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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. Post forecasts an increase of three percent in area planted to biotech crops during the upcoming 2015/16 Brazilian crop year (Oct. 2015 through Sept. 2016). 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 of the report to reflect new information from trade and government sources.

Section I. Executive Summary:

Bilateral agricultural trade between Brazil and United States reached US\$ 6.5 billion in 2014, up 4.3 percent from the previous year. Brazil exported to the United States US\$ 4.8 billion of agricultural commodities and food products and imported US\$ 1.7 billion. U.S. agricultural exports to Brazil are primarily commodities, such as wheat, required to meet local shortfalls, while consumer products account for nearly 20 percent. Post forecasts lower U.S. exports of agricultural products to Brazil in 2015 due to the current difficult economic situation facing the country and devaluation of the Brazilian currency which makes U.S. products more expensive and less competitive compared to other major supplier. On the other side, Brazilian exports of agricultural products to the United States are expected to increase in 2015, mostly due to the devaluation of the Brazilian currency.

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 world food prices and possible food shortages by increasing agricultural production. Grain and oilseeds production increased from 60 million metric tons in 1991 to 202 million tons during the 2014/15 crop year, up 237 percent. In the same period, the cultivated area increased 48 percent from 38.5 million hectares in 1991 to currently 57 million hectares.

A record of R\$ 216.6 billion (US\$ 70 billion) in credit lines at subsidized interest rates were announced in late May 2015 for the upcoming 2015/2016 crop season (Oct. 2015 – Sept. 2016). The total amount allocated is 20 percent higher from the last crop season. These farm aid packages, although at higher interest rates, in support of agricultural production combined with the higher use of agricultural technology have streamlined the agricultural sector in Brazil.

According to commodity analysts, availability of subsidized credit lines and with stable world commodity prices are likely to contribute to the continued use of modern production technology such as biotech events in the next crop year. The adoption rate of biotechnology is expected to increase in the 2015/16 crop season to reach an average of 78 percent for total corn, soybean and cotton planted area. 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

PART 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 sugar cane, potatoes, papaya, rice and citrus. Except for sugar cane, 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 July 2015, there are 45 GE events approved for commercial cultivation in Brazil, of which 25 events for corn, 12 for cotton, six for soybeans, one for dry edible beans, and, most recently one for eucalyptus. Ten years since the first commercial approval of biotech soybeans in Brazil, the total area planted to GE crops during the last crop season (2014/15) reached 42 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 2014/2015 soybean crop season (Oct. 1, 2014 through Sept. 30, 2015) 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 2014/2015 (both winter and summer crops) increased by less than one 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 2014/2015 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 expected to be commercially cultivated this next crop season of 2015/2016.
- **GE Eucalyptus.** Recently approved, it will only be commercially available by 2015/16.

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. 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) for commercial production in Brazil can be imported. Imports are approved by CTNBio on a case-by-case basis. In order to meet shortfalls in production, Brazil imports GE corn from Argentina and GE cotton from the United States.

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.
 - 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 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. For additional information on CTNBio, please see GAIN BR 5632.

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 2012	Herbicide Tolerant Insect resistant	Bayer	GHB614 T304- 40xGHB1A	Gossypium hirsutum L.	Textile Fibers Food and Feed
Cotton 2012	Glyphosate Herbicide	Bayer	GHB14 LL Cotton 25	Gossypium hirsutum L.	Textile Fibers Food and Feed
Cotton 2012	Herbicide Tolerant	Bayer	GHB614 LL Cotton 25	Gossypium hirsutum L.	Textile Fibers Food and Feed
Cotton 2012	Glyphosate Herbicide	Monsanto	MON15985 MON 88913	Gossypium hirsutum L.	Textile Fibers Food and Feed
TwinLink 2011	Glyphosate Herbicide	Bayer	T 304-40 x GHB 119	Gossypium hirsutum L.	Textile Fibers Food and Feed
GlyTol cotton 2012	Herbicide Tolerant	Bayer	GHB 614	Gossypium hirsutum 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 2015	Herbicide Tolerant Insect Resistant	DuPont	TC1507, MON 00810-6, MIR 162, MON 810	Herbicide Tolerant	Food, Feed, Imports
Corn Zea Mays 2015	Herbicide Tolerant	DuPont	TC1507 X MON 810, MIR 162 X MON 603	Glufosinate Herbicide Ammonium	Food, Feed, Imports
Corn Zea Mays 2015	Herbicide Tolerant	Monsanto	NK603 x T25	Glyphosate and Glufosinate Herbicides	Food, Feed, Imports
Corn Zea Mays 2015	Herbicide Tolerant	Dow Agro Science	DAS 40278-9	Herbicide Tolerant	Food, Feed, Imports
Corn Zea Mays 2014	Glyphosate Tolerant Insect Resistant	Syngenta Seeds	MIR 604 Bt11xMIR162 xMIR604xGA21	Glyphosate Tolerant Glufosinate Ammonium	Food, Feed, Imports
Corn Zea Mays 2013	Herbicide Tolerant Insect Resistant	Dow Agrosiences and Dupont	TC 1507 DAS 59122-7	Glyphosate Herbicide Ammonium	Food, Feed, Imports
Corn Zea Mays 2011	Herbicide 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	Herbicide Tolerant	Bayer CropScience	Liberty Link T 25	Ammonium Glyphosate	Food and

2007				tolerant	Feed
Imported Corn 2005	Herbicide Tolerant Insect Resistant	Bayer	Cry 9 (C) NK 603	Glyphosate Ammonium Lepidoptera Resistant	Feed

Soybeans

Crop - year	Trait Category	Applicant	Event	Trait Description	Uses within Brazil
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 Ready 2008	Herbicide Tolerant	Monsanto (Monsoy)	Roundup Ready GTS- 40-30-2	Glyphosate Herbicide Tolerant	Food and Feed

c. 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 (CQB) 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".

d. 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

e. Additional Requirement

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

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 one percent of GE in its final composition must be labeled. Another important change is the decision to withdrawal symbol "T" black on yellow tringle in GE labels. The Bill is now at the Senate.

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 # 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 one 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 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.

h. Trade Barrier

Brazil allows imports of biotech products on a case-by-case basis. All imports of GE products must have the pre-approval of CTNBio. Approvals take into consideration food safety, toxicology and environmental aspects, and are generally science based. After approval is granted, there are no further trade barriers.

i. Intellectual Property Rights

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 RR soybean technology.

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 taken up by the state court. According to Monsanto, royalties are being collected without interruption in that state.

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

k. 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.

l. 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.

m. 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.

n. Low Level Presence policy

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

PART C: MARKETING

a) 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, 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.

b) Public/Private Opinions:

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

c) Marketing Studies:

The following organizations offer articles and studies in their home pages 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/>

PART D: CAPACITY BUILDING AND OUTREACH

a) Activities

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. Trilateral conference held in Accra, Ghana in 2011;
5. FAS/Brasilia and Washington New Technologies Division FAS posts in Cairo, Nairobi, Pretoria, Maputo, and Lagos together with State, Embrapa, MAPA, CTNBio, and the Brazilian Development Agency (ABC) supported the visit of a delegation of 20 African regulators, scientists, and farmers who visited Brazil to learn more about Brazilian and U.S. experiences with agricultural biotechnology. Brazilian and U.S. biotech experts led discussions on regulatory, scientific, and communications issues related to agricultural biotechnology. African participants posed many excellent questions which sparked lively discussions. After the seminar component in Brasilia, which took place at Embrapa headquarters, the African delegation

members traveled to Goias to visit farms and acquaint themselves with biotech varieties of corn and cotton. The delegation also attended a local farm exposition.

6. The U.S. Department of Agriculture (USDA) and the Brazilian Ministry of Agriculture, Livestock and Food Supply (MAPA) signed early in 2015 the terms of an agreement creating the High Level Working Group of Biotechnology (HLWGB).

b) Strategies and Need

There are opportunities for trilateral cooperation with Brazil to support agricultural biotechnology in sub-Saharan Africa and Central America but they depend on adequate USG funding as well as an adequate planning horizon (i.e., at least 10 months).

CHAPTER 2: ANIMAL BIOTECHNOLOGY

PART E: 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 is nascent. Brazil has had experience with GE animal research for over 10 years. EMBRAPA has been successful with GE dairy cattle. Embrapa 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. Recently, the state of Ceará 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 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.

There is no development being carried out at present that would likely lead to a commercial release of GE animals within the next five years.

b) Commercial production

Brazil does not commercially produce GE animals. However, 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 only cloned cattle for use as elite show and breeding animals. And, 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.

Because of this change in regulation, the first auction of a cloned animal was conducted in November of 2009 and sold by the price of US\$900,000 (for half of a cow). Trade sources expect that with the possibility of genetic registration, cloned bovine animals will expand in the near future. The average cost of these animals is estimated at one million dollars. Products of these animals cannot be sold in Brazil since there is no specific legislation yet. See policy section below.

Other experiments in Brazil also include cloning of equines. Despite the success of the project, cost of this type of animal is very high, but it is expect to increase in 2015.

On April 10, 2014 CTNBio approved the first commercial release of GM mosquitoes in Brazil. The GM *Aedes aegypti* mosquitoes are produced by a British company, Oxitec.

As of June 30, 2015 Brazil has 20 GE vaccines released by CTNBio for commercial use.

c) Biotechnology Exports

None for commercial use

d) Biotechnology Imports

None for commercial use

PART F: POLICY

a) Regulation

GE animals and GE vaccines are under the same legislation as GE plants and subject to the approval of CTNBio. However, no GE animals have been subject to CTNBio approval as research is in its early stages.

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 currently 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 for 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, such as origin of the animal, characteristics of the animal, destination of the animal in Brazil, purpose of imports (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 (MS); and, b) when the cloned animal and its products involve genetically modified organisms the authorization will fall under the 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 pressures 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) 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.

c) Trade Barriers

All imports of GE animal products must obtain prior approval from CTNBio. Approvals take into consideration food safety, toxicology and environmental aspects, and are generally science based. Imports are on a case by case. Once approval is granted, there are no further trade barriers.

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/For a

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 G: MARKETING

a) Market Acceptance

Since there have been no commercial releases of GE animals and their derived products or livestock clones, and their offspring of clones, 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.

b) 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.

c) Market Studies

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

PART H: CAPACITY BUILDING AND OUTREACH

a) Activities

Second International Workshop for Regulation of Animal Biotechnology: Preparing Markets for New Animal Products Opportunities, August 18-21, 2014, Brasilia, DF, Brazil.

b) Strategies and Needs

Private companies and the governments of the United States and Brazil are scheduled to conduct a workshop on GE animals and cloning in Brasil. Targeting selected countries as presenters and participants, the workshop will bring together technology providers, researchers, policy makers and supply chain representatives to share knowledge and discuss strategies for moving forward to the development, legislation, regulation and marketing of animals and their derived products.