Transgenic Research **PC1258:** 1–9, 2003.

Safety, risk and the precautionary principle: rethinking precautionary approaches to the regulation of transgenic plants

Gregory Conko
Competitive Enterprise Institute, Washington, DC 20036, USA (E-mail: gconko@cei.org)

Accepted 4 July 2003

Key words: Cartagena Protocol on Biosafety, precautionary approach, precautionary principle, Rio Declaration, risk analysis, transgenic plants

Abstract

Operationalizing the Cartagena Protocol on Biosafety will require resolving disputes about the meaning of the term 'precautionary approach' in the treaty text. Although the terms precautionary approach and precautionary principle have been referred to in the regulation of transgenic plants for nearly a decade, no customary expectation of what actions it requires has developed. If specific obligations for regulators, regulated entities, or both are not established, compliance will be impossible. This essay examines various interpretations of the precautionary principle, discusses their shortcomings, and suggests a way to rethink the regulation of transgenic plants that focuses on genuine uncertainty. Transgenic plants with familiar phenotypes should be subject to considerably less regulatory scrutiny than those whose risks are genuinely unknown, or known to pose heightened risk.

Introduction

Ever since completion of the Cartagena Protocol on Biosafety in January 2000, government regulators, political activists, plant breeders, and risk analysis professionals have debated the protocol's inclusion of the term 'precautionary approach' in the agreement's definition of the rights and obligations of governments in regulating the transboundary movement of transgenic organisms. Under the terms of the protocol, governments are encouraged to take a precautionary approach to the domestic regulation of transgenic organisms. Governments are also free to reject individual shipments of transgenic organisms from other countries if they are believed to be unsafe, even if there is insufficient scientific evidence to demonstrate a cause and effect relationship.

For many years, disagreements have raged over whether the precautionary approach – or precautionary principle, as it is sometimes described – is a useful tool for managing the risks of technologies and products. Resolving these disputes is made difficult by a lack of a formal, established definition for either term, making unclear exactly what either means and what each requires of governments and innovators. Although the precautionary principle has been referred to in the regulation of a variety of substances – including transgenic plants – for at least a decade, no customary expectation of what action or actions it requires has developed. Now that the Biosafety Protocol has been ratified by 50 governments, and will likely go into effect by the time this article appears in print, debates about implementation of the precautionary principle are no longer simply academic. As Stone (2001, p. 10795) notes, "the crucial work requires turning from general principles to inescapable specifics: Under what circumstances are which *ex ante* measures warranted, and subject to what constraints?" A legal dictum must create some obligations for regulators, regulated entities, or both – otherwise compliance is impossible.

This essay will discuss various interpretations of the precautionary principle and describe a possible difference between the principle and 'precautionary approach'. It will next examine the relative merits of those interpretations and the shortcomings of relying too heavily on precautionary regulation. It will conclude with thoughts on the kind of the kind of

precautionary regulation that is appropriate for transgenic plants. When implementing the Biosafety Protocol, it will be essential for countries to choose a set of elements from the various interpretations that allows regulators to balance the potential risks of a new technology against the potential risk-reducing benefits of that technology. If this cannot be done, the precautionary principle and precautionary approach will prove to be inadequate tools for risk management.

Various interpretations of the precautionary principle

The most universal description of the precautionary principle is that it "seeks to impose early preventive measures to ward off even those risks for which we have little or no basis on which to predict the future probability of harm" (Wiener, 2001, p. 4). Although no action can be said to be risk-free, nor is any risk perfectly predictable, the precautionary principle is generally not used to describe regulatory measures taken to prevent or mitigate against risks such as automobile accidents or house fires, where years of prior experience allow both the likelihood and magnitude of potential harm to be estimated with some certainty. Instead, the precautionary principle tends to be applied in cases such as the introduction of entirely new products and technologies, where neither variable can be estimated with any certainty.

Because uncertainty about future events is itself difficult to characterize *a priori* – we can never know exactly how much we do not know – it is not altogether clear in exactly which situations the principle is to be used. Furthermore, no indication seems to be given for how much data gathered over how long a time period will be necessary to satisfy these requirements (see, e.g., Raffensperger & Tickner, 1999). For example, scientists now have considerable amounts of experiential data from field trials and commercial use of many products of recombinant DNA technology, including several varieties of transgenic plants. Still, advocates of the precautionary principle maintain that all products of rDNA modification must be subject to the principle's restrictions, and they are at a loss to identify when we will know enough to permit wide-scale environmental release.

Even the scholarly literature – both for and against adoption of the principle – gives no clear guidance on how or when the principle should be applied. Indeed, it may not even be appropriate to talk about 'The' precautionary principle. Sandin (1999) found at least 19 different formulations – all of them vague, some of them contradictory. Perhaps the only thing that can be said with any certainty is that current discussions should differentiate between this concept and the safety margins scientists build into their risk assessments (European Commission, 2000; Isaac, 2001). The precautionary principle at the center of our current debate is not a risk assessment tool; our debate is about risk management.

Morris (2000) identifies two basic versions of the precautionary principle as it applies to risk management: one strong, one weak. In the strong version, uncertainty about the exposure to and/or magnitude of a risk necessarily warrants some regulatory response to prevent or mitigate against it. This strong version is characterized by a January 1998 statement crafted by a group of scholars and environmental activists at the Wingspread Conference Center in the US state of Wisconsin. According to the Wingspread version:

> "When an activity raises threats of harm to the environment or human health, precautionary measures ***should*** be taken, even if some cause-and-effect relationships are not fully established scientifically" (Raffensperger & Tickner, 1999, pp. 353–354, emphasis added).

It has been noted, however, that science can never prove the absence of a risk and, further, that all activities pose some non-zero risk of adverse effects (Wildavsky, 1988; Harris & Holm, 2002). Taken literally, this strong precautionary principle would mean that no action could ever be taken because an assurance of absolute safety can never be given. This is an impossible standard, and one that would lead to decision paralysis, not to greater safety. Critics have long suggested that this anti-change feature of the precautionary principle is evidence that it is prone to misuse – not to drive society toward a more optimal regulation of risk, but simply to stand in the way of technological evolution. Surely, then, for precaution to be operationalized in any meaningful way, we must rely on a different interpretation.

In the weak, and more common, version identified by Morris, uncertainty does not itself necessitate action. Instead, the weak formulation holds that uncertainty should neither be used as an excuse for government inaction, nor as a justification to prevent a regulatory response. This weak version is best characterized by the Ministerial Declaration of the 1992 United Nations Conference on Environment and

Development (the 'Earth Summit') in Rio de Janeiro, also known as the 'Rio Declaration'. According to Principle 15 of the Rio Declaration:

> "Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing ***cost-effective*** measures to prevent environmental degradation" (United Nations, 1992, emphasis added).

The identical phraseology can be found in the preamble of the Convention on Biological Diversity (UNEP, 1994) and in the operative text of the Cartagena Protocol on Biosafety (Secretariat of the Convention on Biological Diversity, 2000). Indeed, in some form or another, a weaker rather than a stronger version can be found in most legally binding texts, including in national laws and multilateral agreements (Wiener, 2001), so it is on this version that we should concentrate our attention, rejecting the stronger interpretation.

In the so-called weak version, governments may act at their discretion to restrict or ban products or activities even before obtaining proof that a harm is imminent, but no obligation to do so seems to be implied. Note, also, that many weaker versions, including the Convention on Biological Diversity and Cartagena Protocol, also include the caveat that regulatory measures ought to be "cost-effective", which seems to place a boundary around the type of regulatory actions that may be enforced. The European Commission's Communication on the precautionary principle acknowledges a need for precautionary measures to be "based on an examination of the potential benefits and costs of action or lack of action" (European Commission, 2000, p. 4).

Although skeptics have questioned the appropriateness of the European Commission's own application of the precautionary principle, especially as it relates to transgenic crops (Adler, 2002; Conko & Miller, 2001), few scholars would suggest openly that no attempt should be made to ensure that precautionary measures do more good than harm. Indeed, Goklany (2001a, b) has even argued that the precautionary principle itself requires regulators to consider the risks that may arise from regulatory interventions themselves, as well as those that may arise from the new technology. Still, while Goklany's advice is sound, it is far from clear that the precautionary principle creates an obligation on the part of regulators to balance the risks of action against the risks of inaction in setting policy. Few commentators, other than Goklany, have endorsed this more balanced application.

Weiner and Rogers (2002) add an even stronger version to this list, in which uncertainty requires shifting the burden of proof to the proponent of the activity. For example, in addition to the text reproduced above, the Wingspread Statement further requires that "the proponent of an activity, rather than the public, should bear the burden of proof" of the safety of the activity in question (Raffensperger & Tickner, 1999, p. 354). In this interpretation, governments should forbid products or activities until proponents have demonstrated their safety. New products should not be marketed until prior authorization has been granted by the government.

However, the precautionary principle has most often been invoked in cases where a governmental pre-market approval process is already enforced – including pesticides, food additives, and transgenic organisms. For example, every country in the world where transgenic crops are currently being grown commercially already has a pre-market approval process in which the producer is required by law to demonstrate some aspect of safety to the satisfaction of at least one regulatory body. Although the prior government authorization is itself clearly precautionary in nature, precautionary principle advocates envision placing additional, restrictive measures over this existing regulatory apparatus. Thus, it is not at all clear that 'shifting the burden of proof' is a distinction that can genuinely be made among versions of the principle. Whether one applies a weak or strong version, it is producers who bear the burden of proof.

Nor is prior existence of a pre-commercialization approval process the only condition that would shift the burden of proof in the weak version. The European Union is generally judged to utilize a weak version of the principle (Wiener, 2001). Yet its February 2000 Communication – an attempt to explain when and how the principle would be applied under its auspices – makes clear that, "Where there is no prior authorization procedure, ... a specific precautionary measure might be taken to place the burden of proof upon the producer" (European Commission, 2000, p. 5). The main difference between the weak and strong precautionary principle, then, seems to be that the weaker version simply grants more discretion to regulators in when they are to enforce precautionary measures. We might also speculate, then, that it is simply the act of a governmental pre-commercialization assessment

that characterizes precaution in the sense meant by advocates.

Precautionary principle or precautionary approach?

Can any other distinction be made among various interpretations of precaution? As noted in the Introduction, the Cartagena Protocol uses the term 'precautionary approach' not 'precautionary principle', as do the Convention on Biological Diversity and the Rio Declaration. Can we say that the 'precautionary approach' is the weaker version and 'precautionary principle' the stronger – or that, in some other way, the two terms have decidedly different meanings? This too is unclear. Indeed, the European Commission's communication on the precautionary principle treats the two as identical (European Commission, 2000), as does a brochure published by the Canadian government's environmental regulatory agency (Environment Canada, 2003).

It seems largely – though not exclusively – to be the United States government and certain corporations and industry associations that seek to differentiate between the two terms (see, e.g., Wirthlin Worldwide, 2000). The distinction usually drawn between them by these advocates has largely to do with distinguishing between the procedural methods used for conducting risk assessment and making approval decisions. In this view, the precautionary principle is an open-ended and necessarily subjective search for reassurance regarding any hypothesized risks, regardless of how implausible or unlikely they may be. Innovators must demonstrate that their new products are in some way 'safe', but identifying who will be involved in the judgment and on what criteria evaluation will be based remains intentionally undefined. The precautionary approach, on the other hand, is the term used to describe more organized attempts by risk managers to evaluate the likelihood of specific risks prior to commercialization.

The important distinction made here is that, under a precautionary approach, risk management judgments are made in a standardized, formulaic way. Risk assessments are performed to estimate the probability that a given item will produce a fully characterized and plausible harm using an established procedural framework and testing methodology (USDA, 2000; Wirthlin Worldwide, 2000). The methodology may vary, as may the individual risks for which different items must be tested. But the harms may not be purely speculative – a biologically or chemically plausible link between the substance and the harm must be demonstrated – and decisions must be made on the basis of data produced in the risk assessment and other available data in the published scientific literature. An example can be found in the regulation of synthetic chemical insecticides in the United States.

A risk of toxicity, carcinogenicity, and teratogenicity is known to arise from many individual chemical compounds – a link that has been established scientifically. Taking a precautionary approach, the US Environmental Protection Agency (EPA) requires insecticides to be tested using established methodologies to determine the maximum exposure (measured by an amount of the substance per unit of body weight) at which no observable adverse effects appear in laboratory animals. Once determined, the EPA's precautionary approach then establishes a legally 'safe' exposure level by adjusting the no observable adverse effect level downward by a factor of 10 to account for the difference between lab animals and humans, by an additional factor of 10 to account for variation among human populations, and often by a third factor of 10 to account for the difference between adults and children (National Research Council, 1987, 1996).

This 100-fold or 1000-fold difference is thought to create a very wide margin of safety, and this risk management decision is said to be precautionary in nature. There is a substantial room for discretion by regulators in interpreting the results of laboratory assessments and other published findings. But an important difference between this precautionary approach and the precautionary principle is that, once these procedural requirements are satisfied, the new pesticide product must be allowed on the market. No additional speculative claims are permitted to influence the decision-making unless they are formally adopted into the regulatory framework with an established methodology and a theoretically achievable standard of evidence.

Again, it should be noted that this distinction between precautionary principle and precautionary approach is contested. Many European regulations are structured in a similar fashion. Nevertheless, the key features of the two-concept theory are worth remembering. Reliability, regularity, and impartiality of legal rules are essential for proper planning by businesses and individuals (Tribe, 1978). Without a clear definition, precaution provides neither evidentiary standards for demonstrating 'safety' nor procedural criteria for

obtaining regulatory approvals no matter how much evidence is mustered. This turns effective planning by innovators into a regulatory guessing game. Ultimately, if producers are unaware of what the regulatory boundaries are, and what they are likely to be in at least the near-term future, they will be increasingly unwilling to take risks in developing the new products that eventually would improve net safety (Lofstedt, 2002). It can also contribute to the perverse situation in which only the largest, most financially secure firms can afford to produce products – and then, only those products that are most likely to be profitable. Academic and publicly funded institutions will find it increasingly difficult to produce transgenic products targeted at resource-poor populations in an environment in which the precautionary principle is used most subjectively.

An even more important problem with open-ended precautionary regulation is one of fundamental unfairness. Written, established laws clearly stating what is and what is not unlawful behavior is an essential bulwark of the freedoms protected by constitutional democracies (Tribe, 1978). Yielding wide discretion to government regulators often leads to dubious public policy. Although reliance on regulatory agencies and courts to define and elaborate statutory policy and to create a set of expectations is not unusual, the reluctance of precautionary principle advocates to define what purports to be a fundamental principle makes confusion and mischief inevitable. The legal rights of producers and consumers, as well as the legal obligations of regulators must be more clearly defined to prevent governmental judgments from being overly subjective. Thus, in at least these two aspects, the precautionary approach practiced by US regulatory agencies does appear to be superior to the precautionary principle advocated by environmentalists and European governments.

Could a predictable regulatory apparatus, based on scientific evaluations and established rules be what less radical advocates of the precautionary principle hope to operationalize? Certainly, the rhetoric used by some suggests that it is. The European Commission, in its February 2000 communication on the precautionary principle asserts that regulatory measures taken under the auspices of the precautionary principle should be 'proportional,' 'non-discriminatory,' and 'consistent'. Furthermore, decision-makers should carefully weigh 'potential benefits and costs'. And decisions should be "subject to review in the light of new scientific data" (European Commission, 2000).

Yet, practical application of the precautionary principle by the European Commission shows that it has often been invoked even when the evidence for safety has been quite strong – for example, to ban use of supplemental growth hormones in beef cattle (World Trade Organization, 1998) and the use of phthalate plastic softeners in medical devices and childrens' toys (Durodié, 2000), or to justify the European Union's 5-year *de facto* moratorium on new transgenic crop variety approvals (Kessler & Economidis, 2001; Nature Biotechnology, 2002). These decisions lead many critics to suspect the precautionary principle is not simply intended to ensure that regulatory decisions take into account both the potential harms and the potential benefits of a product before it is commercialized. A simple precautionary approach to regulation of veterinary drugs, industrial chemicals, and transgenic crops would – and actually has – found these three technologies safe enough for commercialization, whereas invocation of the precautionary principle has enabled regulators to disregard the substantial evidence of safety in their risk management decisions, arguably leading to an environment of even greater risk.

The two risk problem

Although advocates are right that human health or the environment can at times be jeopardized when no formal precautionary measures are taken, the contrary point – that human health or the environment can also be jeopardized when action is blocked – is also true. Consider the situation in southern Africa during the summer and autumn 2002, for example, where, in the midst of a severe food shortage, food aid shipments containing transgenic maize were rejected due to concerns about potential health and environmental risks. The result is that one is left to wonder what measures should be used to ward off which risks.

The reason for enforcing precautionary measures, advocates reply, is that the failure to regulate risky activities sufficiently could result in severe harm to human health or the environment, but 'over-regulation' causes little or no harm – the choice is between saving money on the one hand and saving lives on the other (Page, 1978; Raffensperger & Tickner, 1999). In this sense, only measures taken to restrict activity can be viewed as 'precautionary'; concern about the potential negative effects of over-regulation cannot be viewed as taking precaution. But as the situation

in southern Africa demonstrates, precautionary over-regulation can have its own human costs. Cross (1996, p. 860) notes that this "unsupported presumption that an action aimed at public health protection cannot possibly have negative effects on public health" is the precautionary principle's 'truly fatal flaw'.

Because all activity entails risk, stopping an activity when evidence of risk arises, even temporarily, does not necessarily lead to improved health or environmental outcomes. Deciding to stop an activity on the basis of nothing more than speculation about a potential risk is even worse. Yet this is exactly the position taken by many precautionary principle advocates – asserting that the novel risks introduced by new technologies must always be presumed greater than established risks, even if the latter are less well characterized. Precautionary principle advocate O'Brien (1999, pp. 207–208) offers an allegory, paraphrased here:

> Imagine a woman standing by an icy mountain river. A team of risk assessors urges her to wade across, as the risk to her dying is only one in forty million. The woman refuses to cross. 'Why?' the risk assessors ask. The woman points upstream and says, 'Because there is a bridge'.

In this story, the woman incorporates the precautionary principle into her decision-making process by assessing the alternatives and choosing the dry, warm, and safe bridge over the risk of the icy cold river. It is naïve, however, to suggest that risk assessors have for decades advocated courses of action without noticing such obvious low-cost alternatives. This view glosses over the fact that many technologies, while risky, are themselves the lowest-cost choice. There is not always a bridge – and when there is, one may have to traverse dangerous terrain to reach it. Confronted with uncertainty, it is not altogether clear which route leads to safety and which to danger. A thorough analysis had estimated risks of wading across the river to be relatively small. Nevertheless, the woman assumed without any further analysis that reaching the bridge and crossing it must necessarily be safer. This is the kind of one-dimensional choice the precautionary principle encourages risk managers to make.

'Precaution', in the sense meant by precautionary principle advocates, will often tend to trap society into older, more harmful situations. At times – for example, when the principle is applied to remove important technologies from the market – precaution can even lead to a perverse net increase in overall risk. A general shortcoming of all versions of the precautionary principle – and even the precautionary approach as defined by the US government – is that they examine risk in a vacuum, neglecting the fact that technologies or activities that are themselves risky may, in fact, actually lower overall risk by eliminating or mitigating more problematic risks that arise from accepted technologies or behaviors (Wiener, 2001; Wildavsky, 1988).

Whether or not we consciously recognize it, every decision about avoiding or taking on a given risk will necessarily entail tradeoffs. By-products of water chlorination can cause bladder cancers at high doses, but chlorination prevents illnesses such as cholera. Asbestos fibers can cause lung diseases and cancers, but asbestos use helps prevent fires and improves transportation safety. Medicines often are toxic and/or carcinogenic, but they also may cure or reduce the adverse effects of a disease. Gene flow from transgenic plants may upset the balance of flora and fauna in an ecosystem, but adoption of transgenic plants could reduce the total amount of land needed to produce food, thus saving ecosystems from fragmentation or development. And even when an allegedly safer alternative exists, such as replacing chlorine with ozone or ultraviolet (UV) light in water disinfection, the higher cost can reduce the financial resources available for other health or environmental interventions, or they may be considerably less effective than the alternative technologies (Sobsey, 2002). The key to managing risks effectively is to ensure that public health and environmental interventions not only reduce the obvious risks, but that they also not increase *net* risk.

The point should be obvious, but it must be made: The history of mankind shows that, with admitted exceptions, technological progress tends to improve human and environmental health, not degrade it. Choosing any of the technologies described above necessarily will lead to an increase in risk along one axis. But, avoiding any of these technologies will lead inexorably to an increase in risk along another. And, where other alternatives are available, they too will bring their own unique sets of risks. The question for regulators is which way leads to greater safety and which to greater danger? No policymaker who considers only one side of any risk tradeoff can be said to exercise genuine caution.

We risk increasing both the likelihood and magnitude of harm by assuming, *a priori*, that rejecting, or even just delaying by a matter of months or years, the introduction of new technologies necessarily is the

safer choice. Yet this is exactly what the precautionary principle would have us do. Even a minimalist, well-defined precautionary approach can increase risk if it fails to consider the risks of innovation as well as the risks of stagnation. The goal then must be to design regulatory systems that better use accumulated knowledge to segregate low-risk/low-uncertainty and high-risk/high-uncertainty products and apply a level of precaution that is appropriate for each.

What type of precaution is appropriate for transgenic plants?

How can we design a regulatory system for transgenic plants that minimizes our *net* exposure to ecological and human health hazards? It would have to take legitimate risks seriously, while acknowledging the risk-reducing benefits of new applications. It would also have to acknowledge that much is already known about the risks of recombinant DNA. And it must reject the now widespread model that subjects all new transgenic varieties to the same lengthy, expensive review processes. The starting point should be a brief review of what we know about the risks of rDNA modified organisms as a class.

It is generally acknowledged that molecular techniques for genetic modification do not themselves confer any inherent risk on the modified organisms. Rather, the risk of any organism, modified by rDNA or conventional techniques, or unmodified, has solely to do with the genotype and phenotype of the organism, the environment into which it is to be introduced, and the use to which it is to be put (National Research Council, 1989; Institute of Food Technologists, 2000). Although rDNA techniques expand the range of genes that may be transferred between organisms far beyond what can be performed with wide-cross hybridization, the risks associated with transgenic organisms are the same in kind as those associated with conventionally modified organisms with the same traits. Consequently, it is unwise and scientifically unjustified to make a judgment about the risk of transgenic organisms that is separate from genotype or phenotype. 'Transgenic' is not a useful class for either risk assessment or risk management. It is therefore also unjustified to subject all transgenic plants to the same pre-commercialization approval process designed to deal with the riskiest cases.

Government evaluation of rDNA modified organisms should be structured to apply varying levels of regulatory scrutiny to organisms depending upon scientific familiarity with their phenotypes. Instead, most government regulatory systems are highly rigid, created in a way that subjects even very low-risk transgenic products to precautionary scrutiny appropriate only to moderate- and high-risk organisms. Even in the best scenario – a well-defined and predictable precautionary approach characterized by established decision rules – this imposes substantial financial costs on developers, who may never be able to meet the regulatory requirements of bringing products to market, a burden that falls especially hard on those in public and academic research centers. In extreme cases, such as the west European regulatory environment in which decision-making is overtly guided by the precautionary principle, even otherwise unassailable product applications must clear a highly subjective regulatory approval process, making commercialization a guessing game. The precautionary principle in this case has ceased to be a prudent attempt to deal with uncertainty, and instead appears to have become a cover for ulterior political motives.

Consider that, due to the precautionary principle, transgenic herbicide-tolerant oilseed rape and soybean face extraordinary hurdles to commercialization in the European Union, but herbicide-tolerant rape and soybean varieties developed with selection or mutation breeding may be commercialized without any special oversight or review (other than standard assessments for agronomic characteristics), even though considerably less is known about the molecular basis of the herbicide-tolerance trait in the conventional varieties. Surely, if the precautionary principle is to provide any meaningful guidance to regulators, then greater regulatory requirements ought to be required for the less well-characterized conventionally modified varieties. But this is not how the principle has been applied in the European Union. Nor is this how the US government's precautionary approach has been applied to better-characterized transgenic varieties.

If precaution is truly intended to move society in the direction of greater overall safety, we must reconsider the way transgenic organisms have been regulated for most of the past two decades. Rather than assume that all transgenic plants fall into a high-risk category, and therefore that they should be subject to strict precautionary regulation, in most cases it will be possible to characterize the likely risk that individual organisms will pose prior to regulatory assessments, based on prior knowledge of the host crop and transferred genetic material. An example would be when

rDNA techniques are used to modify plants with nucleic acid sequences from donor species related closely enough for normal sexual reproduction. Regulatory models could then apply less strict scrutiny – perhaps even no formal pre-commercial review – to those new varieties whose phenotypes are known to, or are likely to, pose low risk. Greater precautionary scrutiny would only apply to new varieties whose risks are genuinely unknown, or known to pose heightened risk. Barton et al. (1997), Strauss (2003), and Hancock (2003) have all suggested ways to rethink the regulation of new crop variety introductions so that greater regulatory precaution is applied only where substantial uncertainty still exists about the expected behavior of the modified crop in question.

Fortunately, the Cartagena Protocol text provides broad latitude to member governments in establishing regulatory systems for transgenic varieties. While the text repeatedly refers to using a precautionary approach, guidelines for risk assessment contained in Annex III of the agreement properly focus on the biological characteristics of individual products. Thus, while the Protocol recommends that the regulation of transgenic organisms be based upon the precautionary principle, it creates an opportunity for imaginative governments to carve out a more defined, and less biased, precautionary model.

Unfortunately, this open-ended design is also among the Protocol's primary drawbacks. That governments have great flexibility in determining the kind of risk analysis and risk management apparatus to implement means that some may choose the inadvisable approach of institutionalizing a systemic bias against transgenic technologies. Too often, the precautionary principle has, in practice, been used to legitimize a bias against change. How societies resolve the many questions about use and misuse of the precautionary principle will have a great influence on whether the forces of technological and institutional change that have done so much to make the world a safer place over the last several centuries survive or perish. Our goal must instead be a regulatory apparatus that is attuned to the risks of moving too quickly into the future, and one that also is attuned to the risks of staying too long in the past.

References

Adler JH (2002) The precautionary principle's challenge to progress. In: Bailey R (ed.), Global Warming and Other Eco-Myths. (pp. 265–291) Prima Publishing, Roseville, CA.

Barton J, Crandon J, Kennedy D and Miller HI (1997) A model protocol to assess the risks of agricultural introductions. *Nat Biotechnol* **15**: 845.

Conko G and Miller HI (2001) Food safety: the precautionary principle is the wrong approach. *Eur Affairs* **2**: 122–128.

Cross FB (1996) Paradoxical perils of the precautionary principle. *Washington Lee Law Rev* **53**: 851–925.

Durodié B (2000) Plastic panics: European risk regulation in the aftermath of BSE. In: Morris J (ed.), Rethinking Risk and the Precautionary Principle. (pp. 140–166) Butterworth–Heinemann, Oxford, UK.

Environment Canada (2003) A Canadian Perspective on the Precautionary Approach/Principle. Accessed 18 June 2003. http://www.ec.gc.ca/econom/pamphlet_e.htm.

European Commission (2000) Communication from the Commission on the Precautionary Principle. COM, Brussels, 2 February 2000, P. 1.

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

Goklany I (2001b) The Precautionary Principle: A Critical Appraisal of Environmental Risk Assessment. Cato Institute, Washington, DC.

Hancock JF (2003) A framework for assessing the risk of transgenic crops. *BioScience* **3**: 512–519.

Harris J and Holm S (2002) Extending human lifespan and the precautionary paradox. *J Med Philos* **27**: 355–368.

Institute of Food Technologists (2000) IFT Expert Report on Biotechnology and Foods. Institute of Food Technologists, Chicago, IL.

Isaac GE (2002) Agricultural Biotechnology and Transatlantic Trade: Regulatory Barriers to GM Crops. CAB International, Oxfordshire, UK.

Kessler and Economidis (2001) EC-sponsored Research on Safety of Genetically Modified Organisms: A Review of Results. Office for Official Publications of the European Communities, Luxembourg.

Lofstedt R (2002) Introductory paper for the conference, The Precautionary Principle: Risk, Regulation and Politics. Merton College Oxford, Oxford, UK, 5–11 April 2002.

Morris J (ed.) (2000) Rethinking Risk and the Precautionary Principle. Butterworth–Heinemann, Oxford, UK.

National Research Council (1987) Regulating Pesticides in Food. National Academy Press, Washington, DC.

National Research Council (1989) Field Testing Genetically Modified Organisms. National Academy Press, Washington, DC.

National Research Council (1996) Carcinogens and Anti-Carcinogens in the Human Diet. National Academy Press, Washington, DC.

Nature Biotechnology (2002) The fear factor. *Nat Biotechnol* **20**: 957.

O'Brien M (1999) Alternatives assessment: part of operationalizing and institutionalizing the precautionary principle. In: Raffensperger C and Tickner J (eds), Protecting Public Health and the Environment: Implementing the Precautionary Principle. Island Press, Washington, DC.

Page T (1978) A generic view of toxic chemicals and similar risks. *Ecol Law Quart* **7**: 207–244.

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

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

Secretariat of the Convention on Biological Diversity (2000) Cartagena Protocol on Biosafety to the Convention on Biological Diversity: Text and Annexes. Secretariat of the Convention on Biological Diversity, Montreal.

Sobsey MD (2002) Managing Water in the Home: Accelerated Health Gains from Improved Water Supply. WHO/SDE/WSH/02.07. World Health Organization, Geneva.

Stone C (2001) Is there a precautionary principle? *Environ Law Rep* **31**: 10790–10799.

Strauss SH (2003) Genomics, genetic engineering, and domestication of crops. *Science* **300**: 61–62.

Tribe LH (1978) American Constitutional Law. The Foundation Press, Mineola, NY.

UNEP (1994) Convention on Biological Diversity: Text and Annexes. UN Doc. UNEP/CBD/94/1. United Nations Environment Programme, Montreal.

United Nations (1992) Rio Declaration on Environment and Development. UN Doc. A/CONF.151/5/Rev. 1. United Nations, New York.

USDA (2000) A Description Of The US Food Safety System. Washington, DC, US. Food and Drug Administration and US Department of Agriculture. 3 March 2000. http://www.fsis.usda.gov/OA/codex/system.htm.

Wiener JB (2001) Precaution in a multi-risk world. Duke Law School Public Law and Legal Theory Working Paper Series, Working Paper No. 23. Durham, North Carolina.

Wiener JB and Rogers MD (2002) Comparing precaution in the United States and Europe. *J Risk Res* (in press).

Wildavsky A (1988) Searching for Safety. Transaction Publishers, Oxford, UK.

Wirthlin Worldwide (2000) The Precautionary Principle: Throwing Science Out with the Bath Water. Wirthlin Worldwide, McLean, Virginia.

World Trade Organization (1998) EC Measures Concerning Meat and Meat Products (Hormones): Report of the Appellate Body. AB-1997-4. World Trade Organization, Geneva, 16 January 1998.