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Position Paper

Legal and regulatory concerns about transgenic plants in Brazil

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Abstract

Brazil has a biosafety law that was approved in 1995. This law provides for a horizontal type of regulation that coordinates other existing regulatory frameworks in the areas of agriculture, health and environment. Various federal government departments are responsible for implementing the law. The National Technical Biosafety Commission is the national competent authority on biosafety with overall responsibility. In the case of *Bt* plants or any insecticidal organism, the Agrochemical Law also applies and authorization for laboratory, greenhouse and field studies must be obtained from the Plant Protection Secretariat, the Brazilian Institute of Environment and the National Agency of Health. Furthermore, the National Environmental Council must issue a license for commercialization of any GMO. There is pressure needed for capacity building and to harmonize the regulatory and administrative frameworks among the different federal departments involved. Some perspectives and challenges for the commercial registration of transgenic crops are discussed.

Keywords: Biosafety; GMO; Regulation; Capacity building; Genetically modified crops

1. Introduction

In this paper, I present an overview of the Brazilian biosafety regulation, particularly with reference to the commercial registration of pest resistant transgenic crops. I report further on our experience with implementation of biosafety regulations, the problems we had and still have, and suggest possible alternatives to handle them. Finally, I comment on these regulations based on my ideas of what are the emerging needs for Brazil to manage biosafety and to be prepared to fully implement agriculture biotechnology in the country.

1.1. The biosafety framework

Brazil approved a biosafety law in 1995 (law no. 8974/95) that provides for a horizontal type of regulation that interfaces with other existing regulatory frameworks in the areas of agriculture, health and environment. Several federal departments are involved in the implementation of the biosafety regulation. National Technical Commission on Biosafety (CTNBio), is the national competent authority. It is composed of 36 members, with multidisciplinary representation from various federal departments and representatives of the public (Fontes et al., 1998). Its secretariat is based at the Ministry of Science and Technology. The CTNBio mandate includes the development and implementation of biosafety policies, proposition of the Code of Ethics on genetic manipulation, determination of GMO risk levels and environmental studies. Futhermore, the commission overviews the risk assessment made by the Institutional Biosafety Commissions, on a "case-by-case" basis, and considers other technical and scientific issues on biosafety (Varella et al., 1998). Every private and public organization working with genetic engineering must establish an Institutional Biosafety Commission and apply for a Certificate of Quality on Biosafety (CQB) (Fontes, 1999).

Six years after its first meeting, CTNBio has certified 165 institutions working on biotechnology and granted approval for over 1000 field trials (Oda et al., 2002). More than 90% of the petitions for field trials were submitted by local Brazilian offices of large multinational

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companies. These companies develop the transgenic seeds in their country of origin and import them into Brazil for field trials. In most cases, temperate varieties containing the transgene are backcrossed with Brazilian varieties in the field or greenhouse as a means of introducing the gene into local, high market value varieties. As the research is not yet developed in Brazil, many companies do not have local personnel specialized in molecular biology or genetic engineering. In this case, members of the company's Institutional Biosafety Commission need to be trained on the fundamentals of the Brazilian biosafety framework, as well as on the general scientific bases that support the regulations. At universities and other public institutions, although the Institutional Commission's members are mostly senior scientists, there is a need to integrate knowledge from different specialties which are relevant for biosafety in order to provide a solid background for risk analysis and risk management. To educate and promote consciousness on biosafety, selected members of CTNBio visit these institutions, as well as private companies, once or twice a year. During these visits, CTNBio members present seminars and discuss with the institutions' technical staff the current issues on biosafety, problems related to the application of the guidelines, and other relevant issues. This has been a most profitable experience that helps to build knowledge and consciousness among those working with biotechnology, and also provides an opportunity to add transparency of, and confidence in, the work developed by CTNBio.

1.2. Field trials and registration of pest resistant crops

Risk assessment for commercial release culminates with a final report by CTNBio, which is legally binding. The registration of new varieties follows other sets of regulations on seed production and marketing implemented by the Ministry of Agriculture. If the transgenic plant or its products will enter the human food chain, they must also be regulated under the food safety regulations implemented by ANVISA, the National Agency for Health and Surveillance of the Ministry of Health.

Other important bodies that are involved in the regulation of transgenic plants include the National and State Surveillance System, which is responsible for the inspection at the ports of entry, research laboratories, field experiments and field trials, and commercialization. Inspection Agencies from the Ministries of Agriculture, Environment and Health have the following functions according to the biosafety law: inspection, registration, operating license, importing license, application of penalties and fees, and temporary license for field trials (Varella et al., 1998).

1.3. The regulation of pest resistant crops

In the case of plants expressing insecticidal proteins from *Bacillus thuringiensis* (Bt) or any pesticidal organism, the Pesticide Law also applies. This law rules on research, experimentation, production, packing and labeling, transportation, storage, commercialization, commercial advertising, utilization, importation, exportation, final destination of residues and packages, registration, classification, control and inspection of pesticides, their components and similar products (ANDEF, 1991). Transgenic plants that produce pesticidal substances are included in the definition of similar products, according to law: ''Products and agents for chemical, physical or biological processes, to be used in production, storage and processing of agricultural products, in pastures, etc., the purposes of which being to change the flora and/or fauna composition, in order to protect against the damaging action of live beings, is considered as being noxious.''

In this case, authorization for laboratory, greenhouse and field studies of *Bt* crops must be obtained from the SDA (Plant Protection Secretariat—Ministries of Agriculture), IBAMA (Brazilian Institute of Environment—Ministry of Environment), and ANVISA. The proponent of laboratory, greenhouse and field research must apply for a Special Temporary Registration (Acronym in Portuguese is RET). These agencies listed above will also grant consent for commercialization, each dealing with its own specific area.

1.4. Bt crop varieties

Bt varieties of cotton, corn, sugar cane and soybean (Table 1) were granted approval from CTNBio for field trials in different regions beginning in 1997. Although all the laboratory research and field trials had a CTNBio permit, they did not have a RET. In the year 2000, a court

Table 1
Insect-resistant transgenic crops expressing *B. thuringiensis* toxins that are being field-tested in Brazil

Crop plant	Toxin expressed	Target Lepidoptera species
Cotton	Cry1Ab, Cry1Ac	*Heliothis virescens*, *H. zea*, *Spodoptera frugiperda*, *Trichoplusia ni*, *Pseudoplusia includens*, *Pectnophora gossypiella*
Corn	Cry1Ab, Cry1Ac, and Cry1F	*Spodoptera frugiperda*, *Helicoverpa zea*, *Diatraea sacharalis*
Sugarcane	Cry1Ab	*Diatraea sacharalis*
Soybean	Cry1Ac	*Anticarsia gemmatalis*

injunction suspended or canceled these tests until they were granted RET approval by SDA, IBAMA, and ANVISA. As the guidelines ruling the application for the RET were not yet in place, the companies could not apply for new field trials. An inter-ministerial decree that regulates this issue has been recently approved and it is expected that field trials of *Bt* crops will soon resume.

Another set of regulations that applies to GM crops, including pest resistant varieties, is resolution 305 of CONAMA, the National Environmental Council. It defines criteria and procedures to be observed for the environmental licensing of activities and undertakings that make use of GMO's or products thereof, which are effectively or potentially pollutants.

In summary, the biosafety regulatory framework in Brazil is still under development. The proponents of biotechnology research and development have to follow at least three sets of regulation: the Biosafety Law, the Pesticide Law, and the CONAMA resolution.

1.5. The need for capacity building

In the process of evaluating each individual petition submitted to CTNBio and other competent federal departments, important experience has been gained, some of which was promptly translated into improvements of the guidelines and administrative procedures. Others, however, more complex in nature, are still to be implemented. For example, there is a pressing need to harmonize the regulatory and administrative frameworks among the different federal departments involved in the risk assessment of GMOs. In order to achieve a more interactive attitude in the decision making process, it will be necessary to greatly increase dialog and communication among the different parties involved. A possible mechanism to approach this situation is the establishment of databases and networking systems to facilitate the identification, development and dissemination of balanced information on biosafety. In this need for networking, there should be a more efficient link between administrative and surveillance bodies, in particular the federal and state inspection offices located at the ports of entry. Wider access (including the CTNBio secretariat) and expansion of the existing databases will be necessary, as well as the development of training programs on biosafety for field inspectors. This training must include, besides an overview of the country's biosafety framework, the scientific principles on which the biosafety regulation is based, providing a better understanding and promoting the individual's own involvement and compromise with biosafety.

The need for capacity building became imminent for the safe development and application of biotechnology in Brazil. The growing number of public and private laboratories working with biotechnology, as well as the environmental releases of GMO's in different locations and regions throughout the country, requires qualified personnel to conduct risk assessment, monitoring and risk management. A program designed to train members of the Institutional Biosafety Commission and personnel to act as biosafety regulators and process analysts is needed, aiming at the development and strengthening of the country's endogenous capacities. This biosafety training may consider the following strategies: (a) to carry on a manifold effect in order to reduce the operational costs of training (to train the trainers); (b) to give priority to members of the Institutional Technical Biosafety Commission, who act as supervisors of biosafety procedures within their institutions, and to inspectors from federal and state agencies linked to the Ministries of Agriculture, Health and Environment, and (c) to provide for an updated and continuous education program for CTNBio members and for other regulatory personnel in the federal departments concerned with the implementation of biosafety regulation, in order to ensure the incorporation of the more recent scientific knowledge and regulatory experience gained on biosafety worldwide. However, the program should include access to databases and international networking systems to allow for an effective update and dissemination of information.

1.6. Challenges ahead

As experience on biosafety is being gained in Brazil, we begin to recognize some of the challenges that must be faced in developing biotechnology in a country with large biodiversity. Cultivated plants which have been introduced into the country centuries ago have evolved to give origin to local races or have wild or weedy relatives in Brazil. Gene flow has become, thus, one of the relevant issues in risk analysis. On this subject I will call attention to the issue of gene flow to wild relatives and local races. Ancestors and related species of cultivated plants are mainly found in the tropical areas of the south. While countries of high biological diversity, as with any other country of the world, will greatly benefit from the new technological developments, we should look closely to any threat to the in situ conservation of germplasm that forms the bulk material for genetic breeding and biotechnology, and that is strategic for the future of the world's food security. The introduction of genes that confer changes to species adaptability into cultivated species may threaten the survivorship of wild and weedy relatives that could receive these genes through cross-pollination. This issue should be seriously addressed, in a crop-by-crop basis, with the objective to help decision-making authorities to determine how far they can go in developing biotechnology without risking food availability for future generations.

Gene flow between related plants may provide opportunity for the introduced gene to unintentionally move to neighboring countries. This possibility should be carefully evaluated and included within risk assessment schemes. In addition, a system of consultation between countries should be established, in order to prevent accidental movement of GMO's from one country to another.

Capacity building in risk assessment and risk management, and information dissemination should be priorities in biosafety capacity building in Brazil. The scientific information necessary for proper implementation of a coherent and science based regulatory process is mostly lacking in tropical regions and areas of high concentration of biodiversity. Scientific and technological capacity building in fundamental scientific areas relevant to biosafety is thus crucial for a proper implementation and application of the international biosafety protocol. Developing countries should be encouraged, and international policy mechanisms, including funding, should be provided for building intellectual capabilities on biosafety. Along with human resources, research in the area must be implemented to make available the scientific information relevant for properly conducting science based risk assessments.

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