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## Uruguay

## Biotechnology

## Annual

## 2005

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**Report Highlights:**

Uruguay ranks 10th among countries in the number of acres planted with biotech varieties. Currently, there are three events approved for commercialization: one soybean variety (MON 40-3-2) and two corn varieties (MON 810 and BT11). The new government, which took office in March 2005, has yet to define its biotech policy.

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Includes PSD Changes: No  
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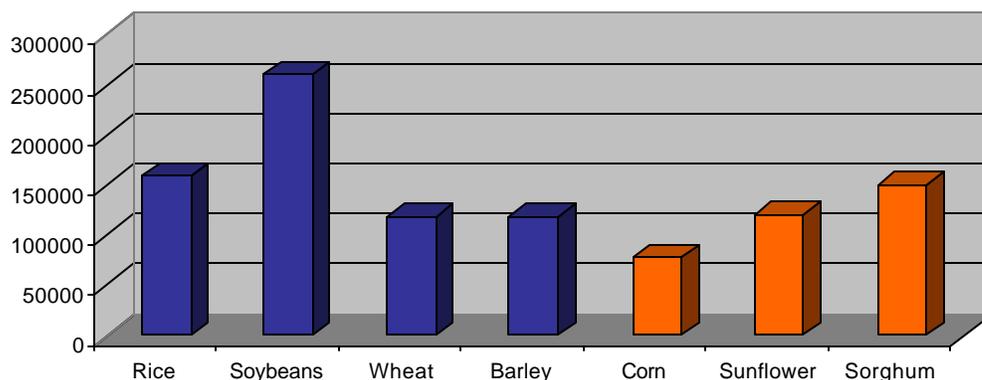
## Executive Summary

Uruguay, a relatively small country located between Argentina and Brazil, now ranks 10<sup>th</sup> among countries in the number of acres planted with biotech varieties.

In 1995 the Government of Uruguay (GOU) 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 genetically modified organisms (GMOs). In 2000, per Decree 249/00, a regulatory framework was established to authorize the introduction, use and manipulation of GMOs in the country. Labeling provisions are not yet in place. There is no law or regulation governing the use of labels such as “non GMO” or “biotech free”. However, under the current government, which just took office in March 2005, draft laws are being debated, and the GOU may present new restrictive proposals to the Congress. So far, the new administration has not yet defined its biotech policy. It is possible that with the new government in place, the approval process for biotech events could take more time than before. In addition, it seems that consumer associations will have a more active role in the approval process.

## Production

*Uruguay Main Crop Area (has.) 2003-04  
(Biotech and conventional crops)*



**Note:** Only Soybeans and Corn are authorized biotechnology crops

Authorized Biotech events for production and commercialization are:

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

Corn, event MON 810 (approved 2003)

Corn, event Bt 11 (approved 2004)

## Soybeans

The influx of Argentina capital into the Uruguayan countryside has changed the face of Uruguayan agriculture. Similar to Argentina in climate, culture, infrastructure, and in some instances, soil structure, many Argentines view the Uruguayan production regions as an extension of the productive region of Argentina (the so-called Pampa Humeda). Soybean harvested area,

alone, increased from 77,000 has. in MY2002/03 to over 240,000 has. in MY2004/05. Approximately 98 percent of total soybean area is planted with Round-up Ready soybeans.

The advantages of production in Uruguay are many. The most attractive difference between the two countries is the absence of agricultural export taxes. Soybean exports in Argentina are taxed at 23.5 percent. Additionally, a newly constructed bridge over the Argentine Delta area now facilitates transit between Argentina's main soybean port area, Rosario, and Uruguay.

## Corn

Until August 2003, GMOs were only used in soybean production in Uruguay. In 2003, after much uncertainty, the authorization for the importation and commercialization of Monsanto's insect-resistant corn (variety MON 810) was released by the GOU. More recently in 2004, Bt 11 corn was approved arousing opposition among environmentalists and leftists.

Immediately following the controversial decision to allow MON 810 maize, the opposition to the ruling government drafted a bill proposing a system that would require a new law be passed for each event and called for a one-year moratorium on the release and use of GMOs to allow time for a complete debate of the issue. At the request of the opposition, a statement was issued by Parliament urging the President to halt the liberalization of GMO maize, based on the country's goal of becoming a "natural country" and on the application of the precautionary principle.

While the battle between the opposition and the President was developing, the Ministry of Environment (MOE) unexpectedly entered the fray and issued strict regulations under which MON 810 could be planted. Based on provisions already established in the General Environmental Protection Act, the MOE claimed to be in charge of the prevention and control of potential environmental hazards deriving from the creation, manipulation, use and release of genetically modified organisms, in as much as they may affect biodiversity and the environment as a whole. However, the president at the time, Jorge Batlle, pressured the MOE and the regulation was significantly toned down.

To further complicate the issue, Parliament requested an interpellation with then Minister of Agriculture Martin Aguirrezabala concerning his approval of MON 810. The opposition faction who instigated this action made a rather emotional presentation about GMOs, predicting that the approval of this event would lead to the invasion of Uruguay by multi-national companies, would oust the small producers, and in the end would ruin the image of "Uruguay: Natural Country". Minister Aguirrezabala testified before Parliament in a grueling eight-hour session, indicating that there is no evidence suggesting foods produced through biotechnology pose a threat to health. On the contrary, he pointed to GMOs' potential to ensure food safety, dramatically reduce hunger and malnutrition, and raise agricultural productivity. Minister Aguirrezabala also said that the use of GMOs does not interfere with the "Uruguay, Natural Country" theme, since the environmental and human health benefits of GMO technology include lower pesticide and insecticide use, reduced spoilage, and greater nutritional value.

Aguirrezabala further argued that the proposed bill requiring a law for each event would be neither convenient nor reasonable, since GMO evaluation is an activity of a technical nature. He noted that the current legal framework of the country is sufficient and includes all the necessary safeguards to preserve the commercial viability of Uruguayan products. The Minister's

explanations were considered satisfactory and the testimony ended without any calls for follow-up.

Transgenic maize (MON 810) was commercially planted in 2003 for the first time. In 2004, Bt 11 maize was approved for production and commercialization. At the moment, total Bt corn area is 30,000 has.

### **Rice**

Uruguay is traditionally a rice exporter. Thus, the 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.

However, there is one event under research. Rice lines LLRICE06 and LLRICE62, which are genetically engineered to express tolerance to glufosinate ammonium, the active ingredient in phosphinothricin herbicides, are currently under research in Uruguay.

### **Other Crops Under Development**

In general, approval of new events in Uruguay is linked to approvals granted in Argentina. All studies and research done in the neighbor country are taken into account.

### **Corn**

There are several corn varieties currently under research:

#### **NK603**

The NK603 line of maize was developed to allow the use of glyphosate, the active ingredient in the herbicide Roundup, as a weed control option.

#### **NK 603 x MON 810**

NK603 x MON 810-hybrid maize consists in the combination of two genetically modified parental inbred lines, derived from maize transformation events NK603 and MON 810, respectively, by traditional breeding. No additional genetic modification is involved.

NK603 × MON 810 maize results from a single conventional cross of the inbred parental lines NK603 maize and MON 810 maize, homozygous in their respective inserted sequences. By crossing NK603 and MON 810 maize, NK603 × MON 810 maize inherits the inserted DNA fragments from both its parental lines.

#### **Herculex: DAS-01507-1 (TC 1507)**

The GMO maize line TC1507 was genetically engineered to resist European corn borer (ECB), Southwestern corn borer, fall armyworm, and black cutworm by producing its own insecticide. Herculex has been recently approved in Argentina and is under investigation in Uruguay.

## White Clover

Recently approved for research, this variety, the first forage event under study in Uruguay, was developed in Australia by Professor German Spangenberg, an Uruguayan botanist currently at La Trobe University.

Numerous biotechnology strategies are being considered with respect to the improvement of nutritional quality through altering the biosynthesis of lignin, soluble carbohydrates, and protoantocianins and the regulated expression of proteins rich in essential amino acids, resistant to rumen. Attempts are also being made to increase resistance to pathogens and pests and to manipulate growth and development in order to increase persistence and delay senescence, impede flowering and negatively regulate pollen allergens.

## Policy

Domestically, the GOU has set up guidelines and procedures to oversee and regulate the introduction of biotechnology products into the environment and market. Oversight and regulatory responsibilities are vested in the Risk Assessment Commission of Genetically Modified Plants, which is headed by the Ministry of Livestock, Agriculture and Fisheries (MGAP.) Member organizations also include the Ministry of Housing, Land Management and the Environment, the Ministry of Public Health, the National Seed Institute; and the National Agricultural Research Institute. The Commission is responsible for considering, on a case-by-case basis, the potential risks and benefits of each new biotech product.

Biosafety regulations were established following the mandate of the Convention of Biological Diversity. At the 1992 Earth Summit in Rio de Janeiro, world leaders agreed on a comprehensive strategy for "sustainable development" -- meeting our needs while ensuring that we leave a healthy and viable world for future generations. One of the key agreements adopted at Rio was the Convention on Biological Diversity. This pact among the vast majority of the world's governments sets out commitments for maintaining the world's ecological underpinnings economic development ensures. The Convention establishes three main goals: the conservation of biological diversity, the sustainable use of its components, and the fair and equitable sharing of the benefits from the use of genetic resources. Uruguay (along with Chile and Costa Rica) adapted this existing legislation for seeds and plant health inspection services.

The regulatory procedure, which does not cover laboratory research, includes risk assessment and risk management. It includes consultation with a broad range of specialists and stakeholders (social scientists and representatives of civil society) apart from those usually included (toxicologists, nutritionists, molecular biologists, and plant breeders). However, the final decision on the release of GMOs falls within the scope of both the MGAP and the Ministry of Economics and Finance.

Main duties of the Risk Assessment Commission include:

1. To create the rules to perform the risk assessment for the introduction, use, and manipulation of GMOs and their parts,
2. To analyze case by case, using sound science, the risk inherent in each product,

3. To provide advice to the competent authorities (Ministry of Livestock, Agriculture, and Fisheries, and the Ministry of Economy and Finance) regarding authorizations,
4. To advise the competent authorities about risk management and communication measures to be adopted in each case; and,
5. To advise the Uruguayan Government (GOU) about plant GMO biosafety.

The Risk Assessment Commission will also create working groups for specific tasks when necessary and will request technical advice from universities and public or private research centers, as well as of independent specialists recognized by their technical proficiency.

The commission includes representatives of the following ministries:

1. Ministry of Livestock, Agriculture and Fisheries (this representative occupies the presidency of the Commission),
2. Ministry of Environment (this representative occupies the vicepresidency of the Commission),
3. Ministry of Public Health,
4. National Seed Institute (INASE); and,
5. National Agricultural Research Institute (INIA).

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

### **Cartagena Biosafety Protocol**

Uruguay has yet to ratify the Cartagena Biosafety Protocol to the 1992 Convention on Biological Diversity (CBD). Up until the Protocol's entry into force (September 2003) Uruguay operated within the framework of the GRULAC Group (Group of Latin American and the Caribbean Countries) in 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 biotech at international for a, in the past, and is highly likely to continue to do so.

### **Traceability and labeling**

Related biotechnology issues such as traceability and labeling (T&L) of GMOs are currently the focus of an internal debate that is being carried out at the governmental level.

As to the European Union's T&L regulations, MGAP contacts have told us that traceability would be a difficult issue in Uruguay since there are commercial, not only scientific, issues at play. They believe 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 imposed on Uruguay. However, they have repeatedly made it very clear that the GOU would not support the EU in its efforts to force the issue in international fora.

With regard to labeling of biotech products, contacts at the GOU working level indicate that the GOU does not have a clear position on the issue. Reportedly, however, the MGAP's own

position is that labeling should be mandatory for products that are substantially different from their original version, and for those products with a lowered safety threshold.

Meanwhile, there are currently several draft bills enforcing the mandatory labeling of products containing genetically modified components.

### **Stacked genes**

No policy. A stack event is considered to be a whole new event, and it must undergo a full review.

### **Coexistence**

No policy. The European Union's norm was used as a base, but adapted to Uruguay.

### **Refuges**

It is mandatory that 10% of the planted area is kept as a refuge. Uruguay is a small country; therefore, the Seed Institute (INASE) visits the producers in person.

### **Royalties**

All seeds pay extended royalties and the seed law makes a provision for the use of seed at the following year. The company requests the producer to sign a contract promising to pay royalties the next year, therefore they sign a contract between parts.

### **Trade Barriers / Pending legislation**

The current government, favors full "end-product" and "process-based" labeling. In that respect, a bill has been drafted advocating the enforcement of an authorization by-law system for GMOs, while calling for a one-year moratorium on the release and use of GMOs to allow time for a complete debate on the issue. On several occasions during the past administration the opposition publicly urged the former president to halt the liberalization of transgenic crops, based on the country's goal of becoming a "natural country" and on the application of the precautionary principle.

### **Marketing**

There is still misunderstanding and misperception about the safety of GMO plants and foods on human health or in the environment. NGOs have opposed the introduction of GMO crop planting and strongly request labeling on GMO products.

The opposition is based mainly on the controversy between GMO crops and the concept of "Uruguay Natural" and on the lack of scientific evidence regarding the innocuousness for human health.

Consumer associations raised concerns about possible negative impacts on human health and the environment. They mainly advocate labeling and traceability and local field trials of GMOs 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. Clover is used in pastures, and for this reason “natural meats” will cease to be reliably “natural” according to their arguments. But the problems for the beef industry won't be as serious as the problems for the dairy industry, because clover is used more often in dairy production. Additionally this is a threat to the sheep industry. More than anything, clover is used to feed sheep exported to Arab countries that want absolutely nothing to do with GMOs.

Uruguayan meat comes from animals that don't consume GMOs”, A study prepared by the National Meat Institute (INAC) concludes that based on the existence of control systems for the entry and use of GMOs in Uruguay, the use of pastures of genetically modified origin in animal feed in pasture production systems is considered to be highly unlikely.

There are no relevant, specific studies on the marketing of biotechnology products in the country.

### **Capacity Building and Outreach**

#### **2002**

- A. FAS Buenos Aires organized a biotechnology seminar in Uruguay that was successful in terms of attendance (over 300 participants).
- B. Through Cochran funds, FAS Buenos Aires sponsored two-week biotechnology training in the United States for 3 Uruguayan Government officials, organized by ICD and Michigan State University.

#### **2004**

- A. FAS Buenos Aires selected 2 Uruguayan journalists that participated in a US Grains Council activity in Hawaii, where they learnt about the papaya industry.
- B. The Agricultural Counselor accompanied State's Biotech Negotiator to Uruguay to participate in a series of round tables on biotechnology organized by Embassy Montevideo.
- C. Through Cochran funds, FAS Buenos Aires sponsored two-week biotechnology training in the United States for 1 representative of the Uruguayan Seed Chamber, organized by ICD and Michigan State University.
- D. Two Uruguayan producers attended the Farmer-to-Farmer workshop at the University of Zamorano in Honduras.
- E. FAS Buenos Aires sponsored the trip of an Argentine Expert to participate in a seminar in Santiago, Chile, directed to the Chilean Parliament.

**2005**

- A. The Agricultural Counselor accompanied State's Biotech Negotiator to Uruguay to participate in a series of round tables on biotechnology organized by Embassy Montevideo.
- B. FAS Buenos Aires in concert with FAS Santiago organized and accompanied a Southern Cone CODEL to the United States, to demonstrate how the United States uses and regulates agricultural biotechnology.

**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,
- A two-day conference directed mainly to Congressmen, but also to media, academia and government officials among others,
- 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; and,
- Workshop in risk assessment that will be directed to Argentine, Paraguayan and Uruguayan experts.

**APPENDIX A: Status of Products Approval**

Crop	Trait Category	Event/ Applicant	Trait Description	Status
Soybean	Herbicide Tolerant	40-3-2 Monsanto	Glyphosate Herbicide Tolerant	Approved Feed and/or Food
Maize	Insect Resistant	MON 810 Monsanto	Resistant European Corn Borer	Approved Feed and/or Food
Maize	Insect and Herbicide Tolerance)	Bt 11 Syngenta Seeds	Resistant EuropeanCorn Borer and Glufosinate Ammonium	Approved Feed and/or Food
Maize	Herbicide Tolerance	NK 603 Monsanto	Gliphosate Herbicide Tolerant	Research
Rice	Herbicide Tolerance	LLRice 06 Bayer	Glufosinate resistance	Research
White Clover	Virus Resistance	LXR Phytogene	Alfalfa.Mosaic Virus	Research
Maize	Insect and Herbicide	TC 1507 Herculex	Resistant to European Corn Borer and to	Research

	Tolerance	DowAgro Sciences	Glufosinate Ammo nium	

**APPENDIX B: Relevant Current Laws and Regulations****Law 16.466: Environmental Impact Evaluation Law – 1994**

This law states that it is of general and national interest to protect the environment against any type of degradation, destruction or contamination, as well the prevention of the negative or noxious environmental impacts.

**Law 17283: Environmental Protection Law – 2000**

Art. 23 Biosafety. The Ministry of Environment will apply the measures needed to prevent and control environmental risks from the creation, manipulation, use or environmental release of GMOs until a competent authority is designated.

**Law 9202: Public Health Law – 1934**

This law establishes the Ministry of Health as the regulatory organization in all the issues related to public health.

**Law 16811: Seed Law: 1997**

This law regulates the production, certification and trade of seeds, the National Register of Production Fields and the protection of plant creations.

INASE, among other duties must:

- Control the seed production and trade, overseeing for the compliance of the rules established by the law.
- Control the national registration of cultivars.

**Law 3921: Plant Protection Law – 1911**

This law prevents the introduction and dissemination of plant pests.

The MAGP is responsible for the development and organization of the plant health protection in Uruguay, and for the administration and supervision of the national system for plant protection and phytosanitary surveillance.

**Decree 249/00 - August 2000**

The objective of Decree 249/00 is to promote the safe use of biotechnology by creating an adequate level of protection for GMOs, preventing adverse effects on agricultural production and conservation and sustaining biodiversity.

The introduction, use and manipulation of plants and their genetically modified parts, independently from the manner or regime under which this operation is performed, will only be allowed with previous authorization, granted by the competent authorities.

**Applications of Decree 249/00**

The development of events under contained use.

- Development of tests and field trials under specific biosafety conditions.
- The evaluation of trials according to law 16811

- Seed multiplication
- Initial production or importation (with the intended use of food, feed or processing).

### **APPENDIX C: Process to Obtain Approval from GOU**

The process to obtain approval from GOU involves a formal application (form SOL-OGM- 1) that includes the following data:

- A.** Applicant: name, address and registration number in the general register of seed producers and traders.
- B.** Legal responsible: name and address
- C.** Technical responsible
- D.** Specie:
  - Regular name
  - Botanical name
- E.** Event
- F.** Cultivar, if applicable
- G.** Origin of material
- H.** Proposed use
  - 1. Development of experiments under contained use
  - 2. Development of tests and field trials under protection or under specific Biotech conditions.
  - 3. Evaluation of National Production Cultivars
  - 4. Seed multiplication
  - 5. Production or first time importation with the intended use (food or feed processing)
  - 6. Other:
- I.** Countries where application has been submitted (if any) indicating which states and date of submission
- J.** Countries where authorization has been granted (if any) indicating states and date of approval.

Once the applicant has complied with this request, the risk analysis commission will perform the risk analysis evaluation on the following basis:

- Case by case
- Adherence to sound science
- The impact on the environment, biological diversity and the eventual effects on human, animal, and plant health.
- Compliance with international guidelines.

After the risk analysis evaluation is performed, the Commission will advise the competent authorities about risk management and communication measures.

Before adopting a resolution, the Competent Authority will publish in national newspapers the name of the GMO, name of the applicant, requested use as well as a summary of the risk analysis evaluation. During a 20 days period after publication, the public has the opportunity to voice opposition.

Failure to comply with all conditions of a granted authorization may lead to cancellation of the permit and to legal actions.

