

USDA Foreign Agricultural Service

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Global Agricultural Information Network

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Uruguay

Biotechnology - GE Plants and Animals

Paraguay Biotechnology Annual Report

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Report Highlights:

Despite the ending of an 18-month de facto moratorium on biotechnology approval and evaluation in July 2008, there have been no approvals of new Living Modified Organisms (LMO) events in the country since 2004.

There are three events approved for commercialization in Uruguay: one soybean variety (MON 40-3-2) and two corn varieties (MON 810 and Bt 11).

Section I. Executive Summary:

Uruguay is a country of 3.5 million people and highly dependent on agricultural trade. Agriculture and agri-industry represent more than 25 percent of Uruguay's GDP. The main agricultural sectors are beef, soybeans and forestry. In recent years, strong commodity prices and more efficient production have transformed crop production and increased its importance in the Uruguayan economy. The oilseed, grain, and forestry sectors are expected to continue to expand in the near future. Sheep and wool production, while once a very important activity, is projected to decline as ranchers shift to more profitable beef, dairy, or other crops.

According to the International Service for the Acquisition of Agri-Biotech Applications (ISAAA), Uruguay now ranks 9th among countries in the number of acres planted with biotech varieties, as production of crops has increased in recent years. In 2010, 880,000 hectares were sown with biotech varieties.

In January 2007, the President of Uruguay signed a decree imposing a de facto moratorium for 18 months on the review and approval for new events. The moratorium was lifted in July 2008, but no new approvals have been granted since then.

The current regulatory framework requires consultations with a broad range of specialists and stakeholders (including civil society), involves participation of several ministries as well as various commissions, and includes a fee which has to be paid by the applicant seed company. The cost varies according to the level of evaluation requested.

Section II. Plant Biotechnology Trade and Production:

In recent years Uruguay has experienced an agricultural revolution, with crop area estimated at several times the harvested area of 2000/2001. Sustained world-wide demand and favorable local conditions for the expansion of crops (available land, efficient technicians and companies, and stability of the business framework) are key factors behind the phenomenon.

The suspension of new biotech event approvals has had its largest impact on corn production since new varieties suitable for conditions in Uruguay are not yet being approved. Also, climate change experts predict that weather conditions in Uruguay might become more severe – particularly drought. Those potential conditions and changes in weather patterns would make it even more critical for farmers to have access

to
seeds better adapted to more difficult conditions.

There are currently three authorized biotech events for production and commercialization in Uruguay:

Soybeans, event 40-3-2 (approved in 1996)

Corn, event MON 810 (approved 2003)

Corn, event Bt 11 (approved in 2004)

Uruguay allows field testing of biotech crops.

The events submitted for evaluation are:

Corn: GA21; GA21 x Bt 11; NK 603; NK603 x MON 810;

Hercullex; Hercullex x NK603; BT11xMIR162 x GA21; MON89034xMON88017.Soybeans :
RR2Y (MON89788) ; LL (A2704-12).-

Soybeans

Soybean harvested area increased from 77,000 hectares in MY2002/03 to 820,000 hectares in 2010. More than 99 percent of total soybean area is planted with Round-up Ready soybeans. Potential area for increased soybean production is fairly limited compared to neighboring countries.

Corn

The authorization for imports and commercialization of Monsanto's insect-resistant corn (variety MON 810) was approved by the Government of Uruguay (GOU) in 2003. Syngenta's insect resistant Bt 11 corn was approved in 2004. The approval of both varieties aroused opposition among environmentalists and other groups.

Evolution of area planted (conventional corn and Bt)

Year	Total Area (has)	Bt Area (has)
2003	44,923	1,150
2004	60,601	23,300
2005	53,400	30,000
2006	85,000	46,000
2007	140,000	95,000
2008/2009	135,000	110,000
2009/2010	110,000	90,000

Rice

No biotech rice varieties have been approved. Adoption in Uruguay of rice varieties containing biotech events will depend, almost exclusively, on the acceptance of these events in Uruguay's export markets. Rice producers are very open to the idea of biotechnology, but they are unlikely to adopt new technologies that may jeopardize their export markets.

Section III. Plant Biotechnology Policy:

The GOU first formally endorsed the use of biotechnology and took concrete steps towards the oversight and regulation of biotechnology products by creating a risk assessment commission for living modified organisms (LMOs) in 1995. The first biotech authorization occurred in 1996 when the use of biotech soybeans was approved. In 2000, Decree 249/00 created the Risk Assessment Commission of Genetically Modified Plants (CERV in Spanish) and established a regulatory framework to authorize the introduction, use, and manipulation of LMOs.

On January 29, 2007, the GOU decreed "the suspension of evaluation of new requests for authorization to introduce events of living organisms of vegetable origin and their genetically modified parts for any of the purposes defined in decree 249/2000, by the Commission of Risk Assessment of Genetically Modified Vegetables". This moratorium applied to the introduction of new biotech events for both production and field testing. During that period, a group composed of representatives of different Ministries (Agriculture, Health, Economy and Environment) re-evaluated and strengthened the current policy. Their work focused on social issues, scientific research, and agricultural production. The timeframe for the re-evaluation process was set for 18 months.

The moratorium was lifted in July 2008 with the derogation of Decree 249/00 and the creation of a new regulatory framework by Decree 353/08. No new approvals have been granted since then.

Between the prior suspension of approvals and until the National Coordination Committee (CNC in Spanish) developed a proposal for a biosafety framework, there were at least 4 years during which Uruguay did not approve or conduct field tests on new events. In 2009 the GOU approved (under the new regulatory framework) field tests for new events on corn and soybeans specifically for exportation.

Current Regulatory Procedure

Through Decree 353/08 signed on July 2008, Uruguay developed a new regulatory system for evaluation of new LMOs which requires participation of several Ministries as well as interaction of various groups.

The regulatory procedure includes risk assessment, risk management, and risk communication. It requires consultation with a broad range of specialists and stakeholders (including scientists and representatives of civil society). The final decision on the release of biotech seeds, however, falls within the scope of an inter-ministerial National Biosafety Commission (called GNBio), which is chaired by the Minister of Agriculture.

Authorizations may be granted for different applications:

- a. Contained use (laboratory scale)
- b. Field trials
- c. Production and commercial use for direct consumption or transformation
- d. Importation or exportation with specific destination for direct consumption or transformation

Approvals from Argentina, the United States, Canada, and the European Union are taken into account as a precedent in the approval evaluation process.

A description of the approval process and of all intervening groups follows:

National Biosafety Commission (GNBio)

The Minister of Agriculture, MGAP (chair); Minister of Health, MSP; Minister of Economy and Finance, MEF; Minister of Housing, Territorial Ordering and the Environment, MVOTMA; Minister of Foreign Affairs, MRREE; Minister of Industry, Energy and Mining, MIEM.

This commission is the last responsible to make decisions over a submitted request. It takes into account all macro political aspects. It has the authority to define policies to be followed with respect to LMO application.

Commission for Risk Management (CGR)

Composed by one delegate of each of the ministries represented within GNBio. This commission is

also
representative of the Ministry of Agriculture.

It advises GNBio on LMO biosecurity issues; elaborates reference terms for risk assessments; manages in process; is responsible for follow-up and monitoring of authorized events, and is tasked with preparing
ional Biosafety Law for LMOs within the timeframe of one year.

Evaluation of Risk in Biosecurity (ERB)

Members: Composed of experts proposed by the CGR and designated by GNBio among specialists in the different areas of risk assessment.

Functions: Identifies national and/or regional capacity for network collaboration. The Commission is responsible for considering, on a case-by-case basis, the potential risks and benefits of each new biotech product; assure case-by-case risk assessment evaluation based on sound scientific methods; writes an operational plan (pre-report) of risk assessment according to CGR directives; advises CGR based on the results of the analysis of risk assessment, and provides information during the consultation process.

Institutional Articulation Committee (CAI)

Members: Technical experts from different institutions such as the MGAP; MSP; MGAP; MVOTMA; Ministry of Education; Technological Laboratory of Uruguay, LATU; National Institute of Agricultural and Livestock Research, INIA; National Seed Institute, INASE; Pasteur Institute; and University of the Republic, UDELAR.

Performs technical risk assessment of new events; prepares a technical report. The group will be selected
d by the ERB coordinator.

Summary of the Authorization Process

1. CGR receives a new request.
2. CGR elaborates reference terms case by case and
 - Delivers to ERB for risk assessment.
 - Informs the civil society (through public channels).
1. ERB elaborates proposal for risk assessment, calls CAI, adjusts (or not) the proposal, initiates the evaluation and/or analyzes results of the evaluation.
2. ERB prepares report for CGR.
3. CGR elaborates recommendation for GNBio considering report from ERB and other factors.

- Begins open consultation with civil society.
4. CGR receives and replies to public comments.
 5. CGR elaborates final report with recommendation to GNBio.
 6. GNBio makes the final decision.
 7. CGR informs final decision to requestor and to civil society thru public consultation.

Public consultations are planned to evaluate the impact of the LMO authorization, and they occur at three different levels:

1. *Definition of policies:*

Provide collaboration to GNBio on the design and follow up of biosafety policy for LMOs. The institutions, private sector and civil society will be invited to designate a representative.

1. *Authorization process for requests of new events:*

Information stage: Once the request is received, it will be announced to the society through channels of public information.

Consultation Stage: Prior to the recommendation to GNBio, results are informed through public hearing and there is a period open for suggestions.

1. *Control and claims of new authorized events:*

Reception of claims through a technical secretariat that will channel the requests to the institutions in charge of monitoring and control.

Distribution of responsibilities

The applicant pays: Every request entails an expense, which has to be assumed by the applicant.

Among

other things, this expense would be used in the event there is a need to hire specialized technical staff for specific studies. 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.

Cost ranges: UY\$ 11,650 (approx. US\$ 492) for laboratory scale evaluation, to UY\$ 163,100 (approx. US\$ 6,880) for evaluation for commercial use, importation or exportation.

The applicant delivers basic information: Two copies in Spanish language must be submitted, one hard

copy and the other one in digital format.

The form may be found at: <http://www.inase.org.uy/>

Cartagena Biosafety Protocol

Uruguay has yet to ratify the Cartagena Biosafety Protocol to the 1992 Convention on Biological Diversity

(CBD). Until the Protocol's entry into force (September 2003) Uruguay operated within the framework of

the GRULAC Group (Group of Latin American and -Caribbean Countries) for pursuing the implementation

of the biosafety principles outlined in the Cartagena Protocol. There is a commission within the Parliament

that is currently analyzing the possibility of country ratifying the Cartagena Protocol.

Uruguay, a member of the former Miami Group, has strongly concurred with USG positions on biotechnology

at international fora in the past, and is likely to continue to do so.

Traceability

Issues related to biotechnology such as traceability and labeling (T&L) of biotech seeds are currently the focus of an internal debate that is being carried out at the governmental level.

With respect to the European Union's T&L regulations, contacts at the Ministry of Livestock, Agriculture

and Fisheries, (MGAP) report that traceability is a difficult issue since it is more a commercial concern,

rather than a scientific one. These contacts report that since Uruguay is very dependent on the European

market as an outlet for its agricultural products, some kind of traceability system will probably be necessary.

However, they have repeatedly made it very clear that the GOU would not support mandatory requirements

in international fora.

Labeling

Uruguay has adopted voluntary labeling of "GM" or "non GM" products, as applicable to those food products for which an analysis of the final product can determine the presence of -genetic modification.

Stacked genes

Policy is similar to the US.

Coexistence

No policy. The European Union's regulations are currently being used on an informal basis, but adapted to Uruguay's framework.

Refuges

It is mandatory that 10% of the planted area be kept as a refuge. Uruguay is a small country and the National Seed Institute (INASE) visits the producers in person, thus maintaining a strict control.

Royalties

Farmers are required to pay extended royalties on all biotech seeds. Uruguay's seed law makes a provision for the use of seeds in subsequent -years (for farm saved seed). Seed companies require producers to sign a contract promising to pay royalties the next year.

Trade Barriers / Pending legislation

On several occasions during the past administration the opposition publicly urged the former president to halt the liberalization of LMO crops based on the country's goal of becoming a "natural country" and on the application of the precautionary principle.

A biosafety law is still pending and it is estimated that a bill will be presented to Congress in the near future.

Section IV. Plant Biotechnology Marketing Issues:

There is still misunderstanding and misperception about the safety of biotech plants and foods on human health and the environment. NGOs have opposed the introduction of biotech crop planting and strongly request labeling on biotech products. There is a scattered and unorganized, movement against biotechnology led by NGOs. A major issue is the potential conflict between production of biotech crops and the "Uruguay Natural" marketing campaign for products from Uruguay.

Consumer associations have raised concerns about possible negative impacts on human health and the environment. They mainly advocate labeling, traceability and local field trials of biotech seeds prior to

approval. They also question the potential for toxicity and allergenicity of biotech products.

There is some resistance in the meat industry to the approval of White Clover, one of the events that were under research before the moratorium. Clover is used in pastures, and for this reason “natural meats” will cease to be reliably “natural” according to their arguments. The largest potential issue in this area is for the sheep industry. Clover is used to feed sheep exported to Middle Eastern countries, where biotechnology is highly controversial.

Post is unaware of any relevant, specific studies on the marketing of biotechnology products in the country.

The Uruguayan Seed Chamber has conducted a survey among farmers on the use of Bt corn seed that provided the following conclusions:

- Bt corn has a high penetration level (80% of total area planted).
- Bt seed provides good performance compared to conventional seed.
- Total cost of pest control is lower with the utilization of Bt corn.
- 86% of consulted farmers are more satisfied with the pest control with Bt seed than conventional seed.
- 9 out of 10 farmers do not report any damage related to the use of Bt corn,
- 100% of consulted farmers use refuges.
- 30% of consulted farmers plan to increase the area dedicated to Bt corn, 50% reported they will maintain the same area, and 18% reported will diminish the area (the reasons voiced are not related to Bt seed).
- Farmers are even more optimistic when talking about the future of Bt seeds.
- 86% believe that global area planted will increase in the next 5 years, and 66% of them reported that they will personally increase the use of Bt seed in that timeframe.

Section V. Plant Biotechnology Capacity Building and Outreach: Proposed Activities

FAS Buenos Aires proposes a continuation of education and outreach as well as a more targeted information campaign. Specific activities may include:

- Workshops in different cities to target audiences around the country.
- Coordination with local universities to demonstrate the benefits of biotechnology in Uruguay.
- Continue Cooperator, Cochran and International Visitor program activities.

- Special activities designed for consumer association leaders and consumers in general.
- Workshop especially directed to medical doctors and nutritionists, explaining the innocuousness of biotech products.
- Workshop on risk assessment that will be directed to Argentine, Paraguayan and Uruguayan experts.

Section VI. Animal Biotechnology:

Currently, Uruguay has no genetically engineered animals, and they are not yet in the process of developing specific regulation, although the proposed Biosecurity Law includes plants, animals and microorganisms.