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Report Highlights:

Mexico has not officially reported any approvals for genetically engineered (GE) agricultural products for food and feed use since May 2018. Additionally, Mexico has not approved any permit applications for cultivation of GE crop (cotton and alfalfa) since 2019, citing the precautionary principle. Cotton is the only GE crop planted in Mexico, and while production reached a record in marketing year (MY) 2018/2019, the lack of updated seed availability and other challenges have significantly reduced production and quality. On January 1, 2021, a Mexican presidential decree entered into force under which existing authorizations for biotech corn will be revoked and new authorizations prohibited until biotech corn is completely phased out by January 31, 2024. In 2021, Mexico's imports of GE corn and soybeans were valued at approximately U.S. $5 billion and U.S. $3 billion, respectively, with supplies mainly from the United States.

EXECUTIVE SUMMARY

Mexico's biotechnology regulatory policy environment has become increasingly uncertain under its current administration. On January 1, 2021, a Mexican presidential decree entered into force under which existing authorizations for biotech corn will be revoked and new authorizations prohibited until biotech corn is completely phased out by January 31, 2024. Mexico's National Register of Biosafety (NRB), which the Intersecretarial Commission of Biosafety of Genetically Modified Organisms (CIBIOGEM) is legally required to update, reports no decisions on applications for GE products for food and feed use since May 2018. The NRB further reports no planting permit approvals for GE crops since 2019; 34 planting permit applications for GE cotton have been denied or unaddressed, and one planting permit application for GE alfalfa was denied. For products of microbial biotechnology, Mexico's regulation only requires notification to federal authorities, and no additional regulatory process is necessary. This regulation has allowed for greater development of the sector, producing billions of dollars' worth of international trade in related products.

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CHAPTER1: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

a) RESEARCH AND PRODUCT DEVELOPMENT

Mexico is currently not conducting any genetically engineered (GE) plants or crops research development for commercialization within the next five years. Researchers on this area have been unable to test their developments in the fields since 2019. 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 since 2019, for experimental, pilot planting, or commercial use.

b) COMMERCIAL PRODUCTION

Cotton

Cotton is the only GE crop produced commercially in Mexico, with traits including resistance to lepidopteran insects and tolerance to the herbicides dicamba, glufosinate ammonium, and glyphosate. Producers have faced a cotton seed shortage since 2019, as the GOM continues to deny or leave unaddressed planting permit applications for GE cottonseed, citing the precautionary principle and concerns about GE varieties intermixing with traditional wild cotton populations in the south of the country. In 2019 and 2020, there were 19 and 15 applications for planting of GE cotton, respectively, and all were rejected. In 2021 and 2022, there were no GE cotton planting permit applications; one application for commercial release of GE alfalfa, filed in 2021, was rejected. The GE cotton events approved for planting in Mexico are outdated, and producers report that they do not have sufficient seeds for planting. Cotton is grown in various parts of the country, with drastically varying growing conditions. Available varieties are often not compatible to all areas, creating even more volatility, quality uncertainty, and increasing costs of production.

In Mexico, the process of obtaining approval to plant cotton is granted through permits from SADER and is distributed to the seed companies for a specific number of hectares in a specific region. After obtaining permits, companies then sell seeds directly to producers within the approved region.

Planted area for cotton in MY 2022/23 is forecasted at 201,000 hectares (ha), producers report that they rely upon saved or outdated seed usage from year to year, resulting in yield uncertainty and volatility in some growing areas. Current planted area levels are down approximately 11 percent from MY 2018/19, which saw record production. This reduction in planted area is a direct result of a lack of GE seeds. U.S. cottonseed exports to Mexico reached U.S. $14.5 million in 2020, down from a high of U.S. $18.12 million in 2018. In 2021, cottonseed trade reach only U.S. $ 1.9 million. Historically, all cottonseed is

imported from the United States, however, contacts suggest that only 40 percent of the cotton seeds planted this growing period were bought from official U.S. companies. This percentage is likely to decrease further in the following years, as old varieties will be discontinued for production.

Soybean

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

Corn

On October 13, 2021, Mexico's Supreme Court upheld an indefinite injunction against permits for domestic commercial cultivation of GE corn, which has been in place since a 2013 federal district court ruling (see Report MX2013-2075: Mexican Judge Blocks GE Corn Permits).

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.

Mexico's production of cotton does not fulfill domestic demand. Export levels of GE cotton will depend heavily on cotton quality, as lower quality cotton fiber is not acceptable for domestic textile industry use. MY 2022/23 exports are forecasted at 0.4 million bales, on unexpected high levels of poor-quality cotton exports to Turkey, and Pakistan. The production of GE cotton is mainly for domestic consumption for processing of diverse national and export products. Mexico is a significant supplier of jeans and t-shirts to the United States (made in Mexico with GE cotton).

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 2022/23 to increase at 1.1 million bales, an increase of 10 percent from MY 2021/22 on increased global textile and apparel demand.

Corn

Mexico is the world's second largest importer of GE corn, with supplies mainly from the United States, Brazil and Argentina. Imports have increased in recent years, with 2021 levels reaching 17.4 million metric tons (MT), valued at U.S. $5.1 billion and accounting for approximately 39 percent of Mexico's national consumption.

On October 19, 2022, the Government of Mexico published a decree to temporarily exempt select importers from payment of import duties for certain goods and to facilitate administrative procedures as applied to the importation of select basic goods (mostly food items). It quotes extensively from the presidential corn decree that entered into force on January 1, 2021, reaffirming the prohibition set forth in that decree on the import of GE corn. The October 2022 decree is valid through February 2023 and may be extended until December 2023. See Report MX2022-0057 for more detail.

Soybean

Mexico is the world's third largest importer of GE soybeans, with supplies from the United States and Brazil. Soybean imports reached 5.6 million MT, valued at U.S. $3.1 billion, in 2021.

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 imported 250,000 MT in 2021.

e) FOOD AID

Mexico is not a recipient of food aid.

f) TRADE BARRIERS

On January 1, 2021, a Mexican presidential decree entered into force under which existing authorizations for biotech corn will be revoked and new authorizations prohibited until biotech corn is completely phased out by January 31, 2024. According to the NRB, maintained by CIBIOGEM, COFEPRIS has not issued any official decisions on applications for GE products for food and feed use since May 2018. However, on November 11, 2022, multiple secretariats jointly published a "progress report" on GOM actions to date in implementing the presidential corn decree; it states that, during 2021 and 2022, COFEPRIS has 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.

Twenty-eight legal challenges (amparos) to the decree have been filed by different corn use companies, including seed, oil, food, and feed producers, and agricultural associations in seven states.

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	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 Biosafety Law, which was published in the Federal Register (Diario Oficial) in March 2005. This law addresses several 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 to the storage and movement of GE corn.

In April 2011, GOM published in the 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. 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 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 called the Native Corn Protection Law was published that reinforces many provisions of the Biosafety Law and related regulations but the law also calls for a consultative commission (not yet established) that can give opinions to the president regarding the conservation of native corn varieties.

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 is 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.

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, and to the environment and biological diversity, posed by activities carried out with GE production of animals, planting of GE plants, or use of GE microorganisms. In addition SADER reviews the risk assessments of each application for cultivation. SADER is responsible for deciding for planting crops, livestock, and fisheries what activities 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, including 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.

National Service of Agri-food Health, Safety, and Quality (SENASICA): The National Service of Agri-food Health, Safety, and Quality. SENASICA is an Agency within SADER that has responsibilities similar to those carried out in the United States by the U.S. Food and Drug Administration (FDA) and by USDA's Animal and Plant Health Inspection Service (APHIS) and Food Safety Inspection Service (FSIS).

The Secretariat of Environment and Natural Resources (SEMARNAT): Environmental protection, including biodiversity and wildlife species, is the responsibility of SEMARNET. All other forest and wildlife species of plants, animals or microorganisms 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 (planting, production, or use) 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, plants or microorganisms. In instances where 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 interagency process.)

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 of *Genetically Modified Organisms* (CIBIOGEM): Biotechnology policy activities for both, planting, and consumption of GE organisms in Mexico, are coordinated by CIBIOGEM, not an authority, but an interagency body that is part of 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 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 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/AUTOHRIZATIONS

Mexico does not make a distinction between food and feed approvals, and COFEPRIS is responsible for approving GE products for consumption. From 1995 to 2018, 181 GE commodities were approved for food and feed use. Corn has 90 events authorized for consumption.

In Mexico, approval (authorization) for GE products for consumption is distinguished from approval (permits) for planting or environmental release in that authorizations for products for consumption 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. The list of received applications must be published by the authorities in the NRB. 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 and there is no information in the NRB about the applications 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. 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 found here).

Although the main approving authority is SADER (through SENASICA), SEMARNAT issues a binding opinion through the General Direction of Environmental Risk (DGIRA).

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) in the dossier or request, if any, for the missing information. SENASICA submits the dossier to SEMARNAT that has 3 days to ask for additional information, if needed.
- Once received, the complete dossier must be published by the authorities in the NRB. 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 (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 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 the application, 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.

More information can be found here.

c) STACKED or PYRAMIDED EVENT APPROVALS/AUTHORIZATIONS

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

GE cotton cultivation were the only applications submitted during 2020 (two for experimental field trials, four for pilot trials, and nine for commercial release), and all were denied. One application in 2021 was submitted for alfalfa and that was denied. There were no applications during 2022. There have been no permits for planting GE crops since 2019. All denials have been based on negative opinions by SEMARNAT.

e) INNOVATIVE BIOTECHNOLOGIES

Mexico has not determined the regulatory status of innovative biotechnologies (such as genome editing) in plants or plant products. Genome editing is under discussion by technical areas in SADER.

f) COEXISTENCE

Biosafety Law Provision 90 establishes that GE crops 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

There has been no monitoring activity reported since 2018. 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. 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), 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

Advances in agricultural biotechnology can help to overcome challenges of climate change and food security. Agricultural biotechnology has created crops that require fewer pesticides to grow, and others that are more resistant to drought and pests that could help farmers in Mexico and the United States. Emerging techniques like gene editing have produced crops that contain high levels of vitamins and minerals, or that can be stored for long periods, making them great tools in the fight against hunger. Biotechnology is one of the most reliable answers to mitigate climate change through efficient use of energy in farming, carbon sequestration and reduced synthetic fertilizer usage. Planting GE crops has shown significant reduction in the amount of greenhouse gases emitted. This reduction occurs due to GE crops do not need as much maintenance as regular crops; farmers are not wasting as much fuel to power their equipment, resulting in a reduction of greenhouse gases emitted.

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 that represents the major biotechnology developers and crop protection. 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 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 prefer 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

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

c) EXPORTS

Mexico does not export any GE animals.

d) IMPORTS

Mexico is highly dependent upon imports of genetics for artificial inseminations 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. 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 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 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 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 GE animals and that it is essential to educate the public about this issue.

b) MARKET ACCEPTANCE/STUDIES

None.

CHAPTER 3: MICROBIAL BIOTECHNOLOGY

PART G: PRODUCTION AND TRADE

a) COMMERCIAL PRODUCTION

For microbial biotechnology, agri-food applications include the development of 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:

- Use of biocatalysts to produce capsaicinoids. Without the need to plant and harvest a single plant, it has the capacity to produce a wide variety of capsaicinoids with modulable sensation, controlled and standardized pungency, as well as suitable physical properties. (Applied Biotec Cuernavaca, Morelos).
- Process of production and use of biopreservative microorganisms for the control of pathogenic and deteriorating microorganisms in fresh cheeses (Sigma Alimentos Lácteos Jalisco).
- 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).

b) EXPORTS

Mexico exports many products that use microbial biotechnology in their production chain. From July 2021 to June 2022, Mexico exported $53 million in cheese and curd, $5.8 billion in beer, $10 million in wine, $502 million in condiments and sauces, $275 million in enzymes, and $582 million in fruit juice, among other products.

c) IMPORTS

Mexico imports many products that use microbial biotechnology in their production chain. From August 2021 to July 2022, Mexico imported $689 million in cheese and curd, $31 million in beer, $348 million in wine, $385 million in condiments and sauces, $1.2 billion in enzymes, and $76 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. 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 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 or a permit if the microbe will be released to the environment.

b) APPROVALS/AUTHORIZATIONS

There is no need for approvals if the use of the GE microbe will be confined. Only a notification is needed. Currently there are no applicants 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 I: MARKETING

a) PUBLIC/PRIVATE OPINIONS

Biotech and microbiology researchers are 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