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Mexico

Agricultural Biotechnology Annual

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Report Highlights:
Mexico continues to send mixed signals regarding its stance toward acceptance of biotechnology.

On the one hand, scientists in Mexico are developing important advances in biotechnology crops which afford the country more opportunities to enter into sustainable agriculture, including crop varieties that can better tolerate drought conditions as well as other benefits like a reduction in fertilizer and herbicide use or genetic engineered (GE) trees.

Cotton has been the major Mexican biotechnology success story. The Confederation of Mexican Cotton Associations (CMCA) stated that pesticide application has dropped by over 50 percent since the use of

GE seeds while at the same time yields have increased dramatically. The binational program for the Eradication of Pink Bollworm and Boll Weevil include the use of GE seeds. *Bt* cotton directed against the pink bollworm has been used in Mexico since 1996. GE seed use covers about 95 percent of the planted area for cotton in the country. As a result of these actions, according with The National Service of Health, Food Safety, and Food Quality (SENASICA), 85 percent of the cotton producing area of the country is free of the pink bollworm and 70 percent is absent of boll weevil.

On the other hand, the commercial release of GE corn has not met with such success in Mexico. Although GE permits are pending, the Mexican government has yet to approve a GE corn permit for commercial planting. In a further setback that took place in September 2013, a federal judge effectively suspended the plantings of all GE corn in Mexico by placing a provisional injunction against all such plantings with no clear timeline for solution after almost two years.

Section I. Executive Summary:

With a growing population, an expanding economy, and a more market-oriented agricultural sector, biotech proponents insist Mexico needs to take advantage of the best technology possible in order to produce food and fiber in a more sustainable way. However, in 2013, the only GE crop in commercial production in México was cotton, with a permitted area totaling 25,000 ha. During 2014, there were no commercial releases for growing any GE crops in Mexico. All applications for experimental, pilot and commercial releases of GE corn are blocked by a provisional injunction with no clear date for resolution.

Mexico is equipped with knowledge and expertise in agricultural biotechnology and has regulatory systems in place to assess biotechnology products. However, Mexico is at crossroads due to negative perceptions of the technology, fears about the environmental impacts of GE crops that some opponents have used to disseminate among some sectors of the society. To address the challenge of the negative public perception, both strategic engagement with stakeholders and effective messaging based on science is necessary. This will help not only resolve biotech marketing issues, but could also be the incentive for Mexican scientists and industry to invest more in biotechnology applications which could ultimately contribute to address national food security needs.

SECTION II:

CHAPTER 1: PLANT BIOTECHNOLOGY
PART A: PRODUCTION AND TRADE

a) PRODUCT DEVELOPMENT:

The Mexican scientific community has been torn by an on-going legal battle over transgenic maize (corn). Almost two years after activists challenged scientists' right to plant experimental genetically modified (GM) varieties of the crop, maize research is still being stymied by a legal stalemate. On July 5, 2013 a coalition of activist groups filed a class-action lawsuit to stop the Mexican government from granting permits to plant GM maize. Then in September 2013, a judge ordered a halt to experimental and commercial planting until a final verdict is reached — a resolution that reportedly could take years. The lawsuit and ruling have thwarted plans of various companies. This issue has also resulted in stalling public-sector biotechnology researchers. Many researchers noted that they were frustrated because they

are close to producing GM maize strains tolerant to drought and frost and other varieties that reduce the need for herbicides and fertilizers. These researchers decry that the lawsuit threatens to derail work that could boost maize yields, reduce imports, and help to protect against crop threats such as climate change.

The National Laboratory of Genomics for Biodiversity (LANGEBIO) at the Research Center and Advanced Studies (CINVESTAV), Irapuato Mexico campus, and a private Mexican Company are developing GE plants that will be able to absorb and optimize the use of phosphorus. These plants will improve the use of fertilizers and weed control, which compete for the phosphorus element. The trait tries to give the plants a selective advantage over the rest, so that the GE crops can achieve sufficient phosphorus, an element essential for the growth of plants absorbing phosphites rather than phosphates. In this way farmers will 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 reduce 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 but the experimental releases will be done in Argentina because Mexican requirements are difficult to complete by national researchers. The Mexican scientist in charge of this research articulated that "in Argentina regulatory requirements are more accessible, science-based and sensible. In Mexico, more than 100 requirements must be fulfilled before a researcher can obtain a permit for experimental planting, thus for some making the whole process unaffordable".

GE corn "CIEA-9" was developed by CINVESTAV, Mexico City. This research group seeks to develop drought-tolerant GM maize that can also resist low temperatures. Using antisense RNA, this team has 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 the water needed by a normal plant. "This strategy is a way to save many of our local maize varieties" says Dra. Beatriz Xoconostle, in charge of this research. Its traits of tolerance to drought and cold have been proved in a greenhouse setting. 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 was in place. This action could help to change the perception that biotechnology crops are used only by multinational companies (See MX2064). The next stage of this research, and the last step required by Mexican law before CINVESTAV can apply for a permit for commercial planting, will be to cultivate 4-hectare experimental plots of CIEA-9 to test productivity. But the team will have to wait until a final decision has been made on the previously mentioned lawsuit before they can go ahead with the productivity testing.

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

Mexico's National Institute of Forestry, Agriculture and Livestock Research (INIFAP) have been doing research on GE beans (*Phaseolus vulgaris*). In 2014 they were granted the first permit for experimental release in Celaya, Guanajuato of the event FMA-pdf1.2-INIFAP, with tolerance to fungus *Colletorichum lindemuthianum, Fusarium lateritium* y *Rhizoctonia solani.*

The non-profit International Maize and Wheat Improvement Center (CYMMYT) have tested

experimental releases of GE wheat over the last seven years as presented in Table 1. Of all the different events that have been tested in experimental releases on plots of 0.1 hectares at the Tlaltizapan Morelos site, the trait was shown to be drought resistant.

Table 1 shows the different GE wheat events that have been tested by CIMMYT. During 2008 and 2009 there was only one release per year; in 2010 there were 6 releases, and in 2011 and 2012 there were 14 each year. In 2013, there were no applications to do experimental releases, but in 2014 CYMMT tested 5 events.

Table 1. Mexico: GE wheat events tested in Tlaltizapan, 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

In February 2013, Bill Gates and Mexican business magnate, investor and philanthropist, Carlos Slim, opened new biotechnology facilities within CIMMYT headquarters near Mexico City. Gates and Slim said they plan to use their foundations to promote research and the development of agricultural technology to increase productivity and reduce hunger among the poor people. With a staff of 1,100 in Mexico and 13 regional offices around the world, CIMMYT is helping to reduce hunger and raise living standards in many poor countries through programs focused on increasing corn and wheat productivity. These new facilities at CIMMYT will allow for the development of GE corn and wheat and provide greater opportunities to countries who want to take advantage of these GE crops.

b) COMMERCIAL PRODUCTION:

Based on Mexico's Biosafety Law (See "Policy" section, Part B of this Chapter), transgenic seeds must go through three different 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 the pilot testing and afterwards the commercial production stage. Even for the commercial phase, all permits to release GE crops have an expiration date. A permit is usually only valid 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.

The most important GE crop produced in Mexico is cotton. Although cotton growers in northern Mexico have adopted the use of GE seed varieties, other factors, such as weather and technology can explain

differences in production levels. For example, in the Mexican state of Tamaulipas, all cotton production is in non-irrigated areas, which significantly reduces yields. The CMCA stated that biotechnology continues to be an important tool in reducing pesticide usage in Mexico's cotton sector. CMCA stated that pesticide application dropped by over 50 percent due to use of GE seeds while yields have increased dramatically. For MY 2012/2013, 87 percent of the total area planted was GE cotton. Mexico's Agricultural and Fishery Information System (SIAP) stated that nearly 95 percent of the total surface planted was GE cotton. Cotton is used for the fiber and the seeds are used for feed.

The second GE crop that has reached the commercial state under the Mexican regulation is soybeans. The first commercial permits for GE soybeans were in 2012 with 253,500 ha. Soybean production is industrialized for food and feed products. Mexican honey producers, however, have expressed great concern with the government's approval of GE soybeans for commercial production – particularly since the European Court of Justice ruled that honey which contains trace amounts of pollen from GE crops authorized for human consumption in the EU - must be labeled if the amount of GE pollen surpasses 0.9 percent. Because of this ruling, and now that GE soybeans may be planted commercially in Mexico, all honey shipments from Mexico must undergo laboratory testing to identify and quantify the type of GE presence. As a result, Mexican honey producers filed a court injunction against the approval of GE soybeans for commercial production. Private sources stated that due to this legal dispute, SAGARPA recommended growers do not plant these GE soybean varieties in the states of Campeche, Quintana Roo and Yucatan until this on-going issue is resolved. Sources stated that as a result of this issue, approximately 15,000 hectares were not planted to GE soybeans in 2012 and there have been no more applications for commercial or pilot releases of GE soybeans during 2013 to 2015.

Table 2. Mexico: Area Permitted for Release of GE Crops, 2014 Applications (Hectares)

	Experimental	Pilot	Commercial	Total
Cotton	232	580,000	0	580,232
Corn	0	0	0	0
Soybean	4.8	0	0	4.8
Wheat	0.5	0	0	0.5
Bean	0.37	0	0	0.37
Lemon	0.75	0	0	0.75

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

As it is presented in Table 3, in 2013 there were 25,000 hectares of GE crops permitted in commercial production in Mexico, however in 2014 there was none.

Table 3. Mexico: Commercial production of GE crops in 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.

The GOM has continued to move forward in its support of biotechnology despite the strong opposition from some quarters. At the same time, there is continued uncertainty about the GOM decision-making process, especially related to decisions and delays about whether or not to grant commercial permits.

Delays in decision-making are coming not only from the Secretariat of Environment and Natural Resources (SEMARNAT) but also within the different entities of the SAGARPA, and now on corn blocked by the legal injunction. Corn remains the most "sensitive" of Mexico's biotech regulations for all GOM government agencies.

c) EXPORTS:

Mexico has a deficit in cotton and soybean production and does not cover domestic demand. The production of GE crops is for domestic consumption. There is some export of soybean oil however the oil does not contain any proteins and therefore no need to declare GE content.

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 in this country. 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. Ironically, white and yellow corn imports come from countries that produce mainly GE crops such as the United States and Argentina, according to 2014 data from the SIAP.

Although 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 almost 100 percent of total cotton imports. Mexico also depends on the importation of GE oilseeds like GE soybeans and GE rapeseed. Soybeans are imported almost totally from the U.S.; meanwhile rapeseed is imported mostly from Canada (Table 4).

It is important to note that Mexico has authorized for consumption 116 GE events from nine species (Table 5), considering that all these are equivalent to conventional, and then they can be imported without the need to be labeled.

Table 4. Mexico: Total Imports of crops with GE content.

	2011/2012	2012/2013	2013/2014	2014/2015
Corn	10,881	7,700	7,800	11,200
Cotton	992	1,100	1,036	1,100
Soybean	3,606	3,300	3,450	3,740
Rapeseed	1,520	1,450	1,480	1490
1000 MT				

Source: MX4020, MX4026 and MX4029.

e) FOOD AID RECIPIENT COUNTRIES:
Mexico is not a food aid recipient country.

PART B: POLICY

a) REGULATORY FRAMEWORK

Mexico has grown biotech crops since 1988 and is one of the original six countries to first adopt such technologies. Mexico struggled with a government regulatory structure until its Biosafety Law was passed in 2005. With the provisions of that law fully implemented, Mexico was ready to move forward with expanding biotech crop production. While Mexico has a unique issue as the center of origin for corn, none of the other biotech regulations are considered unusual. The GOM has in place its own regulatory system but can also support its decisions based on the experience and implementation in other countries like the United States for corn, soybeans and cotton. Additionally, the GOM can look to Brazil for science-based research where all three major crops are widely grown and India where biotech cotton is a major crop. Finally, the GOM has the option to regard the research by major importers like the European Union, Japan, South Korea and China.

Mexico's comprehensive biotech regulation is the Biosafety Law, which 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 foment the safe use of modern biotechnology and prevent and control the possible risks associated from the use and application of biotechnology products to human health, plant and animal health, and environmental well-being.

In November 2012, SAGARPA and SEMARNAT published in Mexico's Federal Register their 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 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 organisms (GEO). (NOTE: The Mexican Biosafety Law states that the "confined use" of a GEO 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 sources, this agreement helps them gain access to information about who is engaged in confined use of GEOs and this information enables them to track their progress. On the other hand, this agreement allows developers, universities, and research institutes engaged in the confined use of GEOs 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 on December 2014 and took effect last June 30 (GE seeds labeling).

This Mexican Norm (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 agricultural production. According to Provision 9 and 12 of the Biosafety Law on Genetically Modified Organisms it is necessary to determine in a NOM the information and characteristics of labels for GE seeds. This NOM establishes 35 requirements as label characteristics and six about package features. Number 6 specifically notes that there is not in accordance with international norms.

Complete access to the regulations directly or indirectly related to biotechnology and biosafety are listed by the Inter-secretarial Commission on Biosafety of Genetically Modified Organisms (CIBIOGEM) Normativity. Description of the CIBIOGEM is presented in the next 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/or enforce biotechnology regulations. In general, the responsibilities and the roles of the Mexican Government Secretariats are as follows:

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 with GEOs and based on the 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 GEO-related activities are permissible and issues permits and receive notifications for those activities. SAGARPA also provides guidelines and parameters for all GEO-related experiments and activities. These activities include: experimental field trials, pilot program releases, commercial releases, marketing, and GEO imports. Finally, SAGARPA is responsible for monitoring and mitigating the effects that accidental or permitted release of GEOs may cause to animals, plants, aquatic health, and biological diversity.

SEMARNAT:
Environmental protection, including biodiversity and wildlife organisms falls under SEMARNAT's domain. All other organisms fall under the competence of SAGARPA. Nevertheless, the role of SEMARNAT is to analyze and assess, on case-by-case basis, all of the potential risks that activities carried out with GEOs may cause to the environment and biological diversity. This analysis is based on the risk assessment studies and results drafted and filed by the interested parties. In addition, SEMARNAT is responsible for permitting and licensing activities that involve the environmental release of GE wildlife organisms 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 GEOs. In instances in which SAGARPA has primary responsibility for the specific kind of organism, 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)

Secretary of Health: (SALUD)
The role of the Secretary 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 GEOs authorized 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 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 GEOs and their products and by-products. Several agencies comprise CIBIOGEM, including Mexico's National Council of Science and Technology (CONACYT), and representatives of six Secretariats: Agriculture, Environment and Natural Resources, Health, Treasury, Economy, and Education. The CIBIOGEM presidency is held for periods of two years on a rotating basis among the Secretariats of SAGARPA, SEMARNAT, and Health. Currently the Secretary of SAGARPA is in the first year of his 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 then approved by the President of Mexico.

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

Corn is the most sensitive subject in Mexico. Mexico is part of Mesoamerica, the center of origin for corn. GE opponents claim that gene flow of GE corn with landraces could be detrimental. Supporters argue during the evolution through domestication of corn, there has been a continuous gene flow among different landraces and even hybrids; without scientific evidences that gene flow with GE corn could be detrimental.

Mexico's Biosafety Law states that centers of origin for native corn and other native species are off limits to biotech plantings. Public concerns were, and still are important, with Mexico being the center of origin for several crops. Regulatory policies in Mexico still prevent GE corn from leaving the confined laboratory setting in the areas determined by the GOM as center of origin. The "precautionary principle" favored by the European Union seems to be invoked in Mexico which has further delayed its use in the field.

The change of administration, which came into office in December 2012, has resulted in delays for the

releases of some permits. This is due in part to the increased learning curve for the 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.

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

Unlike the United States, Mexico does not make a distinction between food and feed approval, but rather the Secretary 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 as can be seen in Table 5. 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. However, permits usually are only for one growing period and even for commercial release they need to be granted every cycle. Environmental release is regulated by SAGARPA in the case of domesticated species (crops, livestock or 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. Provide 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 organisms, are prohibited in the entire production chain of organic products and the product must be labeled as GEO-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.

There are two regulations (NOMs) related to the Biosafety Law being drafted since the last Administration. According to SAGARPA officials, the two NOMs will be submitted for public comment later this year. 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

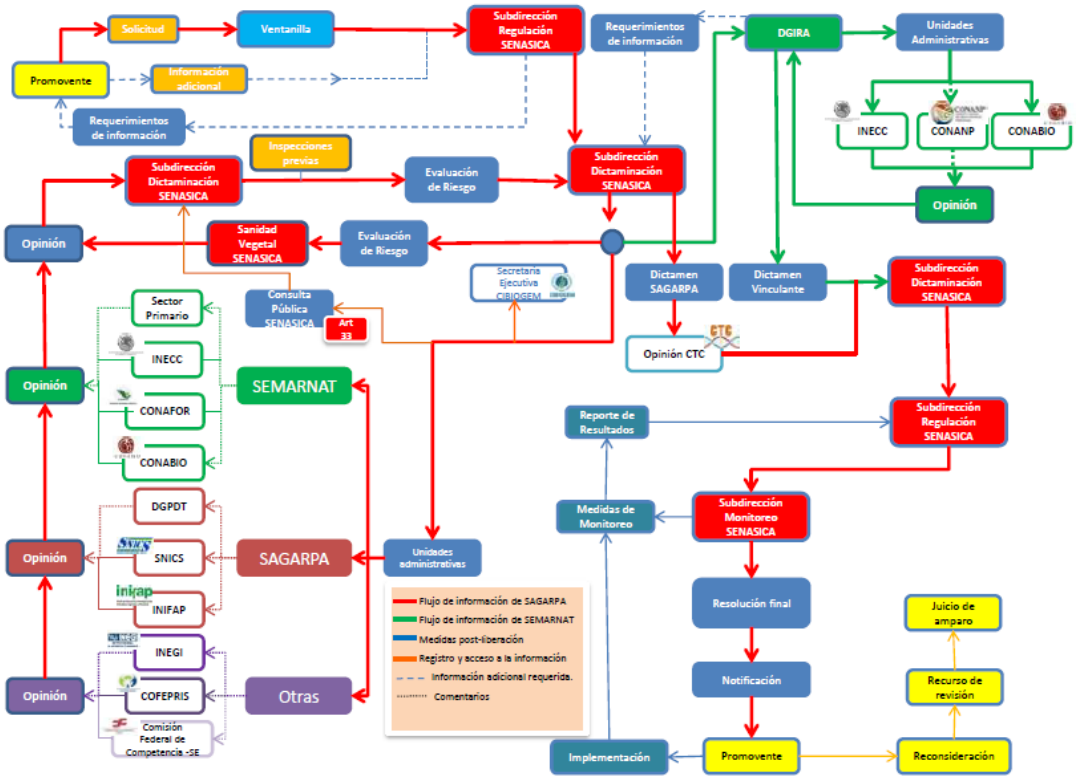
during the experimental and pilot stages.

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 1 presents a general chart that illustrates the complicated approval for permit procedure, but it does portray a complete visual for each part of these procedures is that is presented by 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. However, this is not always adhered to.

Fig. 1. Procedure for the resolution of permits.



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 Organisms 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 Table 5 illustrates information about authorizations since 1995 and Table 6 presents information regarding the resolution of permits for the last 5 years.

Table 5. Mexico: Authorized Events for Consumption in Mexico

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

b) FIELD TESTING

Field testing of GE crops started in Mexico in 1988 and had grown continuously with participation from both private and public institutions up until 2005, when the Biosafety Law was published. After the Law was published, only private institutions were able to comply with all 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 RR 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. It is expected GE corn to be the next commercial GE crop permitted, but as previously stated, the final resolutions have been delayed and on hold until resolution of a legal injunction. Table 6 presents a summary of the crops permitted for environmental release on different phases, particular information of the traits of the crops, area of the field release and municipalities which can be found on the Mexican Register of GE organisms.

Table 6. Mexico: Status of the Resolutions of Permit Requests for the Environmental Release of GEOs, Submitted from 2010 to 2014*

		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 (8 NA)	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
	common bean	1	0	0	1
	wheat	5	0	0	5
	lemon	3	0	0	3

*Information as of July, 2015 ** Includes the Events Non-approved (NA) and in Risk Assessment Process (RA).

Source: N ational Information System for Biosafety and Biotechnology at CIBIOGEM

c) STACKED EVENT APPROVALS

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

d) ADDITIONAL REQUIREMENTS

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

f) COEXISTENCE

The Biosafety Law, Provision 90, establishes that free zones of GE organisms 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 GEOs 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 to the conventional food and feed (i.e. grains) but labeling is required for seeds for planting (Provision 101). Labeling information should include the fact 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 has been included in a Mexican Official Norm, NOM (GE seed labeling NOM). An example of the labeling following this new NOM is presented in the figure 2.

Fig. 2, México: Example of a Label for RR Soybeans

h) TRADE BARRIERS
Mexico's Biosafety Law and the Implementation Rules do not specify a threshold limit for GE seeds, but sources stated 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.

i) 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 as Law of Industrial Property.

j) 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 also 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).

k) INTERNATIONAL TREATIES/FORA
Mexico is also part of the International Plant Protection Convention (IPPC), member since 1969 of the Codex Alimentarius (Codex), and the World Organization for Animal Health (OIE) and member of the Organization for Economic Co-operation and Development (OECD). Mexico has a delegation participating on the biotechnology working groups at these international fora, usually coordinated by CIBIOGEM.

l) RELATED ISSUES.
Not applicable.

m) MONITORING AND TESTING
Mexico did face a case of Low Level Presence (LLP) in 2000. However, since then the monitoring experience of GEOs has become much better developed. Authorities in charge of the monitoring programs are SAGARPA and SEMARNAT. Additionally, there are two monitoring networks coordinated by CIBIOGEM; one is the Mexican Network of Laboratories for Detection of GEO (RNLD-OGE). Government, public and private laboratories that comply with the standards for detection are part

of this network and facilitate the detection in case GOM needs a trustable resolution. The second is the Mexican Network for Monitoring of GEO (Red MOGE), whose aim is to monitor for the presence of GEO and the effects (positive and/or negative) of this presence to the environment. Government, public institutions and biotechnology companies are part of this network.

n) LOW LEVEL PRESENCE POLICY

The Secretary of Health regulates and grants Authorizations for GEO intended for direct use as food or feed, or for processing (FFPs). Additionally two Secretariats, SAGARPA and SEMARNAT, are involved in the regulation of GEO's intended for intentional introduction into the environment. Depending on the given use to the GEO under evaluation, one of these 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 a GEO that is not authorized in Mexico for FFP (these cases are within the scope of the Codex Alimentarius);

2) GEO released into the environment without the corresponding permit
2.1) GEO 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) GEO that corresponds to *commercial seed* for intentional planting but lacks a permit.

Most of the situations referred to in number 2 above 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 authorised 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 GE). Therefore, spillage of a commodity, and its subsequent germination, does not necessarily represents a case of LLP; it is seen as an accidental release of a GEO 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 authorised 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 of GEO 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 two 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 the products derived from these crops are directed for authorized uses and not to be saved and re-planted. (A common practice in some agricultural systems where farmers buy certified seed each planting season.)

PART C: MARKETING

a) MARKET ACCEPTANCE

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 any significant lobbying and educational outreach that may be necessary. Generally, Mexican consumers are concerned with the price and quality of their food and not its genetic composition. However, Mexicans 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. For Mexicans, corn is a symbol of their 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 some non-governmental organizations opposed to the adoption of this technology.

b) PUBLIC/PRIVATE OPINIONS

AgroBio is a private organization that represents the major biotechnology developers active in Mexico. 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 public. AgroBio has a webpage with science based information about GEOs and is very active with some members of academia and other open spaces for outreach, although with a very low profile. They organize and/or participate in workshops on biotechnology and biosafety. Every year they organize the AGROBIO awards. These awards of excellence are presented for research in biotechnology, conservation; and for journalism in GE plants and food security issues.

c) MARKETING STUDIES

Not applicable.

PART D: CAPACITY BUILDING AND OUTREACH

a) ACTIVITIES

FAS Mexico City has helped organize capacity building and outreach events that included sending key Mexican stakeholders to the U.S. to learn more about science based biotechnology. Post has also supported international speakers who traveled to Mexico to present information to select audiences

about the benefits of biotechnology.

The Cochran Fellowship Program has been very useful to demonstrate the benefits of biotechnology to Mexican officials who participate in the biotechnology short course at Michigan State University (MSU). In 2012, there were two participants, one from SAGARPA and one from SEMARNAT. In 2013, three participants from SAGARPA, SEMARNAT and CIBIOGEM participated in this same program. Feedback from program participants showed that they appreciated the academic content of the course, practical exercises conducted in laboratories, greenhouse and field visits, as well as the opportunity for the participants to share information first-hand about ways agricultural biotechnology is applied in the U.S. as well as in other countries. Participant feedback also indicated that their course objectives were met and many noted that the information they acquired during the course and the sharing of experiences with participants from other countries strengthened their technical knowledge and understanding of the use of GEOs and their use in sustainable agriculture.

In 2014, there were six Mexican participants from SEMARNAT, SAGARPA and CIBIOGEM who took part in the Biotechnology short course at Michigan State University courtesy of the Cochran Fellowship Program. Additionally in 2014, three Mexican officials participated in the Missouri State University course on Regulation of Biotechnology, funded by the U.S. Soybean Export Council. In 2015, eight participants are scheduled to take an advanced biotech short course also funded by the Cochran Fellowship Program.

FAS Mexico City has been successful in competing for State Department funded biotechnology projects. The State Department has been a valuable funding resource that helps post select and bring in expert international speakers to Mexico for various biotech outreach activities During these events scientists not only participated as authoritative speakers in their field, but also met with high level GOM decision makers and shared their first-hand knowledge about the benefits of science based agricultural biotechnology.

In 2014, the State Department's Ag Biotech Outreach Program approved and funded post's proposal for the development of educational videos in Spanish related to agricultural biotechnology. The main purpose of this activity was to clearly communicate the basics in layman's terms about the science-based benefits of GEO consumption for human health, its safe use for the environment, including co-benefits and coexistence with different activities.

b) STRATEGIES AND NEEDS

Mexico does not have a public national strategy, but CIBIOGEM coordinates efforts of all the Secretaries involved in biotechnology and biosafety and have developed a set of outreach initiatives including weekly seminars transmitted by the Inter‐American Institute for Cooperation on Agriculture (IICA) to other Latin American countries, as well as the Opening Doors Day outreach event and presenting other educational activities for the general public on National Science Day. Additionally, CIBIOGEM has a webpage where regulations and science-based information about GEOs and some activities related to the social media can be found.

While maintaining a low profile, CIBIOGEM has organized several capacity building and outreach activities directed to authorities, academy and journalists.

Through the North America Biotechnology Initiative (NABI), Mexico continues to harmonize its regulatory approach to agricultural biotechnology with its NAFTA partners, the United States and Canada. NABI is a forum for technical information exchange and for high-level policy discussion on biotechnology. It exists to identify and solve issues of common interest as well as to identify areas for further cooperation. This forum helps Mexico identify and address regulatory gaps and promotes a trilateral harmonized approach to agricultural biotechnology regulations. For example, under NABI Mexican CIBIOGEM, SAGARPA, SEMARNAT and Health officials have routine conference calls with their counterparts (i.e., USDA, EPA, and FDA) in the United States and Canada.

For the last several years SAGARPA has organized Regional Forums to discuss and educate the public about, among other things, GE crops. For example, in June of 2013, a public consultation forum was conducted in Ciudad Obregon. The most recent consultation forum, in July 2014, was conducted in Irapuato, Guanajuato.

Mexico is equipped with knowledge and expertise in agricultural biotechnology and has regulatory systems in place to assess biotech products. However, Mexico is still at crossroads due to partial negative public perception of the technology and concerns about the environmental impacts of GE crops. To address the challenge of the negative public perception, both strategic engagement with stakeholders and effective messaging based on science is necessary. This engagement should help strengthen and improve the quality of communication among different stakeholder groups, including the media, public, and Government of Mexico.

CHAPTER 2: ANIMAL BIOTECHNOLOGY

PART E: PRODUCTION AND TRADE

BIOTECHNOLOGY PRODUCT DEVELOPMENT:
According to official sources, genetic engineering is not being used in Mexico for the development of agriculturally relevant animals and no work is being done in this area. However, if it were to be carried out in the future, the relevant institutions would be the Biotechnology Institute of Mexico's National Autonomous University (UNAM) and the Center of Research and Advanced Studies of the National Technical Institute (CINVESTAV).

a) COMMERCIAL PRODUCTION:
There are no genetically engineered animals or products derived from animals intended for or currently in commercial production in Mexico. Despite the significant human and physical infrastructure that Mexico has in the biotech 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.

b) BIOTECHNOLOGY EXPORTS:
Not applicable.

c) BIOTECHNOLOGY IMPORTS
Not applicable.

PART F: POLICY

a) REGULATION:
In Mexico, biotechnology regulation is generally applied to organisms 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 biotech framework that regulates the development, commercial use, import and/or disposal of genetically engineered animals or products derived from these animals. Similarly, SAGARPA, SEMARNAT and Health are the Mexican Secretariats that monitor and/or enforce biotechnology regulations for Animal Biotechnology (see Chapter 1. Part B).

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.
(Same regulations as GE plants, see Chapter 1. Part B).

ii. Assessments of the political factors that may influence regulatory decisions related to animal biotechnologies, including clones and GE animals.
The partial negative public perception in Mexico toward GE plants can 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) LABELING AND TRACEABILITY:
(Same as for GE plants, see Chapter 1. Part B).

c) TRADE BARRIERS:
Not applicable.

d) INTELLECTUAL PROPERTY RIGHTS (IPR):
(Same as for GE plants, see Chapter 1. Part B).

e) INTERNATIONAL TREATIES/FORA.
Mexico is member of the Codex Alimentarious 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 are some subjects that come up for discussion related to GE fish, GE insects and GE microorganisms.

PART G: MARKETING

a) MARKET ACCEPTANCE:
(Same as GE plants, see Chapter 1, Part C).
b) PUBLIC/PRIVATE OPINIONS:
Official sources indicate that 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.

c) MARKET STUDIES:
Not applicable.

PART H: CAPACITY BUILDING AND OUTREACH
a) ACTIVITIES: Not applicable.

b) STRATEGIES AND NEEDS:
In general, the public and regulators lack knowledge about genetically engineered animals and it is essential that they become educated and informed about this subject.

Author Defined:

For More Information
FAS/Mexico Web Site: We are available at http://www.mexico-usda.com.mx or visit the FAS headquarters' home page at www.fas.usda.gov for a complete selection of FAS worldwide agricultural reporting.

Useful Mexican Web Sites: Mexico's equivalent of 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.senasica.gob.mx/ and at http://www.conacyt.gob.mx/cibiogem/ The equivalent of the U.S. Department of Commerce (SE) can be found at www.economia.gob.mx, and the equivalent of the U.S. Food and Drug Administration (SALUD) can be found at www.salud.gob.mx. 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.