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2016

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Report Highlights:
Negative public perceptions regarding biotechnology have influenced political will. The Mexican Supreme Court and the National Commission on Human Rights established that indigenous groups in the state of Yucatan where the release of transgenic crops into the environment is sought must be consulted prior to granting commercial permits. Although it goes against the Federal Biosafety law, in October 2016, Yucatan declared its state ¨Genetically Modified Organism (GMO) ¨ free zone, to include crops and all GE products. The states of Quintana Roo and Campeche have proposed to adopt a decree similar to that of Yucatan during the Conference of the Parties, COP8 in Cancun. Mexico City and the state of Tlaxcala have decreed their states ¨GMO¨ free zone, to include GE crops in 2009 and 2011, respectively.

Section I. Executive Summary:

With a growing population, an expanding economy and a more market-oriented agricultural sector, biotech proponents insist that Mexico needs to take advantage of the best technology available in order to produce food and fiber in a more sustainable way. Mexico is equipped with knowledge and expertise in agricultural biotechnology and has regulatory systems in place to assess biotechnology products. Mexico, however, is at crossroads due to negative public perception of the technology; cultural prejudices that opponents have used to disseminate among sectors of the society. Both strategic engagement with stakeholders and effective messaging to the general public are necessary. This will help address biotech marketing issues and incentivize Mexican scientists and the industry to invest more in biotechnology applications, which could ultimately contribute to addressing national food security needs.

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CHAPTER1: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

a) PRODUCT DEVELOPMENT:

Mexican producers and the scientific community have been affected by a legal battle over transgenic corn. On July 5, 2013, a coalition of anti –biotech groups filed a class-action lawsuit to stop the Mexican government from granting permits to plant genetically engineered (GE) corn. In September of that year, a judge ordered a halt to experimental and commercial planting until a final verdict is reached — a resolution that has taken years. The lawsuit and ruling have thwarted the plans of biotechnology companies and stalled public-sector biotechnology researchers. The lawsuit derails work that could boost corn yields, reduce imports and help protect against threats, such as climate change.

The National Laboratory of Genomics for Biodiversity (LANGEBIO) at the Center for Research and Advanced Studies of the National Polytechnic Institute (CINVESTAV), Irapuato Mexico campus, and a private Mexican-American company are developing genetically engineered plants that will be able to absorb and optimize the use of phosphorus. As shown in Figure 1, these plants will improve the use of fertilizers and weed control, which compete for the phosphorus element. The trait gives the plants a selective advantage over the rest. The GE crops can achieve sufficient phosphorus, an element essential for the growth of plants absorbing phosphites rather than phosphates. As a result, farmers would need less fertilizer and herbicides, as weeds, unable to assimilate phosphite, will not compete for it. In theory, the use of these new GE crops reduces the amount of fertilizer required between 30 and 50 percent, eliminates or reduces the use of herbicides, and is harmless to humans and animals. The group is developing GE tobacco as the first crop tested in Mexico, however, the experimental releases will be done in Argentina, because Mexican requirements are difficult to complete by national researchers. There are over 100 requirements that must be fulfilled before a researcher can obtain a permit for experimental planting; making the process costly.

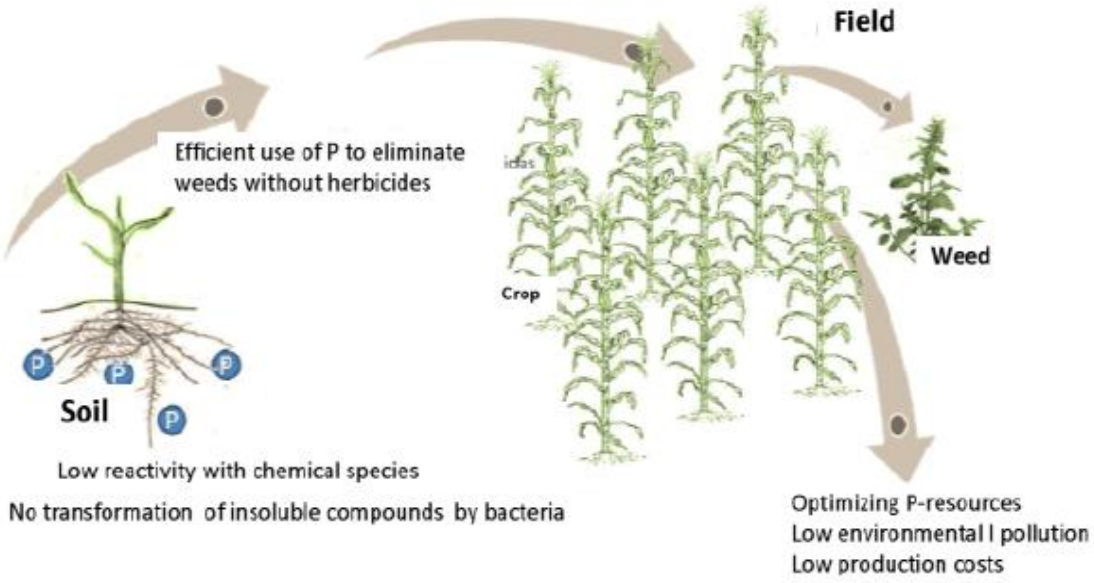


Figure 1. Genetically engineered to improved use of fertilizer and weed control
Source: Stela Genomics.

Genetically engineered corn "CIEA-9" was developed by CINVESTAV, Mexico City. This research group seeks to develop drought-tolerant GE corn that can also resist low temperatures. Using antisense RNA, the team modified the plant's metabolism by inhibiting an enzyme that destroys trehalose, a sugar involved in stress response. The result is a variety that requires only two-thirds of water needed by a normal plant. On August 23, 2012, the Government of Mexico (GOM) granted 4 hectares of biotech-derived corn for experimental release in Sinaloa, Mexico. This was the first permit granted to a Mexican Public Research Center since the Biosafety Law came into force in 2005. The next stage of this research, and the last step required by Mexican law prior to applying for a commercial planting permit, is to cultivate 4-hectare experimental plots of CIEA-9 to test productivity. The team, however, must wait until a final decision has been made on the class action lawsuit before they can proceed.

The same research team in CINVESTAV is developing a GE lemon tree (*Citrus aurantifolia*) resistant to the disease known as Huanglongbing (HLB). They obtained three release permits in 2014 to test different events in Tecoman, Colima.

Mexico's National Institute of Forestry, Agriculture and Livestock Research (INIFAP) initiated research on GE beans (*Phaseolus vulgaris*). In 2014, it was granted a permit for experimental release in Celaya, Guanajuato, of the event FMA-pdf1.2-INIFAP with tolerance to *Colletorichum lindemuthianum, Fusarium lateritium* y *Rhizoctonia solani.* There is uncertainty regarding the future of this research and public investment, as the researcher in charge of this permit has departed INIFAP.

The non-profit International Maize and Wheat Improvement Center (CIMMYT) has tested experimental releases of GE wheat over the last seven years. With a staff of 1,100 in Mexico and 13 regional offices around the world, CIMMYT is helping reduce hunger and raise living standards in many poor countries through programs focused on increasing corn and wheat productivity. Genetically engineered wheat events have been tested by CIMMYT in experimental releases on 0.1 hectare plots in Tlaltizapán, Morelos. The trait tested has been drought resistant.

Table 1. **Mexico: GE Wheat Events Tested at Tlaltizapán, Morelos.**

Year	Events
2008	rd29a-DREB1A
2009	rd29a-DREB1a
2010	Lip9-DREB1A, Osnac6-DREB1A, ubi-DREB1A, ubi-SnRK2C, ubi-AtGolS2, Osnac6-Osnac6
2011	rd29a-DREB1A, Lip9-DREB1A, ubi-DREB1A, osnac6-DREB1A, ubi-SRK2C, ubi-AtGolS2, osnac6-osnac6, Lip9-DREB2A CA, Lip9-NCED3, osnac6-AREB1dQT, osnac6-DREB2A CA, Ubi-AREB1dQT, uBI-DREB2A CA, Lip9-AREB1dQT
2012	rd29a-DREB1A, ubi-DREB1A, osnac6-Osnac6, osnac6-DREB1A, ubi-AtGolS2, Lip9-DREB1A, ubi-SRK2, Cosnac6-DREB2A CA, Lip9-DREB2A CA, Lip9-NCED3, Ubi-DREB2A CA, Ubi-AREB1dQT, Lip9-AREB1dQT, Osnac6-AREB1dQT
2014	ubi-SRK2C, Lip9-DREB1A, ubi-DREB1A, ubi-AtGolS2, Lip9-DREB2A CA
2016	AVP1 – XX, NAS2 - XX

In February 2013, the Bill & Melinda Gates Foundation and the Carlos Slim Foundation opened new biotechnology facilities within CIMMYT headquarters near Mexico City to promote research and the development of agricultural technology to increase productivity and reduce hunger. These new facilities will allow for the development of GE corn and wheat.

b) COMMERCIAL PRODUCTION:

Based on Mexico's Biosafety Law, transgenic seeds must go through three testing phases: experimental, pilot, and commercial. Biotechnology developers (companies and national or international research public centers) try to complete experimental testing as soon as possible in order to begin pilot testing and afterwards the commercial production stage, as permits are usually valid only for a single growing season. The area permitted by the Secretariat of Agriculture, Livestock, Rural Development, Fishery and Food (SAGARPA) for experimental and pilot testing purposes do not respond to a fixed limit, it is variable in accordance with the objectives proposed by the developer.

Cotton

The most important GE crop produced in Mexico is cotton. On January 22, 2015, SAGARPA through the National Health Service Food Safety and Quality Service (SENASICA) gave official recognition to the state of Chihuahua for reaching the status of "free zone from pink worm in cotton." On February 3, 2016, SAGARPA gave this recognition to the states of Baja California and Sonora. SAGARPA recognized the United States Department of Agriculture (USDA) for its support and assistance in the Binational Program for the Eradication of Pink Bollworm and Boll Weevil. Control actions were taken to successfully eradicate these pests by using integrated pest management, GE seeds, and applying the sterile insect and pheromone mating disruption techniques. Both techniques used biological material provided by USDA. GE crops to produce *Bacillus thuringiensis* proteins are known as *Bt*. *Bt* cotton directed against the pink bollworm has been used in Mexico since 1996. As a result of these actions, 85 percent of Mexico's cotton producing area is now free of pink bollworm and 70 percent of boll weevils are depleted. Since 1996, according to officials, farmers from Chihuahua have saved 30 percent on their production costs. For example, most cotton growers from Chihuahua have reduced from 18 to one the number of insecticide applications needed, while at the same time increasing their yields from 3.7 to 7.7 bales of cotton per hectare. In Mexico, the 2015/16 total cotton production and harvested area estimates

were 0.9 million bales in a harvested area of 130,000 hectares, based on figures from SAGARPA. According to the Food and Fisheries Statistics Service (SIAP), nearly 95 percent of the total surface planted was GE cotton.

Soybeans

The second GE crop that reached the commercial state under the Mexican regulation is soybeans. The first commercial permits for GE soybeans were in 2012. Soybean production is industrialized for food and feed products. Some honey producer groups in the state of Yucatan have been vocal about their displeasure of the government's approval of GE soybeans for commercial production. Particularly since the European Court of Justice ruled that honey containing trace amounts of pollen from GE crops authorized for human consumption in the European Union must be labeled if the amount of GE pollen surpasses 0.9 percent. According to sources, the state of Yucatan exports over 90 percent of its honey production to Europe. In 2012, honey producers initiated eight court injunctions against the permits and filed a complaint with the National Commission on Human Rights. In 2015, the Mexican Supreme Court and the National Commission of Human Rights gave their resolutions on the injunctions. These resolutions established that there is no evidence of any damage to the trade of honey, environment or health, but recommended a consultative process with indigenous communities in the areas where the release of GE crops is sought before continuing with the permit for commercial production (Process of the Indigenous Consultation).

The Inter-secretarial Commission on Biosafety of Genetically Modified Organisms (CIBIOGEM) and the National Commission for the Development of Indigenous Peoples (CDI) are the government authorities responsible for coordinating the consultations. In some communities the process has been transparent and expedited, and there is a willingness to accept the use GE soybean. There are other localities, however, where this process has been delayed.

Sources have indicated that as a result of this issue, approximately 15,000 hectares of GE soybeans were not planted in 2012. There have been no applications for commercial or pilot releases of GE soybeans since 2013, however, producers planted GE soybean crops based on the 2012 permit.

Table 2. Mexico: Area Permitted for Release of GE Crops, 2015 Applications (hectares)

	Experimental	Pilot	Commercial	Total
Cotton	0.36	200,000	0	200,000.36
Alfalfa	0.112	0	0	0.112

Source: Mexican National Information System for Biosafety and Biotechnology at CIBIOGEM.

In 2013, there were 25,000 hectares of GE cotton permitted for commercial production; however, since 2014 there have been no commercial production of any transgenic crop.

Table 3. Mexico: Commercial Production of GE Crops, 2013 Applications

Crop	Event	Area permitted (Ha)	Trait	Use
Cotton	MON-88913-8	25,000	Glifosate tolerant	Fiber and feed

Source: Mexican National Information System for Biosafety and Biotechnology at CIBIOGEM.

There is uncertainty about the GOM decision-making process, particularly related to delays about whether or not to grant commercial permits. Corn is blocked by a legal injunction and soybean is being subjected to a consultative process. Corn remains the most sensitive of Mexico's biotech regulations for all governmental agencies.

c) EXPORTS:

Mexico has a deficit in corn, cotton, and soybean production and does not cover domestic demand. The production of GE crops that have been without commercial permits since 2014 is for domestic consumption.

d) IMPORTS:

Mexico depends on imports of corn for feed while at the same time it reconciles concerns with the costs associated with restrictive policies against cultivating GE corn. The GOM has instituted trade policies that allow users to competitively source food and feed grains from global markets to avoid higher costs for Mexican consumers of meat, dairy, and poultry products. White and yellow corn imports come from countries that produce mainly GE crops such as the United States, Argentina, Brazil, and South Africa according to data from SIAP.

Although the production of cotton is important, it covers only 50 percent of Mexican domestic consumption. The United States remains the main cotton supplier to Mexico which accounts for nearly 100 percent of total imports. Mexico also depends on the importation of GE oilseeds like GE soybeans and GE rapeseed. Soybeans are imported mainly from the United States, and rapeseed is imported mostly from Canada.

It is important to note that Mexico has authorized for consumption 146 GE events from nine species. Considering that these are equivalent to conventional, they can be imported without the need to be labeled.

Table 4. Mexico: Total Imports of Crops with GE Content.

	2013/2014	2014/2015	2015/2016
Corn	11,269	12,000	12,500
Cotton	968	1,070	1,050
Soybean	3819	3850	4050
Rapeseed	1,486	1,500	1,540
1000 MT			

Source: FAS GAIN reports MX6023, MX6014 and MX6010.

e) FOOD AID:

Mexico is not a food aid recipient country.

f) TRADE BARRIERS:

Mexico's Biosafety Law and the Implementation Rules do not specify a threshold limit for GE seeds, but sources state that this could be interpreted in two ways: a) a zero-tolerance or b) that it can have a two percent tolerance of impurities as any other seed and part of those impurities can be GE seeds.

According to SAGARPA, there is a two percent foreign material tolerance in imports of GE seed. Inspections may be done at warehouses in order to avoid rejections at the border. This percentage level is a potentially serious area of contention for many importers.

PART B: POLICY

a) REGULATORY FRAMEWORK:

Biotech crops have been grown in Mexico since 1988. Mexico is one of the original six countries to first adopt the technology. Mexico struggled with a government regulatory structure until its Biosafety Law was passed. Mexico follows the international standards in biotechnology regulation, except that Mexico has a unique regulatory issue for the center of origin for corn.

The Biosafety Law was published in Mexico's Federal Register (*Diario Oficial*) in March 2005. This law addresses a number of legislative issues for the regulation of research, production, and marketing of biotech-derived products. Mexico's Biosafety Law and its Implementation Rules (*Bylaw*) are designed to promote the safe use of modern biotechnology and prevent and control the possible risks associated from the use and application of biotechnology products to human, plant, and animal health and environmental well-being.

In November 2012, SAGARPA and SEMARNAT published in Mexico's Federal Register the Agreement to Determine the Centers of Origin and Centers of Genetic Diversity of Corn in Mexico. This Agreement is part of the legal process required by Mexico's Biosafety Law and includes a map delineating the areas in seven northern states of Mexico (Baja California, Baja California Sur, Chihuahua, Coahuila, Nuevo León, Tamaulipas, Sinaloa, and Sonora) where the use of GE corn seed is forbidden. This agreement is also very restrictive as it relates to the storage and movement of GE corn. According to Provision 86 of the Biosafety Law, the centers of origin and genetic diversity of corn in Mexico, as well as the geographic areas in which the related species in question are found, shall be determined jointly by an agreement issued by SEMARNAT and SAGARPA. Both Secretariats have established their decreed measures. So far, only seven Mexican States require protection of such species and geographic areas.

In April 2011, SAGARPA published in Mexico's Federal Register an agreement defining the Notification Process for the Confined Use of GE Products. (NOTE: The Mexican Biosafety Law states that the "confined use" of a genetically modified organism is any activity by means of which the genetic material of an organism is modified or through which this organism is modified, grown, stored, used, processed, marketed, destroyed or eliminated. In order to carry out such confined use activities, physical barriers or a combination of chemical or biological barriers are to be used with the aim of effectively limiting contact with people and the environment. For purposes of this law, the area of the facilities or the scope of the confined use space cannot be part of the environment END NOTE). According to SAGARPA, this agreement helps gain access to information about who is engaged in the confined use of GE products and to track their progress. On the other hand, this agreement allows developers, universities, and research institutions engaged in the confined use of GE crops to conduct work on events through a formalized notification process to authorities.

A labeling standard that includes general labeling specifications for GE seeds intended for planting, cultivation, and agricultural production was published in Mexico's Federal Register in December 2014

and took effect in June 2015 (GE seeds labeling NOM). This NOM establishes the characteristics and content of the labels that must contain genetically engineered seeds and propagation materials to be released as a crop or for agricultural production. According to Provisions 9 and 12 of the Biosafety Law on Genetically Modified Organisms, it is necessary to determine in an Official Mexican Standard (NOM) the information and characteristics of the labels for GE seeds. This NOM establishes 35 requirements as label characteristics and six regarding the package features and mentions specifically in one of its numerals (Numeral 6), that the GE seeds labeling NOM is independent from international rules.

Access to the regulations directly or indirectly related to biotechnology and biosafety are listed in the Inter-secretarial Commission on Biosafety of Genetically Modified Organisms (CIBIOGEM) Normativity. A description of CIBIOGEM is presented in section (ii).

i. The responsible government ministries and their role in the regulation of the GE plants, regarding food, feed and environmental safety issues.
The Biosafety Law defines the respective responsibilities and jurisdictions of the Mexican secretariats and agencies that monitor and enforce biotechnology regulations. The responsibilities and the roles of the Mexican secretariats are as follows:

The Secretariat of Agriculture, Livestock, Rural Development, Fisheries and Food (SAGARPA):
The role of SAGARPA is to analyze and assess, on a case-by-case basis, all of the potential risks to animal, plant, and aquatic health, as well as to the environment and biological diversity, posed by activities carried out by bioengineering and based on risk assessments and results drafted and filed by the interested parties. SAGARPA is responsible for deciding in the cases of crops, livestock, and fisheries what biotech-related activities are permissible and issues permits and receive notifications for those activities. SAGARPA also provides guidelines and parameters for all GE-related experiments and activities. These activities include: experimental field trials, pilot program releases, commercial releases, marketing, and GE imports. SAGARPA is responsible for monitoring and mitigating the effects that accidental or permitted release of a transgenic may cause to animals, plants, aquatic health, and biological diversity.

The Secretariat of Environment and Natural Resources (SEMARNAT):
Environmental protection, including biodiversity and wildlife species falls under SEMARNAT's domain. All other species fall under the competence of SAGARPA. The role of SEMARNAT is to analyze and assess, on a case-by-case basis, all of the potential risks that biotech activities may cause to the environment and biological diversity. This analysis is based on risk assessment studies and results drafted and filed by interested parties. In addition, SEMARNAT is responsible for permitting and licensing activities that involve the environmental release of GE wildlife species and is charged with providing guidelines and parameters for such activities. SEMARNAT also monitors the effects on the environment or biological diversity that may be caused by the accidental release of transgenic crops. In instances in which SAGARPA has primary responsibility for the specific kind of specie, SEMARNAT is still responsible for issuing bio-safety opinions prior to SAGARPA's resolution. (NOTE: SAGARPA, not SEMARNAT, issues approval for environmental release for crops, livestock and fisheries, although SEMARNAT renders an opinion to SAGARPA beforehand through their inter-agency process. END NOTE)

Secretariat of Health (SALUD):
The role of the Secretariat of Health is to assure the food safety of biotechnology-derived agricultural products destined for use as medicines or for human consumption. Health also assesses, on a case-by-case basis, studies drafted and filed by interested parties on the safety and potential risks of GE authorized events under the Biosafety Law. While the Biosafety Law is the regulatory framework, the Implementation Rules contribute to the harmonization and consolidation of the previously fragmented nature of Mexico's biotech policies. For example, the Implementation Rule changes in 2009 allowed developers and research institutions to experiment with biotech corn in approved regions of Mexico.

ii. The role and membership of the Biosafety Committee/Authority
Biotechnology policy activities in Mexico are coordinated by the Inter-secretarial Commission on Biosafety of Genetically Modified Organisms (CIBIOGEM), but the body has no enforcement function. Created in 1999, CIBIOGEM coordinates federal policy related to the production, export, movement, propagation, release, consumption, and advantageous use of biotechnology and their products and by-products. Several agencies comprise CIBIOGEM, including Mexico's National Council of Science and Technology (CONACYT) and representatives from six Secretariats: SAGARPA, SEMARNAT, Health, Finance and Public Credit, Economy, and Education.

CIBIOGEM´s presidency is held for a period of two years on a rotating basis among the Secretariats of SAGARPA, SEMARNAT, and Health. Currently, SAGARPA is in the second year of its tenure as President of the Commission. CIBIOGEM has a Vice President, permanently held by the Director General of CONACYT. According to the Biosafety Law, CIBIOGEM is led by an Executive Secretary who is nominated by CONACYT after consultations with the member Secretariats and approved by the President of Mexico.

iii. Assessments of the political factors that may influence regulatory decisions related to plant biotechnologies.

Under the current administration, which entered into office in December 2012, there have been delays in the release of permits. This could be in part to the increased learning curve for new authorities. Additionally, GE corn and GE soybean have been blocked by provisional legal injunctions that have no specific timelines for resolution. Almost every week the subject of GE corn comes into prominent play in the Mexican media, often in ways that could be deemed emotional. Although it goes against the Federal Biosafety Law, in October 2016 the state of Yucatan declared itself ¨GMO free zone, ¨ to include GE crops and all GE products. The states of Quintana Roo and Campeche have proposed during the COP8 in Cancun to adopt a similar decree to that of Yucatan. Mexico City in 2009 and the state of Tlaxcala in 2011 declared their states ¨GMO free zones¨ to include GE crops.

According to the Federal law, GMO free zones are by SAGARPA by means of agreements to be published in the Federal Official Register, with a previous dictate from CIBIOGEM, and the opinion of the National Commission for the Understanding and Utilization of Biodiversity, taking into consideration what is established in the Mexican official norms relative to organic agricultural products. This has not adhered to in regards to the self-declared ¨GMO free zones¨ from the states of Tlaxcala, Yucatan, and Mexico City.

iv. Any distinctions made between the regulatory treatment of the approval for food, feed, processing,

and environmental release.
Mexico does not make a distinction between food and feed approval, but rather the Secretariat of Health approves both for animal and human consumption. Since 1995, there have been a growing number of GE commodities approved for food and feed. Corn is the species with 50 percent of the events approved for consumption.

The difference between approval (Authorization) for food and feed and approval (Permits) for environmental release is that authorizations are definitive, unless there is some new scientific evidence that shows harm to health. Permits, however, are usually only for one growing period and need to be granted every cycle. Environmental release is regulated by SAGARPA in the case of domesticated species (crops, livestock, and fishery) and by SEMARNAT in the case of wild species. SEMARNAT is the agency responsible for issuing biosafety opinions and this is done before any resolution can come from SAGARPA.

v. A reference to pertinent and pending legislations and regulations with the potential to affect U.S. exports and why.
The Organic Products Law was published in the Federal Register on February 7, 2006. This law establishes additional regulations for the use of biotech-derived food products. There are three specific areas in which this law regulates biotech-derived products:

i. Provision 27 of the Law states that the use of all materials, products, and ingredients or inputs that come from, or have been produced with genetically engineered, are prohibited in the entire production chain of organic products and the product must be labeled as GE-free.
ii. The Law also prohibits the use of substances or forbidden materials referred to in Provision 27 that alter the organic characteristics of the products, and
iii. The Law allows SAGARPA to impose a fine on any firm or individual that is found guilty of violating the law.

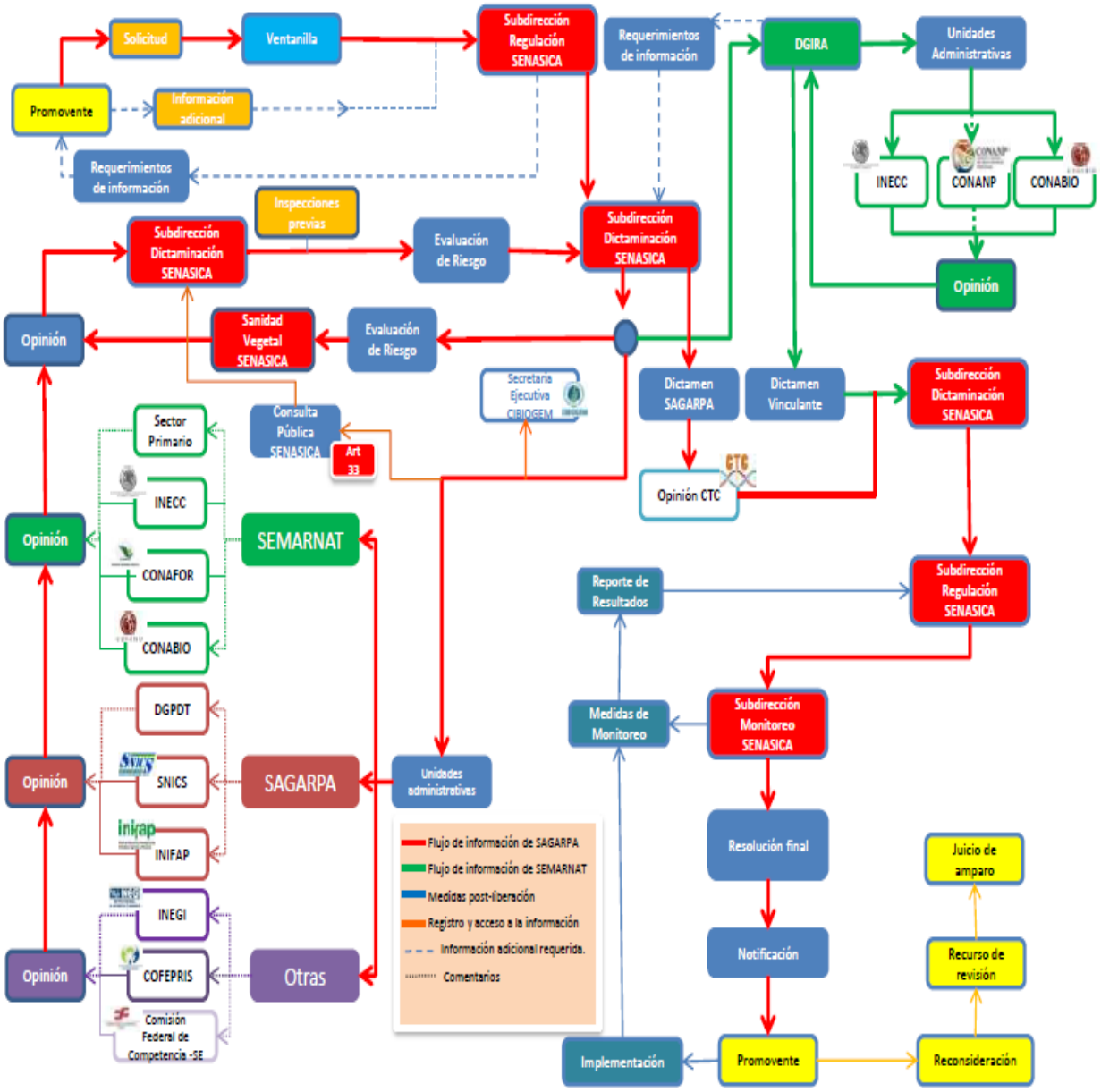
Two regulations (NOMs) related to the Biosafety Law have in draft since the last administration and according to SAGARPA officials will be submitted for public comment in 2017. These include:

1. A standard for plant risk assessment that establishes the requirements for the assessment of potential risks GE animals could cause to plant health, the environment, and biological diversity during the experimental and pilot stages.

2. A standard for plant risk assessment that establishes the requirements for the assessment of potential risks that GE plants could cause to plant health, the environment, and biological diversity during the experimental and pilot stages.

vi. The timeline usually followed for approvals.
The procedure followed for approvals has different timelines depending if it is for consumption authorization or for an environmental production release permit.

Figure 2. Procedure for the Resolution of Permits.



Source: CIBIOGEM

For consumption authorizations, the Biosafety Law established that the Secretariat of Health has a maximum of six months after receiving the completed application to make a ruling. In the case of permits for environmental release, the Biosafety Law and its Implementation Rules (Bylaws) establish a maximum of six, three, and four months for the resolution by the authorities for experimental, pilot or commercial release, respectively. This timeframe is not always adhered to.

vii. If no legislation and/or regulations are in place, provide information of any known discussions regarding regulation, research, or trade policies on biotechnologies.
Not applicable.

b) APPROVALS:

The Mexican Register of GE contains a list of all applications for authorizations and permits, the resolutions by the competent authorities (until now only the Secretariat of Health and SAGARPA) and a section for the confined notifications. All this information is presented on the CIBIOGEM website (Mexican Register of GE).

Table 5. Mexico: Authorized Events for Consumption.

Crop		Authorized events
Alfalfa	*Medicago sativa*	4
Canola	*Brassica napus*	9
Cotton	*Gossypium hirsutum*	33
Corn	*Zea mays*	70
Potato	*Solanum tuberosum*	3
Rice	*Oryza sativa*	1
Soybean	*Glycine max*	22
Sugar beet	*Beta vulgaris*	1
Tomato	*Lycopersicum esculentum*	3
		146

Source: http://www.cibiogem.gob.mx/OGEs/Documents/COFEPRIS-Salud/lista-evaluacion-inocuidad.pdf

c) STACKED or PYRAMIDED EVENT APPROVALS:

For stacked or pyramided events, the Biosafety Law does not require additional reviews for a plant that combines two or more already-approved GE traits. In practice, the GOM evaluates them as a different event than the parental ones.

d) FIELD TESTING:

In 1988, field testing of GE crops started in Mexico and had grown continuously with the participation from both private and public institutions up until 2005, when the Biosafety Law was published. After publication of the Law, only private institutions were able to comply with all of the requirements. It has only been in recent years that CIMMYT and CINVESTAV applied for field testing.

To date, the only crops that have reached commercialization are cotton and soybean. The first field tests for both crops were carried out in 1995 for *Bt* cotton and for herbicide tolerant soybeans. About 15 years later for cotton and 17 years later for soybeans, with the development of new regulations came the first commercial release permits granted in 2010 and 2012, respectively. GE corn is expected to be the next commercial GE crop permitted, but as previously stated, the final resolutions have been delayed and on hold until the resolution of the legal injunction.

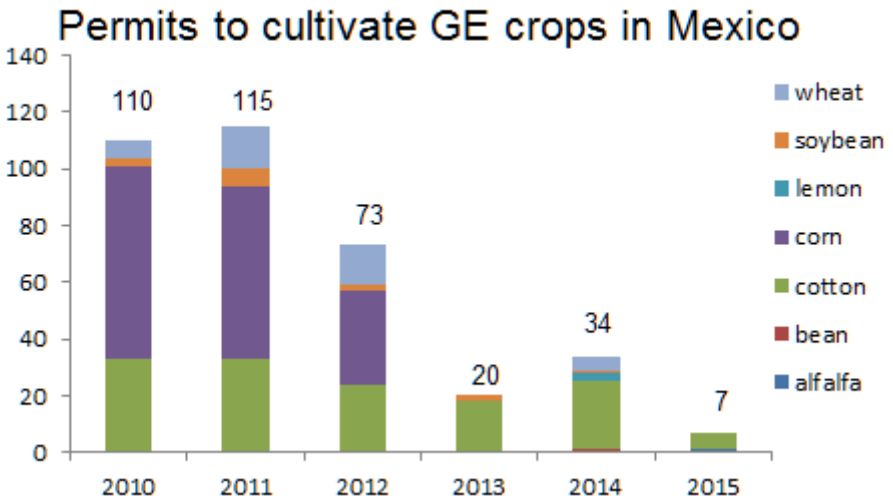
Table 6. Mexico: Status of Permit Requests for GE Environmental Release, 2010 to 2016*

		Experimental	Pilot	Commercial	Total Permitted
2010	Cotton	13	19	1	33
	Corn	67	1 (8 NA)	0	68
	Soybean	0	3	0	3
	Wheat	6	0	0	6

2011	Cotton	20	9	4	33
	Corn	55 (4 NA)	6 (11 NA)	0	61
	Soybean	1 (1 NA)	5	0	6
	Wheat	15	0	0	15
2012	Cotton	15	6	3 (3NA)	24
	Corn	14(12 RA)	19(8 RA, 3 NA)	(6 RA)	33
	Soybean	0	0	2	2
	Wheat	14	0	0	14
2013	Cotton	9(8NA)	8(2NA)	1	18
	Corn	(25 RA)	(23 RA)	(13 RA)	0
	Soybean	2(1 NA)	0	0	2
2014	Cotton	11	13 (2 NA)	(4 NA)	24
	Corn	(3 NA)	(1 NA)	0	0
	Soybean	1	0	0	1
	Bean	1	0	0	1
	Wheat	5	0	0	5
	Lemon	3	0	0	3
2015	Alfalfa	1	(1 NA)		1
	Cotton	2(2NA,2 RA)	4(7 NA,1 RA)	(2NA, 2 RA)	6
2016	Alfalfa	0	(1 RA)	0	0
	Cotton	(6 RA)	7 RA)	(2 RA)	0
	Corn	(4 RA)	0	0	0
	Wheat	(2 RA)	0	0	0

*Information as of December, 2016 ** includes the events non-approved (NA) and in risk assessment process (RA).
Source: National Information System for Biosafety and Biotechnology at CIBIOGEM

Figure 3. Decrease in the Number Permits for Cultivation of GE Crops in Mexico.



Source: National Information System for Biosafety and Biotechnology at CIBIOGEM

e) INNOVATIVE BIOTECHNOLOGIES:

Mexico has not determined the regulatory status of innovative biotechnologies (such as genome editing) in plants or plant products. The topic is under discussion.

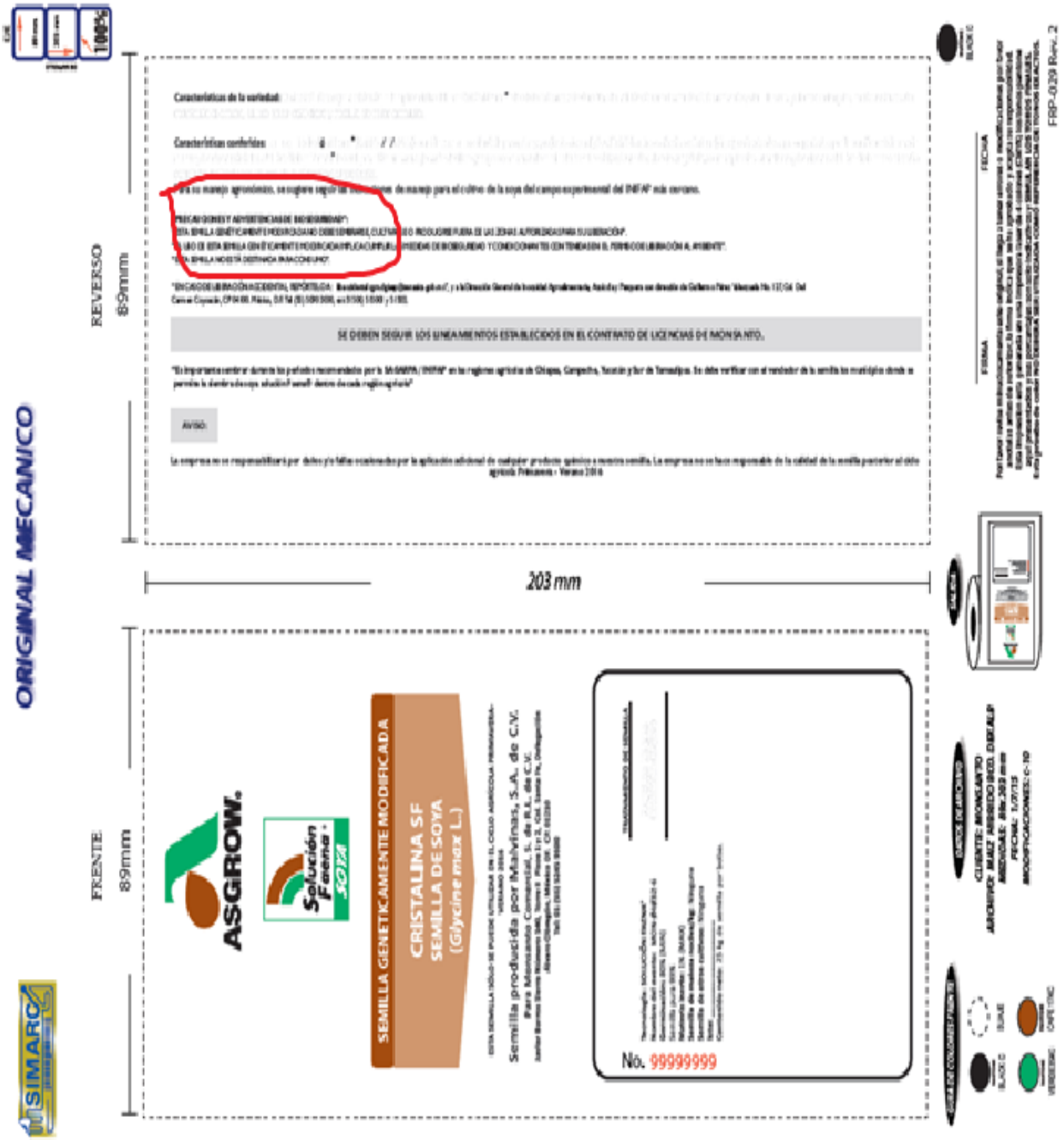
f) COEXISTENCE:

The Biosafety Law, Provision 90, establishes that ¨GMO free zones¨ may be considered for the protection of organic agricultural products and others of interest to the soliciting community. The free zones will be established when GE crops of the same species to the ones resulting from production processes yielding organic agricultural products coincide, and when it is scientifically and technically demonstrated that their coexistence is not viable or that they would not comply with the normative requirements for their certification. Such zones will be determined by SAGARPA by means of agreements to be published in the Federal Official Register, with a previous dictate from CIBIOGEM, and the opinion of the National Commission for the Understanding and Utilization of Biodiversity, taking into consideration what is established in the Mexican official norms relative to organic agricultural products.

g) LABELING:

The Biosafety Law does not require labeling for packaged foods and feeds (commodities) that are equivalent in health and nutritious characteristics to the conventional food and feed (i.e. grains). Labeling is required for seeds for planting (Provision 101), in this way the producers can follow the biosafety measures established for GE crops on a case by case basis. Labeling information should include that the planting seeds are genetically-engineered, the characteristics of the acquired genetic combination, implications with regard to special conditions and growing requirements, and changes in reproductive and productive characteristics. Labeling information is included in a Mexican official norm, NOM (GE Seed labeling NOM).

Figure 4. Mexico: Example of a Label for Herbicide Tolerant Soybeans



h) MONITORING AND TESTING:

Mexico faced a case of Low Level Presence (LLP) in 2000. Since then, the experience in biotechnology monitoring has become better developed. Authorities responsible for the monitoring programs are SAGARPA and SEMARNAT. Additionally, there are two monitoring networks coordinated by CIBIOGEM:

The Mexican Network of Laboratories for Detection of ¨Genetic Modified Organisms¨. This network is composed of government, public, and private laboratories, which complies with the standards for

detection. The network facilitates detections in cases where a trustable resolution is needed.

The second is the Mexican Network for Monitoring of ¨Genetic Modified Organisms¨ (Monitoring), whose aim is to monitor for the presence of biotech and the effects (positive and/or negative) of this presence to the environment. Government, public institutions, and biotechnology companies are part of this network. Monitoring is done regularly (but random) or following a complaint of unintended release.

i) LOW LEVEL PRESENCE POLICY:

The Secretary of Health regulates and grants Authorizations for GE intended for direct use as food or feed, or for processing (FFPs). SAGARPA and SEMARNAT are involved in biotech regulation intended for intentional introduction into the environment. Depending on the given use, one of the secretariats is in charge of the decision making process that could lead to issuing a permit. In relation to these different approval systems, there could be different cases of LLP.

The different situations of LLP that can occur are:
1) Presence in the food chain of an unapproved trait that is not authorized in Mexico for FFP (these cases are within the scope of the Codex Alimentarius);

2) Released into the environment without the corresponding permit

2.1) Genetic engineering that are *commodities* that have been authorized for FFP, that function biologically as seed, and are unintentionally released into the environment or intentionally used for planting

2.2) Genetic engineering that corresponds to *commercial seed* for intentional planting, but lacks a permit.

Most of the situations referred to in Number 2 represent cases of non-compliance with the Biosafety Law and require the adoption of measures bound to enforce compliance of the regulation. Some of these measures could include the application of administrative and penal sanctions.

Mexico has faced incidents of unintended release:

1. Train derailments resulting in cargo spills of commodities that functioned as seed: Grains that enter the country as commodities are authorized for FFP by the Secretariat of Health, but they cannot be legally planted. In the specific case of corn, commodity shipments could be assumed as above the threshold level for LLP in practically all cases, although some events could occur at low levels (most imports of corn is transgenic). Therefore, spillage of a commodity, and its subsequent germination, does not necessarily represents a case of LLP; it is seen as an accidental release that has been approved for use as FFP, but not for environmental release. Following notification of an incident, the competent authority corroborates the presence of GE grains and proceeds to establish control and mitigation measures directed at bringing the situation back into compliance.
2. Unintentional planting of grains authorized for FFP that have entered the country as commodities: This case has been associated with the lack of knowledge of the kind of grain/seed (GE) being used and also to agricultural practices still predominant in traditional systems that include experimentation with new varieties, and selection of seed from each harvest for use in

subsequent cultivation cycles. On a case-by-case approach, monitoring programs are established to determine levels of presence. According to the detected frequencies and the events identified, an *ex post* risk assessment can be applied to determine mitigation measures associated with the presence of GE plants.

3. Presence of GE plants detected for parcels cultivating GE corn without the corresponding permit: For these cases, if the detected level is high, it is not considered as a situation of LLP. These situations have been treated as illegal releases into the environment and are associated with biosafety response measures as well as administrative procedures for the application of the corresponding sanctions.
4. A case of LLP of GE seeds has been documented: If the percentage is below the actual standard established for genetic quality (in the case of corn, the qualification rule is 2 percent) then the case falls under the Federal Law of Seed Production, Certification and Commercialization (LFPCCS) and no sanction proceeds apply under the Biosafety Law. To prevent possible future cases of non-compliance of the Biosafety Law derived from a LLP situation, the competent authority should identify and stipulate proper management measures. For example, they should ensure that the products derived from these crops are directed for authorized use and not to be saved and re-planted.

j) ADDITIONAL REGULATORY REQUIREMENTS:

The Biosafety Law and the Implementation Rules (Bylaws) established more than 100 requirements for approval of GE crops. There are no more additional requirements. Authorizations for consumption are definitive; meanwhile permits for environmental release (even commercial) are limited to a growing season.

k) INTELLECTUAL PROPERTY RIGHTS (IPR):

Mexico is part of the World Intellectual Property Organization (WIPO), the World Trade Organization (WTO) as well as the International Union for the Protection of New Varieties of Plants (UPOV) and has in place the Mexican legislation to address intellectual property rights of the industry, including agro-biotechnology as the Law of Industrial Property.

l) CARTAGENA PROTOCOL RATIFICATION:

In 2002, the Mexican Senate ratified the Cartagena Protocol on Biosafety (CPB). This ratification helped ensure final congressional approval for the Biosafety Law in February 2005, as Mexico was obligated under the CPB to pass domestic legislation that harmonizes its domestic laws with its international obligations. Mexico has been actively participating at the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety (COP MOPs) and working groups of experts (Ad Hoc Technical Experts Group, AHTEG, and online forums) coordinated by the Secretariat of the Cartagena Protocol (See http://bch.cbd.int/onlineconferences/rt-ra-la3.shtml).

Mexico is hosting in December 2016 the thirteenth meeting of the Conference of the Parties to the Convention on Biological Diversity serving as the eighth meeting of the Parties to the Cartagena Protocol on Biosafety (COP-MOP 8), and the second meeting of the Conference of the Parties serving as the meeting of the Parties to the Nagoya Protocol on Access and Benefit-sharing (COP-MOP 2).

Mexico signed the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the

Cartagena Protocol on Biosafety in February 2012. Mexico was the fifth country to ratify the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity (CBD).

m) INTERNATIONAL TREATIES/FORA:

Mexico is part of the International Plant Protection Convention (IPPC), a member since 1969 of the Codex Alimentarius (Codex), and the World Organization for Animal Health (OIE) as well as a member of the Organization for Economic Cooperation and Development (OECD). Mexico has a delegation participating on the biotechnology working groups at these international fora, usually coordinated by CIBIOGEM.

n) RELATED ISSUES:

The core challenge of climate change adaptation and mitigation in agriculture is to produce (i) more food, (ii) more efficiently, (iii) under more volatile production conditions, and (iv) with net reductions in global greenhouse gas emissions from food production and marketing. GE crops could play a central role in enabling Mexican producers to meet these core challenges. However the political will is needed.

PART C: MARKETING

a) PUBLIC/PRIVATE OPINIONS:

Non-governmental organizations (NGOs) have been very active detractors of biotechnology in Mexico. AgroBio is a private organization that represents the major biotechnology developers. The organization's main objectives are to promote the positive use of biotechnology as well as to share and to disseminate scientific knowledge to policy makers, lawmakers, and the general public. They organize and participate in workshops on biotechnology and biosafety. Every year they organize the AGROBIO awards. These awards of excellence are presented for research in biotechnology and conservation, in addition to journalism in GE plants and food security issues.

b) MARKET ACCEPTANCE/STUDIES:

In general, Mexican consumers, producers, importers, and retailers remain disengaged from the biotechnology debate, with the latter often opting to let industry trade associations conduct significant lobbying and educational outreach. There is more concern about the price and quality of food over genetic composition. However, consumers across the socio-economic spectrum, generally draw a distinction between conventional and genetically engineered corn, as many have concerns about the integrity of Mexico's native corn species. In Mexico, corn is a symbol of heritage, so acceptance of this technology may well be tied to the perception of protection of this native plant. This debate has been amplified by NGOs opposed to the adoption of this technology.

In a recent study funded by CIBIOGEM, it was observed that in terms of benefits and risks perceived in the use of GE products, the perception of utility was positive only with regard to the use of GE crops to increase agricultural production, leaving far below the utility of the same to the benefit of the economy and environment. By the contrary, high risks are perceived in the use of GE products. For the individuals interviewed, it is considered that the use of GE crops could have health consequences. As for the attitude towards purchases, it was observed that the individuals surveyed showed some

preference to buy transgenic products if they were lower in fat content than the conventional or organic. Regarding the trust attributed to those who work with GE products, it was observed that universities and scientists, at the national level, are those who consumers have the greatest confidence. According to the study, the general public lacks confidence in companies that develop GE products.

CHAPTER 2: ANIMAL BIOTECHNOLOGY

PART D: PRODUCTION AND TRADE

a) PRODUCT DEVELOPMENT:

According to official sources, genetic engineering is not being used in Mexico for the development of agriculturally relevant or any other animals. No work is being done in this area.

b) COMMERCIAL PRODUCTION:

There are no genetically engineered animals or products derived from animals intended for commerce or currently in commercial production in Mexico. Despite the significant human and physical infrastructure that Mexico has in the biotechnology area, it has lagged behind in research in different areas that affect the development of biotechnological applications, such as the production of genetically engineered animals.

c) EXPORTS:

Not applicable.

d) IMPORTS:

Not applicable.

e) TRADE BARRIERS:

Not applicable.

PART F: POLICY

a) REGULATORY FRAMEWORK:

In Mexico, biotechnology regulation is generally applied to species and does not make a particular differentiation among plants or animals. As in the case of plant biotechnology, the Biosafety Law, its Implementation Rules and Agreements are the comprehensive legal frameworks that regulate the development, commercial use, import and disposal of GE animals or products derived from these animals. Similarly, SAGARPA, SEMARNAT and Health are the Mexican Secretariats that monitor and enforce biotechnology regulations for animal biotechnology.

i. The responsible government ministries and their roles in the regulation of the GE animals and/or livestock clones, regarding food safety, animal welfare, and environmental safety issues.

The Biosafety Law defines the respective responsibilities and jurisdictions of the Mexican secretariats and agencies that monitor and enforce biotechnology regulations. The responsibilities and the roles of the Mexican secretariats are as follows:

The Secretariat of Agriculture, Livestock, Rural Development, Fisheries and Food (SAGARPA):
The role of SAGARPA is to analyze and assess, on a case-by-case basis, all of the potential risks to animal, plant, and aquatic health, as well as to the environment and biological diversity, posed by activities carried out by bioengineering and based on risk assessments and results drafted and filed by the interested parties. SAGARPA is responsible for deciding in the cases of crops, livestock, and fisheries what biotech-related activities are permissible and issues permits and receive notifications for those activities. SAGARPA also provides guidelines and parameters for all GE-related experiments and activities. These activities include: experimental field trials, pilot program releases, commercial releases, marketing, and GE imports. SAGARPA is responsible for monitoring and mitigating the effects that accidental or permitted release of a transgenic may cause to animals, plants, aquatic health, and biological diversity.

The Secretariat of Environment and Natural Resources (SEMARNAT):
Environmental protection, including biodiversity and wildlife species falls under SEMARNAT's domain. All other species fall under the competence of SAGARPA. The role of SEMARNAT is to analyze and assess, on a case-by-case basis, all of the potential risks that biotech activities may cause to the environment and biological diversity. This analysis is based on risk assessment studies and results drafted and filed by interested parties. In addition, SEMARNAT is responsible for permitting and licensing activities that involve the environmental release of GE wildlife species and is charged with providing guidelines and parameters for such activities. SEMARNAT also monitors the effects on the environment or biological diversity that may be caused by the accidental release of transgenic crops. In instances in which SAGARPA has primary responsibility for the specific kind of specie, SEMARNAT is still responsible for issuing bio-safety opinions prior to SAGARPA's resolution. (NOTE: SAGARPA, not SEMARNAT, issues approval for environmental release for crops, livestock and fisheries, although SEMARNAT renders an opinion to SAGARPA beforehand through their inter-agency process. END NOTE)

Secretariat of Health (SALUD):
The role of the Secretariat of Health is to assure the food safety of biotechnology-derived agricultural products destined for use as medicines or for human consumption. Health also assesses, on a case-by-case basis, studies drafted and filed by interested parties on the safety and potential risks of GE authorized events under the Biosafety Law.

While the Biosafety Law is the regulatory framework, the Implementation Rules contribute to the harmonization and consolidation of the previously fragmented nature of Mexico's biotech policies. For example, the Implementation Rule changes in 2009 allowed developers and research institutions to experiment with biotech corn in approved regions of Mexico.

ii. Assessments of the political factors that may influence regulatory decisions related to animal biotechnologies, including clones and GE animals.
The negative public perception in Mexico toward GE plants could affect the decisions related to animal biotechnologies.

iii. Provide a reference to pertinent and pending legislations and regulations with the potential to affect

U.S. exports and why.
Not applicable

iv. If no legislation and/or regulations are in place, provide information of any known discussions regarding regulation, research, or trade policies on this technology.
Not applicable.

b) INNOVATIVE BIOTECHNOLOGIES:

Mexico has not determined the regulatory status of innovative biotechnologies (such as genome editing) in animals or animal products. The topic is under discussion.

c) LABELING AND TRACEABILITY:

The Biosafety Law does not require labeling for packaged foods and feeds (commodities) that are equivalent on health and nutritious characteristics to the conventional food and feed.

d) INTELLECTUAL PROPERTY RIGHTS (IPR):

Mexico is part of the World Intellectual Property Organization (WIPO), the World Trade Organization (WTO) as well as the International Union for the Protection of New Varieties of Plants (UPOV) and has in place the Mexican legislation to address intellectual property rights of the industry, including biotechnology as the Law of Industrial Property.

e) INTERNATIONAL TREATIES/FORA:

Mexico is member of the Codex Alimentarius, but does not participate in working groups related to animal biotechnology. In the Biotechnology Regulation Working Group of the OCDE, where Mexico actively participates, there have been subjects raised related to GE fish, insects and microorganisms.

f) RELATED ISSUES:

Not applicable

PART G: MARKETING

a) PUBLIC/PRIVATE OPINIONS:

There is no current outspoken opposition to GE animals. On the other hand, it is expected there could be opposition to GE animals considering that a certain segment of the public is opposed to GE crops. In general, official sources have stated that the public lacks knowledge about genetically engineered animals and that it is essential to educate the public about this issue.

b) MARKET ACCEPTANCE/STUDIES:

Please see Part C: Marketing, b.

For Additional Information:

USDA FAS home page at www.fas.usda.gov for a complete selection of FAS worldwide agricultural reports.

Useful Mexican Web Sites:

Mexico's equivalent to the U.S. Department of Agriculture (SAGARPA) can be found at www.sagarpa.gob.mx, information about GE crops can be found at http://www.gob.mx/senasica and at http://www.conacyt.gob.mx/cibiogem/ The equivalent to U.S. Department of Commerce (SE) can be found at http://www.gob.mx/se/, and the equivalent to the U.S. Food and Drug Administration (SALUD) can be found at http://www.gob.mx/salud. These web sites are mentioned for the reader's convenience but USDA does NOT in any way endorse, guarantee the accuracy of or necessarily concur with the information contained on the mentioned sites.