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Brazil

Agricultural Biotechnology Annual

Brazil - Agricultural Biotechnology Report

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Report Highlights:
Brazil is the second largest producer of biotech crops in the world. The adoption rate of biotechnology in the upcoming 2017/2018 crop season (Oct. 2017 through Sept. 2018) is expected to reach an average of 81 percent for total corn, soybean and cotton planted area. The increase is mostly attributed to the greater use of biotech soybeans and corn and increased availability of subsidized credit for farmers, although at higher interest rates than last crop year. Post has also updated other sections, such as the intellectual property rights and list of events 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 reached a record of US$ 6.3 billion in 2016, up 1 percent from the previous year. Brazil exported to the United States US$ 4.7 billion of agricultural commodities and food products and imported US$ 1.6 billion. U.S. agricultural exports to Brazil are primarily commodities, such as wheat and cotton, required to meet local shortfalls, while consumer products account for nearly 20 percent of exports. However, in the past two years ethanol exports to Brazil began to increase substantially. For 2017, Post estimates a major increase in U.S. exports of agricultural products to Brazil by 17 percent due mostly to an increase of ethanol exports of over 100 percent, while Brazilian exports of agricultural products to the United States are expected to increase by only 2 percent.

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 sometimes 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 higher global demand by increasing agricultural production. However, for the first time in recent years, grain and oilseeds production during the upcoming crop season (2017/2018) is expected to be lower by 8 percent from the previous crop year at 220 million metric tons, reflecting the impact of poor weather conditions. The adoption rate of biotechnology in the 2017/18 crop season is expected to reach an average of 94 percent for total corn, soybean and cotton planted area.

The federal government announced on June 6, 2017 a total of R$ 200 billion (US$ 57 billion) in credit lines at subsidized interest rates for the upcoming 2017/2018 crop season (Oct. 2017 – Sept. 2018). The total amount allocated is up 2.4 percent from last year's funds. The average interest rates for production costs are 8.5 percent per year, investment credit 7.5 percent and warehouse and technological innovation 6.5 percent per year. According to the Ministry of Science and Technology (MCT), Brazil is the second largest plant biotech producer in the world, after the United States.

Section II.

Chapter 1: PLANT BIOTECHNOLOGY

ART A: PRODUCTION AND TRADE

a. Product Development

Brazilian and multinational seed companies and public sector research institutions are working on the development of various GE plants. Currently, there are a number of biotech crops in the pipeline waiting for commercial approval, of which the most important are sugarcane, potatoes, papaya, rice and citrus. Except for sugarcane, most of these crops are in the early stages of developments and approvals are not expected within the next five years.

b. Commercial Production

As of November 17, 2017, there are 68 GE events approved for commercial cultivation in Brazil, of which 39 events are for corn, 15 for cotton, 11 for soybeans, one for dry edible beans, one for eucalyptus, and, most recently one for sugarcane. The total area planted to GE crops during the last crop season (2016/17) reached 45 million hectares, which places Brazil as the second largest producer of GE crops in the world. GE events with herbicide tolerance traits lead the adoption rate with 65 percent of the total area planted followed by insect resistance with 19 percent and stacked genes with 16 percent.

- **Soybeans:** During the 2016/2017 soybean crop season (Oct. 1, 2016 through Sept. 30, 2017) area planted to GE soybean was nearly 29 million hectares, up 9 percent from the previous crop season. The adoption rate of GE soybean seeds is currently at 93 percent.

- **Corn:** The area planted to GE corn during 2016/2017 (both winter and summer crops) increased by less than 1 percent and reached 13 million hectares. The adoption rate of GE corn seeds for the total corn crop is currently at 83 percent.

- **Cotton:** The area planted to GE cotton during the 2016/2017 crop season reached 600,000 hectares and the adoption rate of GE cotton is currently at 67 percent.

- **GE Dry Edible Beans**: Although approved in 2011, GE dry edible beans are not expected to be commercially cultivated until the 2019/20 crop season.

- **GE Eucalyptus**. Recently approved, it will not be commercially available until 2019/20.

- **Sugarcane**. Recently approved, it will not be commercially available until 2019/20.

c. Exports

Brazil is one of the leading exporters of biotech soybeans, corn and cotton. China is the main importer of Brazilian biotech soybeans and cotton, followed by the European Union. Corn exports are mainly bound for Iran as well as Vietnam and other Asian countries. Brazil is also considered the largest exporter of conventional soybeans.

d. Imports

According to Brazilian legislation, only GE events approved by the National Technical Commission of Biosafety (CTNBio) can be imported into Brazil on a case-by-case basis. The Agriculture Ministers of Argentina, Bolivia, Brazil, Chile, Paraguay, and Uruguay participated in the Southern Agricultural Council (CAS) meeting on August 29, 2017 and delivered a joint statement calling for improvement and access of GM products to third markets. At the same event, they also stated the need in the region to work together to reduce the asynchrony in the approvals of biotech events.

e. Food Aid Recipient Country

Brazil is not a food aid recipient from the United States and it is not likely to be in the near future.

Brazil is also a source of food aid for some countries in Africa and Central America. Brazil donates mostly rice and dry beans, which are currently not biotech products.

PART B: POLICY

a. Regulatory Framework

The regulatory framework for agricultural biotechnology in Brazil is outlined in Law# 11,105 of March 25, 2005. This law was modified by Law# 11,460 of 2007 and Decree # 5,591 of 2006. There are two main governing bodies that regulate agricultural biotechnology in Brazil:

1. 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.
2. 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 issues are debated and approved by 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. Law#11,460 of March 21, 2007 modified Article 11 of Law# 11,105 of March 24, 2005 and established that a simple majority of votes is needed out a total of 27 on CTNBio's board to approve new biotechnology products.

On June 18, 2008, CNBS decided that it will only review administrative appeals that are of national interest, involving social or economic issues, as per the Brazilian Biotechnology Law. CNBS will not evaluate technical decisions on biotech events that are approved by the CTNBio. CNBS 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.

b. Approvals

Cotton

Crop - year	Trait Category	Applicant	Event	Trait Description	Uses within Brazil
Cotton 2017	Herbicide Tolerant Insect Resistant	Bayer	BCS-GH002-5xBCS-GH004-BCSGH005-8xSYN-IR102-7		Textile Fibers Food and Feed
Cotton 2017	Herbicide Tolerant	Monsanto	MON88701-3		Textile Fibers Food and Feed
Cotton 2016	Herbicide Tolerant Insect Resistant	Monsanto	COT102xMON15985 X88913		Textile Fibers Food and Feed
Cotton 2012	Herbicide Tolerant	Bayer	GHB614 T304-40xGHB1A	Gossypium hirsutum L.	Textile Fibers Food and Feed
Cotton 2012	Herbicide Tolerant Insect Resistant	Monsanto	MON 15985 X 89913		Textile Fibers Food and Feed
Cotton 2012	Herbicide Tolerant	Bayer	GHB614 LL Cotton 25	Gossypium hirsutum L.	Textile Fibers Food and Feed
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 2017	Herbicide Tolerant Insect Resistant	Syngenta	SYN-BT011-1 xSYN-IR162-4 xMON89034 xMON00021-9		Food, Feed, Imports

Corn 2017	Herbicide Tolerant Insect Resistant	Syngenta	SYN-BT011-1 xSYN-IR162-4 xMON89034		Food, Feed, Imports
Corn 2017	Insect Resistant	Syngenta	SYN-IR162-4xMON89034		Food, Feed, Imports
Corn 2017	Herbicide Tolerant Insect Resistant	Monsanto	MON89034-3xDAS01507-1 xMON00603-6 xSYN-IR162-4		Food, Feed, Imports
Corn 2017	Herbicide Tolerant Insect Resistant	Dow	MON89034 xTC1507xNK603 xMIR162		Food, Feed, Imports
Corn 2017	Insect Resistant	Syngenta	MIR162 xMON89034		Food, Feed, Imports
Corn 2017	Herbicide Tolerant Insect Resistant	Syngenta	Bt11xMIR162 xMON89034		Food, Feed, Imports
Corn 2017	Herbicide Tolerant Insect Resistant	Syngenta	Bt11xMIR162 xMON89034 xGA21		Food, Feed, Imports
Corn 2016	Approved only for human and animal food	Monsanto	MON87460		Food, Feed, Imports
Corn 2016	Approved only for human and animal food	Syngenta	3272		Food, Feed, Imports
Corn 2016	Herbicide Tolerant	Monsanto	MON87427		Food, Feed, Imports
Corn 2016	Herbicide Tolerant Insect Resistant	Monsanto	MON97411		Food, Feed, Imports
Corn	Herbicide	Dow	MON89034-3x		Food,

2016	Tolerant Insect Resistant	AgroSciences	MON88017-3x DAS01507x DAS59122-7		Feed, Imports
Corn 2016	Herbicide Tolerant Insect Resistant	Dow AgroSciences	MON89034x TC1507xNK603 xDAS40278-9		Food, Feed, Imports
Corn 2015	Fertility Restauration	Du Pont	SPT 32138		Food, Feed, Imports
Corn 2015	Herbicide Tolerant Insect Resistant	Syngenta	BT11xMir162		Food, Feed, Imports
Corn 2015	Insect Resistant	Syngenta	5307		Food, Feed, Imports
Corn 2015	Herbicide Tolerant Insect Resistant	Syngenta	BT11xMIR162x MIR604xTC1507 x5307xGA21		Food, Feed, Imports
Corn 2015	Herbicide Tolerant	Dow AgroSciences	DAS40278x9x NK603		Food, Feed, Imports
Corn 2015	Herbicide Tolerant Insect Resistant	Du Pont	TC1507xMON810 xMIR162		Food, Feed, Imports
Corn 2015	Insect Resistant	Du Pont	MON 810x MIR 162		Food, Feed, Imports
Corn 2015	Herbicide Tolerant Insect Resistant	Du Pont	MIR 162xNK603		Food, Feed, Imports
Corn 2015	Herbicide Tolerant Insect Resistant	Du Pont	TC 1507xMIR 162		Food, Feed, Imports
Corn 2015	Herbicide Tolerant Insect Resistant	DuPont	TC1507, MON 00810-6, MIR 162, MON 810	Herbicide Tolerant	Food, Feed, Imports
Corn 2015	Herbicide Tolerant	DuPont	TC1507 X MON 810, MIR 162 X	Glufosinate Herbicide	Food, Feed,

			MON 603	Ammonium	Imports
Corn 2015	Herbicide Tolerant	Monsanto	NK603 x T25	Glyphosate and Glufosinate Herbicides	Food, Feed, Imports
Corn 2015	Herbicide Tolerant	Dow Agro Science	DAS 40278-9	Herbicide Tolerant	Food, Feed, Imports
Corn 2014	Insect Resistant	Syngenta Seeds	MIR 604		Food, Feed, Imports
Corn 2014	Glyphosate Tolerant Insect Resistant	Syngenta Seeds	MIR 604 Bt11xMIR162 xMIR604xGA21	Glyphosate Tolerant Glufosinate Ammonium	Food, Feed, Imports
Corn 2013	Herbicide Tolerant Insect Resistant	Dow Agrosciences and Dupont	TC 1507 DAS 59122-7	Glyphosate Herbicide Ammonium	Food, Feed, Imports
Corn 2011	Herbicide Tolerant Insect Resistant	Monsanto	MON 89034 X MON 88017	Glyphosate Herbicide	Food, Feed, Imports
Corn 2011	Herbicide Tolerant Insect Resistant	DuPont (Pioneer)	TC1507 X MON 810	Glyphosate Herbicide Ammonium	Food, Feed, Imports
Corn 2011	Herbicide Tolerant	DuPont (Pioneer)	TC 1507 x MON 810 x NK 603	Glyphosate Herbicide Lepidoptera R.	Food, Feed, Imports
Corn 2010	Herbicide Tolerant Insect Resistant	Monsanto	MON 89034 x TC 1507 x NK 603	Glyphosate Herbicide Ammonium	Food, Feed , Imports
Corn 2010	Herbicide Tolerant Insect Resistant	Monsanto	MON 88017	Glyphosate Herbicide Ammonium	Food, Feed, Imports
Corn 2010	Herbicide Tolerant Insect Resistant	Monsanto	MON 89034 x NK 603	Glyphosate Herbicide Ammonium	Food, Feed, Imports

Corn 2010	Herbicide Tolerant Insect Resistant	Syngenta	BT 11 x MIR 162 x GA 21	Glyphosate Herbicide Ammonium	Food, Feed, Imports
Corn 2009	Herbicide Tolerant Insect Resistant	DuPont Brazil	TC 1507 x NK 603	Glyphosate Tolerant Insect Resistant	Food, Feed, Imports
Corn 2009	Insect Resistant	Monsanto	MON 89034	Lepidoptera Resistant	Food, Feed, Imports
Corn 2009	Insect Resistant	Syngenta	MIR 162	Lepidoptera Resistant	Food, feed, Imports
Corn 2009	Herbicide Tolerant Insect Resistant	Monsanto	MON 810 x NK 603	Glyphosate Tolerant Lepidoptera R.	Food, Feed, Imports
Corn 2009	Herbicide Tolerant Insect Resistant	Syngenta	BT 11 x GA 21	Glyphosate Tolerant Lepidoptera R.	Food, Feed, Imports
Corn 2008	Herbicide Tolerant Insect Resistant	Dow AgroScience	Tc 1507 Herculex	Glyphosate ammonium Herbicide Tolerant	Food and Feed
Corn 2008	Herbicide Tolerant	Syngenta	GA 21	Glyphosate Tolerant	Food and Feed
Corn 2008	Herbicide Tolerant	Monsanto	Roundup Ready 2 NK 603	Glyphosate Tolerant	Food and Feed
Corn 2008	Insect Resistant	Syngenta	Bt 11	Lepidoptera resistant	Food and Feed
Corn 2007	Insect Resistant	Monsanto	MON 810 Guardian	Lepidoptera resistant	Food and Feed
Corn 2007	Herbicide Tolerant	Bayer CropScience	Liberty Link T 25	Ammonium Glyphosate tolerant	Food and Feed
Imported Corn 2005	Herbicide Tolerant 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 2017	Herbicide Tolerant Insect Resistant	Dow	DAS 44406-6 x DAS 81419-2	Herbicide Tolerant Insect Resistant	Food and Feed
Soybeans 2017	Insect Resistant	Monsanto	DAS 87751-7	Insect Resistant	Food and Feed
Soybeans 2016	Herbicide Tolerant	Monsanto	MON 87708-9	Herbicide Tolerant	Food and Feed
Soybeans 2016	Herbicide Tolerant Insect Resistant	Dow Agro Science	DAS 81419-2	Herbicide Tolerant Insect Resistant	Food and Feed
Soybeans 2015	Herbicide Tolerant	Bayer	MST-FG072-2 A5547-127	Herbicide Tolerant	Food and Feed
Soybeans 2015	Herbicide Tolerant	Dow Agro Science	DAS 44406-6	Herbicide Tolerant	Food and Feed
Soybeans 2015	Herbicide Tolerant	Bayer	MST-FG072-2	Herbicide Tolerant	Food and Feed
Soybeans 2015	Herbicide Tolerant	Dow Agro Science	DAS 68416-4	Herbicide Tolerant Gluphosinate ammonium	Food and Feed
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	Herbicide Tolerant	Monsanto (Monsoy)	Roundup Ready GTS-	Glyphosate Herbicide Tolerant	Food and Feed

Ready 2008			40-30-2		

c. Stacked Event Approvals

Stacked events follow the same approval process as single events and are treated as new events. In Brazil, it is estimated that stacked events account for 20 percent of the total area in Brazil planted to GE crops.

d. Field Testing

CTNBio is responsible for granting prior approval for all field trials in Brazil. The technology provider must obtain from CTNBio a Certificate of Quality in Bio Safety (CQBs) to perform field testing. All providers must create an Internal Biosafety Commission (CIBio), and indicate for each specific project a principal researcher, defined in CTNBio's regulations as the "Principal Technical Officer."

e. Innovative Biotechnologies

There is no new regulation published for genome editing in Brazil. The regulatory aspects of genome editing are still under discussion at the ministry of Science, Technology and Innovation (MCTI), and could be approved by the end of the first half of 2018.

The CRISPR/Cas9 technology is being used by two universities in Brazil (Federal University of São Paulo and State of São Paulo University of Campinas) and Brazil's Agricultural Research Corporation – EMBRAPA.

In view of the lack of regulatory framework for these new technologies, CTNBio is reviewing on case-by-case basis.

f. Coexistence

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 biome.

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 regulates the registration of biotech and non-biotech seeds.

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

g. Labeling

On April 29, 2015 Brazil's House of Representatives approved Draft Bill # 4148/2008 by 320 to 135 to amend the current GE labeling legislation Executive Order 4,680/2003. The new Draft Bill establishes that only products which have more than 1 percent of GE in its final composition must be labeled. Another important change is the decision to withdraw the requirement for a GE label of a "T" symbol in black in a yellow triangle. The Bill is still under consideration at the Senate and likely will continue there for another year or two due to a major election year in 2018. Currently Executive Order 4,680/2003 is in force as per information below.

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 1 percent limit. In addition to the federal agencies, Normative Instruction # 1 also authorizes the state and municipal consumer defense officials to enforce the new labeling requirements.

On December 26, 2003 the Ministry of Justice published Directive # 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 1 percent. The requirement became effective March 27, 2004.

On April 24, 2003, the President of Brazil published in Brazil's Federal Register (*Diario Oficial*) Executive Order # 4,680/03, establishing a tolerance limit of 1 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.

h. Monitoring and Testing

Monitoring of GE crop events is conducted by the Ministry of Agriculture, Livestock and Food Supply (MAPA). According to the legislation in force, MAPA oversees inspection of these events intended for agriculture, animal use, and related-fields in the agro-industry. The Ministry of Health through the National Surveillance Agency (ANVISA) also inspects the events for toxicology, while the Ministry of the Environment through the Brazilian Institute of Environment and Renewable Natural Resources (IBAMA) monitors and inspects the events and their impact on the environment. The provider's CIBios are an essential component for monitoring and testing the work of genetic engineering, manipulation, production and transportation of GMOs and to enforce regulations on Biosafety. Monitoring and testing in Brazil relates to risk assessment.

i. Low Level Presence Policy

Brazil has a zero tolerance policy for unapproved GE food and crop events.

j. Additional Regulatory Requirement

Once an event is approved by the CTNBio, it requires no further review.

k. Intellectual Property Rights (IPR)

The current 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. Multinational companies such as Monsanto, Syngenta and BASF, have licensing agreements with the Brazilian Agriculture and Livestock Research Enterprise (EMBRAPA), which is linked to MAPA to develop plant biotech crops, mostly for soybeans, corn and cotton. In general, at the beginning of the new crop year, technology providers negotiate payment agreements with individual Brazilian states and farmer associations for the collection of royalties. 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 Roundup Ready (RR) soybean technology.

On November 8, 2017, soybean and corn growers of the state of Mato Grosso (Brazil's largest producing state), filed a court case against Monsanto to cancel the patent of Monsanto's Intacta RR2 PRO. The local growers, under the umbrella of their association (APROSOJA-MT) claim irregularities in the registration of the event and failure to prove technological innovations, as Intacta RR2 PRO is not a "new technology," but rather "genetic engineering." The patent protection for Intacta RR2 PRO extends through October 2022. This is the second time producers from Mato Grosso challenged Monsanto in Brazil. In 2012, APROSOJA-MT claimed Monsanto was charging royalties over a patent that had expired two years earlier and in 2013, after the legal dispute, Monsanto stopped collecting royalties linked to its first-generation RR technology. If producers win the 2017 case, they expect to save R$130.00 (about US$40.00) per hectare, or R$2.6 billion (about US$ 815 million) for the 2017-18 crop season. According to APROSOJA-MT, during the 2016/17 crop season, 53 percent of Brazil's soy area was planted with Intacta technology, 40 percent with Roundup Ready seed technology, and only 7 percent is non-GM. Note: there is no update on this legal case as of December 20, 2017.

l. Cartagena Protocol Ratification

In November 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 closed already. 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 an operator. The GOB is also opposed to the mandatory use of insurance or other financial instruments for the shipment of living modified organisms (LMOs).

m. International Treaties/Fora

Like the United States, Brazil promotes science-based standards and definitions in international fora with an aim to remove unscientific sanitary and technical barriers to trade. Brazil supports labeling of GE plant products in international fora.

n. Related Issues

Brazil continues to be a reliable partner with the United States in conducting joint outreach in third countries. Global food security and the particular role of biotechnology therein, is a driving force behind the enhanced collaboration.

PART C: MARKETING

a. Public/Private Opinions:

A recent poll conducted in the second quarter of 2016 about public perception of biotech products concluded that 80 percent of Brazilians are concerned with the word "*transgenic*" and that 33 percent of Brazilians think that consuming these products can do harm. According to Brazilian analysts, the bad image of "transgenic" products is related to the high use of pesticides in Brazil. The poll also showed that most Brazilians do not know which biotech plants are grown in Brazil.

The marketing campaign "Brazil Better without Transgenic" is against the use of GE crops in Brazil. The campaign is 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 GE plant and plant products in Brazil is more effective among large retailers and food processors than among Brazilian consumers in general.

b. Market Acceptance

Acceptance of biotech crops in Brazil is widespread among producers. According to the Brazilian Farm Bureau (CNA), the latest full survey among Brazilian farmers, which covers the last three years, showed an 80 percent acceptance rate of biotech crops.

However, meat processors, the food processing industry and Brazilian and retailers are less receptive to biotechnology, especially the French-owned hypermarkets located throughout Brazil. These groups are concerned that a marketing campaign against their products would be spearheaded by environmental and consumer groups, although tests conducted by these groups showed a minimum of biotech residues in several consumer ready products,

The Brazilian Food Industry Association indicated that 74 percent of Brazilian consumers have never heard of biotech products. In general, Brazilian consumers are disengaged from the biotechnology debate as they are more concerned about price, quality and the expiration date of their foods. However, a small number of consumers avoid GE plant products and their derivatives.

c. Marketing Studies

The following organizations offer articles and studies regarding Brazil-specific studies on the marketing of GE plants and plant products. All the studies are in Portuguese:

National Association of Biosecurity (Anbio): http://www.anbio.org.br/
Biotechnology Information Council (CIB): http://www.anbio.org.br/
Brazilian Food Industry Association (Abia): http://www.abia.org.br/

CHAPTER 2: ANIMAL BIOTECHNOLOGY

PART D: PRODUCTION AND TRADE

a. Biotechnology Product Development

Brazil is the second largest producer of GE plants in the world, but research and application of animal biotechnology, including animal cloning and GE animals has been underway for the past 12 years. EMBRAPA has been successful with GE dairy cattle and research with recombinant proteins is in the pipeline. Two calves born in 2013 are part of this research. Another project is GE technology to improve the health of beef cattle and also to increase cattle weight. The state of Ceará also produced two GE goats that yield higher levels of a human antimicrobial protein proven effective in treating diarrhea in young pigs. The research demonstrates the potential for food products from GE animals to benefit human health. This project is in cooperation with the University of California at Davis.

Brazil has a well-developed research system for cloned animals under the national coordination of EMBRAPA. Cloning research started in the late 1990s in Brazil, mostly focused on cattle. In March 2001 Brazil was successful in cloning a Simmental heifer, named "Vitoria." The second clone was born in 2003 from cells of a Holstein cow named "Lenda da EMBRAPA". The third clone was obtained from a native cow named “Junqueira” in April 2005 that is on an endangered species list.

b. Commercial production

Commercial Somatic Cell Nuclear Transfer (SCNT) cloning in Brazil is practiced by a small number of companies, mostly under a partnership with EMBRAPA. These companies have cloned cattle for use as elite show and breeding animals. Since May 2009, MAPA changed its regulation to allow the genetic registration of cloned cattle under the Brazilian Zebu Cattle Association (ABCZ), since this breed of animal (Brazilian Zebu, similar to the Brahman in the United States) represents about 90 percent of the cattle base in Brazil.

On April 10, 2014, CTNBio approved the first commercial release of GM mosquitoes in Brazil. The GM Aedes aegypti mosquitoes (OX513A) were produced by a British company, OXITEC, which was sold to INTREXON from the United States. Despite the commercial approval by CTNBio, Brazil’s National Health Surveillance Agency (ANVISA), Ministry of Health and equivalent to the Food and Drug Administration in the United States, has not approved the commercial use in Brazil of OX513A, but rather provided a Temporary Special Registry (RET, in Portuguese) for research use only.

As of December 20, 2017, Brazil has 28 GE vaccines released by CTNBio for commercial use, 14 microorganisms, and one medication for treatment of skin cancer.

c. Biotechnology Exports

None for commercial use.

d. Biotechnology Imports

None for commercial use.

PART E: POLICY

a. Regulatory Framework

GE animals and GE vaccines are under the same legislation as GE plants and subject to the approval of CTNBio.

However, animal cloning follows a different policy. Currently, there is no systematic regulatory framework in place in Brazil either at federal or state levels related to cloned animals and their products. A draft bill is still before Brazil's Senate (# 73, dated March 7, 2007), that proposes to regulate the cloning of animals, including wild animals and their offspring.

The draft bill proposes to make MAPA responsible for the registration of all institutions, both private and public, that conduct research on cloned animals, including the authorization for commercial sales and imports of cloned animals for genetic or food purposes.

Since there is no specific regulation in place for cloned animals and their products, MAPA cannot authorize any imports of cloned animals or their products (meat or dairy products) to Brazil. The same applies to the progeny of cloned animals and their products.

Under the Draft Bill #73, the authorization for imports of cloned animals and their products will be provided within 60 days after MAPA receives all documentation from the exporting company. Required information includes: origin of the animal, characteristics of the animal, destination of the animal in Brazil, and purpose of import (i.e. genetic or food).

The proposed legislation also differentiates between two types of authorization for imports of cloned animals and their products: a) for pharmaceutical or therapeutic use, the authorization will be under ANVISA, which is connected to the Ministry of Health and b) when the cloned animal and its products involve genetically modified organisms the authorization will fall under CTNBio, under the Ministry of Science and Technology.

Draft Bill #73 does not make reference to labeling of products derived from cloned animals. However, political analysts expect strong pressure from anti-biotech groups in Brazil to apply the same principles of Brazil's Biotech Law and use Brazil's Consumer Defense Code to pressure the government for a specific label for cloned animals and their products.

b. Innovative Biotechnologies

Not available.

c. Labeling and Traceability

The same regulations and laws and administrative bodies apply to GE animals, although some specific requirements such as labeling and traceability have not yet been developed for GE animals.

The regulatory framework for animal cloning is under review in Congress and will likely fall under the authority of MAPA. There are no specifics in the draft legislation for animal cloning regarding labeling and traceability for products of animal cloning.

Brazilian consumer law applies to all products of GE plants, GE animals or animal cloning in terms of basic and general information about the product for the consumer.

d. Intellectual Property Rights (IPR)

The Brazilian 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. Since there are no commercial releases of GE animals and products, this area of IPR has not been tested.

e. International Treaties/Fora

Brazil is a member of both the Codex Alimentarius (CODEX) and the World Organization for Animal Health (OIE). Brazil is also a signatory to parts of the Cartagena Protocol.

PART F: MARKETING

a. Public/Private Opinions

Brazilian cattle producers are strong advocates of this new technology and support the approval of animal cloning regulation in Congress and that the authority for this new area fall under the auspices of MAPA.

b. Market Acceptance

This area has not been tested in terms of consumer and retailer acceptance or rejection. However, Brazilian cattle producers are enthusiastic about the potential of this new technology.

c. Market Studies

Most market studies can be found on the home page of EMBRAPA: http://www.embrapa.br/