Required Report: Required - Public Distribution **Date:** December 16,2020

Report Number: MX2020-0062

Report Name: Agricultural Biotechnology Annual

Country: Mexico

Post: Mexico City

Report Category: Biotechnology and Other New Production Technologies

Prepared By: Adriana Otero

Approved By: Karisha Kuypers

Report Highlights:

Mexico has not approved any biotechnology food or feed products since May 2018 and there is no official indication when approvals will resume. In 2019, Mexico stopped approvals of glyphosate imports and rejected all permit applications for cultivation of genetically engineered (GE) cotton, citing the precautionary principle. Cotton is the only GE crop planted in Mexico. In 2020, the denial of cultivation permits, together with the lack of GE seeds, low glyphosate stocks, and reduced global demand for textiles and clothing, resulted in an estimated 36 percent annual decrease in the area of GE cotton planted in Mexico. Mexico is one of the world's largest importers of GE corn and soy.

EXECUTIVE SUMMARY

Mexico's biotechnology regulatory policy environment has become increasingly uncertain under its current administration. Mexico has not approved any biotechnology food or feed products since May 2018, and there is no clarity when approvals will resume. There are currently 19 biotech food and feed products pending approval, almost all of which have passed their statutory review and approval deadline.

In November 2019, Mexico's Secretariat of the Environment unilaterally stopped approving import permits for the herbicide glyphosate, citing the precautionary principle and concerns about glyphosate and transgenic crops' effects on human health and the environment.

The Secretariat of Environment also issued negative opinions (rejections) on all permit applications for cultivation of GE cotton in 2019, again based on the precautionary principle. Cotton is the only GE crop cultivated in Mexico. With the rejection of all permit applications for seeds, cotton producers now have access to only a few outdated GE seed varieties that are not compatible in all growing areas. The estimated area of GE cotton planted in Mexico was down 36 percent in 2020.

For products of microbial biotechnology, Mexico's regulation only requires notification to federal authorities. No additional regulatory process is necessary. This has permitted a greater development of the sector, producing billions of dollars' worth of international trade in related products.

TABLE OF CONTENTS

CHAPTER 1: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

a) PRODUCT DEVELOPMENT

Mexico currently has no GE plants or crops under development that would be commercialized within the next 5 years. Mexico's National Service for Food Health, Safety, and Quality (SENASICA), which is part of the Secretariat of Agriculture and Rural Development (SADER), did not approve any applications for environmental release of GE crops, specifically cotton, in 2019.

b) COMMERCIAL PRODUCTION

Cotton

The only GE crop produced commercially in Mexico is cotton. Even before the rejection of new GE cotton cultivation permits in 2019, Mexico's slow pace approval of GE crops resulted in a smaller variety of seeds available to producers. The only GE cotton traits still approved for cultivation in Mexico are:

a) Resistance to lepidopteran insects and tolerance to the herbicide glyphosate;

b) Tolerance to the herbicides dicamba, glufosinate ammonium, and glyphosate;
c) Glyphosate tolerance;
d) Resistance to lepidopteran insects and tolerance to the herbicides dicamba, glufosinate ammonium and glyphosate.

The Secretariat of Environment and Natural Resources (SEMARNAT) issued negative binding opinions (i.e. rejections) on all applications for GE cotton planting requests made in 2019 for planting in 2020. SEMARNAT is responsible for reviewing and issuing binding opinions for permits, while SADER, through SENASICA, supplies permits directly to seed companies. In its negative opinions, SEMARNAT stated it rejected the cotton events because of concerns that GE varieties of cotton would cross with traditional wild cotton populations found in the south of the country. They also stated that the lack of indigenous consultation process conducted by the government was cause for rejection. However, wild cotton populations are not found in northern Mexico, where the commercial cotton is grown. The permit rejections have had significant ramifications for cotton planting in Mexico, as producers now only have access to a few outdated GE seed varieties that are not compatible in all growing areas.

Planted area is forecasted at 146,000 hectares (ha), a 36 percent reduction compared to the previous marketing year (MY), although contacts state that seed sales are only sufficient to plant 84,000 hectares. Planted area in Chihuahua, the country's largest producer, is forecast at 103,217 ha, a 35 percent reduction from the previous MY. This reduction in planted area is a direct result of a lack of GE seeds, low glyphosate stocks, and reduced global demand for textiles and clothing.

In November 2019, SEMARNAT unilaterally stopped issuing import permits for glyphosate, citing the precautionary principle and concerns about glyphosate's impact on human health and the environment. SEMARNAT officials have promoted the need for Mexico to transition to an agro-ecological model of agriculture, a system of agriculture without the use of GE crops or agrochemicals. Although glyphosate use is still allowed within Mexico, Mexican officials have stated that they plan to 'phase-out' usage of glyphosate over the next 3-5 years, although no details of this plan have yet been released.

Additional applications for GE cotton seed planting permits were made in 2020 for planting in 2021 but to date SEMARNAT has issued no response on these applications.

Soybean

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

Corn

The cultivation of GE corn is currently blocked by a provisional legal injunction with no clear timeline for resolution.

c) EXPORTS

Mexico's production of corn, cotton, and soybeans does not meet domestic demand. The

production of GE cotton is mainly for domestic consumption, although record cotton production in MY 2018/19 helped exports reach 525,000 bales in MY 2019/20. Exports in MY 2020/21 are expected to only reach 200,000 bales, due mainly to the lower cotton demand worldwide because of the COVID-19 pandemic, as well as lower expected production, low global prices, and a weakened global economy. Mexico exports GE cotton mainly to Turkey, Pakistan, India and China.

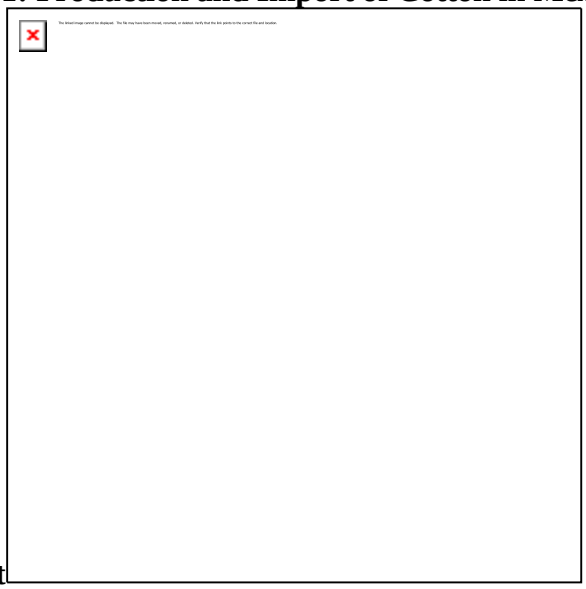
d) IMPORTS

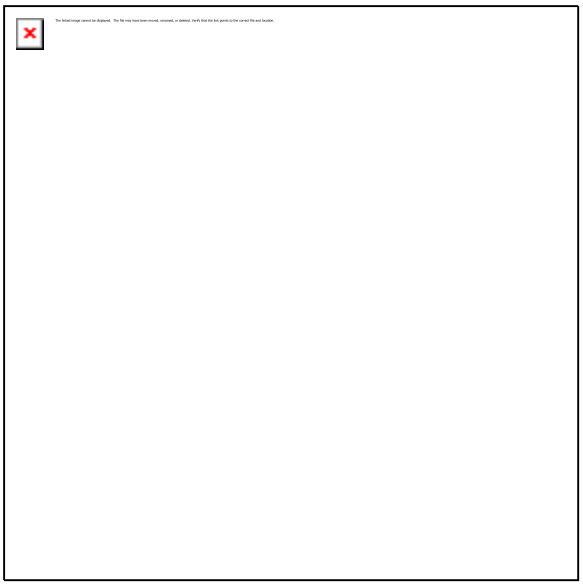
The Federal Commission for Protection Against Sanitary Risk (COFEPRIS), part of the Secretariat of Health, authorizes the importation of GE crops for food and feed on a case by case analysis. As of October 2020, there were 181 different events authorized, of different crops: alfalfa (4), cotton (36), rice (1), rapeseed (10), tomato (3), lemon (2), corn (90), potato (6), sugar beet (1), and soybean (28).

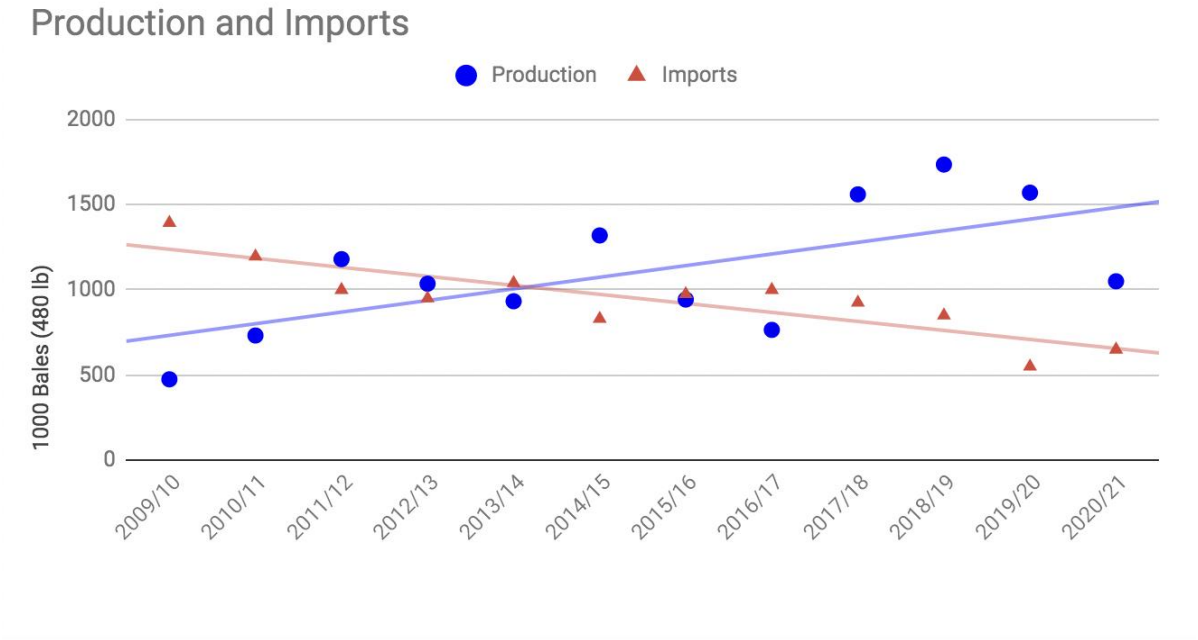
Cotton

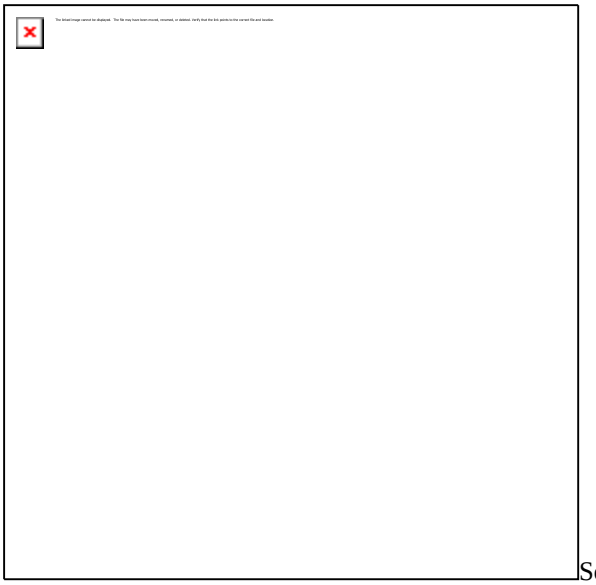
The United States is the main cotton supplier to Mexico and accounts for nearly 100 percent of total imports. Prior to the seed shortage of the last two years, cotton production in Mexico had been increasing, due to the use of GE seeds, successful pest management programs, and investment in equipment that allowed for precision techniques in harvesting. Figure 1 illustrates the increase in cotton production and the resulting reduction of imports in Mexico in the last decade.

Figure 1: Production and Import of Cotton in Mexico, 2009-Present






Production and Imports
Production
Imports
2000
1500
1000
500
0
1000 Bales (480 lb)
2009/10
2010/11
2011/12
2012/13
2013/14
2014/15
2015/16
2016/17
2017/18
2018/19
2019/20
2020/21



Source: Import data from Mexican National Institute of Statistics and Geography (INEGI) through Trade Data Monitor (TDM); Production data from USDA's Production, Supply and Distribution system (PS&D, USDA).

Corn

Mexico is the world's second largest importer of GE corn, mainly from the United States, Brazil and Argentina. Imports have increased in recent years, reaching more than 18 million metric tons (MT) in MY 2020/21, which represents 40 percent of the national consumption.

Soybean

After China and the European Union, Mexico is the world's third largest importer of soybeans, importing 96 percent of soybeans consumed in the country, mainly from the United States and Brazil. Soybean imports are expected to increase by 100,000 MT in MY 2020/21 to reach 6.1 million MT because of the moderate increase in feed demand, strong processor demand, and population growth.

Rapeseed

Almost all rapeseed consumed in Mexico is imported from Canada and the United States, with only a small amount produced domestically.

Table 1. Mexico: Total Import of Crops with GE Content (1000 MT)

	2018/2019	**2019/2020**	**2020/2021**
Corn	16,658	17,300	18,250
Cotton*	850	550	600
Soybean	5,867	6,000	6,100
Rapeseed	1,471	1,250	1,300

1000 MT; *1000 480 lb. Cotton Bales
Source: FAS GAIN reports MX2020-0015, MX2020-0045 and MX2020-0022.

e) FOOD AID

Mexico is not a recipient of food aid.

f) TRADE BARRIERS

Mexico is one of the world's main importers of GE crops and until recently, there have been few or no trade barriers. Mexico's Biosafety Law and Implementation Rules does not specify a low level presence (LLP) 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 2-percent foreign material tolerance in imports of GE seed. Nevertheless, the uncertainty is a potentially serious area of contention for many seed importers. Inspections may be done at warehouses to avoid rejections at the border.

An emerging area of concern is lack of processing of biotechnology food and feed approvals within COFEPRIS. No biotechnology food or feed products have been approved since 2018. As of October 1, 2020, there are currently 19 pending applications for biotech food and feed, 18 of which have exceeded the statutory timeline for response.

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, the Agreement to Determine the Centers of Origin and Centers of Genetic Diversity of Corn in Mexico was published. 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 restrictive as it relates to the storage and movement of GE corn.

In April 2011, an agreement was published in Mexico's Federal Register defining the Notification Process for the Confined Use of GE organisms. 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.

A labeling standard that includes general labeling specifications for GE seeds intended for planting, cultivation, and agricultural production was published in the Federal Register in December 2014 and took effect in June 2015. This Mexican Norm (NOM) establishes the characteristics and content of the labels for genetically engineered seeds and propagation materials intended 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 lay out in a NOM the information and characteristics of the labels for GE seeds.

In 2018, a standard was published that establishes the requirements for the risk assessment of GE plants during the experimental and pilot stages of cultivation.

Biotechnology Related Regulations

On April 4, 2020, a Congressional decree called the Native Corn Protection Law was published which reinforces many provisions of the Biosafety Law and related regulations but also calls for a consultative commission that can give opinions to the president regarding the conservation of native corn varieties. To date, there is no official indication that the GOM has made efforts to establish this commission.

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 law lays out three specific areas regarding the regulation of biotech-derived products:

- Provision 27 states that the use of all materials, products, 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;
- The use of substances or forbidden materials referred to in Provision 27 that alter the organic characteristics of the products is prohibited;
- SADER can impose a fine on any firm or individual that is found guilty of violating the law.

Complete access to 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 SADER is to analyze and assess, on a case-by-case basis, 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, plants, 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 binding bio-safety opinions prior to SADER's resolution. (NOTE: It is SADER (through SENASICA) rather than SEMARNAT that issues approval for the environmental release for crops, livestock and fisheries, although SEMARNAT renders a binding opinion to SADER beforehand through their inter-agency process. END NOTE)

Secretariat of Health (SALUD): The role of the Secretariat of Health, through COFEPRIS, 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.

Intersecretarial Commission for Biosafety and Genetically Modified Organisms (CIBIOGEM): Biotechnology policy activities in Mexico are coordinated by CIBIOGEM, an interagency body that is part of Mexico's National Council of Science and Technology (CONACYT). It is composed of representatives from six secretariats: SADER, SEMARNAT, SALUD, Finance and Public Credit, Economy, and Education. While the body has no enforcement function, it is responsible for coordinating 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. CIBIOGEM's presidency is held for a period of two years on a rotating basis among the Secretariats of SADER, SEMARNAT, and SALUD. Currently the Secretary of SALUD is in the second year of its tenure as President of the Commission. In 2021, the Secretary of SADER will hold the presidency. 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.

b) APPROVALS

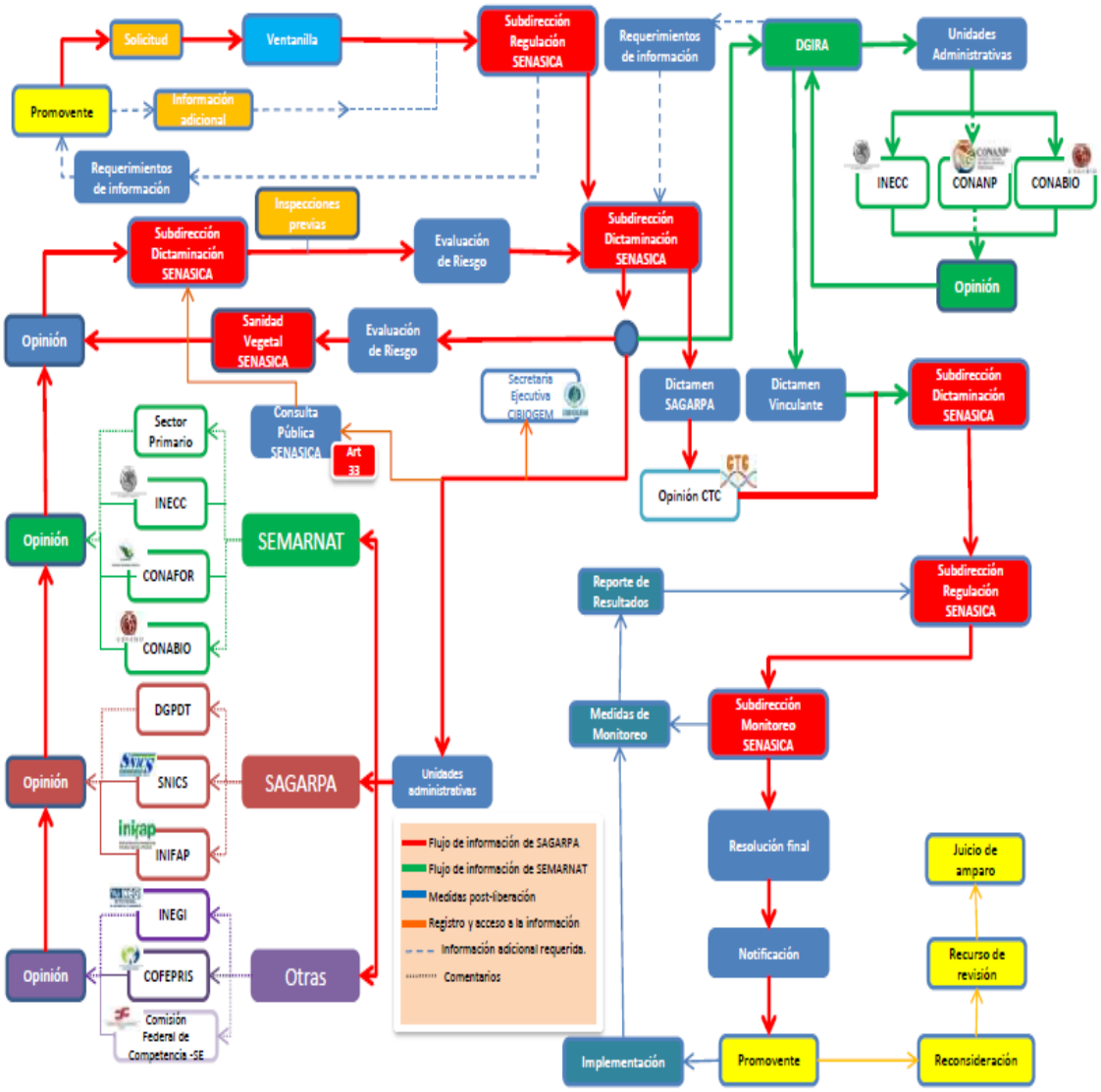
Mexico does not make a distinction between food and feed approvals, and COFEPRIS is responsible for approving both. From 1995 to 2018, a growing number of GE commodities were approved for food and feed. Corn is the commodity with the most events authorized for consumption (90 out of 181).

In Mexico, approval (authorization) for food and feed is distinguished from approval (permits) for environmental release in that authorizations for food and feed are definitive (not time-limited). 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.

For consumption authorizations, the Biosafety Law established that the Secretariat of Health through COFEPRIS has a maximum of 6 months to make a ruling after receiving the completed application. While these timelines were not always met, the approval process occurred relatively smoothly. However, since May 2018, COFEPRIS has not issued any authorizations for GE food and feed products.

A permit for the release of GE crops into the environment is required for both planting and importing seed. As demonstrated in Figure 2, the procedure for the approval of permits for experimental, pilot or commercial release of GE crops is complex, as multiple commissions and committees inside SADER and SEMARNAT must provide opinions about the release (a complete explanation of the procedure can be find here). Although the main approving authority is SADER (through SENASICA), SEMARNAT issues a binding opinion through the Directorate General of Environmental Risk (DGIRA).

Figure 2. Procedure for the Resolution of Permits.



Source: CIBIOGEM

Cultivation Permit Approval Process:

- The applicant must present to SENASICA a dossier with all the requirements (Art. 5, 16, 17 and 19 of the Biosafety Rules) for the GE crop according to the phase of release (experimental, pilot or commercial).

- SENASICA will review that all the information is complete (10 days) and receive the dossier or ask for the missing information. SENASICA submits the dossier to SEMARNAT that has 3 days to ask for additional information if needed. The applicant will have 20 days to complete the dossier.

- Once received, the complete dossier must be published by the authorities in the National System of Biosafety. SENASICA will make the information of the application available

for public consultation; any person, including the Governments of the States in which the respective release will be carried out, may issue their opinion. These opinions must be technically and scientifically supported and received within 20 business days, and the opinions issued will be considered by SENASICA for the establishment of additional biosecurity measures.

- SENASICA carries out the consultation with the National Institute of Statistics and Geography (INEG), the National Institute of Forestry, Agricultural and Livestock Research (INIFAP), the National Institute of Ecology and climate Change (INECC), the National Commission for the Knowledge and Use of Biodiversity (CONABIO), and the National Forestry Commission (CONAFOR), in addition to receiving the binding opinion of SEMARNAT, regarding the release of genetically modified crops.

- SEMARNAT will be responsible for issuing a biosecurity report as a binding opinion, prior to the resolution of SENASICA, as a result of analysis and risk assessment based on the study prepared and presented by the interested parties, regarding the possible risks of the GE crop in question may pose to the environment and biological diversity.

- SENASICA will issue its resolution on the release permit as a result of the analysis of the information and documentation provided by the interested party.

- SENASICA may issue the permit to carry out the release activity to the environment in question, and may establish monitoring, control, and measures additional to those that were proposed by the interested party in the permission; or it may deny permission in the following cases:
    - When the request does not comply with the provisions of the Biosafety Law or the regulations as requirements for the granting of the permit;
    - When the information provided by the interested party, including that relating to the possible risks that the GE crop could cause is false, incomplete or insufficient; or:
    - When SENASICA concludes that the risks presented by the GE crop in question would adversely affect human health or biological diversity, or cause serious or irreversible damage to animal, plant or aquaculture health.

- SENASICA will resolve the permit request, including those related to importation, within the following maximum periods, counted from the business day after the request has been admitted: six months for experimental release to the environment; three months for release to the environment in a pilot program; and four months for commercial release to the environment. These timelines are not always met.

c) STACKED OR PYRAMID 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 on their own.

d) FIELD TESTING

Only applications for GE cotton cultivation were submitted during 2019: 4 for experimental field trials, 9 for pilot trials, and 6 for commercial release. All 19 permit applications were denied based on negative opinions by SEMARNAT. Additional applications were submitted in 2020 but SEMARNAT has yet to issue any response.

e) INNOVATIVE BIOTECHNOLOGIES

Mexico has not determined the regulatory status of innovative biotechnologies (such as genome editing) in plants or plant products. Innovative biotechnologies are 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 and TRACEABILITY

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 first is the Mexican Network of Laboratories for Detection of GMOs, which is composed of government, public, and private laboratories that comply with 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 GMOs, 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.

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 additional requirements. Authorizations for consumption have no time limits, while 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 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). Mexico has in place legislation to address intellectual property rights of industry, including agro-biotechnology under its 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 and FORUMS

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

The agriculture chapter of the United States-Canada-Mexico Agreement (USMCA) details commitments and coordination on agricultural biotechnology. 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 also creates 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 through conventional biotechnology, including recombinant DNA methods, and through newer technologies, such as 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 GOM has not approved any new varieties of GE crops for food and feed since May 2018.

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.

CHAPTER 2: ANIMAL BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

a) PRODUCT DEVELOPMENT

Mexico does not have GE animals under development that might be commercialized within the next 5 years.

b) COMMERCIAL PRODUCTION

Currently, there is no commercial production of GE animals or cloned animals for the purpose of production.

c) EXPORTS

None.

d) IMPORTS

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

e) TRADE BARRIERS

None.

PART B: POLICY

a) REGULATORY FRAMEWORK

The same regulation for GE plants will be applied for commercialization of GE livestock animals and insects. 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 GE animals for food or feed use would require an authorization from COFEPRIS, while the production of GE 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.

b) APPROVALS

None

c) 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, primarily at the technical level.

d) LABELING and TRACEABILITY

Same regulations as GE plants.

e) ADDITIONAL REGULATORY REQUIREMENTS

Same regulations as GE plants.

f) INTELLECTUAL PROPERTY RIGHTS (IPR)

Same regulations as GE plants.

g) INTERNATIONAL TREATIES and 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 Organization of Economic Cooperation and Development (OECD), 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.

h) RELATED ISSUES

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 GE animals or products derived from animals intended for commerce or currently in commercial production in Mexico.

PART C: 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 GE animals and that it is essential to educate the public about this issue.

b) MARKET ACCEPTANCE/STUDIES

None

CHAPTER 3: MICROBIAL BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

a) COMMERCIAL PRODUCTION

According to data from OECD Key Biotech Indicators, 426 companies that carry out or use biotechnology research activities operate in Mexico, a figure lower than the more than 2,562 companies that exist in the United States (2016 data, last information for Mexico).

Other analysis[1] lists 553 companies, of which 59 percent are companies that are developers of a new process or products in addition to being users of biotechnology. Of these, seven percent are considered "large" companies, seven percent are "medium", twelve percent are "small," and 21 percent are "micro" companies. There are no details on company size for 51 percent of these entities.

In Mexico, 47 percent of companies carry out agri-food biotechnology projects, 33 percent conduct health-related projects, and 19 percent are industrial. The same company can carry out projects in one, two or even all three applications. Those that develop a technology with application in health or agri-food areas commonly also use it in industrial-related bioprocesses.

Agri-food biotechnology represents the application of various techniques using biological systems, living organisms, or their derivatives in order to produce new varieties of plants and animals with particular characteristics or advanced reproduction techniques of plants and animals. For microbial biotechnology, agri-food applications include the development of

[1] Biotechnology Panorama 2017

functional foods such as prebiotics and probiotics, or the creation of various inputs, products and processes used in the primary sector and in the food and beverage industry, like alcoholic beverages or lactic products, among others.

Some examples of companies using microbial biotechnology in Mexico and their resulting products include:

- Development of new highly effective and environmentally friendly surfactants for the agrochemical sector (Oxiteno Mexico- Mexico City).
- Development and implementation of the "Alibio Biotechnological Package" for pest control and diseases in tequila agave (Alliance with the Biosphere- Mexico City).
- Biodegradable product, made from recycled cellulose, for the agro-industrial sector (Verdek Sustainable Transformations- Mexico City).
- Integration of a technological package for two products with prebiotic properties obtained by enzymatic synthesis from cane juice and / or commercial grade sugar (Centro of Research and Assistance in Technology and Design of the State of Jalisco-Jalisco).
- Process of production and use of bio-preservative microorganisms for the control of pathogenic and deteriorating microorganisms in fresh cheeses (Sigma Alimentos Lácteos Jalisco).
- Transfer of a biotechnological process for the production of phytostimulants microbials for horticultural use (Laboratorios Agroenzymas- Estado de México).
- Implementation of techniques, methodologies and procedures manual for the characterization of the Baktillis product for new applications of Biological Control in agricultural crops for the national and international market (Biokrone-Guanajuato).
- New 100% natural-organic food additive as an alternative to antibiotics used in the animal sector (Nutrition and Healthy Genetics-Guanajuato).
- New technology to obtain a broad spectrum biological insecticide through Biphasic fermentation in an organic substrate (Bioamin-Coahuila).
- Development and pilot testing of prototypes of organic compound-based herbicides with allelopathic activity for its application in crops of economic importance (Green Corp Biorganiks de México-Coahuila).
- Development of a new biofertilizer based on the activity of microorganisms Potassium solubilizers for its assimilation in crops (Environmental Analysis and Inputs-Coahuila).
- Production of an inoculant of nitrogen fixing bacteria (Azospirillum sp) for the corn production in Sinaloa (Proveedora de Insumos Agropecuarios y Servicios-Sinaloa).
- New generation of bioinsecticides based on entomopathogens for the effective control of agricultural, urban and industrial pests capable of substituting chemicals conventional (Agrobiological Control-Sinaloa).
- Development of a microbiological inoculum for its application in forage corn silage (Nutek-Puebla).
- Biotechnological process for the production of bioactive microorganisms for the control of garlic soft rot (Solutions in Agroindustry and Biotechnology-Puebla)
- Bacteria isolated from mango foliage that can be used as a substitute for mango products, a chemical synthesis that are used in agriculture without the problems of toxicity (License of the IBt patent to Agro & Biotecnia-Morelos).
- Proteomics: applied to biotechnological processes in animal feed (NutecUAQ-Querétaro).

- Enzymes that degrade fiber: Collection of fungi that partially degrade the fiber of stubble and agro-industrial by-products. Enzymes for hydrolysis of the fiber for the production of bioethanol and the fermented product is used to replace cereals in ruminant feeding (FEMSA-Querétaro).
- Final trials of recombinant vaccines with immunopotentiators to increase the immune response of birds against Newcastle disease (IASA-Puebla).
- Development of a polyvalent "diva" vaccine against avian influenza h5n2-h7n3 in plant tissue and its production under industrial parameters (Viren-Querétaro)
- Potency tests and pre-scaling of a bivalent recombinant vaccine against Newcastle disease and Avian Influenza (IASA-Mexico City).
- Newcastle vaccine production in transgenic alfalfa cells for health use animal (Unima Soluciones Naturales-Jalisco).
- Innovation of an anti-cytokine antibody (VEGF) for its use in pet cancer (CICESE licensed its technology to a company-Baja California).
- Bacilux®, a product used in the bioaugmentation and degradation of fats in decanters wastewater and grease traps (Biotechnological Solutions for the Environment. Environment-Nuevo Leon)
- Gene characterization in new laccase isoenzymes of *P. sanguineus* for the effluent and soil bioremediation (ITESM-Nuevo León).
- Immobilization processes of cells and enzymes, for the transformation of saccharides of the whey in value-added functional additives (Grupo Chen-Nuevo León).
- Enzymes that degrade fiber: Collection of fungi that partially degrade the fiber of stubble and agro-industrial by-products. It recovers the enzymes for the hydrolysis of the fiber for the production of bioethanol and the fermented product is used to substitute cereals in ruminant feeding (FEMSA-Querétaro).
- Process of production and use of biopreservative microorganisms for the control of pathogenic and deteriorating microorganisms in fresh cheeses (Sigma Alimentos Lácteos Jalisco).
- Pilot and pre-commercial development of eco-rational bioproducts produced from microorganisms with beneficial activities and their technology transfer for use in the agricultural sector (Lidag-Nuevo León).
- Bioprocess of production of thermotolerant fungi solubilizers of phosphates by solid fermentation from cane cachaza (Ingenio Quesería-Colima).
- Manufacture of ecological bioplastics, 100% biodegradable, biocompatible and compostable,
- developing technologies for the use of renewable resources that do not compete with the food production (Biopolymex-Morelos).
- Design of tests for the evaluation of commercial enzymes in biomass treatment *Stevia rebaudiana* leaf (Corporativo Agroindustrial de Stevia-Puebla)
- Production of enzymes for industrial uses: starches, detergents, textiles, tannery, brewery, bakery, dairy, supplements, proteins, marinades, animal nutrition, sugar, fruits and vegetables (Enmex-Estado de México).
- Optimization of enzyme production processes with less color and no activities collateral enzymes (Enmex-State of Mexico).
- Improvement of the quality of a product based on amylolytic enzymes (Frutibases-Nuevo León).

b) EXPORTS

Mexico exports many products that use microbial biotechnology in their production chain. From August 2019 to July 2020, Mexico exported $29 million in cheese, $4.3 billion in beer, $5 million in wine, $425 million in condiments and sauces, $185 million in enzymes, and $407 million in fruit juice, among other products.

c) IMPORTS

Mexico imports many products that use microbial biotechnology in their production chain. From August 2019 to July 2020, Mexico imported $588 million in cheese, $56 million in beer, $245 million in wine, $301 million in condiments and sauces, $911 million in enzymes, and $53 million in fruit juice, among other products.

d) TRADE BARRIERS

None

PART B: POLICY

a) REGULATORY FRAMEWORK

As in the case of plant and animal biotechnology, the Biosafety Law and its Implementation Rules and Agreements are the comprehensive legal framework that regulates the development, commercial use, import and disposal of GE microbes or products derived from these microbes. Similarly, SADER, SEMARNAT, and SALUD are the Mexican Secretariats that monitor and enforce biotechnology regulations for microbial biotechnology.

The responsibilities and the roles of the Mexican Secretariats are the same as indicated for Plant Biotechnology. The use of GE microbes for food or feed use would require an authorization from COFEPRIS, while the confined production of GE microbes would require a notification to SADER or a permit if the microbe will be released to the environment.

b) APPROVALS

There is no need for approvals if the use of the GE microbe will be confined. Only a notification is needed. There are no applications for permits for the release of GE microbes into the environment.

c) LABELING and TRACEABILITY

Same regulations as GE plants.

d) MONITORING AND TESTING

Same regulations as GE plants.

e) ADDITIONAL REGULATORY REQUIREMENTS

Same regulations as GE plants.

f) INTELLECTUAL PROPERTY RIGHTS (IPR)

Same regulations as GE plants.

g) RELATED ISSUES

Same regulations as GE plants.

PART C: MARKETING

a) PUBLIC/PRIVATE OPINIONS

The COVID-19 pandemic has brought to light many previously unknown aspects of the biotechnology sector, as discussion of PCRs, RNA, antibodies, and vaccines are now common on television and in the press. Biotech researchers are also regularly in the media to explain how the causes of a disease are investigated, how diagnostic kits are developed, and what are the steps to develop a vaccine. All these communications help to educate the public about microbial biotechnology and to help develop positive perception of the benefits of this scientific field.

b) MARKET ACCEPTANCE/STUDIES

No recent studies.

Attachments:

No Attachments