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## Brazil

## Biotechnology

## Annual Agricultural Biotechnology Report

## 2008

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**Report Highlights:**

Post included updates regarding the approval of new biotech events and some changes in biotech policy. As of June 18, 2008 all approvals of biotech events in Brazil by the National Technical Commission on Biosafety (CTNBio) are now conclusive and cannot be appealed to the National Biosafety Council (CNBS), which will consider only issues of social and economic interests. This decision eliminates a major constraint for approval of biotech events in Brazil. Higher commodity prices and a record amount of credit allocated to the 2008-09 crop season will likely increase the use of agricultural biotechnology in Brazil.

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**SECTION I: Executive Summary**

Bilateral agricultural trade between Brazil and United States reached a record of US\$ 5.9 billion in 2007 with record Brazilian exports to the United States of US\$ 5.2 billion and record imports from the United States of US\$ 648 million, the highest level in 10 years. The United States agricultural exports to Brazil are primarily agricultural commodities required to meet local shortfalls. Brazil is a major producer and exporter of agricultural products, such as soybeans, cotton, sugar, cocoa, coffee, frozen concentrated orange juice, beef, poultry, pork, tobacco, hides and skins, fruits and nuts, fish products, and wood products. As a result, the United States and Brazil are often competitors in third markets, while the United States is a major destination for Brazil's exports of sugar, coffee, tobacco, orange juice, and wood products.

Brazil is responding to soaring world food prices and its impact on inflation by increasing agricultural production. A record amount of credit at subsidized interest rates has been announced for the upcoming 2008-09 crop season (Oct 2008 – Sep 2009). Earlier this year, the Brazilian government rolled old farm debts estimated at nearly US\$ 50 billion. According to commodity analysts, these policy measures are likely to contribute to the use of modern production technology such as biotech events in the next crop year.

**SECTION II: Biotechnology Trade and Production****Current Approved Products**

<b>Crop</b>	<b>Trait Category</b>	<b>Applicant</b>	<b>Event</b>	<b>Trait Description</b>	<b>Reviewed Uses within Brazil</b>
Cotton Gossypium hirsutum	Insect Resistant	Monsanto	BCE 531	Lepidoptera Order	Textile fibers Food and Feed
Soybeans Glycine max (L.) Merrill	Herbicide Tolerant	Monsanto (Monsoy)	TTS-40-3- 2	Glyphosate Herbicide Tolerant	Food and Feed
Corn Zea Mays	Insect Resistant Herbicide Resistant	AVIPE (Pernambuco Poultry Producers	Cry 1a (c) Cry 1a (b) PAT/bar MEPSPS	Lepidoptera resistant Glophosinate tolerant	Import/ Processing /Feed
Corn Liberty Link	Herbicide tolerant	Bayer CropScience		Ammonium- Glyphosate tolerant	Food
Corn Zea Mays	Insect resistant	Syngenta Seeds	Bt 11	Lepidoptera resistant	Food and Feed
Corn Zea Mays	Insect resistant	Monsanto	MON 810	Lepidoptera resistant	Food and Feed

Source: CTNBio

**Soybeans:**

Soybean biotech seeds are registered under the Ministry of Agriculture, Livestock, and Food Supply (MAPA) and meet the requirements of Brazil's Plant Variety Protection Law. This means they can be legally used for planting. Post expects that biotech soybean seeds will account for 58 percent of the upcoming 2008/09-crop. According to market analysts, soybean producers that plant biotech varieties in Brazil have a 25 percent higher profit compared to those that plant conventional seeds, despite the payment of royalties. The significant increase in the price of Glyphosate Herbicide is likely to moderate the increase in the use of biotech soybeans in the upcoming crop year.

**Cotton:**

On March 17, 2005, The National Technical Commission on Biosafety (CTNBio) legalized the planting and commercialization of one biotech cotton variety owned by Monsanto. The approval of the insect resistant BT variety have been under deliberation by CTNBio since 2005 with only the Ministry of Environment voting against and effectively blocking planting and commercialization. Current requests by Monsanto and Bayer are pending approval of additional biotech cotton varieties. It is estimated that Monsanto Bolgard will account for 8 percent of the upcoming 2008-09 cotton crop.

**Corn:**

In 2007, The National Biosafety Technical Commission – CTNBio approved three biotech corn varieties:

- 1) Liberty Link corn (herbicide tolerant – ammonium glyphosate tolerant) from Bayer CropScience;
- 2) MON 810 (insect resistant – lepidopterus) from Monsanto;
- 3) Bt 11 (insect resistant) from Syngenta

However, because of the joint position of the Ministry of Environment and Ministry of Health in opposition to the release of these corn varieties, the final decision was taken to the National Biosafety Council (CNBS). Under the current legal framework established by Brazil's Biosafety Law 11,105/2005, CNBS is the highest institutional body to give a final decision to release biotech products for planting and sale. On February 12, 2008 the National Biosafety Council (CNBS) approved by a vote of 7-4 Liberty Link corn (Bayer CropScience) and MON 810 from Monsanto) corn varieties and on June 18, 2008 CNBS approved by a vote of 8-3 Syngenta's Bt 11. Post expects that biotech corn seeds will account for 10 percent of the first corn crop during 2008-09 crop year.

**SECTION III: Biotechnology Policy****Regulatory Framework**

The regulatory framework for agricultural biotechnology in Brazil is outlined in law 11,105 of 2005, altered by law 11,460 of 2007 and Decree Number 5,591 of 2006. There are two main governing bodies regulating agricultural biotech in Brazil, which consists of the following:

- a) The National Biosafety Council (CNBS, in Portuguese). This council falls under the Office of the President and is responsible for the formulation and implementation of the national biosafety policy (PNB, in Portuguese) in Brazil. It establishes the principles and directives of administrative actions for the federal agencies involved in biotechnology. It evaluates socio-economic implication and national interests regarding approval for commercial use of biotech products. No safety considerations are evaluated by CNBS. Under the presidency of the Chief of Staff of the Office of the President, 11 cabinet ministers comprise CNBS and a minimum quorum of 6 ministers is needed to approve any relevant issue.
- b) The National Technical Commission of Biosafety (CTNBio, in Portuguese) was initially established in 1995 under the first Brazilian Biosafety law (Law # 8,974). Under the current law, CTNBio was expanded from 18 to 27 members to include official representatives from 9 ministries of the federal government, 12 specialists with scientific and technical knowledge from 4 different areas including animal, plant, environment, and health (3 specialists from each area), and 6 other specialists from other areas such as consumer defense and family farming. Members of CTNBio are elected for two years with a possibility of being reelected for an additional two years. CTNBio is under the Ministry of Science and Technology. All technical related issues are debated and approved under CTNBio. Imports of any agricultural commodity for animal feed or for further processing, or any ready-to-consume food products, and pet food containing biotech events must be pre-approved by CTNBio. Approvals are on a case-by-case basis. For additional information on CTNBio, please see GAIN BR 5632.

Note:

Law 11,460 of March 21, 2007, changed article 11 of law 11,105 of March 24, 2005 and established that a simple majority of votes is needed out of 27 total voters on CTNBio's board, to approve new biotech products.

On June 18, 2008 the National Biosafety Council (CNBS) decided that it will only review administrative appeals that are of national interest, involving social or economic issues, as per the Brazilian Biotech Law. CNBS will not evaluate technical decisions on biotech events that are approved by the National Technical Commission of Biosafety (CTNBio). The Council considers all approvals of biotech events by CTNBio as conclusive. This is an important decision that, along with the change in majority voting, eliminates a major barrier for approval of biotech events in Brazil.

### **Product Authorizations**

In Brazil, a technology provider must file an application for approval to sell agricultural biotech products with CTNBio. A company must file a single application for each biotech event. CTNBio will evaluate the need for any further environmental impact studies. After the approval of CTNBio, three other ministries have an important role in the registration process:

- a) Ministry of Agriculture, Livestock, and Food Supply (MAPA) for products used in agriculture, livestock, and agribusiness (processing);
- b) Ministry of Health, regarding use of products for humans and pharmaceutical uses; and,
- c) Ministry of Environment for products that require registration and inspection for use in the natural ecosystem.

### **Field Testing**

Field-testing of biotech crops is allowed in Brazil, but CTNBio must previously approve this research. The technology provider must obtain from CTNBio a Certificate of Quality in Bio Safety (COBs) to perform field-testing.

### **Coexistence of biotech and non-biotech crops**

There is no national policy in place regarding the coexistence of biotech and non-biotech crops in Brazil. Law 11,105 of March 2005 established the legal framework under which biotech crops can be produced and marketed in Brazil. Conventional or non-biotech crops are produced throughout the country with agricultural zoning and environmental limitations mostly applicable in the Amazon region.

Law 9,456 of April 25, 1997, the so-called Plant Variety Protection law establishes the legal framework for registration of both biotech and non-biotech seeds, but the law does not favor one over the other.

Decree 2,366 of November 5, 1997, established the National Plant Varieties Protection Service under the Ministry of Agriculture, Livestock, and Food Supply (MAPA) and regulates the registration of biotech and non-biotech seeds.

Organic agriculture is growing rapidly in Brazil. Growth is estimated at 20 percent per year, but commercial production is still limited mostly to grains and vegetables, although it is increasing in the meat and dairy sectors. The growth in organics in Brazil has been recently boosted by the interest of the Brazilian supermarkets in providing organic products.

There are approximately 1,200 certified farmers and two private institutions with the authority to certify organic products. There are no official trade statistics about organic products either for imports or exports.

The rapid growth of organic farming in Brazil has prompted the Brazilian government to regulate the sector. On December 24, 2003 the President of Brazil signed law 10,831 which provides the legal framework for organic farming. On December 27, 2007, Presidential Decree No. 6,323 was published which contains the standards for production, classification, processing, packaging, imports, distribution, identification, and certification of the quality of organic products, of both animal and plant origin.

Both domestic and imported organic products must be labeled with the term "organic product" and the name and registration number of the certifying organization. For bulk products, a "certificate of organic quality" must accompany the shipment. The Office of Agricultural Protection (SDA) of the Ministry of Agriculture, Livestock, and Food Supply (MAPA) has the authority to approve imported organic products.

### Technology Fees

The new Biosafety Law, which provides a clear regulatory framework for the research and marketing of new biotechnology crops in the country, has encouraged Brazil's federal government to embrace and protect new technologies that benefit agriculture.

During the 2005/06-crop year, Monsanto was not able to reach an agreement with Brazil's Seed Producer's Association regarding collection of royalties. The new strategy of Monsanto was to negotiate directly with the so-called "seed multipliers" and a preliminary agreement was reached to collect a fee of R\$ 0.88 per kilogram of RRS seed (equivalent to R\$ 35.20 per bag of 40 kilograms). Trade sources indicate that this is equivalent to US\$ 8.00 per acre, nearly half of the value paid by U.S. soybean producers. During the 2006/07-crop year, Monsanto and producers negotiated a proposal that included a standard royalty of two percent for both certified and non-certified (pirated) seeds, and apply a discount of 20 to 22 percent for the use of certified seeds.

### Labeling

On April 24, 2003 the President of Brazil published in Brazil's Federal Register (Diario Oficial) Executive Order number 4,680/03 establishing a tolerance limit of **one percent** (see note below) for food and food ingredients destined for human or animal consumption containing or being produced through biotech events. The Executive Order also declared that consumers need to be informed of the biotech nature of the product.

Note: The previous regulation (Executive Order Number 3,871 of July 18, 2001) established a four percent threshold, which was considered too high by environmentalists and consumer groups. Executive Order 4,680 revoked Executive Order 3,871.

On December 26, the Ministry of Justice published in Brazil's Diario Oficial, Directive Number 2,658/03 approving the regulations for the use of the transgenic logo, which basically was the same as reported in our GAIN BR 3614. As per Article Two of Directive 2,658/03 use of the new required logo would be effective as of February 23, 2004 (60 days after the publication in the Diario Oficial of Directive 2,658/03). It applies for biotech products for both human and animal consumption with biotech content above one percent. On February 27, 2004 The Ministry of Justice published in the Diario Oficial Directive Number 786 that extended for another 30 days the effective date of Directive 2,658/03. The new effective date was March 27, 2004.

On April 2, 2004, the Civil Cabinet of the Presidency published Normative Instruction Number 1, signed by 4 cabinet ministers (Civil Cabinet, Justice, Agriculture, and Health) that established the conditions by which Directive 2,658/03 will enforce the labeling of products containing biotech events above the one percent limit. In addition to the federal agencies, Normative Instruction Number 1 also authorizes the state and municipal consumer defense officials to enforce the new labeling requirements.

#### **SECTION IV: Marketing Issues**

There is a public publicity campaign "Brazil Better without Transgenic" against the use of biotech crops in Brazil sponsored by Greenpeace and supported by certain environmental and consumer groups, including government officials within the Ministry of Environment, some political parties, the Catholic Church, and the Landless Movement. However, the acceptance of biotech crops in Brazil is strong among producers. According to the Brazilian Farm Bureau (CNA), the latest survey among Brazilian farmers dated from 2001 showed an 80 percent acceptance rate of biotech crops.

Acceptance is low among meat processors and the food processing industry. These groups fear the publicity campaign against their products sponsored by Greenpeace and other environmental and consumer groups. However, tests conducted by Greenpeace showed a minimum of biotech residues in several consumer ready products. Brazilian retailers also are reluctant to accept biotech products, especially the large supermarkets under French ownership. Reliable information about consumer acceptance of biotech products in Brazil is currently not available.

#### **SECTION V: Capacity Building**

Post has developed and implemented two major outreach activities over the past six years that were important in the development of biotech regulations in Brazil.

1. First Biotechnology Workshop, August 20-21, 2002 for a select group of Brazilian scientists from various ministries, universities, and scientific foundations;
2. Second, Brazilian Congressional Visit to the United States in 2004 with representatives from select Brazilian NGOs and institutes;
3. Third, Brazilian Corn Growers Visit in 2008 to the United States with selected representatives from the House Agricultural Committee.