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Report Highlights:

On January 29, 2021, the Court of Constitution dismissed an opposition lawsuit filed back in 2020 against the biosafety technical regulation approved on October 1, 2019 by the Ministry of Economy as part of the regulatory harmonization process with Honduras. The court confirmed that the regulation complied with the regulatory pathway approved under the local and regional standard regulatory practices. The Ministry of Agriculture has published all corresponding manuals of operation to review petitions.

Executive Summary:

Guatemala is a net agricultural exporter. In calendar year 2020, Guatemala exported $6.0 billion in agricultural products to the world (excluding related products), while importing $3.4 billion. The United States reported exports to Guatemala of $1.4 billion in 2020, with bulk commodities representing $473 million. Corn exports totaled $255 million, followed by wheat ($132 million), and cotton ($46 million). Most of the corn exported to Guatemala is yellow corn, and the United States has 86 percent of the market share. Depending on prices, Guatemala sometimes imports yellow corn from Argentina or Brazil.

Guatemala has not yet approved any biotech crop for planting. The Ministry of Agriculture (MAGA) is responsible for the authorization of petitions of GE plants and animals, though the existing regulation only applies for plants, as animal biotech regulation is not yet in place. Individuals, universities, farmer associations, cooperatives, or companies interested in a GE plant must file a petition to MAGA. MAGA has in place forms and checklists to verify that petitions comply with corresponding requirements. The approval phase will follow contained, pre-commercial, and commercial phases. Before a GE plant is approved for the pre-commercial phase, if intended to be planted in a territory officially recognized as indigenous, the petitioner will follow a consultation process and obtain a prior consent approval; without a consent approval, MAGA will not authorize the pre-commercial phase. Petitions can only be approved for agricultural areas, under MAGA authority, outside of protected areas under the National Council of Protected Areas (CONAP) mandate.

Guatemala doesn't govern GE derived products of animal, microbial, or plant origin. GE derived products fall under regular and non-GE policies and rules. GE plant derived products, if non-processed, must be accompanied by phytosanitary or plant health certificate, attesting the product is free of quarantine pests, if applicable. For GE animal derived products, an animal health or export certificate must accompany the product, certifying the products comply with food safety standards. For processed food products (animal or plant origin), an export certificate or certificate of free sales needs to be presented to the Ministry of Health, for sanitary registration of the product before commercialization.

Petitions for innovative biotech plants follow a similar paperwork process as a GE plant, but if determined by MAGA that it is not a GE plant, the petition gets authorization to follow the normal commercialization channel as if it were conventional plant material. For all plants, including conventionally bred plants, exporters must verify that there are phytosanitary requirements in place for the plant's genus. If there is no previous history of importing that genus of plant, a market access request must be submitted to MAGA. The exporter must also present a risk analysis based on Guatemala's list of quarantined pests. This process is in place for any new genus or family of plants without previous history of importation, independent of the technology used for its production or reproduction.

Guatemala doesn't have any regulation in place for biotech microbes.

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

Content

CHAPTER 1: PLANT BIOTECHNOLOGY

PART A: Production and Trade

a) PRODUCT DEVELOPMENT: Guatemala allows for applications of 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" and its implementation manual, approved through Ministerial Decree 271-2019. The rule is fully in place as the Supreme Court and the Court of Constitution have both confirmed its legality after activist opposition. At present, there are no developments in the pipeline.

b) COMMERCIAL PRODUCTION: The regulation allows for universities, research centers, and companies or production associations, cooperatives, groups, or individuals to submit for review an application for the evaluation and approval of commercial production of biotech crops, following field experiment 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. 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 utilization and the environment, the biotech crops may be approved for commercial use.

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

d) IMPORTS: Guatemala is a net importer of animal feed, and in 2020, Guatemala imported roughly 1.3 million metric tons (MT) of biotech corn valued at around $255 million from the United States. The breakdown was 1.2 million MT of yellow corn and 43,000 MT of white corn. Yellow corn is the most widely imported grain. All yellow corn goes to the feed industry. The food processing industry imports white corn for chip production, cereals, porridges, and drinks. In 2020, the feed industry also imported 465,000 MT of soybean meal from the United States, valued in $182.5 million. In addition, Guatemala also imported 115,000 MT of biotech soybeans and other soy products that are widely consumed in the food market, mostly from the United States.

e) FOOD AID: Guatemala is a food-aid recipient country. It has the highest rate of chronic malnutrition in Latin America and is among the five highest rates in the world. Guatemala receives roughly 1,800 metric tons 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. The COVID-19 pandemic has resulted in additional food aid to Guatemala, including the recent ETA and IOTA storms on October-November of 2020.

f) TRADE BARRIERS: After a *de facto moratorium* in place for the past 15 years, resulting from the lack of a sound regulatory framework, Guatemala agreed to a harmonized regulation with Honduras,

under the advanced Customs Union process. The new rule entered into force on October 1, 2019. On November 29, 2019 the regulation was opposed by some indigenous organizations. The opposition groups basically claimed that agricultural biotechnology poses a threat to biodiversity and indigenous rights, and that the government did not follow a consultation process with indigenous groups during the drafting of the regulation. The Supreme Court and the Court of Constitution ruled against the oppositions filed, confirming that the Government of Guatemala followed local and regional regulatory procedures corresponding to the Ministry of Economy and Ministry of Agriculture's mandates.

The ministries have explained that the origin of the indigenous groups' opposition relies on the confusion about the consultation processes followed by the Guatemalan government institutions. The consultation processes of the Ministries of Economy and Agriculture are strictly regulatory and are discussed among technical working groups, and do not imply automatic approval of all petitions. The regulation is a framework that allows for a science-based risk evaluation by technical experts, and requires prior consent approval if intended for agricultural use in officially recognized indigenous territories.

The indigenous consultation process is a specific consultation before an investment takes place in a specific territory, responding to C169 - Indigenous and Tribal Peoples Convention (1989) of the International Labor Organization of the United Nations. The indigenous communities´ consultation process is embedded in the operative manual of the Ministry of Agriculture when a specific GE petition gets filed in one of these territories.

PART B: Policy

a) REGULATORY FRAMEWORK: 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 or not 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. 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.

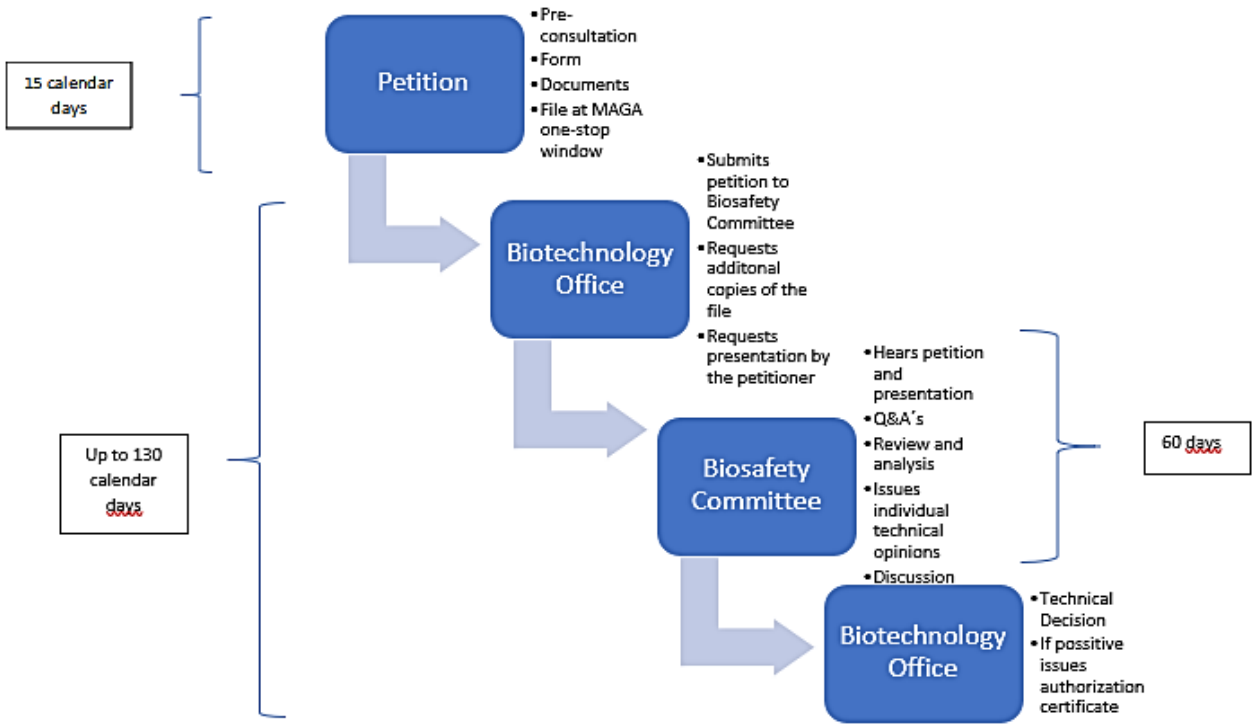
If a confined use experimental field trial is approved through a risk evaluation process, a certification permit is granted, and a monitoring and evaluation process accompanies it. MAGA is directly responsible for the monitoring and evaluation. If the experimental confined use field test proves effective 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 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: 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 Form DFRN-01-R-042, which is a strictly technical consultation process, to MAGA regulators, 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: 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. The Biosafety Committee may provide additional guidelines to preserve agricultural technologies and its corresponding stewardship to avoid losing 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 an UPOV law to become a member. The latest review of the law initiative at UPOV in Geneva took place in October of 2017. 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.

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. CONAP has maintained an active social consultation process related to GE technologies applied to agriculture, health, and environment. 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 Diversity Biological 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, 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, including organized farmer groups and the food industry. On the other side, those that oppose biotechnology are represented by human rights groups that have been misled to believe that farmers will be forced to abandon native seeds for GE seeds. Indigenous groups have not discontinued the planting of native seeds despite the introduction of public and commercial seeds of different crop varieties or hybrids. For instance, the Almolonga Valley in the highlands of Guatemala is a very prominent horticultural production indigenous territory that uses vegetable hybrid seeds. This valley is the main horticultural exporting region for Mexico and Central America.

b) MARKET ACCEPTANCE/STUDIES: The opposition to biotechnology is only in the realm of planting crops, as biotechnology food products have historically been widely consumed and there are no major consumer concerns on 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 the social concern 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) 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: Guatemala and Honduras are interested in a joint GE animal regulation at the national level.

b) APPROVALS: 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 malaria but has not yet raised the need with the government.

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 is not a producer of biotech microbes.

b) EXPORTS: Guatemala does not export biotech microbes.

c) IMPORTS: Guatemala imports GE bacteria to produce recombinant proteins for developing diagnostic kits widely used in agricultural research and production.

GE and non-GE formulations of *Bacillus thuringiensis* (Bt) and other biopesticides are widely imported for plant pest and disease control. Biotech microbe-derived enzymes are imported for their use in food (especially in fermentation processes) and other industrial products, such as cleaning detergents. The only microbial biotech-derived food ingredients imported by Guatemala are those traditionally used in the production of alcoholic beverages, dairy products, and processed products. Likewise, Guatemala imports alcoholic beverages, dairy products, and processed products which may contain microbial biotech-derived food ingredients.

d) TRADE BARRIERS: Unknown.

PART H: Policy

a) REGULATORY FRAMEWORK: N/A.
b) APROVALS: 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