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IMPLEMENTATION OF BIOSAFETY REGULATIONS IN A DEVELOPING COUNTRY: THE CASE OF MEXICO[1]

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ABSTRACT

Advances in biotechnology have offered new opportunities for the development and release of transgenic plants to the farming world. However, there are concerns about deployment of transgenic varieties alongside traditional crops and natural flora and fauna. National biosafety committees are emphasised in order to facilitate access to biotechnology, but also safeguard against uncontrolled release of transgenic plants. To be effective, a national biosafety committee should have a legal status, and should be composed of a few technical people, say from the departments of biotechnology, agriculture and natural resources.

Key Words: **Biotechnology, National Biosafety Committees, transgenic plants**

RÉSUMÉ

Des progrès réalisés en biotechnologie ont offert de nouvelles possibilités de développement et de diffusion de plantes transgéniques pour le monde agricole. Cependant, il y a des inquiètudes quant à l'usage de variétés transgéniques à côté de cultures traditionnelles et de la flore et la faune naturelles. Les comités nationaux de biosécurité sont appelés à faciliter l'accès à la biotechnologie, mais en même temps, à prévenir contre la sortie incontrôlée de plantes transgéniques. Pour être efficace, un comité national de biosécurité devrait avoir un statut légal, et devrait être composé de quelques techniciens, issus par exemple des départements de biotechnologie, agriculture et ressources naturelles.

Mots Clés: **Biotechnologie, Comités Nationaux de Biosécurité, plantes transgéniques**

INTRODUCTION

Tobacco plants were first transformed with a bacterial gene in 1983. The enormous potential of this approach has been exploited, mainly by large biotech companies in industrialised countries, to obtain new agronomic varieties with novel phenotypes, or to accelerate the transfer of already known phenotypes to a broader set of commercially important plant species.

After eleven years of waiting and despite serious limitations of the new techniques such as the restriction to single gene phenotypes, the first products of this technology have been made

[1] *The opinions discussed in this article are personal and do not represent the official position of the Mexican National Biosafety Committee for Agriculture.*

available to the general public in the USA through the commercialisation of the FLAVR SAVR tomato. During this waiting period, new scientific developments have taken place which have increased the range of plant species that can be modified through genetic engineering. New phenotypes have also been obtained through the use of strategies such as antisense RNA, and by the use of novel genes derived from diverse plant pathogens, fungi, bacteria and several plant species.

During this period, however, as the new scientific developments evolved, scientists, environmentalists and other groups began to question the safety of deploying the new transgenic varieties alongside the traditional crops and the natural flora and fauna of, in many cases, an already stressed environment (Maloney and Lesser, 1993). These groups first appeared, and were most active in the industrialised countries where this technology was developed. They recognised the need to understand how to handle the new plant genotypes that were becoming available to the plant breeders, producers, and seed companies. In many instances, the phenotypes were completely novel and were not expected to occur naturally. The most common examples of these were the different plant species into which a gene from *Bacillus thuringiensis* was inserted to confer resistance to insect pests.

Experts recognise the danger of uncontrolled spread of the new traits to wild relatives not subject to farming controls. However, the industrialised countries are virtually free of wild species of the important crops (some of the exceptions being sunflower, oats, and rye). As a result of these concerns, developing countries, where most of the centres of origin or diversity of majority of the important crops are found, have begun to address these issues through local or regional biosafety committees. The need for such committees in developing countries stems from their need to have access to this technology, which could certainly provide an extremely useful tool for agricultural development, and to ensure that these countries are not subjected to any unnecessary ecological risks by allowing transgenic plants to be tested or commercially released in their territories.

ORIGINS OF THE BIOSAFETY COMMITTEE IN MEXICO

In 1988, a transnational company requested for permission from the Ministry of Agriculture and Water Resources (SARH) of the Mexican government, to introduce and test seeds of a transgenic variety of tomato that contained a gene of *Bacillus thuringiensis* aimed at confering resistance to insect pests, more specifically to "Pin worm" *Keifereia lycopersicella,* a severe tomato pest in the northwestern state of Sinaloa.

The Ministry treated this request normally without realising that these were genetically engineered tomato plants and thus the permit was granted. The reason why the nature of the seeds was unnoticed, was that the request was submitted through the official channel concerned with the normal in-flow of seeds between the U.S. and Mexico which was never suspicious.

A normal permit was, therefore, granted. However, the company realised that the uniqueness of the seeds had not been noticed. It, therefore, contacted scientists at the Plant Genetic Engineering Department of the Irapuato Unit of CINVESTAV who, once aware of the real situation decided to look into the matter. The transnational company agreed to wait until a proper review of their proposal was done before introducing or testing any transgenic material in Mexico.

Once the situation was fully explained to the officials at SARH, a Biosafety Committee was assembled and placed under the jurisdiction of the Plant Health Department. This committee included officials from the Ministry of Urban Development and Ecology, and the Ministry of Health; and the research branch (INIFAP) of the Ministry of Agriculture, and of the Seed Inspection Services. Others included scientists of the Irapuato Unit of CINVESTAV and the Postgraduate College of Agriculture.

After long technical and political discussions within this large committee, the request in question was accepted but the test was allowed to take place under severe containment. This committee, like similar committees in other countries at that time, was more concerned with the possibility of gene transfer via pollen than with the possible effects the transgene could have if transferred to wild relatives.

EVOLUTION OF THE BIOSAFETY COMMITTEE

Several problems were identified concerning the functionality of the Biosafety Committee. There were too many people involved and with wide ranging interests (policy, human health, agriculture, etc.) which made it more difficult to reach a technical decision. Furthermore, it was often difficult to have all the members attend meetings, partly because several members were high ranking officials with very busy agendas.

The Plant Health Department then decided to reduce membership and to form an eminently technical committee by selecting scientists involved in the fields of biotechnology and agriculture. This became an advisory committee charged with presenting technical advice on the different requests submitted to the General Director of the Plant Health Department who would then make a decision.

Thus, the National Committee for Biosafety in Agriculture (CNBA) was formed, under the coordination of the Plant Health Department of the Ministry of Agriculture and Water Resources. The objective of this committee was to look into each submitted request, mobilise, conduct field trials, or deregulate transgenic plant varieties in the Mexican territory. The CNBA comprised of six members, three from government agencies under the Ministry of Agriculture and Water Resources (the Plant Health Department; Seed Certification Service; and the National Institute for Research in Forestry, Agriculture and Livestock (INIFAP). The other three members were from research institutions (CINVESTAV - Irapuato; the Postgraduate College of Agriculture; and the Institute of Biotechnology from the National Autonomous University).

To give a legal status to the CNBA, its constitution and objectives were inserted into the already existing legislation which was approved by parliament, thus avoiding the long and complicated process of creating new legal structures. It was very important that this legislation clearly stated only the structure and objectives of the CNBA, permitting the elaboration of a set of regulations which could be changed and adapted following the rapid advance of biotechnology and molecular biology, through a not so complicated process and without the need for parliamentary action.

To acquire the necessary experience to produce the required set of regulations, a series of meetings were held by the members where current issues of biosafety were discussed. In attendence were regulators, scientists, policy makers and biotech companies from developed countries where majority of the field trials were taking place. These meetings and workshops were arranged by organisations, especially the International Services for the Acquisition of Agri-biotech Applications (ISAAA), the Inter-American Institute for Cooperation in Agriculture (IICA), and The United States Department of Agriculture (USDA). This proved to be a very efficient way of gaining experience that could be readily applied to the Mexican situation.

CRITERIA AND IMPORTANT POINTS TAKEN INTO CONSIDERATION

Analysis of risks focuses on the product rather than the technology used in the process of generating such a product. This approach acknowledges that in most cases genetic manipulation is used to speed up the development of a new variety that could also be obtained through traditional plant breeding. It also recognises that traditional plant breeding could generate products that could pose some risk to the environment, in some cases a risk comparable to that associated with transgenic varieties.

The focus on the product rather than the technology involved also implies that genetic engineering, as a methodology to obtain new agricultural varieties, *per se* , should not be taken as dangerous. Negative attitudes by a regulatory committee towards the technology could block public, academic and the private sector from having access to this technology.

Also, previous experience suggests that focus should not be so much on the containment conditions proposed for the field trial. After all, when a large commercial company wants to test its products in Mexico, it usually assesses agronomic behavior of already tested and selected

transgenic varieties. If the trials are successful, commercialisation is the obvious goal, therefore, containment would not be the best alternative.

Historical attitude of a population towards a specific plant variety also becomes an issue that needs to be taken into account. This is most likely to occur in centres of origin or diversity where a culture has developed around crops that have become the basis for nutrition. One example is maize in Mexico and Central America. Maize is linked to Mexican history and culture since prehispanic times, and has become a symbol of sustenance for small and large scale growers alike.

Therefore, when analysing proposals that include such crops, care should be taken not to generate unnecessary apprehension in the public sector, which could later have repercussions on the assessment of proposals which include less controversial crop species. It might be necessary to create extensive awareness among the public concerning the proposed tests before the actual release, so that it is aware of the implications of such a controlled release and it understands the work of the Biosafety Committee.

The possible benefits obtained through the use of this technology should also be taken into consideration, although these should be defined by each country on the basis of their own economic, social, political or agricultural situation. The relative importance given to these benefits may vary depending on the problems being addressed. Some possible benefits that may be worthwhile consideration are discussed below:

Reduction of damage to the environment and biodiversity. A reduction in the quantity of pesticides and herbicides through the incorporation of disease-, pest-, or herbicide-resistance genes would be desirable. It would mean less pollution of land and water, and reduced exposure of workers to toxic chemicals. Reduced chemical usage would also, most likely, result in increase in savings through a reduction of production costs and greater sales associated with an increased consumer acceptance for commodities produced with fewer chemicals.

Higher yields. An increase in yield presumably could decrease the need for more land cultivation at least to a certain extent. Extensive, rather than intensive farming is the most common production form in many developing countries. Unfortunately, the land added to expand the less unproductive farms is usually taken from ecological reserves such as tropical forests, thus endangering many plant and animal species, some of which have great commercial value. This decrease in the biodiversity is an extremely difficult problem since, in many instances, it can not be remedied and is very difficult to control in remote areas.

Increase in *Per Capita* income. If production costs could be brought down as a consequence of the use of transgenic varieties, higher profits could result for growers translating into better health, and a generally higher standard of living.

RISKS

The risks to be considered and evaluated by the Biosafety Committees, should be defined locally and depending on the crop variety being analysed. There is, however, lack of full knowledge regarding the possible risks involved in the release of transgenic materials in centres of origin or diversity. Up to now, evaluation of the risks has been through extrapolations of plant breeding experiences, introductions of foreign species into new ecosystems, and experimental data obtained with some transgenic materials. Some of the risks that merit consideration are listed below:

Appearance of new weeds. Ecological disturbances are known to occur when a foreign plant is introduced into a new ecosystem. Although in such cases a whole genome with a high capacity for adaptation is introduced into a completely new environment, there is a possibility that the introduction of a specific transgene into a wild relative could confer upon it new characteristics that would turn this plant into a weed that could colonise and modify ecosystems not available to them before. There are cases where more knowledge is required to evaluate the possible risks associated with certain traits, such as stress tolerance. In this case, one may be talking about a plant whose capacity to occupy a new niche has

been considerably enhanced and it could, therefore, displace species which are not competitors under normal circumstances.

Appearance of new pests. This is mainly related to transgenic varieties harbouring coat protein (CP) genes of different viruses (through transcapsidation or template switching), to fungal resistance and to the use of *Bt* genes to confer insect resistance. In the case of plants that have been transformed with *Bt* genes, care should be taken not to eliminate the possibility of using an already well proven biological insecticide with many desirable characteristics. In this case, transgenic plants should be designed and used according to a carefully planned system that minimises the risks of inducing resistance to *Bt* toxin in the insect population.

Disappearance of wild species. Transfer of genes to wild species that might decrease their survival rate could lead to their disappearance.

Toxicity. Formation of new toxic compounds in transgenic plants or in wild species that have acquired a transgene, which somehow modifies the normal metabolism of the plant directing it to synthesise a new compound or increasing the amount of an otherwise low level toxic substance normally present in the plant.

Germplasm pollution. This is currently a point of concern. However, it has been difficult to agree on what constitutes a genome pollutant. If it is interpreted as genes not present in the "ancestral" or "original" species, then it would certainly be difficult to find such unpolluted species close to any agricultural area where commercial varieties of any crop species are grown. However, if a "pollutant gene" happens to increase the chance of survival of an "ancestral" species, would it be considered nevertheless undesirable?

OPERATION OF THE NATIONAL COMMITTEE FOR BIOSAFETY IN AGRICULTURE

Proposals are submitted following, to a great extent, the model used by the United States Department of Agriculture (USDA). In general terms these should contain the following information:

(i) Person responsible for the intended field release in Mexico: name, address, telephone number, fax, etc.

(ii) Nature of the regulated article: botanical description of recipient plant, precise origin of transgenes.

(iii) Details of introduction of the material into Mexico: possible dates, transport, type of container, amount of material, etc.

(iv) Description of the genetic constructs: vector, regulatory sequences, DNA sequence data, description of ORF's, number of transcripts, number of proteins expected, marker genes, etc.

(v) Detailed description of the transformation system: *Agrobacterium*, biolistics, gene copy number, etc.

(vi) Detailed phenotypic description of transgenic plants: differences expected with the non-transformed variety, phenotype of the transgene, etc.

(vii) Exact condition for the intended release: exact location, time of year, protocol of field test, etc.

(viii) Biosafety information: internal risk assessment, data concerning the ecosystem around the test site, proposed containment measures, proposed remediation, disposal methods, monitoring of tests, etc.

Not all the above points may apply, in some cases specific points need to be stressed, depending on the crop. However, all this information is usually submitted in considerable detail.

Once the CNBA receives this information, it is sent to its members for an initial review, and if the information is considered complete, a decision must be communicated to the proponent within 120 days, otherwise new information is requested and reviewed again until complete. The CNBA then analyses the proposal and if previous tests of the same material have taken place in another country (usually the US), information on these results are requested for. Also, if the opinions of specific experts are necessary, they are invited to participate during the discussions of the CNBA. These may be from national institutions or from the proponent's laboratory or company.

Once all the relevant information has been analysed, a recommendation is sent to the Director General of the Plant Health Department. If the proposal has been accepted, local authorities of the State where the test is going to take place are informed of this decision. They should consult with local growers and if there are no objections to the test, the applicant is officially approved. If a proposal is rejected, the applicant may request for a new revision provided they substantiate their case.

In every case, the Plant Health Department may be free to send its personnel to certify or review any aspect of the test at any time. Furthermore, members of the CNBA may visit the premises at any time during field tests. If conditions are not optimal or recommendations have not been implemented, the test may be cancelled immediately. The costs of the visits are covered by the applicant. Once a field test is finished, a final report must be submitted to the CNBA.

When an applicant wishes to field-test a material for which a permit has already been granted, a proposal is submitted to the CNBA which stresses the objectives and any specific changes with respect to the original petition. These proposals are usually reviewed much faster, provided that the previous experience and results have been satisfactory.

After accumulating successful field experience with a particular transgenic variety, a petition for "deregulation" may be submitted to the CNBA, which will thoroughly review it and if no objections emerge the petition may be approved. The deregulated status means that a particular plant species or variety which has been transformed with a specific gene, through a specific process, and containing specified regulatory sequences, may be grown, transported and essentially treated as its non-transgenic progenitor. This does not imply a permit to commercialise such product as this decision does not bind the Ministry of Agriculture and Water Resources.

CONCLUSIONS

Developing countries are often the recipients of assistance from the developed countries, most often to alleviate short term problems. However, a long term solution to the many problems that underdeveloped countries face will only be possible through the assimilation, and implementation of the technologies that would enable them to confront their most acute problems with their own people and resources. Biotechnology, together with modern plant breeding do offer a possible solution to many agricultural problems. It is imperative that developing countries have access to this technology if they are to provide better living conditions for their people and for future generations (Zandvoot, 1995).

The Mexican model can not be applied directly to any other country because it evolves continuously and responds to very specific needs. However, this model can be used to set up similar committees in other countries. The implementation of a National or Regional Biosafety Committee could be the first step towards grasping the potential and associated risks of Biotechnology (Maloney and Lesser, 1993). Each country, based on its own levels of technical competence, economic status and even social structure and history has to decide on how to make the best use of Biotechnology.

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