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Brazil

AGRICULTURAL BIOTECHNOLOGY ANNUAL

Agricultural Technologies Report

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Report Highlights:

Post included updates regarding the approval of new biotech events and included a new section on animal genetic engineering. According to the Ministry of Science and Technology, Brazil is the leader in agriculture biotech research, and will likely become the second largest biotech producer during the next crop year of 2009/2010.

Section I. Executive Summary:

Bilateral agricultural trade between Brazil and United States reached a record of US\$ 7.3 billion in 2008 with Brazilian exports to the United States of US\$ 6.2 billion and imports from the United States of US\$ 1 billion, the highest level in 15 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 the world financial crisis and possible food shortages by increasing agricultural production. A record US\$ 52 billion in credit at subsidized interest rates was announced for the upcoming 2009-10 crop season (Oct 2009 – Sep 2010). Last 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. According to the Ministry of Science and Technology (MCT), Brazil is the leader in agriculture biotech research, and will likely become the second largest biotech producer during the next crop year.

Section II. Biotechnology Trade and Production:

Current Approved Products

Crop	Trait Category	Applicant	Event	Trait Description	Reviewed Uses within Brazil
Cotton Gossypium hirsutum	Insect Resistant	Monsanto	Bollgard BCE 531	Lepidoptera Order	Textile fibers Food and Feed
Cotton Gossypium hirsutum	Herbicide Tolerant	Monsanto	Roundup Ready MON 1445	Glyphosate Tolerant	Textile fibers Food and Feed
Cotton Gossypium hirsutum	Tolerant Herbicide glufosinate ammonium	Bayer	LibertyLink Cotton – LLC Cotton25	Glufosinate ammonium Tolerant	Textile fibers Food and Feed
Corn Zea Mays	Herbicide tolerant	Bayer Crop Science	Liberty Link Corn, T25	Ammonium- Glyphosate tolerant	Food an Feed
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
Corn Zea Mays	Herbicide tolerant	Syngenta Seeds	Corn Event GA21	Tolerance to Glyphosate herbicide	Food and Feed
Corn Zea Mays	Herbicide tolerant	Bayer Crop Science	Roundup Ready 2 Corn Event NK603	Glyphosate herbicide tolerant	Food an 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

Soybeans Glycine max (L.) Merrill	Herbicide Tolerant	Monsanto (Monsoy)	TTS-40-3-2	Glyphosate Herbicide Tolerant	Food and Feed
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Source: CTNBio, as of July 10, 2009.

Soybeans:

Post expects that biotech soybean seeds will account for 65 percent of the upcoming 2009/10-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.

Cotton:

Post expects that biotech cotton seeds will account for 20 percent of the upcoming 2009/10-crop year.

Corn:

Post expects that biotech corn seeds will account for 42 percent of the upcoming 2009/10 corn crop year.

Section III. New Technologies:

The National Technical Commission of Biosafety (CTNBio) issued on April 27, 2009 Normative Resolution Number 7 which regulates the development, commercial use and/or import of genetically engineered animals and their release into the environment. Regulation regarding contention was previously issued on November 27, 2007 under Normative Resolution Number 2. Both regulations are available in English at <http://www.ctnbio.gov.br>

Currently, the majority of the work performed for genetically modified animals is conducted by government institutions, such as public universities and centers for disease controls using imported GM animals for research on specific diseases. All genetically modified animals or products from these animals to be imported into Brazil must be approved by CTNBio.

There are no products currently in the market derived from GM animals. Animals or products derived from genetically modified animals intended for commercial production are still in the research stage and mostly conducted by Brazil's Agricultural Research Service (EMBRAPA), linked to the Ministry of Agriculture, an agency similar to the ARS-USDA system in the United States. Current research is mostly targeted at dairy cattle and other small animals. More information on GM animal research can be found at Embrapa's Center for Genetics and Biotechnology Research (CENARGEN) home page <http://www.cenargen.embrapa.br/>

Because this new technology is only at the research stage in Brazil, there have not been any studies regarding public perception of products from GM animals. However, as research advances, it is

expected that the NGOs will launch marketing campaigns against GM animals and products.

Labeling of GM animals. Please see section on Labeling.

Section IV. 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.

- 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, CNBS is comprised of 11 cabinet ministers and needs a minimum quorum of 6 ministers to approve any relevant issue.

- a. 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.

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 important decision, 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 (CQBs) 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 regulate the registration of biotech and non-biotech seeds.

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. Monsanto changed its strategy and began to negotiate directly with the so-called "seed multipliers" and accepted in a preliminary agreement 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** 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.

On December 26, 2003 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. It applies for biotech products for either human or animal consumption with biotech content above one percent. The requirement became effective 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 V. Marketing:

There is a marketing 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.

However, acceptance is low among meat processors and the food processing industry. These groups fear the marketing campaign against their products sponsored by Greenpeace and other environmental and consumer groups. Although, 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 French-owned hypermarkets. Reliable information about consumer acceptance of biotech products in Brazil is currently not available.

Section VI. Capacity Building and Outreach:

Post has developed and implemented the following three major outreach activities over the past six years:

1. Biotechnology Workshop, August 20-21, 2002 for a select group of Brazilian scientists from various ministries, universities, and scientific foundations;
2. Brazilian Congressional Visit to the United States in 2004 with representatives from select Brazilian NGOs and institutes;

3. Brazilian Corn Growers Visit in 2008 to the United States with selected representatives from the House Agricultural Committee.