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Prepared By: Adriana Otero

Approved By: Rhiannon Elms

Report Highlights:

Mexico has not reported any official biotechnology food or feed products approvals since May 2018. Additionally, Mexico has rejected or delayed all permit applications for cultivation of genetically engineered (GE) cotton in 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 coupled with additional challenges in the sector has significantly reduced production (approximately a 33 percent reduction) and quality. On January 1, 2021, a Decree entered into force calling for a phase-out glyphosate and GE corn by January 2024, and its replacement with sustainable and ‘culturally appropriate’ alternatives. Mexico is one of the world’s largest importers of GE corn and soybeans, with 2020 imports reaching approximately U.S. \$3.1 billion and U.S. \$2.2 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. There is a growing backlog of biotech food and feed products currently pending approval, many of which have passed the statutory review and approval deadline. During the first week of December 2021, the [National Register of Biosafety](#) (NRB), managed through Mexico's National Science and Technology Council (CONACYT), was updated to reflect applications for GE planting permits for 2020 and 2021. The first update since March 2020 reflected 15 applications in process for GE cotton in 2020 (two for experimental, four for pilot, and nine for commercial), and one application for the commercial planting of GE alfalfa in 2021. CONACYT is the government entity responsible for maintaining the NRB and notifying all applications and resolutions for permits for planting GE seeds and authorizations for consumption of GE products. For products of microbial biotechnology, Mexico's regulation only requires notification to federal authorities, and no additional regulatory process is necessary. This has allowed for greater development of the sector, producing billions of dollars' worth of international trade in related products.

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PART I: MARKETING

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CHAPTER1: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

a) PRODUCT DEVELOPMENT

Mexico currently has no genetically engineered (GE) plants or crops under development for commercialization within the next five years. 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. No permits for experimental or pilot planting have been granted in 2019, 2020 or 2021.

b) COMMERCIAL PRODUCTION

Cotton

Cotton is the only GE crop produced commercially in Mexico, with traits to include resistance to lepidopteran insects and tolerance to the herbicide glyphosate; tolerance to the herbicides dicamba, glufosinate ammonium, and glyphosate; glyphosate tolerance; and to lepidopteran insects and tolerance to the herbicides dicamba, glufosinate ammonium and glyphosate.

Producers have faced a cotton seed shortage since 2019, as GOM continues to reject or delay approvals for GE cottonseed permits, citing the precautionary principle and concerns about GE varieties intermixing with traditional wild cotton populations in the south of the country. The only events approved for planting in Mexico are outdated and unavailable on the world market, and producers report that they don't 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 distributed directly to seed companies who apply by requesting a specific number of hectares. After obtaining permits, companies then sell seeds directly to producers within the approved area.

Planted area for MY 2021/22 is forecasted at 159,000 hectares (ha), a 35 percent reduction compared to MY 2018/2019. This reduction in planted area is a direct result of a lack of GE seeds. U.S. cottonseed exports to Mexico reached U.S. \$13 million in 2020, down from a high of U.S. \$17 million in 2018. Through June 2021, trade is down 86 percent compared to the same period in 2020, only reaching U.S. \$2 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

GE soybean received commercial planting approval in seven states in 2012, however, domestic honey producers initiated eight court challenges and filed a complaint with the National Commission on Human Rights. In 2015, Mexico's Supreme Court ruled that there was no evidence of damage to honey trade, the environment, or health. However, the court mandated a consultative process in seven communities within Campeche, Yucatan and Quintana Roo. While the consultation process was

transparent and with acceptance by many, some communities indicated they did not have enough information to be properly consulted. As a result, in June 2017, the company announced it would not commercialize GE soybeans in the seven states to avoid interfering with consultations. In September 2017, the National Health, Food Safety and Quality Service (SENASICA) revoked the original 2012 permit after GE soybean was detected in non-authorized areas. There have been no applications for GE soybean planting since 2013.

Corn

GE corn planting is restricted by a collective GE corn lawsuit -filed by a group of citizen petitioners-claiming that “GE corn affects the human right to conservation, sustainable use, and fair and equitable sharing of the biological diversity of native corn”. The 2013 lawsuit was filed against several GOM secretariats, including SADER and Environment and Natural Resources (SEMARNAT), both of which at the time defended the importance of science based regulatory processes that followed national laws and international agreements when issuing decisions related to GE permit issuance. However, the ruling in favor of the plaintiffs in October of 2013, resulted in the creation of a preventive measure that suspended the issuance of permits for experimental, pilot, and commercial release of GE corn in Mexico. Following the ruling, several appeals were filed on specific elements (precautionary measure, for example) of the ruling, and on procedural and technical grounds. One such lawsuit, decided in March 2016, allowed for the resumption of experimental planting of GE corn. However, companies and public research centers have not submitted requests for permits due to the preference for commercial market certainty before investing in experimentation.

Additionally, on December 31, 2020, the GOM published a decree that calls for a phase-out of GE corn used for human consumption by January 2024 (more information in Trade Barriers Section F ahead).

Alfalfa

There is currently one existing application for commercial planting of alfalfa with reduced biosynthesis of lignin and tolerant to glyphosate currently awaiting a decision from SENASICA. This alfalfa was granted an experimental permit in 2014, and with a pilot permit in 2018. Alfalfa would be the third approved GE crop in Mexico.

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. MY2020/21 exports are forecasted at 0.5 million bales, on unexpected high levels of poor-quality cotton exports to Turkey, Pakistan, and China. The production of GE cotton is mainly for domestic consumption for processing of diverse national and export products. During COVID-19 the textile industry adapted production to new demand for household products like sheets and towels, and personal protective equipment. As both the Mexican and U.S. economies recover, demand for apparel is strong, and expected to increase for the foreseeable future. Mexico is a significant supplier of jeans and t-shirts to the United States (made in Mexico with GE cotton), and according to the Office of Textile and Apparel (OTEXA), cotton t-shirts exported to the United States increased 53 percent in the first five

months of 2021, compared to the same period in 2020.

d) IMPORTS

The Federal Commission for Protection Against Sanitary Risk (COFEPRIS), as 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 official updates on approvals or denials published in the NRB.

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 to increase in 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 MY 2021/22 levels forecasted to reach more than 17 million metric tons (MT), approximately 39 percent of the national consumption.

Soybean

Mexico is the world's third largest importer of soybeans, with supplies from the United States and Brazil. Soybean imports are expected to increase by 250,000 MT in MY 2021/22 to reach 6.25 million MT on a 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 Imports with GE Content (1000 MT)

	2019/2020	2020/2021	2021/2022
Corn	16,526	16,500	17,000
Cotton*	570	1000	1100
Soybean	5,748	6,000	6,250
Rapeseed	1,312	1,350	1,390

1000 MT; *1000 480 lb. Cotton Bales

Source: FAS GAIN reports [MX2021-0050](#), [MX2021-0021](#) and [MX2021-0028](#)

e) FOOD AID

Mexico is not a recipient of food aid. In September 2021 Mexico provided 1.7 tons of food aid to Haiti. In July 2021 Mexico provided food aid to Cuba. There is no information about the GE content on these foods.

f) TRADE BARRIERS

Mexico's biotechnology regulatory policy environment has become increasingly uncertain under its current administration. The NRB, a responsibility of CIBIOGEM, CONACYT has not updated or included application submissions for GE products for food and feed since May 2018 but notes that COFEPRIS has not made any decisions during 2019 and 2020. There is a growing backlog of biotech food and feed products currently pending approval, many of which have passed their statutory review and approval deadline of six months.

On January 1, 2021, a presidential [decree](#) (courtesy translation in the Annex) entered into force under which "the use of genetically modified corn grain in the diet of Mexican women and men," as well as glyphosate, is to be phased out by January 2024. GE corn grain is to be replaced by "sustainable and culturally appropriate alternatives." During the transition period, glyphosate will not be used in any government-sponsored program. The decree directs authorities to revoke existing GE corn product authorizations and abstain from authorizing new GE corn products so long as such decisions meet two criteria: conformity with "applicable standards" and "sufficiency of glyphosate-free corn kernel supplies." Mexico is currently not self-sufficient in corn production and imports almost 40 percent of total consumption.

Twenty-six lawsuits (amparos) or challenges to the decree have been filed by different corn use companies -including seed, oil, food, and feed producers- and agricultural associations in seven states, with two additional under review.

PART B: POLICY

a) REGULATORY FRAMEWORK

Mexico's comprehensive biotech regulation is the [BL](#), 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 BL 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 BL 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. 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 BL 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 BL and related regulations but 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 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 BL 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: 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 imports of GE animals, plants or microorganisms. 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: 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, plants 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 interagency 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 BL.

Intersecretarial Commission for Biosafety of Genetically Modified Organisms (CIBIOGEM): Biotechnology policy activities in Mexico are coordinated by CIBIOGEM, 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 first 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 BL, 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, COFEPRIS is responsible for approving GE products for consumption. From 1995 to 2018, several 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 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 BL 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) 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 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), in addition to receiving the binding opinion of SEMARNAT, regarding the release of GE 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 BL 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 PYRAMIDED EVENT APPROVALS

For stacked or pyramid events, the Mexican biosafety regulation does not require additional reviews if the stack is a combination of two or more already approved genetically engineered traits. However, in practice, Mexican government regulators consider these to be different events from the parental ones and will evaluate them on their own.

d) FIELD TESTING

As of the first week of December 2021, the NRB directory has been updated with applications for GE planting permits for 2020 and 2021, its first update since March 2020. The update reflected 15 applications for GE cotton in 2020 (two for experimental, four for pilot, and nine for commercial), and one application for the commercial planting of GE alfalfa in 2021. The applications are listed as under evaluation process. 2019 applications reflect seven cotton planting denials (three for commercial planting and four for pilot phases) and 12 under evaluation (four experimental, five pilot, and three for commercial phases).

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

BL 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 BL 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 BL 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 agrobiotechnology 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 BL 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).

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 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

Mexico published its General Climate Change Law ([LGCC](#)) in 2012, with implementation carried out through the Inter Secretarial Commission on Climate Change ([CICC](#)). In 2016, Mexico ratified the Paris Agreement that includes its NDC target of a 22 percent reduction of Greenhouse Gases (GHG) and Short-Lived Climate Pollutants (SLCP's) emissions, and a 51 percent reduction of black carbon by the year 2030. Mexico has also pledged that 35 percent of energy generated by 2024, and 43 percent in 2030, would be clean (see [INDC Mexico](#)). Mexico renewed their 2016 Nationally Determined Contribution's ([NDC](#)) in December 2020 with no new or increased emissions reductions targets.

PART C: MARKETING

a) PUBLIC/PRIVATE OPINIONS

Non-governmental organizations (NGOs) are very active opponents of biotechnology in Mexico. 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. There is more concern about the price and quality of food rather than its genetic composition.

CHAPTER 2: ANIMAL BIOTECHNOLOGY

PART D: PRODUCTION AND TRADE

a) 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

None.

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

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 BL 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.

APPROVALS

None

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.

LABELING and TRACEABILITY

Same regulations as GE plants.

ADDITIONAL REGULATORY REQUIREMENTS

Same regulations as GE plants.

INTELLECTUAL PROPERTY RIGHTS (IPR)

Same regulations as GE plants.

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.

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

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.

MARKET ACCEPTANCE/STUDIES

None.

CHAPTER 3: MICROBIAL BIOTECHNOLOGY

PART G: 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 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 to produce new varieties of plants and animals with characteristics of interest or advanced reproduction techniques of plants and animals. 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. It can be used in food industry for the production of sauces, condiments and processed food. ([Applied Biotec Cuernavaca, Morelos](#)).
- Process of production and use of bio-preservative 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 2020 to June 2021, Mexico exported \$47 million in cheese and curd, \$5.2 billion in beer, \$5.5 million in wine, \$433 million in condiments and sauces, \$203 million in enzymes, and \$474 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 \$536 million in cheese and curd, \$49 million in beer, \$226 million in wine, \$320 million in condiments and sauces, \$983 million in enzymes, and \$61 million in fruit juice, among other products.

d) TRADE BARRIERS

None

PART H: POLICY

a) REGULATORY FRAMEWORK

As in the case of plant and animal biotechnology, the BL 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 I: 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 and microbiology [researchers](#) (link in Spanish) 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:

Courtesy translation of the presidential Decree that calls for a phase-out of glyphosate and GE corn by January 2024, the latter of which is to be replaced by a “sustainable and culturally appropriate” alternative: [Corn Decree Eng.docx](#)