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Report Highlights:

The Ministry of Agriculture, Livestock and Food (MAGA) has a regulation in place for the approval of biotech crops. The regulation was harmonized with Honduras in 2019, and El Salvador adopted the same regulation at the end of 2022. MAGA has not responded to approval applications despite having regulatory requirements to do so. Stakeholders expect that the new administration taking power in January 2024 is more likely to follow established regulatory procedures.

Executive Summary:

Guatemala is a net agricultural exporter but imports most of its animal feed ingredients such as corn, DDGS (Distilled Dried Grains with Solubles), soybean meal, and soybean oil from other countries like the United States, Brazil, and Argentina. The country is also a food aid priority for the United States and the United Nations programs, receiving Genetically Engineered (GE) products derived from corn and soy. The country also imports a variety of GE derived products used by the food and feed industries.

Although Guatemala has a national policy for biosafety coordination, only two institutions have rules in place: MAGA and the Ministry of Environment and Natural Resources (MARN), through the National Council of Protected Areas (CONAP). MAGA is responsible for receiving and analyzing petitions for the domestic production of Genetically Engineered (GE) plants and animals in agricultural lands. CONAP is responsible for non-agricultural lands, strictly considered protected areas under conservation, where no GE plants or animals are permitted.

In 2019, as part of the Central America Customs Union initiative, Guatemala and Honduras signed a biotechnology harmonization agreement for regulatory criteria. Under the agreement MAGA now uses a set of forms and checklists to verify that petitions comply with corresponding requirements. Innovative biotechnologies are considered within the same rule, and once a plant is verified as being non-GE it is approved as conventional.

Note: All links provided in this report reference documents only available in Spanish.

Content

CHAPTER 1: PLANT BIOTECHNOLOGY

PART A: Production and Trade

a) RESEARCH AND PRODUCT DEVELOPMENT: Guatemala allows applications for experimental, pre-commercial, and commercial production of GE plants under "RT 65.06.01:18, "Biosafety Technical Regulation for Live Modified Organisms-LMO- for Agricultural Use" (Annex 1) and its implementation manual, approved through Ministerial Decree 271-2019. At present, there are no developments in the research pipeline.

b) COMMERCIAL PRODUCTION: The regulation mentioned above allows for universities, research centers, private companies, production associations, cooperatives, groups, or individuals to apply for the evaluation and approval of commercial production of biotech crops, following experimental confined use and field test pre-commercial phases. The confined use phase is to evaluate the effectiveness of new traits of interest, under field experimental conditions and with strict biosafety measures. The pre-commercial phase is to evaluate the effectiveness in multiple sites. Once the pre-commercial phase concludes and is evaluated to be effective and safe for human and/or animal utilization and the environment, the biotech crops may be approved for commercial production in Guatemala. Currently, there are no GE products approved for production in Guatemala, and therefore there is no legal production.

c) EXPORTS: The regulation allows for the import and export of GE plants and derived products.

d) IMPORTS: In 2022, Guatemala exported $7.5 billion in agricultural products to the world (excluding related products), while importing $5.3 billion. The United States reported agricultural exports to Guatemala of $1.8 billion in 2022, with corn representing 16 percent of the ag trade ($297 million), followed by soybean meal with 14 percent ($257 million) of total ag exports.

Despite being a net exporter of agricultural products, Guatemala does not produce significant amounts of yellow corn or soybean meal for animal feed, and therefore is a net importer of animal feed. In 2022, Guatemala imported roughly 978,000 metric tons (MT) of biotech corn from the United States, of which 926,000 MT were yellow corn and 51,000 MT white corn. Yellow corn is the most widely imported grain and is used in the animal feed manufacturing industry. Guatemala imported from the United States $27 million in distiller's dried grains with solubles (DDGS), $2.7 million in corn products, $2.8 million in corn seed, and $1.2 million in corn flour, among other corn products. In 2022, the feed industry also imported 505,000 MT of soybean meal from the United States, valued in $257 million.

The food processing industry imports white corn for chip production, cereals, porridges, and drinks. In addition, Guatemala also imported 71,000 MT of soybean oil and other soy products, mostly from the United States, that is widely consumed in the food market.

e) FOOD AID: Despite being a net agricultural exporter, Guatemala is a food-aid recipient country. It has the highest rate of chronic malnutrition in Latin America and in 2022 had the sixth highest rate worldwide, after Angola, Timor, Niger, Papua New Guinea, and Libya. Guatemala receives roughly 1,800 MT of direct food aid from the United States each year, in addition to the imports cited above. In-kind food donations consist largely of beans, corn-soy blend, rice, and vegetable oil, which are provided as school meals in some of the poorest municipalities in the highlands of Guatemala. Guatemala is also considered a high-risk country in terms of climate change vulnerability, demanding seasonal food aid on a yearly basis.

f) TRADE BARRIERS: Guatemala has no significant barriers to the import of biotech products intended for food, feed, and processing. Guatemala's inability to follow its own existing biotech regulations has become a trade barrier.

PART B: Policy

a) REGULATORY FRAMEWORK:

Table 1
Biotechnology Legal and Regulatory Terms in Guatemala

Legal term (in Spanish)	**Legal Term (in English)**	**Laws and Regulations where term is used**	**Legal Definition (in English)**
Organismo Vivo Modificado (OVM) u Organismo Genéticamente Modificado (OGM)	Living Modified Organism (LMO) or Genetically Modified Organism (GMO)	Law 44-2003 (2006)	Any living organism that possesses a new combination of genetic material obtained using modern biotechnology.
Nueva combinación de material genético	New combination of genetic material	Regulation RT 65.06.01:18 (2018)	New combination of genetic material is a stable insertion in the genome, of one or more genes or DNA sequences that codify for double strand DNA, RNA, proteins, or regulatory sequences that could not be obtained through conventional breeding or that may not be found in nature.

Source: RT 65.06.01:18 - "Biosafety Technical Regulation for Live Modified Organisms-LMO- for Agricultural Use – Annex 1

Guatemala's GE regulations fall under RT 65.06.01:18 - "Biosafety Technical Regulation for Live Modified Organisms-LMO- for Agricultural Use," Ministerial Decree 270-2019 -"Creation of the Guatemalan Biosafety Agricultural Technical Committee", and Ministerial Decree 271-2019 – "Manual of Technical Procedures for the Confined Use of Experimental, Pre-Commercial and Commercial Use of Genetically Modified Seed", establishing technical procedures for field trials, pre-commercial field tests, and commercial approvals of biotech plants.

Guatemala applies the "LMO" definition of Art. 3 (h) of the Cartagena Protocol on Biosafety, considering a GE plant as any new combination of genetic material obtained through modern biotechnology. In addition, the manual defines the new combination of genetic material as a stable insertion in the genome, of one or more genes or DNA sequences that codify for double strand DNA, RNA, proteins, or regulatory sequences that could not be obtained through conventional breeding or that may not be found in nature.

The regulatory process requires that a national biosafety committee reviews, inquires, and makes a final decision whether to approve a petition for the pre-commercial or commercial phases. The National Biosafety Committee is composed of representatives from the Animal Health Directorate, Plant Health Directorate, Food Safety Directorate, and Plant and Animal Genetics Directorate within the Ministry of Agriculture, Ministry of Environment, the Biotechnology Committee at the Council of Science and Technology, representatives of the Chamber of Agriculture, and the private and public universities. Members must have technical and scientific backgrounds and knowledge of biotechnology.

Petitions are subject to a 130-day maximum review process, but MAGA has not yet responded to applications submitted since April 2022. Approvals are for planting of agricultural seeds or propagation materials only in agricultural areas, under the Ministry of Agriculture's mandate, leaving protected areas outside the scope of the rule. MAGA does not require approvals for GE food, feed, or processing, as these do not fall under the "LMO" definition, nor does the Ministry of Health.

If a confined use experimental field trial is approved through a risk evaluation process, a certification permit is granted, and a monitoring and evaluation process accompanies it. MAGA is directly responsible for the monitoring and evaluation. If the experimental confined use field test proves effective and safe, a new petition process starts for a pre-commercial field test. The pre-commercial field test permits to evaluate GE plant traits in different sites to test its safety and effectiveness in different locations. The pre-commercial phase follows a similar petition and approval process as the pre-commercial, starting from the basis of the previous confined use field test, adequately terminated (GE plants destroyed) and the results report presented. If the pre-commercial phase demonstrates once more effectiveness and safety, a new petition process may advance for a commercial phase.

b) APPROVALS/AUTHORIZATIONS:

Before 2018, Guatemala did not approve any biotech products for commercial production, despite having enacted a regulation in 2006 that was intended to create an approvals process for the importation, production, and export of biotech seeds. Following passage of the 2006 regulation, some biotech field trials were approved through a lengthy process, but MAGA never responded to requests to evaluate the results and move forward with approvals for commercial production. Although MAGA is and has been the competent authority on agricultural biotechnology regulations, the Ministry of Environment, through CONAP, has been influential in restricting the use of biotechnology in the country through its role as the focal point of the Cartagena Protocol and has opposed the domestic use of biotechnology in the agricultural sector.

In the years 2018-2020, MAGA supported technical working groups which drafted a harmonized regulation with Honduras, under the advanced Central American Customs Union process, to evaluate biotech solicitations on a case-by-case basis. This included all stages from research and development to commercialization. The new rule entered into force on October 1, 2018. On November 29, 2019, the regulation was opposed in court by some domestic activist organizations. The opposition groups claimed in their lawsuit that agricultural biotechnology poses a threat to biodiversity and indigenous rights. However, the Supreme Court and Constitutional Courts reviewed these claims and determined that the regulations followed all domestic and international agreements.

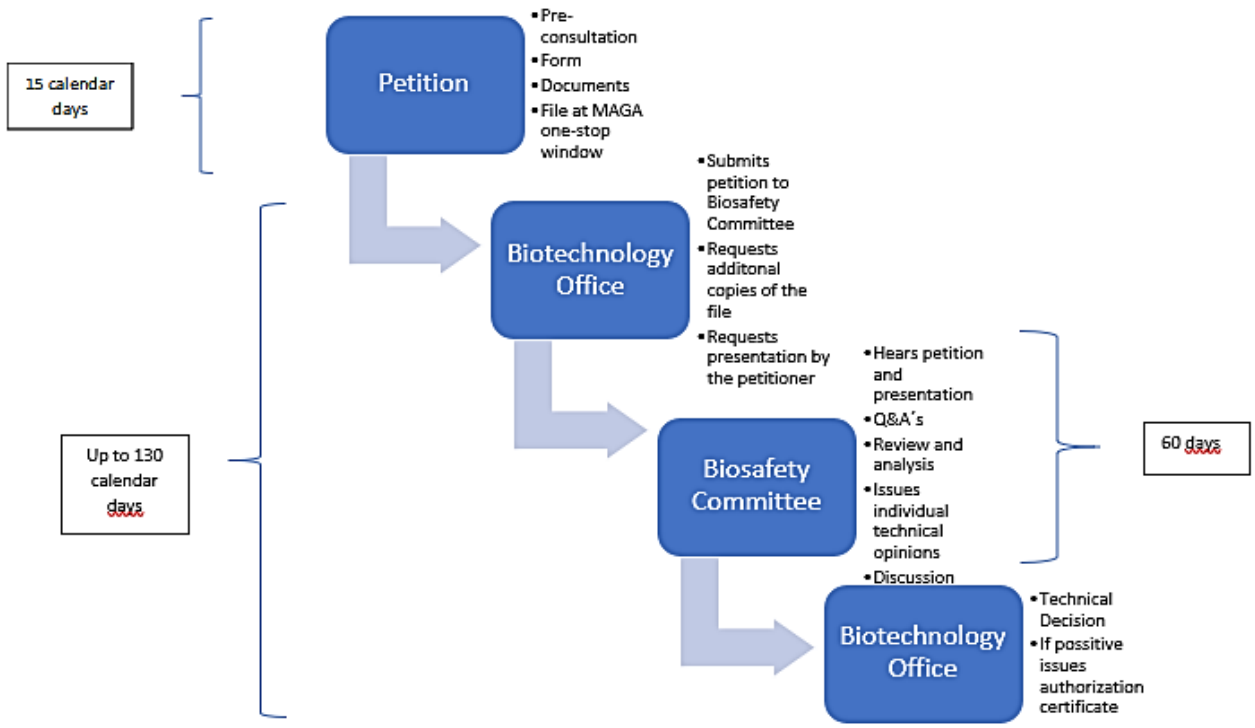
The first applications were submitted in April 2021 for an ornamental petunia, and later in July 2021 for insect and herbicide resistant corn for confined field trials, followed by a gene edited mustard green with a less bitter taste in September 2021. MAGA approved all three applications but just one field trial was established. However, after April 2022 MAGA received at least three more applications, but has not responded to any of them within the timeframe laid out in the regulation (30 calendar days). This caused concern with domestic and international companies who were planning to make investments and/or strategic partnerships in the Guatemalan agricultural sector after seeing the first applications successfully move through the new regulatory process. Guatemala, with its rich agricultural resources and strategic location, has the potential to become a hub for seed production and exports of improved varieties of fruits and vegetables if the new regulations are enforced in a science-based and transparent manner.

The new regulation establishes a straightforward mechanism for research and field trials, as well as pre-commercial and commercial approvals of GE seeds or propagative materials, based on risk assessments. The simplified procedure expedites approval of GE products with prior safe use in either Guatemala or Honduras.

Petitions start by an interested party submitting to MAGA regulators Form DFRN-01-R-042, which is a strictly technical consultation process, to verify that the genetic material complies with the “LMO” definition. MAGA responds to the petition and if confirmed to be an “LMO”, the petitioner can request a pre-consultation with MAGA regulators to understand the regulatory process and verify all the information that is required. The petition for confined use is for greenhouse or field experimental purposes and can be filed by a company, university or research center using Form DFRN-01-R-044.

If a petition for experimental confined use field trial is approved, a certification is issued. The following diagram is a summary of the approval process which can be found as part of Annex 1 of the operative manual and constitutes the standard mechanism for review and approval of a petition, either for experimental confined use field trial or pre-commercial field trial.

Figure 1. GE approval process for a petition, either for experimental confined use field trial or pre-commercial field trials.



Source: Summary based on Annex 1 - "Manual of Technical Procedures for the Confined Use of Experimental, Pre-Commercial and Commercial Use of Genetically Modified Seed", which establishes technical procedures for field trials, pre-commercial evaluations, and commercial approvals of biotech plants.

The experimental confined use is approved through the process outlined in Figure 1. The approval is notified through a certification authorization and is valid for 2 years. If the field testing needs to be extended, a renewal petition must be presented 15-days prior to the end of the confined use authorization. The pre-commercial authorization also follows the same approval process outlined in Figure 1. In this case, the experimental confined use must have been closed and results presented within the next 60 days after closure. The results will be part of the pre-commercial petition process. The authorization for pre-commercial use will be valid for 5 years, and its renewal can be presented 30-days

prior to the due date. The closed pre-commercial phase should also be reported 60 days after the closure. For commercial approval, the report for the pre-commercial phase must be presented and the petition is analyzed; if approved, a commercial certificate is authorized, requiring to then register the seed. Commercial approvals are good for 5 years and may be renewed. Both the pre-commercial and commercial authorizations will be notified to the Biosafety Clearing House of the Cartagena Protocol.

c) STACKED or PYRAMIDED EVENT APPROVALS/AUTHORIZATIONS: The regulation considers stacked events as a sole petition request if the stacked events have been previously evaluated and approved in any other country, either as singles or stacked. If the events have not been previously evaluated somewhere else, they will need to be evaluated both as singles and as stacked as part of the confined experimental field test phase.

d) FIELD TESTING: RT 65.06.01:18 and the manual establish three phases for final commercial release of a "live modified organism (LMO)": a) confined experimental field testing on a small scale, b) pre-commercial field testing of the technology on a medium scale, and c) commercial approval. Each phase requires a petition and approval process, as outlined in Figure 1. The authorization for confined experimental field testing is valid for 2 years and the pre-commercial field testing is valid for 5 years, and both can be renewed. The commercial phase authorization is valid for 5 years and requires registration of the seed. Each phase is subject to monitoring and evaluation by MAGA. Each phase needs to present its mitigation and final report prior to filing the next phase for that petition.

e) INNOVATIVE BIOTECHNOLOGIES: Guatemala, as a World Trade Organization (WTO) member, supported the 2018 International Statement on Agricultural Applications of Precision Biotechnology at the WTO Committee on the Application of Sanitary and Phytosanitary Measures in Geneva. RT 65.06.01:18 does not regulate innovative technologies, only "LMOs". Any innovative technology that does not fit the "LMO" definition is not regulated under the present rule. The very first process before a petition is requested consists of submitting Form DFRN-01-R-042 to the Biotechnology Office for its analysis. The Biotechnology Office may request additional information. If the new genetic material does not comply with the definition of an "LMO", and the new combination of genetic material can be obtained through conventional breeding or may be found in nature, the plant follows the same commercialization pathway as any non-GE planting material.

f) COEXISTENCE: MAGA regulations allow for the coexistence of different production technologies through sound protocols that have their own independent certification processes. The same Plant Genetics and Natural Resources Directorate is responsible for issuing approvals for organic and GE plantations. In addition, this Direction is also responsible for approving seed production operations and seed registration. The Biosafety Committee may provide additional guidelines to preserve agricultural technologies and its corresponding stewardship to avoid displacing any issued certification, either conventional, organic or GE.

Guatemala is an important agricultural producer and exporter in Central America, with most of the conventional agriculture products exported worldwide, while organic products are mainly exported to

high end markets in the United States, Japan, and the EU. In addition, MAGA maintains a positive list of approved agrochemicals, fertilizers, biopesticides and biofertilizers for the different agricultural technologies utilized in Guatemala, regulated by Central American Customs Union regulations, following international guidelines.

g) LABELLING and TRACEABILITY: Guatemala does not require labeling GE content in food or feed and follows Codex guidelines. Traceability is an option for export certification purposes.

h) MONITORING AND TESTING: N/A.

i) LOW LEVEL PRESENCE (LLP) POLICY: N/A.

j) ADDITIONAL REGULATORY REQUIREMENTS: N/A.

k) INTELLECTUAL PROPERTY RIGHTS (IPR): Guatemala respects IPR though its Intellectual Property Rights Law, Decree 57-2000, ruled by the Ministry of Economy. MAGA protects IPR through a registration process for agricultural inputs, including seeds. Guatemala approved adhesion to the International Union for the Protection of New Varieties of Plants (UPOV) in 2009 but has yet to approve the law to become a member. On September 6, 2023, the Agricultural Commission of the Congress of Guatemala introduced Law Initiative 6283-2023, corresponding to UPOV-91 adoption in Guatemala. The Law Initiative specifically spells out that the law does not apply to existing wild, native, creole, original, autochthonous, or endemic varieties, which will continue to be protected under present Guatemala biodiversity protection laws and institutions. The lack of approval of the UPOV law negatively impacts investments in the country and Guatemalan developers, who cannot register the products and cannot obtain IPR to exchange/trade improved materials with other partners, including local developments.

l) CARTAGENA PROTOCOL RATIFICATION: The Guatemalan Congress approved the Cartagena Protocol in 2003 by Legislative Decree 44-03. The Protocol took effect in January 2005. The point of contact for the Cartagena Protocol in Guatemala is the Technical Office for Biodiversity (OTECBIO), which is part of the Council of Protected Areas (CONAP). CONAP leads the "LMO Biosafety National Policy 2013-2023" through Presidential Decree 207-2014. The policy mandates CONAP to coordinate regulatory efforts with the different ministries, such as the Ministries of Agriculture, Environment, and Health. The policy dictates that the Ministries are the competent authorities responsible for the establishment and implementation of their corresponding regulations.

m) INTERNATIONAL TREATIES AND FORUMS: Guatemala is a member of the World Trade Organization (WTO) and its Sanitary and Phytosanitary (SPS) Agreement which includes the World Organization for Animal Health (OIE), International Plant Protection Convention (IPPC), and CODEX Alimentarius, where MAGA plays an active role as the competent authority in each of the SPS organizations. In addition, the Ministry of Environment and CONAP participate in the United Nations (UN) environmental chapters, including the climate change meetings (COP) and the UN annual conferences on biological diversity (COP-MOP) and other related forums. The Ministry of Economy has

an active role at the WTO and leads the Central American Customs Union process, where Central American regulations are discussed in technical working groups and approved through the Council of Ministries of Economy.

n) RELATED ISSUES: MAGA´s operative manual specifies that a prior consultation process is required with indigenous groups before submitting a petition for planting "LMOs", and recognizes centers of origin and genetic diversity of wild relatives, where "LMOs" will not be authorized, as spelled out in Articles 12.2 and 12.3:

> Article 12.2 Planting of Genetically Modified seeds in the territories
>
> The applicant must obtain the free, prior, and informed consent of the community, whenever it is legally recognized as an indigenous group, to comply with the United Nations Declaration on the Rights of Indigenous Peoples (UNDRIP), the Convention on Biological Diversity and Convention 169 of the International Labor Organization. A written consent must be presented as part of the petition process. The absence of consent will imply that these areas do not have authorization for use and therefore are considered areas of restricted use according to article 21 of RT: 65: 06.01: 18 until the corresponding consent is obtained.
>
> 12.3 Areas recognized as centers of origin and genetic diversity of wild relatives of cultivated species.
>
> The Directorate of Plant and Animal Genetics and Native Resources will recognize through scientific studies carried out with the technical and scientific support of the Biosafety Committee and other relevant institutions like CONAP, areas defined as centers of origin and genetic diversity of wild relatives of cultivated species.

PART C: Marketing

a) PUBLIC/PRIVATE OPINIONS: Opinions about agricultural biotechnology in Guatemala are divided. Science and agriculture faculties at the universities have publicly expressed their interest in biotechnology, in addition to organized farmer groups and the food industry. On the other side, those that oppose biotechnology are represented by human rights groups that believe that farmers could be forced to abandon native seeds for GE seeds. However, indigenous groups have not discontinued the planting of native seeds following the introduction of improved and hybrid seeds, and allowing commercial farmers access to modern biotech seeds likely not have any impact on farmers' access to native seeds.

b) MARKET ACCEPTANCE/STUDIES: The ideological opposition to biotech crops is only in the realm of domestic planting, as biotech food products have been widely consumed for decades and there are no major consumer complaints about the health risks. In addition, the use of biotechnology in the

health sector is not a concern at all. Biotechnology-derived drugs, use of biotechnology in medical treatments, and applications of biotechnology in all other fields and industries are not part of public controversy or discussions. As mentioned later in Chapter 3, there is wide use of GE microbes in different industries, including environmental remediation, but that hasn´t raised concerns.

CHAPTER 2: Animal Biotechnology

PART D: Production and Trade

a) RESEARCH AND PRODUCT DEVELOPMENT: Guatemala has no GE animal research or development.

b) COMMERCIAL PRODUCTION: Guatemala has no production of GE animals.

c) EXPORTS: Guatemala is not a GE animal exporter.

e) IMPORTS: Guatemala has not imported, nor shown interest in importing, GE animals.

d) TRADE BARRIERS: Unknown.

PART E: Policy

a) REGULATORY FRAMEWORK:

For information on regulatory terms relating to use of animal agricultural biotechnology in Guatemala, see Chapter I, Part B.

Guatemala has no regulatory process that would allow for domestic use of animal biotechnology.

b) APPROVALS/AUTHORIZATIONS: Guatemala has not approved any GE animals.

c) INNOVATIVE BIOTECHNOLOGIES: Guatemala has not discussed the use of innovative biotechnologies in animals.

d) LABELING AND TRACEABILITY: Guatemala has not started to discuss GE animals, in general.

e) ADDITIONAL REGULATORY REQUIREMENTS: Guatemala has no regulation in place for GE animals.

f) INTELLECTUAL PROPERTY RIGHTS (IPR): Guatemala has no regulations in place for GE animal IPR.

g) INTERNATIONAL TREATIES and FORUMS: As member of the WTO, Guatemala reports to the OIE, IPPC, and CODEX, and follows their guidelines. CONAP represents Guatemala at the COP-MOP.

h) RELATED ISSUES: Guatemala approved RT 65.06.01:18, which regulates plant and animals, in 2019, but only a specific application manual for plants has been developed. There are no considerations at this point on drafting a regulation for biotech animals.

PART F: Marketing

a) PUBLIC/PRIVATE OPINIONS: Academia has shown interest in using GE mosquitoes to control dengue and malaria but has not yet raised the need with the government. The Government of Guatemala declared it will be malaria free in 2024, but dengue continues to spread to levels not reported since 2019, leading on August 31, 2023, to the declaration of a national emergency due to more than 150 percent increase in dengue in 2023 and more than 12,000 affected people. GE mosquitos have proven to be effective biological controls that reduce the infected mosquito populations while reducing chemical spraying controls.

b) MARKET ACCEPTANCE/STUDIES: There are no assessments on potential market acceptance of GE animals.

CHAPTER 3: Microbial Biotechnology

PART G: Production and Trade

a) COMMERCIAL PRODUCTION: Guatemala's food processing industry, which potentially involves microbial biotechnology, including liquors and beverages, constituted 46 percent of the industrial activity in 2022 and represented 18 percent of Guatemalan total exports. In 2022, imports in this sector grew 20 percent, while exports increased 23 percent. The industry includes sauces and preparations, condiments and seasonings, fruit and vegetable juices, fermented and unfermented liquors, bread, pastry, cakes, biscuits, and other bakers'

wares, beer from malt, prepared foods from swelling or roasting cereals or products, food preparations, cheese and curd, and enzymes.

b) EXPORTS: Guatemala exported $2.5 billion in processed food products in 2022. There are neither official statistics nor estimates on exports of microbial biotechnology products. However, Guatemala exports alcoholic beverages, dairy products, and processed products that may contain microbial biotech-derived food ingredients.

c) IMPORTS: Guatemala imported $2.6 billion in processed food products in 2022. There are neither official statistics nor estimates on imports of microbial biotechnology products. However, Guatemala imported alcoholic beverages, dairy products, and processed products that may contain microbial biotech-derived food ingredients.

d) TRADE BARRIERS: Unknown.

PART H: Policy

a) REGULATORY FRAMEWORK

For information on regulatory terms relating to use of microbial biotechnology in Guatemala, see Chapter I, Part B.

Guatemala has not ruled on microbial biotechnology, but the existing regulation applies to "LMO" use in agriculture.

b) APPROVALS/AUTHORIZATIONS: N/A

c) LABELING AND TRACEABILITY: N/A

d) MONITORING AND TESTING: N/A

e) ADDITIONAL REGULATORY REQUIREMENTS: N/A

f) INTELLECTUAL PROPERTY RIGHTS (IPR): N/A

g) RELATED ISSUES: N/A

PART I: Marketing

a) PUBLIC/PRIVATE OPINIONS: N/A

b) MARKET ACCEPTANCE/STUDIES: N/A

Attachments:

No Attachments