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## **Paraguay**

### **Agricultural Biotechnology Annual**

#### **Paraguay Annual Biotech Report**

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**Report Highlights:**

Paraguay is the seventh largest soybean producer in the world producing about two percent of the world's soybean production. Soybean production has become a driver of Paraguay's economy, and almost all of the 2.8 million hectares planted in crop season 2011/12 are biotech.

On July 14, 2012, the Paraguayan Minister of Agriculture granted commercial approval to Monsanto's Bt cotton. The current government, which just took office in June 22, 2012, is taking concrete steps to correct the use of illegal seeds and has sent positive signals about biotech. Currently Round Up Ready (RR) Soybean and Bt Cotton are the only two biotech varieties commercially approved in the country.

Paraguay's royalty collection system for soybeans is a well documented success story in the region, and continues to operate as an agreement between Monsanto and the farmers. A similar scheme is under discussion for the recently approved cotton variety.

**Section I. Executive Summary:**

The main agricultural exports of Paraguay are soybeans and cotton. Soybeans are grown mainly in eastern Paraguay along

the border with Brazil. Soybeans are produced on large mechanized farms, while cotton production is less centralized and is mainly produced on small subsistence farms. Paraguay is also the largest exporter of organic sugar to the United States. The United States has good relations with Paraguay.

According to the International Service for the Acquisition of Agri-biotech Applications, (ISAAA), Paraguay is the seventh largest soybean producer in the world (after the United States, Brazil, Argentina, India, Canada and China), producing about two percent of the world's soybean production. Before the 2004/2005 season, Paraguay did not allow the use of biotech seeds and now, the biotech soybean area accounts for 95 percent of the country's total soybean crop. This is considered a large increase over time; however Paraguay's rate of biotechnology advancement for other varieties is well behind the rate in neighboring countries, particularly Brazil and Argentina. The delay in adoption has generated concern in the agricultural sector and has encouraged the use of illegal seeds containing events that are not approved.

The current government which just took office in June 2012 is taking concrete steps to correct the use of illegal seeds and has sent positive signals about biotech. On July 14, 2012 the Paraguayan Minister of Agriculture granted commercial approval to Monsanto's Bt cotton. It is possible that five corn varieties that have been under analysis for several years, as well as two cotton varieties might be approved in the short term with this new administration in place. The current government is well aware of the urgent need of the country to be able to compete with its neighbors (mainly Argentina and Brazil) and to stop the use of illegal seeds.

Paraguayan farmers agreed in March 2005 to pay royalties to Monsanto for the use of its living modified organism (LMO) soybean varieties starting the 2004/2005 crop year. Since then, Monsanto and farmers have agreed upon the price of royalties paid based on each year's production level. A similar model is currently under discussion between the companies and farmers for the recently approved Bt cotton event and will eventually be negotiated for corn once approvals are granted.

Paraguay is still working to pass and implement a biosafety law that would regulate the eventual production and commercial release of LMO products in the country. Although a draft biosafety bill has been submitted for approval and is pending in the National Congress since 2003, Post contacts have reported that this bill is currently under discussion in the House of Representatives and might be sent to the Senate before the end of the year.

## Section II. Plant Biotechnology Trade and Production:

There are currently eleven soybean RR varieties and one cotton variety (Bt) approved for planting and commercialization. About 96 percent of Paraguay's 2.8 million hectares of total soybean area was planted with RR varieties for the 2011/12 season.

For more detailed information on soybean production, please see Paraguay Oilseeds & Annual Report in the Global Agricultural Information Network (GAIN) system.

There are currently five corn varieties under the final evaluation stages: MON 810; NK 603; and VT3PRO (all three Monsanto varieties); TC1507 (from Dow-Pioneer); and Bt11 (from Syngenta) as well as two cotton varieties, RR and BtRR (both Monsanto varieties). According to Post contacts, it is expected that all these varieties will be approved and available in the market for the next crop season (MY2012/2013) if not earlier.

### Varieties Approved for Planting and Commercialization

Crop	Trait Category	Event/ Applicant	Trait Description	Status
Soybean	Herbicide Tolerant	M-SOY 7878 Monsanto	Glyphosate Herbicide Tolerant	Approved Feed and/or Food
Soybean	Herbicide Tolerant	M-SOY 8080 Monsanto	Glyphosate Herbicide Tolerant	Approved Feed and/or Food
Soybean	Herbicide Tolerant	AW 5581 Monsanto	Glyphosate Herbicide Tolerant	Approved Feed and/or Food
Soybean	Herbicide Tolerance	AW 7110 Monsanto	Glyphosate Herbicide Tolerant	Approved Feed and/or Food
Soybean	Herbicide	A6019RG	Glyphosate	Approved

	Tolerance	NIDERA	Herbicide Tolerant	Feed and/or Food
Soybean	Herbicide Tolerance	A 8000RG NIDERA	Glyphosate Herbicide Tolerant	Approved Feed and/or Food
Soybean	Herbicide Tolerance	A 8100RG NIDERA	Glyphosate Herbicide Tolerant	Approved Feed and/or Food
Soybean	Herbicide Tolerance	CD 212RR COODETEC	Glyphosate Herbicide Tolerant	Approved Feed and/or Food
Soybean	Herbicide Tolerance	CD 213RR COODETEC	Glyphosate Herbicide Tolerant	Approved Feed and/or Food
Soybean	Herbicide Tolerance	CD 214RR COODETEC	Glyphosate Herbicide Tolerant	Approved Feed and/or Food
Soybean	Herbicide Tolerance	CD 219RR COODETEC	Glyphosate Herbicide Tolerant	Approved Feed and/or Food
Maize	Herbicide Tolerance	NK 603 Monsanto	Gliphosate Herbicide Tolerant	Approved experimentation
Maize	Insect Resistant	MON 810 Monsanto	Resistant EuropeanCorn Borer	Approved experimentation
Maize	Herbicide Tolerance Insect Resistance	MON 810 x NK603	Gliphosate Herbicide Tolerant Resistant European Corn Borer	Approved experimentation
Maize	Herbicide Tolerance Insect Resistance	VT3PRO	Gliphosate Herbicide Tolerant Resistant Lepidoptera & Coleoptera	Approved experimentation
Maize	Herbicide Tolerance Insect Resistance	TC1507	Gluphosinate Herbicide Tolerant Resistant European Corn Borer	Approved experimentation
Maize	Herbicide Tolerance Insect Resistance	Bt11	Gluphosinate Herbicide Tolerant Resistant European Corn Borer	Approved experimentation
Cotton	Insect resistance	Bt Monsanto		Approved commercialization
Cotton	Herbicide Tolerant	RR Monsanto		Approved experimentation
Cotton	Insect resistance and Herbicide tolerant	BTRR Monsanto		Approved experimentation

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

Paraguay is not a recipient of food aid.

### **Section III. Plant Biotechnology Policy:**

#### **Current Situation of Regulatory Framework**

The Ministry of Agriculture is the national authority in charge of the approval, regulation of use in field trials, laboratory trials, and commercial approvals of biotech events. The Biosecurity Commission (COMBIO) is the main body that acts as the Minister of Agriculture's main advisor in approvals of biotech events.

The criteria used to evaluate new events include:

- Possibility of negative effects for the environment
- Possibility of negative effects for the human health
- Capability of the requestor
- Biological characteristics of the event
- Molecular phenotypic mechanism expressed
- Sexually compatible species

*Summary of the current situation related to the regulation of Biotech events in Paraguay:*

Biosecurity Law	No
Specific Regulations for Biotech events	Yes
Institutional framework	Yes
UPOV 78 agreement	Approved
Cartagena Protocol	Signed and Ratified

### **Biosafety Law**

The current regulatory framework applied to biotech seeds and to biosecurity is incomplete. Paraguay, in recognition of its need to regulate biotech seeds, has proposed several biosecurity laws based on discussions within COMBIO, regulations in place in MERCOSUR countries, and the results of three public hearings. The country is still working to pass and implement a biosafety law. Since 2003, the Paraguayan National Congress has been evaluating a draft biosafety bill that would regulate the production and commercial release of LMO products in Paraguay. The Ministry of Agriculture drafted the bill collaboratively with the Food Agriculture Organization (FAO), and with input from interested sectors of the Paraguayan society. As the bill is currently written, the Ministries of Agriculture, Environment, and Health will jointly enforce the law, while COMBIO will continue to advise the Ministries on technical issues. The National Service of Seed and Vegetable Quality (SENAVE) would advise the Ministry of Agriculture on policy issues. According to private contacts, the house of Representatives has partially approved the bill, and therefore it is estimated that the bill will be presented to the Senate before the end of the year.

### **Biosecurity Commission (COMBIO)**

COMBIO is the commission in charge of analyzing and advising on the introduction, field trials, and environmental release of biotech plants. This commission acts as an advisory organism and includes representatives (13 in total) of the Ministry of Health, the Ministry of Agriculture and Livestock, and the Ministry of Environment, as well as representatives of scientific institutions, the academia, and the farming sector.

Functions of the commission include:

- Receipt and evaluation of requests for use of new biotech events
- Risk analysis (carried out by a private company)
- Control and inspection (as requested by the involved ministries)
- Information exchange with national and/or international public and private institutions in reference to risk analysis and approval for commercialization of LMOs
- Technical advice to the Ministry of Agriculture in reference to policy implementation and national strategy related to biosecurity

(See appendix A for a complete description of the approval process)

Other institutions involved in the approval process are:

### **National Service of Plant Quality and Health (SENAVE)**

The specific functions of this institution related to biotech events include the inspection and control of the areas of work where biotech events are manipulated, and of the national cultivars registry. SENAVE also acts as an advisory body to the

Minister of Agriculture on policy issues.

**National Food and Nutrition Institute (INAN)**

Part of the Ministry of Health, is in charge of the evaluation for human consumption, according to the proposed use.

**Paraguayan Institute of Agricultural Technology (IPTA)**

This institution created in 2010, is in charge of conducting the field trials for biotech events.

**Secretary of Environment (SEAM)**

SEAM is the authority that evaluates environmental impact issues the environmental licenses now required for the commercial approval of a biotech event.

In 2010, the private sector supported by the Institute for the Incorporation of Biotechnology (INBIO), lobbied with different agencies of the government to change requirements for environmental licenses. In October 2010, as a result of this action, the Paraguayan Minister of Agriculture (MAG) signed a resolution that allows for field trials of GM seeds. The resolution eliminated the requirement that the analysis of new varieties include environmental licenses issued by the Secretariat of Environment (SEAM) for experimental field trials. Delays in issuing the licenses had been a serious barrier to completing the analysis of new varieties. Under the MAG resolution, the requirement for environmental licenses was removed for field trials, but remains in force for the final approval before commercial production.

**Traceability**

No provision for a traceability system is in place nor has this been included under the proposed law. Tests for biotech content in shipments arriving to Paraguay are not conducted either.

**Labeling**

Biotech products that are marketed may be required in the future to bear a label that contains specific information required by the Ministry of Industry and Commerce. When questioned about labeling requirements, officials of the Ministry of Agriculture, indicated that Paraguay should establish information labeling requirements according to CODEX resolutions. However, this is not stated in the proposed bill, where provisions for labeling are vague.

**Stacked Genes**

Paraguay does not have a policy on stacked genes. COMBIO has not yet concluded the discussion whether they would issue a special form for stacked genes, or if they would just continue analyzing each event on a case-by-case basis, requesting more information especially in reference to the possible synergic effects and the metabolic routes, among other evaluation criteria.

**Coexistence**

Paraguay has not yet established a policy on coexistence.

**Royalties**

***Framework Agreement signed in support of Royalty Collection System***

Paraguayan farmers agreed on March 2, 2005 to pay royalties to Monsanto Co. for its biotech soybeans beginning in the 2004/2005 crop year. The agreement was signed between Paraguayan farm groups and Monsanto's Paraguayan branch. Paraguayan farmers, as well as those in Brazil and Argentina, had used Roundup Ready soybean seeds for years without paying royalties. The price is negotiated between the provider of the technology (in this case Monsanto) and the user (the farmer), informing the GOP once the price is set. In 2011 they paid \$4.40 per bag of seed used to sow one hectare, based on yields of the last campaign.

According to the agreement, a portion of those royalties will go to crop research and germplasm improvement within the country. INBIO receives payment of 10% of received royalties every crop year from Monsanto. INBIO is an organization that integrates representatives of the whole Paraguayan agricultural sector and is in charge of financing training and research related to biotechnology. Investment percentages are used as follows: 55% research; 15% grants; and 30% to strengthen the sector thru marketing, education and promotion.

Although this royalty collection scheme is only negotiated for soybeans, a similar scheme is currently under discussion for cotton and will eventually be negotiated for corn once approvals are granted. This system is a positive step in closing Latin America's biotech black market.

### **Cartagena Biosafety Protocol (CBP)**

In 2003, Paraguay ratified the Cartagena Biosafety Protocol (CBP). Since early 2010, the Foreign Affairs Ministry is in charge of the provisions of the CBP. Over the last couple of years, Paraguay has become a strong player in meetings of the parties sending delegations with full technical expertise, although the Biosafety Clearing House is still in process.

### **Section IV. Plant Biotechnology Marketing Issues:**

Paraguay's rate of biotechnology advancement in new varieties is well behind the rate in neighboring countries, particularly Brazil. The delay in adoption has generated concern in the agricultural sector and has encouraged the use of illegal seeds containing compositions Paraguay has not approved.

The public understanding of biotech foods remains relatively low and consumers' opinions are just as divided now as they were seven years ago when the LMO soybean variety was approved. The government opposition has softened thanks to split opinions among the current executive cabinet. The Minister of Agriculture is optimistic while the SEAM fraction still feels that the risk associated with agricultural applications, and even environmental and health applications, are increasingly unacceptable. Very recently with the new government in place, the Minister of Agriculture has been able to move the biotechnology efforts forward a few steps by approving the Bt cotton event, and it is expected that this tendency will continue. The current government is well aware of the urgent need of the country to be able to compete with its neighbors (mainly Argentina and Brazil) and to stop the use of illegal seeds.

The recent approval of Bt cotton event generated anti biotech reactions among several nongovernmental organizations (NGOs), but uninformed opinion and factual distortions fail to persuade producers that champion progress. In rural areas some NGOs pressure small farmers to avoid agricultural biotechnology, reinforcing the concept that biotech crops pose risks to human health, the environment and food quality, and that biotechnology threatens traditional farming and rural society by increasing the economic power of multinational corporations. These public attitudes are shifting mainly before the evidence of the indisputable improved performance of LMO crops, but some voices remain hostile towards biotech.

There are no relevant studies on marketing of biotechnology products in Paraguay.

### **Cotton Project**

The Federation of Agricultural Associations (Union de Gremios in Spanish) and Monsanto are proposing the implementation of a social project to use LMO cotton seeds as a means to increase production for small farmers. The technology creates efficiency for any size farm, including of the small producer with just one hectare. The project will help 150,000 families, who may be able to take advantage of the current cotton record prices in the market.

The project involves five cotton gins, a public breeder (university or government breeding center that is capable to perform the testing and approval for existing adapted *Bollgard* varieties) and perhaps INBIO. Monsanto contributes the *Bollgard* trait and certain varieties of germplasm into this new entity in exchange of conditional royalties. Monsanto's conditions include that the gins must implement a business model in which the trait is provided to the cotton growers with no initial payment, and a set fee per kilo of cotton they deliver, estimated to be equal to historic insecticide costs per kg cotton (historic yields). The grower keeps yield advantages.

Monsanto would only capture royalties after seed capital has been paid back and cotton growers have been successful.

## **Section V. Plant Biotechnology Capacity Building and Outreach:**

2004

- A. FAS Buenos Aires selected one Paraguayan journalist that participated in a U.S. Grains Council biotech activity in Hawaii. The participant learned about the U.S. papaya industry's success due to biotech varieties.
- A. With Cochran funding, FAS Buenos Aires sponsored two-week biotechnology training in the United States for one representative of the Paraguayan government, organized by FAS and Michigan State University.
- A. FAS Buenos Aires selected two Paraguayan producers that attended the Farmer-to-Farmer workshop at the University of Zamorano, Honduras.
  
- A. FAS Buenos Aires organized a two-day conference directed to Paraguayan Congressmen, but also to media, academia, government officials, and the public in general, as a continuation to a seminar organized in 2002. The activity was very successful in terms of attendance (48 congressmen in attendance the first day and 300 people in attendance the second day).

2005

- A. FAS Buenos Aires, in concert with FAS Santiago and OCB, organized and accompanied a Southern Cone Congressional Delegation to the United States to demonstrate how the United States uses and regulates agricultural biotechnology. One Paraguayan congressman participated in the activity.
  
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- A. FAS Buenos Aires, in concert with the U.S. Codex office, organized a working meeting where representatives of several Latin America and Caribbean Countries, as well as Canada and the U.S., discussed their countries' positions regarding labeling of biotech foods.
  
- A. FAS Buenos Aires organized a working breakfast for Paraguayan journalists, where regional experts from neighbor countries as well as Paraguayan experts presented the region's current situation and future expectations on biotechnology, followed by an open debate and discussion.

2009

Buenos Aires organized a Biotechnology Seminar that included over 250 participants, and also a dinner for key decision makers of the country.

FAS Buenos Aires sent a Paraguayan representative to participate in a seminar on biotechnology and climate change in Chile.

FAS Buenos Aires organized a Farmer to Farmer workshop with farmers from Argentina, Paraguay and the United States in the cities of Asuncion and Encarnacion, where the farmers discussed their experiences using biotech seeds.

### **Proposed activities**

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

- A. Workshops to target producers and consumers in different cities around the country, in areas that rarely have access to “first hand” information.
- A. Coordination with local universities to demonstrate the benefits of biotechnology in Paraguay.
- A. Continue Cooperator, Cochran and International Visitor Program activities
- A. Workshop specifically targeting medical doctors and nutritionists, explaining the innocuousness of biotech products.
- A. New strategies along with more frequent and sustained efforts to better educate small farmers to understand biotechnology.
- A. Conduct a regional workshop in risk assessment directed to Argentine, Paraguayan, and Uruguayan experts.
- A. Organize a seminar especially directed to journalists.
- A. Organize a national workshop on Risk Assessment targeting government officials.
- A. Conduct special activities designed for Consumer Association leaders and consumers in general.
- A. Organize a seminar on genetically modified and cloned animals.

## **Section VI. Animal Biotechnology:**

Paraguay has no policy in place regarding genetic engineering or cloning of agriculturally relevant animals. The government approach for new technologies is to regulate if deemed necessary.

Paraguay participated and signed a position document on animal cloning during a Coning Meeting in Buenos Aires in March 2011. The document was signed by Argentina, Brazil, New Zealand, Paraguay, and the United States. In that document, the signatory countries agreed that:

1. Regulatory approaches related to agricultural technologies should be science based, and no more trade-restrictive than necessary to fulfill legitimate objectives, and should be consistent with international obligations.
1. Expert scientific bodies around the world have reviewed the effects of somatic nuclear transfer (SCNT) cloning on animal health and the safety of food derived from livestock clones. There has been no evidence indicating that food from clones or the progeny of clones is any less safe than food from conventionally bred livestock.
1. The sexually-reproduced progeny of SCNT clones are not clones. These progeny are the same as any other sexually-reproduced animal of their own species. There is no scientifically justifiable basis for imposing a regulatory differentiation between the progeny of clones and other animals of the species.
1. Restrictions specifically aimed at food from the progeny of clones – such as bans or labeling requirements –could have negative impacts on international trade.
1. Any audit and enforcement measure addressed to progeny of clones would be impossible to apply legitimately and would result in onerous, disproportionate and unwarranted burdens on livestock producers.