APPLYING THE PRECAUTIONARY PRINCIPLE TO AGRICULTURAL BIOTECHNOLOGY

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Summary

This paper sets out a framework for applying the precautionary principle to the release of new and existing genetically engineered (GE) crops. The framework aims to assist NGOs, scientists, regulators and others who are currently addressing issues related to genetic engineering and/or the precautionary principle. The steps outlined here suggest a way forward in the current genetic engineering debate by emphasising positive, yet precautionary actions to protect the environment and public health.

Existing statements and analyses of the precautionary principle have identified several core elements. These elements can be used to structure a more detailed framework for applying the principle to particular issues, such as genetic engineering.

(1) Protection of public health and the environment is the primary aim of the precautionary principle. However, evaluation of hazards and benefits of a specific technology must be preceded by several larger considerations: long-term goals, alternatives to reaching those goals, open decision-making processes, and a research agenda that supports precautionary action.

(2) More specific steps in precautionary decision-making are required when a particular technology or activity is recognised as potentially—but not yet proven to be—harmful. This requires that potential for harm is acknowledged and documented in some way. Harms should be characterised broadly including consideration of: indirect, non-linear effects; standards against which harm is assessed; distribution of harm; and the degree of potential harm both in biological and social terms.

(3) Recognition of scientific uncertainty is a third element of the precautionary principle. Interactions among complex ecological, social and political systems place limits on our predictive capacities, and we must therefore acknowledge an irreducible element of ignorance in all decision-making. Specifically, sources and types of uncertainty should be identified (ranging, for example, from technical difficulties to pervasive indeterminacy), and a weight-of-evidence standard for determining the likelihood of harm should be adopted, rather than relying on strict, quantitative standards evidence akin to “beyond reasonable doubt”.

(4) Anticipatory action despite scientific uncertainty is a central tenet of the precautionary principle. Such actions may range from conditional approvals with ongoing monitoring of effects to a complete, permanent ban.

1 This paper was written by Katherine Barrett (Project Coordinator, SEHN). However, many of the ideas expressed here were articulated at a meeting in October 1999 among members of SEHN, Institute for Agriculture and Trade Policy, Consumer’s Union, Union of Concerned Scientists, Funders Working Group on Biotechnology, Benbrook Consulting Services, and the Community Nutrition Institute.
(5) Shifting the burden of proof places responsibility on developers of potentially hazardous technologies to demonstrate that this activity is necessary and that there are no safer alternatives. Proponents must also assume responsibility for testing for harm, monitoring for effects, notifying those who may be affected, and bearing financial costs of any damage incurred. While proponents must shoulder these responsibilities, they must not act in isolation or in secrecy. All analyses and data must be conducted through open, transparent processes and must be subject to review by multidisciplinary, independent third parties.

A. Goals of The Paper

This paper proposes a framework for applying the precautionary principle to agricultural biotechnology, specifically to the release of new and existing genetically engineered (GE) crops into the environment and food systems. The framework draws on several sources: research on the potential environmental and public health effects of GE crops and the policies used to evaluate these effects; existing interpretations and applications of the precautionary principle; and recent conversations among non-government organisations (NGOs) involved in sustainable agriculture, environment, trade and health issues.

The framework presented here does not outline detailed data requirements for safety assessments or pre-market testing. This is one aspect of a precautionary approach—one that is best developed on a case-by-case basis, and applied after several prior steps have been implemented. Rather, our goal is to present a broad view of the precautionary principle and to suggest a way forward in the current debate on GE crops by incorporating and applying key elements of the precautionary principle. The framework is therefore intended to be dynamic and iterative. If the past few decades have revealed anything about technology and society, it is that decisions about complex and contentious issues require ongoing and meaningful dialogue among people with a wide range of experience, knowledge and values. Case-specific details must therefore evolve through our continued discussions.

B. The Problem

This paper addresses two urgent questions: First, how can we wisely evaluate and thus avoid adverse environmental and health effects of GE crops, particularly in light of the proclaimed yet unproven benefits of these crops? Second, how can we translate the core elements of the precautionary principle into policies that address the tenuous but not necessarily incongruent
relationship between technological development and protection of public health and the environment?

(1) GE Crops: The Need for Precaution

The large-scale introduction of GE crops during the past five years represents an unprecedented change in the world’s food and agricultural systems, not only in terms of the type of technology, but also in terms of the pace and scale of its development and commercialisation.

The term “genetically engineered” most often refers to plants, animals and microorganisms that are developed using recombinant DNA (rDNA) techniques to transfer one or several genes across the reproductive and taxonomic boundaries of species, genera, or even kingdoms. It is this rDNA process, as well as the types of “products” made possible through rDNA technology, that distinguish GE crops from those created through the traditional breeding practices of hybridisation and selection. More specifically, rDNA methods allow the construction and introduction of genetic sequences that would not, under other circumstances, be found in a particular crop. To date, these genetic sequences have been extracted primarily from bacteria and viruses, but in theory, genes from any organism can be excised, modified, and introduced into a plant. New genetic inserts contain not only genes for specific traits, but may also contain marker genes (such as those for antibiotic resistance), regulatory sequences (such as promoter sequences to ‘switch on’ the new genes) and portions of the vector which is used to transport the new genes into plant cells. Both the process of the development and the final products of genetic engineering are therefore qualitatively different from traditionally bred crops and from parent varieties. For example, the activated form of the Bacillus thuringiensis toxin containing in Bt corn and potatoes could not have been introduced through conventional breeding.

The consequences of such differences have been the subject of debate since the mid 1970s.²  A growing number of scientific studies indicate that consumption and widespread, unconfined planting of GE crops could result in unforeseen and potentially serious environmental

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and health effects. Fewer studies have tested the long-held claims that GE crops will increase yields and lower chemical inputs. The results of these studies are variable but suggest that GE crops, like most plants, are significantly affected by local conditions such as weather, soil types, and levels of weed and insect infestations.

Despite accumulating evidence, however, there remains significant uncertainty regarding the long-term hazards and benefits of GE crops. Our relative lack of knowledge about the impacts of GE crops (compared to the speed of development and marketing) is due in part to the strong ties among biological, ecological, social and political systems. For example, political commitments and value assumptions affect research priorities and therefore determine the kinds of technologies that are funded, and the extent to which hazards are investigated.

To date, US and Canadian government regulations for GE crops have focused on narrowly circumscribed risk assessments, the relevance of which depends on several problematic and largely unchallenged assumptions:

- GE crops are not inherently different—or more hazardous—than non-GE crops;
- Complex interactions in open systems can be adequately predicted through controlled experiments in closed systems;
- Observations in small-scale trials can be extrapolated to large-scale releases;
- Any unforeseen hazards of GE can be controlled once they occur;

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National Center for Good and Agricultural Policy. Washington DC.

GE crops are necessary to feed a growing population and support domestic economies. Clearly, there is a need for a more comprehensive, transparent and ultimately more precautionary research and regulatory agenda for GE crops. Regulations must address the novelty, uncertainty, complexity and high stakes of releasing GE crops into the environment and food systems, and must carefully integrate case-by-case assessments with systems-level analysis.

2) The Precautionary Principle: The Need for Effective Implementation

The precautionary principle was first incorporated into environmental policy in Germany over 20 years ago. It has since been invoked internationally in many treaties, declarations and laws on health and the environment. More recently, precaution has come to the forefront of trade and biosafety negotiations for genetically engineered organisms under the World Trade Organisation and the Cartagena Biosafety Protocol. However, while few would argue that caution is entirely unnecessary, debate continues over what pre-caution should entail, particularly in terms of the required level of scientific evidence, and the relationship between risk assessment, cost-benefit analysis and the precautionary principle. Those pushing for more comprehensive safety procedures and a separation of trade and environmental interests tend to favour a strong precautionary principle in some cases taking the form of a complete ban on GE crops and food. Those vying for more relaxed safety regulations and fewer trade restrictions tend to collapse a weaker precautionary approach into existing risk analyses. In this case, precaution becomes one option for managing risks once they have been identified through standard risk assessment procedures. Such disagreements extend well beyond on GE organisms, as precaution and/or risk assessment are used in frameworks for broader regulations on health, environment and trade.

What is missing from, and urgently needed in these discussions is greater agreement on what the precautionary principle entails, and a practical framework for its implementation. While strict, universal rules for applying the precautionary principle are (arguably) neither possible nor

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desirable, clear guidelines can nonetheless be developed through specific case studies and applied, as appropriate, to other issues and contexts. The remainder of this paper reviews core elements of the precautionary principle and sets out such a framework for GE crops.

C. Core Elements of the Precautionary Principle

The precautionary principle can be stated generally as: “When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically” (Wingspread Statement, 1998). While interpretations vary, many declarations and analyses of the precautionary principle include similar core elements which may provide a useful framework for implementation. Further clarification and refinement of these elements will be necessary if application of the precautionary principle is to be consistent (if not uniform) and effective.

(1) Protection of Public Health and the Environment

The primary goal of the precautionary principle is to protect public health and the environment from anthropogenic harm. As such, the principle entails both descriptive and prescriptive elements. Precaution provides a way of understanding and describing the world as a complex, interrelated system that is inherently uncertain and vulnerable to harm. Precaution is also an expression of values which give central priority to protection of these vulnerable systems. Implementing the precautionary principle therefore requires us to first step back from the details of a particular issue (such as introduction of a specific GE crop) to ask broad questions about the kind of world in which we want to live, our long-term goals and direction, and the range of viable means to reach those goals.

A precautionary approach suggests not only the kind of action needed to protect the environment and health, but also the process through which such actions should be decided and implemented. Questions about responsibility and fair decision-making processes—about whose voices are heard and whose are excluded—are therefore inherent to a precautionary approach. These aspects of the precautionary principle are not simply ‘invoked’ under specific circumstances but suggest a standard of responsibility, fairness and transparency that should be applied when considering the impacts of any technology.
(2) Identifying Potential Harm

More specific steps in precautionary decision-making are required when a particular technology or activity is recognised as potentially—but not yet proven to be—harmful. This points to a need for some level of evidence that the technology poses a significant hazard, and that these hazards be identified and documented in some way. Subsequent steps in implementing the precautionary principle will depend in part on the type and severity of potential harm.

(3) Recognition of Scientific Uncertainty

Recognition of potential harm is one element of the precautionary principle. However, an additional, equally important element is acknowledgement of uncertainty—that we have not, and perhaps are unable to, identify all consequences of our actions. This uncertainty extends beyond technical or methodological problems of scientific investigation (such as insufficient data or inadequate models) to recognise that situations involving many complex systems cannot be predicted accurately through experimental methods alone. Although a level of harm must be recognised, the standards of evidence for demonstrating harm (and safety) under the precautionary principle are different than those under narrower risk-based policies. This raises two further questions: How can lack of knowledge be suitably addressed? What is an appropriate standard of evidence under uncertainty?

(4) Anticipatory Action Despite Scientific Uncertainty

A central tenet of the precautionary principle is proactive, anticipatory measures to protect health and the environment, despite persisting scientific uncertainty. The emphasis on anticipation requires that steps be taken not simply before harm occurs but before there is conclusive proof that harm will occur. The emphasis on action requires deliberate effort to investigate potential effects of technologies and to explore alternatives. Investigation of specific hazards and preventative measures must therefore be grounded in a research and policy agenda that encourages broad, long-term thinking, supports active investigation of potential harms and benefits, and is open to alternatives rather than committed to particular technology or policy
direction. What kind of research is needed to address complex and uncertain technologies such as genetic engineering? What kind of actions are consistent with precaution?

(5) **Shifting the Burden of Proof**

A final and important element of the precautionary principle says that the proponents (developers or exporters) of a potentially hazardous technology should bear the burden of demonstrating that the technology is reasonably safe and that there are no safer alternatives. This shifts the burden away from the public (individuals, citizens’ groups, government agencies, importing countries) who must otherwise demonstrate the harmfulness of a technology before restrictions are applied. This move also shifts prior presumptions about a technology from a risk-taking position of “safe until proven harmful” to a precautionary position of “harmful until proven safe”. Yet there remain significant questions regarding shifting the burden of proof: How can we ensure that proponents (who have a vested interest in demonstrating safety, not harm) follow research protocols that are sufficiently stringent to detect harmful effects, and do not simply assume that “lack of evidence of harm is evidence of lack of harm”? At the same time, how can we avoid imposing the impossible burden of “proving safety”? Finally, how can we ensure that proponents assume responsibility for the long-term, unprecedented and/or irreversible effects of the technologies they develop and employ?

D. **Applying the Precautionary Principle to GE Crops**

The following section outlines a general framework for applying the core elements of the precautionary principle to the release of genetically engineered crops. Key steps and considerations of the framework are summarised in Table 1.

(1) **Protection of Public Health and the Environment**

Precaution encompasses a broad vision for protecting public health and the environment. Before attempting to define, much less quantify the hazards specific to genetic engineering, the precautionary principle invites us to articulate common, general goals for agricultural and food systems, and requires us to establish decision-making processes appropriate for reaching those goals. These prior steps should include:
Setting Goals

As a decision-making framework, risk assessment tends to focus on questions of tolerance: How much harm are we willing to accept? How safe is safe enough? In contrast, the precautionary principle challenges us to set broad goals for agriculture and to evaluate role of genetic engineering in achieving those goals. This process might lead us to question the general direction that genetic engineering technology takes us; whether GE crops play a unique and necessary role in agriculture; and what trends or problems genetic engineering claims to solve, or is likely to perpetuate. These prior questions provide a necessary context for evaluating the potential hazards and benefits of GE crops.

Assessing Alternatives

Once broad goals for agriculture have been articulated, it is necessary to consider a range of means for achieving these goals. However, as discussed below, fair comparison among alternatives is contingent upon a research agenda that actively supports a broad range of agricultural practices and technologies, such as traditional breeding, organic agriculture, integrated pest management, and publicly accessible seed banks for open-pollinated, traditional and heirloom varieties. Cost-benefit analyses may be helpful choosing among alternatives if the parameters of “costs” and “benefits” are defined broadly and democratically (see “Definitions of Harm” below).

Research to Support Long-Term Goals and Precautionary Approaches

The current research agenda of both publically and privately funded institutions tends to support biotechnology as the solution to agricultural problems. The US government has spent billions of dollars on biotechnology research and development. Yet only a fraction of this amount has been allotted to the investigation of potential hazards of GE organisms, or for research on sustainable and organic agriculture. There is also evidence that long-term, multidisciplinary and participatory studies are not well supported by current academic reward systems.8

8 Task Force on Incentives and Barriers CSARE. 1998. Incentives and Barriers to Public Interest Research and Scientific Public Service. Consortium for Sustainable Agriculture Research and Education.
An appropriate research agenda under the precautionary principle would provide proportionate funding for a diversity of agricultural practices (as described above), as well as in-depth studies on potential hazards and benefits of genetic engineering. This kind of research is necessarily long-term and multidisciplinary, and emphasises the “public good” rather than private or proprietary interests. Participatory, community-based research which draws on range of experience and expertise is an effective way to understand and evaluate the impacts of complex technologies such as genetic engineering. By this approach, first-hand knowledge of those who are most affected by changes in agricultural systems (such as farmers, producers and consumers) are considered as valuable as the more focused research of specialists.

Open Decision-Making

Much of the current controversy over genetic engineering stems from a tradition of closed decision-making among government and the biotechnology industry. Risk assessment experiments are conducted primarily by product developers, and much of the data is considered confidential business information. Until very recently, neither the US nor Canadian government had made significant attempts to determine public opinion on GE foods, or to establish mechanisms for public input. Consultations held by the US Food and Drug Administration in 1999 and the Canadian Biotechnology Strategy in 1998 suggest belated recognition that biotechnology will not be successful without broad public acceptance.

The precautionary principle emphasises the need to establish open, transparent and democratic processes of decision-making before significant commitment has been made to research, development and marketing. Specifically, in all stages of a precautionary approach, it is necessary consider both substantive and procedural aspects of questions: How do we know what we claim to know? Whose perspectives, assumptions, commitments and values have been represented? Whose have been excluded? What processes are in place to ensure broad, open and

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10 On FDA public meetings see: www.fda.gov/oc/biotech/default.htm; www.biotech-info.net/FDA_hearings.html

On the Canadian Biotechnology Strategy consultations see: strategis.ic.gc.ca/SSG/bh00156e.html
fair participation in decision-making? One way to broaden decision-making is through consensus conferences. In this process, a lay panel or citizens’ jury poses questions to a panel of “experts”, and makes recommendations in a final report. Consensus conferences on agricultural biotechnology have been held in Canada, Denmark and the United Kingdom, although recommendations have not significantly influenced North American policies on GE crops.\textsuperscript{11}

\textbf{(2) Identifying Potential Harm}

Recognition of potential harm is often cited as the first step in a precautionary approach. However, as discussed above, this step must first be grounded in a broad vision for agriculture, a comprehensive research agenda, and open decision-making processes. At this second stage, we are necessarily dealing with known, precedent and/or foreseeable harms, while bearing in mind that there may be many other unforeseeable and unpredictable types of harms (see “Uncertainty” below). The following questions should be considered:

\textit{What counts as ‘harm’?}

Current regulations for GE crops focus primarily on the direct effects of adding a new genetic sequences to a single crop.\textsuperscript{12} Under the precautionary principle, definitions of harm must be expanded spatially, temporally and conceptually to include, for example indirect ecological effects on soil composition and beneficial insects; impacts on food security; the “opportunity costs” of supporting GE crops at the expense of other agricultural practices; and the political consequences of committing to, and imposing, a largely untested and non-negotiated technology. General types of harm that should be included are listed in Table 1.

\begin{table}
\centering
\caption{Types of Harm Associated with GE Crops}
\begin{tabular}{|l|}
\hline
1. \textit{Direct Effects}\\
2. \textit{Indirect Ecological Effects}\\
3. \textit{Food Security Impacts}\\
4. \textit{Opportunity Costs}\\
5. \textit{Political Consequences}\\
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\end{tabular}
\end{table}

\textsuperscript{11} Sclove and Scammell, M.L., note 10.
On Canadian consensus conference: Citizen’s Panel Report. 1999. Citizen Conference on Food Biotechnology. Calgary, AB. /~pubconf/; note that recommendations of the panel were not binding on government

What standard is used to measure or limit definitions of harm?

Canadian and US policies for GE crops use the concept of substantial equivalence to measure potential hazards relative to current practices of large-scale, industrial agriculture. The necessity, acceptability and safety of “conventional” agricultural practices are therefore unchallenged assumptions buried in GE risk assessments, and existing hazards are consequently perpetuated if not compounded by the addition of GE crops. Under the precautionary principle, assumptions about standards of evaluation must be openly debated and actively investigated. Is “no greater harm” than existing agriculture an acceptable standard? What level of harm does “no greater harm” actually entail? While we can learn from existing technologies and previous experience, we should question direct extrapolations of safety under the guise of substantial equivalence, particularly as GE crops are not promoted as substantially equivalent in other contexts (such as control of proprietary information or proclaimed benefits).

What is the distribution of potential harms?

Most of the GE crops currently on the market are engineered for agronomic traits such as herbicide tolerance or insect resistance. Their primary purpose is to increase production efficiency and convenience, but it remains unclear whether these crops will directly benefit farmers or consumers.13 Assumptions that increasing the profits and growth of private agribusiness corporations will ultimately benefit the general public are problematic both from an economic and an ethical point of view. Potential harms and benefits cannot be simply aggregated and weighed; effects on specific populations must be identified and accounted for when invoking the precautionary principle. Some GE crops that are currently in the research and development stage hold promise greater benefit for the public good (for example, crops containing vitamin supplements or vaccines).14 However, even if these prove to be viable projects, it is necessary to first ask broad questions about how and why this technology is implemented: What is the source

13 See note 4.

of problem that these crops aim to solve? Are there alternative, locally developed and locally controlled solutions? Who will be responsible for unforeseen harm?

What is degree of potential harm?

Several interpretations of the precautionary principle specify that preventative action should be taken only if the threat of harm is “serious”; for example, if it is irreversible, widespread, long-term, accumulative, persistent, toxic or imposes a critical load on the environment. These physical dimensions of harm add to the severity of potential impact and suggest more restrictive precautionary measures. In some cases these qualification may simply beg the question because we do not always know in advance if a technology will have “serious” effects. The precautionary principle alerts us to these dimensions of harm, but, as discussed elsewhere in this paper, advises us also to recognise uncertainty, carefully assess alternatives, and err on the side of caution.

In addition to physical aspects of harm, related psychological and social dimensions must also be considered. For example:

- Has the technology been adopted voluntarily through transparent processes, or has it been imposed or introduced through closed decision-making? This is a key issue in current debates over biotechnology; the controversy is as much about choice and control as it is about safety. In North America, GE foods have been introduced without public consultation, general acknowledgement or explicit acceptance. The option of saying “No” to GE foods is further denied by the lack of labelling laws in the US and Canada. It is well documented that thresholds for involuntary risk are much lower than for risks willingly accepted. Therefore, simply mitigating harm, or balancing risks against potential benefits is unlikely to resolve the debate or appease consumers if GE foods continue to be imposed rather than openly negotiated.

15 For example:
Bergen Ministerial Declaration on Sustainable Development in the ECE Region. 1990
Final Declaration of the Third International Conference on Protection of the North Sea. 1990
Ministerial Declaration of the Second World Climate Conference. 1990
Rio Declaration on Environment and Development, 1992

16 For overview of points raised in this section see: Krinsky, S., Golding, D. eds. 1992. Social Theories of Risk. Praeger. Westport, CT; especially, Renn pp. 53-79; Slovic, pp. 117-152
• What are the “ripple effects” or indirect, downstream impacts of this technology? Evaluation of GE crops is not simply a matter of tabulating discrete events such as gene flow or creation of a new weed because these effects tend to “ripple out” from their source to cause a wide variety of downstream impacts. Such ripple effects of GE crops include: economic impacts of market failure on farmers; ecological impacts of increased agrochemical use and/or shifts in types of chemicals used; and the replacement of traditional or local practices with genetically engineered varieties. These impacts are starting to be realised internationally and contribute to the overall severity of potential harm.

• What does this particular technology signal or portend about the future direction of technological development and related hazards? The possibility that currently marketed GE crops signal only the beginning of an agricultural “gene revolution” also adds to the severity and gravity of current hazards. What is the next turn of the technological treadmill? Where will we be in twenty years if the technology continues at its current rate?

These social dimensions of hazard are no less “real” than physical aspects such as toxicity. Rather, they are essential in evaluating the overall degree of potential hazard, and help us to clarify the ways in which GE technology is essentially connected to other technologies and political, cultural and economic systems. These issues are critical to a precautionary evaluation of GE crops, but have been largely overlooked in existing regulations based on risk assessment.

(3) Recognition of Scientific Uncertainty

The above steps address preliminary questions about the type and scale of harm posed by a technology or activity. However, because the precautionary principle applies to conditions of uncertainty, answers to these questions are necessarily provisional and incomplete; they alert us to the potential for known harms to occur and the possibility of greater, unprecedented harm, but cannot comprehensively identify or predict the outcomes of our actions. Under the precautionary principle, we must further probe the limits of our knowledge: What evidence do we have for potential harms and benefits? Why do we not have more evidence? What questions have not yet

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17 ESRC 1999, note 5.
been asked, and why? What questions cannot be answered? These considerations can be grouped under two broad headings: (1) types of uncertainty and (2) standards of evidence.

Types of uncertainty

In discussing “uncertainty” it is important to distinguish among several terms:

• A hazard is a specific adverse event such as gene escape to wild plants.
• Risk is the known probability of that event occurring. It is often difficult to quantify probability for complex situations. However, in some cases such as pollen dispersal, we know the event will occur; the probability is one.
• Uncertainty describes situations in which we don’t know, or cannot calculate the probability of a hazard, but we know, at least, the kinds of hazards to consider.
• Ignorance refers to situations where we don’t even know what kinds of hazards to look for. This is the chance of completely unexpected and unprecedented hazards.
• Finally, indeterminacy, or “great” uncertainty, describes the inevitable gap between limited, experimental conditions and the open-ended world in which technologies are actually used. Indeterminacy suggests that we can never fully predict the effects of technologies through isolated experiments because assumptions inherent in experimental design are unlikely to reflect real-world situations (and vice versa).

By definition, risk assessment frameworks tend to focus on risk—the probability of known events. Assessments may also address uncertainties but usually in the limited sense of current, temporary deficiencies in knowledge. Many such technical and methodological uncertainties of GE crops can be reduced through better-designed research (see “Anticipatory Action” below). For example, we may not know how Bt crops will affect soil micro-organisms simply because experiments have not been designed to detect such effects. Similarly, uncertainties due to local variability of field trials may be partially addressed by conducting trials in diverse locations under a range of conditions. However, these types of unknowns contribute only a small part of the greater uncertainty surrounding GE crops; ignorance and indeterminacy must also be acknowledged and addressed. Of course, we cannot identify all that we don’t know, but we can attempt to identify the reasons for our ignorance and the factors that contribute to indeterminacy.
One significant contributor to great uncertainty are the assumptions, commitments and values of those who are making decisions. These factors frame the types of questions asked, the appropriate methods to address those questions, and, ultimately, the conclusions drawn about potential hazards and benefits. For example, assumptions that GE plants are substantially equivalent to plants developed through breeding have shaped the scope and conclusions of existing biotechnology policies. Ignorance and indeterminacy, therefore, cannot be eliminated simply through more experimentation; it is equally important to articulate assumptions and to acknowledge that research results are necessarily limited and conditional.

While precise, universal calculations of cause-and-effect are not possible for such complex and value-laden issues, the effects of great uncertainty can be partially addressed through other means. In addition to more intensive research on specific, isolated effects, more extensive research is also required. The latter would broaden the basis upon which decisions are made by opening the decision-making process to a range of perspectives, values and knowledge, and would diversify options (hedge bets) by encouraging a variety of agricultural practices, as recommended in other sections of this paper.

Standards of Evidence

Under conditions of uncertainty we do not know, and often cannot calculate the probability that harm will occur. We know that there is potential for harm but recognise that direct cause-and-effect relationships or “proof” of harm may be impossible to establish. An important question when invoking the precautionary principle is therefore, How much evidence of harm do we need before taking action? Do we take precautionary measures if there is any possibility of harm?

Existing statements of the precautionary principle suggest that action should be taken if there is “reason to believe” that harm will occur, or if harm is “possible” or “plausible”. This suggests that a weaker standard of evidence than strict causality or proof “beyond reasonable doubt” which, in scientific terms, would require experimental data that were replicable and had low p values. That is, the precautionary principle suggests that under conditions of uncertainty,

the “weight of evidence” is a more appropriate standard. As discussed in the introduction to this paper, there is growing evidence that GE crops do pose serious environmental and health threats. This evidence is derived from several sources including confined laboratory studies, field studies, and the direct experience of farmers growing GE crops. However, the question remains: What constitutes a balance of evidence? The criteria outlined in Table 1 can function as a guideline, but no single criterion is sufficient. Specific definitions of acceptable evidence and methods to weigh available information will vary according to the case, and will depend on open processes of deliberation and information exchange.

(4) Anticipatory Action Despite Scientific Uncertainty

The form of action taken under the precautionary principle may range from a complete ban on GE crops to conditional approval depending on the type of harms raised, the potential for these harms (i.e. the stakes) and the degree of uncertainty and complexity involved. Regardless of the form of precautionary action taken, all research and decision-making should include prior questions about goals, needs and alternatives (discussed above) as well as on-going processes of monitoring, information feedback, liability and responsibility (as outlined below). A range of precautionary actions are outlined below and summarised in Table 1.

Research on potential hazards and benefits

If the above steps indicate convincingly that there are no more acceptable, less-harmful alternatives to GE crops, and that GE crops contribute positively to long-term agricultural goals, then in-depth testing of potential hazards, benefits and uncertainties is warranted. This might be considered “pre-market testing” although approval is by no means inevitable at this stage. In contrast to current policies, the precautionary principle moves this kind of testing to a later stage in the decision-making process. We might speculate as to whether any commercialised GE crops would have reached this stage under a more precautionary approach.

Specific research questions and testing methods will depend on the characteristics of the crop under investigation. Several recent studies have outlined guidelines for evaluating GE crops which could be adapted to particular cases. More general guidelines are outlined in Table 1.

**Conditional approvals with monitoring**

Larger-scale testing may be warranted if field trials reveal no evidence of hazard. Of course, lack evidence does not provide proof of safety, and low frequency events are not necessarily low probability events. Small-scale, short-term and confined trials, no matter how well designed, cannot accurately predict scale-dependent, delayed and long-term effects, or interactions among complex systems. Some impacts of GE crops will simply not occur or will not be detected at small scales. Therefore, initial approvals for larger-scale tests should be conditional. For example, approvals could be granted for a finite time period and for specific locations, with mandatory on-going monitoring. Extended approvals would be subject to further review of new and existing information.

While conditional, large-scale testing seems a logical progression from small-scale to commercial releases, several questions must be addressed before proceeding in this direction. First, who is responsible for monitoring? Should proponents, government, third parties and/or neighbouring farmers assume this responsibility? Second, what, specifically, would monitoring entail (e.g. in terms of frequency, geographic scope, types of effects)? Third, monitoring assumes that most adverse effects can be identified and then reversed or controlled. How will irreversible or uncontrollable impacts be addressed?

**Moratoria**

If small-scale or large-scale testing reveals further evidence of hazard or fails to address uncertainty, a moratorium on specific activities (e.g. unconfined release or commercialisation) may be justified while in-depth studies, consultation and deliberation continue.

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Phase-Outs and Bans

The most stringent precautionary action would be a permanent ban on development and release of new GE crops, and a phase-out of crops already in the food system. This action may be warranted if potential harms and uncertainties remain unacceptable and or irresolvable through other means. Close attention to alternatives would be required, in this case, to ensure that banning GE crops does not simply perpetuate reliance on other harmful practices (such as intensive, chemical-based agriculture).

(5) Shifting the Burden of Proof or Burden of Responsibility

It might be argued that under current biotechnology policies, developers of GE crops already assume the burden the proof because they must conduct experiments to convince government regulators that their GE crops are safe. These arguments point to an urgent need to clarify what is meant by burden of proof (a term borrowed from a legal context), and/or to re-frame this element of the precautionary principle as a broader “burden of responsibility” which may be more applicable in an administrative context. Components of this responsibility may include:

Responsibility for Testing

Perhaps the most common definition of “shifting the burden of proof” is a requirement that proponents demonstrate the safety of their products. While in principle this requirement imposes a justifiable demand on those who stand to benefit most from a potentially hazardous activity, in practice it is impossible to conclusively prove lack of harm. On the other hand, it is quite easy to demonstrate that GE crops have no adverse effects under limited experimental conditions—especially if experiments are not sufficiently stringent to detect an effect. These points threaten to undermine the goals of the precautionary principle by portraying precaution as an unreasonable standard, or by granting proponents the benefit of the doubt rather than a burden of proof.

The first point may be addressed through comparative rather than absolute testing in which proponents would be required to demonstrate that there are no less damaging alternatives.
The second point emphasises that all tests performed by proponents should conform to precautionary research methods outlined above (including recognition of uncertainty, consideration of alternatives, testing for benefits and adopting broad definitions of harm) as well as the further conditions outlined below.

**Open consultation and third party review**

Democratic decision-making is essential under the precautionary principle, particularly in light of the complexity of issues, potential conflicts of interest, closed industry-government relations, and reliance to date on “lack of evidence” arguments. In addition to the participatory research methods discussed above, shifting the burden of proof should also include an independent review of testing procedures, data and conclusions and public disclosure of information relevant to evaluating safety prior to approvals for release. Such an expanded peer review process for GE testing could take several forms. For example, proponents could conduct tests (as in current regulations) and submit all data to broad, third party review, or proponents could supply funds for tests conducted by third parties.

**Notification and informed consent**

Notification and informed consent have become central issues in the GE debate, particularly in the context of trade. However, these measures should not be considered substitutes for other types of precautionary action, but rather as minimum requirements. Given that potential harm and uncertainty have been recognised, the public has a positive right to know which foods contain GE organisms, and proponents have a corresponding positive duty to inform. Notification and informed consent should include provisions for labelling, tracing and segregating human and animal food that may contain or may be derived from GE organisms; fair advertising practices; and advanced informed agreement between importing and exporting countries prior to transfer of all GE crops and food.

**Protective measures**
Proponents should also bear responsibility for adopting measures to protect against adverse impacts. Such measures could include controlling gene flow (e.g. through molecular systems that limit expression of transgenes to specific tissues or stages of development), delaying resistance in insect populations (e.g. by planting refugia of non-GE crops) or restricting use of antibiotic resistance markers. However, it should be noted that these are generally preventative rather than precautionary measures: they address known hazards but are less applicable to unprecedented impacts. Although such measures are unlikely to be completely effective, proponents nonetheless have a duty to take all known cautionary steps.

**Liability and financial responsibility**

Assurance or performance bonds are a further mechanism for shifting the burden of responsibility that may be useful for GE crops. Under this system, proponents would be required to post a bond equal to the financial costs incurred if the worst-case situation were to materialise. If lesser harm, or no harm occurred within a specified period of time, the balance of the bond would be returned to the proponent. Environmental bonding could be used in conjunction with other precautionary measures, such as conditional approval and broad-scale testing and monitoring.

There are a number of problems with this approach that are yet to be resolved. First, bonds are well suited to known, expected hazards and to accidents with a quantifiable probability of occurrence (i.e. precedent harms), but are less useful under conditions of great uncertainty or where there is potential for catastrophe. Second, a system based on financial bonds and compensation assumes that harms will be in fact be detected within a specified period and that observed harm can be attributed to a particular party. Finally, perhaps the most problematic assumption of this system is that monetary values can be attached to all harms and that damage is compensable, remediable and/or reversible.

Despite these problems, a bonding system is nevertheless consistent with the precautionary principle in several ways: It provides incentive for proponents to adopt the least harmful activity and to use stringent testing and monitoring procedures; it moves future costs, which are often

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discounted, into the present and ensures sufficient funds are available if harm should occur; it shifts prior presumptions from innocent-until-proven-guilty to guilty-until-proven-innocent; and it shifts the burden of proof to proponents who must show that harm has not occurred.

E. Conclusions and Further Study

The precautionary principle has become an urgent international issue, particularly in the wake of the failed WTO meetings in November 1999, and the successful Biosafety Protocol meetings in January 2000. There is now a need to develop a framework for applying the precautionary approaches to specific technologies. This paper outlines such a framework for genetically engineered crops.

As noted throughout however, several issues regarding genetic engineering and the precautionary principle require further research and discussion. Among the most pertinent of these issues are:

- **Research:** How can we establish and support a research agenda that supports and encourages the type of long-term, multidisciplinary studies required to address the potential effects of GE crops, as well as a diversity of agricultural practices and technologies?

- **Evidence:** What, specifically, should be included in a weight-of-evidence standard for GE crops? What types of questions and definitions of harm are relevant for particular crops? How can this evidence be gathered and documented without imposing harm? How can social and economic effects be included in evaluations?

- **Decision-making:** What changes are needed to make decision-making more democratic, representative, and open? What is needed to implement these processes?

- **Burden of proof:** How can we ensure that proponents bear due responsibility for potentially hazardous technologies (including financial responsibility and adequate testing procedures)?

Clarifying these points through continued collaborative effort, and applying the above framework to specific cases studies of GE crops, will help to promote technologies and decision-making processes that are respectful of individual, social and environmental values.
Table 1. Summary of Framework for Applying the Precautionary Principles to GE Crops.

<table>
<thead>
<tr>
<th>Core Element of the Precautionary Principle</th>
<th>Step in Precautionary Framework</th>
<th>Specific Considerations</th>
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</table>
| Protection of Public Health and the Environment | Setting Goals | • Articulate broad long-term goals for agriculture  
• Determine how agricultural biotechnology may further or hinder these goals  
• Articulate the problems that GE crops aim to solve  
• Identify the sources of these problems  
• Assess claims that GE technology is necessary to achieve goals and address problems |
| Assessing Alternatives | • Research and assess a range of alternatives to genetic engineering  
• Include people with a diversity of interests and values in the assessment; ensure assessments open to public scrutiny and revision  
• Evaluate social and political factors that encourage or discourage alternatives |
| Research to Support Long-Term Goals | • Ensure adequate funding and support for a broad range of agricultural technologies and practices  
• Ensure long-term, multi-disciplinary, and participatory studies on potential effects are well supported, funded and distributed |
| Open Decision-making | • Establish open decision-making processes  
• Ensure these processes are timely, effective and binding  
• Ensure decisions are reversible and processes iterative  
• Ensure information is made freely available (i.e. not proprietary or confidential business information) |
| Identifying Potential Harm | Defining Harm | • Consider:  
• Biological, ecological, social, economic and political effects  
• Direct, indirect, cumulative and synergistic effects  
• Immediate, delayed, persistent and long-term effects  
• Effects of cultural or geographic context  
• Whether commitment to agricultural biotechnology forecloses other options |
| | Defining Standards | • Identify standards against which agricultural biotechnology is assessed (e.g. industrial-scale, chemical-based agriculture)  
• Consider potential effects of these standards  
• Assess whether GE crops perpetuate potentially harmful trends in agriculture |
| Distribution of Harm | • Evaluate distribution of hazards and benefits  
• Determine if agricultural biotechnology tends to concentrate or distribute authority (empowers or disempowers those who may be affected) |
|----------------------|--------------------------------------------------------------------------------------------------|
| Degree of Harm       | • Evaluate evidence that harm is potentially irreversible, widespread, long-term, accumulative, persistent or toxic  
• Consider whether potential harms been accepted voluntarily or imposed  
• Evaluate links among physical, political, social, and psychological dimensions of harm |
| Recognition of Scientific Uncertainty | • Distinguish among situations of certainty, risk, uncertainty, ignorance and indeterminacy  
• Identify technical and methodological uncertainties  
• Articulate assumptions and limitations that contribute to “great uncertainty”  
• Evaluate ways in which these uncertainties bear on (qualify) research results; ensure this influence acknowledged  
• Assess means of reducing uncertainties  
• Consider who may benefit and who may be harmed from these uncertainties (e.g. if technology proceeds or is halted due to uncertainty) |
| Types of Uncertainty | Consider:  
• Accuracy. Experiments can be repeated with similar results under similar conditions  
• Validity. Evidence is relevant to ‘real world’ conditions (i.e. have uncertainties and local contingencies been acknowledged)  
• Sources. Identify sources of evidence (e.g. Have a number of people advanced or supported this claim; Are opinions divided along professional, disciplinary or political lines?)  
• Plausibility. Evidence seems reasonable or believable  
• Coherence. Relation of evidence to existing theories, data or case studies. Can the evidence be supported through diverse means, e.g.  
~ quantitative and qualitative data  
~ correlation, pattern, association  
~ experimental data  
~ experiential information (e.g. What can be learned from past experience with similar technologies? What are the experiences of those who use the technology?)  
~ local, context-specific information (e.g. case-studies)  
~ general principles |
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<tr>
<th>Anticipatory Action</th>
<th>Research on Potential Hazards and Benefits</th>
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<tr>
<td></td>
<td>• Consider broad definitions of harm and temporal/spatial scales (see “Identifying Potential Harm” above)</td>
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<td>• Ensure conclusions are sensitive to false negatives as well as false positives, and error biases are made explicit</td>
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<td>• Calculate statistical power of the data (if conclusions are based on statistical analyses)</td>
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<td>• Determine if experiments and conclusions are context specific or conditional (e.g. Are results extrapolated to more general circumstances? How are effects of conditionality assessed and acknowledged?)</td>
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<td>• Assess potential benefits through similarly comprehensive and rigorous methods</td>
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<td>Conditional Approvals &amp; Monitoring</td>
<td>• Establish appropriate and effective responsibility for monitoring</td>
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<td></td>
<td>• Specify which parameters will be monitored, and through what processes</td>
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<td></td>
<td>• Specify measures to be taken if adverse effects are detected</td>
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<td>• Specify measures to be taken if irreversible effects are detected</td>
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<td>Moratoria</td>
<td>• Continue appropriate and adequate research on the hazards of GE crops and alternative technologies</td>
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<tr>
<td>Phase-Outs &amp; Bans</td>
<td>• Ensure alternatives have been adequately investigated</td>
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<td>Shifting the Burden of Proof</td>
<td>Testing</td>
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<td></td>
<td>• Ensure proponents assume due responsibility for testing environmental and health effects of GE crops</td>
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<td></td>
<td>• Ensure appropriate research methods (outlined above) been adopted</td>
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<tr>
<td>Consultation &amp; Review</td>
<td>• Establish independent review process for data, methods and conclusions of tests conducted by proponents</td>
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<td>• Ensure public disclosure of data prior to decision-making</td>
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<tr>
<td>Notification &amp; Informed Consent</td>
<td>• Establish processes for appropriate labelling, tracing, and segregation of GE</td>
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<td>• Ensure fair advertising practices</td>
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<td>• Establish processes for advanced informed agreement among exporters and importers</td>
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<td>Protective Measures</td>
<td>• Ensure proponents adopt all known protective measures</td>
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<tr>
<td>Liability &amp; Financial Responsibility</td>
<td>• Establish procedures for environmental bonds</td>
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<td>• Ensure proponents are held liable for adverse effects</td>
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