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Report Highlights:

On March 15, 2019, Guatemala and Honduras approved a harmonized biotechnology and biosafety regulation for Genetically Engineered (GE) plants, the first in Central America. The rule establishes corresponding regulatory procedures for the commercialization of GE plants for Guatemala and Honduras.

Executive Summary:

The harmonized biotechnology regulation for Guatemala and Honduras took effect on October 1, 2019. On March 15, 2019, Guatemala and Honduras approved RT 65.06.01:18, "Biosafety Technical Regulation for Live Modified Organisms-LMO- for Agricultural Use," through the Minister of Economy's authority under the Central American Customs Union framework. The regulation was published by the Ministry of Economy of Guatemala under Ministerial Decree 281-2019. On October 7, 2019, the Ministry of Agriculture published Ministerial Decree 270-2019 for the "Creation of the Guatemalan Biosafety Agricultural Technical Committee" and Ministerial Decree 271-2019, the "Manual of Technical Procedures for the Confined Use of Experimental, Pre-Commercial and Commercial Use of Genetically Modified Seed."

The rule and its corresponding procedures follow the Sanitary and Phytosanitary (SPS) Agreement of the World Trade Organization (WTO), as well as the Cartagena Biosafety Protocol, for which both Guatemala and Honduras are signatories.

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CHAPTER 1: PLANT BIOTECHNOLOGY

PART A: Production and Trade

a) PRODUCT DEVELOPMENT: Guatemala allows for experimental, pre-commercial, and commercial production of GE plants approved under RT 65.06.01:18, "Biosafety Technical Regulation for Live Modified Organisms-LMO- for Agricultural Use" and its implementation manual.

b) COMMERCIAL PRODUCTION: The recently approved regulation will allow for companies or groups to submit for review an application for approval of commercial production of biotech crops, following approval of the experimental and pre-commercial phases. The experimental phase is to evaluate the effectiveness of new trait(s) not previously evaluated elsewhere, under confined use. The pre-commercial phase is to evaluate the effectiveness in multiple sites. Once the pre-commercial phase concludes, the biotech crops may be approved for commercial use.

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

d) IMPORTS: Guatemala is a net importer of animal feed. In 2018, Guatemala imported roughly 1.12 million metric tons (MT) of biotech corn valued at around $223 million, virtually all from the United States. The breakdown was 1.06 million MT of yellow corn and 52,350 MT of white corn. Corn is the most widely imported grain. All yellow corn goes to the feed industry. The food processing industry imports white corn. In 2018, the feed industry also imported 416,406 MT of soybean meal from the United States. Soy products are also used as a dairy-substitute in the food industry.

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 food aid from the United States each year. In-kind food donations consist largely of beans, corn-soy blend (biotech derived food product), rice, and vegetable oil, which are provided as school meals in some of the poorest municipalities.

f) TRADE BARRIERS: Guatemala had a *de facto moratorium* in place with the previous existing regulation that did not allow for the commercial production of GE plants. The recently approved regulation, which was harmonized with Honduras, provides a science-based risk assessment and decision-making process to consider applications for commercial production.

Part B: Policy

a) REGULATORY FRAMEWORK: The recently approved 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" establish technical procedures for field trials, pre-commercial evaluations, and commercial approvals of biotech products.

Petitions are subject to a maximum 270-day review process. Approvals are for agricultural use only, under the Ministry of Agriculture's mandate, leaving protected areas outside the scope of the rule because protected areas are under the mandate of the National Council of Protected Areas (CONAP).

The National Biosafety Committee is composed of representatives from the Animal Health Direction Plant Health Direction, Food Safety Direction, and Plant and Animal Genetics 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.

b) APPROVALS: The new regulation establishes a straightforward mechanism for research and field trials, as well as pre-commercial and commercial approvals based on risk assessments.

c) STACKED or PYRAMIDED EVENT APPROVALS: The recently approved regulation considers stacked events as a sole petition request if the events have been previously evaluated in other country(ies). If the events have not been previously evaluated somewhere else, the events will need to be evaluated independently as part of the confined experimental phase.

d) FIELD TESTING: RT 65.06.01:18 and Ministerial Decree 271-2019 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 evaluation of the technology on a medium scale, and c) commercial approval and release.

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 are not regulated under the present rule.

f) COEXISTENCE: Ministerial Decree 271-2019 establishes clear rules to allow the coexistence of different production technologies, through the definition of planting areas, the use of natural barriers, and different flowering times. Guatemala is an important agricultural producer and exporter in Central America.

g) LABELLING and TRACEABILITY: Guatemala is a member of the WTO and participates in Codex Alimentarius. Guatemala largely implements Codex guidelines regarding food safety and standards. In addition, Guatemala follows the regional technical regulations established for general and nutritional labeling of packaged food products, which does not require labelling GE contents.

h) MONITORING AND TESTING: No policy in place.

i) LOW LEVEL PRESENCE (LLP) POLICY: No policy in place.

j) ADDITIONAL REGULATORY REQUIREMENTS: N/A.

k) INTELLECTUAL PROPERTY RIGHTS (IPR): Guatemala became a member of the International Union for the Protection of New Varieties of Plants (UPOV) in 2009 but has yet to approve UPOV law. In October 2017, UPOV in Geneva reviewed Guatemala's law initiative, which, if approved by the Guatemalan Congress, could spur innovation in agricultural production.

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 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. The Ministry of Agriculture will implement RT 65.06.01:18, as it corresponds to its mandate.

m) INTERNATIONAL TREATIES and FORUMS: Guatemala is a member of the World Trade Organization (WTO), the World Organization for Animal Health (OIE), International Plant Protection Convention (IPPC), CODEX Alimentarius, and the International Union for the Protection of New Varieties of Plants (UPOV). Given budgetary constraints, Guatemala's participation in international fora is somehow limited. Guatemala actively participates in the United Nations (UN) climate change meetings (COP), and CONAP attends the UN conference on biological diversity (COP-MOP).

n) RELATED ISSUES: Guatemala faced a major challenge on the use of agricultural biotechnologies now that Guatemala and Honduras have a one territory SPS status. As physical borders are lifted, allowing for the free circulation of people and goods, both countries are aware that the lack of a regulatory framework will impose unnecessary legal burden on both countries. It is confusing for farmers to understand why they cannot use the technologies that their neighbors already use commercially when there is free transit of goods and seeds. To avoid "illegal" transit of seeds, government authorities negotiated a unified and harmonized regulation that would allow both countries to comply with regional integration and compliance with international commitments.

PART C: Marketing

a) PUBLIC/PRIVATE OPINIONS: Opinions about biotechnology in Guatemala are divided. Science and agriculture faculties at the universities have publicly expressed their support for biotechnology. Groups that oppose biotechnology are human right activists, indigenous groups, and some small farmers. These anti-biotechnology activists say biotechnology is a threat to biodiversity or a threat to their culture. Some groups make the mistaken claim that farmers will be forced to abandon native seeds for GE seeds. Through RT 65.06.01:18, the Ministries of Economy and Agriculture have established a technical position to address the challenges of opening borders between Guatemala and Honduras, in compliance with its regional and international commitments.

b) MARKET ACCEPTANCE/STUDIES: Guatemala has not assessed market acceptance of GE plants or products used in the textile or food industries, but the vast majority living in urban areas understand that many different food products have biotech origin or components. The consumers are more concerned with food prices than the technologies used in its production.

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 has not discussed GE animal regulation at a national level.

b) APROVALS: Guatemala has not approved any GE animals.

c) INNOVATIVE BIOTECHNOLOGIES: Guatemala has not discussed innovative biotechnologies.

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

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

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

g) RELATED ISSUES: Guatemala recently approved RT 65.06.01:18, which regulates plant and animals, but only a specific application manual for plants has been developed.

PART F: Marketing

a) PUBLIC /PRIVATE OPINIONS: Academia has shown interest in using GE mosquitoes to control malaria but has not yet raised the issue with the government.

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

Attachments:

No Attachments