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Agricultural Biotechnology Annual

Uruguay Annual Biotechnology Report 2012

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Report Highlights:
The Government of Uruguay (GOU) approved five genetically modified (GMO) corn events in 2011. There are currently eight biotech events available for production and commercialization in the country: one soybean and seven corn varieties. Planted area with GMO varieties has steadily increased for both soybeans and corn, to reach a total area of 1.1 million hectares planted in 2011.

Uruguay has a predictable regulatory process, is a global leader in intellectual property protection, and maintains a strong enforcement system in the seed industry. These combined traits create good potential for counter season production for American companies.

Section I. Executive Summary:

Uruguay is a country of 3.5 million people, with 2 million hectares of crop production, and is highly dependent on agricultural trade. Potential arable land is estimated in 4 million hectares. Agriculture represents 10 percent of Uruguay's GDP and 67 percent of the country's total exports are agricultural products. The main agricultural sectors are beef, soybeans and forestry. In recent years, strong commodity prices and more efficient production based on genetically modified organism (GMO) varieties 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. It is expected that this year, soybeans will be the country's leading export item displacing beef for the first time.

According to the International Service for the Acquisition of Agri-Biotech Applications (ISAAA), Uruguay now ranks 10th among countries in the number of hectares planted with biotech varieties, as production of crops has increased in recent years. In 2011, 1.1 million hectares were sown with biotech varieties in Uruguay.

Currently there are eight authorized biotech events for production and commercialization in Uruguay. Under the current regulatory framework, five GMO corn varieties were approved in 2011. These approvals were the first granted since 2004. The current government has demonstrated a positive attitude towards biotechnology, and it is expected that they continue to support the development and use of new technologies.

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 timeframe for the complete evaluation process takes about two years.

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Section II. Plant Biotechnology Trade and Production:

In recent years Uruguay has experienced an agricultural revolution, with current crop area estimated several times larger than harvested area of MY 2000/2001. Sustained world-wide demand and favorable local conditions; available land, efficient technicians and companies, and stability of the business framework, are key factors behind the phenomenon. The area dedicated to biotech varieties has steadily increased from 77,000 hectares of soybeans and 1,150 hectares of corn planted in 2003/2004, to 950,000 million of soybeans and 145,000 hectares of corn planted in 2011/2012.

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

Crop	Event	Year of Approval
Soybeans	40-3-2	1996
Corn	MON 810	2003
Corn	Bt 11	2004
Corn	TC 1507	2011
Corn	GA 21	2011
Corn	NK 603	2011
Corn	GA 21 X NK 603	2011
Corn	MON 810 x NK 603	2011

The events submitted for evaluation are:

Corn: Bt11xMIR162xGA21; MON89034xMON88017; TC1507xNK603; TC1507xNK603xMON89034

Soybean: A2704-12 (LL); A5547-127 (LL); MON89788xMON87701 (RR2YxBt); BPS-CV127-9

Uruguay allows field testing of biotech crops.

Counter Season Production

Uruguay's consistent soil and established government regulatory system, as well as Intellectual Protection (IP) and trustworthy business ethics, create good potential for counter season production. The area dedicated to counter season production significantly increased from 2010 to 2011, but lowered slightly in 2012. According to private contacts, there are two reasons for the decrease in planted area: higher production cost in Uruguay compared to Argentina (US$100 per hectare more expensive in Uruguay), and the approval timeframe of the events, that used to take up to 6 or 7 months. Up to this season, companies had to apply for approval every season to renew the permits. However, the GOU recently changed the regulatory framework and now they grant automatic renewal of permits for events approved only for exportation. This change makes the Uruguayan industry confident and they foresee a good business opportunity in counter season production. It is expected that production of these export varieties will increase in 2013. At the moment, only soybeans are produced for American companies.

Evolution of Planted Area for Counter Season Production:

MY2009/10	1000 hectares
MY2010/11	2200 hectares
MY2011/12	2000 hectares

Soybeans

Soybean harvested area increased from 77,000 hectares in MY2002/03 to 950,000 hectares in MY2011/12. 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.

For more detailed information on Soybean production, please see the Uruguay Oilseeds and Products Annual in the Global Agricultural Information Network (GAIN) system.

Corn

The first authorization (for imports and commercialization) for a GMO corn variety was granted by the Government of Uruguay (GOU) in 2003 to Monsanto's insect-resistant corn (variety MON 810). Syngenta got approval for its insect resistant Bt 11 corn in 2004, and then in 2011, five additional corn varieties were approved. Uruguay now has seven corn varieties approved.

Bt corn has a high penetration level (over 90 percent), and with the new corn varieties approved available, most farmers expressed their intention to increase the area planted.

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
2008/09	135,000	110,000
2009/10	110,000	90,000
2010/11	100,000	80,000
2011/12	158,000	145,000*

*estimated

Source: Cámara Uruguaya de Semillas (CUS)

Rice

No biotech rice varieties have been approved. In Uruguay, adoption 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 GMOs 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 GMOs.

In 2007 the GOU issued a decree for "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 the moratorium, 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. 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.

The first approvals for commercialization granted after the new regulatory framework was implemented occurred in 2011, when five corn varieties were approved.

In 2012, the government granted the automatic renewal of permits for events to be used for counter season production (for exportation purposes only). In the past, companies had to request permits every year.

Decree 249/00 www.cus.org.uy/es/biotecnologia/normativa-vigente.../doc/47/raw
Decree 353/08 http://www.mgap.gub.uy/portal/hgxpp001.aspx?7,1,144,O,S,0,MNU;E;2;2;12;5;MNU

Current Regulatory Procedure

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; and Minister of Industry, Energy and Mining, MIEM.

This commission is the last responsible to make decisions over a submitted request. It takes into account, among others, all macro political aspects. It has the authority to define policies to be followed with respect to biosafety in all scopes of GMO application.

Commission for Risk Management (CGR)

Composed by one delegate of each of the ministries represented within GNBio. This commission is also chaired by the representative of the Ministry of Agriculture.

It advises GNBio on GMO biosecurity issues; elaborates reference terms for risk assessments; manages the participation process; is responsible for follow-up and monitoring of authorized events, and is tasked with preparing a bill for a National Biosafety Law for GMOs within the timeframe of one year.

Evaluation of Risk in Biosecurity (ERB)

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 and coordinated by the ERB coordinator.

(Please see Appendix A for a graph and summary of the process)

Public consultations are planned to evaluate the impact of the GMO 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 GMOs. 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 public 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: Approximately US$ 500 for laboratory scale evaluation, to approximately 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

In 2011, Uruguay ratified the Cartagena Biosafety Protocol to the 1992 Convention on Biological Diversity (CBD). The focal point is set at the Ministry of Foreign Affairs.

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.

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 continued to be internally debated at the governmental level.

With respect to the European Union's T&L regulations, contacts at the 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. Evaluation of the stacked events is focused on the possible interactions between the single events contained in the particular trait. The key consideration is whether crossing two or more approved GM plant lines, using traditional plant breeding, is likely to pose any new or additional food safety risks over and above what was previously considered as part of the safety assessment of each parental GM line.

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

Uruguay has an innovative and efficient royalties' collection system not only for license holders but for farm saved seed as well. Farmers are required to pay extended royalties on all biotech seeds. It is estimated that in 2011, 95 percent of total soybean planted area paid royalties. Uruguay's seed law makes a provision for the use of seeds in subsequent years (for farm saved seed) and seed companies require producers to sign a contract promising to pay royalties the next year. In this sense, the small size of the country is an advantage for IPR and seed companies. Farmers are visited by representatives of the Uruguayan Breeders Association (URUPOV), for crop information, and when they buy seed they sign a document in case they are willing to use as farm saved seed and even so, indicating they will pay extended royalties to the plant breeder.

Trade Barriers / Pending legislation

On several occasions during the past administration, the opposition publicly urged the former president to halt the liberalization of GMO 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 was 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. However, the Uruguayan Seed Chamber (CUS) contracted a group of specialist that are working on a study related to marketing and the socioeconomic impact of biotechnology in Uruguay. It is expected that the first results would be issued in October 2012.

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:

There is an ongoing research collaboration project between the Institute Pasteur Montevideo, and the Animal Reproduction Institute of Uruguay (IRAUy) to produce genetically modified sheep. The ultimate goal of the project is to obtain animals that could produce human growth hormone and insulin

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