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Report Highlights:

The Government of Mexico (GOM) is creating uncertainty about the future acceptance of biotechnology and genetically engineered (GE) crops in Mexico. Due to a lack of regulatory action by the federal agency in charge of biotechnology authorizations, no biotechnology events for food or feed have been approved since May 2018. Cotton is currently the only permitted commercial crop cultivated in the country. Use of GE cotton seed for cultivation has been a success for Mexico, as it has increased domestic production and decreased cotton imports during the last decade. However, for the 2020 cotton planting season, all new applications for GE cotton cultivation have been rejected or are past their legal deadline for response.

EXECUTIVE SUMMARY

Although Mexico has knowledge and expertise in agricultural biotechnology, the anti-biotechnology rhetoric and actions of the current presidential administration is creating concern about the future of biotechnology in Mexico. Even though Mexico has regulatory systems in place to evaluate biotechnology products and is one of the countries with the most authorizations for food and feed use in the world, the regulatory agency responsible for authorizing food and feed events is seemingly no longer processing applications. The last event approved by the GOM was in May 2018. GE Cotton has been a success story for Mexican producers and also benefits the national textile industry. However, a reduced number of permits granted for GE cotton planting in 2019 created a shortage in seed availability. For the 2020 planting cycle, all new applications for cotton cultivation permits have been rejected or delayed. As a result, producers will have only a few, older seeds options available as the planting season begins. GE cotton is currently the only biotech commercial crop cultivated in Mexico, as long legal battles and a lack of public acceptance have suspended cultivation of corn and soy. 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.

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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, one of the most important centers in the world for sequencing and functional analysis of the genome of plants,

animals and microorganisms, finished sequencing of avocado in August 2019. 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 public cluster of life science laboratories in the state, and maintains an Institute of Biotechnology, which specializes in plant molecular biology, molecular medicine and biotechnology, and a Center for Genomic Sciences. In Mexico City, the Department of Biotechnology and Bioengineering at the Center for Research and Advanced Studies of the National Polytechnic Institute (CINVESTAV) plays an important role in the use of biotechnology to resolve national problems working in coordination with the National /` for Agri-Food Health, Safety and Quality (SENASICA).

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 developed GE soybean and cotton in Mexico although it is now conducting experimental trails in Argentina because of 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" to develop drought-tolerant GE corn that can also resist low temperatures. Using antisense ribonucleic acid, this team modified the plant's metabolism by inhibiting an enzyme that destroys trehalose, a sugar involved in stress response. The result is a variety that requires only two-thirds of the water needed compared to that of a normal plant. Unfortunately, after two field tests, Mexico put in place a prohibition on GE corn cultivation and the group closed the project. They also developed 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. The group is using CRISP/Cas9 to develop soybean tolerant to the Asian soybean rust (*Phakopsora pachyrhizi*); safflower to produce oil with a better fatty acid profile by the edition of the gen fad2-1 and; soybean with the reduction of trichomes where the white fly (*Bemisia tabaci*) could lay its eggs, by editing the gen agl1.

Mexico's National Institute of Forestry, Agriculture and Livestock Research (INIFAP) has been doing research on GE common beans (*Phaseolus vulgaris*) for the event FMA-pdf1.2-INIFAP, with drought tolerance and tolerance to fungi *Colletorichum lindemuthianum, Fusarium lateritium* y *Rhizoctonia solani.*

The non-profit International Maize and Wheat Improvement Center (CIMMYT) has 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 resistance. 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 permits 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

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 and Rural Development (SADER) for experimental and pilot testing purposes does not have a fixed area limit; rather it is variable and in accordance with the objectives proposed by the developer.

Cotton

The only GE crop produced commercially in Mexico is cotton. In Mexico, the process of obtaining approval for planted area is granted by permits from SADER directly to seed companies, based on applications requesting a specific number of hectares. After obtaining permits, companies then sell seeds directly to producers within the approved area. The slow approval of GE cotton seed events by the Mexican Government has exacerbated supply

challenges in the past. The development of GE cotton varieties typically requires five to six years and the sharp increase of Mexican production over the past three years was not factored into seed production. The slow pace of GE cotton event approval also resulted in a smaller variety of seeds available to companies and producers. For example, the Mexican Government only has four approved GE events for commercial production while Brazil has 17 approved events.

Mexican producers find it difficult to find new sources of seeds during a seed shortage, as the only events approved for planting in Mexico are currently outdated and often no longer unavailable on the world market. For example, producers faced a shortage of available cotton seed for the 2019 planting season when fewer companies than expected received permits. The situation is even more difficult for the 2020 planting season. Of the 19 new permit applications submitted for this planting season, 7 have been rejected and 12 are pending but past the legal deadline for response. Unfortunately, at this time planting has already started for this season, which leaves producers with only a few and very old options for available seeds.

Soybeans

GE soybeans obtained commercial approval under the Mexican regulatory system in 2012 and production was industrialized for food and feed products. However, honey producer groups in the state of Yucatan were vocally opposed to the government's approval of GE soybeans for commercial production because of concerns that GE pollen would be present in the honey and prevent its export to other countries. 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 resolutions on the injunctions that established a lack of evidence of damage to the trade of honey, the environment, or health. The resolutions recommended a consultative process with the complainant indigenous communities before continuing with the permit for commercial production.

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 consultations process was transparent and, in some communities expedited where there was a willingness to accept the use of GE soybean. Other localities delayed the process.

On September 15, 2017, the Secretariat of Agriculture (formerly called SAGARPA, now SADER) 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 areas outside the permit limits. This was the first time that SAGARPA penalized the applicant of the permit for illegal planting rather than the producers who planted it. Monsanto appealed the decision administratively; however, SENASICA revoked the permit definitively in January 2018. Monsanto appealed that decision and eventually won the court litigation in March 2019. The court resolution states that because "there is no evidence of harm" the authority cannot cancel the permit. However, even though Monsanto won the case and can use the commercial permit for GE soybean, they withdrew the permit.

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

Table 2. Mexico: Area Permitted for Release of GE Crops, 2018 Applications (hectares)

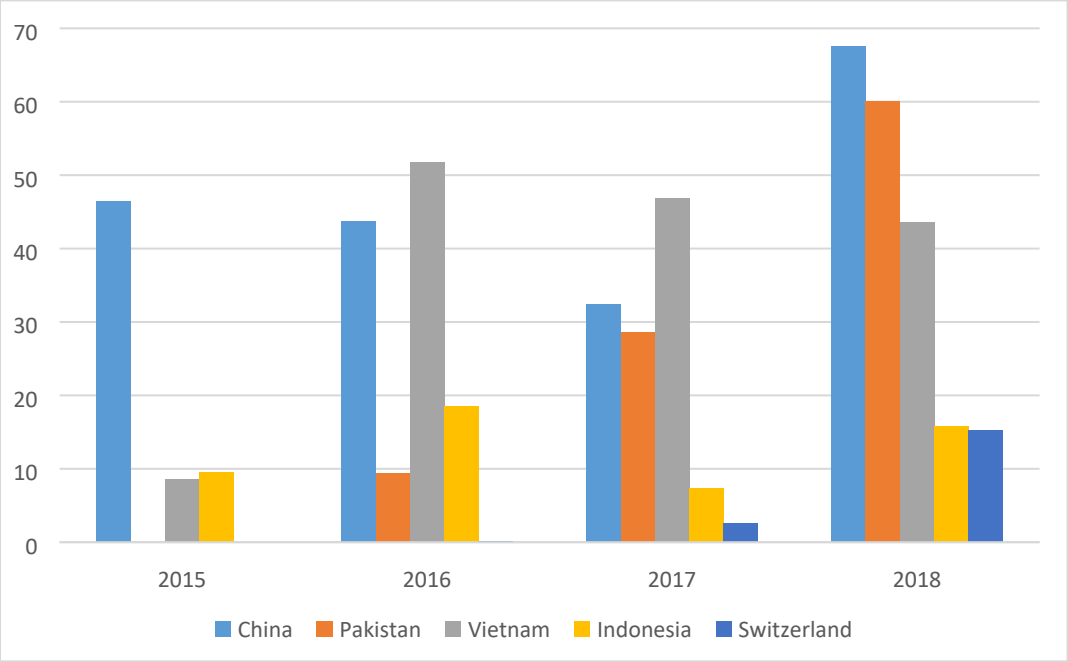
	Experimental	Pilot	Commercial	Total
Cotton	3	143	502,000	502,146
Wheat	1.05	0	0	1.05

Source: Mexican National Information System for Biosafety and Biotechnology

c. EXPORTS:

Mexico has a deficit in corn, cotton, and soybean production and does not meet domestic demand. The production of GE cotton is mainly for domestic consumption, however recent high production has helped exports to reach almost 600,000 bales annually to China, Pakistan, Vietnam, Indonesia, and Switzerland.

Figure 1. Top Five Export Destinations for Mexican GE Cotton

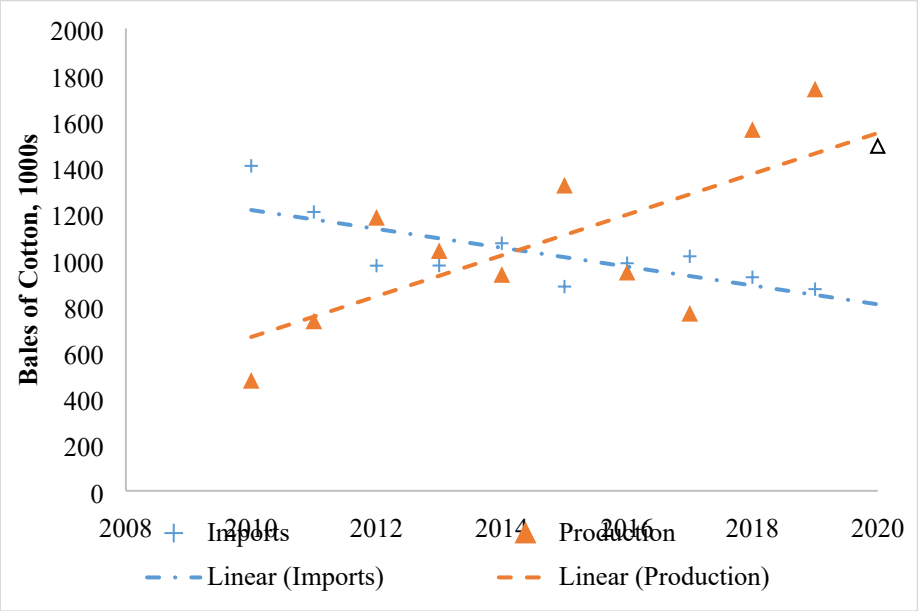


Source: Trade Data Monitor, LLC. In 1000s 480 lb. Bales

d. IMPORTS:

Although domestic production of cotton is important, it 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. Cotton production in Mexico has increased over the last ten years due to the use of GE seeds, successful pest management programs, and investment in equipment that allows for precision techniques in harvesting. The chart below (Fig. 2) illustrates the increase in cotton production and the resulting reduction of imports.

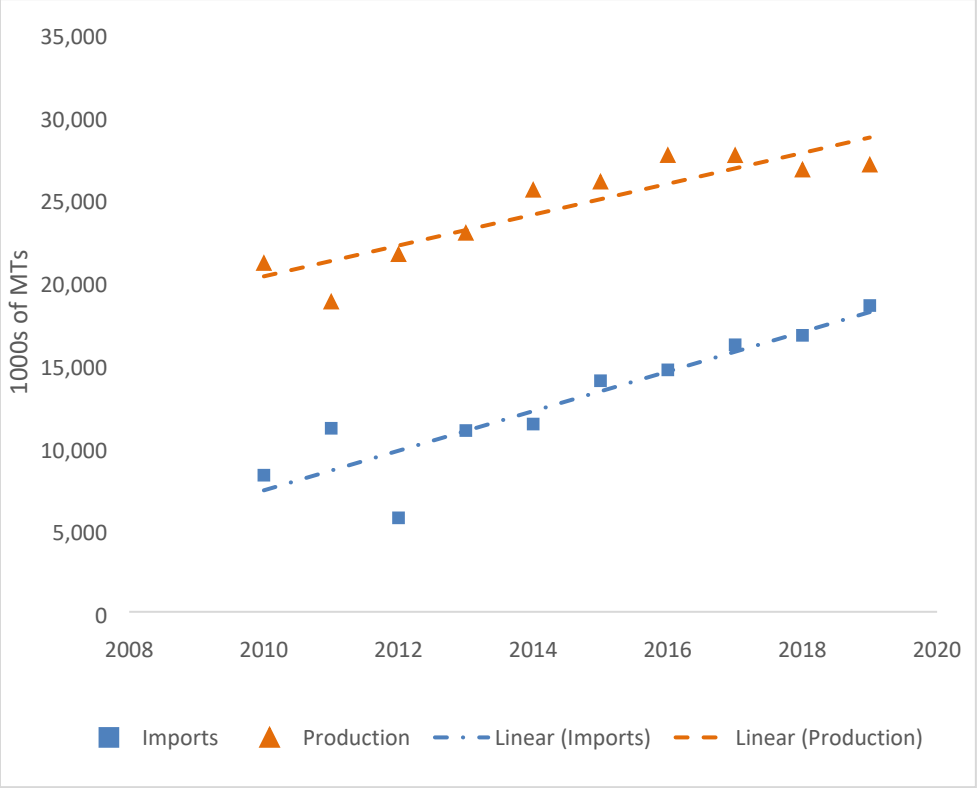
Figure 2. Mexican Cotton Production and Imports From 2010 - 2019



Source: Imports data from Mexican National Institute of Statistics and Geography (INEGI) through Trade Data Monitor, LLC. Production data from Production, Supply and Distribution (PS&D, USDA).

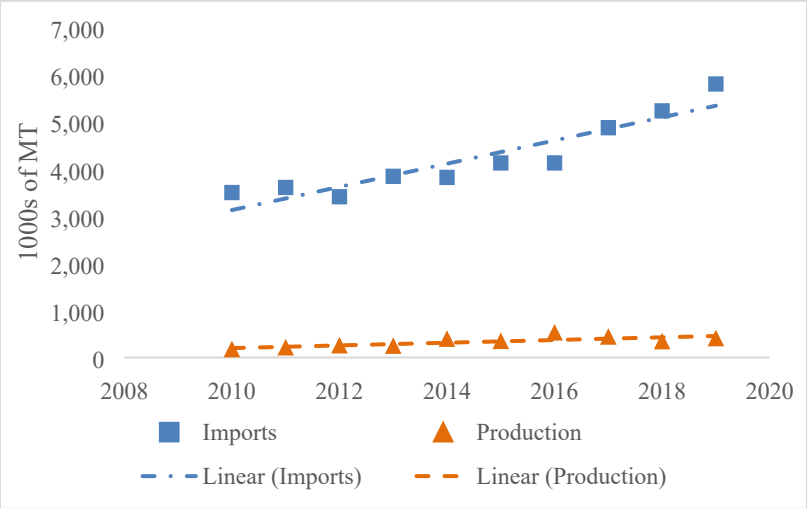
In contrast, although domestic corn production has increased, both corn and soybean imports have increased during the same period (Figs. 3 and 4).

Figure 3. Mexican Corn Production and Imports From 2010 - 2019



Source: Production, Supply and Distribution data (PS&D, USDA). 1000 MT

Figure 4. Mexican Soybean Production and Imports From 2010 - 2019



Source: Production, Supply and Distribution data (PS&D, USDA). 1000 MT

Mexico depends on imports of corn for animal feed while at the same time it must deal 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). 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.

	2017/2018	**2018/2019**	**2019/2020**
Corn	16,129	16,700	17,800
Cotton*	930	850	875
Soybean	4,873	5,230	5,260
Rapeseed	1,472	1,500	1,520
1000 MT			

Source: FAS GAIN reports MX9012, MX9031 and MX9014. 1000 MT *1000 480 lb. Cotton Bales

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. However, there have been no new authorizations of food or feed events since May 15, 2018.

e. FOOD AID:

Mexico is not a food aid recipient country.

f. TRADE BARRIERS:

Mexico's Biosafety Law and 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 SADER, 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.

On August 13, 2019, the National Supreme Court of Justice (NSCJ) invalidated a decree from the Mexican state of Yucatan in which it declared itself a Genetically Modified Organisms (GMO) free zone in 2016, to include all crops and genetically engineered (GE) agricultural products. The Mexican state of Yucatan declared itself a "GMO" free zone without the endorsement of the Secretariat of Agriculture and was challenged by the Federal government in the National Supreme Court of Justice. According to the biosafety law, GMO free zones are determined by SADER, with a prior dictate from CIBIOGEM, and the opinion of the National Commission for the Understanding and Utilization of Biodiversity (CONABIO). The plenary of the NSCJ determined that the planting of GE crops is a federal competence and clarified that the government of Mexico, through SADER, must respond to any requests submitted by communities of Yucatan to declare free zones for planting GE crops.

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 (*Bylaws)* 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 Secretariat of Environment and Natural Resources (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 SEMARNAT and SADER. 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 here.

Ministries and Agencies Responsible for Biotechnology Regulation

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 and Rural Development (SADER): The role of SAGARPA (now SADER) 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. SADER 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 receives notifications for those activities. SADER 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. SADER 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 SADER. The role of SEMARNAT is to analyze and assess, on a case-by-case basis, 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 SADER has primary responsibility, SEMARNAT is still responsible for issuing bio-safety binding opinions prior to SADER's resolution. (NOTE: SADER, not SEMARNAT, issues approval for environmental release for crops, livestock and fisheries, although SEMARNAT renders an opinion to SADER 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.

CIBIOGEM: 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 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: SADER, 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 SADER, 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.

Approvals and Permits Process

Mexico does not make a distinction between food and feed approval and 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 commodity with the most events authorized for consumption, with 90 out of 181 total events approved.

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 SADER 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 binding biosafety opinions and this is done before any resolution can come from SADER.

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 SADER to impose a fine on any firm or individual that is found guilty of violating the law.

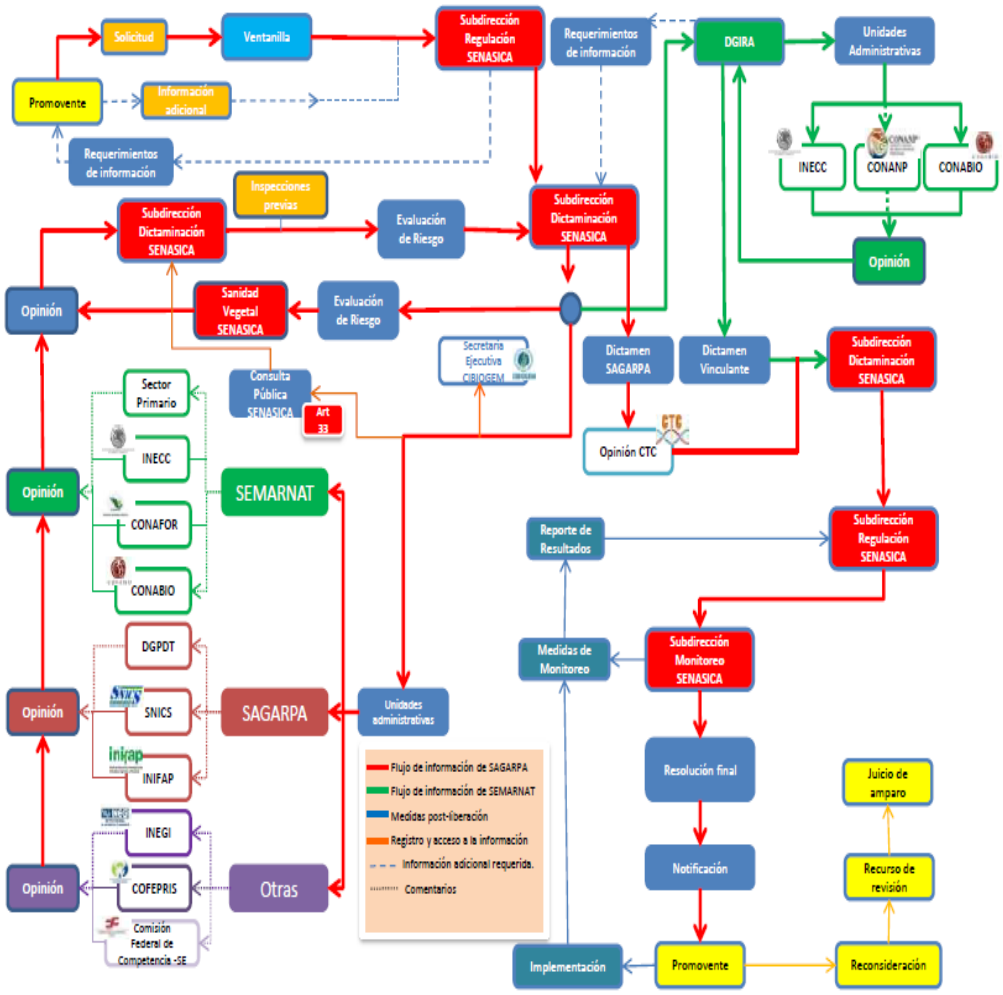
A standard that establishes the requirements for the risk assessment of GE plants during the experimental and pilot stages is in a NOM submitted for public comments in 2017 (see FAS GAIN report MX6051).

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 5). Multiple commissions and committees inside SADER and SEMARNAT must provide opinions about the release. The main authority is SADER 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.

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.

Figure 5. Procedure for the Resolution of Permits.



Source: CIBIOGEM

Current Policy Environment

Under the current administration, there have been delays in the release of permits and approvals for food and feed. There have been no approvals for food or feed products of biotechnology since May 2018. Additionally, GE corn is currently blocked by provisional legal injunction that has no clear timeline for resolution. The subject of GE corn appears in the Mexican media, often with strong emotions. Although it goes against the Federal Biosafety Law, as mentioned before, in October 2016 the state of Yucatan declared itself a “GMO” free zone, stating it would be free of 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 SADER. On September 24, 2019, the Mexican Senate overwhelmingly approved an initiative that would require the protection of native corn as part of Mexico’s cultural patrimony. The bill is currently pending discussion in the Chamber of Deputies, although no hearing date has been set.

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 SADER), and a section for the confined notifications. All this information is presented on the National Information System for Biosafety and Biotechnology. The list of authorizations from SALUD has not been updated since May 2018.

Table 4. Authorized Events for Consumption in Mexico

Crop		Authorized events
Alfalfa	*Medicago sativa*	4
Canola	*Brassica napus*	10
Cotton	*Gossypium hirsutum*	30
Cotton	*Gossypium barbadense*	6
Corn	*Zea mays*	90
Lemon	*Citrus aurantifolia*	2
Potato	*Solanum tuberosum*	6
Rice	*Oryza sativa*	1
Soybean	*Glycine max*	28
Sugar beet	*Beta vulgaris*	1
Tomato	*Lycopersicum esculentum*	3
Total		181

Source: National Information System for Biosafety and Biotechnology

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). All GE crops authorized in Mexico developed in the United States must present a letter from the Food and Drug 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 was formerly relatively fast, although no food or feed authorizations have been granted since May 2018. Mexico is one of the countries with the most authorizations for food and feed in the world.

c. STACKED OR PYRAMIDED EVENT APPROVALS:

For stacked or pyramid events, the Mexican biosafety regulation does not require additional

reviews if the stack is a combination of 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 5. There were applications for only cotton and wheat during 2018 and only for cotton in 2019. In 2019, 19 permit applications for field testing were submitted but, at this time, all applications have been denied or are past their mandatory response date.

Table 5. Status of the Resolutions of Permit Requests for field testing in Experimental or Pilot state of GE crops, submitted from 2018 to 2019*

		Experimental	Pilot	Commercial	Total Permitted
2018	Cotton	4	10 (2NA)	6	20
	Wheat	7			0
2019	Cotton	(4RA)	(5RA)(4NA)	(3RA)(3NA)	0

*Information as of March 2020 includes the events non-approved (NA) and in risk assessment process (RA).
Source: National Information System for Biosafety and Biotechnology

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 technical areas in SADER.

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 SADER 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 SADER 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 randomly) 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 (LFPCCS) and no sanction process applies under the Biosafety Law. To prevent possible future cases of non-compliance of the Biosafety Law derived from an 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.

The agriculture chapter of the United States-Canada-Mexico Agreement (USMCA), when finally ratified by all three countries, details protections and coordination on agricultural biotechnology, an issue that is not addressed in the current NAFTA agreement. USMCA requires the United States, Mexico, and Canada to make publicly available the details on the approval process for crops produced with biotechnology, encourage producers to submit concurrent applications for approval, and ensure that decisions on those applications are made in a timely manner. Further, when an import into a member country is found to have a low level presence of an unapproved crop produced with biotechnology, the importing country is to act quickly so as to not unnecessarily delay the shipment. USMCA will also create a Working Group for Cooperation on Agricultural Biotechnology to help with information exchange and advance transparent, science and risk-based regulatory approaches and policies in other countries and international organizations. The provisions of USMCA apply to crops produced with conventional biotechnology methods, including recombinant DNA and gene editing.

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 to ease restrictions on GE crop authorizations.

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 and government officials 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 SADER. 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:

There are 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, SADER, SEMARNAT, and SALUD 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 SADER.

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

Attachments:

No Attachments