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Report Highlights:
After eight months of intensive debate among several agencies of the federal government, the President of Brazil signed Decree Number 5,591 on November 23, 2005 that implements the provisions of the Biosafety Law Number 11,105 of March 24, 2005. With this legal framework in place, the National Technical Commission on Biosafety (CTNBio) resumed its operations and started to evaluate nearly 500 pending requests for research and commercial approvals of biotech products in Brazil. However, environmentalists and anti-biotech groups who are represented on the board are boycotting CTNBio.

Includes PSD Changes: No
Includes Trade Matrix: No
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SECTION I. EXECUTIVE SUMMARY

The United States-Brazil bilateral agricultural trade reached a record of nearly US$ 4 billion in 2005 with record Brazilian exports to the United States of US$ 3.7 billion. The United States agricultural exports to Brazil totaled nearly US$ 300 million, primarily agricultural commodities to meet local shortfalls. Historically, 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 of Brazil's exports of sugar, coffee, tobacco, orange juice, and wood products.

Brazil's national Congress approved on March 2, 2005 the Biosafety Bill, which replaced the previous legal framework in use since 1995 under which agricultural biotechnology was developed in Brazil. Brazil's President Lula signed the Biosafety Bill on March 24, 2005, and it became law number 11,105. This law, which also includes provisions for stem cell research, became effective on March 28, 2005 after its publication in Brazil's official registry (Diario Oficial). On November 23, 2005 President Lula signed Decree Number 5,591 that implemented the provisions of the Biosafety Law.

This long-waited Decree allowed the National Technical Commission on Biosafety (CTNBio) to resume its normal operations and to evaluate nearly 500 pending requests for research and commercial approval of biotech products in Brazil. However, because of the new composition of CTNBio, including several environmentalists and anti-biotech members, the meetings of CTNBio have become deadlocked regarding decisions on research and commercial approvals of new biotech products.

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 Restistant	Monsanto	BCE 531	Lepidoptora Order	Textile fibers Food and Feed
Soybeans Glycine max (L.) Merrill	Herbicide Tolerant	Monsanto (Monsoy)	TTS-40-3-2	Glyphosate Herbice 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 Gluphosinate tolerant	Import/Processing /Feed

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. Due to the passage of the new biosafety law, Post expects that biotech soybean seeds will account for 45 to 55 percent of the upcoming 2006/07-crop. The following constraints still impede biotech soybeans from expanding more rapidly:

1) Lack of biotech seed on hand. ABRASEM, the Brazilian Association of Seed Producers, estimates that there are 4.5 million bags of biotech seed for next year, enough to cover 30% of the current planted area in Brazil. Monsanto also reported that they do not have sufficient seed ready to supply next year's crop. The main producers of RR soybean seed in Brazil are Embrapa, with 20%, followed by Pioneer, Fundacep (Central Experiment and Research Foundation), and the Mato Grosso Foundation.

2) Seed not yet developed for conditions outside the South. Seed brought in from Argentina across the southern border has worked well in the southern region. There are 38 varieties approved for use, including 19 developed by Monsanto, 10 by Embrapa, and 9 by other companies. But, according to ABRASEM and contacts at Embrapa, appropriate varieties for the warmer and more humid regions have begun to be researched more recently, and will not be ready for next year's crop. There are two projects currently targeting biotech seeds that are appropriate for the center-west and Amazon climates. One is a joint Monsanto/Embrapa project that takes conventional varieties already adapted for the region and adds the glyphosate resistant gene. The expected launch of these biotech seeds is at least one year away. The other project, creating new transgenic seeds for the warmer climates outside of Southern Brazil, has just begun to be researched by Embrapa and BASF.

3) Adverse weather is affecting seed quality. After negotiating with the government for seven years for approval to produce biotech seed, the sector now confronts the effects of adverse weather that has cut seed production. Producer debt attributed to the problems derived from the valuation of the Brazilian currency is also affecting market growth. According to ABRASEM, an initial forecast of 7 million bags for next year's harvest has been cut to 4.5 million.

On the other hand, there are several points that support biotech soybean expansion in Brazil. The main motivator for growing biotech soybeans is lower production costs. The Parana Department of Agricultural Economics has reported that biotech soybeans cut 20% of the costs of producing conventional varieties (see chart below), and this savings has been verified by other sources. Farmers in the south have been growing roundup ready soybeans for several years, both with and without paying royalties. They obviously continue to do it because it is cost-effective. In the case of Argentina, planting soybeans with RR seed began in 97/98, and within 5 years they were almost entirely biotech. A study performed by Nidera showed that Argentine farmers saved $1 billion per year with biotech seed.

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 with only the Ministry of Environment voting against 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, some regions are prohibited from planting biotech seed 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.

However, producers will not be able to plant biotech cottonseed in crop year 2006/07. The new biotech seed must be registered with MAPA following studies on the value of the use of the seed. It is expected that this study and registration could take up to two years and thus some in the industry do not expect the sale of biotech seed before 2007. Nevertheless, some producers believe they will be able to buy imported seed from the United States and Australia for use in the upcoming crop. It is not yet clear whether CTNBio will authorize imports of biotech cottonseeds, but trade sources estimate that illegal planting of biotech cottonseed will be as high as 30 percent of the planted area.

Corn:

CTNBio has approved in previous years biotech corn imports from Argentina for animal feed at the request of the Pernambuco Poultry Association (AVIPE). However, this was done after an intense court battle. The powerful pork and poultry industry pressures for corn imports, during periods of domestic shortages, but want to segregate imported corn for internal use only, such as the Northeast of Brazil, to avoid market problems with their exports to the European Union. CTNBio has blocked corn imports from United States for animal feed.

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 established in previous legislation. CTNBio had its authority confirmed by law 11,105 after intense public debate over the ability of a commission to waive environmental studies before approving a biotech product. CTNBio's membership 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.

Political and other social and economic factors that may influence regulatory decisions related to agricultural biotechnology are handled by the CNBS above. All technical related issues are debated and approved under CTNBio. Imports of any agricultural commodity for feed or for 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 BR5632.

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 CQBs (Certificate of Quality in Bio Safety) to perform field-testing.

Field testing approved by CTNBio for biotech crops in 2004 totaled 21 trials, of which, 11 were for corn, followed by soybeans 3, eucalyptus 3, cotton 2, and rice and dry edible beans, one each. Information on traits being tested is available only for corn:

Field-testing, 2004: Corn

Trait Category	Quantity
Insect resistance/Gluflosinate tolerant	2
Amonia Glufosinate Tolerant	1
Insect Resistance	5
Glufosinate tolerant	3

Source: CTNBio

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 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 is 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.

For the 2006/07-crop year, Monsanto and producer are negotiating a proposal that includes 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. An agreement is expected for early August 2006 and the purpose is to reduce the use of pirated seeds, which is expected to drop to less than 40 percent in the state of Rio Grande do Sul.

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.

The Ministry of Justice published on October 3, 2003 in its home page Public Consultation Number 1, which regulates Article 2, Paragraph One, of Executive Order Number 4,680 of April 24, 2003 regarding the symbol (logo) for transgenic products.

Note: For further details on Public Consultation Number 1, please see GAIN 3614, dated 10/17/2003. The Brazilian government failed to notify the World Trade Organization (WTO) about this public consultation. In addition, the period for public comments (15 days) was not in compliance with WTO rules. Public Consultation Number 1 received 157 written comments, of which 88 favorable to the logo, 54 unfavorable, and 15 related to questions and doubts.

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 BR3614. 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.

U.S. corn exporters have been disadvantaged by the reluctance of Brazilian food industry to use biotech (meat processors and food industry in general). Even with the approval of the new Brazilian Biosafety law, all biotech corn imports (including those from Argentina under the Mercosul Free Trade Agreement) must have a formal approval from CTNBio on a case-by-case basis. Imports of biotech corn for animal feed remains blocked because CTNBio has not approved biotech corn for commercial use in Brazil.

SECTION VI: Capacity Building and Outreach

Post has developed and implemented two major outreach activities over the past three 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. Brazilian Congressional Visit to the United States in 2004 with representatives from select Brazilian NGOs and institutes.