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Approved by:

Alan Hrapsky, Agricultural Counselor
U.S. Embassy

Prepared by:

Joao F. Silva, Agricultural Specialist

Report Highlights:

Updates were made regarding the approval process for biotech events in Brazil as a result of Law 11,460, from March 21, 2007. Despite the changes made in the structure of the National Technical Commission on Biosafety (CTNBio) to speed the approval of biotech events in Brazil, near all new approvals are subject to court injunctions filed by anti-biotech groups within and outside the government, and by unsupportive government prosecutors.

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SECTION I: EXECUTIVE SUMMARY

United States-Brazil bilateral agricultural trade reached a record of US\$ 4.2 billion in 2006 with record Brazilian exports to the United States of US\$ 3.9 billion. The United States agricultural exports to Brazil totaled nearly US\$ 300 million, primarily agricultural commodities 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's President signed on March 21, 2007 Law Number 11,460 which alters provisions of the Biotech Law 11,105 from 2005. The main change involved a reduction in the number of votes needed to approve individual biotech events by the National Technical Commission on Biosafety (CTNBio). The purpose of this change was to speed the approval process of new biotech events, which has been blocked by anti-biotech groups since 2006.

Although CTNBio has resumed its normal operations and approved new events, such as Bayer Crop Science's "Liberty Link" corn, the approval process of biotech products in Brazil remains a major hurdle for companies, mostly multinationals. Nearly all approvals of new biotech events by CTNBio are subject to court injunctions, filed by anti biotech groups within and outside of the government, and from unsupportive government prosecutors. These injunctions suspend temporarily the implementation of CTNBio's decisions, until the court renders its final decision. In addition, the strong anti-biotech position of the state government of Parana causes more problems and often financial losses to companies that conduct biotech research or that export biotech products through the port of Paranagua, such as soybeans. Recently, after one year and four months, Syngenta regained control from the courts of its Experimental Station for seed research, which had been invaded by the landless movement in Parana.

SECTION II: BIOTECHNOLOGY TRADE AND PRODUCTION

Status of Product Approvals

Crop	Trait Category	Applicant	Event	Trait Description	Reviewed Uses within Brazil
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 (Poultry Producers from Pernambuco	Cry 1a (c) Cry 1a (b) PAT/bar MEPSPS	Lepidopteran resistant Glophosinate tolerant	Import/Processing /Feed
Corn Liberty Link	Herbicide tolerant	Bayer CropScience		Ammonium- Glyphosate tolerant	Food

Source: CTNBio

Soybeans:

Soybean biotech seeds are also 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 nearly 35-40 percent of the upcoming 2007/08-crop. According to market analysts, soybean producers that plant biotech varieties in Brazil have a profit of 25 percent compared to those that plant conventional seeds, despite the payment of royalties. However, the significant increase in the price of Glyphosate Herbicide will 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 a biotech cotton variety owned by Monsanto. The approval of the insect resistant BT variety was under deliberation by CTNBio since September 2005 with only the Ministry of Environment voting against and effectively blocking planting and commercialization. It was no surprise that CTNBio voted in favor of the use of biotech cotton given that in November the commission approved the sale of cottonseeds with 1 percent biotech material. However, it is surprising to some in the industry that the decision by CTNBio came so soon. The Brazilian Cotton Producer's Association (ABRAPA) was not expecting approval of biotech cotton for several months or even years.

The Ministry of Environment and environmental NGO's are opposed to the release of biotech cottonseed due to the possibility of crossing with native cotton species. However, CTNBio did require that Monsanto prepare an impact study on the effects of planting the seed. Furthermore, in some regions the federal government prohibits planting of biotech seeds and buffer zones on cotton farms are required.

In addition to this approval, current requests by Monsanto and Bayer are pending for approval of additional biotech cotton varieties. Currently, input costs in Brazil are very high and insecticides comprise about 40 percent of the production costs for cotton with producers spraying up to 14 times a year. It is estimated that use of biotech seed will reduce the cost of production by U.S. \$130 per hectare. Therefore, it is expected that adoption of this biotech variety will make cotton even more attractive to producers in Mato Grosso and Bahia.

Corn:

After nine years waiting for approval, on May 17, 2007 CTNBio approved the commercialization of Bayer Crop Science's "Liberty Link" corn (herbicide tolerant – ammonium-Glyphosate tolerant) stating that it does not present a threat to human, animal or environmental health. However, producers still cannot use "liberty Link" corn seed because a final decision depends on approval of the National Biosafety Council (CNBS).

SECTION III. BIOTECHNOLOGY POLICY

Regulatory Framework

The new regulatory framework for agricultural biotechnology in Brazil is outlined in law 11,105 and Decree Number 5,591 and basically 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:

Although under the current law, CNBS is supposed to handle all political, social and economic factors that may influence regulatory decisions related to agricultural biotechnology, the expansion in the number of members that compose CTNBio created a major deadlock for approval of new biotech products in Brazil. The reason was because of the two-thirds majority required under law 11,105/2005 for CTNBio members to approve any biotech event

However, after an intense debate in the National Congress (house and senate), a new draft bill was approved and signed into law by President Lula. He maintained the changes introduced by Brazil's House and confirmed by the Senate regarding the number of votes needed by CTNBio to make any board decision. The new law 11,460 of March 21, 2007, changed article 11 of law 11,105 of March 24, 2005 and established a majority of votes needed out 27 total voters on CTNBio's board, to approve new biotech products.

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 ministers 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 the National Technical Commission on Biosafety (CTNBio) the so-called CQB (Certificate of Quality in Bio Safety) 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.

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 May 19, 1999, the Minister of Agriculture, Livestock, and Food Supply (MAPA) published in the *Diario Oficial* (Brazil's Federal Register) Normative Instruction Number 7, 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 producer 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 logo required 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 Transgenics" 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 VI: Capacity Building and Outreach

Post has developed and implemented two major outreach activities over the past five 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.