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ARTICLE

Environmental Risk and the Precautionary Principle: "Late Lessons from Early Warnings" Applied to Genetically Modified Plants

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ABSTRACT The environmental risk associated with genetically modified organisms (GMO) implies that new approaches to risk assessment, risk management and risk communication are needed. In this paper we discuss the role of the precautionary principle in policy responses to GMO risk. We first discuss application of the criteria in the European Environment Agency report "Late lessons from early warnings: The precautionary principle 1896–2000" to environmental GMO risk, with focus on crop plants. Moreover, we discuss Bayesian analysis in the context of improving the informational basis for decision-making under uncertainty. Finally, environmental uncertainties are intertwined with economic uncertainties. Providing incentives for improved risk assessment, risk management and risk communication is crucial for enhancing environmental and social responsibility and thereby facilitate implementation of precautionary approaches. We discuss environmental and social screening of companies as an example of how such incentives can be provided.

KEY WORDS: Environmental risk, precautionary principle, Bayesian analysis, genetically modified organisms

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Introduction

Some scientists express concerns about potential irreversible impacts of releasing genetically modified organisms (GMO) into the natural environment, while others emphasize their potential benefits in increasing agricultural output and enhancing certain aspects of food quality, as well as potential environmental benefits such as reduced pesticide and herbicide use, soil conservation and phytoremediation of polluted soil and surface water (Wolfenbarger and Phifer, 2000). Despite the large research efforts in GMO risk assessments, see, e.g., EU (2001), unresolved issues remain in the assessments of long-term environmental risk. The purpose of this article is to discuss the role of the precautionary principle in policy responses to GMO risk.

Since the precautionary principle was introduced in environmental risk management at the 1992 Rio conference on environment and development, the issue of when and how to use the precautionary principle has given rise to much debate. The European Commission has established some guidelines in its Communication on the precautionary principle, suggesting that "The precautionary approach should be considered within a structured approach to the analysis of risk which comprises three elements: risk assessment, risk management, risk communication. The precautionary principle is particularly relevant to the management of risk" (European Commission, 2000: 2). However, as we argue in this article, the intertwining of environmental and economic risks in relation to GMO crops suggests that a precautionary approach should involve all three elements.

Moreover, risk perception varies between stakeholder groups, and risk may be seen as having an element of social construction (Slovic, 2001). Risk communication between stakeholder groups may influence perceived risks and improve risk assessments, as well as providing incentives for improved risk management. As a background for our discussion of the precautionary principle, we first discuss some recent controversies in GMO risk analysis, considering that the environmental and health related uncertainties are intertwined with economic and social uncertainties (Batie and Ervin, 2001). We then discuss regulatory efforts of the EU and OECD in light of the precautionary principle and discuss some of the literature on the precautionary principle. A recent overview of the application of the precautionary principle in relation to GMOs is given by Myhr (2002) and Myhr and Traavik (2002). We argue that decision-making under uncertainty needs to incorporate a precautionary perspective based on environmental responsibility.

We discuss three different approaches to implementation of the precautionary principle, each of them comprising risk assessment, risk management and risk communication. Rather than contributing to a precise definition of a precautionary principle, we consider it more fruitful to provide interpretations of what we see as a precautionary perspective in various contexts. Our first approach is to discuss to what extent the potential risks associated with GMO, in particular crop plants, represent a relevant example in the context of the European Environment Agency report "Late lessons from early warnings: The precautionary principle 1896–2000" (EEA, 2001). The report describes the environmental and health costs of not responding to credible scientific "early warnings" and summarizes some of the "late lessons" that may be drawn from these experiences, with the aim to "prevent, or at least minimise, future impacts of other agents that may turn out to be harmful, and to do so without stifling innovation or compromising science" (EEA, 2001: 11). The EEA report does not include any examples of false alarms, where actions taken on the basis of a precautionary approach later may have turned out to be unnecessary. Despite invitations to industry to submit such cases, "no suitable examples emerged" (EEA, 2001: 12).

Second, in order to provide a more formal interpretation of the precautionary principle, we discuss Bayesian analysis in the context of improving the information basis for decision-making under large uncertainty about potentially irreversible effects on the ecosystem. The precautionary approach taken by decision makers is reflected in their evaluation of risk.

Finally, we discuss implementation of precautionary strategies via economic incentives. We focus on the possibility of providing economic incentives for biotechnology companies to improve their risk assessment, risk management and risk communication. We suggest that so-called ethical investment funds, where companies are included according to environmental and social performance, may provide incentives for companies to enhance their environmental and social responsibility, and thereby facilitate implementation of precautionary strategies. In this context, the term "ethical" refers to the inclusion of environmental and social responsibility into corporate values. A further discussion of ethical concerns, in particular the fundamental ethical principle of the dignity of man, see, e.g., Beyleveld and Brownsword (2000), is beyond the scope of this paper.

Uncertainty Issues: Environmental and Economic Risk

It is argued frequently that genetic modification techniques provide a faster and more effective method for a process that has been carried out for ages, namely, the development of desirable characteristics in crops and animals through selective breeding. However, this argument overlooks the qualitative difference between the two types of processes. Selective breeding permits the concentration of certain characteristics already inherent within a particular species, or enhanced by hybridization between closely related species. The unpredictability created by introduction of genetic material from entirely unrelated species is a qualitatively different issue that raises a number of environmental and health related safety concerns. The environmental risks related to GMO crops include herbicide resistance and the development of superweeds, nontarget adverse effects on beneficial organisms such as pollinators, and loss of biological and genetic diversity.

Herbicide-tolerant weeds, called superweeds, may evolve through gene flow from transgenic plants to wild plants. Recent studies show that herbicide-resistance has been transferred from GMO crops to weeds (Ellstrand *et al*., 1999). For example, glyphosate tolerance is now known in rigid ryegrass, a pernicious weed. If glyphosate resistance spreads, there is concern that more toxic herbicides may be required. The empirical question is to what extent it is likely that the GMO crop or its hybrids with wild relatives will persist outside cultivation. Wolfenbarger and Phifer (2000) review a number of studies on rapeseed that indicate that self-sustaining populations of transgenes outside cultivation seem unlikely, whereas establishment through hybridization with wild relatives seems more likely.

Moreover, genetic modifications may enhance the ability of an organism to become an invasive species. Invasive species have been categorized as one of the three most pressing environmental problems, in addition to global climate change and habitat loss (Wolfenbarger and Phifer, 2000). The vulnerability of ecosystems to invasive species is exacerbated by human activity, such as clear cutting of forests and other changes in land-use. In practice, few introduced organisms become invasive, yet an issue for risk management is how to identify those modifications that may lead to or augment invasive characteristics (Warwick and Small, 1999).

Another source of uncertainty is the direct non-target effects on beneficial and native organisms. Plants engineered to produce proteins with pesticidal properties, such as *Bacillus thuringiensis* (Bt) toxin, have direct and indirect effects on populations of non-target species, such as pollinators. The laboratory study suggesting that adverse effects may occur when monarch butterfly larvae ingest Bt corn pollen (Losey *et al*., 1999) was criticized for its lack of relevance to field conditions, and a recent two-year field study suggests that the impact of Bt corn pollen on monarch butterfly populations is negligible (Sears *et al*., 2001). Ladybird larvae, which contribute to controlling harmful insects, have been affected adversely by genetically modified corn. Bt corn can release toxin through its roots into the soil and affect the soil microfauna important for the decomposition of organic material in the soil (Saxena *et al*., 1999).

The perceived risk of GMO is amplified by the interactions of environmental and health risks with social and economic risks. Public concern about GMO food has not been based solely on concern about environmental and health related risks, see Burton *et al*. (2001) and Noussair *et al*., (2002). Economic risks have been cited widely too, as dicussed by Harhoff *et al*. (2001). Such economic risks include the fear that the world's food supply increasingly will be controlled by a few large firms, the concern about these firms engaging in anti-competitive practices such as the integration of seed and agri-chemical manufacturers, as well as the issue of ownership rights over genetic resources being transferred to the private sector. The introduction of terminator genes gives rise to particular consideration. This type of genetically modified crops does not yield fertile seeds. Farmers can no longer depend on own production of seeds, but have to buy seeds and, moreover, may be threatened by litigation even if their native crops unintentionally are polluted by windspread GMO (Warwick and Meziani, 2002).

Adoption of GMO crops may reduce the genetic diversity in important food crops. When it comes to corn, the species *Zea mays* is no longer found in the wild, but close relatives, known as teosinte (*Z. diploperennis, Z. perennis, Z. luxurians, and Z. nicaraguensis*) represent valuable gene reservoirs together with several local cultivated land races of *Zea mays*. These unique resources might be contaminated by GMO maize by pollen flow. If GMO seeds are released, they might compete out the local land races with their unique genetic variation. In November 2001 *Nature* published an article by Eric Quist and Ignacio Chapela, showing that transgenes are found in five out of seven native varieties of maize in Mexico (Quist and Chapela, 2001). After a number of critical reviews of the Quist and Chapela results, *Nature* claimed in an editorial note of 11 April 2002 that "the evidence is not sufficient to justify the publication of the original paper". Withdrawing a published article is a surprising response to a situation of controversy, which normally will find its resolution through subsequent publication of new results and open debate.

Elements of the Precautionary Principle

In 1986, OECD published its first safety considerations for GMOs (OECD, 1986). The subsequent OECD work on safety in biotechnology has been based on the concepts of substantial equivalence and the familiarity principle (OECD, 1993a, 1993b). Substantial equivalence and the familiarity principle emphasize the similarity between conventionally bred crop plants and their GMO counterparts. The controversies over GMO risk assessment, risk management and risk communication suggest that relying on substantial equivalence and the familiarity principle may not capture all the relevant risk elements and that precautionary strategies may be appropriate, see Myhr (2002).

The EU guidelines require that measures based on the precautionary principle should be proportional to the expected environmental harm that one wishes to avoid, moreover, they should be non-discriminatory in their application, consistent with similar measures already taken, based on an examination of the potential benefits and costs of action or lack of action, subject to review, in the light of new scientific data, and capable of assigning responsibility for producing the scientific evidence necessary for a more comprehensive risk assessment (European Commission, 2000: 3). The precautionary principle has recently been taken into account in EU legislation on GMO (European Council 2001). For example, the directive emphasizes that monitoring of potential cumulative long-term effects should be carried out, and that the introduction of GMOs into the environment should be carried out according to the "step by step" principle.

The controversy over how to interpret the precautionary principle and apply it as a tool for decision-making has inspired a large literature. A key element in recent applications of the precautionary principle is the recognition that not all future outcomes are well defined at the time of risk assessment. What is referred to as uncertainty can hide the distinction between uncertainty, risk and ignorance, where the concept of ignorance applies in situations where the definition of a complete set of outcomes is problematic, see Funtowicz and Ravetz (1990), Wynne (1992) and Stirling (1999). The usefulness of the concept of ignorance lies in its reminder that unexpected events are easily overlooked in risk assessment. Hazards not identified will not be analysed, unless the risk assessment process explicitly searches for "early warnings" of unexpected effects.

Natvig and Gåsemyr (1996) and Natvig (1987) show that a standard risk aversion argument leads to preferring a decision based on larger probabilities for less severe consequences compared to one with smaller probabilities for more severe consequences. This risk aversion argument is strengthened if the uncertainties in probabilities and consequences are larger in the latter decision, and even more if ethical concerns about the consequences are more apparent. In this case, risk aversion can be interpreted as an application of the precautionary principle.

Gollier *et al.* (2000) argue that the intuition behind the precautionary principle leads, in light of substantial uncertainty, to other preventive strategies than what is usually called for by the notion of risk aversion in standard decision-making under uncertainty. Gollier and Treich (2003) provide a further economic interpretation of the precautionary principle in terms of option values. Sandsmark and Vennemo (2003) relate the precautionary principle to the pricing of risk in financial models and suggest that investments contribute to a precautionary approach if their risk profile is uncorrelated or negatively correlated with average risk in society.

Klinke and Renn (1999, 2002) analyse precautionary strategies where ignorance about future potential outcomes is explicitly taken into account. They provide a classification of the domain of ignorance that should be addressed in risk assessments by considering the potential extent of damage vs. the potential probabilities of occurrence for different types of environmental risk. In their view, the challenge of designing a precautionary approach involves improving and refining the knowledge of potential hazards and their probabilities, initiating timely action when there are reasonable grounds for concern, and improving communication between stakeholder groups.

Communication on risk perception is an important part of implementing a precautionary approach (Shrader-Frechette, 1991). In the terminology of Klinke and Renn (1999, 2002), a precautionary strategy must induce decision makers to avoid opening Pandora's box of long-term environmental and health hazards. An important element in this strategy is expanding the scope of risk assessments and systematically taking "early warnings" into account.

Late Lessons from Early Warnings

In this section we discuss the relevance of the twelve late lessons of the EEA report in the context of GMO risk. We focus on environmental risk and also discuss possible interactions between environmental, health related, social and economic consequences of GMO adoption.

1. Acknowledge and respond to ignorance, as well as uncertainty and risk, in technology appraisal and public policy-making

Many of the case studies in "Late lessons" illustrate that the scope of the risk assessments was not broad enough, and unexpected outcomes were not considered. The question in our context is how unexpected outcomes can be taken into account in risk assessments of GMO crops. Ecosystems are complex, and not every risk associated with the release of new organisms can be identified, much less taken into account. Some risks derive from rare events, and it may take many years for problems to emerge. At larger spatial scales, there is a greater possibility for contact with sensitive species or habitats or for landscape-level changes. Although the likelihood that GMO crops, like other cultivated species, will establish in wild conditions seems small, it is important to give particular attention to those traits of the modified plants that enhance their competitiveness in natural surroundings.

The novelty of the GMOs and lack of experience with their adoption emphasize the potential risk and point to the importance of systematically looking for "early warnings". One aspect of the novelty of the genetic modification technology is the possibility to introduce genetic material from entirely unrelated species, e.g., genes from Arctic flounder in order to improve cold tolerance in potatoes. Crossing the species border, in contrast to traditional selective breeding, that is limited by the available genetic variability within the organisms and its close relatives, implies an unpredictability that raises a number of environmental and health related safety concerns. Some of the main concerns related to human health risks include toxic or allergic reactions of genetic modification, direct uptake of genetic material, and increased antibiotics resistance (Donaldson and May, 1999). Although direct uptake of genetic material into human cells seems extremely unlikely, Traavik (1999) argues that the lack of reliable data on the direct uptake of genetic material into human cells precludes any assessments of risk levels, and that the precautionary principle should be applied.

2. Provide adequate long-term environmental and health monitoring and research into early warnings

Many of the case studies in "Late lessons" indicate the value of systematic, long-term monitoring and well-planned research, essential to the identification of potential hazards. Monitoring of GMO crops is discussed by Marvier *et al.* (1999). Marvier (2001) suggests that 30 or more years of sampling might be required in order to assess probability distributions of environmental effects. Monitoring of potential cumulative long-term effects is included in the new EU legislation (European Council, 2001). In light of the long time horizon before reliable data can be obtained, it is important to establish criteria for detecting "early warnings".

3. Identify and work to reduce "blind spots" and gaps in scientific knowledge

A "blind spot" in scientific knowledge may occur as a result of failing to acknowledge and respond to ignorance, in the sense of not addressing potential hazards that are considered outside the normal domain for risk assessment. The study by Quist and Chapela (2001) on genetic contamination of corn landraces in Mexico, discussed above, provides an example of "blind spots". Another example is the controversial study by Ewen and Pusztai (1999), indicating that rats fed on genetically modified potatoes suffered from stunted growth, intestinal damage, and immune system problems. The Pusztai experiments lead to substantial controversies in the scientific community, and Pusztai was suspended from the Rowett Research Institute and subjected to investigation, see Hadfield (2000) for a further discussion. It is a challenge for the scientific community, industry and government to cooperate in order to initiate new research to test controversial results, provide information, improve communication between academic and industry research, and ensure independent research funding. A strategy of risk communication and cooperation could enhance the capacity of overcoming "blind spots" and detecting "early warnings".

4. Identify and reduce interdisciplinary obstacles to learning

Improving risk assessment, risk management and risk communication in relation to GMOs requires a broad interdisciplinary approach involving microbiologists, botanists, entomologists, ecologists, the medical profession, statistical experts as well as social scientists. Conflicting expert opinions and differences in risk perception may preclude formal risk assessment. Given the complexity of the uncertainties, it is important to refine the statistical methods for improving the informational basis for decision-making under uncertainty and conflicting opinions. Recently, more attention has been given to the Bayesian approach of updating probabilities based on new information. As we will discuss in the following, Bayesian analysis offers a framework for consistent evaluation of conflicting expert opinions and contributes to a formal interpretation of the precautionary principle.

5. Ensure that real world conditions are accounted for adequately in regulatory appraisal

The complexity of ecological systems presents considerable challenges for experiments to assess the risks and benefits of GMO. The lack of relevant and reliable empirical data on long-term and large-scale adoption of GMO crops makes it difficult to apply traditional risk management methods based on probability distributions. Laboratory-based research on field adoptions of GMO crops is not representative of conditions on real farms. In experimental studies, the dynamics of gene flows from GMO crops to weeds will best be described by the use of commercial-sized plots (Klinger and Ellstrand, 1999). Establishing systematic monitoring as well as criteria for detecting "early warnings" is required. Before the EU moratorium was lifted, the UK government initiated field scale trials of rapeseed, in order to evaluate farmland biodiversity by adopting herbicide-resistant crops. Unexpected findings include cross-pollination between GM and wild rapeseed (Firbank *et al.*, 2003, Wilkinson *et al.*, 2003).

6. Systematically scrutinize the claimed justifications and benefits alongside the potential risks

If a technology is introduced to replace a previous technology causing environmental problems, new problems associated with the new technology may readily be overlooked. In the context of GMO risk, this dilemma is illustrated by the trade-off between adoption of GM crops and use of herbicides and pesticides (Wesseler, 2001). In a cost-benefit analysis of the adoption of GMO crops in Europe, Wesseler (2001) has analysed the benefits of GMO adoption in terms of reduced pesticide use, with its positive impact on human health, ground water quality and bio-diversity.

In risk assessments for GMOs, the choice of null-hypothesis has important policy implications. With a null-hypothesis that GMO food is safe, the burden of proof lies on the government, public interest groups or consumers. A null-hypothesis that GMO food is unsafe places the burden of proof on the biotechnology industry. It is important to avoid a situation of "no evidence of harm" being misinterpreted as "evidence of no harm". The assumption that GMO crops are "safe until proven otherwise" is discussed by Marvier (2001) in a review of a number of applications for approval of GMO crops by the US Department of Agriculture. For a toxicity study of Bt cotton she found that it relied on a small sample, only n=4, and did not give a statistically significant conclusion, whereas an increase to only eight replicates would give a statistically significant result that this Bt cotton did harm the tested species. In another study, of Bt potatoes, she found that the investigators repeated experiments only when a statistically significant non-target effect of Bt toxin was detected. If the assumption "safe until proven otherwise" is to be maintained, the rigor of testing must be improved considerably.

7. *Evaluate a range of alternative options for meeting needs alongside the option under appraisal, and promote more robust, diverse and adaptable technologies so as to minimize the costs of surprises and maximize the benefits of innovation*

Adoption of genetically modified crops in agriculture worldwide is often seen as a means for securing food supplies in poor countries and alleviating hunger. But there is no guarantee that increased food production will reach the starving people. A more precautionary approach to increasing world food supply would be to not only promote adoption of GMO crops, but also to promote environmental improvement in traditional agriculture, innovations in organic farming, and preservation of genetic diversity in agriculture.

Moreover, a precautionary approach to GM technologies should also address how incentives can be created to enhance more rapid adoption of less intrusive genetic modification tehcniques, for example intra-genetic techniques like chimeroplasty (Beetham *et al.*, 1999). Although chimeroplasty also may induce novel mutations, this technique eliminates some of the most prominent unpredictabilities of transgenics, since foreign DNA is not integrated and no new promoter is added.

8. *Ensure use of "lay" and local knowledge as well as relevant specialist expertise in the risk appraisal*

Lay knowledge is complementary to expert knowledge, with its firm grounding in real world conditions and independence from any particular professional perspective. The use of lay and local knowledge is important for improvements in traditional and organic agriculture. Traditional agriculture in poor countries often suffers from lack of property rights and financial resources, and limited access to markets. Improving these conditions could enhance productivity in traditional agriculture and provide alternatives to industrial agriculture. Sustainable development of agriculture involves preservation of local knowledge and culture along with environmental improvements.

9. *Take full account of the assumptions and values of different social groups*

In the context of GMO risk, different stakeholder groups have widely diverging risk perception. Attention should be given to differences in risk perception between experts and the public (Slovic, 2001). Some consumers are mostly concerned with potential health effects of GMO food, while others are attentive to the relationship between the quality of food and how it is produced and thus focus on the relationship between health and environmental effects. The failure of market prices to reflect potential health and environmental risk can give GMO crops an unjustifiable advantage in the market place. It is difficult for consumers to obtain non-GMO corn, as separate storage for GMO corn is usually not provided due to higher costs.

Public concern about GMO risk is also related to the market concentration. Genetic modifications of crops have primarily been motivated from the production side, in order to increase agricultural output, rather than from a consumer demand and health perspective. Batie and Ervin (2001) refer to this as "technology-push" rather than "demand-pull". Manufacturing of GM seeds takes place in an industrial structure characterized by strong integration of seed and herbicide production. Adoption of herbicide-tolerant GM crops and new market opportunities for herbicide may create incentives to promote GM crops too early, relative to socially optimal levels of risk assessment. If early adoption of a new technology is highly profitable, and there is scientific controversy about long-term environmental and health effects, it is likely that public concern is relatively high. In this situation, industry has a role to play in the implementation of the precautionary principle, by improving risk communication with various stakeholders, providing improved risk assessments, and acknowledging risk management as their contribution to social and environmental responsibility. From the viewpoint of the biotechnological industry, national and international regulations and stakeholder reactions, such as consumer response to information about the effect of GMO food, is a source of uncertainty.

10. Maintain the regulatory independence of interested parties while retaining an inclusive approach to information and opinion gathering

The recent focus on corporate social responsibility has improved the conditions for dialogue between companies and stakeholders considerably. This creates a potential for improved risk communication.

Appropriate risk assessment for GMOs is crucially dependent on information produced and owned by the companies whose products are being assessed. A problem for independent risk assessment is to obtain access to this information (Myhr and Traavik, 2002). Improved risk communication could contribute to develop strategies for sharing information.

11. Identify and reduce institutional obstacles to learning and action

Policy responses to GMO risk reflect different national approaches, as illustrated by the controversies between the United States and the European Union on GMO risk. In the European Union, a de-facto moratorium on GMO food was implemented in 1998 and has recently been lifted. In the United States, field releases of GMO may be implemented after notifying the US Department of Agriculture, without any formal public risk assessment (Goldburg, 1999: 70). The US Food and Drug Administration requests that companies voluntarily consult with the agency before marketing GMO food. However, transgenic crops that produce insect toxins must undergo two separate reviews of environmental safety, by the EPA and the USDA, before commercial marketing (Marvier, 2001). Improving national and international regulatory frameworks is an important step in implementing a precautionary perspective. The Cartagena protocol on biosafety is currently in the process of ratification. The protocol seeks to establish an international framework for safe management of all potential uses of GMOs that could affect biodiversity, such as transboundary movements of GMOs. A precautionary approach to biotechnology may challenge trade liberalization in agriculture, see Eggers and Mackenzie (2000).

Attitudes to GMO risk differ widely in Europe and the United States. A cultural difference in risk perception is illustrated by the following quotation from the textbook by Raven and Johnson (2002: 417).

> "It does no good whatsoever to tell a fearful European that there is no evidence to warrant fear, no trace of data supporting danger from GM crops. A European consumer will simply respond that the harm is not yet evident, that we don't know enough to see danger lurking around the corner. "Slow down", the European consumers say. "Give research a chance to look around all the corners. Let's be sure." No one can argue against caution, but it is difficult to imagine what else researchers can look into—safety has been explored thoroughly. The fear remains, though, for the simple reason that no amount of information can remove it. Like a child scared of a monster under the bed, looking under the bed again doesn't help—the monster still might be there next time.

In claiming that "The fear remains, though, for the simple reason that no amount of information can remove it", the authors illustrate the need for improved risk communication. An important element of a precautionary strategy is to improve communication on risk perception between stakeholder groups and develop a realistic basis for improved confidence.

12. Avoid "paralysis by analysis" by acting to reduce potential harm when there are reasonable grounds for concern

In contrast to the preceding 11 lessons that call for more information, for example by searching out blind spots within disciplines, reaching out to other disciplines, and taking into account lay and local knowledge and wider social perspectives, the twelfth lesson warns against using the call for more information as an excuse to postpone timely action to reduce potential hazards. The novelty of the genetic modification techniques and their applications, the long time horizon before health and environmental consequences can be assessed, potentially irreversible effects on biodiversity, widely divergent risk perceptions of different stakeholder groups, various types of ethical concerns, and enormous economic interest at stake for the companies; these and numerous other factors contribute to the complexity of the risk analysis, yet they indicate reasonable grounds for concern and provide the rationale for a precautionary approach. The challenge is to design precautionary strategies that can prevent, or at least minimize, future harmful impacts while at the same time promoting innovation.

A Bayesian Approach

A key element in the precautionary principle is how the information basis for risk assessment, risk management and risk communication can be improved. Recently, more attention has been given to the Bayesian approach of updating probabilities as a promising avenue for incorporating new information and divergent risk perceptions in a systematic way. In this section, we discuss a simple example, adapted from Natvig (2000), that illustrates how new information can be applied to update probability distributions. We focus on the uncertainty about potentially irreversible effects on the ecosystem of implementing a particular GMO crop. The example illustrates a pessimistic starting point, and we discuss the sensitivity of the conclusion to the evaluation of risk.

We formalize the decision problem by the following stylised example. Assume that the decision maker is a regulator, considering whether to approve a particular GMO crop, subject to given regulations and standards, or not to approve that particular crop. The option of not approving the GMO crop is denoted R (radical option), and the option of approving the GMO crop is denoted C (conservative option). Assume that the environmental safety of this GMO crop is characterized by two states, either it is environmentally safe relative to anticipated standards, denoted by G (good outcome), or it is not environmentally safe relative to anticipated standards, denoted by B (bad outcome).

Experts assess the following subjective probability distribution for the safety of this particular GMO crop, $P(G)=0.4$ and $P(B)=0.6$. In order to improve the basis for the decision problem, independent experts are consulted on the safety issue. Two groups of experts evaluating the same data may reach opposite conclusions, depending for example on how they view the burden of proof. Assume that the experts may give either of two conclusions, $E(+)$=positive evaluation, that is, the GMO crop is safe relative to anticipated standards, or $E(-)$=negative evaluation, that is, the GMO crop is not safe relative to anticipated standards.

Consider now the situation where the experts conclude that the GMO crop is environmentally safe relative to anticipated standards. They emphasize, however, that their evaluation is subject to large uncertainty. Denote by $P(E(+)|G)$ the conditional probability of a positive evaluation given that it is safe, and by $P(E(+)|B)$ the conditional probability of a positive evaluation given that it is not safe. The experts conclude that $P(E(+)|G)=0.9$ and $P(E(+)|B)=0.2$. Hence, there is a 20 per cent probability that the experts will give a positive evaluation even if the GMO crop is not safe.

Given the evaluation of the experts, the decision maker would like to update the à priori probability distributions $P(G)$ and $P(B)$ based on the conditional probabilities $P(E(+)|G)$ and $P(E(+)|B)$ and use the new conditional probabilities $P(G|E(+))$and $P(B|E(+))$ in the decision problem. Recall that the definition of conditional probability is

$$P(G|E(+)) = \frac{P(G \cap E(+))}{P(E(+))}.$$

In order to find $P(G \cap E(+))$, note that the definition of conditional probability implies that

$$P(E(+)|G) = \frac{P(G \cap E(+))}{P(G)}$$

and hence we obtain $P(G \cap E(+)) = P(E(+)|G)P(G) = 0.36$. In order to find $P(E(+))$, consider the two disjoint events $G \cap E(+)$ and $B \cap E(+)$ and note that

$$\begin{aligned} P(E(+)) &= P(G \cap E(+)) + P(B \cap E(+)) \\ &= P(E(+)|G)P(G) + P(E(+)|B)P(B) = 0.48. \end{aligned}$$

Hence, we obtain

$$P(G|E(+)) = \frac{P(E(+)|G)P(G)}{P(E(+)|G)P(G) + P(E(+)|B)P(B)} = 0.75$$

and $P(B|E(+)) = 1 - 0.75 = 0.25$. As compared to the situation before the positive expert evaluation, the probability that the GMO crop is safe has increased from $P(G) = 0.4$ to $P(G|E(+)) = 0.75$, whereas the probability that the GMO crop is not safe has declined from $P(B) = 0.6$ to $P(B|E(+)) = 0.25$. Based on the positive evaluation of the independent experts, it seems considerably more likely that the GMO crop will be safe relative to anticipated standards.

If the independent experts had arrived at the second conclusion, that is, the GMO crop is not safe relative to the anticipated standards, the decision problem would have had to be based on the updated conditional probabilities $P(G|E(-))$ and $P(B|E(-))$. In this case we have $P(E(-)|G) = 1 - P(E(+)|G) = 1 - 0.9 = 0.1$ and $P(E(-)|B) = 1 - P(E(+)|B) = 1 - 0.2 = 0.8$. Proceeding as above we find

$$P(G|E(-)) = \frac{P(E(-)|G)P(G)}{P(E(-)|G)P(G) + P(E(-)|B)P(B)} = 0.08$$

and $P(B|E(-)) = 1 - 0.08 = 0.92$. As compared to the initial probability assessment, the negative evaluation implies that the probability that the GMO crop is safe has declined from $P(G) = 0.4$ to $P(G|E(-)) = 0.08$, and the probability that the GMO crop is not safe has increased from $P(B) = 0.6$ to $P(B|E(-)) = 0.92$. Based on the negative evaluation of the independent experts, it seems considerably less likely that the GMO crop will be safe relative to anticipated standards.

The precautionary approach taken by the decision maker is reflected in the evaluation of risk. In order to choose between *R* and *C* the decision maker has to evaluate the risk, that is, subjectively assess the gain or loss of each decision relative to the inherent uncertainty. The decision maker is faced with two types of loss, the environmental cost in the event that the GMO is not safe and is approved, and the loss of potential gains from GMO implementation in the event that the GMO is safe and is not approved. Table 1 illustrates the trade-off between the two types of loss, relative to the correct decisions of not approving the GMO crop if it is not safe and approving the GMO crop if it is safe.

Table 1 illustrates a scenario where it is assumed that the most serious mistake is to approve in the event that the GMO crop is not environmentally safe. In this case the loss is 1000, representing the environmental damage that may result from implementation of the GMO crop. If, on the other hand, the GMO crop is safe and not approved, the loss is 100, representing the loss of potential gains from safe GMO crops. The correct decisions, where a particular GMO crop is approved if it is safe, and not approved when it is not safe, correspond to zero loss.

The evaluation of potential gain and loss as exemplified in Table 1 can be expressed as a value function $V(R)$ and $V(C)$. Combining the value function with the conditional probabilities based on the positive expert evaluations, $P(G|E(+))=0.75$ and $P(B|E(+))=0.25$, we obtain the following expected value of the gain in each situation, $EV(R)=-100\cdot 0.75+0\cdot 0.25=-75$ and $EV(C)=0\cdot 0.75-1000\cdot 0.25=-250$. The expected loss of not approving is smaller than the expected loss of approving, hence, the appropriate decision is not to approve although the conditional probability that the GMO crop is not safe, given the positive expert evaluation, is as low as 0.25.

This conclusion is highly sensitive to the choice of value function, that is, the assessment of potential gain and loss. Table 1 illustrates a pessimistic evaluation of risk, where the loss of approving an unsafe alternative is ten times higher than the loss of not approving a safe alternative. Assume now a more optimistic evaluation of risk, for example that the loss from approving if the GMO crop is not safe is reduced to -300, reflecting a much higher willingness to accept risk. In this case we find that $EV(R)=EV(C)=-75$ and the decision maker is indifferent between approving or not. The difference

Table 1. A numerical example of risk evaluation: Gain from decisions "not approving" vs. "approving" a particular GMO crop

		State	
		GMO safe	GMO not safe
Decision	Not approving (*R*)	−100	0
	Approving (*C*)	0	−1000

between the evaluation of uncertainty in these two examples can be interpreted as an application of the precautionary principle. The evaluation of risk as implied by the weights of the gains and losses in the objective function given in Table 1 implies a much lower willingness of society to accept the risk of a GMO crop not being safe, expressing a precautionary approach from the decision maker.

Consider now the effect of taking the negative expert evaluation, with $P(G|E(-))=0.08$ and $P(B|E(-))=0.92$, into account. Applying the risk evaluation in the second example we obtain $EV(R)=-100\cdot 0.08+0\cdot 0.92=-8$ and $EV(C)=0\cdot 0.08-300\cdot 0.92=-276$. In this case the argument for not approving a particular GMO crop is strengthened considerably.

This stylised example illustrates how Bayesian analysis offers a consistent framework for revising probabilities in view of new information. A key parameter in empirically based risk management is the relationship between the social evaluation of potential risks and potential benefits associated with GMO adoption. A crucial point is whether the price of non-GMO food increases relative to GMO food. Evidence from North America indicates a premium paid for non-GMO food as consumers become more aware of the potential risks (Warwick and Meziani, 2002). As discussed above, the risks associated with field releases of GMO crops have similarities with the risks of invasive species and loss of biodiversity. Hence, estimates of the cost of invasive species (Pimentel *et al.*, 2000) and the value of biodiversity (Kunin and Lawton, 1996) may give a starting point for risk evaluation. Nonetheless, as the analogies are somewhat limited, direct experimentation and monitoring are the primary tools for risk assessment.

Incentives for Social and Environmental Responsibility

A precautionary strategy includes risk assessment, risk management as well as risk communication. Improved risk communication between industry, the scientific community, government and consumers may provide incentives for better risk assessment and risk management, thus improving conditions for detecting "early warnings". The approach of a company towards risk reflects its commitment to environmental and social responsibility. The challenge is to identify the performance of individual companies with respect to environmental and social responsibility, in order to provide incentives for further improvements and to facilitate implementation of precautionary strategies.

Recently, much focus has been given to how investment funds with different types of environmental and social screening of companies may provide incentives for companies to improve their social and environmental responsibility in order to be included in these investment funds (see, e.g., Angel and Rivoli, 1997; Khanna and Anton, 2002; Aslaksen and Synnestvedt, 2003). The increased demand for "screened" investments by individuals and organizations reflects that these stakeholders expect a positive effect of their investment choice on environmental and social development.

A key element in screening of companies is to establish criteria for inclusion of companies based on social and environmental performance relative to other companies within the same industry. For the biotechnology industry, their approach to risk is clearly relevant for whether they qualify among the "best in class" companies or not. Based on our discussion of GMO uncertainties, the criteria should include information on how companies perform on risk assessment, risk management and risk communication. Companies could be evaluated on questions like the following:

- To what extent does the company provide relevant information on environmental and health risks of GMOs to regulators, the academic community and consumers?
- To what extent does the company provide a choice between GM and GM-free food and seeds?
- To what extent does the company cooperate with and support independent research?
- To what extent does the company contribute to development of alternative technologies?

Evaluating companies on the basis of this type of questions can provide information on how the company scores on social and environmental responsibility, relative to other companies in the industry. This information enables investors to choose between companies with different social and environmental performance. Many studies indicate that companies are increasingly sensitive to publicity about lack of environmental and social responsibility. The existence of investment funds with various types of screening may strengthen the incentives for companies to improve their environmental and social practices, including their approach to environmental risk.

Conclusions

Despite the large research efforts in GMO risk assessments, unresolved issues remain in the assessments of long-term environmental risk. In view of the considerable uncertainty and potentially irreversible effects on the environment, regulatory policies need to incorporate various elements of the precautionary principle. The widely divergent interests and risk perceptions of stakeholder groups represent a challenge for implementing a precautionary perspective.

"Late lessons from early warnings" gave examples of situations where early warnings of hazards had been discounted by the interests of various stakeholders. The large economic incentives for early adoption of GMO crops may conflict with incentives for sufficient risk assessment, risk management and risk communication. More focus on the environmental and social responsibility of industry may provide incentives for improved risk communication between industry and stakeholders. Applying criteria for environmental and social screening of companies in the biotechnology industry could provide incentives for better risk communication, thus promoting better risk assessment and risk management and improving conditions for detecting "early warnings".

In this article we have discussed three approaches to a precautionary perspective, establishing criteria for detecting "early warnings", applying Bayesian analysis for improving the information basis for decision making under large uncertainty, and providing incentives for improved risk management. These precautionary strategies may enhance the environmental responsibility of stakeholders and contribute to a more comprehensive discussion of the available policy responses to GMO risk.

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