Transitions in Agbiotech: Economics of Strategy and Policy

EDITED BY
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Proceedings of NE-165 Conference
June 24-25, 1999
Washington, D.C.

Including papers presented at the:

International Consortium on Agricultural Biotechnology
Research Conference
June 17-19, 1999
Rome Tor Vergata, Italy

PART FOUR: Regulation and Trade

19. Issues in the Release of Transgenic Crops in Developing Countries: The Mexican Case Study

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Issues in the Release of Transgenic Crops in Developing Countries: The Mexican Case Study

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Chapter 19

Issues in the Release of Transgenic Crops in Developing Countries: The Mexican Case Study

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Introduction

The objective of this paper is to examine issues concerning the regulation of genetically modified organisms (GMOs), also referred to as biosafety.[2] The number of different GMO technologies and applications is increasing rapidly, as is the number of these technologies available for application in developing countries. However, the regulatory framework for experimentation, controlled environmental release, and comercialization of GMOs is nascent. International involvement has helped to establish a basic regulatory framework in most developing countries in anticipation of the new technologies (Krattinger and Rosemarin 1994; Lesser and Maloney 1993; Tzotzos 1995). This paper will address some of the issues and challenges that this regulatory framework faces with the maturing of agricultural biotechnology. Mexico will be used as a case study in order to illustrate issues and conflicts that have arisen.

The regulation of agricultural biotechnology and GMOs can be seen as having three main phases. The first is the anticipation of new technologies and the proposals for domestic and international regulation and possible legal and scientific implications. The second is the establishment of the regulatory framework, the building of institutional capacity to handle regulation, and the movement from predictions to the decision components of actual biosafety regulation. The third stage is the continued monitoring and evolving regulation of new and approved GMOs through an established regulatory framework. It is the proposal of this paper to discuss this second phase and discuss the possibilities for the transition to the third phase. Most LDC's currently find themselves in the beginning of the second stage.

It is crucial to recognize that beyond the objective scientific biosafety approval of new technologies, the regulatory framework will shape the future of agricultural biotechnology research. Furthermore, regulators have to integrate economic, environmental and political factors that influence policy and which help determine acceptable levels of risk for any risk assessment. Facing the issues of path dependency that regulation creates, the goal of biosafety is to protect the safety of the population and the environment while fomenting the development of new technologies. The corresponding dangers for misguided policy are both the stifling of technological development through the discouragement of investment and research, and the possible environmental and human consequences, which have a strong dynamic component (one popular metaphor is "letting the genie out of the bottle"). Equally important is to recognize that

the lack of a regulatory framework can endanger human health and natural resources, as well as the present and future possibilities for the seed industry and the application of agricultural technology.

For developing countries there is also the added question of how the regulation of agricultural biotechnology will affect the transfer of technologies developed elsewhere to local agriculture. The high costs in basic biotechnology research leave many such programs out of reach of most developing countries. The problem arises that the technologies developed may be more suited to developing country agriculture, and the basic ecological research relevant to environmental release may be missing from the transfer structure. Finally in the deployment and regulation of GMOs, legal and enforcement structures are used in developed countries which are less relevant in developing countries.

General Biosafety Issues

Any biosafety regulation must respond to the questions "Why regulate?" and "What to regulate?" An early division of philosophy was between the US system of regulating individual GMO products, and the European preference to regulate transformation processes. However, under the product approach, transformation processes are also often deemed appropriate or not. For example an important aspect of genetic transformation is to include a selectable marker; one of the most commonly used is a gene for anti-biotic resistance. If a product is not approved because of preoccupations about the human health implications of antibiotic resistance then anyone working on transformation will look for other selectable markers. If a product is deemed safe, then it is likely that similar product using similar transformations will make it through the regulatory process. Thus a ruling on a specific GMO may have the indirect effect of being an informal policy on a class of transformation processes.

There are several salient lessons to be learned from the regulation of the pharmaceutical industry. One major unstated goal of regulation is actually to "legitimize" GMO products and overcome possible public skepticism by having new technologies approved by a panel of experts and monitored by the government (Marois, Grieshop, and Butler 1991). In the developed countries case, regulations can also serve as barriers to entry, aiding oligopolistic behavior by the few firms large enough to meet all the costs of regulation. This is not the best model for the developing countries which either need to interest corporations in addressing local problems or arrange for the transfer of technology to local investigators where the corporations might not have incentives to do so. Another interesting aspect of the pharmaceutical model is the transfer of new products (intellectual property) developed in the first world to developing countries with the desire for companies to collect returns on R&D expenditures.

The major problem of new regulations is that they can discriminate disproportionately against certain technologies, can discourage research investment, or lengthen the time of product development. Indeed the pace of agricultural biotechnology is so incredibly rapid that, in the

words of an entomologist studying Bt maize, increases in the pace of breeding generate a "moving target that is difficult to hit" (Ostlie 1994). The regulator must be able to keep up with the technology but not slow the research. There are other ways in which regulations need to be designed to not cause undue burdens. For example, in the case that conventional research techniques and biotechnology can produce the same product in different time horizons, it is not desirable to increase the cost of the biotech path by requiring additional years of work for regulation. In addition, regulators need to be judicious in distinguishing between regulations which allow for a general release and those requiring constant monitoring. A recent letter from a group of agricultural scientists protests that the EPA should not regulate plant pesticides because the regulation places an undue burden on the GMO crop that the conventional one does not bear. Regulation of the buildup of pest resistance is not used on conventional pesticides nor conventional breeding (Qualset and Cook 1996).

In developing countries the regulatory framework must also be seen in terms of the liberalization of the agricultural sector and the globalization of agriculture. Developing countries which are scaling back on applied agricultural research are increasingly dependent upon multi-national corporations for agricultural technology. A member of the Mexican biosafety committee reports, "There is a constant flow of permits between the US and Mexico. As soon as a product is regulated in the US, we are sure that in a short time we will have the same application" (Serratos 1997). Finally, biosafety will have to be compatible with national trade policies designed to attract foreign investment and to increase the size of the export agriculture sector.

Biosafety regulation for developing countries faces challenges different from those in developed countries because many developing countries are important centers of biological diversity. Centers of diversity are characterized by a wide range of wild relatives of domesticated crops, semi-domesticated species, complex agricultural systems, and high biological diversity of pests. The modeling of ecological responses to a GMO can only be based on current knowledge of the agricultural ecology, which in many cases is deficient. As an input into risk analysis, the valuation of biodiversity in terms of wild relatives and landraces is close to impossible and the valuation of biodiversity of other components of the agricultural system beyond any known methodology. Furthermore, the seed systems in place in centers of diversity may be difficult to monitor and may have particular problems for biosafety regulations. The resilience of traditional seed systems and their foundation in subsistence agriculture makes a transition to dependence upon a formal seed sector or the corporate research pipeline particularly problematic.

Risk Assessment

Biosafety regulation involves an applied form of risk assessment. Risk analysis, the initial component of risk assessment, requires identifying the magnitude and probability of possible hazards. In the case of release of GMOs in developing country centers of diversity, the

principal risk assessment centers on environmental release, which involves a complexity of environmental and ecological interactions, many of which are not well understood. "It has been proved that it is virtually impossible to formulate a 'quantitative' assessment of risk to the environment resulting from the deliberate release of a modified plant" (Dale and Kinderlerer 1995). The basic scientific questions concern the probability and frequency of movement of a gene to a wild relative or a resulting hybrid, and the fitness and potential weediness of such hybrids. Preliminary research on geneflow indicates that it is significant in many species of economic importance. However the knowledge of resulting fitness and even a methodology for measuring fitness are not well established. The regulator faces the problem of needing empirical data from experience to learn to identify hazards and measure probabilities, but that approval cannot be given without a minimum of empirical data.

Once risks have been defined, the goal of risk assessment is to identify an acceptable threshold, but the question becomes "what is acceptable?" A starting point in environmental release is a valuation of genetic resources. Both nationally and internationally there is a value acknowledged for genetic resources, but no methodology on how to assign value. Furthermore, the scale and scope of the resources at stake is one important reason for developing country risk assessment to vary from the developed country case. Although attempts are being made to standardize North American biosafety regulations across Canada, the US and Mexico, in the opinion of one member of the Mexican biosafety committee, "there was a unilateral decision by the United States to deregulate transgenic maize" (Serratos 1997). The Mexican biosafety review differs markedly from the US example in the case of maize.

In defining acceptable levels of risk there is an almost inevitable move towards needing to identify if not quantify the possible benefits. It is this step which most importantly takes the biosafety regulation process away from objective science to a subjective evaluation. The acceptable level of risk will depend on whether the modification is for a trait, a pest, or some sort of management issue relevant to local farmers. The acceptable level could also take into account that the GMO may entail technology that is less environmentally hazardous than that currently being used. The line of reasoning quickly extends to what type of farmers the technology will affect, and possible changes to the agricultural system because of broad use of the new technology. Thus socio-economic evaluation becomes difficult to avoid although it is not the purpose of a biosafety review (Lesser and Maloney 1993).

In making a tradeoff for risk analysis, the structure of the seed industry indicates that many times while public resources are at risk, it may be mainly private benefits in the form of profit to be weighed against. Even from limited field trials it is possible that the private companies benefit from experiments in the centers of origin, as they can generate interesting conditions for the test crop and not necessarily be of any use to host country. On the other hand developing countries may be willing to take risks to face food security issues, balancing an unknown ecological risk against known risks of social unrest, food imports, and populations pressure (Alvarez-Morales 1997). In such cases risk assessment may introduce a subjective or

implicit valuation of the utility of the new technology in the context of the developing country and for the R&D expenditures of private corporations.

The release of a GMO at this point can also become inherently political for the regulatory authority. In the Mexican case it seems that the regulators need something "good" or "popular" to approve, i.e. products appealing to the public that will reinforce the regulator's own credibility. For instance maize nurseries for US-focused research projects may not be worth the political risk for the regulators, due to unquantifiable environmental risks and palpable political risks (Velez 1999). In this way other technologies which are not needed in the country or are only of peripheral importance may not be worth the risks because of low level of benefits. Currently the first generation transgenic maize (herbicide resistant or Bt) would be in this category of exchanging a high political risk for moderate to low agronomic potential of the trait.

Regulatory Problems in Mexico

The unfortunate reality in most developing countries is that the ideal world of laws and regulations contrasts sharply with the practical world with fuzzy legal regimes and minimal enforcement. The challenge is precisely to develop regulations that take into account the lack of knowledge of laws, a coherent judicial system, or systematic enforcement.

For instance, in Mexico, laws for human health currently require approval and labeling for the importation of transgenic food. The millions of tons of US transgenic corn being imported this year are supposedly destined for livestock or industrial use only, but there is no system for tracking grain shipments once they are in the country, not to mention the fact that separation of transgenic and non-transgenic grain at the border is impossible. Indeed the Mexican government has an extensive network of subsidized grain stores throughout the country, which are principally supplied with imported US feed grain. Thus it is possible that transgenic maize could be unintentionally distributed to villages throughout the very centers of maize diversity.

In reality the regulation of GMOs is following much of the regulatory framework of the regulation of pesticides. The principal regulatory authority for GMOs is the General Directorate of Plant Health (DGSV) of the Secretary of Agriculture (SAGAR), that has an extensive history of regulation of importation and release of pesticides in Mexico. Of course the main providers of GMOs are the same trans-national corporations that have dominated the agro-chemical industry in Mexico and have established relationships with the DGSV. Unfortunately the regulation of agricultural chemicals in Mexico has been problematic and inconsistent, and hopefully not as relevant to the deployment of GMOs as it might seem. One major lesson, however, is that despite rulings regulating for agrochemical products with regional restrictions due to environmental or entomological reasons, enforcement is minimal and inter-regional trade occurs. Another important issue is that the recommendations for application procedures and safety precautions are seldom followed if even understood by the applicators and handlers.

This is an important lesson for the controlled release of GMOs to follow management plans or monitoring. Certainly the nature of newer generations of agricultural chemicals themselves is more benign, the level of consciousness and amount of information available to farmers and workers has increased, and regulatory capacity has improved, but the lessons from pesticide use and abuse are fundamental.

Mexico's Biosafety Regulation

National Biosafety Committee

The principal body responsible for the regulation of biosafety in Mexico is the National Biosafety Committee, (CNB). The legal basis for the CNB is established through a norm published by the Secretary of Agriculture (SAGAR) that is the basis for biosafety regulation (Mexico 1994; Mexico 1996). The CNB is designed to advise the Director of Plant Health (DGSV) on the approval and regulation of GMOs. It is important to note that the CNB is technically only an advisory body, and thus its rulings are not binding on the DGSV. Furthermore the establishment of the CNB by administrative norm means that it has no true legal power, and that any legal power is derived only through the DGSV-SAGAR.

The CNB is composed of a panel of experts from Mexican academic and research institutes, with relevant professional and academic backgrounds. Members are drawn from the most important national institutions involved in applied genetic research, and most members are currently involved with some form of research relevant to biosafety issues. Service on the committee is unremunerated and is undertaken in addition to all other commitments a member may have. The meetings are scheduled by the DGSV in accordance with the number of applications made for the liberation of GMOs. Representatives from the Secretretary of Health (SS) attend meetings in order to address human health consequences of GMOs. The committee operates in an *ad hoc* manner, addressing only specific applications for liberation and does not make any general rulings on biosafety.

To date, the committee has successfully met the challenges of the first wave of applications for releases of GMOs. Factors that have contributed to its success include the flexibility of its formation, the breadth and depth of the personal knowledge of its members, the limited scope of applications, and, in many cases, their similarity to applications approved for release in the United States. The meetings and rulings of the CNB are confidential, however, and rulings are not published. Furthermore the committee has no published history of past rulings, nor has a set of internal rulings on decision processes been established. Up to this point the limited membership of the committee has relied on group memory, but certainly this becomes problematic as the membership grows and evolves. The committee has previously relied on the expertise of its core members for the crops under study, but as the list of GMO applications grows there will be a need to either include more members, or start sub-committees with relevant experience to other crops.

General Directorate of Plant Health – DGSV

The regulatory authority established by Mexican law is the General Directorate of Plant Health (DGSV), in a logical and obvious extension of the DGSV's previous responsibilities to regulate pesticides and pathogen-related plant health. The DGSV has a sub-director, who is in charge of coordinating meetings, and a staff person who sorts through release applications and coordinates relevant materials for the CNB. The sub-director is also involved in international coordination of biosafety and attends international meetings on biosafety issues. The two principal areas for the regulation of GMOs as established by law are for the environmental release (also referred to as planting of field trials) and for the importation and movement of seed within Mexico. The application contains a long list of questions about the modified plant, source of construct, process of transformation, and environmental conditions of a field test. Furthermore applicants must provide detailed information on the exact size and location of field trials, as well as biosafety measures to be undertaken.

The DGSV staff collects the applications, sets the agenda for CNB meetings, and is charged with following up on any restrictions the CNB may require for release. The DGSV has a network of inspectors in every state that are responsible for enforcing restrictions involved in plant health. This network will be utilized to monitor field tests and ensure compliance with any requirements specified in the applications.

SAGAR

Several other departments within the Secretary of Agriculture, Livestock and Rural Development (SAGAR) are potentially involved in biosafety. There is an agency that deals with regional quarantines that has a national network of inspection stations located along major transportation routes. The quarantine system has proven effective when used for specific campaigns, but use for general monitoring of seed shipments would be difficult. The enforcement of border restrictions on the importation of GMOs would require a campaign to identify and train customs officials on behalf of the SAGAR. At this point even though it is illegal to import GMO seed without a permit, no-one is looking.

The applied agricultural research agency, INIFAP, with its network of national plant breeding experiment stations, is the most important resource for field tests and knowledge of local agricultural conditions. INIFAP is a logical place for the government to channel resources needed to provide additional information related to field trials, as well as the human resources of local specialists such as pathologists, entomologists, etc. that will be necessary for monitoring of GMO releases. Finally, the National Seed Certification Committee (SNICS) is responsible for approving the release of new varieties in Mexico. While this is not directly related to biosafety, the SNICS requires three years of multi-location testing for any new plant before being released as a variety in Mexico. This requirement ensures that any GMO will go through the CNB long before possible commercial release.

Environment

Within the Secretary of the Environment, Natural Resources and Fisheries (SEMARNAP), biosafety regulation efforts are conspicuously missing. Despite being invited, SEMARNAP has not sent a representative to the CNB, has not established any norms or rulings on GMOs, nor has it made clear which department within the SEMARNAP will be responsible. Whether an environmental ministry should be involved in regulating GMOs is a subject of some debate, but the complete absence from the discussion is equally worrisome. Legally the SEMARNAP is charged with protecting Mexico's biodiversity, so it could be involved with the regulation of agricultural GMOs as they relate to wild relatives. In addition, just as the DGSV is directly responsible for GMOs as relating to agriculture, SEMARNAP will be responsible for regulating environmental release of all other GMOs, such as animals and microbes used for bio-remediation. The costs of SEMARNAP's absence from discussions and not developing the relevant capacity are high.

Within the SEMARNAP the National Ecology Institute (INE) is responsible for drafting norms with relevant scientific background. The PROFEPA is the enforcement arm of SEMARNAP and could have some enforcement capacity to help in the monitoring of compliance with GMO release plans. The departments of forestry and fisheries will have to develop regulations on the deployment of transgenic trees for pulp and paper and transgenic fish for aquaculture. Related, but not part of SEMARNAP, the interdepartmental Commission on Biodiversity (CONABIO), is supposed to coordinate relevant agencies for biodiversity conservation and develop a national database on biodiversity. A significant level of institutional capacity and human and informational capital exists within SEMARNAP that could be useful as input to the CNB and DGSV in assessing environmental risks of GMOs.

Health

The Secretary of Health (SS) is responsible for the approval of GMOs for human consumption. A representative attends the meetings of the CNB to obtain information and advice on regulation. The institutional capacity is small and incipient, because up to now there has been little in the way of health regulations for GMOs. The published norm is that all GMOs sold for human consumption must be labeled, but it remains to be seen whether the SS will be able to enforce labeling or make rulings on what falls under labeling laws.

Crops: Two Important Cases – Potato and Maize

GMO potato and maize provide two useful case studies for biosafety regulation in Mexico and developing countries in general. The potato because it is an example of technology transfer and a variety developed by and for Mexico. Maize highlights the issues of release of GMOs in a center of diversity.

Potato

The first commercial GMO product developed in Mexico was a potato resistant to the PVX and PVY viruses. The potato has been celebrated as an example of North - South transfer of biotechnology, and is discussed thoroughly in a paper by Matin Qaim (Qaim 1998). In brief, a technology to transform potatoes patented by Monsanto was transferred to a Mexican biotechnology research institute (CINVESTAV). The transfer was facilitated by the International Service for the Acquisition of Ag-Biotech Applications (ISAAA) and funded by a grant from the Rockefeller Foundation. Three important criteria were used by the ISAAA to select this model project: 1) the variety transformed had a purely domestic and no export market, 2) the variety was not grown in any developed countries in competition with Monsanto's seed products, and 3) the technology was already completely developed, so no additional basic research was necessary.

This project illustrates three salient points with regard to biosafety regulations. 1) The seed system and seed saving behavior of small farmers, who cannot afford to buy new seed every year and thus recycle both seed (and accompanying pathogens) each year, was explicitly taken into account in analyzing the impacts of the technology and selecting the project. Socio-economic evaluation, which is a problematic aspect of biosafety, is important to the benefits of the project. 2) The time saved by using biotechnology is one of the principal benefits of the transformation. Although virus resistance can be introduced through conventional breeding, the process is very time intensive. The issue of how to regulate a biotechnology product that could potentially be produced by traditional breeding has yet to be resolved. 3) Monsanto donated the technology (of little or no commercial value) and has received positive PR for the goodwill gesture and for GMO crops in general. However, it is even more important that a path was paved through the regulatory framework for a Mexico-specific GMO; a path which Monsanto's own products will have to follow. In retrospect the response to this specific GMO was responsible for building up the institutional and regulatory capacity of the CNB which will be necessary for Monsanto's products to gain public acceptance in the future.

Maize

The release of a GMO such as maize in Mexico, a center of maize diversity and domestication, highlights that the potential environmental consequences for GMO release in a developing country may be much greater than in a developed country. Certainly the release of transgenic maize is the most politically problematic and scientifically the most challenging issue facing Mexican regulators. At the writing of this paper, in May 1999 the environmental release for field trials had been stopped since October 1998, due to the lack of consensus within the CNB.

Wild Relatives. The closest wild relative of maize is teosinte, which grows as a weed in maize fields as well as in the wild. The population biology and genetic relationships between

maize and teosinte are not completely understood, and basic research on this issue is still underway. Crosses in the field are common, and geneflow in both directions has been documented. International conferences have been held to gather expert opinions on the subject as specifically relating to the implications of the release of transgenic maize without arriving at a clear consensus (Hruska and Pavon 1997; Serratos, Wilcox, and F. 1997). The Mexican seed trade association is currently funding research designed to quantify the geneflow and to study the stability of hybrids.

Before it is possible to assess the risks of releasing of a GMO into an environment with wild relatives, there are two phenomena that need quantification. From an ecological perspective, the introduction of the novel genes could present a danger to the genetics of the wild population. However, quantifying a tolerable level of genetic "pollution" or resulting fitness effects is purely subjective and methodologically intractable. From an agronomic perspective, if teosinte exists as a weed now, the introduction of a new gene has the possibility of making it a more persistent weed. For instance in the case of herbicide tolerance, high selection pressure from repeated herbicide applications could make a stray genetic event dominant. Certainly there are management prescriptions for regional releases, or spatial or temporal rotations that could be enacted to mitigate these effects, but in the Mexican case any restrictions would have to be designed with low levels of enforcement or coordination assumed.

One of the world's leading experts on teosinte pointed out at a 1997 conference held in Mexico that, "without at conservation policy to protect teosinte, the biotechnology issues are a moot point" because of other risks to the wild populations (Wilkes 1997). The risk to teosinte from grazing and enclosure may be much more drastic and immediate than the possible flow of genes. This raises an interesting point for the consideration of the threat of GMOs to wild populations, the question of whether the scope of a biosafety risk assessment should take into account the other possible environmental risks to biodiversity (in this case greater, immediate and documented).

Landraces. Other than wild relatives genetic resources for maize lie in the landraces, or farmer-bred varieties, that still dominate rural Mexico. It is important to note that among farmers that are not integrated into the formal seed system, informal seed trade is high, and genes are traded and passed on both within and between communities. Furthermore many farmers are partially integrated into formal seed systems, and recycling of hybrids by farmers is a common practice; landraces may be grown beside commercial hybrids, and seeds may be stored together or even mixed to ensure geneflow (Louette 1997; Perales 1998). Also labor migrates from low technology landrace areas to higher technology export-oriented areas that could be seen as a source of flow of technology and germplasm. Thus subsistence farmers who are the guardians of landraces are affected by developments in the commercial sector, even without being directly integrated into it.

The predominance of landraces in many areas can be seen as a failure of the formal seed system or as a result of the biological resilience of local maize populations to stress

conditions. At any rate the level of extension and agricultural information is very low for managing technological innovations in local production. Furthermore there are significant coordination problems for subsistence farmers, who are characteristically isolated, farm very small plots, and use minimal inputs. Risk assessment in this area must take into account the almost certain movement of genes into landraces and local populations and the difficulty of coordinating farmers to respond to developments.

Finally, maize in Mexico must be seen in the face of the crop's cultural and historical importance (Alvarez-Morales 1997). Beyond the effects on landrace populations from geneflow from GMOs, the possible socio-economic effects, while not directly relevant to biosafety, cannot be ignored. Maize is the mainstay of the Mexican diet, and its role in the food supply must be taken into consideration. Mexicans both rural and urban consume up to 2 kg daily of maize, often subsidized and distributed by the Mexican government. This maize is often US feed corn, which in the future may be GMOs that have not even been tested for human use.

Release and Monitoring

Biosafety regulation can be temporary; once a crop has shown no possible dangers and is considered safe, restrictions may be removed. At this point only one crop has been completely deregulated, the famous Flavr-Savr™ tomato, which was deregulated four years ago. This was also the first crop to be regulated in the US and was the first crop that the Mexico CNB ruled on. Interestingly, the Flavr-Savr™ tomato never received wide commercial application until recently and is being grown in Mexico.

Crops that have been approved for controlled release include: maize, papaya, melon, chili, wheat, zucchini, potato, tobacco and tomato. Controlled release is usually approved on the condition that measures are undertaken to prevent pollenization: physical barriers (such as a screenhouse), required distance from other plantings, timing of sowing so that flowering occurs at a different time, or hand emasculation of plants.

There are two "pilot" projects for the monitored large scale release of GMOs in Mexico. In both cases planting is limited to the northern states along the US border. The crops are herbicide resistant soy and herbicide resistant and Bt cotton. In both of these cases, it is important to note that in the northern states the agricultural systems are similar to the US, there is no or minimal exposure to wild relatives, and the level of agricultural information and technology is relatively high.

The two pilot projects emphasize a need to clarify the different stages of release are. The information requirements for a biosafety risk assessment create a contradiction between needing a large-scale release to generate information and needing the information to approve the large-scale release. In the past three years, the acreage planted in soy has increased dramatically, and the data will be used to study the implications of deregulation. Data from the

empirical studies in the US was used during the approval process for the large scale release. The releases are termed pilot projects because valuable data will be gathered that will be able to inform further biosafety assessments and because full deregulation of these crops will be studied using the data acquired. However as the total area reached 100,000 hectares in the past year, questions arise about how limited the pilot projects are and what the requirements of monitoring are.

In the case of cotton, the issue arose of the management of resistance within the insect populations. The recommendation of the CNB is for a refugia strategy where 40% of total acreage must be planted to non Bt cotton. The release approval requires a five year study to follow the deployment, with the goal of monitoring the development of resistance. Monsanto is carrying out monitoring in collaboration with the local INIFAP station. A map of each planting must be filed at the time of seed purchase, and the local agent of the DGSV is responsible for monitoring the refugia compliance. Furthermore the seed for oil has been approved for human consumption but will only be processed at certain selected mills.

At this point the CNB is facing increasing numbers of applications for the release of maize, many of the other crops approaching application for larger scale release, and a continuing need to monitor crop management beyond a pilot project. Thus there is a need to clarify the different stages of release.

The lowest level will remain that of controlled release, most importantly where pollenization is strictly controlled. At this point even this level is restricted for maize because of the difficulty with handling the large numbers of applications.

The next level is for release with monitoring. In the case of the two pilot projects already underway, although they are pilot projects with limited releases, the total area is in tens of thousands of hectares for each crop. How to design a sample to monitor such a wide release with limited resources has not been addressed. Monitoring activities could potentially include entomological studies for insect resistance, or studies with molecular markers designed to track the transfer of genes to other plants. In the case of monitoring, the questions arise: Who does it? How strict is it? At this point the fact that the monitoring is done by INIFAP but funded by Monsanto is at the same time a useful collaboration for technology transfer and a possible subversion of the objectivity of the monitoring.

A further possible level is for deregulation with restrictions, for instance the case of cotton which featured a mandate of a specific refuge plan. In the case of refugia the simple fact of lost output on the refuge removes any individual incentives to comply. At this point the enforcement agent is the regional agent of the DGSV, who will supposedly visit fields at random to check on field resistance management plans. Whether an individual DGSV agent will be have the time and resources to visit and enforce in a large area is doubtful.

One alternative is to make the seed company liable for the enforcement of the management plan. The company should be able to internalize the costs as the value of protecting the pesticide's effectiveness will be reflected in future sales. Seed-saving behavior which would be illegal in the presence of plant variety protection is already a problem for some companies. However the seed company may have a different discount rate than society's in terms of capturing rents from a technology or viewing the deployment of a future stream of technologies. Private legal action also presupposes a functioning judicial system, which is not necessarily the case in Mexico or many developing countries.

In trying to control the possible consequences the escape of genes into the environment, possible restrictions are for spatial or temporal rotations of crops in order to reduce selection pressures. Gene flow does and will occur, but probably at a low enough level that such genes are naturally "swamped" by the rest of the population. An important management questions is the application of selection pressure in the agricultural system. An important ecological question is whether a change in fitness will give hybrids an advantage. If a GMO product is released for the large scale but with restrictions on management (as in the case of refugia), a system for enforcement must be in place.

Finally there should be a mechanism so that if problems develop with a GMO technology, it can be re-regulated or recalled from general release. This is not likely in the near future, but the possibility for reviewing environmental damage or non-compliance with release recommendations should be systematically included.

Conclusions and Recommendations for Regulatory Structure

The most important recommendation is for investment in the infrastructure and institutional capacity of the biosafety review committee and the regulatory authority. In Mexico funding and support should be increased for the CNB and DGSV which are the relevant authorities and have been responding successfully to past applications. In Mexico, as in other developing countries, this will be a difficult commitment because funds allocated to biosafety may be taken from programs that address more pressing social needs.

Mechanisms that would require companies seeking biosafety approval to share in the cost of regulation should be explored. For example, as mentioned earlier, Monsanto is underwriting the monitoring of its Bollgard™ cotton in the North, and the Mexican Seed Association is funding a study on teosinte geneflow. Care should be taken to ensure that such mechanisms a) do not discourage investments in technologies important for local agriculture and b) do not subvert the objective nature of the regulatory process.

Recommendations for future biosafety regulation include the following:

1) Scalability and Modularity – The review process must be able to process a large number of applications while maintaining rigor. In Mexico this means that the current CNB review process must be scaled up without losing the flexibility and scrutiny of the current ad hoc approach. Although the current approach is able to capitalize on the collective knowledge of its members, new technologies or crops will require the focus of consultants, increased membership, or sub-committees. The future process must confront the rapid pace of innovation and need to regulate for the unforeseen.
2) Streamline Process – There is an obvious need to economize the regulatory burden when possible, especially for cash-strapped governments. The goal is to maintain a rigorous review process but allow select technologies to move through quickly. This requires well-defined criteria for which products will receive a "fast track" treatment, possibly different levels of treatment, and a periodic review for updating the process.
3) Information Systems – Long term biosafety regulation requires the development of databases on crops, biodiversity and environmental conditions. In Mexico, the CNB must define conditions for borrowing and applying data from other sources, especially other countries. Systematic and consultable records must be kept, with periodic publication of decisions for transparency and establishment of precedents.
4) Economy of Scientific Research – There is a need to develop a mechanism for both funding and administering the basic research required for biosafety decision making. If additional studies are required to inform the risk assessment process for a particular crop or environment, there needs to be a way to signal to the research community, solicit research grants, and at the same time remain independent and objective from the interested parties.
5) Transparency and Public Participation - Due to the controversial nature of GMOs, a long term approach requires participation from the public, typically via environmental and consumer NGOs, which at the very least should be invited to be observers in the decision making process. Public acceptance of GMOs and the government's credibility in systematically facing biosafety issues is undermined by confidential meetings and records. Although the CNB and DGSV have been able to remain relatively isolated from political pressures following the introduction of GMOs in Mexico, greater openness is necessary to build public trust.

In conclusion it is important to be optimistic. In the case of Mexico, the CNB has been able to successfully respond to the first round of GMO technologies and has the flexibility and human capital to continue to do so. Valuable experience from the release off GMOs in the northern states will provide information on the efficacy of monitoring and enforcement for central and southern Mexico. The technologies that are available right now are not needed that urgently. Indeed, were Mexico to forego the first few years of herbicide resistance and Bt maize, the costs would probably not be excessive. There is still time to build up the scientific and regulatory capacity while learning from past and current experiences.

Endnotes

[1]M. E. Van Dusen is a graduate researcher at the University of California, Davis. The author wishes to thank the CIMMYT Economics Program for assistance.

[2]Biosafety can be the safety regulation of any and all aspects of biotechnology, here it will be taken to be specific to the purpose of this paper, the safety regulation of GMOs, principally in the field of agriculture.

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