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PRECAUTIONARY PRINCIPLES IN PRODUCTION OF GENETICALLY MODIFIED FOOD

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Abstract: *The food safety laws of the United States and the European Union are supposed to implement the precautionary principle. But in the case of genetically modified foods, officials on both sides of the Atlantic have systematically disregarded and defiled it. US statute explicitly requires foods with novel additives such as GM foods to be proven safe prior to marketing - and explained how the administrators at the Food and Drug Administration have callously violated the law by covering up the extensive warnings of their own scientists about the unique risks of GM foods and allowing them on the market without any testing. This paper deals win precautionary principles in production of genetically modified food. It outlines the need for precautionary principles and elements of precautionary principles applicable to genetically modified food. This paper spells out the need for long term environmental and health monitoring effects of production of genetically modified food. This paper traces out the benefits alongside the potential risks of genetically modified organisms; incentives for social and environmental responsibility and WTO international law principles in production and consumption of genetically modified food. This paper concludes with some interesting findings.*

INTRODUCTION

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 super weeds, non target 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. Ellstrand, Prentice and Hancock (1999) show that herbicide-resistance has been transferred from GMO crops to weeds. 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. Wolfenbarger and Phifer (2000) reported that, 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.

According to Warwick and Small (1999), the vulnerability of ecosystems to invasive species is exacerbated by human activity, such as clear cutting of forests and other changes

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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.

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. As per the study conducted by Losey, Raynor and Carter (1999) adverse effects may occur when monarch butterfly larvae ingest Bt corn pollen Sears *et al.* (2001) criticized for its lack of relevance to field conditions, and a recent 2-year field study suggests that the impact of Bt corn pollen on monarch butterfly populations is negligible. Saxena *et al.* (1999) reported that ladybird larvae, who contribute to controlling harmful insects, have been adversely affected 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.

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, as it is evident from the works of Burton, Rigby, Young and James (2001) and Noussair, Robin and Ruffieux (2002). Economic risks have been widely reported, as discussed by Harhoff, Régibeau and Rockett (2001). Such economic risks include the fear that the world's food supply increasingly could 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. Warwick and Meziani (2002) note that 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.

Adoption of GMO crops may reduce the genetic diversity in important food crops. Although the wild maize became extinct 2000 years ago, its genes have survived in a large number of local varieties in Mexico. This unique resource is now threatened by genetically modified corn crowding-out the local varieties, effectively contributing to their extinction and leading to an irreversible loss of genes. As per the report of Quist and Chapela (2001) 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.

ELEMENTS OF THE PRECAUTIONARY PRINCIPLE

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.

The EU guidelines (2003) require that measures based on the precautionary principle should be proportional to the chosen level of protection, non-discriminatory in their application, consistent with similar measures already taken, based on an examination of the potential benefits and costs of action or lack of action, 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. The precautionary principle has recently been taken into account in EU legislation on GMO. 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.

According to Natvig and Gasemyr (1996) and Natvig (1987) 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 the ethical problems are more apparent. In this case, risk aversion can be interpreted as an application of the precautionary principle.

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, for example genes from Arctic flounder in order to improve cold tolerance in potatoes. Crossing the species border, in contrast to traditional selective breeding, which 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. As per the works of Donaldson and May (1999), 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. Although, direct uptake of genetic material into human cells seems extremely unlikely. In this context, 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.

LONG-TERM ENVIRONMENTAL AND HEALTH MONITORING

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

GAPS IN SCIENTIFIC KNOWLEDGE

The study by Quist and Chapela (2001) on genetic contamination of corn landraces in Mexico 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. 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, and 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".

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.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 largescale 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. Klinger and Ellstrand (1999) note that the dynamics of gene flows from GMO crops to weeds will best be described by the use of commercial-sized plots.

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. Wesseler (2001) illustrated the trade-off between adoption of GM crops and use of herbicides and pesticides. 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 U.S. Department of Agriculture. For a toxicity study of Bt cotton the researcher 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, the researcher 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.

ALTERNATIVE OPTIONS

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.

Beetham *et al.* (1999) note that, a precautionary approach should also include a more rapid adoption of for example intragenetic techniques like chimeroplasty. Intra-genetic methods are likely to give more stable and predictable organisms than transgenics, as the recipient genome is not destabilized by insertions of foreign DNA, and no new promoter is added.

VALUES OF DIFFERENT SOCIAL GROUPS

In the context of GMO risk, different stakeholder groups have widely diverging opinions on risk perception. Attention should be given to differences in risk perception between experts and the public. 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. Public concern about GMO risk is also related to the market concentration. The failure of market prices to reflect full environmental and health costs 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.

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.

INDEPENDENCE OF INTERESTED PARTIES

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. According to Myhr and Traavik (2002) a problem for independent risk assessment is to obtain access to this information. Improved risk communication could contribute to develop strategies for sharing information.

INSTITUTIONAL OBSTACLES

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. Goldburg (1999) reported that 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. 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. 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. According to Eggers and Mackenzie (2000) a precautionary approach to biotechnology may challenge trade liberalization in agriculture.

It could be noted that “The fear remains, though, for the simple reason that no amount of information can remove. There 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.

The novelty of the genetic modification techniques and their applications, the long time horizon before health and environmental consequences can be assessed, the potentially

irreversible effects on biodiversity, the widely divergent risk perceptions of different stakeholder groups, the ethical concerns, and the 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.

INCENTIVES FOR SOCIAL AND ENVIRONMENTAL RESPONSIBILITY

A precautionary strategy includes risk assessment, risk management and 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 social and environmental responsibility. The challenge is to identify the performance of individual companies with respect to social and environmental 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 or ethical screening of companies may provide incentives for companies to improve their social and environmental responsibility in order to be included in these investment funds It is evident from the works of Angel and Rivoli (1997), Khanna and Anton (2002) and 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 ethical 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. 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 social and environmental responsibility. The existence of investment funds screening for ethical concerns may strengthen the

incentives for companies to improve their social and environmental practices, including their approach to environmental risk.

THE PRECAUTIONARY PRINCIPLE IN THE GMO DISPUTE BEFORE THE WTO

Once clarified the importance of the precautionary principle in the EC GMO legislation; the evolution of the principle within the international community; and its consideration in the multilateral trading system. The parties in the GMO dispute before the WTO, except Argentina, are the same ones than in the Hormones case. Not only are the countries the same but also their position on the legal nature of the precautionary principle has not changed. Furthermore, the US argues that this case presents similar aspects to the Hormones dispute and that the Panel should follow the case law therein and not deals with the legal nature of the precautionary principle. However, the US in its rebuttal submission to the EC first submission maintains that: "it strongly disagrees that "precaution" has become a rule of international law. In particular, the "precautionary principle" cannot be considered a general principle or norm of international law because it does not have a single, agreed formulation."

Therefore, the precautionary principle, according to the US position is not a principle of International Law because there is no consensus on its formulation. The US goes one step further and it maintains that, if the precautionary principle is not a general principle of International Law, it cannot be a rule of customary International Law. On the other hand, the EC disagrees completely with the Complainants position and it considers the precautionary principle to be a principle of International Law. Furthermore, it considers that this principle is the cornerstone of the Cartagena Protocol, which is the final result of the international community's GMO trade regulation efforts.

INTERNATIONAL LAW PRINCIPLES AND WTO AGREEMENTS

As in the Hormones case, the parties view on the legal nature of the precautionary principle is very distant. The US underlines, just as it did in the previous dispute, that it considers the definition of the precautionary principle status a "theoretical" issue. Art. 2.3 of the DSU open the door to the use of public international law rules of interpretation in the multilateral trading system. Treaty interpretation in international law is dealt with by the Vienna Convention on the Law of Treaties. The US considers that "for the purpose of interpreting the WTO Agreement in accordance with the principles in Article 31 (3) of the Vienna Convention" the Cartagena Protocol is not a rule of international law because the US is not a party thereof. However, even if it were a party, the US argues that the Protocol would still not be applicable to the dispute because, according to its position, it would not "change the rights and obligations under any existing international agreements."

On the other hand, the EC reaches a completely opposite conclusion. Firstly, it argues that the WTO does not live in clinical isolation from International Law. Secondly, it maintains the following: "There can be no doubt that the WTO agreements must be interpreted and

applied by reference to relevant norms of international law arising outside the WTO context, as reflected in international agreements and declarations."

The EC stresses that not only can the WTO be interpreted through International Law norms; but that provisions of the multilateral trading system can also be applied by reference to such norms. This would mean that the application of a WTO provision can be based on a norm outside of the multilateral trading system. The EC continues its reasoning maintaining that: the Protocol's provisions on precaution and risk assessment inform the meaning and effect of the relevant provisions in the WTO agreements.

This entails, according to the EC position, that the Cartagena Protocol provisions, which refer to the precautionary principle, can guide WTO members in the interpretation and in the application of the precautionary measures provided for in the SPS Agreement. In other words, the EC maintains that public international law norms can be used in order to interpret and to apply WTO provisions. The precautionary principle present in the Cartagena Protocol is a rule of international law. Hence, the SPS Agreement provisions, which refer to the precautionary principle, can be interpreted and applied in accordance with the Cartagena Protocol's related provisions.

CONCLUSION

The analysis of the scope of the dispute demonstrates the importance of the precautionary principle. The scope of the GMO dispute clearly shows the relevance of the precautionary principle in the controversy.

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. 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 ethical, social and environmental responsibility of industry may provide incentives for improved risk communication between industry and stakeholders. Applying criteria for ethical screening of companies in the biotechnology industry could provide.

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UN Doc. A/CONF.129/15, Vienna Convention on the Law of Treaties, Vienna, 23 May 1969, in force on January 27, 1980, printed in 25 ILM (1986), at 543; Art. 31.3:

WTO law as part of Public International Law has been underlined in previous WTO case law; see Doc. WT/DS2/AB/R Appellate Body Report: United States - Standards for Reformulated and Conventional Gasoline, 1996, p. 621.