



PROPOSAL FOR A NATIONAL BIOSAFETY FRAMEWORK FOR URUGUAY

Summary

DINAMA-UNEP – GEF Project
URU-04-009

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MINISTER OF HOUSING, TERRITORIAL ORDERING AND THE ENVIRONMENT

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Abbreviations

AAP	Prior Environmental Authorization - <i>Autorización Ambiental Previa</i>
rDNA	recombinant Desoxyribonucleic Acid
AGESIC	Agency for e-Government, Information and Knowledge Society - <i>Agencia para el Gobierno Electrónico, la Sociedad de la Información y del Conocimiento</i>
ALADI	Latin American Association for Integration - <i>Asociación Latinoamericana de Integración</i>
ANB	National Biosafety Agency - <i>Agencia Nacional de Bioseguridad</i>
ANC	Competent National Agency - <i>Agencia Nacional Competente</i>
NEA	National Executing Agency
ANII	National Agency for Research and Innovation - <i>Agencia Nacional de Investigación e Innovación.</i>
ANTEL	National Telecommunications Administration - <i>Administración Nacional de Telecomunicaciones</i>
ANV	National Housing Agency - <i>Agencia Nacional de Vivienda</i>
RA	Risk Analysis
BCH	Biosafety Clearing-House
CAAR	Advisory Committee on Risk Analysis - <i>Comisión Asesora de Análisis de Riesgo</i>
CASI	Centers for Access to the Information Society - <i>Centros de Acceso a la Sociedad de la Información</i>
CBD	Convention on Biological Diversity - <i>Convenio sobre Diversidad Biológica</i>
CEAGRO	Agricultural and Livestock Evaluation Committee - <i>Comisión de Evaluación Agropecuaria</i>
CEINDUSTRIA	Industrial Evaluation Committee - <i>Comisión de Evaluación de la Industria</i>
CERA	Environmental Risk Assessment Committee - <i>Comisión de Evaluación de Riesgos Ambientales</i>
CERV	Committee for the Risk Assessment of Genetically Modified Plants - <i>Comisión de Evaluación de Riesgo de Vegetales Genéticamente Modificados</i>
CESALUD	Health Evaluation Committee - <i>Comisión de Evaluación de la Salud</i>
CET	Technical Evaluation Committee - <i>Comisión de Evaluación Técnica</i>
CNC or NCC	National Coordination Committee - <i>Comité Nacional de Coordinación</i>
COTAMA	Technical Advisory Committee on Environmental Protection - <i>Comisión Técnica Asesora de la Protección del Medio Ambiente</i>
CSIC	Sectorial Committee on Scientific Research - <i>Comisión Sectorial de Investigación Científica</i>
CUS	Uruguayan Seed Chamber - <i>Cámara Uruguaya de Semillas</i>
DGSG	General Department of Livestock Services - <i>Dirección General de Servicios Ganaderos</i>
DGSSAA	General Department of Agricultural Services - <i>Dirección General de Servicios Agrícolas</i>
DICyT	Department of Innovation, Science and Technology for Development - <i>Dirección de Innovación, Ciencia y Tecnología para el Desarrollo</i>
DIGESA	General Department - <i>Dirección General de la Salud</i>
DINAMA	National Department of the Environment - <i>Dirección Nacional de Medio Ambiente</i>
DINARA	National Department of Aquatic Resources <i>Dirección Nacional de Recursos Acuáticos</i>
DNPI	National Department of Industrial Property - <i>Dirección Nacional de Propiedad Industrial</i>
DPA	Department for Agricultural Protection - <i>Dirección de Protección Agrícola</i>
EIA	Environmental Impact Assessment
ERA	Environmental Risk Assessment
SE	Substantial Equivalence
FAGRO	Faculty of Agronomy - <i>Facultad de Agronomía</i>
FAO	Food and Agriculture Organization of the United Nations
FCIEN	Faculty of Sciences - <i>Facultad de Ciencias</i>
GEF	Global Environment Facility
FVET	Faculty of Verterinarian Studies - <i>Facultad de Veterinaria</i>

GIM	Interministerial Working Group - <i>Grupo de Trabajo Interministerial</i>
GMB	Ministerial Biosafety Cabinet - <i>Gabinete Ministerial de Bioseguridad</i>
GMI	Ministerial Innovation Cabinet - <i>Gabinete Ministerial de la Innovación</i>
GT	Working Group - <i>Grupo de Trabajo</i>
GT AD	Working Group on “Administrative Aspects”
GT I&D	Working Group on “Regulation in Research and Development with LMOs”
GT IN	Working Group on “Industrial Biotechnology”
GT MA	Working Group on “Environmental Aspects”
GT SE	Working Group on “Socio-economic Aspects”
R&D	Research and Development
IIBCE	Clemente Estable Institute for Biological Research - <i>Instituto de Investigaciones Biológicas Clemente Estable</i>
INAC	National Meat <i>Institute</i> - <i>Instituto Nacional de Carne</i>
INASE	National Seeds Institute - <i>Instituto Nacional de Semillas</i>
INDT	National Institute for the Donation and Transplantation of Cell, Tissues and Organs - <i>Instituto Nacional de Donación y Trasplante de Células, Tejidos y Órganos</i>
INIA	National Institute for Agricultural and Livestock Research - <i>Instituto Nacional de Investigación Agropecuaria</i>
IPMont	Pasteur Institute in Montevideo <i>Instituto Pasteur de Montevideo</i>
LATU	Technological Laboratory of Uruguay - <i>Laboratorio Tecnológico del Uruguay</i>
MEC	Ministry for Education and Health - <i>Ministerio de Educación y Cultura</i>
MEF	Ministry for Economy and Finance - <i>Ministerio de Economía y Finanzas</i>
MGAP	Ministry for Livestock, Agriculture and Fishing - <i>Ministerio de Ganadería, Agricultura y Pesca</i>
MIEM	Ministry of Industry, Energy and Mining - <i>Ministerio de Industria, Energía y Minería</i>
NBF	National Biosafety Framework
MOP	Meeting of the Parties to the Cartagena Protocol
IRM	Insect Resistance Management - <i>Manejo de Resistencia a Insectos</i>
MRREE	Ministry for Foreign Affairs - <i>Ministerio de Relaciones Exteriores</i>
MSP	Ministry for Public Health - <i>Ministerio de Salud Pública</i>
MVOTMA	Ministry for Housing, Territorial Ordering and the Environment - <i>Ministerio de Vivienda Ordenamiento Territorial y Medio Ambiente</i>
OECD	Organization for Economic Cooperation and Development
WHO	World Health Organization
LMO	Living Modified Organism
CP	The Cartagena Protocol on Biosafety
UNDP	United Nations Development Program
UNEP	United Nations Environment Program
PROGRAMA AMSUD-	Program for Scientific Cooperation between the Academic Institutions of
PASTEUR	South America and the Pasteur Institute
RENARE	National Department for Renewable Natural Resources - <i>Dirección Nacional de Recursos Naturales Renovables</i>
SCDB	Secretariat of the Convention on Biological Diversity
DS	Direct Sowing
HGT	Horizontal Gene Transfer
UDELAR	University of the Republic - <i>Universidad de la República</i>

Introduction

Project URU-04-009

The concept of biosafety covers a range of measures, policies and procedures aimed at minimizing the potential risks that biotechnology may pose to the environment and human health.

In 2004 the country had already approved the release into the environment of the three transgenic plants that are now being grown: GTS40-3-2 Soybean (resistant to the glyphosate herbicide) and MON810 and Bt11 corn (insect resistant). In the laboratories of the country research was being made with genetically modified microorganisms and animals, but there was no specific legislation regulating their use or the import-export procedures. There was a fragmented and incomplete regulatory framework for the handling of living modified organisms by modern biotechnology (LMOs) with specific provisions for some applications in plants. In this context, the country understood the need to advance in the discussion and proposal of a National Biosafety Framework (NBF). That framework should include:

- a regulatory system;
- an administrative system to sustain it;
- a decision-making system based on risk assessment and management;
- mechanisms to ensure information from civil society and its participation in decision-making processes.

The National Direction of the Environment (DINAMA), as the National Competent Authority in charge of environmental protection, implemented Project URU-04-009 UNEP-GEF for the **Development of a National Biosafety Framework in Uruguay**. It began in November 2004, with the main objective of developing a proposal for NBF taking into account the provisions of the Cartagena Protocol. The implementation of the project included the participation of stakeholders. This participation became effective through the National Coordination Committee (NCC) and was complemented by integrating the Working Groups (WG) and a series of dissemination events.

One of the main benefits was the organization of existing information and the development of assessments regarding the national situation with respect to biotechnology and LMOs. The project did not work out specific regulatory instruments, but recommendations were made to improve the existing regulatory framework, which for certain areas of application (research, industry, animal LMOs) is still in deficit.

Another important achievement was the proposal for an administrative procedure to make decisions based on the experience in the authorization process of plant events, but also extending to other areas pending regulation, proposing new functions for existing institutions and the creation of new structures that will allow networking. These last achievements are aligned with the State reform promoted by the executive branch. This is a widely discussed proposal in the areas of participation generated by the Project.

Parting from the assessment, significant gaps were identified with regards to monitoring and supervision. The supervision on Biosafety is hampered by the lack of institutional and human capacities and a weak linkage between the actors with responsibilities in this field.

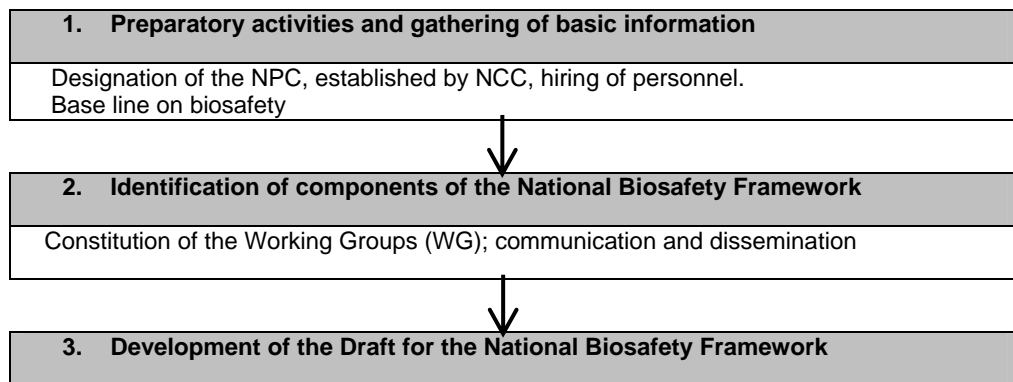
A public opinion study was conducted that revealed an important lack of knowledge on biosafety issues among the general public. The generation of effective tools to ensure access to information and participation is a substantial challenge to overcome the identified knowledge gap. The project created a website containing updated information and easy to read. Simultaneously, the central issues of the project were presented at a series of regional workshops.

The NBF proposal was made concrete in the final draft, released in late September. It contains the recommendations of various Working Groups, the positions adopted by the NCC, as well as others emerging from the project team and the National Implementation Agency. This does not mean that all these proposals have been validated by the competent authorities.

Table 1: Technical details of project URU-04-009

Starting date	November , 2004
Delivery date of the National Biosafety Framework draft	September 30, 2007
Closing date	December, 2007
National Implementation Agency (ANE)	The Ministry of Housing, Land and the Environment (MVOTMA), through the National Division of the Environment (DINAMA), led by Agricultural Engineer Alicia Torres, was the executing agency of the project
National Project Coordinator (CNP)	Agricultural Engineer (PhD) Marcos Frommel was designated as National Project Coordinator who exercised this role until March 31, 2007. The final report was written after Mr. Frommel left this office, thereafter being in charge the Technical Assistants of the Project, Agricultural Engineer Maria Fernanda Pardo and Gonzalo Martinez Crosa, under the coordination of the National Director of the Environment
National Coordination Committee (NCC)	Administrative and consultative body of the Project, with the participation of 72 representatives from 34 organizations with expertise and interests in specific aspects of the development of modern biotechnology. It held 16 meetings between August 31, 2005 and March 14, 2007.

Table 2: Execution strategy



Working Groups

The NCC set up six open working groups constitution with the task of developing recommendations for the NBF on different sectoral aspects. The recommendations of these WG were collected in the final report. The documents prepared by the WG circulated freely between WG and members of the NCC, as it was established.

Two scenarios were initially considered

1. **LMO-free Country:** this would imply absolute restriction on the use of LMOs or their parts in the national territory
2. **Coexistence:** this would imply maintaining different primary production systems (organic production, conventional farming and LMOs) simultaneously or in adjacent fields, without significantly affecting each other, thanks to specific management measures (Altieri, 2005)

Table 3: Characteristics of the working groups

Working Group	Objective	Scope
<i>Regulation in Research and Development of LMOs (WG R&D)</i>	To identify the components that the NBF should contain in terms of the regulation of LMOs for research purposes	The scenario of coexistence was exclusively considered to understand that a LMO-free country would imply the closing of current and future research lines
<i>Industrial Biotechnology (WG IN)</i>	To identify the components of the NBF for the regulation of the use, handling and generation of LMOs in the industrial sector.	The work base was an industrial scenario with application of LMOs, due to the scope of the application of recombinant DNA (rDNA) in the industry sector.
<i>Administrative Aspects (WG AA)</i>	Propose procedures for the review of applications for the	The level of the work was broad, covering the scope

	authorization of LMO use and the administrative components for its implementation.	defined by the NCC for the NBF. The proposal was made on the assumption of a scenario of coexistence in the environment, but adjustments were made for the scenario of an LMO-free country.
<i>Environmental Aspects (WG EA)</i>	To study the environmental aspects related to LMOs and propose elements for managing them within a NBF.	All LMOs released into the environment were considered, including those released unintentionally.
<i>Socio-Economic Aspects (WG SEA)</i>	To assess the socio-economic impact resulting from the use of LMOs in the country and compare agronomic packages with and without them.	It was decided to restrict the analysis to the food industry. The scenario of coexistence was addressed.
<i>Health Aspects (WG HA)</i>	To study the state of risk assessment and management of the use of LMOs from a health perspective.	<i>(The group did not function).</i>

Table 4: Activities developed under the project framework

Date	Activity	Objectives	Participants
August 3, 2005	Workshop for the evaluation of the institutional management (Montevideo)	Evaluation of the process of institutional management and monitoring of transgenic events in Uruguay. Analysis of the operation of the CERV. Strengthening of training of the NCC members	20 invited institutions (State, Private, NGOs)
March 8, 2006	Regional Meeting: North (Tacuarembó)	Expansion of the communication bases from the institutions participating in the NCC Motivation of the upward flow of communication from participating organizations /institutions and Speeding up the flow of information from interested parties to the NCC and within the Project.	Departments of Tacuarembó, Artigas, Salto, Paysandú, Río Negro and Rivera
March 22, 2006	Regional Meeting: Coast and Central (Trinidad)		Departments of Flores, Soriano, Colonia, San José, Canelones, Florida and Durazno
April 5, 2006	Regional Meeting: East (Minas)		Departments of Lavalleja, Maldonado, Rocha, Treinta y Tres and Cerro Largo.

October 26, 2006	Meeting in the Faculty of Science (Montevideo)	Discussion of issues relating to the regulation of scientific activity with LMOs	Representatives from the academic sector
September 11, 2007	Basis to delineate research policies in Agricultural Biotechnology (Montevideo)	Workshop for discussion on the outlines for research policies in agriculture and livestock biotechnology, at the GIM level	Competent institutions, general public
October 30, 2007	Regulation of Transgenic contributions and how it is viewed in terms of Public Health (Montevideo)	Formation of a interdisciplinary working group to support the health component in the GIM.	Academic community, state sector, general public
December 4, 2007	Final Meeting	Presentation of the Final Report of the Project	Authorities, Members of the NCC, NGOs, Academic community, Media, general public

Research

- **Reviews:** A thorough review was made of scientific information, peer-reviewed at the national, regional and international level, on the environmental situation of the Bt Corn and glyphosate-resistant Soybeans.
- **Inventories:** An inventory was made of human and institutional resources in research and development (R & D) of Lepidoptera was conducted in Uruguay. Lepidoptera are insects susceptible to the toxins in presently released transgenic articulate the research teams with one another. A meeting was conducted with leading experts in the field and a proposal for a national database on Lepidoptera was developed. An inventory of the national capacities in biotechnology research was also conducted, which sought to determine the current situation in terms of installed capacity and consolidation programs and R & D in biotechnology at national and regional levels. For its implementation, a survey was conducted, in coordination with the Amsud-Pasteur Program, at academic and business levels on the research, capabilities in infrastructure and human resources devoted to R & D in biotechnology.
- **Study of opinions:** This is a task performed by the NCC, a public opinion survey to assess the degree of knowledge on the subject among different actors of society. This task included politicians, journalists, producers and professionals of biology, in addition, the general public.

Lessons learned

1. **Extent of the phenomenon:** The information horizon on LMOs was extended, transcending commercial plants. The information generated by the Project depicts a

new reality: LMOs and derived products are extensively used in the food industry, in medical research and agriculture.

2. **Public Opinion:** through the study of opinions, the positions of some sectors were identified and evidence was found of the general lack of knowledge of the issue among the population.
3. **Importance of participation:** The constant and systematic contribution of the involved sectors, often defending different positions, enriched the discussion process. Despite the disagreements, a formal working agreement was achieved that resulted in advanced to the degree accepted by the representatives in the NCC. The issue was set on the agenda of all institutions involved.
4. **Future Commitments:** The representatives of the institutions and organizations of the NCC and the participants of the Working Groups expressed their willingness to continue working on the issue.
5. **Regulatory gaps:** The lack of specific regulations in certain areas (research, industry, animal LMOs) constitutes one of the main challenges to face.

Biotechnology in the national context

In Uruguay, biotechnology-related activities occur in the vegetal and animal realm (agrobiotechnologies), in biomedicine, industry and recently in bioinformatics. As to LMOs, there is an enormous lack of information about which industries are handling these organisms, and even the industries themselves are unaware of their origin. At the same time, although it is of public knowledge that there are lines of research centered on agrobiotechnologies and biomedicine, which develop LMOs, the country does not possess a registration system which allows obtaining reliable information on these activities.

In spite of the relative biotechnological backwardness in comparison with the other countries in the region, in the last years the degree of equipment and infrastructure of the biotechnological platforms has improved; examples are the Pasteur Institute in Montevideo (IPMont), the Clemente Estable Institute for Biologic Research (IIBCE), the National Institute for Agricultural Research (INIA) and the Faculty of Sciences (FCIEN).

Uruguay spends minimal percentages of the GDP on R&D, compared with the most developed countries as well as the other countries in the region. On average, the country invests 0.21% of the GDP (ratio R&D/GDP), a number which is elevated to 1.61% if the agro-industrial GDP is considered (ratio R&D/ agro-industrial GDP), since this sector has the highest demand for R&D (MGAP, 2005). In spite of the disadvantageous situation in terms of investment, Uruguay ranks among the 35% of countries with the highest quantity of Internet nodes and has an important national scientific production in terms of publications and patents. The public sector, and particularly the University of the Republic, concentrates the highest number of researchers.

There have been activities to promote national biotechnology in the past, at the level of national as well as regional agencies. But it can be observed that this field still presents a unsystematic development and lacks strategic programs with high levels of interaction. The

initiatives for biotechnological development are carried out by public institutions and private companies.

Uruguay is positioning itself as a country with a good level of capacities for research in biotechnology, in terms like the number of laboratories, qualified human resources, infrastructure and equipment. But there is a lack of economic projections on biotechnological activities, due to the fact that there are not enough qualified human resources in the area of management and technical support. As to the professional training of the human resources, different instances have been encouraged to promote training through postgraduate courses, principally in the area of biological sciences; there is a high percentage of publications in national and international journals; and an important recognition of researchers has been made through the awarding of prizes and/or special distinctions. Nevertheless, qualified human resources are required in biosafety at the government level.

The formation of the new public structures, the Ministerial Cabinet for Innovation (GMI) and the National Agency for Research and Innovation (ANII), constitute promising initiatives to improve the current national situation in matters of biotechnology.

GMO-events in Uruguay

Soybean: Event GTS 40-3-2 (MON-Ø4Ø32-6)

Authorized in our country for production, import and consumption on the 2nd of October 1996 through the Resolution of the Division for Agricultural Protection Services of the Ministry of Livestock, Agriculture and Fishing (MGAP).

Since then, the cultivated surface has noticeably increased and completely taken the place of the conventional soybean cultivation and other farming systems (Hernández *et al.*, 2001; INASE, 2006).

The soybean with this event, also named Roundup Ready® (RR) soybean, was developed through recombinant DNA technology. It is tolerant to glyphosate, the active principle of the Roundup® herbicide. The action mechanism of glyphosate consists in inhibiting the activity of the enzyme 5-Enolpyruvylshikimate-3-Phosphate Synthase (EPSPS). This enzyme is essential for the metabolic route of the shikimate, in charge of the production of aromatic amino acids: phenylalanine, tyrosine and tryptophane (FAGRO, 2005; Monsanto, 2002). The EPSPS is the biological target of glyphosate in the plants, and no other enzyme is inhibited by glyphosate, so that the soybean 40-3-2 permits the use of this herbicide as an alternative for the control of weeds in soybean production (FAGRO, 2005).

No evidence exists of any risk assessment prior to the introduction of soybean 40-3-2 .

Corn: Event MON 810 (MON-ØØ81Ø-6)

Authorized for use, production, commercialization of seeds, products and sub-products, through joint resolution, without number, of the MGAP and the Ministry of Economy and Finances (MEF), on June 20th, 2003. Since then, the adoption rate of Bt corn (MON810 and Bt11) has increased, and is considered to be almost 50% at the present.

The CERV (Committee For the Risk Assessment of Genetically Modified Plants) carried out the Environmental Risk Assessment (ERA) presented by the applicant (CERV, 2002). The authorization of this event in the country was justified by its capacity for the control of lizard plagues. However, the Faculty of Agronomy expressed its disapproval, as the lizard species for which this plant it had been designed, did not exist in the country (Faculty of Agronomy, 2002). Another criticism of the report argued that it was limited to an interpretation of bibliographic material compiled by the applicants, without counter-checking *in vitro* or *in situ* the relevant data which had not been obtained in the country (Martinez, 2006b).

To counteract the risk of resistance appearing in the pests, special handling measures were implemented which include the installation of shelters and the establishment of buffer zones. A shelter is a plot planted with corn without Bt with the same cycle and characteristics. The shelter's purpose is to delay the appearance of varieties of insect pests resistant to the toxin. The norms in force establish a minimum shelter area corresponding to 10% of the plantation. A buffer zone of 250m between the cultivations is also stipulated.

Corn: Event Bt 11 (SYN-BTØ11-1)

Authorized for the use, production, commercialization of the seed, products and the subproducts, through joint resolution, without number, of MGAP and the Ministry of Economy and Finanzes (MEF), on May 7th, 2004.

The corn is planted in a minor quantity compared to MON810, but exact percentages cannot be established to date, because the nature of the Bt events is not broken down in the statistics.

Besides the gene CryIAb, the event Bt 11 contains the gene carrying the code for the enzyme PAT, which grants resistance to the herbicide glufosinate ammonium. This gene was used as a marker, and an ERA was not required by the CERV. The handling measures established by the current norms are identical to those for MON810 corn.

White Clover: Event ipt:atmyb32

It was authorized by the CERV for its evaluation under contained testing conditions in March 2005. This material was developed in Australia and evaluated under laboratory and greenhouse conditions. This event has a transgene which includes an encoded sequence of the enzyme *ipt* (stemming from the bacteria *Agrobacterium tumefaciens*), as well as the promotor-sequence *atmyb32*, isolated from the plant *Arabidopsis thaliana*. Its purpose is to delay the leaf senescence, or the programmed ageing of the cells, thus allowing normal growth to continue for a longer time. The event ipt: atmyb32 contains a major concentration of cytokinines, which are phytohormones present in the plants that act like growth and development regulators. Currently, it is being evaluated in Uruguay (INIA-La Estanzuela) and Argentina (University of Buenos Aires).

The test carried out in Uruguay has an estimated duration of two years, and once finalized, the material must be destroyed. To date, it constitutes the only case of a plant event authorized for research in contained use, protected by Decree 249/000.

Other events

The rest of LMOs evaluated in the country are included in **Table 5**.

On the other hand, there are nationwide research lines in the academic sector which develop LM-plants as study models or for teaching purposes. In the majority of the cases the host organism is *Arabidopsis thaliana*. The situation is similar for microorganisms.

As far as animals are concerned, LMO-development is taking place exclusively on an academic level; these activities are concentrated in the Clemente Estable Institute for Biologic Research (IIBCE), the Medical Faculty and the Pasteur Institute of Montevideo (IPMont). These institutions work with rodents for biomedical purposes. An important progress in this sector is foreseen for the next years as a result of the recent establishment of a laboratory rodents center and a unit of transgenic animals in the IPMont.

Table 5. LM-plants evaluated in the country.

Event	Unique Identifier ¹	Crop	Characteristics	requested application
BT 176	SYN-EV176-9	NaturGard KnockOut™ Corn	Lepidopter- resistance	Evaluation for the National Cultivation Register (INASE)
T 25	ACS-ZM003-2	Liberty Link™ Corn	Glufosinate Ammonium tolerance	Evaluation for the National Cultivation Registration (INASE)
GA 21	MON-00021-9	Roundup Ready™ Corn	Glyphosate tolerance	Evaluation for the National Cultivation Registration (INASE)
CBH 351	ACS-ZM004-3	Starlink™ Corn	Lepidopter resistance Glufosinate Ammonium Tolerance	Evaluation for the National Cultivation Registration (INASE)
NK 603	MON-00603-6	Roundup Ready® 2 Corn	Glyphosate tolerance	Trials and field tests
NK 603 X MON 810	MON-00603-6 x MON-00810-6	Roundup Ready™ YieldGard™	Lepidopter resistance Glyphosate tolerance	Trials and field tests
CP4 (Event not specified)		Eucalyptus	Glyphosate tolerance	Trials and field tests
11 / 25 (Event not specified)		Eucalyptus	Low lignin content	Trials and field tests
gen BAR (Event not specified)		Rice	Glufosinate Ammonium tolerance	Evaluation for the National Cultivation Registration (INASE)
LLRICE62	ACS-OS002-5	Liberty Link™ Rice	Glufosinate Ammonium tolerance	Evaluation for the National Cultivation Registration (INASE) Production and import for direct consumption or transformation

¹ The code between brackets corresponds to the unique identifier according to the OECD (2002) The OECD guideline for the designation of a unique identifier for transgenic plants. In: *Series on Harmonization of Regulatory Oversight in Biotechnology* N° 23, pp. 1-12. Organization for Economic Co-operation and Development, Paris.

Political Framework

The Cartagena Protocol

In 1992, in the realm of the United Nations, the first worldwide agreement addressing aspects related to biological diversity was approved, the Convention on Biological Diversity (SCBD, 1993). The Convention was signed by about 190 governments and has the following purposes: (1) the conservation of the biological diversity; (2) the sustainable use of the components of biological diversity, and (3) the fair and equal distribution of the benefits arising from the use of genetic resources.

The Cartagena Protocol (CP), approved in Montreal in 2000, is a result of the above-mentioned convention, specifically of section 3 of article 19. The CP establishes the guidelines for an international regulatory system to guarantee the safe transfer, handling and use of LMOs subject to transboundary movements. The Protocol specifically refers to the LMOs whose direct introduction into the environment is planned (seeds, young plants, fish, etc.) and genetically modified agricultural products (corn or grains for food or feed). It does not cover pharmaceutical products designed for human beings, which are taken up in other agreements and international organizations, nor derived products of LMOs.

Uruguay accompanied the negotiation process closely which led to the drafting of the CP, sending delegates and position documents. After having signed the CP, it did not participate directly in the meetings of the Parties to the CP (MOP), except for the last one, held in Curitiba in 2006. However, the international process has been reflected in nationwide decisions: for example, in the same year the Cartagena Protocol was approved, the General Law on Environmental Protection Nr. 17.283 was promulgated, with specific dispositions about biosafety, as well as Decree 249/000 establishing an administrative framework for the processing of authorization requests for genetically modified plants for different applications.

Biosafety Policy

One of the first steps in building an NBF is the application for introduction into the country of GTS 40-3-2 soybean. To process these, an Advisory Committee for Risk Analysis (CAAR) was created in the Direction of the Agricultural Protection Services of the Ministry of Livestock, Agriculture and Fishing (MGAP). In the context of the CAAR, other LM-plants were also approved for tests and other use in restricted conditions (without commercial release).

Due to the increasing demand of applications for the release of LM-plants for cultivation, the Committee For the Risk Assessment of Genetically Modified Plants (CERV) was created. Decree 249/000, which created this committee, marks the first step of a state policy on biosafety. Categories of environmental exposure (application levels and competences for respective authorizations were established, risk assessments prior to any authorization were stipulated and some instances of participation and public consultation were created. Based on the CERV's findings, the release into the environment was authorized for the events Bt

MON 810 and Bt 11 corn and for the trials under controlled conditions in the case of NK603 corn (suspended for the moment) and ipt:atmyb32 white clover.

During the same year, the General Law on Environmental Protection N° 17.283 was approved. Article 23 outlines the fundamentals of a national biosafety policy. Among the aspects emphasized by this law are the designation of the MVOTMA as the national authority with a primary competence on LMOs released into the environment, the need for prior authorizations, and an extension of the scope beyond the limits of the CP, insofar as LMOs with pharmaceutical purposes are also considered. Despite the scope of the aforementioned Article 23, at present the administrative framework for prevention and control of risks arising from LMOs presents gaps in some sectors.

During the URU-04-009 project, a process of discussion and exchange between different public, private and civil society actors about the need to revise the biosafety policy developed. After the National Elections in 2004, the new government declared its willingness to revise the adopted decisions on the basis of an adequate debate of the subject for which the broadest possible participation had to be ensured as a key requisite.

As a result of this revision, a Decree was issued to suspend the use, production and commercialization of some varieties of sweet GMO-corn, and in January 2007 the processing of new approval requests for genetically modified plants for any of in the applications foreseen in the currently valid regulation was stopped for 18 months. Decree 037/007, which establishes said suspension, constitutes a significant step in the development of a biosafety policy, creating an Interministerial Workgroup (GIM) to draft a proposal for a legal framework and to design guidelines and policies for biotechnology, incorporating a public participation component in the process.

The GIM is integrated by one delegate and two deputies of every Ministry (MEF, MGAP, MSP, MVOTMA). They meet periodically since May 29th, 2007. Until now, the work of the GIM was concentrated on the provisions of Article 5° of the above mentioned decree (socio-economic, environmental, health, intellectual property aspects, aspects of participation of the social society, cooperation and technology transfer, and aspects of coexistence, all related to the use of LM-plants in agriculture).

On the other hand, the GIM has focused on studying the feasibility of different policy scenarios regarding biosafety (coexistence, GMO-free country). The studies made during the implementation of the URU-04-009 project are being used by the GIM as fundamental input for the formulation of its recommendations. The observations, comments and the contributions made by different civil society organizations, which the GIM invited to bring forth additional considerations to those providing during the project, are also being taken into account.

According to the stipulations of Article 5 of the Decree, the GIM drafted a preliminary Progress Report which is being considered by the corresponding Ministers since August 24th, 2007. In this report, the need to face the challenges of institution-building at three levels is recognized:

- **Policy:** Advancement towards the drafting of a Bill for a National Law on Biosafety
- **Operative Level:** Development of a plan to strengthen new operative abilities required to implement the biosafety policy.
- **Participation:** Creation of institutionalized advisory instances, which can achieve

the goal to advise the Executive Branch on everything related with the implementation of a biosafety policy.

Even if the scope of the assigned task is limited to LM-plants, particularly on those used for agricultural exploitation, the GIM understands that a National Law on Biosafety must cover at least the scope of Article 23 of the Law N^o 17.283.

The MVOTMA recognizes that, as a result of the Project, progress has been made in the gaining of knowledge and dissemination of information; additionally, participation instances have been created, which constitute one of the principal elements of the biosafety policies this government has tried to strengthen. However, it is necessary to continue the debate, to develop dissemination policies on the subject and to define a national position on the ratification of the CP.

Positions and recommendations

1. The CNC recommends considering the revision of the authorizations of the events MON 810 and Bt11 corn and CP4 soybean, until a concrete NBF proposal is presented.
2. Regardless of whether Uruguay decides to ratify the CP or not, the certification analysis should be included in the framework of a national biosafety policy.
3. The call for prohibition is frequently justified by the deficiencies and difficulties to fulfill the norms; but the warning has to be made that if the possibility of building efficient regulation systems is denied, the effectiveness of the prohibition or a moratorium cannot be guaranteed.

Biosafety Regulation System

Regulations in force

Table 6 National Laws

Year	Law	Comments
1934	9.902 - Organic Law of the Public Health Ministry MSP	Establishes the competences of the MSP for the national health policy and specially as food police
1935	9.463 - Creation of the MGAP	Establishes the primary competence of the portfolio in matters of agriculture, livestock and fishing
1984	15.605 - (Decree-Law) Creation of the INAC	Establishes the competence of the institute as to the proposal, counseling and execution of the National Meat Policy
1985	15.591. Customs Codex	Establishes the exclusive competence of the National Customs Department on customs matters, including the traffic control, the customs police and the fulfillment of international agreements on the matter.
1989	16.065 - Creation of the INIA	Creates this mixed institute and assigns it the task of formulating and executing agricultural research programs, participating in the R&D processes in this field
1990	16.112 Creation of the MVOTMAC	Establishes a primary competence of the portfolio through the DINAMA, on matters of environmental protection
1993	16. 408 CDB	The Convention on Biological Diversity is approved
1994	16.466 - Environment	Declares environmental protection as a matter of national interest, defines the environmental impact and prescribes Environmental Impact Assessments for certain undertakings.
1997	16.811 Creation of INASEC	Creates this mixed institute, assigning competences for the development and monitoring of seed-producing activities and counseling of the Executive on the development of a national seed and phytogetic policy.
2000	17.283 General Law on Environmental Protection	Defines Uruguay as <i>Natural Country</i> . Establishes the Precautionary Principle as the basis for decision making in environmental conflicts. Establishes participation and articulation in environmental management. Dictates punctual rules with respect to LMOs.
2000	17.250 Consumer Protection	Stipulates the basic rights of the consumer and all activities for the protection of health and safety, labeling criteria and publicity-related regulations.
2006	17.942 Phytogetic resources for food and agriculture	Approves the FAO Treaty on phytogetic resources for food and agriculture
2006	17.997 Animal Identification and Registration System	Creates a system of individual traceability for cattle and declares, the Animal Identification and Registration System as a matter of national interest to ensure the traceability of animal products on the national territory.

Table 7. Decrees and Resolutions

Year	Legal instrument	Comments
1993	Dec. 261/993	Creates the COTAMA
1997	Dec. 149/997	Establishes DINARA's competences in agricultural matters
1999	Dec. 135/999	Regulates the handling of hospital waste
2000	Dec. 249/000	Creates the CERV and establishes the procedures for the request of authorization for the use of LM-plants in different fields
2002	Dec. 186/002 MGAP	Regulates the registration and operation of animal breeding centers (for vertebrates) for wild fauna, under the control of the RENARE
2003	Res. Min of the 20/06/03 without number (MEF-MGAP)	Authorizes the production and import destined to direct consumption or transformation of MON810 corn
2003	Res. Min. 236A/003 and 276/003 (consolidated text)	Establishes conditions for the introduction, use, production and commercialization of MON 810 corn
2004	Res. Min 290/004 (MEF-MGAP)	Authorizes the production or import for direct consumption or the transformation of Bt11 corn
2004	Res. Min. 292/004	Establishes conditions for the introduction, use, production and commercialization of Bt11 corn
2005	Dec. 05/05/05 (MGAP)	Fixes harmonized tolerance levels in field and laboratory for the production and commercialization of seeds of different certification categories (MERCOSUR). Establishes a 200m buffer zone for corn and 3m for soybean.
2005	Dec. 349/005	Regulates the Law of Environmental Impact Assessment and Environmental Authorizations
2005	Dec. 136/005	Creates the Ministerial Cabinet for Innovation
2006	Res. Min. of the 17/08/06 without number (MVOTMA)	Suspends the use, production and commercialization of genetically modified sweet corn seeds.
2006	Dec. 160/006	Establishes the control, quality and safety norms for the transplant of human cells and tissues.
2007	Dec. 037/007	Establishes the suspension of new requests for transgenic plant and creates an Interministerial Workgroup, whose purpose it is to define the national biotechnology policies.

Voluntary norms

At the moment there is no specific regulation for LMO research and development activities. But the different agencies and institutions directly related with the field of national biotechnology have voluntary norms. These constitute guidelines, regulations or other types of norms, whose purpose it is to maintain the biosafety levels in the research laboratories. This is the case of the **Regulation on the use of animals for testing, teaching and academic research**. This regulation was formulated by the Honorary Committee for Animal Testing of the University of the Republic. It establishes and standardizes animal use for experiments and the necessary installations for this purpose.

Additionally, it determines a protocol for the requests for the use of animals in experiments, teaching and R&D, in the framework of the University of the Republic.

The majority of the laboratories performing R&D have work guidelines which, among other things, include biosafety guidelines based on international norms, the so-called **Good Laboratory Practices (GLPs)**.

Bills in Preparation

- **Bill of Law on Information Access:** Its purpose is to permit free access to information of the national or departmental public administration to every natural or legal person.
- **Bill of Law on Genetic Resources and associated Traditional Knowledge (2006):**
Stipulates the creation of a National Register of traditional knowledge and the implementation of distribution mechanisms for the benefits derived from the use of genetic resources
- **Bill of Law on Sustainable Territorial Regulation and Development (2006):**
Establishes the competences and instruments for planning, participation and intervention on the matter and designs the instruments for the execution of the plans and territorial intervention

Recommendations

1. **Regulation System:** It is necessary to have a clear Regulatory System whose fulfillment is independent from the policies on LMOs. The normative system has to be adequate, and its credibility has to be ensured, starting with the risk assessment process to the management of coexistence with conventional productions.
2. **Update of valid norms:** the NBF proposal has to consider the updating of valid consumer protection norms (law N° 17.250), because it does not contemplate the biosafety-related aspects.
3. **Specific regulations:** it is necessary to establish biosafety regulations for the processes of exclusive LMO-research (this regulation has to be different from the corresponding ones on LMOs for commercial purposes).
4. **Regulation of the biomedical sector:** within the scope stipulated by the CNC for the NBF, it is necessary to fill existing normative gaps referring to LMO-derived products in the biomedical sector.
5. **Articulation with other signed agreements:** It is necessary to take into consideration the international agreements signed by the country referring to commercialization and customs barriers (CBD, WTO, Codex Alimentarius, etc.).

Decision making system

Institutional procedures and competences

With the creation of the Committee for the Risk Assessment of Genetically Modified Plants (CERV), through Decree 249/000, the first legal competences on the subject of LMOs authorizations are created, specifically for plants with agroindustrial application. The CERV operates like an advisory panel and is integrated by representatives of the Ministry of Livestock, Agriculture and Fishing (the institution chairing the committee), the Ministry of Housing, Territorial Ordering and Environment (vice-chair), Ministry for Public Health, National Seed Institute and the National Institute for Agricultural Research. The Decree also establishes a series of application levels, partially related to levels of increasing exposure. The following table lists these levels:

Table 8. LM-plant application levels according to currently valid norms

Section ²	Description
A	Experiments in conditions of contained use
B	Trials and tests in the field or under low protection, under specific biosafety conditions
C	Evaluation for the National Crop Register
D	Seed multiplication under specific biosafety conditions
E	Import, destined to the direct consumption or transformation. Release into the natural environment

The competent authorities for the authorizations defined by the Decree are the MGAP and MEF for the Eastern zone and the General Division for Agricultural Services (DGSSAA) of the MGAP or the INASE in the remaining zones. In addition, the MSP and the MVOTMA can intervene within the range of their competence, established by the Laws N° 9.292 (MSP) and N° 16.112 y 17.283 (MVOTMA).

Table 9 describes the principal institutions with specific competences referring to LMOs for the scopes defined by the CNC:

² Corresponding section of Art. 2 of Dec. 249/000

Table 9. Competences of the public sector

Function	Human health	Agriculture	Industry	R&D	Environment
Definition of policies and regulations	MSP	OPYPA	MIEM	GMI, DICYT, UdelaR	DINAMA RENARE
decision making (resolution)	MSP	DGSSAA, RENARE	DNPI	MEC, UdelaR	DINAMA
ERA	MSP, FMED	INASE	-	FAGRO, FCIEN, FVET, FQUIM, INIA	DINAMA
Information Management	MSP, FMED	INASE, DIEA	DNPI DNI	MEC, DICYT, ANII	DINAMA
Monitoring and Control	DIGESA	INASE	DNPI	ANII	DINAMA

Procedures in place

Agricultural and livestock production

The country has generated an explicit procedure in the scope of agricultural production, by Decree 249/000. This procedure regulates the authorization of LM-plants for the applications indicated in Article 2 (see **table 8**). The valid procedure is summarized in the diagram in **table 10**.

Environment

Within the DINAMA, Environmental Impact Assessments (EIA) are the main measure for environmental protection. For specific undertakings, a Prior Environmental Authorization (PEA) with specific procedures is required. In the impact study, comparisons are made between prior and subsequent conditions for an action in the environment. DINAMA has no specific procedures to assess the impact of LMs released into the environment.

Research and Development (R&D)

There are no defined procedures for R&D with LMOs, with the exception of LM-plants in contained use³. This situation constitutes one of the most important voids identified by the R&D Workgroup.

Health

As in R&D, no specific procedures exist for the health sector in matter of LMOs. However, there are procedures for the assessment of toxicological risks and food harmlessness, in charge of DIGESA. The National Institute for the Donation and Transplant of Cells, Tissues and Organs (INDT) is the agency in charge of safeguarding the quality and safety of procedures related to the manipulation of stem and embryonic cells which are carried out in the country with biological material, and to control its import and export.

³ Decree 249/000. Art. 2 sections a and b

Industry

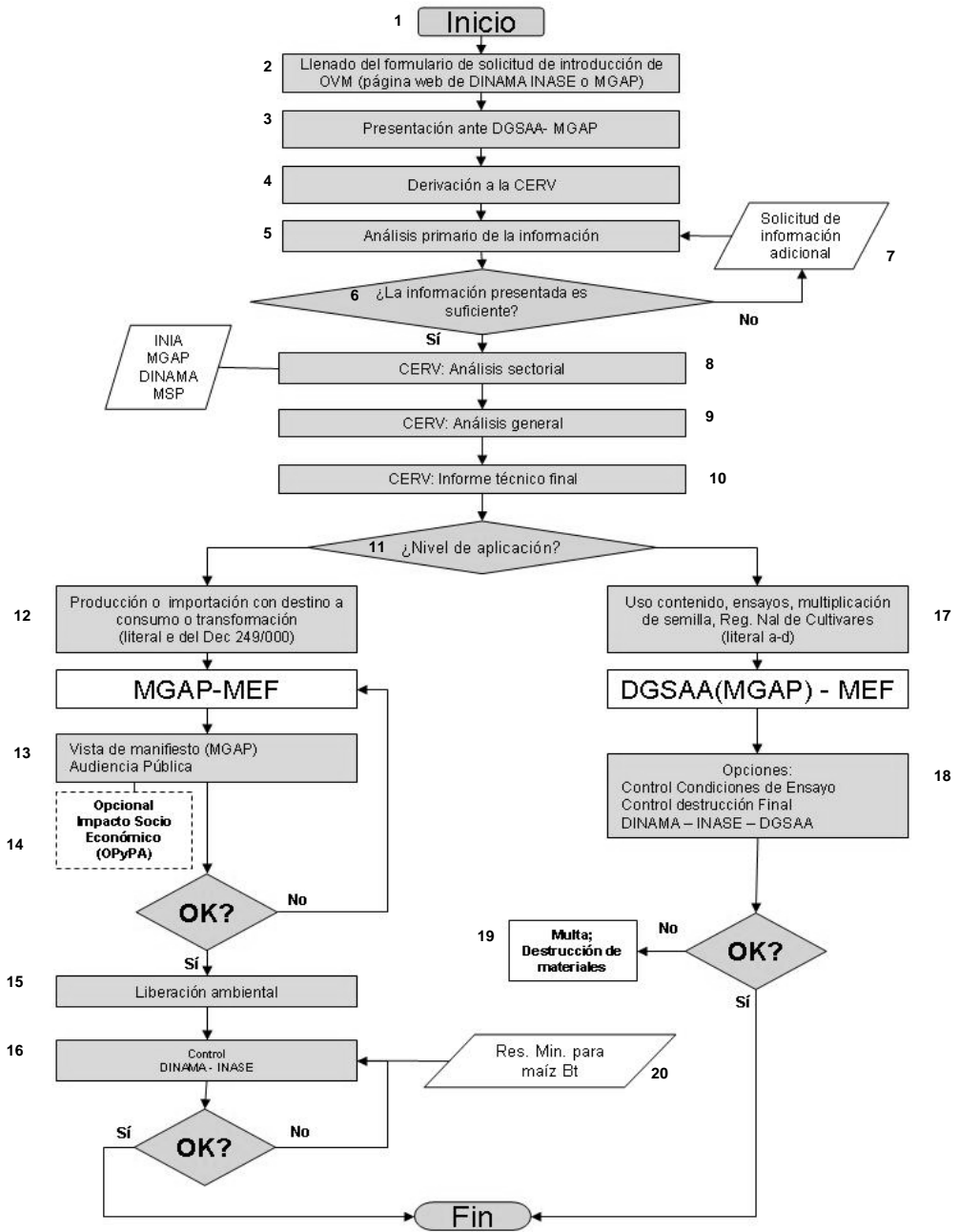
Uruguay has procedures for product certification at the industrial level, based on national and international norms. Imported products have to be approved in a verification process on the fulfillment of the national bromatologic requirements, with the purpose to protect the consumer and ensure that these products are healthy and labeled with understandable, illustrative and truthful information. The LATU is the responsible agency for the control and certification of these industrialized export products, according to the norms established by Decree 338/982. However, the situation referring to LMOs is not framed in any industrial regulation.

According to the Customs Code in effect since 1985 valid, Law N° 15.591, the National Customs Department has the legal authority to make the relevant examinations of the merchandise entering Uruguayan territory, as a sanitary prevention measure.

Table 10.

- | |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <ol style="list-style-type: none">1. Start2. Filled request form for LMO introduction (website of DINAMA, INASE or MGAP)3. Presentation before the DGSAA – MGAP4. Forwarding to the CERV5. Primary information analysis6. Is the presented information enough?7. No → Request for additional information8. Yes: CERV Sectorial analysis9. CERV General analysis10. CERV Final technical report11. Application level?12. Production or import for the purpose of consumption, or transformation (paragraph e of Decree 249/000)13. Public dossier (MGAP). Public audience14. Optional: social economic impact (OPyPA)15. Release into the environment16. Contained use, tests, seed multiplication, National Cultivar Registration (paragraphs a – d)17. Options: Control of test conditions. Control of final destruction. DINAMA – INASE – DGSAA18. Fine. Destruction of the material19. Min. Res. for <i>Bt</i> corn20. End |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

Table 10. LM-plant authorization procedures, according to Decree 249/000⁴



⁴ According to Decree 037/007, the processing of new LM-Plant applications is suspended by the CERV. This implies that the applicant can only present the form to the CERV and wait for a resolution, once the period established by the Decree ends.

Information Management

National systems for environmental and territorial information

Law N° 17.283 establishes an adequate management of environmental information as a basic principle of environmental state policy, in order to ensure its availability and accessibility for stakeholders. The information management on LMOs is vital for an adequate management and especially for an efficient monitoring, which is necessary to handle a new technology, whose risks have not been established in all their extent.

There is a series of information tools, some of which of long duration, which gather relevant data for decision-making on the release of LMOs into the environment. The continued existence of this data-base and qualified human resources for its management represent a positive experience for the drafting of an NBF. An example for these systems is the National Geographic Information System (FFAA), the National Crop Register (INASE) or the Agriculture and Livestock Census (MGAP). Other tools are presently in preparation, like the System of Environmental Information or the National System for Protected Areas (both in the MVOTMA).

Data Base on corn

The management of the corn events released in the country (MON810 and Bt11) is regulated by a set of ministerial resolutions which demand, among other things, the public registration of the transactions and crop declarations of the respective events. In this sense, the DINAMA is the competent authority to receive these forms. During the implementation of the URU-04-009 Project, a data base was created with the information from the forms, which required the hiring of digitalizers to process and enter the information. The aim was to generate a registration program for data on corn which would be compatible with the software available in the DINAMA and with the existing data in the MVOTMA and the MGAP.

Lepidopter data base

The corn events released in Uruguay contain the protein *CryIAb*, which has a specific toxic reaction against Lepidopters (butterflies and moth). The project collected data about human resources (research teams) and institutional resources (biologic collections, data bases) in R&D of lepidopters (Martinez, 2006^a). Based on this data, and meetings and interviews with experts on the subject, the creation of a national lepidopter data base was proposed which would permit an adequate monitoring of the national biodiversity in this group and the design of sustainable management strategies for Bt crops. The prototype of the base was prepared and is being implemented.

R&D data base

As a result of the inventory of national biotechnological capacities (Pardo, 2006b) data bases were generated about the R&D lines in biotechnology and the resources destined to this area for human resources and institutional capacities (Pardo, 2006b). This information made it possible to assess the national situation in the matter and to identify what needs the country will probably face with the drafting of an NBF.

Biosafety Clearing House

This year Uruguay signed the Memorandum of Understanding to join the *Project for Capacity Building for an Effective Participation of the Biosafety Clearing House* (BCH). The BCH⁵ is a Web Portal which gathers all information about LMOs and biosafety-related aspects of State Parties or Non-State Parties to the CP (the latter have to express their interest before the SCDB to spread their information on this website). Given that Uruguay is not a Party to the PC, it still has not delivered all information required by the protocol. However, this new initiative represents a progress towards the consolidation of a National Biosafety Information System.

Risk Assessment

General Concepts

Risk Assessment forms one of three dimensions of a major process named Risk Analysis, which is complemented by Risk Management and Risk Communication. These three components are interrelated in a way which sometimes makes their separation difficult for non-experts.

Risk Assessment is defined as a process based on the technical-scientific method which has the aim to determine and characterize the risks that a new substance, physical factor or practice represents for a determined population or environment. It is the technical-scientific instance which serves as a basis for the ensuing management and communication. The Cartagena Protocol establishes that the Environmental Risk Assessment (ERA) must be the method applied by the State Parties prior to the release of LMPs (SCDB, 2000).

Risk assessment is the process of selecting an action strategy to respond to an already characterized risk. It is based on the technical information obtained from the assessment, but also includes social, legal, political and economic aspects (Omenn *et al.*, 1996). In risk management, the society determines how it will be assumed. The adopted decisions can follow three ways (Hilbeck, Andow, 2004): (1) tolerate the risk in whatever form it appears; (2) live with it and work out measures of mitigation, or (3) avoid it.

The **Risk communication** is the exchange of information and opinions during the entire Risk Analysis process. It comprises the information about the risks, related factors and their perception among the evaluators, managers, consumers, the industry, the academic community and other stakeholders. It also includes the explanation of the risk assessment results and the grounds for decisions adopted through risk management (FAO/PAHO, 2005).

⁵ <http://bch.biodiv.org>

Intentional and unintentional release

In addition to intentionally released LMOs, the environment can receive LMOs unintentionally. The sources of accidental LMO-entry into the environment are:

- **Industrial effluents:** An industry using LMOs in its procedures could discharge them through its effluents, especially in the case of microorganisms. LMOs could also be used for the treatment of water and thereby enter into the environment.
- **Accidental escapes of LMOs in confined use:** This could occur because of a mistake in the biosafety protocols used by the establishments (laboratories, biotheria, nurseries, breeding places, aquariums) or by an accident during the transport of these organisms.
- **Waste:** Recombinant proteins or even whole organisms could enter into the environment if there is no adequate management of waste from industries or research laboratories.
- **Misuse:** One of the sources for unintentional entry is the misuse, which can be defined as the accidental or predetermined unauthorized use of an LMO. In the CNC, the possibility was broadly discussed that a major part of the corn imports from Argentina for forage would be used for sowing, an aspect whose control is not foreseen in the currently valid regulations.

Baseline for an ERA in Uruguay

Soybean Event GTS 40-3-2 (MON-Ø4Ø32-6):

- The possibility of hybridization of transgenic soybean with weeds is practically nought, because there are no related wild species in our country.
- The present monoculture systems for transgenic soybean in our country present a high risk scenario of the appearance of glyphosate-resistant weed biotypes. This assumption is enhanced if the past regional experiences are taken into account.
- The extension of important monoculture areas, followed by the elimination of weeds through the application of herbicides results in the disappearance of the vegetation in which a great number of the natural enemies of soybean pests take refuge and mate (Ribeiro, 2000). This generates an increase in pests and, as a consequence, an increase of the use of insecticides on the crops.

Corn events MON 810 and BT 11 (MON-ØØ81Ø-6 y SYN-BTØ11-1):

- At present, there is enough evidence to consider that the events MON 810 and BT 11 are not adequate for our pest patterns.
- The impacts of the Bt events on the biodiversity are difficult to assess in Uruguay because there is no detailed information about present terrestrial invertebrates in the receiving environments.
- At the level of secondary consumers, the collected information suggests that the strategy for the management of insect resistance of the currently valid regulations (MRI), which establish the creation of refuges with a minimum area of 10%, could be insufficient to comply with the requirements of the model used.

- In addition, this IRM strategy could be affecting the biologic effectiveness of some natural enemies, affecting the survival of its population and the sustainability of the system in the long term.
- The implementation of this measure could have an impact on the population dynamic of some very important ground invertebrates for the sustainability of national agro-ecosystems, like earthworms, a data which has been obtained by the project after the authorization by the CERV.

Other LMOs:

- There is a lack of information on LMOs and its derivatives used in other applications (biomedicine, industry, etc.). It is estimated that the industry uses modified microorganisms for industrial procedures but there are no official registers, or if there are any, they are not accessible. With respect to animals (invertebrates and vertebrates) are knock out rats are used for research. The registration of these animals is not official and is the responsibility of the University of the Republic, through the Honorary Committee of Animal Experimentation.

Proposal for an Administration System

- *Entry of request dossiers:*

National Biosafety Agency (ANB)

The requests and procedures for LMO-authorization are centralized in a one-stop shop, which receives all LMO-applications, for all application levels according to the scope considered by the CNC. This office should have a *supra-ministerial* character to permit the operation of an articulated decision making system on the operative level. Its tasks would be:

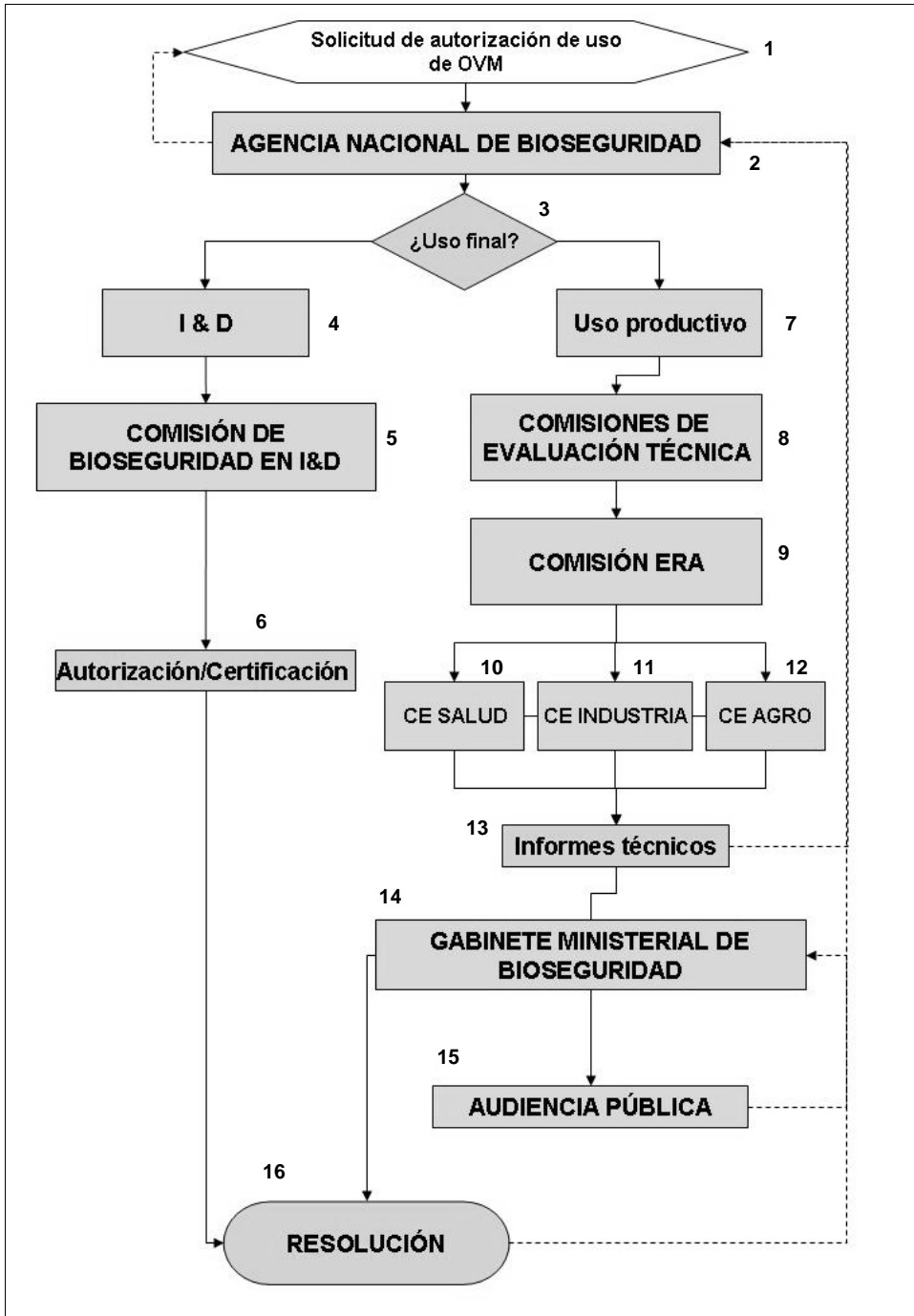
- obtain all the required information about the authorization to start the record,
- deliver the information for its studies to the corresponding person(s)
- meet the Technical Committee (specially for the LMOs handling) and control the work term of the same
- spread basic information about the requests: therefore the study information will be of free access (except those which the company considered as confidential) and it must be created a “table” structure which is charged with the request reception and the delivery of the requested material. It is suggested that this table is situated in the office which receives the requests.

The ANB should constitute itself as an interinstitutional and multisectorial agency for the coordination of biosafety policy and management. This proposal would be in line with other recently created agencies, for example the ANII, the National Housing Agency (ANV), or the Agency for Electronic Government and the Information Society (AGESIC), among others.

In **table 11** the authorization process for LMOs is presented according to their purpose (production or R&D). The processing of applications would pass through different technical committees, depending on the nature and purpose of the studied LMOs. Between the

processing of one request by a committee and another, the file would return to the ANB secretariat, where the corresponding registration and follow-up would be given.

Table 11. Authorization process for LMOs according to their purpose



1. Authorization request for LMO use
2. National Biosafety Agency
3. Final use?
4. R&D
5. Committee on biosafety in R&D
6. Authorization / certification
7. Use in production
8. Technical evaluation committees
9. ERA committee
10. CE health
11. CE industry
12. CE agriculture
13. Technical reports
14. Ministerial cabinet on biosafety
15. Public audience
16. Resolution

- *Authorization process for LMO requests for R&D*

Committee for Biosafety in Research and Development (R&D):

Scope: exclusively for LMOs for R&D purposes

Members: specialists of the different institutions directly involved with R&D

Competences:

- To receive from the one-stop shop the requests for research permits and the notifications of accidental liberation, abnormal situations, and any other corresponding ones should the LMO show unwanted characteristics, so as to study them and issue the corresponding technical findings. This finding would have to be issued in a term according to the times of execution of the research lines, in order to permit their normal development.
- To grant biosafety certificates and accreditations to laboratories
- To generate and update the registration of LMOs and the laboratories manipulating them
- To develop standard biosafety protocols for laboratories (BPL)
- To develop protocols for the import of determined genotypes

This Committee also receives the LMO transport notifications (import and/or internal transport) from the one-stop shop, in order to notify the competent authority which applies the necessary control measures.

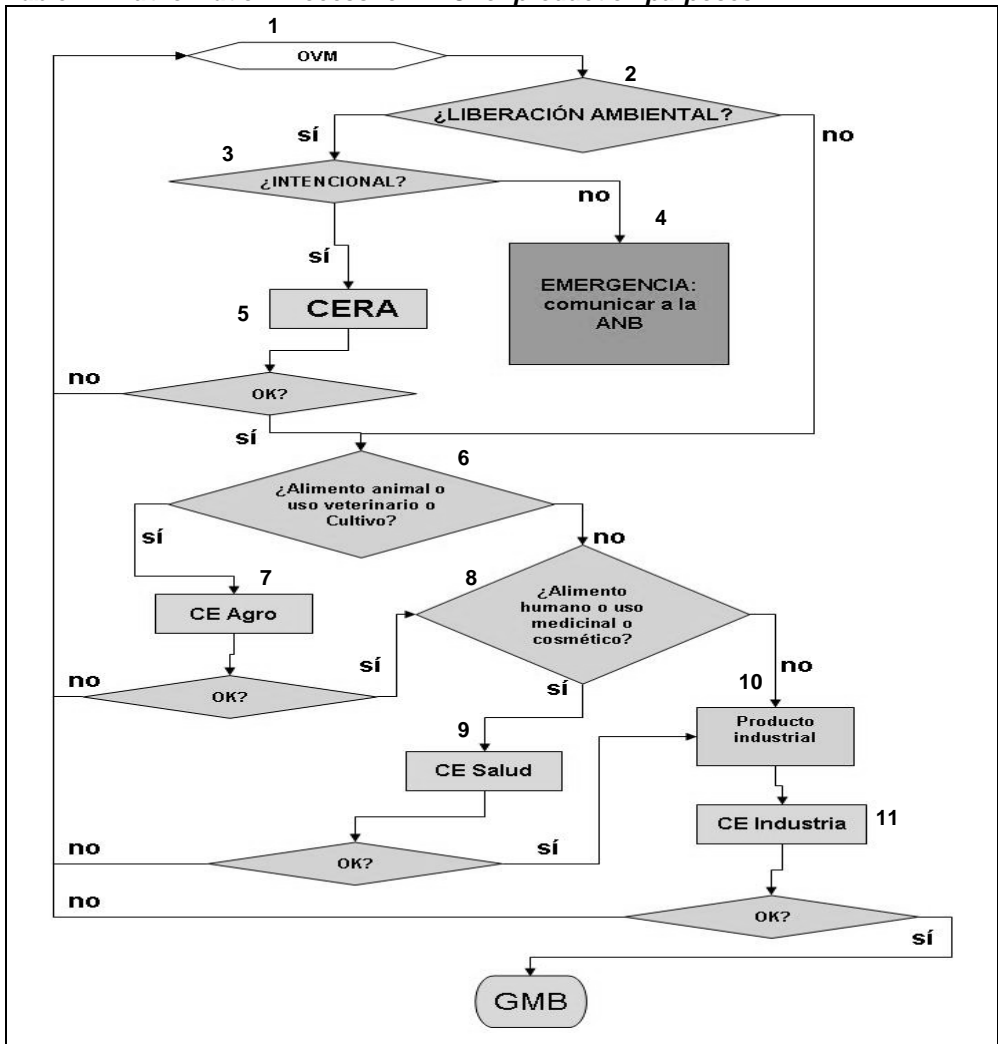
This proposed administration system will also demand the creation of *Internal Biosafety Committees* at the level of institutions and laboratories, which are responsible for the establishment of Biosafety norms and internal monitoring mechanisms, to guarantee and revise research proposals, to identify risks and formulate mitigation recommendations, work out contingency plans for accidents, register research projects, inspect and approve the safety of laboratories.

It would also be convenient to create an Animal Ethics Committee which would have competences regarding any type of research involving manipulation of animal.

- Process of approval of requests for the use of LMOs for production purpose

The file presented to the ANB entrance office is transferred to specific Technical Evaluation Committees (CET) for its study (table 12). These will express themselves on the different LMO application scopes, for which reason they would be formed by technical staff representing the Ministries with competences on the matter which has to be evaluated and by experts qualified on the subject. The latter could be found in an expert certification system, endorsed by the ANB itself. Depending of the destination of the studied LMO, different subgroups of specialized technical staff have to be activated (ERA, health, industry, economy, etc.), and according to the studied event, they will receive the requests to present their findings before the Ministerial Cabinet on Biosafety. By this operational scheme, the work of the technical committees is sped up. At the same time, every committee could request advice and support through consultancies and/or the assistance of national and international experts.

Table 12. Authorization Process for LMO for production purposes



- | |
|-----------------------------------------------------|
| 1. LMO |
| 2. Release into the environment? |
| 3. Intentional? |
| 4. No: Emergency: Communicate with the ANB |
| 5. Yes: CERA |
| 6. Animal feed or veterinary use or cultivation? |
| 7. Yes: CE Agriculture |
| 8. No: Human food or medicinal use or cosmetic use? |
| 9. Yes: CE Health |
| 10. No: Industrial product |
| 11. CE Industry |

Committee for Environmental Risk Assessment (CERA):

Scope: all LMOs for whose application any degree of environmental release is planned

Members: The DINAMA would be the competent agency to constitute the central office for these activities. Its integration would be completed by experts of different research institutes, depending on the nature of the studied LMO.

Competences

- To revise the authorization file and analyze the information sent in by the applicant
- To evaluate the ERA carried out and present technical findings
- Inform its resolution to the ANB

A favorable ERA will be a primary requirement for LMOs for environmental release and the continuation of the application will be subject to whether the CERV considers that the necessary studies have been carried out to properly describe the risks that a reasonable tolerance or mitigation is possible.

Agricultural and Livestock Evaluation Committee (CEAGRO):

Scope: all the LMOs for use as animal feed, veterinary or phytosanitary use and agricultural exploitation as crops or livestock (grazing or breeding) of any kind.

Members: technical representatives of the MGAP, INASE, INAC, INIA, UdelaR and producers.

Competences:

- To study the authorization requests
- To present its technical findings about socio-economic , agronomic-productive aspects, etc. before the ANB
- To determine the technical-financial feasibility of an application in a coexistence framework.

Committee for the Industrial Assessment (CEINDUSTRIA):

Scope: All LMOs which undergo any degree of industrial transformation or are part of industrial processes, with or without release into the environment. The products released to the environment include products designed for cultivation, biological control, biomonitoring or bioremediation, pharmaceutical industry (drugs, hormones, regulation factors, vaccines), food industry (probiotics, food, enzymes, additives, artificial colors, etc.), textile industry (detergents, enzymes, colors, modified fibers, etc.), agro-veterinary industry (rations,

hormones, growth factors, fertilizers, vaccines, etc.).

Members: representatives of the MIEM, MEF, INIA, LATU, UdelaR, industry chambers and consumers

Competences:

- To technically advise on the requests received in the entrance office, referring to industrial LMO application, through a case-by-case study (this will imply the creation of subgroups in order to address the different LMO application levels in the industry, for example the scientific and socio-economic aspects)
- To make case-by-case assessments before new lines, stumps, varieties of LMOs, etc., establishing defined terms in the procedure for the delivery of the technical findings on the requests.
- To send the technical findings on requests of LMO use in the industry to the ANB
- To work out technical material such as manuals and instructions for industrial procedures (Good Manufacturing Practices) which will be submitted to the ANB
- To create an LMO Registration System for the industry
- To recognize laboratories and companies through a certification system
- To work out certification protocols, taking LMOs and industrial processes into consideration
- To carry out a retrospective assessment of the national situation of LMOs which are currently used in the industry (in face of new evidence demonstrating potential risks). In the case of a potential reconversion in the industrial sector or modification of certain procedures, it would be necessary not to hamper the development of the industry. Thus, reasonable terms should be granted.

This committee will be able to receive technical assistance from institutions and organizations which carry out specific consultancies (for example: LATU, Customs, UdelaR, INIA, DINAMA o Consumer Defense).

As in the case of LMO manipulating laboratories, every LMO using company has to create at least one committee which will be responsible for: establishing biosafety regulations and their surveillance, identifying the existing risks, elaboration of mitigation plans, obtaining a written registration which LMO type is used or produced, and realizing internal inspections.

Committee for Health Assessment (CESALUD)

Scope: LMOs or their parts which are destined for human food, biomedical applications (vaccines, hormones, regulation factors, antibiotics and other drugs, xenotransplants) and cosmetics.

Members: MSP, INDT, UdelaR, Laboratories and Consumers.

Competences:

- To study the requests for the authorization of LMOs whose use affects human health to any degree
- To deliver its technical findings to the ANB

- Phase of political decision

Ministerial Cabinet on Biosafety (GMB)

The GMB would be the last responsible instance to make decisions on the presented request. To this end, it would deliver its findings considering the report prepared by the corresponding CET and taking into account all of macro political aspects. This cabinet would have an interministerial character, composed of at least the ministries which could be directly involved. The normative framework will define for this moment which Ministry would be in charge of with the coordination of this Cabinet. It is suggested that, at the time of defining this role, the competences of each state portfolio, their controls and their resources are taken into consideration. The GMB will have the competences to define the policies to be followed with respect to biosafety in all scopes of LMO application.

Public Consultation

Public consultations are planned to evaluate the convenience of the LMO authorization. The ANB will fulfill the role of adapting the *dossier* for the consultation of stakeholders, as well as to fix the date and place of the convocation and to perform the required logistic tasks. The currently valid regulations stipulate these consultations as an requirement for every plant event for production purposes released into the environment, for human or animal consumption or for industrial processing.

- Distribution of Responsibilities

- **The applicant pays:** Every request entails an expense, which has to be assumed by the applicant. Among other things, this expense has to consider the possibility of the hiring of specialized technical staff for specific studies and/or tests. The financing of the performance evaluations of an event in consideration (evaluations at the level of experimental fields) could be assumed in its entirety or partially by the seed companies requesting the authorization of the event under consideration.
- **The applicant delivers basic information to the ERA:** Said information must be in Spanish, one copy presented in written form and one in a digital format.

Recommendations

1. **Environmental Authority:** It is recommended that the DINAMA chair the CERA. The unit which has to be the headquarters of said committee is the Division of Biodiversity and Protected Areas, because it already has human resources suitable for these subjects. Additionally, situating CERA in this division would favor a more effective articulation with the activities of the CDB, the CIISB and the SNAP.
2. **Authority for agricultural issues:** The CE AGRO should be chaired by the MGAP through its general departments (particularly the DGSSAA, RENARE, DGSG)

3. **Health authority:** The DIGESA should chair the CE SALUD and consider the inclusion of the LMO variable into the procedures of toxicological evaluation and evaluations of harmlessness of food, cosmetics and biomedical inputs.
4. The exclusiveness of the duties and functions converts the **National Customs Department** into the institution monitoring of the cross-border transit of LMOs; therefore, its adaptation into a NBF has to be considered, including the valid regulations.
5. The **INASE** must extend its actual competences onto the subject of biosafety and incorporate biotechnological and non-biotechnological alternatives into the currently implemented evaluation process of cultivars. It also should coordinate training instances with the National Customs Department on the subject of checking and monitoring the transboundary transport of LMO seeds.
6. The **LATU** should incorporate the classification and labeling of technological products as “GMO-free” into its present certification system. On the one hand these actions would permit a traceability system, and on the other grant easier access to markets which are very demanding on this issue.
7. It is recommended to **articulate the diverse information tools** to strengthen a National System of Environmental Information. These will be key in any scenario.
8. If the country wants to prevent LMO traffic through its environment, it should possess an **information tool** which allows knowing which LMOs are released in the different countries. This information can be obtained from the BCH, a mechanism for information exchange of the parties to the Cartagena Protocol, but this will not suffice, because the countries which are not parties are not compelled to provide information.
9. There should be an **LMO registration system, which** would have to permit the creation of an inventory of LMOs as well as of laboratories which work with these organisms. It would be desirable to implement systems of periodic updating of this information.
10. The knowledge about Risk Analysis and especially about Environmental Risk Assessment should be strengthened.
11. Criteria for the **accreditation of qualified staff** to carry out the ERA could be fixed.
12. **A visible date of expiry for the ERAs** performed should be stipulated, as well as a priori mechanisms established for the case revision.
13. It should be discussed whether it is convenient, prior to the release of an LMO plant containing insecticide genes, to analyze its effectiveness in controlling our pest patterns. The relevance of this study will depend of the form in which the country assumes the costs of possible failures from the chosen technological package; it will constitute a tool for political decisions, connected with risk management, but separate from the ERA.
14. As to invertebrates, the growth dynamic of their populations and the fast succession of generational cycles compromise the control of the populations released into the environment. The prohibition to release fertile organisms could be adopted as a precautionary measure.

15. The levels of LMO contention should be established and characterized. A criterion of levels for plants already exists in Decree 249/000, but not for other organisms. The authorization competence for every level can vary in structure similar to the one of Decree 249/000.
16. It is recommended not to authorize the liberation of organisms whose primary or secondary center of origin includes Uruguay.
17. The release of genetically modified plants with Genetic use restriction technology (GURT or Terminator) should not be authorized.
18. The ERA should not only consider LMOs, but the whole technological package which it entails. For example: an ERA of the event GTS 40-3-2 soybean should consider, in addition to the intrinsic characterization of this event, the risk of applying glyphosate and of practicing extensive monoculture in the modality of direct sowing without rotation, because these two crop management strategies are inseparably associated with the event.
19. It would be convenient to define restricted areas for the LMO production, which present the nationwide recognized genetic diversity. The territory could be classified in units, according to environmental and production characteristics and differential exclusion levels could be assigned to the release of LMO.

Monitoring and control

Monitoring

Environmental monitoring has been insufficient in the country, although some initiatives are being promoted to improve this situation.

The Cartagena Protocol establishes that each State Party shall have to install and maintain adequate mechanisms, measures and strategies to regulate, manage and control the risks related to the use, handling and transboundary movement of LMOs⁶. The General Law on Environmental Protection (N° 17.283) stipulates prevention and anticipation as priority criterion before any other in environmental management⁷.

Uruguay, a country exporting agricultural raw material, has installed a control system on its borders to preserve the health status of its crops and livestock. In this sense, the MGAP implements a sanitary barrier which prohibits entry into the country for animal and plant products and sub-products, except for those for which the import regulations are applicable. Equally, some measures have been implemented to manage the risks arising from activities which could negatively affect the integrity of the environment. Some are directly related to biosafety.

Chart 13. Risk management measures associated to LMOs

Integrated management of weeds
Management of insect-resistance

As a management measure, the re-sowing of biotypes which are susceptible to potentially resistant species is being considered. Ministerial resolutions 236A/003, 276/003 and 292/004 regulate the sowing conditions for Bt corn. They establish measures for the management of the risk of resistance in these crops through the *shelter strategy*, fixing that a minimum of 10% of the crop area has to be reserved to that aim. INASE is the institution responsible for the monitoring of the fulfillment of these resolutions. The CUS is the one in charge of implementing the Insect-Resistance Management Program (according to Ministerial resolution, without number, of June 20, 2003), and the INASE is the program monitoring institution.

Seed traceability system

The seeds of GMO-corn events have to be filled into duly labeled recipients, on which the name of the event is explicitly stated. The INASE is the institution in charge of controlling compliance with this labeling requirement. The Law on Consumer Defense regulates the information management of consumer products. Among other things, it establishes that advertising which omits information, which could induce the consumer to misunderstand the nature of the product, has to be considered as deceitful.

⁶ CP Art. 16.

⁷ Law N° 17.283 Art 6° inc. B

Inspections

INASE has the competences to control the adequate identification (labeling) of the package of GMO-corn seeds and to control the IRM-Program, as stipulated in the Ministerial Resolutions⁸ corresponding to the corn events MON 810 and BT 11. The existence of an institute with such characteristics constitutes a strategic advantage of the country as to capacity of registration, monitoring and control.

The National Customs Department and DGSSAA are the entities in charge of monitoring transboundary movements of animals, plants and derived products.

Recommendations

1. Monitoring protocols should be established for LMOs released into the environment. They should be more intensive in the first years of the release.
2. The country has the conditions to gradually implement systems for individual traceability for all animal species liberated for grazing (rodeo); therefore, it should be considered that LMOs released as livestock have individual traceability systems as an obligatory requirement for their authorization.
3. It is recommended to monitor the entries of plant or animal inputs for rations and to control the correct destination of plant events, so as to avoid any misuse.
4. The generation of human resources trained on the surveillance of transgenic crops in the country should be considered.
5. The **control of transboundary movements** should be adjusted to the NBF. The National Customs Department is the responsible agency in this matter; therefore, its infrastructure and human resources capacities should be strengthened and adapted to the particular requirements of LMOs.
6. It is necessary to survey the entry into the country of LMOs or other biological material for R&D purposes.
7. The **DGSSAA**, as the agency in charge of controlling the entry of animals, plants and derived products, should adjust its procedures on LMO-matters.
8. A **better intra- and interinstitutional coordination** should be implemented to ensure the due monitoring and control measures.
9. In some countries, **Weed Resistance Committees** have been formed due to the appearance of weeds tolerant and resistant to herbicides; they are in charge of preventing, detecting, managing and training on this problem. Our country should have an entity with similar tasks.
10. An adequate planning for the expansion of soybean monoculture is required, in order to minimize the dangers of a reduced spatial heterogeneity, and avoid the fragmentation of the habitats. It is recommended to consider the connectivity of

⁴⁶ Ministerial resolution, without number ° 20/06/03. (MEF-MGAP). Authorizes the production or import of event MON810 for direct use or corn transformation; Ministerial Resolution 290/004 (MEF-MGAP). Authorizes the production and import for direct use or corn transformation of event Bt 11

protected areas, controlling the territorial ordering of this kind of establishments. This action should favor the exchange of information between the National System of Protected Areas and the actors engaging in agricultural exploitation (MGAP, rural Associations, Business Chambers, etc.)

11. There should be a defined system for the traceability of LMOs for productive use, in order to gather all the information available of the products, with the guarantee of knowing their origin and background with certainty and gain access to specific markets.
12. The labeling of products as "GMO-free" should be considered.
13. The ANB should have the competence of policy management on matters of industrial biosafety, control and monitoring, as necessary.
14. The biosafety certifications for the companies and industrial procedures should be subject to a monitoring and control program endorsed by the ANB.
15. The creation of a system for the declaration and registration of LMOs used in domestic industries should be considered.
16. A certification system should be established to accredit the laboratories and/or institutions to work with LMOs under certain biosafety guidelines and criteria.
17. The authorization for a release of GMOs into the environment and the research lines should be included in an adequate follow-up and monitoring plan.
18. The control of the non-intentional release of LMOs into the environment, be it through escape, by accident or discharge, should be taken particularly into account. This situation should be included in an NBF-proposal through the establishment of a National Mitigation Plan. The Plan should define the role of the competent authorities in this matter, as well as action and communication mechanisms and penalties for infringements.
19. It is also recommended to implement strategies to monitor and control the industrial effluents for those industries which use LMOs in their processes or in the treatment of their sewage.
20. The NBF should establish procedures for the elimination or discharge of LMOs or parts of these and fix penalties for infringements.
21. The development of mechanisms for territorial localization and traceability of individual organisms should be stimulated.
22. There are different certification protocols (organic meat, natural meat, etc.) which have particular requirements as to the content of rations. It is recommended to include aspects referring to rations derived from LMOs among the elements which will need regulation in a scenario of coexistence.
23. In a scenario of a LMO-free country:
 - a. The institutional capacities of the authorities in charge of control should be strengthened. This would imply the training of technical personnel, access to new technologies of LMO-detection, the implementation of control and monitoring programs of the productive activities.
 - b. A contingency plan for the case of the denouncement of LMO-release should be strengthened.

- c. The institutional control capacities should be strengthened, as a necessary and indispensable requisite for compliance with a regulatory framework for LMOs.
- d. Most importantly, the current situation of released plant events (GTS 40-3-2 soybean, MON810 corn and Bt 11 corn) should be reverted. This should be carried out in a gradual program, with a time horizon of at least 5 years. This reconversion process would imply the design of a follow-up plan on the converted areas to avoid non-intentional growth of LMOs.
- e. Training should be given to technical staff on LMO-detection for living organisms or parts of these entering the country. The currently implemented quarantine systems should examine the presence of LMOs or parts of these in the products entering the country, especially in the case of reproductive or embryonic structures. This situation would require capacity-building in the National Customs Department.
- f. It should be determined which institutions would be in charge of implementing the controls which guarantee the non-presence of LMOs in the country.
- g. If a partial restriction of the use (for example, authorization of the use of LMOs for research) is decided, it should be explicit and should also determine which institutions will be responsible of the applicable controls.
- h. It would be necessary to determine a flexible and dynamic mechanism to receive reports of violations of the biosafety regulations in force and forward them to the corresponding agencies for their intervention.

Information access and participation mechanisms

Access to information

A public opinion survey was carried out within the context of the Project (**See table 13**). That study included the general public, professionals, producers, media, and politicians, as shown on the table. Some of the most outstanding results are as follows:

- **Lack of information:** Information handled by the different target groups was poor, with some exceptions. There is no information in the media, and it is not used by professionals, nor discussed in the parliamentary committees.
- **Limited information:** Reference to agriculture and animals was made in all cases when talking about the topic. None of the sectors included in the study talked about other areas of use such as industry and medicine.
- **Hope:** There is an idea that with the use of LMOs in agriculture productivity will be increased and therefore hunger will be reduced in the world.
- **Concerns:** Fear of unknown effects is found at every level. People are concerned about LMOs harming human health or the environment.

Table 13. Public opinion survey about LMOs

Target Population	Observations
General public (Survey, 933 cases)	High level of distrust and rejection of LMOs; most people associate LOMs with food and vegetables. There is little discussion on the subject and little attention is paid.
Agricultural producers (Survey, 200 cases)	Lack of information. They knew almost nothing about regulations in force. 41% of them think the Government is responsible for the lack of information among population. Producers that are using LMOs classified them as beneficial organisms, but the other producers classified them as somehow unfavorable. Some producers do not use LOMs due to the high cost of seeds, the lack of information, or because they consider them harmful.
Professionals in the biological area, but not specialized in LMOs (Survey, 200 cases)	They showed interest in the subject, even if they thought there is little discussion about it. They know corn and soybean, but they associated transgenic products with other vegetables. In general, they did not know the regulations in force or they did not trust them. Agronomists become the main reference among professionals to answer questions. Main positive aspect for using LOMs in production is increased productivity. Main negative aspects: they harm tourism and the image of a natural country, closing markets and generating dependence from multinational companies
Members of Parliament (In-depth interviews,	They did not know the topic, the regulations or the genetic manipulation process. They believe that information to public on the topic is poor. They

15 cases)	<p>also consider that existing information is neutral. This subject is not frequently discussed in the different Committees in the Legislative Power. Positive elements of the LMOs: they increase production and reduce hunger in the world. Negative elements: they harm the environment and they have unknown effects.</p>
Journalists <i>(In-depth interviews, 15 cases)</i>	<p>They have more information about the subject, but they do not know the areas that have been cultivated or the names of the events. They share the opinion that there is no access to information for general public and journalists.</p>

Challenges

There is a digital divide in Uruguay’s territorial context. The concept of Digital Divide refers to the difference between the Governments and sectors of the population in terms of access to information instruments and tools and their ability to use them (ALADI, 2003). Even though almost half of the population of the capital city uses computers frequently, in areas with less than 5,000 inhabitants or in rural areas, less than one fourth of the population has used a computer in the last six months (Pittaluga, Sienna, 2007). If most of information regarding LMOs, biotechnology and biosafety is disclosed through digital means of communication, bridging the digital divide is of vital important to guarantee adequate access to information for civil society and rural producers in particular.

Since 2002, the National Telecommunications Administration (ANTEL, abbreviation in Spanish) has been developing a project named “Uruguay: Information Society”, whose main purpose is to contribute to bridge the digital divide, particularly for people living in rural areas. Since then, twenty five Access Centers to Information society (CASI, abbreviation in Spanish) have been opened in small communities in rural areas. They are community centers with access to internet sponsored by ANTEL and operated by public or private counterparts which provide public access to computer equipment and internet, as well as some computer training for free or at a low cost. The Uruguay’s Digital Agenda for 2007-2008 plans to continue implementing more CASIs within the national territory (Rivoir, Ríos, 2007), which constitutes a positive indicator to achieve said challenge.

Another problem repeatedly mentioned by actors of the CNC, hired consultants and even members of the government, was the resistance from some public sectors to provide information. Different strategies have been utilized in the last decade to overcome that situation.

A National Committee for Information Society was created in 2000, through Decree 225/000, aimed at opening the discussion about a national policy for the development of an Information Society program in the country, including a technological literacy campaign for the population and the modernization of public administration. In 2005 the Agency for the Development of Government Electronic Management, Information Society and Knowledge (AGESIC, abbreviation in Spanish)⁹ was created, which entered into force on September

⁹ Law N° 17.930 National Budget, Art. 72 and Law N° 18.046 Accountability process, Art. 54

12th, 2007. The AGESIC promotes the creation of “one-stop shop” systems which serve as gateways for access to files and steps to be taken, such as the one proposed in this decision-making system.

In compliance with the development of the aims established by the EP regarding information society, a bill for an **Access to Public Information and Information Protection Act** was presented in parliament, establishing the right of natural and legal persons to request have access to and receive information from any institution of the national or departmental public administration. This right includes the freedom to access to information contained in written or photographic documents, in magnetic, digital, or any other format, as well as the right of submitting requests.

Public Participation

There are several nation-wide committees working at the ministry level at present; for instance, the Technical Advisory Committee for the Protection of the Environment (COTAMA, abbreviation in Spanish), created by decree¹⁰, which makes different sorts of decisions, and which advises the MVOTMA and the Executive Power on various environmental issues. The COTAMA is composed by several different actors from the political system, scholars, the business and industrial chambers, rural producers, labor unions, and environmental NGOs, which constitutes an important precedent regarding participation at Government level.

Public consultation

Public consultation has been a mechanism used for decision-making in the environmental area and directly related to environmental impact assessment^{11, 12, 13}.

Regulations in force establish that competent authorities shall hold public information sessions to consult the public prior to the environmental liberation of LM-plants¹⁴. These sessions shall be organized upon the expiry of the stipulated term for the interested parties to revise the corresponding files.

Recommendations

1. We recommend the creation of institutionalized consultation opportunities to advise the EP in relation to the implementation of a national biosafety policy. These opportunities should ensure clear access to the information in order to guarantee informed participation.

¹⁰ Decree 261/993. The creation of the Technical Advisory Committee for the Protection of the Environment and establishment of its purposes

¹¹ Law N° 17.283 Art. 7° item E

¹² Law N° 16.466 Art. 14

¹³ Decree 349/005 Art. 16

¹⁴ Decree 249/000 art. 8

2. There should be information about the origin of the products or about their contents.
3. It is recommendable to have a national inventory of LMOs for industrial use, which would be created and updated by CEINDUSTRIA.
4. It is necessary to ensure the public's adequate access to environmental information. This information should include the descriptive and technical aspects related to the environment, as well as the regulations which correspond to their regulation. The tendency of some sectors of the Government not to allow public access to the national databases is a problem that should be dealt with as a priority.
5. In the search for an adequate management of the information on the biosafety of the biotechnology, the inclusion of these topics in the formal education curricula should be analyzed.

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Annexes

I. **URU-04-009PROJECT TEAM**

National Coordinator

Technical Assistants

Executive Secretary

- Ing. Agr. (PhD) Marcos Frommel
- Ing. Agr. M^a Fernanda Pardo
- MSc. Gonzalo Martínez Crosa
- Graciela Arrambillety

II. **MEMBERS of the NCC**

- Asociación Civil Uruguay para la Protección de los Obtentores Vegetales (URUPOV)
- Asociación de Productores Orgánicos del Uruguay (APODU)
- Asociación Nacional de ONG (ANONG)
- Asociación Rural del Uruguay (ARU)
- Asociación Uruguaya de Empresas de Biotecnología (AUDEBIO)
- Asociación Uruguaya de Productores pro Siembra Directa (AUSID)
- Cámara de Comercio de Productos Agroquímicos (CAMAGRO)
- Cámara Uruguaya de Semillas (CUS)
- Comisión Nacional de Fomento Rural (CNFR)
- Confederación Uruguaya de Entidades Cooperativas (CAF – CUDECOOP)
- Congreso de Ediles
- Congreso de Intendentes
- Consumidores Uruguayos Asociados (CUA)
- Cooperativas Agrarias Federadas (CAF)
- Dirección General de Recursos Naturales Renovables (RENARE)
- Dirección General de Servicios Agrícolas (DGSSAA)
- Dirección Nacional de Medio Ambiente (DINAMA)
- Facultad de Veterinaria (FVET– UdeLaR)
- Federación Rural del Uruguay (FRU)
- Instituto de Investigaciones Biológicas Clemente Estable (IIBCE)
- Instituto Nacional de Carnes (INAC)
- Instituto Nacional de Investigación Agropecuaria (INIA)
- Instituto Nacional de Semillas (INASE)
- Instituto Pasteur de Montevideo (IPMont)
- Laboratorio Tecnológico del Uruguay (LATU)
- Mesa Tecnológica de Oleaginosos (MTO)
- Ministerio de Economía y Finanzas (MEF)
- Ministerio de Relaciones Exteriores (MRREE)
- Ministerio de Salud Pública (MSP)
- Ministerio de Vivienda Ordenamiento Territorial y Medio Ambiente (MVOTMA)
- Oficina de Planeamiento y Políticas Agropecuarias (OPYPA)
- Red de Acción en Plaguicidas y sus Alternativas para América Latina, Filial Uruguay (RAP- AL)
- Red de ONG ambientalistas
- Red Temática de Medio Ambiente (RETEMA- UdeLaR)
- Redes Amigos de la Tierra
- Unión Internacional de Trabajadores de la Alimentación (UITA)

III. GLOSSARY OF TERMS RELATED TO BIOSAFETY

Accident: Any incident involving a significant and unintentional release of an LMO during its confined or specific use that may pose an immediate or later danger, and risks to human health, the environment and biodiversity.

Bacillus thuringiensis: Common bacteria in the soil that produces insecticidal proteins. Some of its genes have been incorporated into several crop species through techniques of modern biotechnology. Uruguay is currently planting two of these genetically modified crops: Mon 810 corn and Bt11 corn.

Biodiversity: Variability of living organisms from all sources, including, among other things, terrestrial and marine ecosystems and other aquatic ecosystems and the ecological complexes of which they are part; this includes diversity within each species, between species and in ecosystems .

Bioinformatics: Scientific discipline that is concerned with all of the aspects related to the acquisition, storage, processing, distribution, analysis and interpretation of biological information through the application of mathematical techniques and tools, biology and computer science, with the purpose of understanding the biological significance of a variety of data. E.g.. online Genetic libraries.

Bioreactor: Living organism used to produce some kind of substance. Genetically modified bacteria have been used to produce human proteins (insulin, clotting factor) and are currently experimenting with the incorporation of these substances in fish and in the milk of cows and other mammals.

Biosafety Clearing House (BCH): Information Exchange Mechanism established by the Cartagena Protocol to assist the parties in the implementation of its provisions and to facilitate the exchange of information and experience with regards to LMOs. <http://bch.biodiv.org/>

Biosafety Clearing-House (BCH): Center for Information Exchange on Biosafety (BCH)

Biosafety: Policies, rules and procedures adopted to ensure an adequate protection of health and safety of the population, a maximum respect for human dignity and the protection of the environment, facilitating the development of activities and business related to biotechnology, as well as the right to information for consumers and citizens.

Biotechnology: A technique that uses living cells, cultivated tissue or molecules from one organism to obtain or modify a product, improve a plant or animal or develop a microorganism to be used for a specific purpose.

Cartagena Protocol: International instrument which aims at ensuring an adequate level of protection in the field of safe transfer, handling and use of living modified organisms resulting from modern biotechnology, which may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements.

Case-by-case: The CP establishes that the ERA should be made on a "case-by-case basis", i.e. each biotechnological transformation event should be assessed for each organism in particular and for every host environment. The criteria for the case-by-case ERAs are established by the current regulations.

Classical Biotechnology: Division of biotechnology that exploits existing organisms in nature for technological purposes.

Coexistence: State in which different systems of primary production such as organic production, conventional agriculture and LMOs are found simultaneously or in adjacent fields without significantly affecting each other, thanks to specific management measures (Altieri, 2005).

Confined Use: Any operation conducted within a facility, installation or other physical structure, involving the handling of LMOs controlled by specific measures that effectively limit their contact with the external environment and their impact on the environment.

Donor: Organism or cell from which the inserted DNA into a genetically modified organism was extracted

Expression: The process by which information encoded in a gene leads to the synthesis of a protein. A gene expression is the transcription of the gene to mRNA, and then into protein. This entails the manifestation of the characteristics specified by that gene in the phenotype.

Familiarity: The concept of familiarity was invoked in the early years of the commercial release of transgenic plants. It is based on the assertion that there are no significant differences between genetically engineered crops and their conventional counterparts in terms of their environmental performance. Based on these criteria, a LMO could be released on the basis of information obtained on their conventional counterparts or other events containing similar characteristics (such as the degree of familiarity with the LMO). In Uruguay, the criterion of familiarity was invoked as part of the approval of Bt-11 corn. This approach has been criticized for not having a scientific basis and many authors consider it opposed to the precautionary approach.

Gene fusion: A gene that encodes a product of interest with an element regulating its expression in the host.

Gene transfer: Scattering of genes incorporated in an LMO to a non-modified population of the same species or of sexually compatible species, by sexual crossing. It also includes the horizontal transfer to prokaryotes.

Gene: DNA sequence constituting the functional unit for the transmission of hereditary characteristics. This sequence contains specific information for the synthesis of a structural protein or enzyme, or regulates its transcription. The genes are located in the chromosomes, occupying a position called locus.

Genetically Modified Food: Food obtained directly from an LMO (corn) containing ingredients derived from LMOs (soya lecithin) or that were produced by processes in which LMOs intervened (transgenic yeast).

Genome: Set of genes of an individual or a species, contained in a haploid set of chromosomes.

Genomics: Area of research that studies the genomes of living organisms and seeks to understand the structure, function and evolution of genes in order to answer fundamental biological questions.

Genotype: Genetic endowment of an individual. Set of genes of an individual, including their allelic composition.

Glyphosate: (N-phosphonomethyl glycine) Systemic herbicide, post-emergent, non-selective and widely used for weed control.

Horizontal gene transfer (HGT): Flow of genetic information into a prokaryotic organism through a transformation mechanism.

Host Organism: The one receiving DNA through artificial procedures.

Insert: DNA sequence consisting of the gene fusion, the selectable marker (if any) and the respective sequences for promotion and termination, transferred to the host organism.

Isogenic crop: Variety of a crop of similar origin as a genetically modified variety, but which does not contain the event.

Knock Out: Replacement of an active gene by an inactive version, using techniques of modern biotechnology, causing the cessation of the expression of this gene. Knock-out

techniques are used to study the function of certain genes in a studied organism. The uses of these techniques have been proposed to remove allergenic proteins in some food for human consumption, with knock-out laboratory varieties of soybean.

Living modified organisms (LMOs): Any living organism that possesses a new combination of genetic material obtained through the application of modern biotechnology.

Misuse: randomly assigned or preconceived unauthorized use of an LMO.

Modern biotechnology: It means the application of in vitro techniques of nucleic acid, including recombinant deoxyribonucleic acid (DNA) and the direct injection of nucleic acid into cells or organelles, or fusion of cells beyond the taxonomic family, that overcome natural physiological barriers of reproduction or recombination and that are not techniques used in traditional breeding and selection.

Phenotype: Visible manifestation of the genotype in a given environment. The phenotype of an individual organism is a biochemical, physiological characteristic, or a specific physical trait (ex. quantity of a nutrient in a plant).

Precautionary principle: Environmental ethics guideline. One possible definition would be that when an activity poses a threat to human health or the environment, precautionary measures should be taken, even if some of the cause-effect relationships have not been scientifically established.

Proteomics: Area of research that seeks to identify and characterize a complete set of proteins and the interaction between them in a given species.

Recombinant DNA: The process involves extracting a segment of DNA from an organism, manipulate it and introduce it into a new organism. It is one of the main techniques of modern biotechnology, whose original purpose is to study gene expressions.

Research and development (R & D): Creative work carried out in a systematic way to increase the volume of knowledge and the use of this knowledge to derive new applications. It includes basic research, applied research and experimental research.

Resistance: 1. Hereditary ability of some biotypes of a weed population to survive and reproduce after being exposed to a dose of herbicide to which the population is originally susceptible. 2. Hereditary capacity of some individuals within a population of insects in order to survive and reproduce after the application of an insecticide.

Risk analysis: Methodological tool to assess, measure and prevent unwanted events related to LMOs affecting humans and the environment. It consists of several phases: risk assessment, risk management and risk communication.

Risk Assessment: Within the risk analysis, a set of methodological tools used to identify hazards to health or the environment and characterize the associated risk by measuring the exposure to risk and the intensity of its effects.

Risk Management: A set of processes that culminate in the presentation of alternative scenarios for decision-making with respect to a particular risk, once the risk has been assessed. These decisions can prevent, mitigate or tolerate the risk, depending on the environmental, social, cultural, political and economic variables, among others.

Risk: Probability of an adverse event, problem or damage and the consequences thereof.

- **Countervailing Risks:** Potential impacts of transgenic crops outside the objectives for which it was created. It usually refers to the impacts on biodiversity, the structures and composition of communities, flows of matter and energy in ecosystems and the structure and dynamics of trophic networks.

Selectable Marker: Gene that is introduced along with the fusion gene and confers resistance to a lethal substance to the cell or tissue. It allows the selection of transformed

cells in an LMO that has undergone a transformation event, since the cells or organisms which are not transformed die.

Step by step: Step by step is understood as stages of increasing environmental exposure, whose authorization requires a lot of studies. A higher level of exposure will require further studies for approval. The step by step concept is implicit in Decree 249/000, already mentioned, as areas of application are applied which require study by different competent institutions.

Substantial Equivalence: The assessment of LMOs used for human and animal consumption is based on the concept of Substantial Equivalence (SE). This concept was introduced by the Organization for Cooperation and Development (OECD) in 1993 and adopted by the FAO and WHO in 1996. It is based on the idea that an existing organism used as food or as a base for food processing can be compared with modified food, in order to assess its safety for human consumption. This comparison is done in terms of composition, nutritional characteristics, allergens and toxin content, among other properties. If the modified food is equivalent to the organism that has been used as comparison (called traditional counterparts or counterpart) then it does not pose new risks and is, therefore, acceptable for human consumption. The application of this concept considers that the traditional counterpart is harmless to human health based on a history of safe use, although some may contain natural toxins or anti-nutritional substances (OECD, 1993). The application of SE criteria has been the subject of controversy within the scientific community because many authors have doubts about its validity

Sustainable Development: Economic development in which the recovery of the exploited resources and ecological conditions is guaranteed. The Brundtland Commission defined sustainable development as "development that meets present needs without compromising the ability of future generations to meet their own needs."

Target species: In Bt crops, it is applied to those species of insects that are the target of insecticidal proteins. We are dealing with species that are susceptible to toxins contained in these plants.

Traceability: 1. the property of the result of a measurement or the value of a standard whereby it can be related to stated references, usually national or international standards, through an unbroken chain of comparisons all having stated uncertainties."(International Standards Organization ISO) 2. The ability to trace LMOs and derivatives along the production and distribution chains in all phases of commercialization "(European Parliament and the Council of the European Union).

Transformation event: The modification of an organism of a specific species through an insert.

Transgenic or Genetically Modified Organism (GMO): Organism containing genes from another species, introduced through modern biotechnology techniques

Transgene: Gen inserted through modern biotechnology techniques into an organism of a different species to the one it naturally exists in.

Transgenesis or Genetic Modification: Set of processes that allow the transfer of a gene into a host organism, and which can usually pass on to their offspring. This technique allows associations of genes that do not exist in nature, overcoming the barriers between species and even kingdoms.

Trophic network: A set of relationships between food chains existing in the species of a biological community and representing the flow of matter and energy through the ecosystem. It describes the routes of solar energy in any ecosystem. The trophic network is formed by various steps or trophic levels.

Vector: Regenerating Agent used to transfer DNA from a donor organism to a host organism.