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GENETICALLY MODIFIED (GM) CROPS: PRECAUTIONARY SCIENCE AND CONFLICTS OF INTERESTS

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ABSTRACT. Risk governance of GM plants and GM food products is presently subject to heated scientific and public controversies. Scientists and representatives of the biotechnology industry have dominated debates concerning safety issues. The public is suspicious with regard to the motives of scientists, companies, and political institutions involved. The dilemmas posed are nested, embracing value questions, scientific uncertainty, and contextual issues. The obvious lack of data and insufficient information concerning ecological effects call for application of the Precautionary Principle (PP). There are, however, divergent opinions among scientists about the relevance of putative hazards, definition of potential "adverse effects," and whether actions should be taken to prevent harm. The reliance on the concept of substantial equivalence in safety evaluation of GM food is equally controversial. Consequently, value assumptions embedded in a scientific framework may be a barrier for employment of the PP. One of our major conclusions is that precautionary GMP usage requires risk assessment criteria yet undeveloped, as well as broader and more long-term conceptions of risk, uncertainty, and ignorance. Conflicts of interest and public participation are other issues that need to be taken into consideration. GMP governance regimes that are justifiable from a precautionary and ethical point of view must transcend traditional scientific boundaries to include alternative scientific perspectives as well as public involvement.

KEY WORDS: conflicts of interests, genetically modified (GM) plants, GM food, the Precautionary Principle, public trust, scientific uncertainty, substantial equivalence

INTRODUCTION

Agro-technological crop cultivation is based on increased yields obtained by traditional breeding or other means. A number of genetically modified crop plants (GMPs) have recently been developed and marketed. The majority of approved and released GMPs can be divided into three groups with regard to inserted transgene: herbicide tolerance (75%), insect resistance (18%), and stacked genes (7%) (both herbicide tolerance and insect resistance) (James, 2001). Almost 68% of the commercial releases have taken place in the US. Worldwide, 36% of the soybeans planted tolerate herbicides, and 7% of the total maize plantings express Bt toxins to resist pests. Less than 1% of total commercial releases have been executed in



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Europe, where use of, and production based on GMPs have been met with a growing skepticism among consumers.

Representatives of research communities and transnational corporations are the main proponents of transgenic crops. They make a case for decreased use of herbicides and other chemicals. This group maintains that herbicide-tolerant crops may provide both better weed control and less crop injury than traditional varieties. Such benefits would boost farming productivity, and hence increase food supplies for the rapidly growing world population. Herbicide-tolerant crops might diminish plowing and mechanical weeding and thereby contribute to soil conservation. Likewise, insect-resistant crops might reduce pesticide use and improve harvests. Thus, increased efficiency would reduce the costs for farmers as well as the prices for consumers. GMPs might be utilized as producers of drugs and vaccines, i.e., plant-derived edible vaccines (Mor et al., 1998). Such edible vaccines for viral and diarrheal diseases have characteristics that are particularly attractive in poor Third World countries (Traavik, 1999). On the other hand, opponents of transgenic crops emphasize the lack of data and comprehension pertaining to environmental and health risk assessment of GMPs. They hypothesize that GMP releases may result in reduced biodiversity and disturbed ecosystem interrelations (Rissler and Mellon, 1996). Environmental introduction of GMPs may have long-term impacts on food chains, and consequently on human and wildlife health. Furthermore, GMPs may have adverse socio-economic effects including changes in community structures and cultures.

Scientific data concerning environmental and health effects are scarce, from industry as well as from public research sources (Domingo, 2000; Wolfenbarger and Phifer, 2000). The Precautionary Principle (PP) has been introduced as a response to scientific uncertainty (Freestone and Hey, 1996). At present, scientific uncertainty concerning the ecological impact of GMP utilization impedes consensus with regard to relevance of hypothetical, but possible hazards (Clark and Lehman, 2001). References to "science based" and "scientific evidence" are open to interpretation, which may influence the framework and scope of risk and safety assessments. In particular, since decisions concerning the framework affect the design, implementation of methods, choice of variables/indicators, and time scales of the study.

We contend that the current framework for GMP regulation is inadequate; it does not cope efficiently with the present scientific uncertainty and public concern. Employment of the PP requires robust scientific approaches with emphasis on scientific uncertainty, the significance of evidence, and the framing of hypotheses (Buhl-Mortensen and Welin,

1998; O’Riordan and Jordan, 1995). With the purpose to address risk and uncertainty, scientists have a responsibility to communicate uncertainty and underlying assumptions (Gibbons, 1999). GMPs are posing nested a dilemma, highlighting the need to take scientific uncertainty, value questions, and contextual issues into account.

Apart from the obvious need to identify, acknowledge, and resolve scientific uncertainty, it is also imperative to address conflicts of interests and public concern. The increasing co-operation between transnational corporations and public research institutions raises ethical questions related to the integrity of research and the objectivity of scientists (DeAngelis, 2000). This calls for public funding of independent risk-related research.

In Europe, skeptical attitudes towards GMPs are evident at the moment. Regulatory authorities, GMP producers, and scientific advisers may have contributed to this by ignoring the ethical and social aspects of science and technology. To promote better decision-making processes, it will be imperative to involve the different stakeholders in both an informative and participatory way to discuss acceptable use of and future developments of GMOs.

THE PRECAUTIONARY PRINCIPLE (PP)

The term “Precautionary Principle” came into English usage as a translation of the German word “Vorsorgeprinzip.” The PP has been accepted by many national governments as a basis for policymaking, and it has also become important in international environmental law and international treaties (CBD, 2000; EU, 2000; Freestone and Hey, 1996). Several interpretations of the principle exist, and the lack of a clear definition of the PP hampers its implementations. The Cartagena Protocol, for instance, states that a denial of GMO import must be based on “credible scientific evidence,” and that the environmental impact must be weighed against the proposed benefits (CBD, 2000). According to the Rio Declaration (1992) precautionary measures should be “cost-effective” and “according to their capabilities.” Both the Cartagena Protocol and the Rio Declaration employ the weighing of cost and benefits. Hence they introduce weak versions of the PP. The Wingspread Statement entails a strong version of the PP, emphasizing that “precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically” (Raffensperger and Tickner, 1999). In the view of its opponents, the PP represents a non-scientific attitude that causes trade hindrance (Adler, 2000), and inhibits technology development as well as economic

benefits (Miller and Conko, 2000). Hence, employment of the PP will depend on the value commitments and perspectives of those involved in the decision-making (Kaiser, 1997).

Employment of the PP implies that the scientists have a responsibility to identify and clarify uncertainty, and to communicate this uncertainty to the public and policymakers. The traditional methods for ensuring trustworthy results may work contrary to the goal of the PP, hence, the scientific method is challenged with regard to reliance on methods, the significance of evidence and framing of research hypotheses (Buhl-Mortensen and Welin, 1998; O’Riordan and Jordan, 1995).

Scientific Uncertainty and Putative Ecological Risks

Release of GMPs into the environment, and the use of food ingredients from GM sources, raise concerns about environmental and health impact. Scientific data concerning environmental and health effects are limited, from industry as well as from public research sources. No long-term studies that elaborate environmental and health effects of GMP use and release have been performed (Domingo, 2000; Wolfenbarger and Phifer, 2000). Scientific literature contains hypotheses and preliminary results indicating possible adverse effects. Such indications have given increased credence to other possible, but unproven processes and interactions. Several aspects of scientific uncertainty with regard to GMP use and release are presented in the following.

Behavior of the specific GMP

Present modification methods for transfer of genes and parts of genes into cells and organism lack control of site for and number of insertions, and the genetic modification process and/or the transgene may introduce unintended properties to the GMP (see Figure 1).

Secondary effects of introduction of transgene(s) may arise from the expression products, or the insertion(s) may cause pleiotropic effects, which divert the gene expression patterns of the recipient plant (De Neve et al., 1999; Ho et al., 2000). The same gene may have changed expression patterns after insertion (Bergelson et al., 1998). Furthermore, changes in expression (especially due to the CaMV promoter) might be affected by external factors such as responses to specific environmental conditions, e.g., climatic differences and xenobiotics, (Traavik, 1999). The insertion(s) of transgene(s) may have unexpected effects on protein production and metabolic activities (Kuiper et al., 2002; Lappè et al., 1999; Novak and Haslberger, 2000; The Royal Society of Canada, 2001).

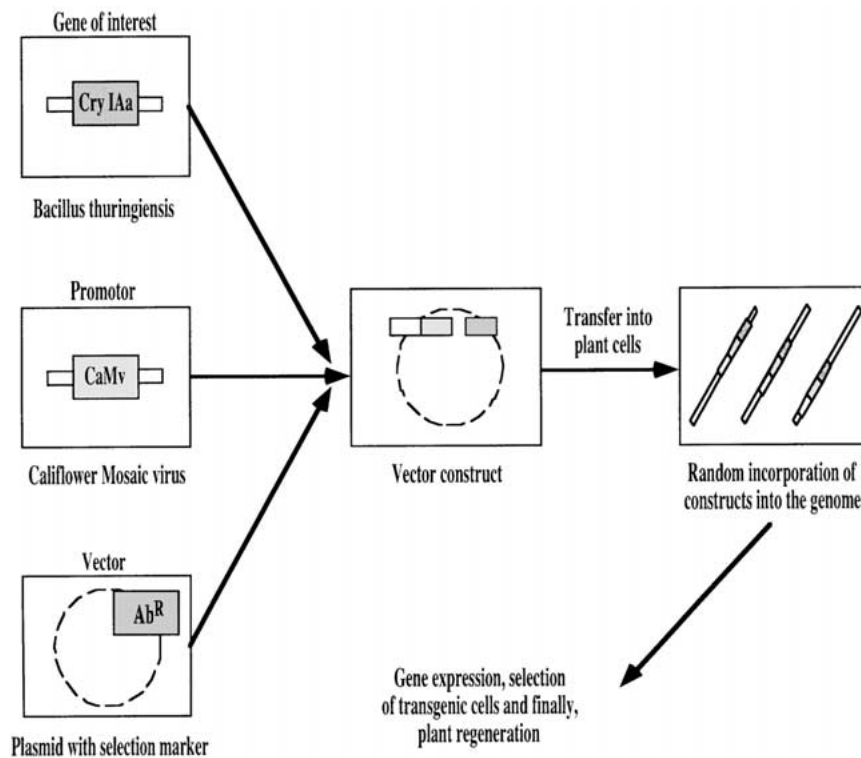


Figure 1. Lack of gene targeting by transgenic modification processes.

Genes, and parts of genes, may be spread by cross-pollination (insect or airborne pollen) to wild or cultivated relatives (Bergelson et al., 1998; Ellstrand et al., 1999; Mikkelsen et al., 1996), and to other organisms by uptake from plant residues or by horizontal gene transfer (Gebhard and Smalla, 1998; Nielsen et al., 1998.). Consequences of gene transfer might be increased fitness or more unpredictable changes. Knowledge about selective forces in the environment, and the potential of horizontal gene transfer both within and across barriers is absent.

Complexity

GMPs may cause unintended non-target effects. Non-target effects include the influence on and interactions with all organisms in the environment, and may be direct or indirect. Direct effects concern ecotoxic effects on other organisms, for instance adverse effects on insects, larval feeding on insect-resistant plants (Losey et al., 1999; Obrycki et al., 2001), or effects on soil organisms (Saxena and Stotzky, 2000). Indirect effects concern effects on consumer health, contamination of wild gene pools,

or alterations in ecological relationships. Disturbance of food chains, for instance, decrease in insectivorous birds due to reduced insect populations, may be considered as an ecological alteration. Furthermore, even if the GMP has been extensively studied before environmental release, changes in interactions with and responses to the environment may go unnoticed. Different climatic and environmental conditions may affect persistence and dispersion of the released GMP.

Detection and monitoring of effects

For a given GMP, environmental consequences important to detect and monitor include reproductive ability, invasiveness, non-target effects, and gene transfer to other organisms (Myhr and Traavik, 1999). For a GMP crop intended for human and animal consumption, potential changes in secondary metabolite profiling or changes in other constituents must be monitored (The Royal Society of Canada, 2001). Feeding experiments must follow up the health relevance of changes introduced by the transgene and the genetic modification process.

IMPLICATIONS OF SCIENTIFIC UNCERTAINTY

GMP applications are encumbered by uncertainty at different levels: technical uncertainty, e.g., lack of scientific understanding; epistemological uncertainty, e.g., limited knowledge concerning properties of the GMP in question; and methodological uncertainties, e.g., concerning choice of methods for detection and identification of effects. Furthermore, there are uncertainties related to the occurrence, magnitude, timing, and significance level of potentially adverse effects. Through identification of risk and uncertainty, there may be factors that remain outside the scope of assessments. Such factors of ignorance represent the unexpected and unprecedented effects. Epistemological uncertainty concerns limited knowledge and involves "borders of ignorance" (Funtowicz and Ravetz, 1990). It is impossible to identify all the relevant effects of GMPs, and ignorance reflects situations where the kinds of effects to look for are unknown. In addition, underlying assumptions and framing of research questions may contribute to further uncertainty and ignorance. If, for instance, the frame becomes too narrow, important questions may be excluded from research.

Among scientists and risk assessors, opinions concerning the relevance of a specific problem, the criteria for significant evidence of harm, or whether preventive actions should be taken, may differ (Myhr and Traavik, 1999). Divergent values make it difficult to agree on factual issues, hence, factual divergences causes disagreement among scientists and risk assessor

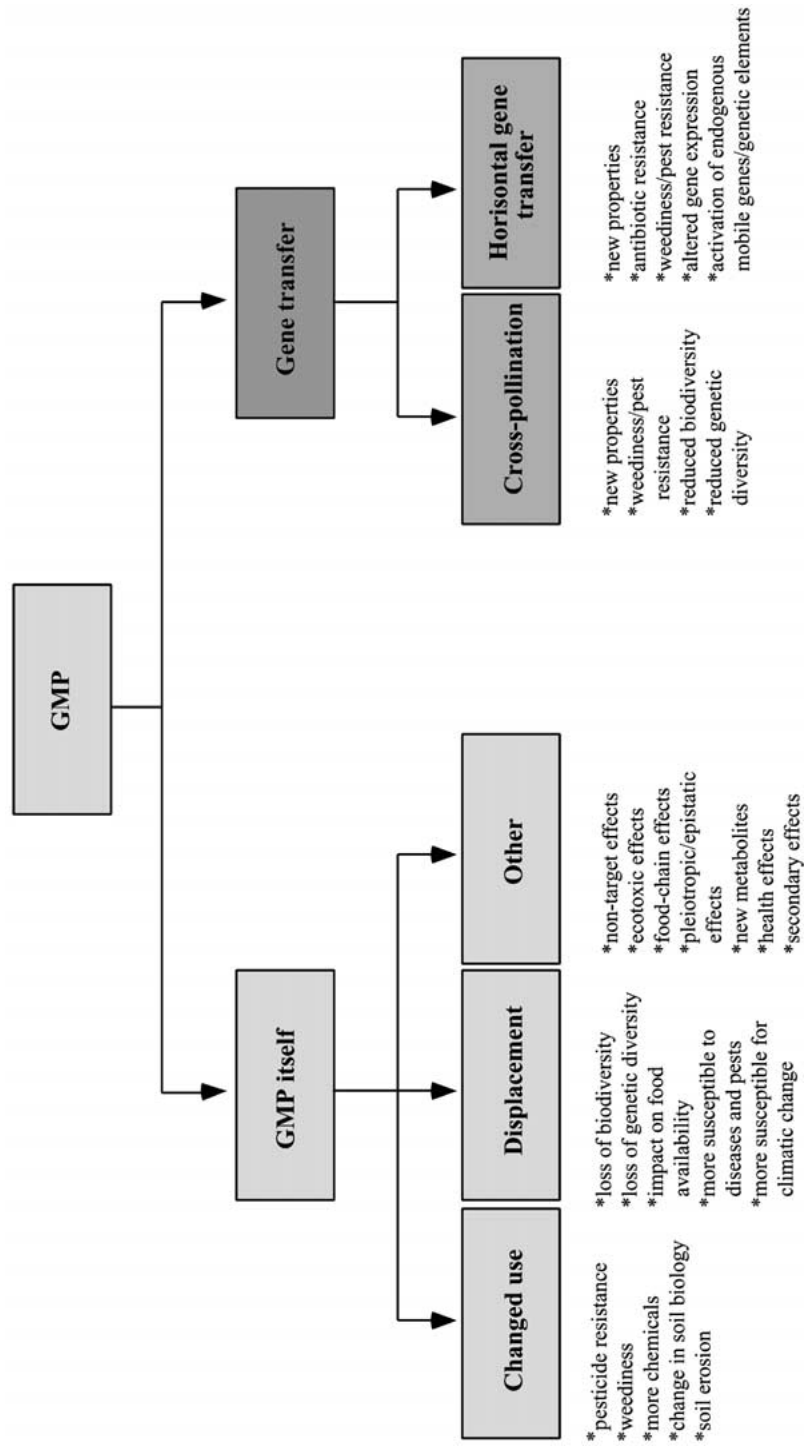


Figure 2. Potential ecological effects from GMP use and release.

and affects initiations of research required in order to reach GMP decisions (Clark and Lehman, 2001; Levidow et al., 2000).

Type-I versus Type-II Errors

Traditionally, most environmental scientists and regulators have been more interested in avoiding type-I errors than type-II errors (Lemons et al., 1997). A type-I error is to accept a false positive result, i.e., is to conclude that ecologically adverse effects will result from GMP use and release, when in fact no adverse effects will result. A type-II error is to accept a false negative result that is to conclude that no GMP related adverse effects will result, when in fact, adverse effects will result. Traditional science attempts to maximize truth and avoid type-I errors. In accordance with the traditional scientific norm, one ought to have complete and supportive information before claiming a cause-and-effect relationship. The concept of significance is defined statistically, in terms of type-I errors, often at a 95 percent confidence level, to ensure that the observed result supports the null hypothesis (*H₀*). However, if there is less than a 95% percent confidence in that there is an effect, *H₀* is not rejected. Scientists in such situations are prone to assume that there is not enough evidence to reject the *H₀*, that there is no effect due to limitations of the experimental design or test, or that the data variables are too similar to detect an effect. The choice of 95% rather than 90% or 99% is, in itself, a value-laden decision. It expresses the balance between type-I and type-II errors that is accepted for an activity. The fact that scientists usually accept such rules is problematic, and demonstrates that the underlying assumptions of traditional science may hinder identification of adverse effects of an activity. While minimizing type-I errors, which are often short-term economic or technological risks, there is a risk of accepting a harmful development, putting health and the environment at risk (Lemons et al., 1997). Given the asymmetry in the consequences depending on the chosen hypothesis, application of the PP would entail prevention of type-II errors at the expense of committing some type-I errors. Since both unequivocal definitions of such terms as “adverse effects” and significant evidence of ecological effects are lacking, it is difficult to avoid type-II errors. An example of this is presented below.

Horizontal transfer of genes between organisms has been demonstrated, but the relevance to risk assessment is still controversial. This is illustrated by an application from Plant Genetic System to market GM oilseed rape, modified to tolerate the herbicide gluphosinate. Different European authorities expressed opposite opinions with regard to the significance of risks resulting from horizontal gene transfer. The Norwegian authorities denied

marketing of the herbicide-tolerant plant, fearing that transfer of tolerance genes to weeds might instigate the excessive use of herbicides (Case documents). The denial was based on a publication by Mikkelsen et al. (1996), where it was found that modified oilseed rape could transmit its transgene to a weedy natural relative, *Brassica campestris*. By gaining herbicide-tolerance, the weedy relative would then possess a unique environmental fitness property and represent a potential agricultural weed problem. Plant Genetic Systems did not consider gene transfer to other organisms as a risk. Neither did the UK authorities, hence the herbicide-tolerant plant was commercially approved (ACRE, 1995). Ecological uncertainty was acknowledged, but different authorities disagreed about the *significance* of the environmental effect. Thus, different interpretations of scientific evidence may limit risk assessment and the quality of scientific advice for regulative purposes.

The Null Hypothesis and the Framework Problem

Current regulatory systems, and many scientists, demand conclusive evidence to guide policymaking. Accordingly, data that has not rejected *H₀*, is often considered as a support of *H₀*. Hence, do those who claim that an activity may have adverse effects, still have the burden of proof. For instance, recent studies have made adverse events more plausible, i.e., non-target effects, horizontal gene transfer, and secondary effects, but they are still given low impact or considered insignificant.

Two recently published studies have evoked heated controversies concerning appropriate test methods and models for risk assessments. In the first case, Ewen and Pusztai reported that feeding GM potatoes expressing the snowdrop bulb lectin (GNA) to rats indicated pathological differences in parts of the rat gastrointestinal tract (Ewen and Pusztai, 1999). The results gave rise to concerns with regard to adverse health effects, i.e., on growth rate and immune functions, of eating lectin-modified plants. In the second case, it was reported in a letter to *Nature* that monarch butterflies were susceptible to *Bacillus thuringiensis* (Bt) toxins expressed in Bt transgenic plants (Losey et al., 1999). The results were obtained in small-scale laboratory tests, with the monarch larvae being fed on milkweed dusted at high levels with Bt maize pollen. The study indicated that survival among those that fed on Bt pollen was significantly lower than among monarch larvae feeding on pollen from non-GM maize. The relevance of this study has been challenged. It was claimed that the experimental conditions were too contained to reflect reality, and that such experiments should include entire life cycles of insects (Crawley, 1999; Shelton and Sears, 2001). Recently, Stanley-Horn and colleagues

(2001) confirmed increased mortality for monarch larvae after fed pollen from Bt-maize deposited on milkweed leaves within and adjacent to Bt fields. However, in another similar study, no adverse effects were observed for monarch and black swallowtail larvae fed on pollen from Bt maize (Zangerl et al., 2001). The significance of these studies can only be verified by further experimentation, with focus in particular on environmental conditions, biodiversity, and species susceptibility over a long-term time frame. Studies at a laboratory level need to be confirmed by increasing “reality” in a risk assessment process, including non-target effects on vertebrate predators (Obrycki et al., 2001).

The controversies over the snowdrop lectin and the monarch studies demonstrate that value-laden assumptions are embedded in scientific methodology and that they are difficult to avoid. The controversies also illustrated that decisions of whether to minimize type-I versus type-II errors affect the initiation of additional risk-related research. The assumption that a practice or a product is safe until proven otherwise, entails a risk of committing a type-II error and may subsequently end in “soft-disasters,” since adverse ecological effects may develop slowly through long chains (Scott et al., 1999).

If scientist and risk assessors consider preliminary results not to be convincing or insignificant, this will cause governments to make decisions in the absence of proper scientific understanding. In the context of public policy and decision-making, scientific uncertainty may cause controversies that are embedded in values. Accordingly, results may be adopted and used by one of the sides in the conflict to justify their opinion. Watkinson et al. (2000) pointed out the need to use predictive modeling to address the potential impacts on birds of GM herbicide-tolerant crops. In the extensive debate that followed, non-governmental organizations (NGOs) used the result to support their claim for a ban on GM crops, while Monsanto termed the paper “inappropriate and misleading” (Sutherland and Watkinson, 2001). Sutherland and Watkinson were surprised by the controversy, and offended by the use and critique of their model. Perhaps they were naïve, but the most important experience with this event, and with the snowdrop lectin and the monarch studies, is that the belief in *Ho* – that GMPs and GM products are safe – is very strong.

“Substantial Equivalence” is Incongruent with Application of the PP

To assess the safety of GM foods, the concept of substantial equivalence was introduced by OECD in 1993, and later affirmed by FAO in 1996 (OECD, 1993; FAO, 1996). The concept is considered a guiding principle to risk assessment with the purpose of determining whether a GM food

product is as safe as the traditionally bred counterpart (non-GM). If a GMO is characterized as “substantial equivalent,” it is considered to represent no new health risk and will then be approved for commercial use.

Conclusions concerning substantial equivalence are based on chemical analyses. Whether use of the concept deals adequately with important risk factors, or limits the scope of investigation, has caused extensive debate among regulators and scientists (Gasson and Burke, 2001; Millstone et al., 1999; Trewavas and Leaver, 1999). The issue of novelty has been central in the heated discussions (The Royal Society of Canada, 2001). Proponents claiming no reason to expect different effects of genetically modified than conventional agricultural products seem to overlook that the present methods for genetic modification entail lack of precision and control with respect to transgene integration. The use of substantial equivalence in safety assessment provides neither the means to detect changes in gene expression patterns of endogenous genes (up/down regulation or epigenetic silencing of genes) nor to determine whether the inserted constructs or parts of it move within the recipient genome. Pleiotropic plant effects may concern changes in level of constituents such as anti-nutrients, allergens, and toxins (Novak and Haslberger, 2000). To get adequate understanding, it will be imperative to initiate research with the purpose to detect changes in expression of gene products in GM foods and to reveal whether such changes have adverse effects on consumers. Consequently, an evaluation of safety should include more comprehensive inquiries based on biochemical and toxicological tests (Millstone et al., 1999). The reliance on the “substantially equivalent” has caused important research on secondary metabolite profiling, immunology studies, and feeding experiments to be left on the shelf.

An authoritative expert committee organized by The Royal Society of Canada (2001) considered that in future safety assessments, it will be imperative to consider the significance of genetic modification at six relevant levels. These levels are genome, transcript, protein, metabolite, health impacts, and environmental impacts. Use of genomics, proteomics, and metabolomics may identify changes in secondary metabolite profiling or changes in other constituents of GMPs (Kuiper et al., 2002). In addition, to assess safety of health it is imperative to employ feeding studies. By using animal studies, changes in tissue structure and metabolic functions of organs can be assessed. Hence, it is disturbing that Domingo (2000), in his literature search on the safety of GM food products, found only eight published animal feeding studies, and most of these were not designed to reveal health effects.

The use of the concept substantial equivalence may be considered an attempt to scale down the complexity of the risk to manageable proportions, using traditional science to solve the complexity of the problem. However, if the research focus becomes too narrow, important aspects of the problem may not be identified. The concept of substantial equivalence are based on narrow frameworks, which subsequently will affect the design, implementation of methods, choice of variables/indicators, and time scales of the study (Clark and Lehman, 2001). For instance, GM products are assessed by analogy to products from chemically intensive farming. More stringent benchmark baselines for comparison of GM products would, for instance, be products from organic agriculture. The decision thresholds for extrapolation of safety to ensure that adverse effects do not exceed those of the non-GM counterpart will be quite different depending on what is their subject, i.e., organic versus chemically intensive agriculture. Furthermore, definition is needed for “the degree of difference” allowed between a GM and the non-GM counterpart before non-substantial equivalence is declared.

In contrast to the use of substantial equivalence, employment of the PP involves a critical awareness to the quality of risk-related scientific advice. This implies identification of areas where scientific understanding is lacking and recognition of the extent of ignorance. Such awareness may in their turn broaden the scope for safety assessments and initiate basic research that either concedes or rules out risks of ecological harm. Hence, the PP entails both descriptive and prescriptive elements (Barrett and Raffensperger, 1999). The PP suggests action needed to protect the health and the environment and the process through which such action should be decided and implemented. Pouteau (2000) has emphasized the need for “ethical assurance” in food chains, concluding that in addition to health and environmental issues, social and ethical issues should also be involved in the safety assessment. With the purpose of ensuring quality, safety factors should be implemented as screening tools in the safety evaluation of food. Consequently, it will be imperative to integrate different scientific disciplines and other stakeholders in the construction of safety standards and procedures for implementation of the quality assurance process.

HOW DO WE DEAL WITH ECOLOGICAL UNPREDICTABILITY?

Although the focus in risk assessments has been primarily on economic and technological considerations, the use and production of GMPs also

affect social and ethical concerns. A more integrative approach to GMP risk issues implies the assessment of time aspects and the complexity of ecological networks. It involves appreciation of uncertainty and looks for sustainable ecological alternatives to potentially harmful technologies. Protection of human and animal health and environmental resources require attention to possible failures in order to recognize adverse effects. Other strategies should be pursued to obtain plants with less potential for adverse effects than the first transgenic generation of GMPs (e.g., chimero-plasty etc. (Beetham et al., 1999)). Equally important is the application of model systems to identify impact on biodiversity (Watkinson et al., 2001), and to measure secondary effects, i.e., compositional analyses and feeding studies (Domingo, 2000). It should be generally recognized that creation of new testable hypotheses in an interdisciplinary and integrated way will enrich the process, with breast cancer research as an example (Holmberg and Braun, 1996). Surgeons and radiotherapists recognized that aggressive therapy of breast cancer failed. Together with clinical scientists, new theories concerning the development of breast cancer were formulated, and laboratory experiments were initiated to test the hypotheses and to translate biological knowledge into clinical practice. The formulation of new theories provided the groundwork for better treatment of breast cancer. In a GMO context, such approaches may include natural science disciplines such as biology, ecology, immunology, pathology, as well as disciplines as law, philosophy, and sociology.

Fully adequate information to support decision-making within ecological studies will rarely, if ever, be achieved. The traditional response to uncertainty has been increased scientific efforts. However, within ecological studies, it will always be uncertainty and ignorance that remains irreducible. Hence, there is a need of approaches that concern how to operate in situations with irresolvable uncertainty or with unequivocal scientific evidence. Ravetz suggests that it is necessary to raise the question of "What if" as a complement to more traditional approaches (Ravetz, 1997). Initiatives such as reframing of the problem may give a better understanding, and cause scientists to discuss and investigate alternative hypotheses and models to solve the problem.

Quality of Scientific Advice

Scientists' responsibility for communication of uncertainty is a controversial issue. In particular, it has been claimed that reporting early warnings based on preliminary results should be avoided (Shelton and Sears, 2001), but we maintain that the scientist has a responsibility for clarification and communication of uncertainty (Myhr and Traavik, 2002). Within

applied science, it is imperative that “early warnings” are communicated to the scientific community, to the regulators, and to the public. If such “early warnings” are not reported, evidence required for the application of the PP may not be known. Hence, the high quality of scientific advice is not dependent on the traditional norm of presenting only absolute and significant evidence. Information of lesser certainty may be of ample quality for its intended function (Buhl-Mortensen and Toresen, 2001). According to Funtowicz and Ravetz (1993), quality assurance of scientific information for policy decisions has been almost universally ignored. They suggest that this is due to the confusion of uncertainty of information with quality of information. Within policy-relevant science, traditional scientific rationality may be too limited. In this context quality assurance concerns not only products of research, but also includes processes, persons, and purposes. Extended peer review processes, involving a broad basis of scientific disciplines as well as other stakeholders, may enable a wider consideration of risk. In this context, communication of uncertainty and underlying methodological assumptions to other scientists, to the regulators, and to the public becomes vital. In addition, alternative scenarios to identify uncertainty and ignorance through the integration of other scientific disciplines and stakeholders are imperative.

Scientific expert committees are usually struggling to reach consensus conclusions (Hansson, 1999). This may create problems with regard to quality assurance of scientific information. Usually contradictory, minority views are not published. Accordingly, uncertainty becomes downplayed. Alternative scenarios or hypotheses of adverse effects are not presented, and are therefore inaccessible to decision-makers, other scientists, and the public. Hansson (1999) argues that “written minority opinions should be encouraged, and should be published along with the majority opinion.”

The European Environmental Agency (EEA) (2002) recently published a report raising the question; Why do not early warnings of hazard cause immediately initiation of research to verify or rule out any risk of harm? Furthermore, the point was made that it seems like no lessons have been drawn from recounting previous experiences of recent adverse effects in other industries.

The twelve studies presented in the EEA report, clearly illustrates how narrow risk assessment framework and the choice of null hypothesis (H_0) affects initiation of early warnings research. The EEA described activities that have been allowed to continue, because to reject a H_0 – that the activity is safe – requires conclusive evidences that fulfill the traditional scientific norm. Moreover, these events exemplify the risk of bias from relying on

hypotheses that dominate mainstream science, and hence the problem of omitted research (Garattini, 2000).

CONFLICTS OF INTEREST

When the scientists decide on hypotheses or questions they want to pursue, the interests and requirements of the institutions and corporations that provide the funding of their research affect their choices. Scientists acting as counselors in regulatory processes may, for instance, be biased towards regulatory outcome serving their own or their founders market interests. Scientists may serve as advisers to both governmental authorities and companies. Universities have been encouraged to seek active collaboration with commercial and industrial partners. All interactions of this kind raise ethical problems with regard to the personal integrity of scientists and the objectivity of their research (DeAngelis, 2000). Recently, these issues has been raised with regard to the UK based farm scale trials with herbicide tolerant crops (Gura, 2001). It has been asked whether the scientists involved are biased towards industrial interests. The purpose with the field trials is to identify impacts on farmland biodiversity by planting herbicide-tolerant crops. The impacts will be compared with those caused by planting conventional crops (DETR, 1999). An ecological model has been developed using selected species as indicator organisms. The Government has solely funded the trial, and the project plan has been submitted to the *Journal of Applied Ecology* for peer review and publication. The independent body advising the British Government (AEBC) and environmental groups have presented critical comments to the design to the study (Gura, 2001). The criticism concerns the framing of questions, especially those related to the range of indicators of biodiversity that are being used to assess the impact of the crops. The critics doubt whether the scope of the field trials are scientifically adequate, for instance that short-term experiences are being used to assess long-term impacts, hence, the scientists seem to make a type-II error.

It is easy to understand that the biotech industry performs research focusing on the benefits of their products, rather than on the probability of adverse effects. Nevertheless, when dealing with common resources such as the environment, the industry and regulators should not be allowed to make important presumptions about the scope of studies and the significance of scientific uncertainty. Hence, there is a need for fundamental knowledge with regard to the inherent characteristics of GMPs as well as their interaction with the recipient ecosystems. Most genetic engineering laboratories in the world are either directly or indirectly, i.e., through

grants and consultant roles, connected to the proponent side of biotechnology applications. We suggest that an expanded peer review processes with regard to GMP production design, and evaluation of risk assessments studies are needed. We also wish to emphasize the immediate demands for public funding of independent research.

To ensure full public disclosure of research funding, several institutions have implemented principles for conflict of interest policies (Gurney and Sass, 2001). To fulfill the public interest, several medical journals and *Nature* have adapted corresponding criteria that ensures independence of industrial influence, and the integrity of research projects, prior to publication. To enforce the integrity of science, conflict of interest policies should include a social contract with scientists to ensure that science and technology are used in socially responsible ways, e.g., address the needs and concerns of the public (Gibbons, 1999).

Issues of Trust: The Public and the Transnational Corporations

The public has witnessed risk assessments of chemical discharges, waste disposals, air pollution and, more recently, mad cow disease. The experience has resulted in lack of confidence in, and mistrust of, political institutions, corporations, and scientists as sources of reliable authoritative information (Aldhouse, 2000). Furthermore, recent failures have highlighted the limitation of scientific advice, the absence of reliable risk assessments, and delays in the initiation of relevant scientific research to verify ecological problems (EEA, 2002). Imposition of risk involves some sort of consent, and opportunities for the public to make free and informed choices. Public information and participation are therefore required in matters with potential long-term effects, as with GMPs. Mechanisms for balancing scientific advice with the involvement of other parties should be examined. We consider the establishment of extended peer communities, also as a means of public involvement, a potentially important instrument both for GMP decision processes and for the choices of directions for future GMP development. Such involvement should preferably be initiated at an early stage. The New Zealand Commission on genetic modification used one public consultation model that started with workshops to identify important questions, is a good example (The New Zealand Commission, 2001). Public concern may, inconceivably enrich the process of scientific investigation by providing practical knowledge.

The issue of trust involves concerns related to: (1) The increasing domination of power and economy by global corporations, and (2) The institutional and political context into which GMPs are introduced (Sagar et al., 2000). Accordingly, to identify the driving forces and those favored

are important factors for public confidence in the sources of information (Wynne, 2001). At the moment, a few transnational corporations (based in the US and Europe) dominate the GMP market. Some of them offer complete packages of seeds, herbicides, fertilizers, irrigation systems, etc. The unified GMP-market represents global control of seeds and crops. Therefore, commercialization of GMP and GM products intensifies economic competition between world powers rather than distribution of power (Sagar et al., 2000). Accordingly, the protection of intellectual property through patents causes inequalities between the rich and the poor and between industrial countries and the Third World. To promote the equal distribution of knowledge, it will be necessary to license plant modification technologies, or make them available without payment to countries lacking competence and economic resources (Dickson, 2000).

FUTURE OPTIONS

The genetic modification of currently available transgenic plants is based on the transfer of genetically simple traits. As earlier discussed, the first GMP generation is unpredictable due to lack of gene targeting and the uncertain action of an inserted foreign promoter/enhancer. The next generation of GMPs must be safer in these respects. Identification and acknowledgement of uncertainty must therefore be explored in a research and policy agenda that encourages broad and long-term considerations. Publicly funded and truly independent research groups and institutions in this area must be supported and enhanced, also in order to emphasize public welfare over private or proprietary interests. Scientific research alone will not resolve all the problems, but participation of different stakeholders from scientists to industry, NGOs, farmers, and the public will provide a needed variety of perspective foci, and knowledge. In the future science that embraces robust, participatory, and transparent approaches will be imperative.

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