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Brazil

Agricultural Biotechnology Annual

Biotech Annual 2012

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Report Highlights:
Brazil is the second largest producer of biotech crops in the world. Post forecasts an increase of 15 percent in the area planted to biotech crops during the upcoming 2012/13 Brazilian crop year (Oct 2012 through Sep 2013). The increase is mostly attributed to higher use of biotech corn due to the increase in approvals of new biotech corn events in Brazil and higher availability of subsidized credit for farmers. Post has also updated other sections of the report to reflect new information from trade and government sources.

Section I. Executive Summary:

Bilateral agricultural trade between Brazil and the United States increased by 31 percent and reached an all-time record of US$ 5.5 billion in calendar year (CY) 2011, of which Brazil exported to the United States US$ 4.7 billion and imported from the United States US$ 829 million.

U. S. agricultural exports to Brazil are primarily agricultural commodities required to meet local shortfalls but exports of consumer-ready food are growing rapidly. 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, seafood 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 higher world food prices and strong world demand by increasing agricultural production. A record US$ 57.6 billion (R$ 115.2 billion) in credit lines at subsidized interest rates was announced in early July 2012 for the upcoming 2012/2013 crop season (Oct 2012 – Sep 2013), up 7.5 percent from last year's US$ 50.4 billion (R$ 107 billion). These farm support packages for agricultural production combined with the higher use of agricultural technology have consolidated the agricultural sector in Brazil. Grain production increased from 60 million metric tons in 1991 to 161 million during the current crop year, up 168 percent. In the same period, the cultivated area increased only 30 percent from 38.5 million hectares in 1991 to currently 49.9 million hectares, reflecting the productivity gains stemming from intensified technology use.

According to commodity analysts, these policy measures combined with record world commodity prices are likely to contribute to the continued 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 a major leader in agricultural biotech research, and is the second largest plant biotech producer in the world, after the United States.

Section II. Plant Biotechnology Trade and Production:

Post forecasts an increase of 15 percent in the area planted to biotech crops during the upcoming 2012/13 Brazilian crop year (Oct 2012 through Sep 2013). If this increase in area is confirmed, Brazil will plant 36.6 million hectares with three biotech crops currently approved in Brazil – corn, cotton and soybeans. Most of the increase in area will come from biotech corn, which has 19 events currently approved for commercial use. Increased subsidized production credit will also contribute to the use of biotech seeds.

During the 2011/12 crop year, Brazil planted 31.8 million hectares with biotech crops. The adoption rate of biotech soybean seeds reached 85 percent (21.4 million hectares), cotton biotech seeds 32 percent (490,000 hectares) and corn biotech seeds 67 percent (9.9 million hectares split equally into two major distinct growing season – summer and winter crops).

Brazil also has in the pipeline other plant biotech crops waiting for commercial approval, mostly for sugar cane, potatoes, papaya and eucalyptus. As of July 2012, there are 34 genetically engineered crops approved in Brazil: 19 for corn, 9 for cotton, 5 for soybeans, and one for dry edible beans, which although approved in 2011, has not yet been commercialized.

INTACTA RR2 PRO: It was approved in 2010 under the name of event MON 87701xMON89788 by the National Technical Commission of Biosafety (CTNBio) and later renamed INTACTA RR2 PRO. This event is pending approval in China in order for Monsanto to begin sales in Brazil by September 2012. The event was already approved by the European Union in late June of 2012.

Cotton

Crop -year	Trait Category	Applicant	Event	Trait Description	Uses within Brazil
Cotton 2011	Glyphsate Herbicide	Monsanto	MON 88913	Gossypium hirsutum L.	Textile Fibers Food and Feed
TwinLink 2011	Glyphsate Herbicide	Bayer	T 304-40 x GHB 119	Gossypium hirsutum L.	Textile Fibers Food and Feed
GlyTol cotton 2010	Herbicide Tolerant	Bayer	GHB 614	Gossypium hirsutumm L.	Textile Fibers Food and Feed
Round Ready Cotton 2009	Herbicide Tolerant Insect Resistant	Monsanto	MON 531 x MON 1445	Gossypium hirsutum L. Glyphosate Herbicide	Textile Fibers Food and Feed
Bollgard II Cotton 2009	Insect Resistant	Monsanto	MON 15985	Gossypium hirsutum L.	Textile Fibers Food and Feed
Wide Strike Cotton 2009	Insect Resistant Herbicide Tolerant	Dow AgroScience	281-24-236/3006-210-23	Gossypium hirsutum L. Herbicide glufosinate ammonium	Food and Feed
Liberty Link Cotton 2008	Herbicide Tolerant	Bayer	LL Cotton 25	Gossypium hirsutum L. Glyphosate Herbicide Ammonium	Textile Fibers Food and Feed
Round Ready Cotton 2008	Herbicide Tolerant Insect Resistant	Monsanto	MON 1445	Gossypium hirsutum L. Glyphosate Herbicide	Textile Fibers Food and Feed
Bolgard Cotton 2005	Insect Resistant	Monsanto	BCE 531	Lepidoptera Order	Textile Fibers Food and Feed

Corn

Crop -year	Trait Category	Applicant	Event	Trait Description	Uses within Brazil
Corn Zea Mays 2011	Herbice Tolerant Insect Resistant	Monsanto	MON 89034 X MON 88017	Glyphosate Herbicide	Food, Feed, Imports
Corn Zea Mays 2011	Herbicide Tolerant Insect Resistant	DuPont (Pioneer)	TC1507 X MON 810	Glyphosate Herbicide Ammonium	Food, Feed, Imports
Corn Zea Mays L 2011	Herbicide Tolerant	DuPont (Pioneer)	TC 1507 x MON 810 x NK 603	Glyphosate Herbicide Lepidoptera R.	Food, Feed, Imports
Corn Zea Mays 2010	Herbicide Tolerant Insect Resistant	Monsanto	MON 89034 x TC 1507 x NK 603	Glyphosate Herbicide Ammonium	Food, Feed , Imports
Corn Zea Mays 2010	Herbicide Tolerant Insect Resistant	Monsanto	MON 88017	Glyphosate Herbicide Ammonium	Food, Feed, Imports
Corn Zea Mays 2010	Herbicide Tolerant Insect Resistant	Monsanto	MON 89034 x NK 603	Glyphosate Herbicide Ammonium	Food, Feed, Imports
Corn Zea Mays 2010	Herbicide Tolerant Insect Resistant	Syngenta	BT 11 x MIR 162 x GA 21	Glyphosate Herbicide Ammonium	Food, Feed, Imports
Corn Zea Mays 2009	Herbicide Tolerant Insect Resistant	DuPont Brasil	TC 1507 x NK 603	Glyphosate Tolerant Insect Resistant	Food, Feed, Imports
Corn Zea Mays 2009	Insect Resistant	Monsanto	MON 89034	Lepidoptera Resistant	Food, Feed, Imports
Corn Zea Mays 2009	Insect Resistant	Syngenta	MIR 162	Lepidoptera Resistant	Food, feed, Imports
Corn Zea Mays 2009	Herbicide Tolerant Insect Resistant	Monsanto	MON 810 x NK 603	Glyphosate Tolerant Lepidoptera R.	Food, Feed, Imports
Corn Zea Mays 2009	Herbicide Tolerant Insect Resistant	Syngenta	BT 11 x GA 21	Glyphosate Tolerant Lepidoptera R.	Food, Feed, Imports
Corn Zea Mays 2008	Herbicide Tolerant Insect Resistant	Dow AgroScience	Tc 1507 Herculex	Glyphosate ammonium Herbicide Tolerant	Food and Feed
Corn Zea Mays 2008	Herbicide Tolerant	Syngenta	GA 21	Glyphosate Tolerant	Food and Feed
Corn Zea Mays 2008	Herbicide Tolerant	Monsanto	Roundup Ready 2 NK 603	Glyphosate Tolerant	Food and Feed
Corn Zea Mays 2008	Insect Resistant	Syngenta	Bt 11	Lepidoptera resistant	Food and Feed

Corn Zea Mays 2007	Insect Resistant	Monsanto	MON 810 Guardian	Lepidoptera resistant	Food and Feed
Corn Zea Mays 2007	Herbicide Tolerant	Bayer CropScience	Liberty Link T 25	Ammonium Glyphosate tolerant	Food and Feed
Imported Corn 2005	HerbicideTolerant Insect Resistant	Bayer	Cry 9 (C) NK 603	Glyphosinate Ammonium Lepidoptera Resistant	Feed

Soybeans

Crop - year	Trait Category	Applicant	Event	Trait Description	Uses within Brazil
Soybeans 2010	Herbicide Tolerant Insect Tolerant	Monsanto	MON 87701 x MON 89788 (Intacta RR2 PRO)	Glyphosate Herbicide Tolerant Insect Resistant	Food and Feed
Soybeans 2010	Herbicide Tolerant	Bayer	Liberty Link A 2704-12	Gluphosinate ammonium	Food and Feed
Soybeans 2010	Herbicide Tolerant	Bayer	Liberty Link A 5547-127	Gluphosinate ammonium	Food and Feed
Soybeans 2009	Herbicide Tolerant	BASF Embrapa	BPS-CV 127-9	Herbicide Tolerant Imidazolinone class	Food and Feed
Soybeans Roundup Ready 2008	Herbicide Tolerant	Monsanto (Monsoy)	Roundup Ready GTS-40-30-2	Glyphosate Herbicide Tolerant	Food and Feed

Section III. Plant Biotechnology Policy:

Regulatory Framework

The regulatory framework for agricultural biotechnology in Brazil is outlined in Law 11,105 of 2005, modified by Decree Number 5,591 of 2006 and Law 11,460 of 2007. There are two main governing bodies that regulate 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 implications 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 re-elected 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 and they are indefinite. 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 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 final. This important decision, along with the change in majority voting, eliminated a major barrier for approval of biotech events in Brazil.

International Organizations

Issues related to the Cartagena Protocol, Codex Alimentarius, OIE and IPCC are handled in Brazil under inter-ministerial committees and negotiated in international forums by the Ministry of External Relations (MRE).

Cartagena Protocol:

In November of 2003, Brazil ratified the United Nations Cartagena Protocol on Biosafety (under the UN Convention on Biological Diversity). With few exceptions, the Government of Brazil (GOB) is supportive of the positions advocated by the U.S. Government regarding the liability and redress provisions under the supplementary agreement to the Cartagena Biosafety Protocol. One notable exception is that the GOB considers the provisions regarding treatment of non-parties to be already closed. The GOB is also opposed to strict liability, but agrees to use a narrow definition of damage and supports the idea of a limited narrow definition of operator. The GOB is also opposed to the mandatory use of insurance or other financial instruments for the shipment of living modified organisms (LMOs).

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

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, called the 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.

Normative Instruction # 04/07 issued by the National Technical Commission of Biosafety National establishes rules, specifically for biotech corn, regarding the coexistence of biotech and non-biotech crops in Brazil.

Intellectual Property Rights (IPR)

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

Multinationals companies, such as Monsanto, Syngenta and BASF, have licensing agreements with EMBRAPA (the Brazilian Agriculture and Livestock Research Enterprise, linked to the Ministry of Agriculture, Livestock, and Food Supply (MAPA) to develop plant biotech crops, mostly for soybeans, corn and cotton.

In general, technology providers negotiate at the beginning of the new crop year payment agreements with individual Brazilian states and farmer associations to collect royalty fees. Monsanto also pursues an export-licensing scheme to collect royalties on soybean and product shipments at ports of destination in countries where Monsanto has a patent on the Round-up Ready (RR) soybean technology.

According to trade sources, Monsanto plans to charge Brazilian farmers for the use of the technology of INTACTA RR2 PRO a fee of US$ 57.50 per hectare (R$115.00 per hectare). According to Monsanto, this new event will result in an increase income to the Brazilian farmer of US$173.00 (R$346.00) per hectare, using the current exchange rate of 2 Reais to one dollar.

Monsanto also obtained an injunction by the state court in Rio Grande do Sul against a decision made by a local judge until the case is discussed in its merit by the state court. According to Monsanto, royalties are being collected in that state without any problem.

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 IV. Plant Biotechnology Marketing Issues:

Acceptance of biotech crops in Brazil is strong among producers. According to the Brazilian Farm Bureau (CNA), the latest full 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 national and international environmental NGOs and consumer groups. Although, tests conducted by NGOs showed a minimum of biotech residues in several consumer ready products, large 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, although an opinion survey conducted in 2010 and sponsored by the Brazilian Food Industry Association indicated that 74 percent of Brazilian consumers were unaware of biotech (GMO) products. In general, Brazilian consumers are disengaged from the biotechnology debate as they are more concerned about price, quality and the date of validity of their foods. However, a small number of consumers more oriented towards organic agriculture and methods avoid plant biotech products.

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. The campaign against plant biotech products in Brazil is more effective among large retailers and food processors than Brazilian consumers in general.

Section V. Plant Biotechnology 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.
4. In 2012, the Office of Agricultural Affairs is engaging with the GOB to carry out trilateral biotech outreach activities in sub-Saharan Africa and Central America, but, these activities have not been finalized yet.

Section VI. Animal Biotechnology:

On April 27, 2009 the National Technical Commission of Biosafety (CTNBio) issued Normative Resolution Number 7 which regulates the development, commercial use and/or import of genetically engineered animals and their release into the environment. The 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 control 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 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 smaller 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 campaigns against GM animals and products. For labeling of GM animals, please see section on Labeling.