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Mexico

Agricultural Biotechnology Annual

Research and Regulation Advance Leaving Ag Biotech at a Standstill

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Report Highlights:
Court injunctions against genetically engineered (GE) corn trials continue to affect Mexican producers and the scientific community, as field trails of GE corn are suspended. Consultations with indigenous groups are required prior to granting commercial permits of GE soybean as established by the Mexican Supreme Court.

Section I. Executive Summary:

Mexico is equipped with knowledge and expertise in agricultural biotechnology. Scientists are developing advances in biotechnology crops, which afford the country more opportunities to enter into sustainable agriculture, including crop varieties that can tolerate drought conditions, as well as other benefits like reduction in fertilizer and herbicide use. Mexico also has regulatory systems in place to evaluate biotechnology products; however, there have been delays in the release of permits and injunctions have suspended the planting of GE corn and soybean. Meanwhile, Mexico depends on imports of corn for animal feed. White and yellow corn imports come from countries that produce mainly GE corn. Mexico also depends on the importation of GE oilseeds like it does GE soybeans.

Section II. Author Defined:

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PART A: PRODUCTION AND TRADE

a. PRODUCT DEVELOPMENT:

There are clusters of the biotechnology industry located in several Mexican states. In Guanajuato, there are institutions that carry out research on biotechnology, including the National Laboratory of Genomics for Biodiversity (LANGEBIO). LANGEBIO is one of the most important centers for sequencing and functional analysis of the genome of plants, animals and microorganisms of potential use for applications in agriculture, medicine, and industry. In Nuevo Leon, the Technological Institute of Higher Studies of Monterrey (ITESM) has a Biotechnology Center, which integrates programs of chemical, agro-biotechnology, biology and biomedical engineering. In Morelos, the National Autonomous University of Mexico (UNAM) leads the cluster of life sciences in the state, and maintains an Institute of Biotechnology, specializing in plant molecular biology, molecular medicine, and biotechnology, and a Center for Genomic Sciences.

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 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 gives the plants a selective advantage over other plants. 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 in Argentina, because Mexican requirements are difficult to complete by national researchers. In Mexico, over 100 requirements must be fulfilled before a researcher can obtain a permit for experimental planting; this makes the process both timely and costly.

CINVESTAV-Mexico City developed GE corn "CIEA-9". This research group seeks to develop drought-tolerant GE corn that can also resist low temperatures. Using antisense ribonucleic acid, 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 that of 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 implantation of the 2005 Biosafety law. This and more permits issued for national developments could change the perception that only multinational companies are utilizing agricultural biotechnology. The next stage of this research, and the last step required by Mexican law before CINVESTAV can apply for a permit for commercial planting, is to cultivate 4-hectare experimental plots of CIEA-9 to test productivity.

The same research team in CINVESTAV is developing a GE lemon tree (*Citrus aurantifolia*) and citrus oranges (*Citrus x sinensis*) resistant to the disease known as Huanglongbing (HLB). They obtained three release permits in 2014 to test different events (Antimicrobiano 1, Antimicrobiano 2 and Antimicrobiano 1 & 2) in Tecoman, Colima. The research team is waiting for the resolution of three experimental and three pilot permits in the same region.

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

The non-profit International Maize and Wheat Improvement Center (CIMMYT) has conducted GE wheat field testing over the past nine years. With a staff of 1,100 employees 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. GE wheat tested in experimental releases on plots of 0.1 hectares in Tlaltizapán, Morelos. The trait tested is drought resistant.

Table 1. **Mexico: GE Wheat Events Tested 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 biotechnology facilities within CIMMYT headquarters near Mexico City to promote research and the development of agricultural technology to increase productivity and reduce hunger. These facilities allow for the development of GE corn and wheat.

A legal battle over GE corn has affected Mexican producers and the scientific community. Years after activists challenged scientists' right to plant experimental GE varieties of the crop, a legal stalemate has stymied corn research. On July 5, 2013, a coalition of activist anti –biotech groups filed a class-action lawsuit to stop the Mexican government from granting permits to plant GE corn. In September 2013, a judge ordered a halt to experimental and commercial planting — 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 threatens to derail work that could boost corn yields and help protect against threats, such as climate change.

b. COMMERCIAL PRODUCTION:

According to the Biosafety Law, GE crops must go through three testing phases: experimental, pilot, and commercial. Permits for field trials 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 area limit, it is variable and in accordance with the objectives proposed by the developer.

Cotton

In January 2017, SAGARPA through the National Service for Agri-Food Health, Safety and Quality (SENASICA) gave official recognition to the region of La Laguna for the eradication of 99 percent of pink bollworm and 50 percent of the Boll Weevil in cotton.

On January 22, 2015, SAGARPA through SENASICA gave official recognition to the state of Chihuahua for reaching the status of "free zone from pink bollworm in cotton." On February 3, 2016, SAGARPA gave this recognition to the Mexican 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 used to

eradicate pests included integrated pest management, GE seeds, and 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, 85 percent of Mexico's cotton producing area is now free of pink bollworm and 70 percent of boll weevil 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 1 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 August 2017, Mexican federal biotechnology regulators took custody of 1,500 hectares of GE cotton fields as a precautionary measure after finding events, not explicitly mentioned on permits that were granted in the state of Chihuahua and La Laguna region (See FAS GAIN report MX7049).

Soybeans

The second GE crop that reached the commercial state under the Mexican regulation is soybean. The first commercial permits for GE soybeans were issued in 2012. Soybean production is industrialized for food and feed products. 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 industry 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, the environment or health, but recommended a consultative process with the indigenous communities 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. The process has been transparent and in some communities expedited, and a willingness to accept the use GE soybean. There are other localities, however, where the communities have delayed this process.

There have been no applications for commercial releases of GE soybeans since 2013.

Table 2. Mexico: Area Permitted for Release of GE Crops, 2016 Applications (hectares)

	Experimental	Pilot	Commercial	Total
Cotton	2	953	9000	9955
Wheat	0.3	0	0	0.3

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

c. EXPORTS:

Mexico has a deficit in corn, cotton, and soybean production and does not cover domestic demand. The production of GE crops is for domestic consumption.

d. IMPORTS:

Mexico depends on corn imports for animal feed while at the same time it reconciles concerns with the costs associated with restrictive policies against cultivating GE corn. 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 the Agro-Food and Fishery Information System (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 that accounts for nearly 100 percent of total imports. Mexico also depends on the importation of GE oilseeds like GE soybeans and GE rapeseed. Imported soybeans are mainly from the United States, and imported rapeseed is mostly from Canada.

Table 3. Mexico: Total Imports of Crops with GE Content.

	2015/2016	**2016/2017**	**2017/2018**
Corn	14,011	14,200	15,500
Cotton	1021	1,028	1,000
Soybean	4,126	4,200	4,380
Rapeseed	1,417	1,500	1,600
1000 MT			

Source: FAS GAIN reports MX7016, MX7011 and MX7007.

Mexico has authorized for food and feed 164 GE events from nine species. Considering that these are equivalent to conventional products, imports are not labeled.

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 2 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 take place at warehouses in order to avoid rejections at the border. This percentage level is a potentially serious area of contention for many importers, because there is uncertainty on the use of zero-tolerance or 2 percent.

The Mexican state of Yucatan declared itself a "GMO" free zone, to include GE crops and all GE products. The 2016 Decree was issued without SAGARPA's endorsement and has been challenged by the Federal government in the National Supreme Court of Justice. This decree could represent an important trade barrier to GE products.

PART B: POLICY

a. REGULATORY FRAMEWORK:

Mexico's comprehensive biotech regulation is the Biosafety Law, published in the 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 health, 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 eight 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 the Secretariat of Environment and Natural Resources (SEMARNAT) and SAGARPA. Both Secretariats have established their decreed measures for these areas on the Agreement. So far, only eight 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.
(NOTE: The Mexican Biosafety Law states that the "confined use" of a "GMO" is any activity by means of which the genetic material is modified or through which this material 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 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 plants, animals or microorganisms, and to track their progress. On the other hand, this agreement allows developers, universities, and research institutions engaged in the confined use of GE plants, animals or microorganisms 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 the Federal Register (*Diario Oficial*) in December 2014 and took effect in June 2015 (GE seeds labeling NOM). 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 for agricultural production. According to Provisions 9 and 12 of the Biosafety Law on GE Organisms, it is necessary to determine in a NOM the information and characteristics of the labels for GE seeds.

Complete 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). 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 secretariats are as follows:

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 with GE animals, plants or microorganisms 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 activities related to GE animals, plants or microorganisms are permissible. It issues permits and receives notifications for those activities. SAGARPA also provides guidelines and parameters for all experiments and activities related to GE animals, plants or microorganisms. These activities include the following: experimental field trials, pilot program releases, commercial releases, marketing, as well as GE animals, plants or microorganisms imports. SAGARPA is responsible for monitoring and mitigating the effects that accidental or permitted release of GE animals, plants or microorganisms may cause to animals, plants, aquatic health, and biological diversity.

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 activities carried out with GE animals, plant or microorganisms may cause to the environment and biological diversity. This analysis is risk assessment based and results are 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 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 GE animals, plant or microorganisms. In instances in which SAGARPA has primary responsibility, SEMARNAT is 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 ensure the food safety of GE derived agricultural products destined for use as medicines or for human consumption. SALUD also assesses, on a case-by-case basis, studies drafted and filed by interested parties on the safety and potential risks of GE animals, plants or microorganisms 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.

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 GE animals, plants or microorganisms 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, SALUD, Finance and Public Credit, Economy, and Education. CIBIOGEM´s presidency is held for periods of two years on a rotating basis among the Secretariats of SAGARPA, SEMARNAT, and SALUD. Currently, SEMARNAT is in the first 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, an Executive Secretary leads CIBIOGEM and 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.

Under the current Administration, there have been delays in the release of permits. Additionally, GE corn and GE soybean are currently blocked by provisional legal injunctions that have no clear timelines for resolution. Almost every week the subject of GE corn comes into play in the Mexican media, often with strong emotions. 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. In 2009, Mexico City, and in 2011, Tlaxcala, declared their states ¨GMO" free zones to include GE crops. According with the Federal law, GE free zones are determined not by local state governments, but by SAGARPA.

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 one commodity with more events authorized for consumption, with 80 of the 164 events approved being corn.

The difference between approval (Authorization) for food and feed and approval (Permits) for environmental release is that authorizations are definitive (that being, not time-limited), unless there is some new scientific evidence that shows harm to health. Permits, however, are usually only for one growing period and granted every planting –harvesting cycle. Commercial permits can be 5, 10 years or not time-limited, however, the responsible party of the permit must present annual reports and are monitored frequently, which can be costly. SAGARPA regulates environmental release of domesticated species (crops, livestock, and fishery). SEMARNAT regulates wild species. SEMARNAT is the agency responsible for issuing biosafety opinions and this is 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.

GOM published the Organic Products Law in the Federal Register February 7, 2006. This law establishes additional regulations for the use of biotech-derived food products. The three specific areas in which this law regulates biotech-derived products are as follows:

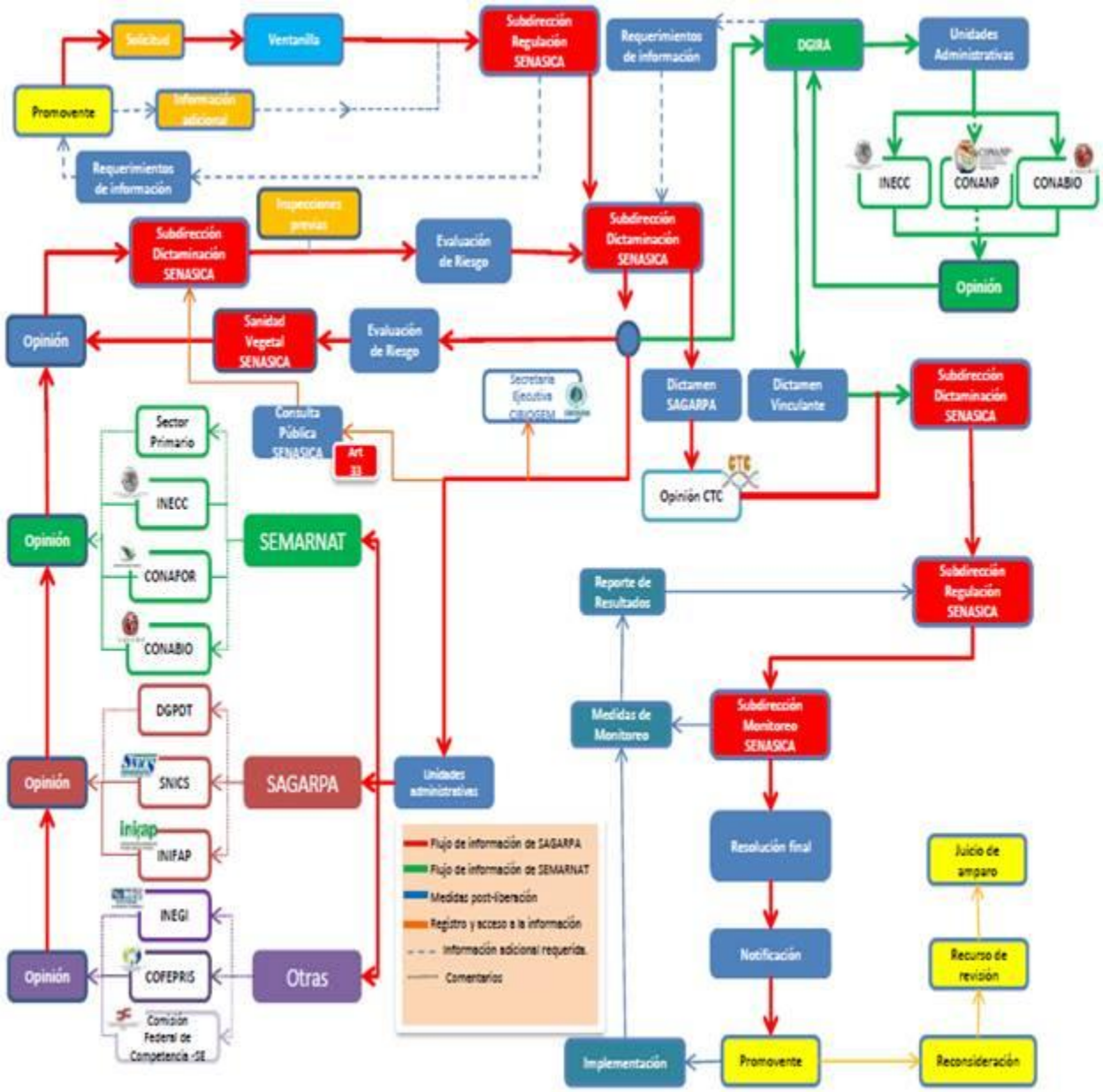
i. Provision 27 of the Law states that the use of all materials, products, and ingredients or inputs that come from, or have been produced with genetically engineered, are prohibited in the entire production chain of organic products and the product must be labeled as GE-free.
ii. The Law also prohibits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

A standard that establishes the requirements for the risk assessment of GE plants during the experimental and pilot stages was included in a NOM submitted for public comments in 2017 (see FAS GAIN report MX6051).

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. 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 (bylaw) establish a maximum of six, three, and four months for the resolution by the authorities for experimental, pilot or commercial release, respectively. These times are not always adhered.

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 SALUD and SAGARPA), and a section for the confined notifications. For additional information, refer to CIBIOGEM´s website.

Table 4. Authorized Events for [Food and Feed] Consumption

Crop		Authorized events
Alfalfa	*Medicago sativa*	4
Canola	*Brassica napus*	9
Cotton	*Gossypium hirsutum*	36
Corn	*Zea mays*	80
Potato	*Solanum tuberosum*	3
Rice	*Oryza sativa*	1
Soybean	*Glycine max*	27
Sugar beet	*Beta vulgaris*	1
Tomato	*Lycopersicum esculentum*	3
Total		164

Source: National System of Biosafety information, CIBIOGEM

NOTE: In the Biosafety Law, it is established that in order to be able to import GE crops, in addition to the technical requirements, the interested party must attach the information and documentation certifying that the GE crop is authorized under the legislation of the country of origin. Failing that, the interested party shall declare that there is no such situation, and shall set out the considerations that support the Secretariat of Health resolution of the application for authorization. The Biosafety Law mentions that for the authorization the GE crop, it must have been approved previously in their origin country, or explained why the interested party considers that the Secretariat of Health has all the elements to resolve the authorization (only for authorizations, not for the permits). There are no crops authorized that are not approved in the country of origin. The GE crops authorized in Mexico developed in United States must present a letter from the Food and Drugs Administration (FDA). The difference with the evaluation of FDA is that in Mexico the law establishes that the authorization must be resolved in 6 months. In Mexico, the recommendation to avoid low level presence problems is to be proactive and obtain the authorization of all the possible GE crops in trade, the process is relatively fast. Mexico is one of the countries with more authorizations for food and feed in the world. END NOTE.

c. STACKED OR PYRAMIDED EVENT APPROVALS:

For stacked or pyramid events, the Mexican biosafety regulation does not require additional reviews that combines two or more already-approved genetically engineered traits. In practice, the Mexican government evaluates them as a different event than the parental ones.

d. FIELD TESTING:

According to the Biosafety law and subsequent regulations, field testing of GE crops is allowed in Mexico. All field testing must obtain a permit following the process illustrated in the Figure 1. Only eleven from 48 applications for permits for field testing in 2016 and 2017 have received a positive resolution, 34 are pending and 3 were rejected for missing information (see table 5).

Table 5. Status of the Resolutions of Permit Requests for field testing in Experimental or Pilot state of GE crops, 2016 and 2017*

		Experimental	Pilot	Total Permitted
2016	Alfalfa	0	1 NA	0
	Cotton	2(5 RA)	6 (4 RA)	8
	Lemon	0	3 RA	0
	Orange	3RA		0
	Wheat	2	0	2
2017	Cotton	6RA	1 (12RA)(2NA)	1
	Alfalfa	1RA		0

*Information as of October 2017 includes the events non-approved (NA) and in risk assessment process (RA). 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 with a previous dictate from CIBIOGEM by means of agreements to be published in the Federal Official Register.

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).

h. MONITORING AND TESTING:

Authorities responsible for the monitoring programs are SAGARPA and SEMARNAT.

The following are two monitoring networks coordinated by CIBIOGEM:

The Mexican Network of Laboratories for Detection of "GMO" 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 in amount and kind of GE crop is needed, for example as evidence in cases of intentional or unintentional release.

The second monitoring network is the Mexican Network for Monitoring of "GMO", whose aim is to monitor for the presence of unauthorized GE plants or animals and their impact (positive and/or negative) on 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 (LLP) POLICY:

The different situations of LLP that can occur in Mexico are:
1) Presence in the food chain of an unapproved trait that is not authorized in Mexico for food, feed and processing (FFP) (these cases are within the scope of the Codex Alimentarius);
2) Released into the environment without the corresponding permit:
2.1) GE crops 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) GE crops 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 faced a low level presence (LLP) case in 2000.

1.Train derailments resulting in cargo spills of commodities that functioned as seed:
GE 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 GE corn). 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 GE 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 as well as agricultural practices still predominant in traditional systems that include experimentation with new varieties and selection of seed from each harvest to be used 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 are 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). Mexico was obligated under the CPB to pass domestic legislation that harmonizes its domestic laws with its international obligations. This ratification helped ensure final congressional approval for the Mexican Biosafety Law in February 2005.

m. INTERNATIONAL TREATIES/FORUMS:

Mexico is part of the International Plant Protection Convention (IPPC), a member of the Codex Alimentarius (Codex since 1969), as well as a member of the World Organization for Animal Health (OIE) and the Organization for Economic Cooperation and Development (OECD). Mexico participates in 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 more food efficiently, under more volatile production conditions, and 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, political will is needed.

PART C: MARKETING

a. PUBLIC/PRIVATE OPINIONS:

Non-governmental organizations (NGOs) are 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 and to share and disseminate scientific knowledge to policy makers, lawmakers, and the general public.

b. MARKET ACCEPTANCE/STUDIES:

In general, 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. NGOs opposed to the adoption of this technology have amplified the debate.

In a recent study funded by CIBIOGEM, it observed that in terms of benefits and risks perceived in GE products use, 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 benefit the economy and environment. By the contrary, high risks are perceived in GE product use. For the individuals surveyed, they considered that the use of GE crops could have health consequences. As for the attitude towards

purchases, there are preferences to buy GE products, if they are lower in fat content than the conventional or organic counterpart. Regarding the trust attributed to those who work with GE products, consumers have the greatest confidence in universities and scientists at the national level. According to the study, the general public lacks confidence in companies developing GE products.

CHAPTER 2: ANIMAL BIOTECHNOLOGY
PART D: PRODUCTION AND TRADE

a. PRODUCT DEVELOPMENT:

According to official sources, genetic engineering is not used in Mexico for the development of agriculturally relevant or any other animals.

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:

No exports of GE or cloned animals.

d. IMPORTS:

Mexico is highly dependent upon imports for genetics in livestock production, particularly for ruminants.

e. TRADE BARRIERS:

The Mexican state of Yucatan declared itself "GMO" free zone, to include GE crops and all GE products. This includes GE animals. The Decree in 2016 was issued without the SAGARPA endorsement and has been challenged by the Federal Government in the National Supreme Court of Justice. This could represent an important trade barrier to GE animal products.

PART E: POLICY

a. REGULATORY FRAMEWORK:

In Mexico, biotechnology regulation is generally applied to species and does not make a particular differentiation among plants, animals or microorganisms. 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.

Same as GE plants

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.

Same regulations as GE plants

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:

Same regulations as GE plants

d. INTELLECTUAL PROPERTY RIGHTS (IPR):

Same as GE plants

e. INTERNATIONAL TREATIES/FORUMS:

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:

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 and animals could play a central role in enabling Mexican producers to meet these core challenges. However the political will is needed.

PART F: MARKETING

a. PUBLIC/PRIVATE OPINIONS:

There is no current outspoken opposition to GE animals. There could be, however, 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:

Not applicable