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Report Highlights:

On October 1, 2020 Guatemala and Honduras opened peripheral customs that allow commercial exchange of agricultural biotechnology. On September 29, 2020 the first application for experimental stage field testing of a Black Sigatoka-resistant GMO banana was submitted to the National Committee on Biotechnology and Biosecurity (NCBB). Honduras has had biotechnology regulations and a NCBB since 1998, and as of September 2020, had more than 38,000 hectares of GE corn production, a small increase compared to 2019

EXECUTIVE SUMMARY

Major U.S. agricultural exports to Honduras are yellow corn, soybean meal, rice, wheat, pork and prepared food products. Honduras' production of genetically engineered (GE) plants is mainly corn used for feed, food and cultivation. Recently, applications have been filed for banana (GE) and a mosquito modified to auto control populations to reduce the transmission of diseases such as dengue.

Honduras has been the only country in Central America, and one of seven countries in Latin America, that allows the commercial cultivation of GE crops. Since 1998, Honduras's biotechnology system has been regulated by the "Biosecurity Regulation with Emphasis in Transgenic Plants" regulation. On March 15, 2019, the El Salvador, Guatemala and Honduras Customs Union approved a Technical Regulation (TR) for the commercial exchange and safe use of agricultural biotechnology. On October 1, 2019 the rule entered into effect for Guatemala and Honduras. The TR applies to plants and the reproduction of animals (such as the mosquito that causes the dengue disease). Procedural Manuals need to be developed for full implementation.

Planted area of GE corn as of October 2020 was estimated at 38,000 hectares (ha), a 1.6% increase compared to last year's 37,386 ha. GE plant cultivation is restricted in three of the 18 departments, Intibucá, Lempira and Gracias a Dios, as well as in the municipality of Pespire, Choluteca. GE planting is also restricted in areas near native corn stocks, regions higher than 1,000 meters above sea level, as requested by those communities. The National Service of Food Safety, Plant and Animal Health (SENASA) is the responsible agency for agricultural biotechnology regulation and policy. The National Committee of Biotechnology and Biosecurity evaluates and analyzes GE requests. There are no regulations for animal clones or pharmaceutical developments. Honduras actively participates in agricultural biotechnology conferences and other international conferences, sharing the experience of Honduran regulations to facilitate processes for the use of agricultural biotechnology. There are no expected changes to the regulations.

Honduras' production of GE corn seed is sold within the domestic market for agroindustry and is exported to Colombia. Honduras imports yellow corn and soybean meal to supply its poultry, livestock, shrimp, and tilapia industries.

The National Committee of Biotechnology and Biosecurity (NCBB) was created in 1998. On January 10, 2018, SENASA published in the official Gazette the *Guide of Processes and Procedures of the Regulatory System for "Genetically Modified Organisms."* The purpose of the guide is to update the procedures of the NCBB, without changing the objectives and its duties and to provide users with the procedures to follow in the field test, pre-commercial, and commercialization stages of new events. By publishing this guide in the Official Gazette, the guide is an official regulation. Previously, these were just internal regulations.

On September 2019, SENASA approved a simplified procedure to approve the requests for gene edited products. The new process helps to shorten the approval time of requests. The committee will conduct a case-by-case study to discuss whether the product can be approved in a simplified way.

TABLE OF CONTENTS

CHAPTER 1: PLANT BIOTECHNOLOGY
PART A: PRODUCTION AND TRADE

a) PRODUCT DEVELOPMENT: There is no development of antibiotics, functional foods/feeds, or pharmaceuticals using GE techniques or GE plants.

On September 29th, 2020 Tropic Biosciences (TB) applied for the experimental stage field testing of a Black Sigatoka-resistant GMO banana to the National Committee on Biotechnology and Agricultural Biosafety (NCBB).

b) COMMERCIAL PRODUCTION: Honduras allows the commercial cultivation of GE crops for corn seed and grain production. Honduras produces "stacked" commercial events: VTPRO/RR, VT3PRO/RR and HX1xRR2. The commercial GE corn seeds are Roundup Ready (RR) and Herculex I (HX1). Area planted with GE corn for commercial seed and grain as of September 2020 is estimated at 38,000 hectares (ha), an estimated increase of 614 ha from 2019. c) EXPORTS: Honduras exports GE corn seeds to Colombia. Honduras exported GE corn seeds to the United States from 2009 to 2014. The export documentation declares the content of GE material. The product exported to the United States received approval from the U.S. regulatory system.

d) IMPORTS: Honduras imports GE crops, processed products, and seeds directly into the country. GE seeds are imported from the United States and Brazil. Most imports of yellow corn and soybean meal from the United States are GE. These imports are to support the poultry, livestock, shrimp, and tilapia industries. In 2019, Honduras imported U.S. corn (mostly GE yellow corn) valued at $102.3 million, a 4.1% decrease compared to 2018. Imports of GE soybean meal from the United States were $95.5 million, a 6.3% decrease compared to 2018.

e) FOOD AID: Honduras has been a food aid recipient since 1999. The Government of Honduras (GOH) has accepted U.S. food donations of soybean meal and yellow corn for the agroindustry. There are no barriers related to biotechnology that impede the importation of food aid.
f) TRADE BARRIERS: Not applicable.

PART B: POLICY

a) REGULATORY FRAMEWORK:
i. The Secretariat of Agriculture and Livestock (SAG), through SENASA oversees the regulation of GE plants. SENASA's Seeds Certification Department initiated the "Biosecurity Regulation with Emphasis on Transgenic Plants", which was approved by the GOH in 1998 through Agreement No.1570-98. The legal basis for this regulation is the Phytozoosanitary Law. The Law was reviewed and modified by Decree No. 344-2005 published in 2006.
The Regulation gives SENASA responsibility for the regulatory framework for agricultural biotechnology, including GE product import requests, field testing, and commercialization requests for GE crops. The regulation applies to food, feed, seed, and environmental safety issues.

On March 15, 2019, the El Salvador, Guatemala and Honduras Custom Union approved a Technical Regulation (TR) for the commercial exchange and safe use of agricultural biotechnology. The TR applies to plants and the reproduction of animals (such as the mosquito that causes the dengue disease). Procedure Manuals need to be developed for full implementation. On October 1, 2019 the rule entered into effect for both countries, although the majority of changes affected only Guatemala, since Honduras has already adopted the underlying regulation.

On September 2019, SENASA approved a simplified procedure to approve products produced using gene editing. The new procedure complies with the GOH SPS commitments to the World Trade Organization. Furthermore, it helps to shorten the approval time of each request.

During 2020 and due to the COVID-19 pandemic, there have been limited advances on biotechnology regulation. On October 1st, 2020 Guatemala and Honduran opened peripheral customs that allow commercial exchange of agricultural biotechnology products, especially potential exports to Guatemala
ii. Role and membership of the National Committee of Biotechnology and Biosecurity: The Biosecurity Regulation with Emphasis on Transgenic Plants provides the procedures to evaluate a request and assigns the scientific analysis to the National Committee of Biotechnology and Biosecurity (NCBB). The NCBB was created in 1998 to provide advice to SENASA in the decision-making process. In January 2018, a new decree was published by SENASA in the Official Gazette to update the procedures of the NCBB, without changing the objectives and its responsibilities. The Committee is composed of scientists from the following ten public and private institutions:

- SENASA: Focal point for the Cartagena Protocol.
- Directorate of Science and Agricultural/Livestock Technology (DICTA)/SAG

- Focal Point of the Codex Alimentarius in SAG
- Ministry of Public Health
- Ministry of Renewable Resources and Environment (Mi Ambiente)
- Competitiveness and Innovation Directorate, Secretariat of Planning (SEPLAN)
- National University of Honduras (UNAH)
- Honduran Foundation for Agricultural Research (FHIA)
- Pan American School of Agriculture - "Zamorano"
- Standard Fruit Company

iii. Assessment of political factors: After the NCBB provides a scientific recommendation, the political decision for an approval of an event and its commercialization is with the Director General of SENASA. The legal grounds of the Phytozoosanitary Law published in 2006 and the regulation with Emphasis on Transgenic Plants are to provide the Director General of SENASA reliable tools for the field trials, semi- commercialization, and commercialization of GE crops.

iv. Honduras does not make distinctions in regulatory treatment for approval between food, feed, processing and environmental release (cultivation). The exceptions are those mentioned in the Cartagena Protocol.

v. Pertinent and pending legislation: The commercialization of GE products in Honduras does not affect U.S. exports. This is because of the approved legal framework, and the acceptance of industry and consumers of GE products from the United States. The Law for the Protection of New Varieties of Plants (UPOV) was approved by Decree 21-2012 of the Honduran Congress in 2012. Although UPOV was approved, the accompanying regulation is still pending. The law can be found in Spanish at SENASA Sub-Direction of Plant Health.

vi. The process for the commercialization of an event has been officially published through the *Guide of Processes and Procedures of the Regulatory System for "Genetically Modified Organisms" for Decision Making*. The publication was made in the Official Gazette No. 34,538 of January 10, 2018. The purpose of the guide is to communicate and provide users with the procedures to follow in the stages of field test, pre- commercial, and commercialization. The approval process is the following:

- The NCBB recommends that companies carry out field tests within normal production cycles: the first cycle of planting begins in May or June, and the second cycle begins in August or September.
- After the test stage is completed, the NCBB advises SENASA to extend the pre-commercial area from one hectare up to 500 hectares, depending on the company's request.
- The regulation for biosecurity indicates that the NCBB should provide an answer to a request within 90 days. The estimated time until commercialization varies according to the questions that the NCBB may raise. In some cases, the NCBB requests more information from field tests as part of the pre- commercial stage.
- After the NCBB reaches a consensus, it provides a scientific recommendation and forwards the decision for approval of an event and its commercialization to the Director General of SENASA.

• The Director of SENASA notifies the resolution and findings of the NCBB to the requesting company.

vii. Legislation or regulation not in place: UPOV's regulation pending. Even though Decree 21-2012 was approved by Congress, a regulation needs to be written and approved for the implementing unit (SENASA Seed Certification Department to be able to enforce it.

b) APPROVALS:

Table 1 shows currently approved events per crop. Authorizations for planting do not have an expiration date.

Table 1. Approved Crop/Events

Approval Year	Company	Crop	Event	Type of Approval	Usage
2002	Monsanto	Corn	MON 810 + NK 603	Commercial	Feed, food and seed production
2010	Pioneer	Corn	TC 1507	Commercial	Feed, food, cultivation
2011	Bayer Crop Science	Rice	LLRice 62	Commercial	Food only
2012	Monsanto	Corn	MON 89034	Commercial	Feed, food and seed production
2013	Monsanto	Corn	MON 88017	Commercial	Feed, food and seed production
2013	Monsanto	Corn	MON 89034 + MON 88017	Commercial	Feed, food and seed production
2015	Dow Agroscience	Corn	MON 89034 + NK 603 + TC 1507	Commercial	Feed, food, cultivation
2020	Syngenta Crop Protection SA	Corn	SYN BT11 x MIR 162 x GA21, Agrisure ® VIP3	Commercial	Feed, food and seed production

Source: SAG's National Service of Food Safety, Plant and Animal Health (SENASA), Seeds Certification Department.

c) STACKED EVENT APPROVALS: Honduras has approved stacked events since 2010. If an event is already registered individually, it does not need to be registered again when it is part of a stacked event. The NCBB requests that a risk analysis of the stacked event be reported to the Biosafety Clearing House of the Cartagena Protocol, but there is no other specific stacked event policy.

d) FIELD TESTING: Honduras currently allows field testing and commercialization of GE crops. The requirements to request field testing and commercial liberation of an event are based on the Phytozoosanitary Law and the Biosecurity Regulation with Emphasis on Transgenic Plants. The process is the following: (1) a company submits a request to SENASA; (2) SENASA's Director summons the NCBB to review the request; and (3) each institution in the NCBB carries out its analysis. Depending on issues raised during the analysis, they continue to meet until a consensus is reached. The area for the field test is usually conducted on one hectare of land.
e) INNOVATIVE BIOTECHNOLOGIES: As noted above, in September 2019 SENASA approved a simplified procedure for approving products produced using gene editing, which will shorten the approval time for such requests.
f) COEXISTENCE: GE corn is not planted in the three departments of Intibucá, Lempira and Gracias a Dios nor in the municipality of Pespire, Choluteca. GE planting is also restricted in areas near native corn stocks, and regions higher than 1,000 meters above sea level at the request of those communities. These rules limit the cultivation of GE crops in those areas and keep those producers from competing with producers that can use GE seeds in other parts of the country.
g) LABELING: SENASA requires labeling for GE corn seed for planting. It does not require labeling for bulk shipments, raw material, packaged foods, feed or other products derived from and/or containing ingredients from GE plants.
h) MONITORING AND TESTING: Not applicable.
i) LOW LEVEL PRESENCE (LLP) POLICY:
Not applicable.
j) ADDITIONAL REGULATORY REQUIREMENTS: After an event is approved for commercialization, it must be registered at the Seeds Certification Department of SENASA prior to use. Registrations are not overly cumbersome and do not expire.
k) INTELLECTUAL PROPERTY RIGHTS (IPR): The law protects intellectual property rights of the developer of new varieties and the variety itself. This is done through the Law for the Protection of New Varieties of Plants approved by Decree 21-2012 by the Honduran Congress in 2012.
l) CARTAGENA PROTOCOL RATIFICATION: The Honduras Congress ratified the Cartagena Protocol on Biosafety to the United Nations' Convention on Biological Diversity in September 2008.
m) INTERNATIONAL TREATIES and FORUMS: Honduras actively participates in discussions related to GE plants within international fora, sharing its positive experience to facilitate processes for the use of agricultural biotechnology. The country approved the Law for the Protection of New Varieties of Plants (UPOV) in 2012. UPOV is an intergovernmental organization established by the International Convention for the Protection of New Varieties of Plants. The Convention promotes an effective system of plant variety protection, with the aim of encouraging the development of new varieties of plants for the benefit of society.

n) RELATED ISSUES: Expanded use of biotechnology has the potential to benefit Honduran society. There are nearly 175,000 ha. of non-GE corn planted in Honduras, using mostly traditional (non-hybrid) seed. According to producer data, average corn yield for traditional (creole) seed is 1.5 metric tons per ha., for improved varieties 4.5 metric tons per ha., for hybrid seed 5.5 metric tons per ha., and for GE seeds 7.6 metric tons per ha.

PART C: MARKETING

a) PUBLIC/PRIVATE OPINIONS: There are certain groups that conduct negative campaigns against GE crops. These groups primarily are against transnational companies that manage seeds, agrochemicals, and mining.

b) MARKET ACCEPTANCE: Market acceptance related to the sale and use of GE plants and products is favorable. Fruit and vegetable producers that grow for export rotate their crops with GE corn. This helps to ensure that the fruit and vegetables exported are free of pesticide residues and pests. Producers who use GE crops see a large increase in yields. The production of GE corn in Honduras creates a sustainable process for medium and big farmers, who have reduced pesticide use, increased no-tillage cultivation, rotation with legumes to consistently produce high yields.

c) MARKET STUDIES: Carlos Almendares, SENASA's former Seeds Certification Chief and Rogelio Trabanino of Zamorano University wrote the guidelines below for firms looking at Honduras as an export market for GE crops. The document is complementary to the "Biosecurity Regulation with Emphasis in Transgenic Plants" issued in 1998 and is meant to ease the process and attract interest in GE crop development for export purposes.

The risk evaluation guidelines indicate that GE crop developers requesting a risk evaluation for a test trial or the commercial liberation of a GE product must provide the following information to the Biotechnology and Biosafety Committee:

- *Personnel involved*: Names, addresses, and telephone numbers of the people that have developed or supplied the event.
- *Purpose of the evaluation*: Provide a detailed description of the purpose of the introduction of the event, including the experimental design and/or the proposed production.
- D*escription of the genetic material*: Provide a description of the desired or real characteristic of the modified genetic material. Also include how the characteristic differs from the parent non-modified organism (i.e., morphologic or structural characteristics, activities and physiological processes, number of copies of the material inside of the recipient organism (integrated or extra-chromosomic) products and secretions and characteristics of growth.
- *Transformation methods*: Country and place where the parent plant, the receptor organism and the vector were collected, developed and produced. Transformation methods and selection processes employed.
- *System used to produce the event:* Provide a detailed description of the molecular biology of the system that will be used to produce the event (for example: donor-recipient-vector).

• *Place of evaluation*: Country and geographic location of the evaluation, specifying the exact description of the areas to be evaluated.
• B*iosecurity measures*: Provide a detailed description of the processes and security measures that have been used or will be used to prevent the contamination, liberation and dissemination of the donor organism, the recipient organism, the vector, the constituent of each event and the event in the country of origin, in the countries that will be in transit and in Honduras .
• P*rogrammed destination*: Provide a detailed description of the programmed destination (including the final destination and all the intermediary destinations), uses, and/or distribution of the event (Example: greenhouses, laboratories, or place of the growth chamber, site of the field test, site of the pilot project, production, spreading, manufacturing site, proposed site of sale and distribution).
• C*ontainment measures*: Provide a detailed description of the procedures, processes and security measures proposed that will be used to prevent the escape and spreading of the event in each of the programmed destinations.
• M*ethod of final disposal*: Provide a detailed description of the proposed method for the final disposal of the event.

CHAPTER 2: ANIMAL BIOTECHNOLOGY
PART D: PRODUCTION AND TRADE

a) PRODUCT DEVELOPMENT: Not applicable.
b) COMMERCIAL PRODUCTION: In discussion**.**
c) EXPORTS: Not applicable.
d) IMPORTS: Not applicable.
e) TRADE BARRIERS: Not applicable.

PART E: POLICY

a) REGULATORY FRAMEWORK: On March 15, 2019, El Salvador, Guatemala and Honduras Custom Union approved a Technical Regulation (TR) for the commercial exchange and safe use of agricultural biotechnology. The TR applies to plants and the reproduction of animals (such as the mosquito that causes the dengue disease). Procedure Manuals for the reproduction of animals such as the mosquito need to be developed. On October 1, 2019 the rule entered into effect for Guatemala and Honduras.
b) APPROVALS: Not applicable
c) INNOVATIVE BIOTECHNOLOGIES: Not applicable.
d) LABELING AND TRACEABILITY: Not applicable.
e) ADDITIONAL REGULATORY REQUIREMENTS: Not applicable.
f) INTELLECTUAL PROPERTY RIGHTS (IPR): Not applicable.

g) INTERNATIONAL TREATIES and FORUMS: Not applicable.
h) RELATED ISSUES. Not applicable.

PART F: MARKETING

a) PUBLIC/PRIVATE OPINIONS: Not applicable.
b) MARKET ACCEPTANCE/STUDIES: Not applicable.

CHAPTER 3: MICROBIAL BIOTECHNOLOGY
PART G: PRODUCTION AND TRADE

a) COMMERCIAL PRODUCTION: Not applicable
b) EXPORTS: Not applicable
c) IMPORTS: Not applicable.
d) TRADE BARRIERS: Not applicable.

PART H: POLICY

a) REGULATORY FRAMEWORK: Not applicable
b) APPROVALS: Not applicable
c) LABELING and TRACEABILITY: Not applicable
d) MONITORING AND TESTING: Not applicable
e) ADDITIONAL REGULATORY REQUIREMENTS: Not applicable
f) INTELLECTUAL PROPERTY RIGHTS (IPR): Not applicable.
g) INTERNATIONAL TREATIES and FORUMS: Not applicable.
h) RELATED ISSUES. Not applicable.

PART I: MARKETING

a) PUBLIC/PRIVATE OPINIONS: Not applicable.
b) MARKET ACCEPTANCE/STUDIES: Not applicable.

Attachments:
No Attachments