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Report Highlights:

Mexico's biotechnology regulatory policy environment has become increasingly uncertain under the current administration. The government has not approved any applications for genetically engineered (GE) products for food and feed use since May 2018 and has not approved any permits for planting GE crops since 2019. The government has also denied or not provided a decision on 34 planting permit applications for GE cotton and denied one application for GE alfalfa. In February 2023, a new Corn Decree entered into force, replacing the December 2020 Corn Decree. The new Corn Decree imposes an immediate prohibition on the use of GE corn for "human consumption," which the decree defines narrowly as corn used in Mexico's masa and tortilla production. The uncertainty in the regulatory environment has made it difficult for businesses to invest in biotechnology in Mexico.

Executive Summary

Mexico's biotechnology regulatory policy environment has become increasingly uncertain under the current administration. In February 2023, a new Corn Decree entered into force, imposing an immediate ban on the use of GE corn in dough and tortillas, calling for the gradual replacement of GE corn for industrial uses and livestock feed, and banning the use of glyphosate by 2024. The 2023 decree replaced the December 2020 Corn Decree, which had banned the use of GE corn for human consumption and required the phasing out of glyphosate by March 2024.

The Government of Mexico (GOM) has not reported approvals on applications for GE products for food and feed use since May 2018 and has not approved any permits for planting GE crops since 2019. Since 2019, the GOM has denied or not provided a decision on 37 planting permit applications for GE cotton and denied one application for GE alfalfa. For products of microbial biotechnology, Mexico's regulation only requires notification to federal authorities, with no additional regulatory steps required. This regulation has allowed the GE microbial sector to develop, producing billions of dollars' worth of international trade in related products.

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PART A: PRODUCTION AND TRADE

a) RESEARCH AND PRODUCT DEVELOPMENT

Mexico's National Service for Food Health, Safety, and Quality (SENASICA), an agency of the Secretariat of Agriculture and Rural Development (SADER), has not approved any GE planting applications for experimental, pilot programs, or commercial use since 2019.

b) COMMERCIAL PRODUCTION

In Mexico, SADER issues planting permits for GE crops. The permits are issued to seed companies for a specified number of hectares in a specified region. Seed companies can then sell directly to producers within the approved region.

Cotton

Cotton is the only GE crop produced commercially in Mexico. GE traits for cotton that are approved to be planted in Mexico include the following: resistance to lepidopteran insects, tolerance to the herbicides dicamba, glufosinate ammonium, and glyphosate. Planted area and yield are constrained by limited access to innovative seed technology and high input costs. The GOM has not approved any GE cotton planting permits since 2019. GOM has restricted glyphosate imports under the Corn Decree published in December 2020 and replaced by a new one in February 2023[1], which phases out the chemical's use by March 2024. Due to the lack of approval of new varieties, the GE cotton seeds imported from the United States are out-of-date varieties, many of which are being phased out of production. The lack of newer seeds is drastically affecting production, with MY2023/24 cotton planted area forecast at 150,000 hectares (ha), a 49 percent reduction compared to MY2028/19, when planting reached a record 243,000 ha (See: Cotton and Products Update). Producers report that they rely upon saved or outdated seeds, resulting in yield uncertainty and volatility in some growing areas (see report MX2023-0043).

Industry submitted 19 applications for GE cotton planting in 2019 and 15 applications in 2020, all of which the GOM rejected. In 2021 and 2022, there were no GE cotton planting permit applications. In 2023, industry submitted three applications for experimental field trials of new cotton events. The GOM has not ruled on these applications.

Soybean

There have been no applications for planting GE soybeans since 2013.

Corn

There have been no applications for planting GE corn since 2014 (see Report MX2013-2075: Mexican Judge Blocks GE Corn Permits).

Alfalfa

[1] Publication of the Corn Decree in the Official Gazette in Spanish: https://www.dof.gob.mx/nota_detalle.php?codigo=5679405&fecha=13/02/2023

In 2021 there was one application for commercial release of GE alfalfa, which the GOM rejected.

c) EXPORTS

GE product exports do not require notification of GE content, but notification for intent to propagate the organisms, following international standards, is required.

As Mexico is a significant yarn, fabric, textile, and apparel producer, most cotton produced or imported is used domestically, with only a small portion exported. During the last five years, exports have been mainly to Turkey, Pakistan, and China. MY 2023/24 cotton exports are forecast at 300,000 bales, a reduction of 33 percent from the previous MY due to the lower global consumption.

d) IMPORTS

The Federal Commission for Protection Against Sanitary Risk (COFEPRIS), a part of the Secretariat of Health, authorizes the importation of GE crops for food and feed. Before May 2018, 181 different events were authorized: alfalfa (4), cotton (36), rice (1), rapeseed (10), tomato (3), lemon (2), corn (90), potato (6), sugar beet (1), and soybean (28). Since that date, there have been no public reports of authorizations for new products.

Cotton

Mexico imports GE cotton from the United States to meet nearly 50 percent of its domestic demand. Cotton imports from the United States are forecasted in MY 2023/24 at 0.9 million bales, no increase from the previous MY.

Corn

After China, Mexico is the world's second-largest corn importer, with supplies mainly from countries that produce GE corn, such as the United States, Brazil, Argentina, and South Africa. Imports have increased recently, with MY2023/24 forecast levels reaching 18 million metric tons (MT), accounting for approximately 39.4 percent of Mexico's national consumption.

Soybeans

Mexico is the world's third largest importer of GE soybeans, with supplies from the United States and Brazil. Soybean imports for MY2023/24 are forecast to reach 6.4 million MT, accounting for approximately 97.6 percent of Mexico's national consumption.

Rapeseed

Almost all rapeseed (canola) consumed in Mexico are GE varieties imported from Canada and the United States, with only a small amount produced domestically. Mexico is forecasted to import 1.5 million MT in MY2023/24.

e) FOOD AID

Mexico is not a recipient of food aid.

f) TRADE BARRIERS

On February 13, 2023, Mexico published a new Corn Decree in its official gazette, replacing the December 2020 Corn Decree. The new Corn Decree places imposes an immediate prohibition on the use of GE corn intended for "human consumption,".

According to the National Register of Biosafety (NRB) maintained by the Intersecretarial Commission for Biosafety of *Genetically Modified Organisms* (CIBIOGEM), COFEPRIS has not issued any official authorizations on applications for GE products for food and feed use since May 2018. However, on November 11, 2022, multiple secretariats jointly published a GOM status report on progress towards implementing the 2020 Corn Decree. The report states that during 2021 and 2022, COFEPRIS issued 14 formal denials for GE products intended for food and feed use. According to the GOM report, the denied products include seven corn events, four cotton events, two canola events, and one soybean event, all of which contained traits for tolerance to glyphosate.

PART B: POLICY

a) REGULATORY FRAMEWORK

Legal term (in Spanish)	**Legal Term (in English)**	**Laws and Regulations where term is used**	**Legal Definition**
Organismo Genéticamente Modificado (OGM)	Genetically Modified Organism (GMO)	• Biosafety Law • Implementation Rules of the Biosafety Law (Bylaws) • Agreement to Determine the Centers of Origin • Notification Process for the Confined Use of GE organisms • GE seeds labeling standard • Risk assessment of GE plants during the experimental and pilot stages standard • Corn Decree establishing various actions regarding glyphosate and genetically modified corn.	Any living organism, human beings exempted, having acquired a new genetic combination, originated through the specific use of modern biotechnological techniques defined in this Law, if the techniques used are the ones established in this Law or in the Mexican official norms derived from it. *Modern biotechnology*: It is considered the application of *in vitro* techniques of nucleic acids, including recombinant deoxyribonucleic acid (DNA and RNA) and the direct injection of nucleic acids into cells and organelles, or the fusion of cells beyond the taxonomic family, exceeding the natural physiological barriers of reproduction or recombination; these are not techniques commonly used in traditional reproduction and selection, and are used to originate genetically modified organisms, and will be determined in the Mexican official norms derived from this Law (Biosafety Law).

Mexico's comprehensive biotech regulation is the Law on Biosafety of Genetically Modified Organisms (hereafter the Biosafety Law), published in the Federal Register (*Diario Oficial*) in March 2005. This law regulates the research, planting, and import/export 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 with using and applying biotechnology products to human health, plant and animal health, and environmental well-being.

In November 2012, the GOM published 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. The agreement 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 planting of GE corn is prohibited. This agreement also restricts the storage and movement of GE corn within this area.

In April 2011, GOM published in the Federal Register 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 carried out with physical barriers or a combination of chemical or biological barriers to be used to limit contact with people and the environment effectively.

In December 2014, the GOM published a labeling standard that includes general labeling specifications for GE seeds for planting, cultivation, and agricultural production. This standard took effect in June 2015. This Mexican Norm (NOM) establishes the characteristics and content of the labels for GE seeds and propagation materials intended to be released as a crop or for agricultural production. According to Provisions 9 and 12 of the Biosafety Law, 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[2] called the Native Corn Protection Law was published that reinforces many provisions of the Biosafety Law and related regulations. The law establishes a new commission (not yet established) to advise the president regarding the conservation of native corn varieties.

The GOM published the Organic Products Law in the Federal Register on February 7, 2006, which specifies biotechnology-related requirements for organic products:

- Provision 27 states that the use of all materials, products, ingredients, or inputs that come from, or have been produced using, genetic engineering is prohibited in the entire production chain of organic products, and such products 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 found guilty of violating the law.

Secretariats and Agencies Responsible for Biotechnology Regulation

The Biosafety Law outlines the responsibilities and jurisdictions of Mexican secretariats and agencies tasked with monitoring and enforcing biotechnology regulations. The duties and the roles of the secretariats are as follows:

The Secretariat of Agriculture and Rural Development (SADER): SADER assesses the potential risks of imported or national GE organisms to animal, plant, and aquatic health, the environment, and

[2] As opposed to Congressional legislation, Congressional Decrees are passed only in the Senate and have to do with national security.

biological diversity. This assessment is done on a case-by-case basis, considering the specific characteristics of the GE product and the intended use. SADER also reviews the risk assessments of each application for cultivation of GE plants. This review ensures that the potential risks of GE crops are carefully considered before they are planted in the environment. SADER is responsible for deciding what activities are permissible for planting crops, livestock, and fisheries, and issues permits and receives notifications from the users for those activities. SADER also provides guidelines and parameters for all experiments and activities related to GE animals, plants, or microorganisms. These recommendations include experimental field trials, pilot program releases, commercial releases, marketing, and GE animal, plant, or microorganism 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 National Service of Agri-food Health, Safety, and Quality (SENASICA): SENASICA is an Agency within SADER that protects agricultural, aquaculture, and livestock resources from pests and diseases of quarantine importance. It also regulates and promotes the application and certification of food contamination and risk reduction systems and their agri-food quality to facilitate national and international trade in goods of plant and animal origin.

The Secretariat of Environment and Natural Resources (SEMARNAT): SEMARNAT protects the environment, which includes biodiversity and wildlife species. Domesticated species fall under the competence of SADER. SEMARNAT analyzes and assesses all applications for planting and the potential risks that activities (planting, production, or use) carried out with GE animals, plants, or microorganisms may cause to the environment and biological diversity of wild species. 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 the accidental release of GE animals, plants, or microorganisms may cause. In instances where SADER has primary responsibility, SEMARNAT is still responsible for issuing binding bio-safety opinions before SADER's resolution. NOTE: SADER (through SENASICA) issues permits for the environmental release of crops, livestock, and fisheries, although SEMARNAT renders a binding opinion to SADER beforehand through their interagency process.)

The Secretariat of Health (SALUD): SALUD, through COFEPRIS, is to ensure the food safety of GE-derived agricultural products destined for use as medicines, for human, and for animal consumption. SALUD also assesses 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.

The Intersecretarial Commission for Biosafety of *Genetically Modified Organisms* (CIBIOGEM): CIBIOGEM is a government agency that coordinates biotechnology policy and applications for the planting and consumption of GE products. CIBIOGEM is part of the National Council of Humanities, Science, and Technology (CONAHCYT), which is an agency that promotes all forms of scientific and technological research. CIBIOGEM does not enforce any laws, but it develops and implements the government's overall strategy for GE products. CIBIOGEM comprises of representatives from six secretariats: SADER, SEMARNAT, SALUD, Finance and Public Credit, Economy, and Education. CIBIOGEM's presidency is held for two years on a rotating basis among the Secretariats of SADER, SEMARNAT, and SALUD. Currently, the Secretary of SADER 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 CONAHCYT. According to the Biosafety Law, CIBIOGEM is led by an Executive Secretary nominated by CONAHCYT after consultations with the member Secretariats and then approved by the President of Mexico.

b) APPROVALS/AUTHORIZATIONS

In Mexico, approval (authorization) for GE products for consumption is distinguished from approval (permits) for planting or environmental release. While authorizations for products for consumption are definitive (not time-limited), permits for planting are usually limited to one growing period and must be granted every planting/harvesting cycle. SADER regulates environmental release in the case of domesticated species (crops, livestock, and fishery), and SEMARNAT in the case of wild species. SEMARNAT is the agency responsible for issuing binding biosafety opinions, which is done before any resolution can come from SADER.

COFEPRIS is responsible for approving GE products for consumption, and does not distinguish between consumption for food or feed. From 1995 to 2018, Mexico approved 188 GE commodities for food and feed use, including 90 corn events authorized for consumption. Under the Biosafety Law, COFEPRIS has a maximum of 6 months to rule after receiving a completed application for a product for consumption. The authorities must publish the list of accepted applications in the NRB. Prior to 2018, while the 6-month maximum for approval was not always met, the approval process occurred relatively smoothly. However, since May 2018, COFEPRIS has yet to report any authorizations for GE food and feed products, and there is no information in the NRB about the applications for GE food and feed products.

A permit for releasing GE crops into the environment is required for planting and importing seeds. The procedure for approving 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 (for further details see SADER website here). Although the central approving authority is SADER (through SENASICA), SEMARNAT issues a binding opinion.

Cultivation Permit Approval Process:

- The applicant must present a complete dossier to SENASICA (Art. 5, 16, 17, and 19 of the Biosafety Rules) for the GE crop according to the release phase (experimental, pilot, or commercial).
- SENASICA will review (within 10 days) whether the dossier is complete and request any missing information. SENASICA will submit the dossier to SEMARNAT, which has three days to request additional information if needed.
- Once received, the complete dossier must be published by the authorities in the NRB. SENASICA will make the application available for public consultation. Any person may issue their opinion, including the Governments of the States. These opinions must be technically and scientifically supported and received within 20 business days, and SENASICA will consider the views published for establishing additional biosecurity measures.
- SENASICA will consult with the National Institute of Statistics and Geography (INEGI), 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).

- SEMARNAT is responsible for issuing a biosecurity report as a binding opinion before the resolution by SENASICA. This report must follow an analysis and risk assessment based on the study prepared and presented by the interested parties regarding the possible risks the GE crop may pose to environment and biological diversity.
- SENASICA will issue its resolution on the release permit based on the analysis of the information and documentation provided by the interested party.
- SENASICA may issue the permit to carry out the release activity and may establish monitoring, control, and other measures in addition to those that were proposed by the interested party; or SENASICA may deny permission in the following cases:
    - If the request does not comply with the provisions of the Biosafety Law or the regulations as requirements for granting the permit.
    - If 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.
    - If 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.

More information on cultivation permit approval process can be found here.

c) STACKED OR PYRAMIDED EVENT APPROVALS/AUTHORIZATIONS

The Biosafety Law does not require additional reviews for stacked or pyramid events if the stack combines two or more already approved GE traits. However, in practice, the GOM regulators consider these to be different events from the parental ones and will evaluate them independently.

d) FIELD TESTING

The GOM has denied all permits for planting GE crops in Mexico since 2019, and all denials were due to opinions by SEMARNAT. There were no applications during 2022. Three GE cotton applications submitted in 2023 are pending resolution.

e) INNOVATIVE BIOTECHNOLOGIES

Mexico has not issued regulations regarding innovative biotechnologies, such as genome editing, in plants or plant products. Genome editing is under discussion by technical departments within SADER.

f) COEXISTENCE

Biosafety Law Provision 90 establishes that GE crop-free zones may be considered to protect organic agricultural products and others of interest to the soliciting community. GE-free zones can be established when GE crops coincide with the same species of organic agricultural products, and their coexistence is not viable, or GE crops would not comply with the normative requirements for their certification.

SADER has the purview to determine GE-free zones with input from CIBIOGEM and the National Commission for the Understanding and Utilization of Biodiversity.

g) LABELING AND TRACEABILITY

The Biosafety Law Provision 101 requires labeling only when there a substantial difference between a conventional product and the corresponding GE product. Since 2021, Mexico's Congress has considered several GE-labeling initiatives, seven of which have not yet been voted on in committee. The eighth initiative, the General Law on Adequate and Sustainable Food, was approved by the Senate on September 19, 2023, and submitted to the Chamber of Deputies (lower house of Congress) for consideration.

The nine initiatives introduced since 2021 propose a variety of reforms to various laws, including the General Law on Health, the Biosafety Law, the Federal Penal Code, and the General Law on Ecological Balance and Environmental Protection.

Recent GE-labeling initiatives/the proposals' Congressional sponsors:

- Adequate Food Law/Rivera: The Mexican Senate approved a bill to create a legal mechanism for the State to ensure that all Mexicans are provided with healthy and culturally appropriate food. The bill's proposed labeling requirements for genetically engineered products are unclear.
- GE Labeling/Sanchez: Initiative to reform the General Law on Health and the Federal Law on Consumer Protection to require the labeling of GE products.
- Federal Penal Code/Fuentes: Initiative to reform the Federal Penal Code to establish criminal penalties for the failure to label GE products.
- Biosafety Law/Ecological Balance Law/Contreras: Initiative to reform the Biosafety Law and the General Law on Ecological Balance and Environmental Protection to strengthen the regulation of GE products.
- Biosafety Law/Rojas: Initiative to reform the Biosafety Law to require the labeling of GE products and to establish a public registry of GE products.
- Health Law/Biosafety Law/Vazquez: Initiative to reform the General Law on Health and the Biosafety Law to require the labeling of GE products and to strengthen the regulation of GE products.
- Health Law/Ecological Balance Law/Carrillo: Initiative to reform the General Law on Health and the General Law on Ecological Balance and Environmental Protection to require the labeling of GE products and to strengthen the regulation of GE products.

- Health Law/Rivera: Initiative to reform the General Law on Health to require the labeling of GE products and to establish criminal penalties for the failure to label GE products.
- http://bit.ly/3Ysb77R: Initiative to reform the Biosafety Law to require the labeling of GE products and to establish a public registry of GE products.

h) MONITORING AND TESTING

There has been no monitoring activity reported since 2018. Authorities responsible for the monitoring programs are SADER and SEMARNAT. CIBIOGEM coordinates two monitoring networks. The first is the Mexican Network of Laboratories for Detection of GMOs, which comprises government, public, and private laboratories that comply with standards for detection. The network facilitates detections where a trusted resolution in amount and kind of GE crop is needed, for example, as evidence in 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 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 detecting unauthorized events in food or feed. Mexico treats unauthorized GE events in seeds as impurities. As with other impurities, there is a 2 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 the approval of GE crops. There are no additional requirements. 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 legislation to address industry intellectual property rights, including agricultural biotechnology, under its Law of Industrial Property.

l) CARTAGENA PROTOCOL RATIFICATION

In 2002, the Mexican Senate ratified the Cartagena Protocol on Biosafety (CPB).

m) INTERNATIONAL TREATIES AND FORUMS

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

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 the approval process for crops produced with biotechnology publicly available, 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 to not unnecessarily delay the shipment. USMCA established a Working Group for Cooperation on Agricultural Biotechnology to facilitate the 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 newer technologies, such as genome editing.

n) RELATED ISSUES

None.

PART C: MARKETING

a) PUBLIC/PRIVATE OPINIONS

Non-governmental organizations (NGOs) are very active opponents of biotechnology in Mexico. Crop Protection, Science and Technology (PROCCYT) is a private organization representing the major biotechnology developers and crop protection. The organization's main objectives are promoting biotechnology's positive use and sharing and disseminating scientific knowledge to policymakers, lawmakers, and the 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. Mexican consumers generally base purchase decisions on price and quality of food rather than its genetic composition.

CHAPTER 2: ANIMAL BIOTECHNOLOGY

PART D: PRODUCTION AND TRADE

a) RESEARCH AND PRODUCT DEVELOPMENT

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

b) COMMERCIAL PRODUCTION

Forma Food is a start-up that manufactures meat in vitro from the culture of muscle cells of the animal.

c) EXPORTS

Mexico does not export any GE animals.

d) IMPORTS

Mexico is highly dependent upon imports of genetics for artificial insemination in livestock production, particularly for milk cows.

e) TRADE BARRIERS

None.

PART E: POLICY

a) REGULATORY FRAMEWORK

For more information on terminology and definitions used by Mexico to refer to agricultural biotechnology, see Chapter 1, Part B, sub-paragraph a. The same regulation applied to GE plants is applicable to the commercialization of GE 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 that regulates 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 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 authorization from COFEPRIS, while the production of GE animals would require a permit from SADER. Public perception in Mexico toward GE plants would likely affect the decisions related to animal biotechnologies.

b) APPROVALS/AUTHORIZATIONS

None.

c) INNOVATIVE BIOTECHNOLOGIES

Mexico has not issued regulations regarding 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 a member of 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

None.

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 in the future, considering that a small segment of the public is opposed to GE crops. In general, the public lacks knowledge about GE animals.

b) MARKET ACCEPTANCE/STUDIES

None.

CHAPTER 3: MICROBIAL BIOTECHNOLOGY

PART G: PRODUCTION AND TRADE

a) COMMERCIAL PRODUCTION

Food and agricultural applications of microbial biotechnology include the development of functional foods, such as prebiotics and probiotics, and the creation of various inputs, products and processes used in the primary sector and in the food and beverage industry, such as alcoholic beverages and lactic products, among others.

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

- The use of biocatalysts to produce capsaicinoids. Eliminating the need to plant and harvest a single plant enables the production of a wide variety of capsaicinoids with modulable sensation (levels of heat), controlled and standardized pungency, and suitable physical properties. (Applied Biotec Cuernavaca; location: Morelos)

- The production and use of biopreservative microorganisms for the control of pathogenic and deteriorating microorganisms in fresh cheeses. (Sigma Alimentos Lácteos; location: Jalisco)

- The production of enzymes for industrial uses: starches, detergents, textiles, tannery, brewery, bakery, dairy, supplements, proteins, marinades, animal nutrition, sugar, fruits, and vegetables. (Enmex; location: Estado de México)

- A biofertilizer based on the bacterium Azospirillum brasilense, which was developed by the university UNAM and transferred for commercialization to the Mexican company Biofactory Siglo XXI.

- The biological fungicide Fungifree AB®, based on a bacterium antagonistic to the fungus that causes anthracnose that attacks mango, papaya, and avocado crops, which was developed by UNAM's Institute of Biotechnology (IBT).

- AnascorpTM, an antivenom against scorpion stings, which was developed at IBT and is marketed in Mexico and the United States.

b) EXPORTS

Mexico exports many products that use microbial biotechnology in their production chain. From June 2022 to May 2023, Mexico exported $42 million in cheese and curd, $5.5 billion in beer, $6 million in wine, $571 million in condiments and sauces, $36 million in enzymes, and $534 million in fruit juice, among other products.

c) IMPORTS

Mexico imports many products that use microbial biotechnology in their production chain. From June 2022 to May 2023, Mexico imported $832 million in cheese and curd, $30 million in beer, $400 million in wine, $482 million in condiments and sauces, $146 million in enzymes, and $98 million in fruit juice, among other products.

d) TRADE BARRIERS

None.

PART H: POLICY

a) REGULATORY FRAMEWORK

For more information on terminology and definitions used by Mexico to refer to agricultural biotechnology, see Chapter 1, Part B, subparagraph a. 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 roles of the Mexican Secretariats are the same as indicated for Plant Biotechnology. The inclusion of GE microbes in a product intended for food and feed use would require an authorization from COFEPRIS, while the confined production of GE microbes would require a notification to SADER.

b) APPROVALS/AUTHORIZATIONS

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

None.

PART I: MARKETING

a) PUBLIC/PRIVATE OPINIONS

No recent polls

b) MARKET ACCEPTANCE/STUDIES

No recent studies

Attachments:

No Attachments