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Uncertain Future for Mexican Agricultural Biotechnology

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Report Highlights:

The incoming Presidential administration is creating additional uncertainty about the future acceptance of biotechnology and genetically engineered (GE) crops in Mexico. Legal injunctions against GE corn trials continue to affect Mexican producers and the scientific community as field plantings of GE corn in Mexico have been suspended. Consultations with indigenous groups were conducted as established by the Mexican Supreme Court to grant the commercial permit of GE soybean but at this time no GE soybeans are being planted in Mexico.

EXECUTIVE SUMMARY

Mexico is equipped with knowledge and expertise in agricultural biotechnology. Scientists are developing advances in biotechnology crops, which afford the country opportunities to develop more sustainable agriculture, including crop varieties that can tolerate drought conditions, as well as other benefits like a reduction in fertilizer and herbicide use. Mexico also has regulatory systems in place to evaluate biotechnology products but delays in the release of permits and current legal injunctions have suspended the planting of GE corn and soybeans. Meanwhile, Mexico depends on imports of corn for animal feed, more than 95 percent of which it imports from the United States. Mexico also depends on the importation of oilseeds like GE soybeans. Even though only GE cotton is currently cultivated, Mexico is one of the countries with the most authorizations for feed and feed use in the world. However, rhetoric by officials of the incoming Presidential administration, along with appointments of several vocal anti-biotechnology activists to key policy positions, is creating concern about the future of biotechnology in Mexico.

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CHAPTER 1: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

a. PRODUCT DEVELOPMENT:

There are clusters of the biotechnology industry located in different states of the country. Several institutions are located in Guanajuato that carry out research on biotechnology, including the National Laboratory of Genomics for Biodiversity (LANGEBIO). LANGEBIO is one of the most important centers in the world for sequencing and functional analysis of the genome of plants, animals and microorganisms, one of the first steps of basic science to search for 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, agrobiotechnology, 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 efficacy of fertilizers and weed control, which compete for the use of phosphorus in the soil. The trait gives the plants a selective advantage over other plants because these GE crops can obtain 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, which are unable to assimilate phosphite, are unable to compete against the GE crops. In theory, the use of these new GE crops would reduce the amount of fertilizer required between 30 and 50 percent, eliminate or reduce the use of herbicides, and is harmless to humans and animals. The group is developing GE soybean and cotton in Mexico but plans are to do the experimental trails in Argentina because of the strict Mexican requirements. In Mexico, a researcher must fulfill over 100 requirements before they can obtain a permit for experimental planting, making the process both time consuming 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 compared to 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 public sector development 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 orange (*Citrus x sinensis*) resistant to the disease known as Huanglongbing (HLB). The team obtained three release permits in 2014 to test different events in Tecoman, Colima. The research team has permits for three experimental and three pilot permits in the same region.

Mexico’s National Institute of Forestry, Agriculture and Livestock Research (INIFAP) has been doing research on GE common 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) have conducted field tests of GE wheat since 2008. 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. GE wheat has been tested in experimental releases on plots of 0.15 hectares in Tlaltizapán, Morelos. The trait tested is drought resistant. For the

period 2018-2019, CIMMYT has experimental permits in process for seven wheat events, as shown in Table 1.

Table 1. Mexico: GE Wheat Events with permit in process at Tlaltizapán, Morelos in winter 2018-2019

Event	Interest character
AVP1	Better biomass production under salinity and drought stress
NAS2	Expression of protein, Fe and Zn.
PSTOL1	Phosphorous starvation tolerance
AVP1-PSTOL1	Better biomass production under salinity and drought stress. Expression of protein, Fe and Zn.
AVP1-NAS2	Better biomass production under salinity and drought stress. Phosphorous starvation tolerance
NAS2-PISTOL1	High potential of yield and expression of protein, Fe and Zn and higher yield.
AVP1-NAS2-PSTOL1	Better biomass production under salinity and drought stress. Expression of protein, Fe and Zn. Phosphorous starvation tolerance

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 technologies 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. The lawsuit and ruling have since stopped the efforts of biotechnology companies and stalled public-sector biotechnology researchers. The lawsuit has prevented any field trial work on GE corn that could boost corn yields and help protect against threats, such as climate change.

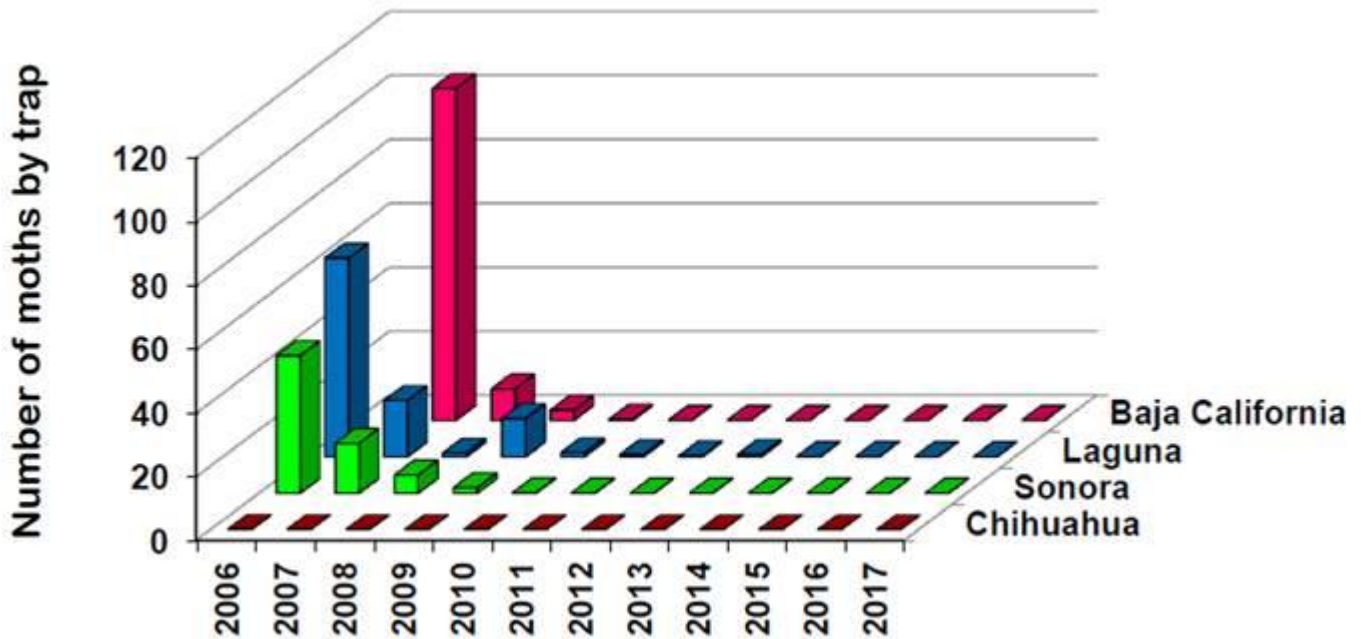
b. COMMERCIAL PRODUCTION:

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

The most important GE crop produced in Mexico is cotton. On 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 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 states of Baja California and Sonora.

Figure 1. Reduction of pink bollworm in cotton regions in Mexico after the use of *Bt* cotton



Source: [Urbano Nava, 2018](#).

Soybeans

The second GE crop that reached the commercial state under the Mexican regulation is soybeans. The first commercial permits for GE soybeans were in 2012. Soybean production is industrialized for food and feed products. 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 commercial permit 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 complaining indigenous communities before continuing with the permit for commercial production (Information on [CIBIOGEM](#)).

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 where there is a willingness to accept the use of GE soybean. There are other localities, however, where the communities have delayed this process.

On September 15, 2017, SAGARPA through SENASICA revoked the 2012 commercial permit for MON-0432-6 GE soybean, after it and another glyphosate-resistant soybean (MON-89788-1) were detected in areas where the planting permit had been suspended as well as outside the permit area. This

was the first time that SAGARPA penalized the applicant for the permit for illegal planting rather than the producers who planted it. Since 2016, no GE soybean has been sold anywhere in the Yucatan peninsula (formed by the states of Campeche, Yucatan, and Quintana Roo). Monsanto appealed SENASICA’s decision but the administrative appeal confirmed SENASICA’s permit revocation in January 2018. Monsanto (now Bayer) is challenging this decision in court.

There have been no applications for commercial releases of GE soybeans since 2013 and there is no planting of GE soybean in the country.

Table 2. Mexico: Area Permitted for Release of GE Crops, 2017 Applications (hectares)

	Experimental	Pilot	Commercial	Total
Cotton	7	163,301	310,000	473,308
Alfalfa	10.87	6	0	16.87

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 imports of corn for animal feed while at the same time it reconciles concerns with the costs associated with its restrictive policies against cultivating GE corn. The Government of Mexico (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 (See Table 3). 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, domestic production accounts for only 50 to 75 percent of Mexican domestic consumption. The United States is the main cotton supplier to Mexico and 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.

	2016/2017	2017/2018	2018/2019
Corn	14,314	16,000	16,700
Cotton	1031	1,044	825
Soybean	4,126	4,300	4,420
Rapeseed	1,543	1,925	1,950
1000 MT			

Source: FAS GAIN reports [MX8024](#), [MX8013](#) and [MX7007](#).

Mexico has authorized 181 GE events from eleven species for food and feed (Table 4). Because these

are considered as equivalent to conventional products, they can be imported without labeling.

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 as either: a) zero-tolerance; or b) 2 percent tolerance of impurities, 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 to avoid rejections at the border. This percentage level is a potentially serious area of contention for many seed importers because of the uncertainty of the use of a zero or 2 percent tolerance.

The Mexican state of Yucatan declared itself a "GMO" free zone in 2016, essentially banning GE crops and all GE products. Yucatan issued its 2016 Decree without SAGARPA's 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 products if the ban is allowed to remain in place.

PART B: POLICY

a. REGULATORY FRAMEWORK:

Mexico's comprehensive biotech regulation is the [Biosafety Law](#), which was 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. So far, only eight Mexican states require protection of such species and geographic areas.

In April 2011, SAGARPA published an agreement in Mexico's Federal Register 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 to be used with the aim of effectively limiting contact with people and the environment. For purposes of this Law, the area of the facilities or the scope of the confined use space cannot be part of the environment END NOTE). According to SAGARPA, this agreement helps gain access to information about who is engaged in 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) [Normativity](#). A description of CIBIOGEM is presented in section (ii).

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:

The Secretariat of Agriculture, Livestock, Rural Development, Fisheries and Food (SAGARPA):

The role of SAGARPA is to analyze and assess, on a case-by-case basis, all of the potential risks to animal, plant, and aquatic health, as well as to the environment and biological diversity, posed by activities carried out 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 and issues permits and receive 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: experimental field trials, pilot program releases, commercial releases, marketing, and 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.

The Secretariat of Environment and Natural Resources (SEMARNAT):

Environmental protection, including biodiversity and wildlife species falls under SEMARNAT's domain. All other species fall under the competence of SAGARPA. The role of SEMARNAT is to analyze and assess, on a case-by-case basis, all of the potential risks that activities carried out with GE animals, plant or microorganisms may cause to the environment and biological diversity. This analysis is based on risk assessment studies and results drafted and filed by interested parties. In addition, SEMARNAT is responsible for permitting and licensing activities that involve the environmental

release of GE wildlife species and is charged with providing guidelines and parameters for such activities. SEMARNAT also monitors the effects on the environment or biological diversity that may be caused by the accidental release of GE animals, plant or microorganisms. In instances in which SAGARPA has primary responsibility, SEMARNAT is still responsible for issuing bio-safety opinions prior to SAGARPA's resolution. (NOTE: SAGARPA, not SEMARNAT, issues approval for environmental release for crops, livestock and fisheries, although SEMARNAT renders an opinion to SAGARPA beforehand through their inter-agency process. END NOTE)

Secretariat of Health (SALUD):

The role of the Secretariat of Health is to 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.

Biotechnology policy activities in Mexico are coordinated by the Inter-secretarial Commission on Biosafety of Genetically Modified Organisms (CIBIOGEM). However, 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 second year of its tenure as President of the Commission. CIBIOGEM has a Vice President, permanently held by the Director General of CONACYT. According to the Biosafety Law, CIBIOGEM is led by an Executive Secretary who is nominated by CONACYT after consultations with the member Secretariats and then approved by the President of Mexico.

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. The subject of GE corn often appear 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. Mexico City in 2009 and the state of Tlaxcala in 2011 declared their states "GMO" free zones to prohibit GE crops. According to Federal law, GE free zones will be determined not by local state governments, but by SAGARPA.

The incoming Agriculture Secretary in the new Presidential administration Dr. [Victor Villalobos](#) has mentioned in different media interviews [1] that there will be no planting of GE crops in this new government. Several new officials named for key policy posts are vocal opponents of biotechnology. The incoming head of the Science and Technology Council ([CONACYT](#)) Maria Elena Alvarez is a founding member of the Union of Scientists Committed to Society ([UCCS](#)). She published a [paper](#) about the presence of GE corn and glyphosate in tortillas. The new Secretary of Environment and Natural Resources (SEMARNAT) Josefa Ortiz Blanco also mentioned [to the media](#) that she would like

to forbid the use of GE crops.

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 90 of the 181 events approved being corn.

The difference between approval (Authorization) for food and feed and approval (Permits) for environmental release is that authorizations are definitive (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 need to be granted every planting-harvesting cycle. Environmental release is regulated by SAGARPA in the case of domesticated species (crops, livestock, and fishery) and by SEMARNAT in the case of wild species. SEMARNAT is the agency responsible for issuing biosafety opinions and this is done before any resolution can come from SAGARPA.

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. The three specific areas in which this law regulates biotech-derived products are as follows:

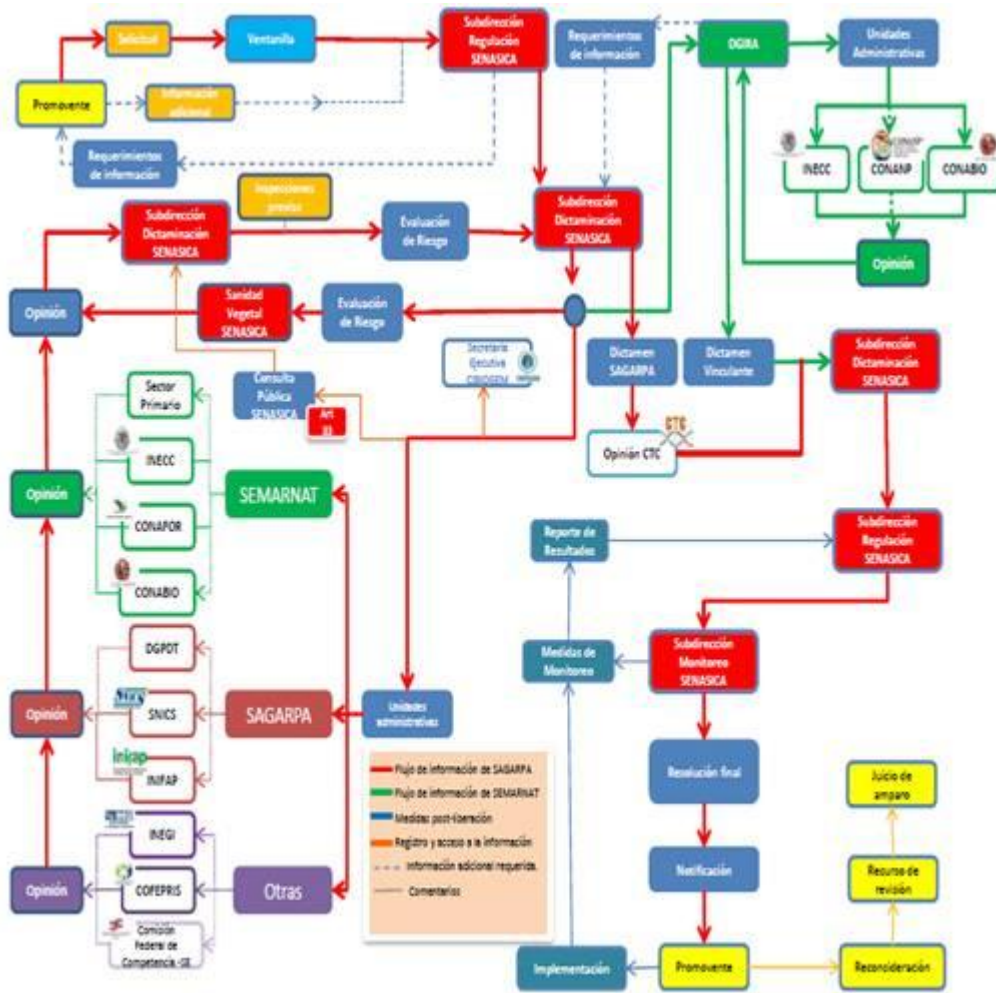
- i. Provision 27 of the Law states that the use of all materials, products, and ingredients or inputs that come from, or have been produced using genetic engineering, are prohibited in the entire production chain of organic products and the product must be labeled as GE-free;
- ii. The Law also prohibits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

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

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

The procedure for the approval of permits for experimental, pilot or commercial release of GE crops is complex (See Figure 1). Multiple commissions and committees inside SAGARPA and SEMARNAT must provide opinions about the release. The main authority is SAGARPA with the assistance of SENASICA but the only binding opinion is the one of SEMARNAT through the General Direction of Environmental Risk (DGIRA). A complete explanation of the procedure can be find [here](#).

Figure 2. Procedure for the Resolution of Permits.



Source: CIBIOGEM

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

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. All this information is presented on the [CIBIOGEM](#) website.

Table 4. Authorized Events for Consumption in Mexico

Crop	Authorized events
Alfalfa <i>Medicago sativa</i>	4
Canola <i>Brassica napus</i>	10
Cotton <i>Gossypium hirsutum</i>	30

Cotton	<i>Gossypium barbadense</i>	6
Corn	<i>Zea mays</i>	90
Lemon	<i>Citrus aurantifolia</i>	2
Potato	<i>Solanum tuberosum</i>	6
Rice	<i>Oryza sativa</i>	1
Soybean	<i>Glycine max</i>	28
Sugar beet	<i>Beta vulgaris</i>	1
Tomato	<i>Lycopersicon esculentum</i>	3
Total		181

Source: [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 Secretary of Health resolution of the application for authorization. The Biosafety Law states that the authorization of the GE crop must be approved previously in the origin country or the interested party must explain why it believes that the Health Secretary in Mexico has all the elements to resolve the authorization (only for authorizations, not for permits). Until now, all GE crops authorized in Mexico developed in the United States must present a letter from the Food and Drugs Administration (FDA). In Mexico, the law establishes that the review for authorization must be resolved in 6 months. Because the recommendation in Mexican law to avoid low-level presence problems is proactive and its goal is to obtain the authorization of all the possible GE crops in trade, the authorization process is relatively fast. Mexico is one of the countries with the most 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 combine two or more already approved genetically engineered traits. However, in practice, Mexican government regulators consider these to be different events from the parental ones and will evaluate them as their own.

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. There were applications for only three crops during 2017 and 2018: alfalfa, cotton and wheat. GE cotton continues to be the favorite of the producers, with 22 permits for field release, 15 permits in process for risk assessment, and only 3 non-authorized permits that were resubmitted because of missing information and authorized as new permits (see Table 5).

Table 5. Status of the Resolutions of Permit Requests for field testing in Experimental or Pilot state of GE crops, submitted from 2017 to 2018*

		Experimental	Pilot	Commercial	Total Permitted
2017	Alfalfa	1	1		2
	Cotton	2	16 (1 RA)(2NA)	3(1NA)	21
2018	Cotton	1	(12RA)	(2RA)	1
	Wheat	(7RA)			0

*Information as of September 2018 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 by the technical areas of CIBIOGEM.

f. COEXISTENCE:

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 are to be established when GE crops coincide with the same species resulting from production processes yielding organic agricultural products, when it is scientifically and technically demonstrated that their coexistence is not viable, or when the GE crops would not comply with the normative requirements for their certification. Such zones will be determined by SAGARPA with a previous dictate from CIBIOGEM and the opinion of the National Commission for the Understanding and Utilization of Biodiversity. Determinations will 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.

There 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 trusted 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:

In Mexico, there is no LLP policy or tolerance for the detection of unauthorized events in food or feed. For seeds, Mexico takes a practical approach that considers unauthorized GE events to be impurities. As with other types of impurities, there is a two-percent foreign material tolerance in imports of GE seed.

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. Release into the environment without a 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 correspond to *commercial seed* for intentional planting but lack a permit.

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

Mexico has faced several types of LLP cases and developed mitigation procedures for how to deal with similar occurrences. These include:

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 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 are GE corn). Therefore, spillage of a commodity, and its subsequent germination, does not necessarily represent a case of LLP. Rather it is viewed as an accidental release of a GE grain 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 entered the country as commodities: This case was attributed to a lack of knowledge of the kind of grain/seed (GE) being used and also of the 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 to be an LLP situation. These situations have been treated as illegal releases into the environment and are associated with biosafety response measures as well as administrative procedures for the application of the corresponding sanctions.
4. An LLP detection of GE seeds: If the percentage is below the actual standard established for genetic quality (the tolerance is 2 percent), then the case falls under the Federal Law of Seed Production, Certification and Commercialization (LFPPCS) and no sanction process applies 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 indefinite; meanwhile permits for environmental release are limited to a growing season. Recipients of commercial permits are required to report every growing season on the implementation of the biosafety measures.

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 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 member of the World Organization for Animal Health (OIE) and the Organization for Economic Cooperation and Development (OECD). Mexico has a delegation participating on the biotechnology working groups at these international fora, usually coordinated by CIBIOGEM.

n. RELATED ISSUES:

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

PART C: MARKETING

a. PUBLIC/PRIVATE OPINIONS:

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

A 2016 [study](#) funded by CIBIOGEM shows that, in terms of benefits and risks perceived in the use of GE products, the perception of utility was positive only with regard to the use of GE crops to increase agricultural production. However, the perceived utility to benefit the economy and environment was much less. In contrast, those interviewed perceived there to be high risks in the use of GE products, particularly regarding health consequences. Regarding the purchase of GE products, there is a preference to buy GE products if they are lower in fat content than the conventional or organic counterpart. Regarding 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 that develop GE products.

CHAPTER 2: ANIMAL BIOTECHNOLOGY
PART D: PRODUCTION AND TRADE

a. PRODUCT DEVELOPMENT:

According to Mexican legislation, animal cloning would be allowed in Mexico, while the production of genetically-engineered animals would require a permit from SAGARPA. However, there is no cloning or genetic engineering of agriculturally relevant animals or any other animals occurring in Mexico at this time.

b. COMMERCIAL PRODUCTION:

There are no cloned or 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 it has in the biotechnology area, Mexico has lagged behind in research in different areas that affect the development of cloning and 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 of genetics for artificial inseminations in livestock production, particularly for ruminants.

e. TRADE BARRIERS:

The Mexican state of Yucatan declared itself a “GMO” free zone, to include GE crops and all GE products. This includes GE animals. The Decree was issued in 2016 without 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.

There is no trade barriers for cloned animals.

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 and its Implementation Rules and Agreements are the comprehensive legal framework, which 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.

The responsibilities and the roles of the Mexican secretariats are the same as indicated for Plant Biotechnology. The introduction of genetically engineered animals for food or feed use would require an authorization from COFEPRIS, while the production of genetically-engineered animals would require a permit from SAGARPA.

The negative public perception in Mexico toward GE plants would likely affect the decisions related to animal 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, primarily at the technical level.

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 regulations 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, other countries have raised issues related to GE fish, insects and microorganisms. Mexico contributed to the generation of the consensus documents.

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. Although GE animals, cloning, and lab-grown meat could play a central role in enabling Mexican producers to meet the core challenges of climate change and its impacts on agriculture, there are no cloned or genetically engineered animals or products derived from animals intended for commerce or currently in commercial production in Mexico.

PART F: MARKETING

a. PUBLIC/PRIVATE OPINIONS:

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

b. MARKET ACCEPTANCE/STUDIES:

N/A

^[1] <https://panoramaacuicola.com/2018/07/20/quien-es-victor-villalobos-virtual-titular-de-sagarpa-en-administracion-de-amlo/>

<https://noticieros.televisa.com/ultimas-noticias/victor-villalobos-intencion-amlo-es-rescatar-campo-situacion-actual/>

<https://www.lucesdelsiglo.com/noticias/descartan-dar-impulso-a-siembra-de-transgenicos/53776>

