000. *Cartagena Protocol on Biosafety*. Secretariat of the Convention on Biological Diversity, http://www.cbd.int/doc/legal/cartagena-protocol-en.pdf (27 September 2012)

Cranor, C. 2004. Toward understanding aspects of the precautionary principle. *J Med Philos* 29:259–279.

Crichton, M. 2004. *State of Fear*. Harper Collins, New York City. 624 pp.

EFTA Surveillance Authority v. Norway, Case E-3/00, 2 C.M.L.R. 47 (European Free Trade Association Court, Luxembourg 2001).

ENDS Europe. 2000. "Opinion divided on EU precaution paper." *ENDS Daily*, March 2, http://www.endseurope.com/114/opinion-divided-on-eu-precaution-paper (6 December 2012)

European Community (EC). 1999. Directive 1999/3/EC of the European Parliament and of the Council of February 22, 1999 on the establishment of a community list of foods and food ingredients treated with ionizing radiation. Pp. L 66/24–L 66/25. In *Official Journal of the European Communities*, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:1999:066:0024:0025:EN:PDF (14 September 2012)

European Court of Justice (ECJ). 2012. *Pioneer Hi Bred Italia Srl v. Ministero delle Politiche agricole alimentari e forestali*, Case No. C 36/11 (September 6).

European Union. 2001. *Proposal for a Council Regulation on State Aid to the Coal Industry*. OJ C 304E, 202 (October 30).

Falkner, R. 2007. The global biotech food fight: Why the United States got it so wrong. *Brown J World Affairs* XIV (1): 99–110.

Farrow, S. 2004. Using risk assessment, benefit-cost analysis, and real options to implement a precautionary principle. *Risk Anal* 24:727–735.

Fedoroff, N. V. 1989. Maiz transposable elements in development and evolution. *Am Zool* 29:549–555.

Finger, R., N. El Benni, T. Kaphengst, C. Evans, S. Herbert, B. Lehmann, S. Morse, and N. Stupak. 2011. A meta analysis on farm-level costs and benefits of GM crops. *Sustainability* 3 (3): 743–762.

Food and Agriculture Organization of the United Nations (FAO). 2009. Global agriculture towards 2050. *High Level Expert Forum: How to Feed the World*, http://www.fao.org/fileadmin/templates/wsfs/docs/Issues_papers/HLEF2050_Global_Agriculture.pdf (19 September 2012)

Foster, K. R., P. Vecchia, and H. Repacholi. 2000. Science and the precautionary principle. *Science* 288:979–980.

Frank, T., R. M. Rohlig, H. V. Davies, E. Barros, and K-H. Engel. 2012. Metabolite profiling of maize kernels—Genetic modification versus environmental influence. *J Agr Food Chem* 60:3005–3012.

Freestone, D. and E. Hey. 1996. Origins and development of the precautionary principle. Pp. 3–15. In D. Freestone and E. Hey (eds.). *The Precautionary Principle and International Law*. Klewer Law International, Netherlands.

Fumento, M. 1994. "To save lives with safer food." *Washington Times*, Tuesday, August 16, p. 15.

Gallager, D. and A. Kwittken. 1994. Current meat inspection system "insufficient" for ensuring food safety, independent panel says. News release. American Gastroenterological Association Foundation, Bethesda, Maryland.

Global Harvest Initiative. 2012. *2012 GAP Report: Measuring Global Agricultural Productivity*, http://globalharvestinitiative.org/GAP/GHI_2012_GAP_Report_Int.pdf (30 March 2013).

Godfrey, H. C. J., I. R. Crute, L. Haddad, D. Lawrence, J. F. Muir, N. Nisbett, J. Pretty, S. Robinson, C. Toulmin, and R. Whitely. 2010. The future of the global food system. *Philos T R Soc B* 365:2769–2777.

Goklany, I. M. 2001. Precaution without perversity: A comprehensive application of the precautionary principle to genetically modified crops. *Biotechnol Law Rep* 20:377–396.

Goldstein, B. D. and R. S. Carruth. 2004. Implications of the precautionary principle: Is it a threat to science? *Int J Occup Med Env* 17:153–161.

Graham, J. 2002. Speech by OMB Regulatory Chief John Graham on role of precautionary principle in risk assessment and risk management. *Daily Environ Rep (BNA)*, pp. 1–4, January 21, 2002.

Graham, J. D. and J. B. Wiener (eds.). 1995. *Risk Versus Risk; Tradeoffs in Protecting Health and the Environment*. Harvard University Press, Cambridge, Massachusetts.

Grandjean, P. 2005. Non-precautionary aspects of toxicology. *Toxicol Appl Pharm* 207:S652–S657.

Gray, G. 2004. The precautionary principle in practice: Comparing US EPA and WHO pesticide risk assessments. *Risk Perspec* 12 (1): 1–6.

Greiner, R., U. Konietzny, and A. L. C. H. Villavicencio. 2005. Qualitative and quantitative detection of genetically modified maize and soy in processed foods sold commercially in Brazil by PCR-based methods. *Food Control* 16:753–759.

Harremoës, P., D. Gee, M. MacGarvin, A. Stirling, J. Keys, B. Wynne, and S. G. Vaz (eds.). 2001. *Late Lessons from Early Warnings: The Precautionary Principle 1896–2000*. European Environmental Agency Environmental Issue Report No. 22/2001, http://www.eea.europa.eu/publications/environmental_issue_report_2001_22 (18 September 2012)

Heinemann, J. A. and O. A. Ell-Kawy. 2012. Observational science in the environmental risk assessment and management of GMOs. *Environ Int* 45:68–71.

Holm, S. and J. Harris. 2000. Precautionary principle stifles discovery. *Nature* 400:398.

Huber, P. 1983. The old-new division in risk regulation. *Va Law Rev* 69 (6): 1025–1107.

Jaggard, K. W., A. Qi, and E. S. Ober. 2010. Possible changes to arable crop yields by 2050. *Philos T R Soc B* 365:2835–2851.

James, C. 2012. Global status of commercialized biotech/GM crops: 2012. In *ISAAA Brief 44-2012*. International Service for the Acquisition of Agri-biotech Applications, Ithaca, New York, http://www.isaaa.org/resources/publications/briefs/44/executivesummary/default.asp (5 March 2013).

Jordan, A. and T. O'Riordan. 1999. The precautionary principle in contemporary environmental policy and politics. Pp. 15–35. In C. Raffensperger and J. Tickner (eds.). *Protecting Public Health and the Environment: Implementing the Precautionary Principle*. Island Press, Washington, D.C.

Kathage, J. and M. Qaim. 2012. Economic impacts and impact dynamics of Bt (*Bacillus thuringiensis*) cotton in India. *P Natl Acad Sci* 109 (29): 11652–11656.

Keeling, P. J. and J. D. Palmer. 2008. Horizontal gene transfer in eukaryotic evolution. *Nat Rev Genet* 9:605–618.

Khush, G. S. 2012. Genetically modified crops: The fastest adopted crop technology in the history of modern agriculture. *Agr Food Sec* 1:14, http://www.agricultureandfoodsecurity.com/content/1/1/14 (25 September 2012)

Khush, G. S., S. Lee, J-I. Cho, and J-S. Jeon. 2012. Biofortification of crops for reducing malnutrition. *Plant Biotechnol Rep* 6:195–202.

Kim, J-H., S-Y. Kim, H. Lee, Y-R. Kim, and H-Y. Kim. 2010. An event-specific DNA microarray to identify genetically modified organisms in processed foods. *J Agr Food Chem* 58:6018–6026.

Kriebel, D. and J. Tickner. 2001. Reenergizing public health through precaution. *Am J Public Health* 91:1351–1355.

Lobell, D. B., K. G. Cassman, and C. B. Field. 2009. Crop yield gaps: Their importance, magnitude, and causes. NCESR Publications and Research Paper 3, http://digitalcommons.unl.edu/ncesrpub/3 (7 September 2012)

Lofstedt, R. E. 2004. The swing of the regulatory pendulum in Europe: From precautionary principle to (regulatory) impact analysis. *J Risk Uncert* 28:237–260.

Lofstedt, R. E., B. Fischhoff, and L. R. Fischhoff. 2002. Precautionary principles: General definitions and specific applications to genetically modified organisms. *J Policy Anal Manag* 21:381–407.

Lotter, D. 2009. The genetic engineering of food and the failure of science—Part 2: Academic capitalism and the loss of scientific integrity. *Int J Sociol Agr Food* 16 (1): 50–68.

Majone, G. 2010. Foundations of risk regulation: Science, decision-making, policy learning and institutional reform. *Eur J Risk Reg* 1:5–19.

Mallaby, S. 2002. "Phony Fears Fan a Famine." *Washington Post*, September 2, p. A23.

Mandel, G. N. 2004. Gaps, inexperience, inconsistencies, and overlaps: Crisis in the regulation of genetically modified plants and animals. *William Mary Law Rev* 45:2167–2259.

Marchant, G. E. 2003. From general policy to legal rule: The aspirations and limitations of the precautionary principle. *Environ Health Persp* 111 (14): 1799–1803.

Marchant, G. E. and K. L. Mossman. 2004. *Arbitrary & Capricious: The Precautionary Principle in the European Union Courts*. AEI Press, Washington, D.C.

Marchant, G. E., D. J. Sylvester, and K. W. Abbott. 2009. What does the history of technology regulation teach us about nano oversight? *J Law Med Ethics* 37:724–731.

Marchant, G. E., B. Atkinson, D. Banko, J. Bromley, E. Cseke, E. Feldstein, D. Garcia, J. M. Grant, C. Hubach, M. Silva, R. L. Swinford, and S. Willman. 2012. The biggest issues for the smallest stuff: Nanotechnology regulation and risk management. *Jurimetrics* 52:243–277.

Marsden, J. L. 1994. Irradiation and food safety. American Meat Institute Issues Briefing (July): 1–4.

McGinnis, E. E., M. H. Meyer, and A. G. Smith. 2012. Analysis of U.S. genetically engineered crop regulation and litigation. *Crop Sci* 52 (3): 991–1002.

McHughen, A. and S. Smyth. 2008. US regulatory system for genetically modified [genetically modified organism (GMO), rDNA or transgenic] crop cultivars. *Plant Biotechnol J* 6:2–12.

Miller, H. I. and G. Conko. 2001. Precaution without principle. *Nat Biotechnol* 19:302–303.

Morris, J. 2002. The relationship between risk analysis and the precautionary principle. *Toxicology* 181–182:127–130.

Morris, S. H. 2007. EU biotech crop regulations and environmental risk: A case of the emperor's new clothes? *Trends Biotechnol* 25 (1): 2–6.

Oerke, E-C. and H-W. Dehne. 1997. Global crop production and efficacy of crop protection—Current situation and future trends. *Eur J Plant Pathol* 103:203–215.

Office of Management and Budget (OMB)/Office of Science and Technology Policy (OSTP). 2007. Updated principles for risk analysis. Memorandum for Heads of Executive Departments and Agencies, http://www.whitehouse.gov/sites/default/files/omb/assets/regulatory_matters_pdf/m07-24.pdf (14 September 2012)

Office of Science and Technology Policy (OSTP). 1986. Coordinated framework for regulation of biotechnology. *Fed Regist* 51:23302–23350, June 26.

Padmanaban, G. 2009. Bt brinjal—Ban or boon? *Curr Sci* 97 (12): 1715–1716.

Park, J., I. McFarlane, R. Phipps, and G. Ceddia. 2011. The impact of the EU regulatory constraint of transgenic crops on farm income. *New Biotechnol* 28 (4): 396–406.

Partridge, M. and D. J. Murphy. 2004. Detection of genetically modified soya in a range of organic and health food products: Implications for the accurate labelling of foodstuffs derived from potential GM crops. *Brit Food J* 106 (3): 166–180.

Pauly, C. and C. Schult. 2013. Trans-Atlantic rifts: European activists could thwart US-EU trade deal. *Spiegel Online*, February 26, http://www.spiegel.de/international/world/plan-for-trans-atlantic-trade-agreement-could-founder-on-eu-concerns-a-885596.html (5 April 2013).

Pew Initiative on Food and Biotechnology. 2004. *Issues in the Regulation of Genetically Engineered Plants and Animals*. April, http://www.pewhealth.org/uploadedFiles/PHG/Content_Level_Pages/Reports/food_biotech_regulation_0404.pdf (23 December 2012)

Pingali, P. L. and G. Traxler. 2002. Changing locus of agricultural research: Will the poor benefit from biotechnology and privatization trends? *Food Policy* 27:223–238.

Potrykus, I. 2010. Lessons from the 'Humanitarian Golden Rice' project: Regulation prevents development of public good genetically engineered crop products. *New Biotechnol* 27 (5): 466–472.

Qaim, M. 2009. The economics of genetically modified crops. *Annu Rev Res Econ* 1:665–693.

Raffensperger, C. and P. L. deFur. 1999. Implementing the precautionary principle: Rigorous science and solid ethics. *Hum Ecol Risk Assess* 5:933–941.

Raffensperger, C. and J. Tickner (eds.). 1999. *Protecting Public Health and the Environment: Implementing the Precautionary Principle*. Island Press, Washington, D.C.

Raney, T. 2006. Economic impact of transgenic crops in developing countries. *Curr Opin Biotech* 17:1–5.

Ricroch, A. E., J. B. Berge, and M. Kuntz. 2011. Evaluation of genetically engineered crops using transcriptomic, proteomic, and metabolomic profiling techniques. *Plant Physiol* 155:1752–1761.

Ronald, P. 2011. Plant genetics, sustainable agriculture and global food security. *Genetics* 188:11–20.

Sandin, P. 1999. Dimensions of the precautionary principle. *Hum Ecol Risk Assess* 5 (5): 889–907.

Sandin, P. and S. O. Hansson. 2002. The default value approach to the precautionary principle. *Hum Ecol Risk Assess* 8 (3): 463–471.

Santillo, D., R. L. Stringer, P. A. Johnston, and J. Tickner. 1998. The precautionary principle: Protecting against failures of scientific method and risk assessment. *Mar Pollut Bull* 36 (12): 939–950.

Seifert, F. 2011. Sustainability and the EU controversy on agri-biotechnology: Radical change or ecological modernization? *Int J Technol Dev Studies* 2 (1): 2–29.

Seufert, V., N. Ramankutty, and J. A. Foley. 2012. Comparing yields of organic and conventional agriculture. *Nature* 485:229–232.

Shelton, A. M. 2010. The long road to commercialization of Bt brinjal (eggplant) in India. *Crop Prot* 29:412–414.

Slovic, P. 1987. Perception of risk. *Science* 236:280–285.

Spielman, D. J. 2007. Pro-poor agricultural biotechnology: Can the international research system deliver the goods? *Food Policy* 32:189–204.

Starr, C. 2003. The precautionary principle versus risk analysis. *Risk Anal* 23 (1): 1–3.

Stokes, E. 2008. The EC courts' contribution to refining the parameters of precaution. *J Risk Res* 11:491–507.

Sunstein, C. R. 2003. Beyond the precautionary principle. Public law and legal theory working paper no. 38. University of Chicago, http://www.law.uchicago.edu/files/files/38.crs_.precautionary.pl-lt.pdf (13 September 2012)

Sunstein, C. R. 2004. Safe and sorry: Another victory for the wrongheaded idea that risk is bad. *Forbes* 173 (14): 48.

Sunstein, C. R. 2005. *Laws of Fear: Beyond the Precautionary Principle*. Cambridge University Press, New York.

Sunstein, C. R. 2006a. Irreversible and catastrophic. *Cornell Law Rev* 91:841–897.

Sunstein, C. R. 2006b. Irreversible and catastrophic: Global warming, terrorism, and other problems. *Pace Environ Law Rev* 23:3–19.

Taub, I. A. 1984. Free radical reactions in food. *J Chem Educ* 61:313–324.

Trouwborst, A. 2007. The precautionary principle in general international law: Combating the Babylonian confusion. *RECIEL* 16 (2): 185–195.

United Kingdom House of Commons Science and Technology Committee. 2006. *Scientific Advice, Risk and Evidence Based Policy Making*. The Stationary Office, London, U.K.

United Nations Conference on Environment and Development (UNCED). 1992. *Rio Declaration on Environment and Development*. U.N. Doc. A/CONF.151/5/Rev. 1, http://www.unesco.org/education/information/nfsunesco/pdf/RIO_E.PDF (19 September 2012)

United Nations General Assembly. 1982. *World Charter for Nature*. U.N. General Assembly Resolution 37/7, 48th plenary meeting.

Urbain, W. M. 1986. *Food Irradiation*. Academic Press, Orlando, Florida.

U.S. Environmental Protection Agency (USEPA). 2008. Implementing the pesticide registration improvement act—Fiscal year 2007. *Pesticides: Regulating Pesticides*, http://www.epa.gov/pesticides/fees/2007annual_report/pria_annual_report_2007.htm (12 September 2012)

U.S. Environmental Protection Agency (USEPA). 2011. *Estimating the Data Generation Costs for Registration of a New Conventional Pesticide Active Ingredient*, http://www.epa.gov/pesticides/ppdc/2011/october/new-conventional.pdf (12 September 2012)

U.S. Environmental Protection Agency (USEPA). 2012a. Accomplishments under the Food Quality Protection Act (FQPA). *Pesticides: Regulating Pesticides*, http://www.epa.gov/opp00001/regulating/laws/fqpa/fqpa_accomplishments.htm (12 September 2012)

U.S. Environmental Protection Agency (USEPA). 2012b. Food contaminants. *America's Children and the Environment*. 3rd ed. draft, http://www.epa.gov/ace/ace3draft/draft_pdfs/ACE3FoodContaminantsReviewPackage3-02-11.pdf (12 September 2012)

U.S. Environmental Protection Agency (USEPA). 2012c. *Pesticide Reregistration Performance Measures and Goals; Annual Progress Report; Fiscal Year 2011*. EPA-HQ-OPP-2011-0959, http://www.regulations.gov/#!docketDetail;D=EPA-HQ-OPP-2011-0959;dct=FR%252BPR%252BN%252BO%252BSR (12 September 2012)

U.S. Environmental Protection Agency (USEPA). 2012d. Sulfuryl fluoride; second request for comment on proposed order granting objections to tolerances and denying request for a stay. *Fed Regist* 77 (84): 25661–25664.

U.S. Environmental Protection Agency (USEPA). 2012e. Accomplishments under the Food Quality Protection Act (FQPA). *Pesticides: Regulating Pesticides*, http://www.epa.gov/pesticides/regulating/laws/fqpa/fqpa_accomplishments.htm (12 September 2012)

Vinocur, B. and A. Altman. 2005. Recent advances in engineering plant tolerance to abiotic stress: Achievements and limitations. *Curr Opin Biotech* 16:123–132.

Wang, W., B. Vinocur, and A. Altman. 2003. Plant responses to drought, salinity and extreme temperatures: Towards genetic engineering for stress tolerance. *Planta* 218:1–14.

Wang, Z-Y. and E. C. Brummer. 2012. Is genetic engineering ever going to take off in forage, turf and bioenergy crop breeding? *Ann Bot-London*, doi: 10.1093/aob/mcs027, http://aob.oxfordjournals.org/content/early/2012/02/28/aob.mcs027.full.pdf (25 September 2012)

Weed, D. L. 2002. Is the precautionary principle a principle? *IEEE Technol Soc Mag* 21 (4): 45–48.

Weiss, C. 2003. Scientific uncertainty and science-based precaution. *Int Environ Agreem-P* 3:137–166.

Wiedemann, P. M. and H. Schütz. 2005. The precautionary principle and risk perception: Experimental studies in the EMF area. *Environ Health Persp* 113:402–405.

Wiener, J. B. 2002. Precaution in a multirisk world. Pp. 1509–1531. In D. J. Paustenbach (ed.). *Human and Ecological Risk Assessment: Theory and Practice*. Wiley, New York.

Wiener, J. B. and M. D. Rogers. 2002.

Comparing precaution in the United States and Europe. *J Risk Res* 5 (4): 317–349.

World Health Organization (WHO). 1966. *The Technical Basis for Legislation on Irradiated Food*. WHO Technical Report 316, Report of a Joint FAO/IAEA/WHO Expert Committee. World Health Organization, Geneva.

World Health Organization (WHO). 1981. *Wholesomeness of Irradiated Food*. Technical Report Series No. 659. World Health Organization, Geneva.

World Health Organization (WHO). 1994. *A Review of the Safety and Nutritional Adequacy of Irradiated Food*. World Health Organization, Geneva.

World Trade Organization (WTO). 2006. *European Communities—Measures Affecting the Approval and Marketing of Biotech Products*. Panel Report WT/DS291/R, http://docsonline.wto.org:80/DDFDocuments/t/WT/DS/293R-00.doc (19 September 2012)

CAST Member Societies, Companies, and Nonprofit Organizations

AMERICAN ASSOCIATION OF AVIAN PATHOLOGISTS ■ AMERICAN ASSOCIATION OF BOVINE PRACTITIONERS ■ AMERICAN BAR ASSOCIATION, SECTION OF ENVIRONMENT, ENERGY, & RESOURCES–AGRICULTURAL MANAGEMENT ■ AMERICAN DAIRY SCIENCE ASSOCIATION ■ AMERICAN FARM BUREAU FEDERATION ■ AMERICAN MEAT SCIENCE ASSOCIATION ■ AMERICAN METEOROLOGICAL SOCIETY, COMMITTEE ON AGRICULTURAL AND FOREST METEOROLOGY ■ AMERICAN SOCIETY FOR NUTRITION ■ AMERICAN SOCIETY OF AGRICULTURAL AND BIOLOGICAL ENGINEERS ■ AMERICAN SOCIETY OF ANIMAL SCIENCE ■ AMERICAN SOCIETY OF PLANT BIOLOGISTS ■ AMERICAN VETERINARY MEDICAL ASSOCIATION ■ AQUATIC PLANT MANAGEMENT SOCIETY ■ COUNCIL OF ENTOMOLOGY DEPARTMENT ADMINISTRATORS ■ CROPLIFE AMERICA ■ DUPONT PIONEER ■ ELANCO ANIMAL HEALTH ■ IOWA SOYBEAN ASSOCIATION ■ MONSANTO ■ NATIONAL PORK BOARD ■ NORTH CENTRAL WEED SCIENCE SOCIETY ■ NORTHEASTERN WEED SCIENCE SOCIETY ■ POULTRY SCIENCE ASSOCIATION ■ SOCIETY FOR IN VITRO BIOLOGY ■ SYNGENTA CROP PROTECTION ■ THE FERTILIZER INSTITUTE ■ UNITED SOYBEAN BOARD ■ WEED SCIENCE SOCIETY OF AMERICA ■ WESTERN SOCIETY OF WEED SCIENCE ■ WINFIELD SOLUTIONS, A LAND O'LAKES COMPANY

The mission of the Council for Agricultural Science and Technology (CAST) *is to assemble, interpret, and communicate credible science-based information regionally, nationally, and internationally to legislators, regulators, policymakers, the media, the private sector, and the public. CAST is a nonprofit organization composed of scientific societies and many individual, student, company, nonprofit, and associate society members. CAST's Board is composed of representatives of the scientific societies, commercial companies, nonprofit or trade organizations, and a Board of Directors. CAST was established in 1972 as a result of a meeting sponsored in 1970 by the National Academy of Sciences, National Research Council.*

ISSN 1070-0021

Additional copies of this Issue Paper are available from CAST. Carol Gostele, Managing Scientific Editor, http://www.cast-science.org.

Citation: Council for Agricultural Science and Technology (CAST). 2013. *Impact of the Precautionary Principle on Feeding Current and Future Generations*. Issue Paper 52. CAST, Ames, Iowa.

CAST®
The Science Source for Food, Agricultural, and Environmental Issues

4420 West Lincoln Way
Ames, Iowa 50014-3447, USA
(515) 292-2125, Fax: (515) 292-4512
E-mail: cast@cast-science.org
Web: www.cast-science.org