Current and Future Trends in Harmonization of Safety Issues in South American Countries

Carmen Vicién[1]

Abstract

In the region a number and variety of genetically modified crop plants and their products are moving from developmental phases into commercialization and widespread use at an accelerating pace.

Evaluation of safe utilization of genetically modified organisms shows inequal development in the countries of the region.

Living organisms do not respect national boundaries; thus, an organism released in one country might spread to neighboring countries. This possibility is particularly likely where countries have common ecosystems, as is the case in many of the South American countries.

Nowadays there is a recognition of the urgency to ensure that national and regional bodies are properly prepared and equipped to deal with the introduction and control of genetically modified crops with the overriding priority of assuring human and environmental safety.

In various fora the importance of harmonizing policies regarding Agricultural Biosafety in the region was indicated. Recently, efforts have been made to identify common actions, namely, the drawing up and agreement of standard criteria to be considered for decisions on the experimental release and commercialization of GMOs and their derivatives, and the development of a regional database to increase knowledge about GMOs and GMO releases.

Introduction

In the Southern Cone of South America[2] a number and variety of genetically modified crop plants and their products are moving from developmental phases into commercialization and widespread use at an accelerating pace.

Transgenic crops are in the market place. When commodity crops are approved for commercial use, there is no way in which controls can be placed on the fate of the harvested crop (Beringer and MacLeod, 1996).

There is thus an urgent need to harmonize risk assessments and approaches to the development and marketing of GMOs, in order to secure human and environmental safety, and to avoid trade barriers.

The purpose of this paper is to review existing regulations and to identify common actions regarding harmonization of safety issues in the Southern Cone of South

[1] Direction of agr. Prod. Secretary of Agriculture, Fisheries and Food, Paseo Colon 982 2p Piso of 220, 1063- Buenos Aires, Argentina

[2] Argentina, Bolivia, Brazil, Chile, Paraguay and Uruguay.

America.

Regulatory procedures: current status[3]

1. Argentina

Regulation in Argentina covers the contained use and the deliberate release of GMOs. The regulatory requirements for genetically engineered crops and vaccines which have not been incorporated into laws are integrated into the overall regulatory system which governs the release of products in the agricultural sector.

Since 1991, Argentina has developoed a review system under the responsibility of the National Advisory Committee on Agricultural Biosafety (CONABIA[4]), which reports to the Secretary of Agriculture, Fisheries and Food. The committee is multidisciplinary with representatives of different governmental agencies, the industry and scientific institutions.

Any person or institution intending to transfer GMOs for use in containment or for the purpose of deliberate release into the environment has to comply with the Genetically Modified Organisms Regulations from the Secretariat of Agriculture, Fisheries and Food (Regulation N° 656 from 1992 and Regulation N° 837 from 1993).

Regarding field trials, Argentina has the largest number and greatest diversity of trials performed in South America (Table 1). Field trials with transgenic crops developed in Argentina have already been performed.

In March 1996, approval was granted for the commercializaion of transgenic soybean; other crops are close to be deregulated.

2. Bolivia

A National Biosafety Committee was established in July 1993; biosafety regulations have been developed. In November 1993, transgenic potatoes expressing antifrost proteins (from the Central University of Venezuela) were evaluated in field trials[5].

Presently, the National Biosafety Committee is being reorganized under coordination of the Secretariat of Natural Resources and the Environment.

3. Brazil

The Congress of Brazil approved and the President of Brazil santioned Law N° 8974 from 1995, which establishes norms for the use of genetic engineering techniques and the release of transgenic organisms into the environment.

The law also gives executive power to create the National Technical Commission of Biosafety, which is linked to the administrative structure of the Ministry of Science and Technology. By Presidential Decree N° 1520 of June 12, 1995, the competence level, administrative links and composition of the Commission were established. The Commission has representatives from the Ministries of Agriculture, Environment,

[3] Information based on BAC/IICA, 1996 and questionnaire to national focal points.
[4] Comisión Nacional Asesora de Biotecnología Agropecuaria.
[5] The trials were carried out based on biosafety regulations appplied and developed at the International Potato Centre (CIP) as well as the National Biosafety Committee and the International Service for National Agriculture Research (ISNAR).

Health, Education, Science and Technology and Foreign Affairs plus representatives from the scientific community, the industry, and the public. It will be operative as soon as the Commission is constituted.

4. Chile

The Ministry of Agriculture decided to regulate trials with transgenic plants using the phytosanitary and seed production regulations already available in Chilean legislation.

Moreover, in 1993, an advisory committee (CALT[6]) for the Servicio Agrícola Ganadero was appointed. Members of this committee are scientists and technical staff of the Ministries of Agriculture and Health, research institutions and universities. A resolution was issued (Res. N° 1927/93) to establish conditions for the introduction to the country of seed from transgenic plants.

Several transgenic species have been introduced and propagated in Chile for reexportation of plant material. Permits have been issued to conduct field trials with: tomato (altered fruit ripening and Lepidopteran insect resistance), rapeseed (glyphosate and ammonium glufosinate herbicide tolerance and oil profile altered), corn (glyphosate and ammonium glufosinate tolerance and Lepidopteran insect resistance), soybean (glyphosate and ammonium glufosinate tolerance and oil profile altered), wheat (glyphosate and ammonium glufosinate herbicide tolerance), tobacco (PVY virus resistance) and sugar beet (ammonium glufosinate herbicide tolerance). No field trials with transgenic plants developed in Chile have been carried out.

5. Paraguay

Paraguay has no regulations in place.

6. Uruguay

Permits for introduction and release of GMOs are issued by the Dirección de Servicios de Protección Agrícola from the Ministry of Livestock, Agriculture and Fisheries. In 1995, a Risk Analysis Committee[7] was established to provide technical advice regarding releases into the environment of corn (insect resistance) and soybean (glyphosate herbicide tolerance). Biosafety standards for risk assessment are being elaborated by the Committee.

Regional harmonization initiatives

The workshop on "Harmonization of Biosafety in the Southern Cone of South America: oversight of transgenic plants" (Buenos Aires, November 16-20, 1992), organized by the InterAmerican Institute for Cooperation on Agriculture (IICA) and the International Service for the Acquisitions of AgriBiotech Applications (ISAAA), facilitated the establishment and review of regulations involving GMOs in the region.

The principal recommendations from the meeting considered (1) development of product specific regulations for introduction and release into the environment of

[6] Comité Asesor para la Liberación de Organismos Transgénicos.
[7] Comité de Análisis de Riesgo.

transgenic plants on the basis of existing legislation, and (2) appointment of multidisciplinary committees to provide technical advice to the national regulatory authorities. The committees should include members representative of different sectors involved in biotechnology. In addition, the type of information required to submit a proposal for field releases of transgenic plants was defined (basic information for risk assessment) (IICA/ISAAA, 1994).

Since 1991, field trials of genetically modified crops have been carried out in a number of countries of the region. The regulatory frameworks in place have common aspects: information requirements to identify hazards associated with releases into the environment are essentially the same, regulatory reviews are focused on the characteristics and risks of the products, and competent authorities responsible for the regulation of activities involving GMOs required expert committees advice. However, there are differences in national regulatory styles, procedures, expertise, scopes and priorities.

In 1995 soybean was expected to be the first commercial transgenic crop in the Southern Cone. The transition from regulated small scale field trials of GMOs to commercial release set up an important step where regional discussions on a common approach were considered to be an urgent priority. The meeting on "Biosafety and Commercialization of GMOs in MERCOSUR[8]" (Buenos Aires, September 19-20, 1995) was organized to identify common actions to harmonize regulations and oversight procedures for the development and commercialization of GMOs in the region. Regarding transboundary movements of transgenic crops, harmonization on risk assessments and exchange of information were considered indispensable.

Participants[9] recommended the establishment of a technical unit on agricultural biotechnology at the MERCOSUR level to facilitate regional harmonization. Urgency in developing national advisory committees and regulatory systems in all the countries, and agreements for the development of a regional biosafety database were considered.

The workshop on "Safety in Agricultural Biotechnology: Moving towards commercialisation of genetically modified crop plants and vaccines"was organized by the Secretariat of Agriculture, Fisheries and Food from Argentina and the Department of the Environment from the United Kingdom[10] (Buenos Aires, March 5-7, 1996).

This meeting provided a worthy opportunity to discuss harmonization of safety issues. Requirements for a legally constituted and comprehensive framework for the control of biotechnological products were examined, including consideration of the possible structure, organization, terms of reference, constitution and membership of

[8] MERCOSUR was formed by Argentina, Brazil, Paraguay and Uruguay.

[9] Representatives of Bolivia and Chile also participated.

[10] The Joint Statement of 8 September 1995 signed in Buenos Aires set out the intention of the UK and Argentina to collaborate closely in a program on safety in agricultural biotechnology. As part of the arrangement, the two countries would apply the UNEP International Technical Guidelines on Safety in Biotechnology and set up voluntary arrangements for the exchange of general information relevant to the guidelines and biotechnology safety, and of information about proposed specific transfers of novel organisms from one country to another.

advisory expert committees, and ways of setting up systems to provide efficient licensing and commercialization of GMOs and their products (SAPyA/DoE, 1996).

The major output from the workshop was an agreement on regional cooperation in biosafety, using key features of the United Nations Environment Programme (UNEP) International Technical Guidelines for Safety in Biotechnology as a basis. The objectives included (1) the drawing up and agreement of standard criteria to be considered for decisions on the experimental release and commercialization of GMOs and their derivatives and (2) the development of a regional database to increase knowledge about GMOs and GMO releases[11] and systems of information exchange (SAPyA/DoE, 1996).

The establishment of a regional standard would contribute to safe development and commercialization of GMOs, make results of risk assessments comparable and facilitate decisions and exchange of information. Furthermore, information exchange was seen as a key in providing biosafety.

Finally, location of centers of origin for certain crops is a point that has to be taken into consideration. Latin America is the center of genetic diversity of several crops, including potatoes. Besides, all the Southern Cone countries have research programs to construct genetically modified potatoes incorporating a variety of traits.

Therefore biosafety assessment of transgenic potatoes represents a special challenge to regulators: few assessments have been made in the region where, in contrast with the majority of the requests for field authorizations, the "center of origin" issue is pertinent.

For those reasons, transgenic potatoes in Latin America were chosen as the focus of a BAC/IICA[12] workshop held in Puerto Iguazú (Argentina, June 23, 1995). Participants recognized that there have been few studies on the environmental impact of transgenic traits, when they are outcrossed into wild populations. Therefore, research on the environmental effects of gene flow specific to centers of diversity to improve the quantification of environmental impact was recommended (BAC/IICA, 1996).

Concluding remarks

Key issues for common criteria on agricultural biosafety in the region were defined in 1992 (IICA/ISAAA, 1992). However, the review of existing regulations shows that evaluation of safe use of genetically modified organisms is not uniform in the countries of the region.

As the number of products entering world markets increases, harmonization of biosafety issues is regarded as an urgent priority. Recently, efforts have been made to

[11] Database would include a glossary, information relating to the organism, information relating to the intended use, characteristics of the potential receiving environment, risk management measures, summary of the analyses of each proposal and data on application and approval for commercialization.

[12] Biotechnology Advisory Commission/Inter-American Institute for Cooperation on Agriculture.

identify common actions, namely, (1) organization of national biosafety committees where these were not already in place and consideration of the establishment of a regional committee; (2) development of regional criteria for the evaluation of consents to release and commercialize GMOs and GMO products; (3) exchange of information on commercialization in accordance with the UNEP International Technical Guidelines for Safety in Biotechnology and (4) development of a biosafety database.

References

1) Beringer, J. and MacLeod, J. (1996) : Commodity crops. *In*: Secretariat of Agriculture, Fisheries and Food (SAPyA)/Department of the Environment (DoE). 1996. Workshop on Safety in Agricultural Biotechnology: Moving towards commercialization of Genetically Modified Crop Plants and Vaccines. Buenos Aires March 5-7, 1996.
2) Biotechnology Advisory Commission (BAC)/Inter-American Institute for Cooperation on Agriculture (IICA) (1995) : Environmental Concerns with Transgenic Plants in Centers of Diversity: Potato as a model. Frederick, R. J., Virgin, I. and Lindarte, E. (eds.). BAC/IICA. pp. 70.
3) Inter-American Institute for Cooperation on Agriculture (IICA) (1994) : Armonización de la Bioseguridad en el Cono Sur: Supervisión de Plantas Transgénicas. Jaffé, W. R. (ed.). IICA. pp. 151.
4) Secretariat of Agriculture, Fisheries and Food (SAPyA)/Department of the Environment (DoE) (1996) : Workshop on Safety in Agricultural Biotechnology: Moving towards Commercialization of Genetically Modified Crop Plants and Vaccines. Buenos Aires, March 5-7, 1996.

Table 1 GENETICALLY ENGINEERED CROPS: PERMITS IN ARGENTINA

		Institution	Crop plant	Trait	Application
1991	1	Calgene Inc.	Cotton	Insect resistance, Bromoxynil tolerance	Field trial
	2	NIDERA S. A.	Soybean	Glyphosate herbicide tolerance	Field trial
	3	Ciba Geigy Arg. SAIC	Corn	Gene marker	Field trial
1992	1	Cargill SACI	Corn	Ammonium Glufosinate herbicide tolerance	Field/greenhouse testing
	2	NIDERA S. A.	Soybean	Glyphosate herbicide tolerance	Field trial
	3	Calgene Inc.	Cotton	Insect resistance, Bromoxynil tolerance	Field trial
	4	Monsanto Arg. SAIC	Cotton	Lapidopteran insect resistance	Field trial
	5	NIDERA S. A.	Rapeseed	Ammonium Glufosinate herbicide tolerance	Field trial
	6	Ciba Geigy Arg. SAIC	Corn	Lepidopteran insect resistance	Field trial
				Glyphosate herbicide tolerance (marker)	Field trial
	7	AGRAR del SUR	Sugarbeet	Glyphosate herbicide tolerance	Field trial
1993	1	Monsanto Arg. SAIC	Cotton	Lepidopteran insect resistance	Field trial
	2	NIDERA S. A.	Rapeseed	Ammonium Glufosinate herbicide tolerance	Field trial
	3	NIDERA S. A.	Rapeseed	Ammonium Glufosinate herbicide tolerance, Male sterile	Field trial
	4	Cargill SACI	Rapeseed	Phytase profile alteration	Field trial
	5	Ciba Geigy Arg. SAIC	Corn	Lepidopteran insect resistance	Field trial
				Glyphosate herbicide tolerance (marker)	Field trial
	6	PAU Semillas SA	Corn	Ammonium Glufosinate herbicide tolerance, Male sterile	Field trial
	7	Monsanto Arg. SAIC	Corn	Glyphosate herbicide tolerance, Lapidopteran insect resistance	Field trial
	8	NIDERA S. A.	Soybean	Glyphosate herbicide tolerance	Field trial
	9	Cargill SACI	Corn	Ammonium Glufosinate herbicide tolerance	Field trial
	10	CEFOBI	Corn	Agronomic properties	Greenhouse testing
	11	CEFOBI	Wheat	Agronomic properties	Greenhouse testing
1994	1	Dekalb Arg. S. A.	Corn	Lapidopteran insect resistance	Field trial
	2	Dekalb Arg. S. A.	Corn	Ammonium Glufosinate herbicide tolerance	Field trial
	3	Dekalb Arg. S. A.	Corn	Lysine level	Field trial
	4	NIDERA S. A.	Soybean	Glyphosate herbicide tolerance	Field trial
	5	Monsanto Arg. SAIC	Corn	Glyphosate herbicide tolerance	Field trial
	6	Cargill SACI	Corn	Ammonium Glufosinate herbicide tolerance	Greenhouse testing
	7	NIDERA S. A.	Soybean	Glyphosate herbicide tolerance	Laboratory testing
	8	Monsanto Arg. SAIC	Cotton	Lepidopteran insect resistance	Field trial
	9	Monsanto Arg. SAIC	Cotton	Glyphosate herbicide tolerance	Field trial
	10	Vander. Arg. Res. SA	Sunflower	Gene marker	Field trial
	11	Vander. Arg. Res. SA	Sunflower	Insects tolerance	Field trial
	12	Monsanto Arg. SAIC	Soybean	Glyphosate herbicide tolerance	Field trial

	13	Dekalb Arg. S. A.	Soybean	Glyphosate herbicide tolerance	Field trial
	14	Ciba Geigy Arg. SAIC	Corn	Lepidopteran insect resistance, Glyphosate herbicide tolerance (marker)	Field trial
	15	Agrigenetics S. A.	Corn	Lepidopteran insect resistance	Field trial
	16	Pau Semilllas SA	Corn	Ammonium Glufosinate herbicide tolerance, Male sterile	Field trial
	17	Calgene Inc.	Tomato	Fruit quality	Laboratory testing
	18	Cargill SACI	Corn	Ammonium Glufosinate herbicide tolerance	Field trial
	19	Cargill SACI	Corn	Ammonium Glufosinate herbicide tolerance	Field trial
	20	NIDERA S. A.	Soybean	Glyphosate herbicide tolerance	Field trial
	21	AgrEvo	Rapeseed	Ammonium Glufosinate herbicide tolerance	Field trial
1995	1	Cargill SACI	Corn	Ammonium Glufosinate herbicide tolerance	Greenhouse testing
	2	Dekalb Arg. S. A.	Soybean	Glyphosate herbicide tolerance	Field trial
	3	Dekalb Arg. S. A.	Corn	Ammonium Glufosinate herbicide and lapidopteran resistance	Field trial
	4	NIDERA S. A.	Corn	Ammonium Glufosinate herbicide tolerance	Field trial
	5	Monsanto Arg. SAIC	Corn	Lepidopteran insect resistance	Field trial
	6	Monsanto Arg. SAIC	Corn	Glyphosate herbicide tolerance	Greenhouse testing
	7	Monsanto Arg. SAIC	Cotton	Lepidopteran insect resistance	Laboratory testing
	8	Monsanto Arg. SAIC	Cotton	Glyphosate herbicide tolerance	Field trial
	9	Northurp King	Soybean	Glyphosate herbicide tolerance	Field trial
	10	Dekalb Arg. S. A.	Soybean	Glyphosate herbicide tolerance	Field trial
	11	Pioneer	Corn	Lepidopteran insect tolerance	Field trial
	12	Pioneer	Soybean	Glyphosate herbicide tolerance	Field trial
	13	Mycogen	Corn	Lepidopteran insect tolerance	Field trial
	14	Ciba Geigy Arg. SAIC	Corn	Lepidopteran insect tolerance, Glyphosate herbicide tolerance (marker)	Field trial
	15	CEFOBI	Cotton	Lepidopteran insect and Ammonium Glufosinate herbicide resistance	Greenhouse testing
	16	Ciba Geigy Arg. SAIC	Corn	Lepidopteran insect tolerance, Male sterile	Field trial
	17	NIDERA S. A.	Corn	Lepidopteran insect and Ammonium Gluposinate herbicide resistance	Field trial
	18	NIDERA S. A.	Soybean	Glyphosate herbicide tolerance	Field trial
	19	Asociados Don Mario.	Soybean	Glyphosate herbicide tolerance	Field trial
	20	CEFOBI	Wheat	Ammonium Glufosinate herbicide tolerance	Field trial
	21	CEFOBI	Corn	Lepidopteran insect and Ammonium Glufosinate herbicide resistance	Field trial
	22	AgrEvo	Corn	Ammonium Glufosinate herbicide tolerance	Field trial
	23	AgrEvo	Soybean	Ammonium Glufosinate herbicide tolerance	Field trial

24	Cargill SACI	Corn	Ammonium Glufosinate herbicide tolerance	Field trial
25	Cargill SACI	Corn	Ammonium Glufosinate herbicide tolerance	Field trial
26	INTA	Potato	Virus tolerance	Field trial
27	NIDERA S. A.	Rapeseed	Lepidopteran insect and Ammonium Glufosinate herbicide resistance	Field trial
28	Cargill SACI	Corn	Lepidopteran insect and Ammonium Glufosinate herbicide resistance	Field trial
29	NIDERA S. A.	Soybean	Ammonium Glufosinate herbicide tolerance	Field trial
30	Ciba Geigy Arg. SAIC	Corn	Ammonium Glufosinate herbicide tolerance	Field trial
31	Ciba Geigy Arg. SAIC	Corn	Lepidopteran insect and Ammonium Glufosinate herbicide resistance	Field trial
32	ZENECA	Corn	Ammonium Glufosinate herbicide tolerance	Field trial
33	Morgen	Soybean	Glyphosate herbicide tolerance	Field trial
34	CIAGRO	Cotton	Lepidopteran insect resistance	Field trial
35	Dekalb	Cotton	Lepidopteran insect and Gluposinate herbicide resistance	Field trial
36	AgrEvo	Rapeseed	Ammonium Glufosinate herbicide tolerance	Field trial

SOURCE: SECRETARIAT OF AGRICULTURE, FISHERIES AND FOOD - NATIONAL ADVISORY COMMITTEE ON AGRICULTURAL BIOSAFETY