Maize and Biodiversity: The Effects of Transgenic Maize in Mexico

Chapter 10
Managing Potential Risks and Enhancing Potential Benefits: Identification and Analysis of Management Tools and Policy Options

for the Article 13 Initative on
Maize and Biodiversity

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Abstract

The present chapter focuses on recommending a set of tools and policy options to manage potential risks and to enhance potential benefits derived from applications of gene modification (GM) of plants through modern biotechnology in maize (*Zea maize*). Specific questions to be addressed in the chapter—with particular reference to the situation in Mexico—include the following:

Rationale for applying GM technology in developing countries

To date, most of the developments in plant gene transfer technology and the different strategies to produce improved transgenic plant varieties have been driven by the market value of the species or the trait. These economical values are in turn mainly determined by their importance to agriculture and/or the economy in the developed world, particularly the United States and Western Europe. This is understandable because significant investments are needed to develop, field-test and commercialize new transgenic plant varieties. It may actually be in the rural and small farm where biotechnology could have a major impact on increased crop production, especially in areas of the world where yields are low due to a lack of technology. This may also contribute to the survival of the small farmer and all the cultural traditions that they represent.

Enhancing the potential benefits

Many of the biological pest problems that affect large-scale maize growers are shared by the smallholder using landraces. Among these are insect pests, rootworms and weeds (in many cases teosinte). Besides these, because the rural communities in many cases use marginal soils, there are specific problems such as drought, soil fertility and aluminum toxicity typical of acidic or basic soils. However, regardless of how many important genetic traits scientists think may be part of the solutions required by rural communities, the only way to ensure that the technology reaches these people is by including them in the research and development process from the very early stages, keeping in mind that the interests of smallholders are different from the large commercial growers. The technology needs to be understood by the people who are going to use it and they must agree to test and compare the new materials with whatever they are using. Benefits should be clear to them in the field rather than in the discourse.

Managing potential risks

Whatever the benefits are, qualitative or quantitative, of applying biotechnology to solve agricultural problems in the developing world, and particularly in the case of Mexico, one thing must be completely clear to all those involved—growers, regulators, scientists, NGOs, politicians, and the public: that the introduction of transgenes into an open pollinated crop, and in particular the maize landraces, which are subject to agricultural practices that promote extensive seed exchange, can inevitably lead to the widespread distribution of transgenes among these crops, maybe with the future impossibility of going back to the original state.

The identification of management tools to mitigate or avoid potential risks involved with the release of transgenic maize will vary according to the specific situation. In general, risk management options can be classified as avoiding, mitigating or tolerating risk. The chapter discusses the available options in two broad categories: (1) Biological tools available to avoid GMO risks associated with gene flow; and (2) Policies and regulations to manage GMO risks. The possible role of a moratorium or ban is not discussed at length in this chapter, but is mentioned in Chapters 1 and 5 of the volume. In addition, several fundamental management issues are not analyzed here because they would each warrant more extensive treatment. These include the role of informed consent, burden of proof, uncertainty, liability, relief, and scientific standards for risk and benefit analysis. These issues have been raised in other chapters in this volume.

Monitoring the release of GM crops

Effective management of potential risks depends very much on the efficiency of the monitoring system to detect any possible alterations at the very early stages. Most scientists and regulators agree with the idea of monitoring post-market releases of GMOs. However, they also agree that monitoring is a very difficult process. Monitoring should be sensitive and timely enough so that it can trigger an alarm if things go wrong, with sufficient notification to permit the application of measures designed to remediate and reverse whatever effect the GMOs have had. Nevertheless, it is impossible to monitor every single parameter that may be associated with a particular release of GMOs as this should take into account the crop, the sexually compatible species, agricultural practices, the environment, and biodiversity directly and indirectly associated with the crops, among others.

I. Rationale for applying GM technology in developing countries

The Green Revolution improved the diets and averted starvation for millions of people. However, the reliance of the new hybrid crops on agrochemicals, such as pesticides, fertilizers and herbicides to obtain the high yield, proved a very strong limitation for small growers many of whom lacked both the economic resources and adequate support by government programs. This eventually led to a widening gap between rich and poor maize farmers, and both groups and the corporate farms. This distinction was most dramatic in developing countries, where large and medium-size agro-industries developed around the new hybrids and technologies, while the resource-poor farmer was left to use low-yield landraces, which in many cases provided only enough grain to sustain the needs of the farmer and his family, leading to subsistence farming.

Nevertheless, it must be pointed out that most often it is the subsistence farmer who is the holder of tradition and ecological knowledge that is present in the “milpa” system; therefore there is an enormous challenge in trying to preserve this local knowledge, and foster its transfer to the new generations, while at the same time providing a better standard of living.

Local food availability and production will certainly be a major problem during the next decades, and population increase in the rural areas will have as consequences migration into the urban areas, immigration, and also for those that remain in the community, the search for new land to use, usually at the expense of the tropical forest which, in spite of the fact that these are invaluable with regard to their role in local, regional and global ecosystems and to the biodiversity contained within them, approximately 11 million hectares of forest are cleared every year by farmers searching for land. Indiscriminate conversion of tropical forest into agricultural land could have greater far-reaching ecological consequences than the use of GMOs or any other technology and, as a consequence, the world’s environment will also be at risk (Fedoroff and Cohen 1999, 5903-5907).

In the tropical and subtropical regions, as well as some other marginal areas, there are specific problems that limit food production, and which may be addressed by new technologies such as the genetic engineering of crops. Some of these problems, such as drought, are common to many countries and affect the productivity of a wide spectrum of crops. Therefore, transgenic strategies to solve these problems are urgently needed. Unfortunately not enough research is being currently undertaken to address these issues (Herrera-Estrella 1999, 5978-5981).

To date, most of the developments in plant gene-transfer technology and the different strategies to produce improved transgenic plant varieties have been driven by the commercial value of the species or the trait (see, for example, Nuffield Council on Bioethics 2003). These values are in turn mainly determined by the importance of the crop to agriculture and/or the economy in the developed world, particularly the US and Western Europe. This is understandable, because significant investments are needed to develop, field-test and commercialize new transgenic plant varieties. However, in order for biotechnology to have a direct impact on the food production of

hungry and impoverished farmers, this technology must be effectively transferred to the developing world and adapted to local crops and/or local varieties of the crops for which it was originally developed. It may actually be in the farms and rural small holder farming where biotechnology could have its major impact by increasing crop production, or nutritional value. This may also contribute to the survival of the small farmer and the cultural traditions that they represent.

It is not necessarily expected that private companies provide solutions to the problems of the rural and small farm, but through national programs aimed to applying this technology specifically to solve problems faced by these communities. Such programs already exist in countries such as Mexico and Brazil. In the case of Mexico, several institutions such as Cinvestav IPN (Irapuato Unit) and UNAM's Institute of Biotechnology have ongoing research programs aimed to the development of maize varieties resistant or tolerant to different biotic and abiotic stress conditions such as viral infections, drought, limiting P, and aluminum tolerance.

II. Applications for small-scale growers: Realizing the potential benefits

An expanding body of literature analyzes the emerging farm-level economic impacts of GM crops in developing countries. Huang *et al*. (2001), for example, estimate the impact of genetically modified, insect-resistant Bt cotton in China. This study indicates that Bt cotton in general has significant benefits for farmers, compared to conventional cotton. Based on surveys conducted in 1999 and 2000, the authors reported that, on average, growers using Bt cotton reduced pesticide use from 55 to 16 kg of formulated product per hectare. In addition, Bt cotton adopters reduced the number of insecticide sprays per crop from 20 to 7. In addition to a 70% pesticide reduction, the authors also noted the almost complete elimination of highly toxic organochlorines and organophoshates insecticides. Preliminary evidence in this study suggests that the use of Bt cotton resulted in significant positive effects on the environment and farmers' health.

Traxler *et al*. (2001) arrived at similar conclusions in their study on farm-level impact of Bt cotton in the Comarca Lagunera region in Mexico. The most notable changes observed were a reduction in pesticide use, an upward yield trend and a decrease in the cost of production. The result has been increased profitability — reaching a nearly US$ 600/ha net benefit during years of very high pest pressure, and equal profitability in low pest-pressure years — and an associated reduction in the risk associated with cotton production failures from insect infestations.

In the developing world, insect-resistant GM maize varieties, resistant to the European corn borer (*Ostrinia nubilalis*) have been approved for commercial planting in The Philippines and South Africa. Preliminary claims from The Philippines point to yield increases of 30 per cent and cost reductions of 20 per cent during the first year of introduction (Pew AgBiotech Buzz, 2003). More research is needed to document the impact of the release of GM maize in these countries, which will be highly relevant to Mexico.

There is a substantial difference between the application of biotechnology to the industrial grower and the small-scale grower in the rural communities. The industrial grower will most certainly be using hybrids or improved varieties, which at some point may offer the possibility to exert some control at the level of seed production and distribution. However, for the small grower in the rural communities, the target of the new technology would have to be the landraces, which, if adopted, would enter the traditional seed distribution scheme of each rural community, drastically reducing the possibility of having any kind of control regarding the production and distribution of seed and grain.

Besides the issues of seed control and distribution, most of the problems that affect the large-scale maize grower are shared by the small grower using landraces. Among these are insect pests, and weeds (in many cases teosinte). Besides these, because the rural communities in many cases use marginal soils, there are specific problems such as drought, soil fertility and aluminum

toxicity typical of acidic or basic soils, which are not offset by the chemical inputs, irrigation, and tools of the large-scale grower.

However, regardless of the number of important genetic traits that can be part of the solutions required by the rural communities, the most transparent and democratic way to ensure that the technology serves the needs of these people, is by including them in the research and development (R&D) process from the very early stages. The technology must be understood by the people who are going to use it, and they must agree to test and compare the new materials with whatever they are using. To achieve acceptance, benefits must be demonstrated to these farmers in the field.

Also, the rural farmers must also be aware of the potential impacts that biotechnology-derived varieties may have on other agricultural resources, their agricultural and commercial practices, and the environment. Rural communities must be included, and they must accept, to be part of a continuous effort with the government to monitor the possible effects of the new varieties, whether these effects are negative, positive or neutral, in order to be able to react on time to enhance the benefits or to mitigate or eliminate the hazards.

The most important aspect of the process is that the communities involved must evaluate the results of field trials, talk to different people and hear different opinions, hopefully coming from well informed sources, and then take the decision themselves regarding acceptance or rejection of the technology. If they accept the technology, they must be involved in the medium- and long-term monitoring efforts that must accompany such releases. Any efforts to impose new varieties without the full cooperation and participation of the communities will certainly face strong resistance and suspicion.

Schemes such as the one mentioned where the community plays a significant role in developing and/or testing new technology, have been implemented through the INIFAP-led program called “Agricultor-experimentador” (Grower-experimenter), in which communities have learned to conduct their own trials with their own improved varieties, record certain types of data and analyze it. Furthermore, cooperation from the rural communities will ensure that, at least to a certain extent, they can take responsibility for the outcome of the project.

III. Present day traits of industrial importance and gene flow

Traits such as insect resistance available as Bt-maize to growers in the US would most certainly be welcomed by farmers in Mexico, although in some cases modifications should be made to accommodate specific requirements. For instance, in the case of insect-resistant maize, achieved through the introduction of a gene or genes from *Bacillus thuringiensis* (Bt) coding for delta endotoxin(s), the effectiveness of the cry1A(b) protein, produced in the Bt crops used in the US against the European corn borer, *Ostrinia nubilalis*, has been challenged when directed against local pests such as the fall armyworm, *Spodoptera frugiperda*, or the stem-borers *Diatrea grandiosella* and *Diatrea saccharalis*.

Therefore the use of a different *cry* gene (such as *cryIF*) may be required to control local pests, with the added advantage that this protein may also have an effect on the widespread cutworm (*Agrotis ipsilon*) present in most maize-growing rural communities. Another important pest that is being now targeted by the agrobiotech companies are the corn rootworms (*Diabrotica sp*).

For large-scale farming, herbicide tolerant maize varieties may also be relevant. In all cases, however, and based on the experience Mexico has already had, if the GM varieties do not include modifications to eliminate or significantly reduce gene flow, these traits will find their way into non GM varieties, the landraces, and from these, possibly to the teosintes. Although for some authors the possibility of introgression of transgenes from commercial varieties of GM maize, into the wild

relatives is rather low and consider gene flow in these cases a low-risk issue (Stewart Jr, et al. 2003, 806-817), others argue that the issue merits much more attention (Gepts and Papa 2003, 89-103).

It needs to be emphasized that even if there is gene transfer to the landraces or the teosintes, the fate of the transgenes will depend very much on their value in the population. If the transgene confers a selective advantage it will be maintained, if the effect of the transgene is neutral or selected against, most likely it will disappear. However, controversy still exists on this issue and to some people this statement may be an oversimplification of a complex phenomenon.

Whatever the benefits are, qualitative or quantitative, of applying biotechnology to solve agricultural problems in the developing world, and particularly in the case of Mexico, one thing must be completely clear to all those involved—growers, regulators, scientists, NGOs, politicians, and the public—that the introduction of transgenes into an open pollinated crop, and in particular the maize landraces, which are subject to agricultural practices that promote extensive seed exchange, will inevitably lead to the widespread distribution of transgenes among these crops, maybe with the future impossibility of going back to the original state.

What is of more concern to most people that follow these issues, is the idea of using maize as a bioreactor to produce pharmaceutical proteins and peptides (Ma, et al. 2003, 794-805), mainly after the escape that occurred involving corn plants modified to produced pharmaceuticals released by ProdiGene (see, for example, Pew initiative on food and biotechnology[1]). In such cases, the biotechnology industry involved would certainly have to prove to the public, and not only to regulators, that they can contain gene flow from the plants they have engineered. Obviously, a simpler and much more effective approach would be not to use food crops as bioreactors altogether.

IV. Biosafety: Tools and policy options to manage potential risks

Issues — such as those related to gene flow — around the introduction of genetically modified organisms (GMOs) resulted in increased public scrutiny and media attention for these products. Debate about the potential risks of GMOs to the environment of human health spurred attention to "biosafety". Biosafety is associated with the safe use of GMOs and, more generally, with the introduction of non-indigenous species into natural or managed ecosystems. Biosafety regulation — the policies and procedures adopted to ensure the environmentally safe application of modern biotechnology — has been extensively discussed at various national and international fora. Much of the discussion has focused on developing guidelines, appropriate legal frameworks, and, at the international level, on developing a legally binding international biosafety protocol – the Cartagena Protocol on Biosafety.

Currently, biosafety reviews generally focus on a number of environmental issues associated with the release of transgenic crops. Two of these relate to the possibility that crops or their relatives may invade new territory, displace existing plant communities, or reduce species biodiversity. They may have added importance in regions that are centers of origin or diversity for the crop. *Weediness* — the potential for a crop to become established and to persist and spread into new habitats as a result of newly introduced genes — is an issue when there is scientific evidence that acquisition of the new genes is sufficient to convert a domesticated species into a successful weed. *Gene flow* — in which new genes are spread by normal outcrossing to wild or weedy relatives of the engineered crop — becomes an issue if the new trait(s) confers a fitness advantage and becomes stably introgressed into the recipient genome. *Toxicity* is an issue associated with human health concerns over allergenicity and the safety of biotechnology foods and potential negative effects on nontarget organisms, especially beneficial species. *Pest and pathogen effects* include a range of possible consequences such as the generation of novel viruses by molecular

[1] http://pewagbiotech.org/

exchange within a transgenic plant, or emergence of target pest populations resistant to an engineered control mechanism, such as the expression of B.t. toxins.

The identification of management tools to mitigate or avoid potential risks involved with the release of transgenic maize will vary according to the specific situation. It may be most desirable to avoid gene flow altogether by *biological means*, as discussed in Section V below. Biological barriers to gene flow would limit any potential risks associated with unintended effects, effects on nontarget organisms, human and animal health issues, and help avoid the consequences associated with transgene transfer to landraces and wild relatives. However, barriers to gene flow would certainly not be an option if improvement of landraces themselves is intended, possibly as a means to preserve them, since these are open-pollinated varieties that would be subject to very intense seed exchange management by the rural farmer. In this case, releases should be subject to risk management strategies and post-release monitoring (discussed in Sections VI and VII below), to try to identify possible effects caused by the transgenes. If a negative effect has been identified with certainty, then mitigation or remediation measures should be implemented to try to stop the negative effects and if possible, bring the system to its original state.

To prepare risk management strategies, the possible hazards must be well defined. To begin, we must answer questions such as:

- What effects may occur?
- How adverse are the effects?
- How likely is it that the effects will occur?
- When and where do the effects occur?

The above questions are discussed in detail in previous chapters of this volume.

At the present moment, and with the available traits in GM maize — insect resistance and herbicide tolerance — the answer to those questions may be determined without much difficulty. However, if any of the anticipated effects were to occur, the situation would merit an immediate response aimed to reducing or eliminating the cause and the effects (EPA 1998).

A non-biological method to avoid risk or harm that has bee proposed, most notably by NGOs that oppose this technology, is the implementation of moratoria or banning the use or importation of GM maize. These are legitimate options that, however, within the present context of Mexican agriculture would not seem viable. Mexico imports approximately 6 million tons of maize a year from the U.S., mainly because it cannot fulfill the needs of different sectors of industry such as those producing animal feed, although the country is largely self sufficient in production of white maize for human consumption.

It has been estimated that requiring the U.S. to segregate the maize that Mexico imports would substantially increase its price, and drastically affect different sectors of the economy. However, to clearly identify the extent of such assumed price increase, a detailed analysis of such costs would have to be undertaken. Furthermore, a ban or moratorium would not necessarily ensure that GM maize would not enter the country. Migrant workers can introduce modified seeds from the northern and southern borders, since it is known that Guatemala and Honduras have been testing GM varieties of white maize.

Furthermore, a moratorium could seriously compromise the acquisition of expertise in the development of crops through biotechnology, which would have an important effect on the rural economies. A possible solution for maize could be the imposition of a moratorium for the unregulated release of commercial GM-maize, but not for conducting research aimed at answering those biosafety issues whose answers are required to conduct proper risk assessments.

V. Biological tools available to mitigate GMO risks associated to gene flow

For the movement of genes two mechanisms are responsible: seed dispersal and pollen flow. Seed dispersal is usually considered a secondary mechanism that is rather unintentional, such as mechanical dispersion during harvest, transportation, or planting. However, in some cases, particularly in the case of the maize landraces within the rural context, seed exchange may be more important than pollen flow as a mechanism of gene dispersal (Sánchez-González 2002). This is best exemplified by the fact that, most likely, the transgenes found in the landraces of Oaxaca (Quist and Chapela 2001, 541-543) were the product not of pollen flow, but the use of seed that somehow was brought into the rural communities (Alvarez-Morales 2003, 47-50).

Transgene movement through pollen is dependent on many factors, which in turn, depend on the particular crop. Some of these variables are, for instance: amount of pollen produced, longevity of pollen, dispersal (wind or insects), receptor plant density, dormancy/rehydration of pollen, distance to receptor plants and genetic barriers (incompatibility).

Biological gene containment may be applied to most commercial varieties of GM crops in the near future, though perhaps only to those that will be developed to produce pharmaceuticals, or other high value traits, or those that would potentially harm the environment if the transgenes were introgressed into sexually compatible species. Nevertheless, gene containment could not be used in cases where open pollinated varieties, such as the maize landraces, are themselves the transgenic products which have been modified to offer the farmer an incentive for growing and maintaining such varieties.

Natural gene flow can be altered by interfering with flower pollination, fertilization, and/or fruit development. Several methods to disrupt gene flow have been proposed although most of them are still being developed (Daniell 2002, 581-586; Lu 2003, 3-8). The main alternatives will be briefly described below, since an in-depth discussion is beyond the purpose of this chapter.

Furthermore, in most cases, the advantages or disadvantages of the techniques mentioned have not been completely evaluated since most of them have not been field-tested and are being developed using model systems. For recent technical information see NRC 2004

Maternal inheritance: Maternal inheritance relies on cytoplasmic organelles--chloroplasts in plants, and mitochondria in animals. Since only the male nucleus is allowed to penetrate the ovule during fertilization, plastids are maternally inherited in the majority of angiosperms and most crops. Maternal inheritance of transgenes is achieved by genetically engineering the chloroplast. There are reports, however, of the inheritance of chloroplast traits in tobacco (0.1-0.5%) and a few other higher plants. This strategy has already been tested in the field, (tobacco, potato and tomato). Some of the advantages of this approach are: tissue specificity (photosynthetic tissues only), no positional effect on gene expression or gene silencing, no need for antibiotic selectable markers, and no random disturbance of genomic sequences.

Male sterility: This is achieved by the use of mutations that interfere with the development and/or function of cells (tapetal cels) required for the formation of functional pollen. This system is being used in GM-rapeseed in Canada and Europe (Barstar Barnase system).

Seed sterility: This is the basis for the “terminator technology,” which is essentially a seed-suicide mechanism that is triggered by a specific external stimulus, such as applicagtion of an antibiotic, a temperature change or osmotic shock.

Cleistogamy and apomixis: In certain plants, self-pollination occurs before the flower opens (cleistogamy), and it has been proposed that engineering such trait into GM crops would minimize the risk of pollen flow. Another option is to produce seeds without fertilization (apomixis), which is a process that occurs naturally in a few plant species. In principle, this method could be used to produce GM plants with reduced risk of gene transfer without compromising seed or fruit production.

Transgenic mitigation: This is achieved by the incorporation of a gene, such as a gene affecting seed dormancy that is neutral to the crop, but deleterious for a weed, and therefore compromises the fitness of the weed. Such a gene requires to be engineered in tandem with the transgene conferring the desired trait to the crop, such that segregation (separation of the genes during the formation of pollen or ovules) would be a highly rare event.

VI. Policy tools: Biosafety regulations and procedures

In addition to the available and emerging tools for biological confinement, national biosafety systems serve as mechanisms to ensure the safe use of biotechnology products that do not impose unacceptable risk to human health or the environment. Each country's ability to conduct appropriate regulatory reviews without imposing unintended constraints to technology transfer is thus a key factor in determining whether or not the potential benefits of new GM products reach end users. Sections below introduce the main international requirements and standards that countries will have to comply with in managing the potential risks posed by GMOs, and how these can be implemented through national biosafety systems.

International instruments for dealing with GMOs

In January 2000, over 130 governments reached agreement on the Cartagena Protocol on Biosafety (CPB), which will regulate the safe transfer, handling and use of *living modified organisms* (LMOs)[2] resulting from modern biotechnology. The ultimate goal of the agreement is to ensure an adequate level of protection to potential adverse effects from LMOs on the conservation and sustainable use of biological diversity, taking also into account their possible risks to human health. To date, over 80 countries have ratified, or acceded to the CPB, including Mexico. The protocol entered into force on September 11, 2003, 90 days after receipt of the 50th instrument of ratification.

The two cornerstones of the CPB are the concepts of *Advance Informed Agreement* (AIA) and the *Precautionary Principle*. AIA enables an importing country to subject all first imports of LMOs to risk assessment before taking a final decision on import. The Protocol provides details on the whole process of notification, acknowledgment and decision, which is supposed to be completed in 270 days. Detailed information will have to be provided by the importer on notification and LMOs should be clearly identified by accompanying documentation. However, the Protocol's AIA procedure does not apply to certain categories of LMOs: LMOs in transit; LMOs destined for contained use; LMOs intended for direct use as food or feed or for processing. It should be noted that, while the Protocol's AIA procedure does not apply to certain categories of LMOs, Parties have the right to regulate the importation on the basis of domestic legislation.

In addition, the precautionary principle, as applied in article 11 of the Protocol, asserts that

> *Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of that living modified organism intended for direct use as food or feed, or for processing, in order to avoid or minimize such potential adverse effects.*

In plain terms, including this principle allows countries to block imports of seeds of genetically modified plant varieties on a precautionary basis even in the absence of sufficient

[2] Living modified organisms (LMOs) are organisms whose genetic material has been altered through modern biotechnology and which are capable of propagation.

scientific evidence of their harmfulness. The protocol does not apply to processed foods derived from LMOs. For bulk commodities containing an LMO component, documentation will have to state that the shipment "may contain" LMOs and that the contents of the shipment are not intended for planting.

Consequently, the most immediate impact of the protocol will be on trade (import and export) of seeds intended for planting. Before a GM seed can be shipped for the first time, the importing country must decide whether or not to approve it. If the seeds are approved for import, they will need documentation provided by the exporter specifying their identity and traits. Under the protocol, a 2-year process, starting on the date of its entry into force, was established through which further documentation requirements will be determined.

In addition, the CPB makes clear that Parties to the Protocol must develop or have access to "*the necessary capacities to act on and respond to their rights and obligations*". The Protocol provides considerable flexibility with respect to how importing countries may meet their obligations with respect to risk assessment and LMO decision-making, and the implementation of these decisions. As stated in Article 16, which deals with Risk Management, each Party has an obligation to "*establish and maintain appropriate mechanisms, measures and strategies to regulate manage and control risks identified in the risk assessment provisions.*" Parties have agreed to carry out these risk management functions under the CPB, but how a country fulfills this obligation is not clarified and only loosely defined in an Annex to the Protocol. It is also recognized that developing country Parties and Parties with economies in transition will require assistance to achieve this, including financial support.

Parties to the Protocol will need to carefully interpret and implement the Protocol's provision in line with existing trade agreements that may affect GMOs, such as those governed by the World Trade Organization (WTO). Within the WTO, biosafety of GMOs falls mainly under the Agreement on Sanitary and Phytosanitary Standards (SPS). The SPS Agreement is very important in reference to LMOs/GMOs as it deals with laws and regulations that concern food and food safety, and animal and plant health. SPS allows WTO member countries, including Mexico, to take restrictive measures to protect a country from food safety risks and invasive species risks from GMOs. SPS requires that such measures be based on scientific risk assessment, and that they do not arbitrarily of unjustifiably discriminate between countries. The agreement allows for *provisional* precautionary measures in cases where scientific information is insufficient. They would be obliged to actively seek additional information for a more comprehensive risk assessment, and to review the provisional measure within a reasonable period. This approach could be in conflict with the more "generous" interpretation of the precautionary approach in the CPB. In addition to SPS, the WTO Agreement on Technical Barriers to Trade (TBT) may apply to GMO labeling. The TBT Agreement is intended to ensure that WTO members do not use technical regulations and standards as disguised measures to protect domestic industries from foreign competition. The TBT Agreement allows governments to adopt technical regulations if they serve to protect health or the environment. Such measures should not be unnecessary trade-restrictive, and not discriminatory.

How GMOs and associated trade disputes are handled by WTO is not yet entirely clear. This may be partially clarified through the WTO dispute settlement procedure initiated by the USA, Canada and Argentina, with the aim to lift the European Union's moratorium on the release of GM products.

The SPS and TBT Agreements encourage the use of international scientific standards. The SPS Agreement recognizes the standards developed by 3 relevant organizations: the FAO/WHO Codex Alimentarius Commission[3], the *Office international des epizooties* (OIE – the World Organisation for Animal Health)[4] and the International Plant Protection Convention (IPPC)[5]. These

[3] http://www.codexalimentarius.net/biotech.stm
[4] http://www.oie.int/eng/en_index.htm
[5] http://www.ippc.int/

standard-setting bodies all have their working groups on safety aspects of GMOs and GM foods, and the resulting standards, recommendations and guidelines may become the basis for WTO Members' sanitary and phytosanitary measures or technical regulations.

Developing and implementing national biosafety systems

National, regional, and international agencies have recognized that successful implementation of international agreements and standards, as outlined above, is contingent on the development of national biosafety capacity. Over the past two decades, national biosafety frameworks, guidelines and regulatory systems have often been implemented on a "piece-by-piece" basis in response to the demands or urgent needs of the moment. Ideally, however, a biosafety system would be developed from a comprehensive plan. The design and implementation of any national biosafety system involves balancing public policy goals with economic, political, and technical realities. However building such a system and making it operational is complicated by the fact that there is no single best approach or standard that reflects national environmental, cultural, political, financial, and scientific heterogeneity.

Recent ISNAR studies (McLean *et al*. 2002; Traynor and Macharia 2003) apply a five-element framework for national biosafety system implementation:

- National policies, strategies and research agendas regarding biotechnology and biosafety;
- National inventory and evaluation of priorities, agricultural policies, existing regulatory regimes, and national scientific and technical means;
- The knowledge, skills and capacity base to develop and implement a biosafety system;
- Development of regulations; and,
- Implementation of regulations—the establishment of appropriate mechanisms for risk assessment, risk management, and risk communication.

(1) National policies and strategies

Ideally, the evolution of a national biosafety system begins by elaborating a national policy consistent with other national policy objectives related to food, agriculture, the environment, and sustainable development. This would form the basis for the development of specific legislation and/or regulations, leading finally to the design and implementation of the elements necessary for risk analysis, inspection, monitoring and enforcement. This ideal progression is rarely the case. In reality, portions of these activities are often completed simultaneously, usually in an attempt to meet short-term needs. Even some countries with long established regulatory systems have yet to complete a comprehensive analysis of human and scientific capacity or clearly articulate an overarching national policy on biotechnology and biosafety.

The importance of a national strategy cannot be overstated as it provides a set of principles to guide subsequent development and implementation of a biosafety system and regulations. Examples include the extent to which social, ethical, and economic factors should be considered, the social acceptability of biotechnology and its products, and linkages with other national policies on food, agriculture, and economic development. From the perspective of biosafety, these policies can define guiding principles and co-coordinating structures for the implementation of biosafety guidelines or regulations.

(2) National inventory and evaluation

A nation's political and legal environment, including societal philosophy, form of government (e.g. monarchy, republic, tribal), legal framework (e.g. constitution, courts), and domestic stability, should contribute to framing the scope and content of a national biosafety system. An inventory and evaluation of national priorities, agricultural policies, existing regulatory regimes, and national scientific and technical means is ideally a prerequisite to the development and implementation of

biosafety-related policies and regulations. This national appraisal provides a means to identify and characterize available resources and regulatory infrastructures, assess their adequacy for supporting a biosafety system, and identify gaps where capacities need to be strengthened.

As previously mentioned, it is rare for a country to review all of the items above prior to actually managing/regulating GMOs. More commonly, and perhaps more practically, countries may evaluate their national capacities on a step-wise basis as dictated by domestic needs: the capability to manage GMOs in contained facilities, followed by confined small and large scale field trials, and finally, the unconfined release of a GMO.

(3) Scientific knowledge, skills and capacity base

The human resource environment that both enables and limits biosafety implementation is shaped by the scope and quality of: competency in the disciplines of biological science; expertise in information acquisition, communications, and management; and, experience in critical analysis and decision-making. A thin, weak, or limited knowledge and skills base tends to produce regulations that are highly protective at the expense of innovation, poorly defined or inconsistent, comparatively rigid, and/or narrowly interpreted. A deep and broad knowledge, skills and capacity base tends to foster more latitude in regulatory development and more flexibility in regulatory implementation (e.g., possibility to allow fast track approvals in some cases, greater "comfort" in accepting externally derived data, and ability to identify unique data needs).

Building a strong base of scientific knowledge in support of the regulatory system, and development of core competencies in biotechnology product evaluation, are fundamental to any national biosafety system. These activities allow an improved scientific basis for assessments of potential risks and/or benefits, and they strengthen the scientific capabilities for risk management, inspection, and monitoring. Limitations in national scientific and technical capacity, identified during the inventory and evaluation, can be addressed through a co-coordinated approach. This would aim to enhance domestic expertise through training but also relies on sub-regional, regional, and/or international co-operation in performing risk assessments, the use of outside experts, and the international academic community.

Maintaining access to scientific expertise is an issue for developed as well as developing countries. Structurally, different approaches to securing scientific advice for decision-making can be taken. In considering the risk assessment of biotechnology products, some countries have implemented a system of expert advisory committees, while others have relied primarily on scientists and professionals working within government agencies. In the latter approach, the mandate for risk assessment may be vested within a single agency exclusively tasked with regulating products of biotechnology (e.g., a gene technology regulator) or it may be distributed between agencies in accordance with their existing responsibilities (e.g., departments of health, agriculture and/or environment).

(4) Development of regulations

Decisions on an appropriate regulatory structure and the legal and political means by which such a structure can be implemented should be informed by the national inventory and evaluation, and through extensive consultation with stakeholders, including the public. Among the key considerations in developing a regulatory framework are: the legislative framework; regulatory "triggers" — i.e., the criteria that individually or in combination make a product subject to regulatory review; transparency and public involvement in the policy making and regulatory decision making processes; and approaches to risk assessment and risk management.

In countries with established biosafety programs, regulatory oversight of GMOs generally began with non-binding, voluntary guidelines. The designated authorities developed information

guidelines and technology developers abided by these, and there is no evidence that the management of GMOs under voluntary regimes has compromised environmental safety. The benefits of implementing voluntary guidelines include the speed by which the guidelines can be put in place and the flexibility they can afford as revisions to incorporate new information requirements can be adopted without delay. However, in the absence of a legal instrument, the public may not have confidence that the government is adequately regulating these products, or that developers are complying with voluntary guidelines. Additionally, enforcement powers may be limited in a voluntary system.

Countries electing to develop a mandatory biosafety system have two choices for establishing legally binding regulations: (1) develop a new act and regulations to specifically address GMOs; or (2) regulate GMOs under the auspices of existing legal instruments such as acts, regulations, ministerial or presidential decrees. The advantage of the former is that an act can be developed to specifically address the product or process to be regulated; it can provide flexibility so that new technical advances can also be captured without significant regulatory amendment; and, it can be perceived by the public as a positive response to addressing concerns about the safety of GMOs. The disadvantages of developing a new act include the extended time it can take to have it passed into law; and, the fact that it may result in the regulation of GMOs in perpetuity so that even if a history of safe use of a specific genetic element is established, GMOs with this element will still be singled out for exceptional regulatory oversight.

Scientific risk assessment is the cornerstone of biosafety regulatory systems and public policy decisions related to the safety and acceptability of GMOs. Even in countries that have incorporated structures and mechanisms for including social, economic or ethical issues in the risk analysis process, a strong scientific capacity and knowledge base is viewed as key to identifying hazards, and assessing their impacts and likelihood. There may be cases where other factors are essential for making final decisions. However, these considerations should be separate from the risk assessment process as such. There is no consensus on how best to reflect socio-economic concerns within a regulatory system. Quantifiable economic impacts may be considered a justifiable component of the product approval process. In such cases, the creation of a regulatory structure that allows separation of the scientific risk assessment and regulatory decision-making processes is advisable. Such a tiered approach provides a system in which the regulatory decision is “informed” both by the scientific risk assessment and by other considerations.

(5) Implementation of Regulations

Generally, the central issues around the implementation of biosafety regulations involve the establishment of appropriate mechanisms for risk assessment, risk management, and risk communication, while managing within existing financial, technical, and human resource constraints. Decisions made during the implementation phase impact directly on the economic costs associated with assessing and mitigating risks and ensuring compliance. Other important considerations include opportunities for international co-operation at a technical level (e.g., sharing human and scientific resources and expertise), and implementing programs for monitoring and inspection.

Implicit in the Cartagena Protocol on Biosafety is the assumption that sub-regional cooperation in information sharing and harmonizing legal and regulatory systems is crucial for effective management of transfer of LMOs across borders. Harmonization can be considered to occur at three fronts: authority, risk analysis, and administration. Harmonization of **authority** is the most difficult to achieve and the delegation of national authority to a regional or sub-regional body rarely, if ever, occurs. Because of the diversity of legal systems, the development of model legislation or regulations is problematic. A more reasonable goal is the development of a checklist of essential elements that can be incorporated into national legal systems in different ways.

The harmonization of **risk analysis** principles, information requirements, and standards of assessment can be instrumental to maximizing the use of institutional, financial, technical and human resources within a region. For small countries, where the national science community is small, the ability to capitalize on external expertise and information may be crucial to their ability to implement a national biosafety system.

Harmonization around **administrative functions** concerns procedures for the implementation of norms, rules, and standards. It includes things like record keeping, communication, information exchange, and notification systems.

Internationally, no country has implemented a systematic process of post-market (or post-approval) **monitoring** or surveillance for GMOs. Many countries recognize the need for long-term monitoring of the cumulative effects, including benefits, of GMOs. However, there are significant complexities in implementing such programs, as discussed in section VI below.

Finally, the process used to develop and implement a national biosafety system should be transparent and the degree to which the public and/or stakeholder or special interest groups should be involved as legislation, regulations or guidelines are being developed must be considered. Additionally, decisions must be made as to the degree of transparency and public involvement that the system will afford after it is implemented, e.g., should the public be consulted or notified before or after a regulatory decision or policy change is made. It is advisable for governments to proactively support a development process that is open, and permits for at least some form of public engagement such as a period of consultation or review prior to the promulgation of acts and regulations or the publishing of guidelines.

The national biosafety system in Mexico

Mexico has an extensive track record in terms of developing and implementing a national biosafety system. The first GMO field trials were approved in the late 1980s / early 1990s, following applications from the national public R&D sector and private companies. As discussed in this section, the national biosafety system has gradually evolved from non-statutory decision-making, to issuing regulations under existing laws, to having a central, comprehensive biosafety law.

Research institutes in Mexico have built up a rich experience in modern biotechnology and genetic modification, dating back to the early 1980s. Priorities for biotechnology research are usually identified by the *Consejo Nacional de Ciencia y Tecnología* (CONACYT) and supported through national programs for scientific research coordinated by CONACYT. The *Centro de Investigación y de Estudios Avanzados* (CINVESTAV) was among the pioneer research institutes in Latin America to experiment with plant genetic modification. As early as 1988, field trials for GM plants were approved, involving a delayed-ripening tomato variety. At that time, there were no biosafety guidelines or regulations in place.

Until recently, biosafety was governed under a diverse set of laws, regulations and official standards that affect plant and animal health, human health and environmental protection (CIBIOGEM 2002). The primary legal mechanism for plant biosafety management was the *Official Mexican Standard NOM-056-FITO-1995*, which sets out the phytosanitary requirements for the transportation within Mexico and the import of GMOs, and for the conduct of field tests. It does not deal with large-scale, commercial releases of GM plant varieties, or with the likely effects on human and animal health. The Standard is now administered by the “Dirección General de Inocuidad Agroalimentaria, Acuicola y Pesquera” (DGIAAP) under the “Secretaria de Agricultura, Ganadería, Desarrollo Rural, Pesca y Alimentación (SAGARPA). The Directorate bases its decisions to grant permits on the opinion of the Specialized Subcommittee for Agriculture, set up in 1989 as a consulting body to the General Directorate of Plant Health (DGSV) known as the National Biosafety Committee on Agriculture (CNBA). In addition, the Intersecretarial Commission for Biosafety and Genetically Modified Organisms (CIBIOGEM) was established in 1999 to oversee and develop GMO-related policies.

To date, under NOM-056-FITO-1995, more than 280 release permits have been issued, including for transgenic maize, tomatoes, cotton, soybean and squash. Traits most widely tested include insect resistance, herbicide tolerance and virus resistance.

With regard to full-scale, commercial releases, the following products have been approved for processing and consumption by the Secretariat of Health: herbicide-tolerant soybean, insect-resistant cotton, insect-resistant potato, herbicide-tolerant canola and insect- and herbicide-tolerant maize. However, these cannot be grown in Mexico as they have not been approved by the Secretariat of Agriculture for commercial production. The only instance of approval by both the Secretariat of Agriculture and the Secretariat of Health was the case of the delayed-ripening tomatoes ("Flavr Savr") of Calgene and Zeneca, which are not longer in use. These tomatoes were "deregulated" before the implementation of the NOM-056-FITO. At the moment, the largest area being planted with GMOs corresponds to GM-cotton, which is grown under the NOM-056-FITO because it is subject to monitoring of the insect population to detect any Bt-resistant insects.

Regarding food safety, the Mexican *Health Act* requires all biotechnology products or their derivatives, which are intended for human consumption, to be notified to the Secretariat of Health. In March 2000, the Mexican Senate passed an addition to Article 282 of the *Health Act* that would require that all genetically modified or transgenic foods be labeled with the phrase "Transgenic Food" or "Food made from transgenic product" and, in both cases, should indicate the gene that was added.

The Mexican government recently worked toward having 1 central biosafety law, which administers confined use and full environmental release of GMOs in the country. The new law also deals with labeling and GMO identification requirements, and identifies "restricted zones" for GMO releases, referred to as *"centers of origin and genetic diversity"* and *"protected nature areas*". In April 2003, the Mexican Senate passed this new legislation, designed to implement the Cartagena Protocol on Biosafety. The legislation allows for the limited release of GM crops, requiring GM seeds to be declared "risk-free" before they are released for human consumption or commercial planting. The legislation also requires GM products to be labeled in an effort to ensure consumer information on nutritional characteristics, composition and advantages of GM crops. To this end, the legislation sets out general criteria that the labels must be truthful, objective, clear, understandable and useful for the consumer. The law is still under review by the Chamber of Deputies (Cámara de Diputados) and it is expected to be approved by September 2004.

VII. Key implementation challenge: Monitoring the release of GM crops

As mentioned in Section V above, at the moment there are very few examples of GM crops which include a mechanism to contain the transgenes they harbor. It may be possible that once these mechanisms are fully developed and tested, they would be required for most GM crops intended to be released in areas where they would co-exist with sexually compatible species, whether wild relatives or landraces.

Exceptions to this requirement would be necessary for landraces modified to make them more attractive to the grower, with special adaptations to the environment or with higher nutritional value, and thus less likely to be abandoned in favor of hybrids crops. In these cases it would be expected that the modified landraces would be subjected to the same patterns of seed exchange management found with their non-GM counterparts.

It must be mentioned that some people see no reason to limit pollen dispersal because they reason that this measure would only be necessary if the transgene is assumed to be harmful, in which case it should not be allowed to be released at all. In such cases one cannot disagree, however, it may also be desirable to include mechanisms that would limit pollen flow in cases where the transgene is not expected to be harmful, but where monitoring would be highly desirable. In these cases, having a limitation on pollen flow may reduce the burden of monitoring to ensuring

that the containment mechanisms are working, to identify any unintended effect of the GM-crop, and to monitor the behavior of specific nontarget populations.

However, in the case of the currently available GM crops, and the possibility of eventually releasing genetically modified open pollinated landraces, the monitoring process becomes essential, but at the same time more difficult since many different issues and parameters should then be taken into consideration. These are discussed below.

What should be monitored? – Determining the end-points

Because short-term experiments and the general characterization of plant traits may not pick up all environmental effects of transgenic crop plants, it becomes important to conduct post-market monitoring to determine if the pre-commercialization testing protocols adequately assessed risks. This is especially important in areas of high diversity such as Mexico, where ecological predictions are difficult to make. It also is important to set up long-term, monitoring programs to record trends in predicted effects, and to detect unintended effects that were not predicted by pre-commercialization testing. Also, post-market monitoring or validation programs are an essential part of any quality control program (NRC 2003). However, it is recognized also that monitoring is a very difficult process. Monitoring should be very sensitive so that it can trigger an alarm if deviations from base level conditions are detected, with sufficient advance as to permit the application of measures designed to remediate and reverse whatever effect the GMOs have had. Nevertheless, it is impossible to monitor every single parameter that may be associated to a particular release of GMOs as this should take into account the crop, the sexually compatible species, agricultural practices, the environment, biodiversity directly and indirectly associated to the crops, among others.

Sensitivity is usually a matter of how well the endpoint or objects of monitoring are chosen, that is, what is the particular situation or organism that needs to be carefully monitored, which will reliably indicate a potential problem. The end points should be chosen on a case by case basis. Because a single crop such as Bt maize can potentially be used in such a wide variety of ecosystems, generic monitoring rules cannot be applied. However, there are guidelines being developed regarding the selection of the end-points, and since the most widespread GMOs carry phenotypes of insect resistance or herbicide tolerance, these traits have been the subject of such discussions (Marvier et al. 1999, 109-125; Schmitz et al. 2003, 117-132, NRC 2003).

A very valuable source of information that should not be forgotten, both when selecting the endpoints, and when analyzing data, is the anecdotal knowledge accumulated by the local growers, farmers and people living around the sites chosen for monitoring. These people usually know their crops and associated biodiversity very well, and have anecdotal records regarding periodic changes to the crop and/or environment, as well as drastic and/or unusual situations that have occurred. This level of familiarity with the local conditions may be useful in discriminating a situation created by the presence of a GMO.

Where should monitoring be conducted and for how long?

The choice of place or places where monitoring should be conducted will usually be determined by the selection of the endpoint organism, favoring those places where even small disturbances to the end-point have a chance of being easily recognized. Also, the decision as to the duration of monitoring would be influenced by the choice of endpoint. However, in this case it is very important to remember that monitoring should be an iterative process, and that the information collected at any stage, should be analyzed and used to re-evaluate the whole monitoring process, which, if necessary, can be modified according to the new findings.

It may be possible to establish certain parameters regarding the duration of mandatory monitoring. Commercial releases of GM varieties for which there are sexually compatible species, could be granted only “provisional” permits pending revision of monitoring data during specific

periods of time (maybe 3, 5 or 10 years) depending on the trait, final use of product, presence of gene flow molecular safeguards, intended place of release, size of release area, and any other relevant parameter.

Monitoring data should then be accumulated, updated and revised every year, and the monitoring process modified if necessary. At the end of the established period, a decision should be made based on the analysis of the data obtained through the monitoring process. This decision may be to declare the product safe, to require further testing or monitoring, or to stop further use of the product.

The fulfillment of the mandatory period of monitoring should not prevent any long term monitoring effort or project to be conducted by any interested party, who should then provide any significant finding to the biosafety authorities, Upon analysis of the data provided, the Biosafety authorities may request to re-examine any particular case.

Who should monitor?

If a monitoring program is required as a condition for release of a GM variety, and to ensure the credibility of such monitoring, the biosafety authorities requesting the implementation of the program should suggest or indicate specific institutions, laboratories, or particular researchers, to form the team in charge of the monitoring process. The entity requesting the release (the applicant), which may be a company, institution, organization, etc., should also appoint their own researcher to this effort.

Another possibility is for the applicant to propose a research team to conduct monitoring, which should include participants from recognized institutions such as INIFAP, UNAM, CINVESTAV, CONABIO, the agricultural universities, among many others. This proposal should be accepted by the biosafety authorities. The costs of monitoring should be borne by the applicant.

If the GM-variety to be released is for the use of large-scale industrial grower, those involved in their use and preferably, the local association of growers should also be included in the monitoring process. In the case of GM-varieties intended to be used by small rural communities, these should also actively participate in the process.

VIII. Managing (potential) risks

Effective management of potential risks depends very much on the efficiency of the monitoring system to detect any possible alterations at the very early stages. If detection occurs at a late stage, dispersal of the transgene may be significant thus reducing the possibility of complete removal, significantly delaying the process, and increasing the associated costs.

If the cause of the problem is associated with transgenes from commercial materials these varieties should be discontinued immediately, and efforts to reverse whatever negative impact occurred should be immediately implemented. In many cases reversal may actually be assisted by growing in the affected areas conventional varieties of the same crop. Monitoring should continue to assess the efficacy of whatever remediation measures where implemented.

In the case of transgenes from a commercial GM crop being transferred to a landrace, remediation would be even more difficult and would depend very much on how early the situation was identified. At an early stage it may be possible to remediate the situation, since transgene dispersal may have been limited. However, if the situation was undetected for a long time, dispersal may have occurred beyond any practical short-term strategies for remediation. In such cases, aggressive programs directed to the removal of GM seed from the affected area must be implemented. In this case it may be possible to exchange from the local growers their seeds with GM-free seed. Similar programs to introduce improved or hybrid seed into some communities have

been known to be successful. Again, monitoring should continue to assess the efficacy of whatever remediation measures where implemented.

If the problem occurred as a consequence of the deliberate release of a GM landrace, as part of a project with participation from the community, the strategy should also be the removal of GM seed from the system through an exchange program. In this case, if the community has been involved in all stages of the program, cooperation from them would significantly increase the chances that remediation would be successful.

Regarding the effectiveness of remediation measures, there are those who believe that the complete elimination of an escaped transgene will most likely be impossible. As an example, they refer to the accidental commingling of Starlink corn with the general food supply of the United States which precipitated a very expensive and concerted effort to recover all of the Starlink seed. Yet, three years after this massive recall, the Starlink transgene still persists at detectable levels in US maize supplies. Nevertheless, as mentioned in section III, other opinion is that what will determine the fate of the transgene in a population is whether or not the transgene confers a selective advantage to the population.

Therefore, it may be possible to expect that in some cases, the situation would go back to its original state by the complete substitution of GM crops by the conventional equivalent varieties and thus removing the source of the transgene. If additional measures are required, these would have to be devised according to the data obtained through the monitoring of the system. Further monitoring should be established to ensure that remediation measures have worked properly and the system has gone back to its original state.

Regardless of whatever measures are taken to minimize the risks associated with the deliberate introduction of GM maize varieties, efforts must be made to ensure that there will always be well defined and protected areas where no introductions of transgenic varieties will be allowed. These areas should be dedicated to *in situ* preservation of teosinte and some of the maize landraces.

These areas may also be required to ensure that growers of organic landraces or GM-free maize would be able to comply with the requirements established by their market. In such case, a system must be implemented to ensure that no GM material enters these protected areas.

IX. Conclusions and recommendations

Based on the discussion above, the authors put forward the following conclusions and recommendations:

(1) There are opportunities for recombinant DNA technology to provide benefits for both the industrial-scale grower as well as for the small farmer in rural communities.

(2) There are potential scientific developments that could be used to eliminate or reduce gene flow, and these should be used as soon as possible in varieties developed to be released where sexually compatible species would co-exist.

(3) The intended introduction of transgenes in open pollinated varieties, such as the landraces, could significantly improve them. However, transgene dispersal would almost certainly not be controlled.

(4) At the international level, various international agreements and instruments enable governments to control the introduction of transgenic organisms into the environment. Ratification of such agreements also entails significant obligations with regard to the development of national biosafety capacity.

(5) Establishing and maintaining a functional, effective biosafety system presents various challenges. It requires adequate and dependable funding. It entails education and coordination across government ministries, universities and research institutes, private

sector interests, individual scientists, and the public. Significant investments may be needed in training and human resource development, information and communications systems, and laboratory and greenhouse facilities.

(6) Imposing a moratorium or (temporary) ban on the introduction of GM maize is a legitimate option to consider, but will be unproductive for various reasons.

(7) Monitoring of limited releases should be a valuable tool to obtain significant data concerning potential risks and benefits of GM maize.

(8) To improve the chances of adoption of this technology within the rural communities, people from these communities should be informed and involved in all the stages of the process: from choosing appropriate traits to testing and deciding whether or not to use the new materials.

Recommendations are as follows:

(1) The agrobiotech industry should assign priority to the introduction of molecular mechanisms to eliminate or significantly reduce gene flow.

(2) Specific areas to maintain the teosintes and maize landraces should be chosen and maintained free of GM-varieties, and appropriate incentives given to farmers to be stewards of these areas.

(3) *In situ* and *ex situ* efforts should be made to preserve the wild relatives of maize and the principal landraces.

(4) Experimentation and monitoring of the present situation in Oaxaca should be started as soon as possible to gain as much experience as possible on processes related to gene stability, persistence, etc.

(5) Experimental field releases of maize must include, whenever possible, experiments aimed at answering biosafety issues.

(6) The rural communities should be continuously informed about developments in the area, and consulted regarding the possible application of recombinant technology to improve the materials they are currently using.

(7) In projects design to address the possibility of improving the landraces for the use by the rural communities, people from these communities must be involved at all stages of the process.

(8) The rural communities should be the ones evaluating and deciding whether or not to adopt GM-varieties for their use.

(9) After complying with regulations regarding pre-commercial testing of GMOs, commercial releases of GM-maize in the future may only be approved on a conditional basis, depending on the trait, and must include a period for monitoring the release before a final decision is made.

(10) Monitoring should be conducted by a scientific group that would be proposed by the Biosafety authorities, or by the applicant with approval by the Biosafety authorities.

(11) The costs associated with the monitoring process should be covered by the applicant.

(12) The data obtained through the monitoring process should be analyzed and discussed periodically, to adjust the monitoring process, if necessary.

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