



**Required Report:** Required - Public Distribution **Date:** December 31, 2024

**Report Number:** MX2024-0062

Report Name: Agricultural Biotechnology Annual

Country: Mexico

**Post:** Mexico City

**Report Category:** Biotechnology and Other New Production Technologies

**Prepared By:** Adriana Otero Arnaiz

Approved By: Alexander Chinh

## **Report Highlights:**

The only genetically engineered (GE) product in commercial production is GE cotton, with obsolete seeds and only in restricted areas. There has been no advance in plant or animal biotechnology development and production, mainly due to policy and regulatory constraints. In 2023, trade in products that may have used microbial biotechnology at some point in their value chain totaled \$14.14 billion.

## **EXECUTIVE SUMMARY**

There have been no permits for planting GE crops since 2019. Cotton is the only GE product planted commercially in Mexico. The absence of new planting permits in recent years has led seed companies to reduce their presence in the Mexican market, to varying degrees. It also has forced Mexican farmers to rely on obsolete GE seeds.

COFEPRIS has not publicly reported any authorizations for GE food and feed products since May 2018. Moreover, there is no information in the National Register of Biosafety (NRB) about pending applications for GE food and feed products.

There has been successful and increasing use of microbial biotechnology in different food sectors. In 2023, trade in products that may have used microbial biotechnology at some point in their value chain totaled \$14.14 billion.

# TABLE OF CONTENTS

CHAPTER 1: PLANT BIOTECHNOLOGY	2
PART A: PRODUCTION AND TRADE PART B: POLICY PART C: MARKETING	2 6 14
CHAPTER 2: ANIMAL BIOTECHNOLOGY	16
PART D: PRODUCTION AND TRADE	16
PART E: POLICY	16
PART F: MARKETING	17
CHAPTER 3: MICROBIAL BIOTECHNOLOGY	18
PART G: PRODUCTION AND TRADE	18
PART H: POLICY	20
PART I: MARKETING	21

### CHAPTER 1: PLANT BIOTECHNOLOGY

## PART A: PRODUCTION AND TRADE

### a) RESEARCH AND PRODUCT DEVELOPMENT

Mexico continues without advance on product development. The 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

### Cotton

Mexico's cotton industry faces significant challenges due to limited access to new genetically engineered (GE) seed technology and restrictions on glyphosate use.

The government has not approved new GE cotton varieties since 2019, restricting planting area and yield. Farmers are forced to rely on outdated, imported GE seeds or saved seeds, leading to yield uncertainty and volatility in some growing regions. Industry applications for new GE cotton planting permits in 2019 and 2020 were all rejected. While the government has not ruled on three applications submitted in 2023 to authorize cultivation of new GE varieties, even if approved, the proposed varieties need to be updated (7-10 years old) and are unlikely to improve yields significantly.

The government restricted glyphosate imports in 2020 and aimed to ban its use entirely by March 2024. However, in March 2024, a joint statement by multiple ministries postponed the ban until a viable alternative was found. While there currently needs to be a quota on glyphosate import, the industry faces uncertainty regarding its long-term availability. Limited access to advanced GE seeds and glyphosate contributes to declining cotton production. For example, Coahuila state experienced a 30-year low in cotton yields in 2023/24 due to using non-tested GE seeds (see report MX2024-0017<sup>1</sup>). These challenges have led some seed companies to pause or restrict their operations in Mexico while farmers seek alternative solutions.

In December 2020, the Corn Decree restricted glyphosate imports, aiming for a complete ban by March 2024. This was further reinforced by a revised decree in February 2023. However, just before the ban was to take effect, a released a <u>Joint Statement</u><sup>2</sup> stating from Secretariats of Economy (Economia), Environment and Natural Resources (SEMARNAT), and SADER, and the Federal Commission for the Protection against Sanitary Risks (COFEPRIS), announced a postponement. The new stance prioritizes finding a viable alternative to glyphosate before completely phasing it out. This decision, echoed by both the previous and current Agriculture Secretaries, provides some relief to the agricultural industry. This has been reiterated by the SADER Secretary Víctor Villalobos and the new appointed secretary Julio Berdegué. According to the industry there is no quota for the importation of the herbicide. Currently, according to industry sources, there are no restrictions on glyphosate imports. This revised

<sup>&</sup>lt;sup>1</sup> USDA Cotton and Products Annual 2024: https://fas.usda.gov/data/mexico-cotton-and-products-annual-9

<sup>&</sup>lt;sup>2</sup> GOM Statement in Spanish Mexican government safeguards the country's agricultural and food security | Ministry of Economy | Government | gob.mx (www-gob-mx.translate.goog)

section clarifies the timeline and reasoning behind the glyphosate policy shift, making it easier to understand the current situation.

## Soybean

There have been no applications for planting GE soybeans since 2013. However, as in the case of cotton, producers can find different sources to obtain seeds, and it is uncertain in how much of the planted area is with conventional varieties.

### Corn

There have been no applications for planting GE corn since 2014 (see Report MX2013-2075<sup>3</sup>: Mexican Judge Blocks GE Corn Permits). On January 1, 2021, Mexico issued a decree calling for a phase-out of GE corn for consumption to be substituted with sustainable and culturally appropriate alternatives. Several companies filed lawsuits against the decree, and some courts ruled in favor of the companies, finding that the decree was unconstitutional and not supported by science. However, in February 2023, Mexico published a new Corn Decree<sup>4</sup> that abolished the previous decree. The new Corn Decree also banned GE corn for human consumption and planting without provide any scientific basis for the ban. There is no information about the efforts of the GOM to the implementation of the Corn Decree and monitoring of the presence of GE corn planted in Mexico.

### Alfalfa

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

### c) EXPORTS

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. As of June 2024, Mexico exported 164,615 bales, which is 56 percent lower than in MY 2022/23 (See report MX2024-0043<sup>5</sup>).

### 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 in the National Register of Biosafety (NRB<sup>6</sup>).

#### Cotton

Mexico imports GE cotton from the United States to meet nearly 50 percent of its domestic demand. Post forecasts MY 2024/25 GE cotton imports at 800,000 bales, a 33 percent increase from the previous

 $https://apps.fas.usda.gov/newgainapi/api/report/downloadreportbyfilename? filename=Mexican \% 20 Judge \% 20 Blocks \% 20 GE \% 20 Corn \% 20 Permits\_Mexico\_Mexico\_10-28-20 13.pdf$ 

https://apps.fas.usda.gov/newgainapi/api/Report/DownloadReportByFileName?fileName=Cotton%20and%20Products%20Update Mexico%20City Mexico MX2024-0043

<sup>&</sup>lt;sup>4</sup> Corn Decree 2023 in Spanish <a href="https://www.dof.gob.mx/nota">https://www.dof.gob.mx/nota</a> detalle.php?codigo=5679405&fecha=13/02/2023#gsc.tab=0

<sup>&</sup>lt;sup>6</sup> National Register of Biosafety information in Spanish https://conahcyt.mx/cibiogem/index.php/sistema-nacional-de-informacion/registro-nacional-bioseguridad-ogms

year's estimate of 600,000 bales due to forecasted low production. As of June 2024 (MY2023/24), Mexico imported 541,117 bales, a 16 percent decrease compared to the same period of MY 2022/23.

#### Corn

Mexico is one of the five main importers of corn in the world. Mainly importing from countries that produce GE corn. According with the Production Supply and Distribution (PSD, USDA<sup>7</sup>), in MY 2023/2024, Mexico's corn imports are estimated at 23.5 MMT, the record highest level, to compensate for lower domestic production and to meet the demand from the animal feed industry. For MY 2024/2025 imports are forecast at 22.5 MMT.

## Soybeans

PSD data shows that Mexico imports 98 percent of the soybean consumed domestically, reaching 6.4 thousand MT during the last two MY, forecasting 190 thousand MT for MY 2024/2025 of GE soybean imports from United States and Brazil.

## 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. According to PSD data Mexico is forecasted to import 1.2 million MT in MY2024/25 as it was estimated for MY 2023/2024.

## 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 February 2023 Corn Decree imposes an immediate prohibition on the use of GE corn intended for "human consumption," defined as corn used in nixtamalization or flour production. The decree also instructs Mexican authorities to gradually substitute GE corn used for animal feed and for human consumption other than in nixtamalization or flour production.

In August 2023, the United States established a USMCA dispute panel<sup>8</sup> on these Mexican measures after technical consultations under the USMCA SPS Chapter and dispute settlement consultations both failed to resolve U.S. concerns.

On December 20<sup>th</sup> the USMCA Panel final report of the genetically modified corn (MEX-USA-2023-31-01<sup>9</sup>) was published in favor of United States because the Mexican measures were not based on an adequate risk assessment, scientific evidence and relevant international standards. The same date the

<sup>&</sup>lt;sup>7</sup> PSD: <a href="https://apps.fas.usda.gov/psdonline/app/index.html#/app/advQuery">https://apps.fas.usda.gov/psdonline/app/index.html#/app/advQuery</a>

<sup>&</sup>lt;sup>8</sup> USMCA dispute panel on GE corn: <a href="https://ustr.gov/about-us/policy-offices/press-office/press-releases/2023/august/united-states-establishes-usmca-dispute-panel-mexicos-agricultural-biotechnology-measures">https://ustr.gov/about-us/policy-offices/press-office/press-releases/2023/august/united-states-establishes-usmca-dispute-panel-mexicos-agricultural-biotechnology-measures</a>

<sup>&</sup>lt;sup>9</sup> AGREEMENT BETWEEN THE UNITED STATES OF AMERICA, THE UNITED MEXICAN STATES, AND CANADA PANEL ESTABLISHED PURSUANT TO CHAPTER 31. MEXICO — MEASURES CONCERNING GENETICALLY ENGINEERED CORN MEX-USA-2023-31-01. FINAL REPORT. December 20, 2024: https://ustr.gov/sites/default/files/Final Report ENG.pdf

Secretariat of Economy and the Secretariat of Agriculture and Rural Development release a joint statement will respect the panel decision.

A proposed reform to Mexico's constitution would ban GE corn in all food products for human consumption. The current restriction on human consumption, per the February 2023 presidential decree, applies only to corn dough (masa) and tortillas. The proposed constitutional reform would also require imported GE corn to be "broken" prior to entry into Mexico further restricting its use. If approved, this constitutional change would override the existing Biosafety Law (2006), which allows for the cultivation and consumption of GE crops. For the reform to enter in place, it must pass with a two-thirds majority in both chambers of Congress and be approved by at least 17 state legislatures, which have happened with other 15 constitutional reforms approved during the last three months.

### PART B: POLICY

### a) REGULATORY FRAMEWORK

Legal term (in official language)	Legal Term (in English)	Laws and Regulations where term is used	Legal Definition (in English)
Organismo Genéticamente Modificado (OGM)	Genetically Modified Organism (GMO)	<ul> <li>Biosafety Law</li> <li>Implementation Rules of the Biosafety Law (Bylaws)</li> <li>Agreement to Determine the Centers of Origin</li> <li>Notification Process for the Confined Use of GE organisms</li> <li>GE seeds labeling standard</li> <li>Risk assessment of GE plants during the experimental and pilot stages standard</li> <li>Corn Decree establishing</li> </ul>	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

\_

<sup>&</sup>lt;sup>10</sup> Joint Statement of Secretariats of Economy and Agriculture on Response to the USMCA Panel Final Inform, in Spanish: https://www.gob.mx/se/prensa/panel-del-t-mec-distribuye-informe-final-en-el-caso-mexico-medidas-relacionadas-con-el-maiz-geneticamente-modificado-mex-usa-2023-31-01

There have been no changes in the Mexico's comprehensive biotech regulation, the <u>Law on Biosafety of Genetically Modified Organisms</u> (hereafter the Biosafety Law<sup>11</sup>), published in the Federal Register (*Diario Oficial*) in March 2005. This law regulates the research, planting, and import/export of biotechderived products.

Mexico's Biosafety Law and its Implementation Rules (Bylaw<sup>12</sup>) 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.

<sup>&</sup>lt;sup>11</sup> Biosafety Law in Spanish: https://www.diputados.gob.mx/LeyesBiblio/pdf/LBOGM.pdf

<sup>&</sup>lt;sup>12</sup> Biosafety Bylaw in Spanish: <a href="https://www.diputados.gob.mx/LeyesBiblio/regley/Reg">https://www.diputados.gob.mx/LeyesBiblio/regley/Reg</a> LBOGM.pdf

In November 2012, the GOM published the <u>Agreement to Determine the Centers of Origin<sup>13</sup></u> 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 <u>Notification Process for the Confined Use of GE Organisms<sup>14</sup></u>. 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<sup>15</sup>) 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 <u>standard<sup>16</sup></u> was published that establishes the requirements for the risk assessment of GE plants during the experimental and pilot stages of cultivation.

**Figure1**. Steps for the Risk Assessment according to the Mexican standard (NOM-002-SAG-BIO/SEMARNAT-2017).

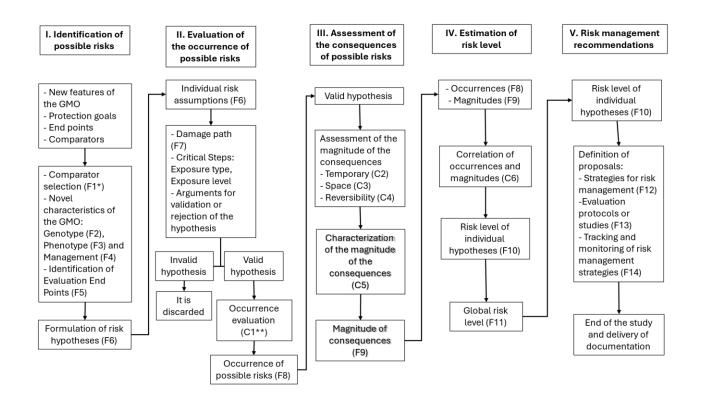
<sup>-</sup>

<sup>&</sup>lt;sup>13</sup> Agreement to Determine the Centers of Origin in Spanish: https://dof.gob.mx/nota\_detalle.php?codigo=5276453&fecha=02/11/2012

<sup>&</sup>lt;sup>14</sup> Notification Process for the Confined Use of GE Organisms in Spanish: https://dof.gob.mx/nota\_detalle.php?codigo=5186327&fecha=15/04/2011#gsc.tab=0

<sup>&</sup>lt;sup>15</sup> NOM-001-SAG/BIO-2014 for GE Seeds Labeling in Spanish: <a href="https://www.gob.mx/senasica/documentos/nom-001-sag-bio-2014">https://www.gob.mx/senasica/documentos/nom-001-sag-bio-2014</a>?state=published

<sup>&</sup>lt;sup>16</sup> NOM-002-SAG-BIO/SEMARNAT-2017 that stablish the characteristics and requirements for the risk assessment for the GE crops planting, in Spanish: <a href="https://dof.gob.mx/nota\_detalle.php?codigo=5542425&fecha=30/10/2018#gsc.tab=0">https://dof.gob.mx/nota\_detalle.php?codigo=5542425&fecha=30/10/2018#gsc.tab=0</a>



## **Biotechnology Related Regulations**

On April 17, 2024 was published in the official Gazette (DOF) the General Law on Appropriate and Sustainable Food (GLASF<sup>17</sup>) that requires the labeling of products containing ingredients that directly come from the use of genetically modified organisms (Article 21):

"Second Title, Promotion and Consumption of Healthy Foods, Chapter III, From the Right to Healthy Nutritional Information, Provision 21. Producers and distributors of processed foods must warn, in addition to the elements required in article 212 of the General Health Law, if its products contain ingredients that directly derive from the use of genetically modified organisms in the terms of the Law" but does not specify which law. The next step is the publication of the bylaw that will stablish the implementation rules and could clarify if the labeling will follow the terms of the Biosafety law.

On April 4, 2020, a Congressional Decree called the <u>Native Corn Protection Law<sup>18</sup></u> 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,

<sup>&</sup>lt;sup>17</sup> GLASF in Spanish: https://www.diputados.gob.mx/LeyesBiblio/pdf/LGAAS.pdf

<sup>&</sup>lt;sup>18</sup> Native Corn Protection Law in Spanish: https://dof.gob.mx/nota\_detalle.php?codigo=5591534&fecha=13/04/2020

- 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

There have been no changes in the attributions of the authorities regarding biotechnology in Mexico. 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 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 SEMARNAT 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 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. It is expected that will change during the first months of the next administration.

### 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 181 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<sup>19</sup>. 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

<sup>19</sup> National Register of Biosafety with information in Spanish: <a href="https://conahcyt.mx/cibiogem/index.php/sistema-nacional-de-informacion/registro-nacional-bioseguridad-ogms">https://conahcyt.mx/cibiogem/index.php/sistema-nacional-de-informacion/registro-nacional-bioseguridad-ogms</a>

the release (for further details see <a href="here">here</a><sup>20</sup>). Although the central approving authority is SADER (through SENASICA<sup>21</sup>), 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:
  - o 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.
  - o 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

<sup>&</sup>lt;sup>20</sup> Process for the permits for release of GE crops to the environment in Spanish: <a href="https://www.conacyt.gob.mx/cibiogem/index.php/mesa-redonda-nal-docs-mesa-trabajo/mesa-redondadocs-trabajood-gisplaogmmca/4729-tramitesdeogm/file">https://www.conacyt.gob.mx/cibiogem/index.php/mesa-redonda-nal-docs-mesa-trabajo/mesa-redondadocs-trabajood-gisplaogmmca/4729-tramitesdeogm/file</a>

<sup>&</sup>lt;sup>21</sup> SENASICA information about the GE crops permits process in Spanish: <a href="https://www.gob.mx/senasica/acciones-y-programas/bioseguridad-para-organismos-geneticamente-modificados-51953">https://www.gob.mx/senasica/acciones-y-programas/bioseguridad-para-organismos-geneticamente-modificados-51953</a>

- 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.
- In the case of areas with indigenous communities the inquiry and participation and indigenous people and communities settled in the zones where the GMOs release is intended shall be carried out in accordance with the methods decided by the CIBIOGEM.

More information on cultivation permit approval process can be found here<sup>22</sup>.

### 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 or not responded to permits for planting GE crops in Mexico since 2019. All denials were due to negative opinions by SEMARNAT. There were no applications during 2022. Three GE cotton applications submitted in 2023 are pending resolution, in these 2023 cases with a positive opinion from SEMARNAT and waiting for the indigenous consultations that according to the Biosafety Law need to be done by CIBIOGEM.

### 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

SADER has the purview to determine GE-free zones with input from CIBIOGEM and the National Commission for the Understanding and Utilization of Biodiversity, following the Biosafety Law Provision 90 that 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.

## g) LABELING AND TRACEABILITY

Mexico requires the labeling of GE seeds (For more information see Chapter 1, Part B, sub-paragraph a); for GE products, the Biosafety Law Provision 101 requires labeling only when there is a substantial difference between a conventional product and the corresponding GE product.

The recently published GLASF requires the labeling of products containing ingredients that directly come from the use of genetically modified organisms in the terms of the law, without certainty if it is in the terms of the Biosafety Law Provision 101 (For more information see Chapter 1, Part B, subparagraph a).

<sup>&</sup>lt;sup>22</sup> Figure showing the attributes and agencies involved in the permits for GE crops process in Spanish: <a href="https://conacyt.mx/cibiogem/images/cibiogem/sistema">https://conacyt.mx/cibiogem/images/cibiogem/sistema</a> nacional/registro/proceso-resolucion-permisos.pdf

### h) MONITORING AND TESTING

There has been no monitoring activity reported since 2018. Authorities responsible for the monitoring programs are SADER and SEMARNAT.

## 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 that currently is only one company for GE cotton in restricted areas, 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<sup>23</sup> 1978 Act). Mexico has legislation to address industry intellectual property rights, including agricultural biotechnology, under its Law of Industrial Property.

### 1) CARTAGENA PROTOCOL RATIFICATION

In 2002, the Mexican Senate ratified the Cartagena Protocol on Biosafety (CPB) and it is party since September of 2003.

## 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.

15

<sup>&</sup>lt;sup>23</sup> List of UPOV Members: https://www.upov.int/edocs/pubdocs/en/upov\_pub\_423.pdf

Mexico is also a member of the Asia-Pacific Economic Cooperation (APEC), which includes many other countries, including Australia, Canada, China, Japan, Indonesia, Malaysia, New Zealand, and the United States, that recognize that agricultural biotechnology is a revolutionary tool that could change the agriculture sector.

### n) RELATED ISSUES

Mexico started a new administration on October 1<sup>st</sup>. The new president has a scientific background, it is expected a more technical management of the issues in the country that the previous administration. However, it is too early to know the direction of her decisions. About biotechnology she has mentioned GE corn ban on planting, even before of the USMCA Panel final report of the genetically modified corn.

Lack of resolution to permits during the last years has led to companies to stablish a pause in the GEseeds market in Mexico or restricted it to some areas. However, producers have found different ways to obtain GE seeds.

### PART C: MARKETING

#### a) PUBLIC/PRIVATE OPINIONS

Genetically Engineered (GE) corn has been a controversial topic in Mexico between scientists who support its use and activists who consider it dangerous, yet this controversy rarely makes it into the national press or public. For other GE crops non-governmental organizations (NGOs) are not as active opponents of biotechnology in Mexico as for GE corn. 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

<u>Forma Food</u> is a plant-based startup from Monterrey that emulates the texture, consistency and flavor of traditional roast beef, offering a viable and attractive alternative for meat lovers and vegan consumers. Initially, they only explored the production of meat from animal cells, but the high cost of the process led them to innovate with vegetable pastes. Their product is designed, among others, for those looking to reduce their meat consumption for health, ethical or environmental reasons.

## c) EXPORTS

Mexico does not export any GE animals or their products.

### d) IMPORTS

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

Products of alternative milk, chicken and meat are imported from United States but the presence on the markets is very low compared with the conventional products.

## e) TRADE BARRIERS

None

### PART E: POLICY

### a) REGULATORY FRAMEWORK

In Mexico, biotechnology regulation is generally applied to species and does not make a particular differentiation among plants, animals, or microorganisms. The same regulation applied to GE plants is applicable to the commercialization of GE animals and insects. 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. For more information on terminology and definitions used by Mexico to refer to agricultural biotechnology, see Chapter 1, Part B, sub-paragraph a.

### b) APPROVALS/AUTHORIZATIONS

None

### a) 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.

## b) LABELING AND TRACEABILITY

Same regulations as GE plants.

## c) ADDITIONAL REGULATORY REQUIREMENTS

Same regulations as GE plants.

## d) INTELLECTUAL PROPERTY RIGHTS (IPR)

Same regulations as GE plants.

## e) 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.

## f) 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:

- Using agrotechnological products based on fungi and beneficial bacteria to increase the yield (Biogea, located in Nuevo Leon)
- 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 may use microbial biotechnology in their production chain. According to data from Trade Data Monitor, LLC, exports reached \$10.8 billion in 2023, with beer accounting for \$5.8 billion. Bear and bread industry have been growing during the last years as it is shown in the figure 2, the bear industry exported \$2.6 billion in 2023. It is forecasted that the market of products that may use microbial biotechnology at some point in their value chain exports increases a 17 percent at \$12.63 billion in 2024 if the public policies does not affect the food industry.

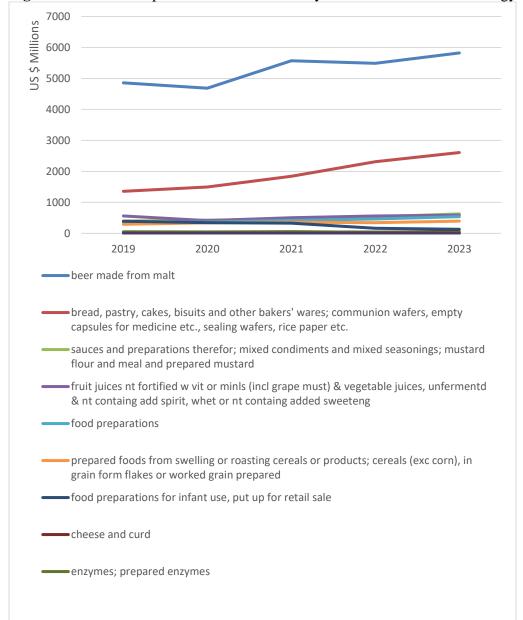


Figure 2. Mexican Exports of Products that May Use Microbial Biotechnology

## c) IMPORTS

Mexico imports, mainly from United States, many products that may use microbial biotechnology in their production chain reaching \$3.34 billion in 2023 and it is forecasted to increase 21 percent for 2024 at \$4.04 billion. For 2023 Mexico imported \$887 million in cheese and curd, that is the category with faster increase, as can be observed in Figure 3.

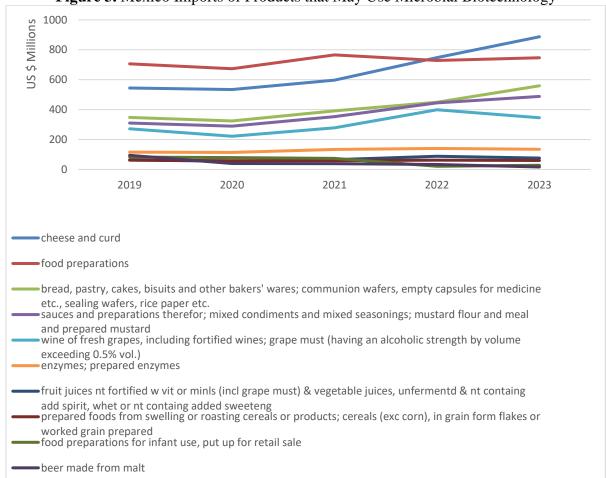


Figure 3. Mexico Imports of Products that May Use Microbial Biotechnology

#### 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