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Report Highlights:

Honduras has made no modifications or changes to its existing regulatory framework. As of October 2023, Honduras had more than 55,000 hectares (ha) of genetically engineered (GE) corn production, a 6% increase from CY 2022. Two crop event approvals were reported during 2023 for extended shelf life and non-browning bananas. Both applications were approved for field testing.

EXECUTIVE SUMMARY

Major U.S. agricultural exports to Honduras are yellow corn, soybean meal, wheat, pork, beer, rice, dairy products, cotton, poultry, and prepared food products. Honduras' production of genetically engineered (GE) plants is mainly corn used for feed, food, and cultivation.

In CY 2023, NCBB approved two applications for GM bananas 2 for field testing: i) a non-browning banana, ii) extended shelf-life banana. Additionally, The Honduran Government is making progress on creating a procedure manual for regulation of GE animals.

Honduras has pioneered regulatory development for biotechnology products in Central America. Since 1998, Honduras's biotechnology system has been regulated under the "Biosecurity Regulation with Emphasis in Transgenic Plants". On March 15, 2019, El Salvador, Guatemala, and Honduras approved a Technical Regulation (TR) for the commercial exchange and safe use of agricultural biotechnology under their tripartite accelerated customs union agreement. On October 1, 2019, the rule entered 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 2023 is estimated at 55,000 hectares (ha), 6% higher than the 38,000 hectares (ha) in the previous year. 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 and in regions higher than 1,000 meters above sea level, as was requested by the Government of Honduras in order to protect native communities.

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

The National Committee on 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 became an official regulation. Previously, these were just internal regulations.

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

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CHAPTER 1: PLANT BIOTECHNOLOGY

PART A: Production and Trade

a) RESEARCH AND PRODUCT DEVELOPMENT: In Honduras there is no development of antibiotics, functional foods/feeds, or pharmaceuticals using GE techniques or GE plants.

b) COMMERCIAL PRODUCTION: Honduras allows the commercial cultivation of GE crops for corn seed and grain production. Area planted with GE corn for commercial seed and grain from October 2022 to October 2023 was 55,000 hectares (ha), a 6% increase from the previous year. The increase in planted area was a consequence of a general market recovery after the economic reopening in Honduras after COVID 19 and Climatic phenomena in the Sula Valley.

c) EXPORTS: Honduras exports GE corn seeds to Colombia. Honduras exported GE corn seeds to the United States from 2009 to 2014. In shipments containing these seeds, documentation declares the content of GE material. The product exported to the United States has 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 2022, Honduras imported U.S. corn (mostly GE yellow corn) valued at \$293.53 million, a 44% increase compared to 2021. Imports of GE soybean meal from the United States were \$187.28 million, a 23% increase compared to 2021.

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:

Table 1: Legal and Regulatory Terms used in Honduras

Legal term (Spanish)	Legal Term (in	Laws and Regulations	Legal Definition (in
	English)	where term is used	English)
Reglamento de	Biosecurity Regulation	Agreement No.1570-98	The biosecurity
Bioseguridad con	with Emphasis on	and modified by	regulation gives
énfasis en plantas	Transgenic Plants	Decree No. 344-2005	SENASA responsibility
transgénicas		published in 2006	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.
Comisión Nacional de	National Committee of	SENASA Agreement	It is an advisory body
biotecnología y	Biotechnology and	No. 177-2017	and chaired by the
Bioseguridad Agrícola	Agriculture Biosecurity	100.177 2017	Department of
(CNBBA)	(NCBB)		Certification of Seeds
	(ITCDD)		and Phyto genetic
			Resources of the
			National Agricultural
			Health Service
			(SENASA).

	1		
			The function of the
			Biosafety Committee is
			to carry out all the
			technical evaluations
			that are required in the
			biotechnology projects
			that are carried out in
			the country. These
			include risk assessment
			at each step of the
			process and for each
			-
			specific case, this
			involves carrying out
			laboratory tests,
			analysis, investigation
			and expert consultation.
			This second it is
			This committee meets
			at least three times a
			year and is in charge of
			providing technical
			advice to whoever
			consults on the subject.
			W/how on any listing is
			When an application is
			made to allow an
			experiment in the
			country, a complete
			study is made that
			includes: type of
			organism, its
			construction and
			behavior, the objective
			of the modification,
			information provided
			by the provider and
			also by international
			organizations, as well
			as the experience with
			said organism in other
			countries.
Acuerdo CD SENASA	SENASA Agreement	SENASA Agreement	This regulation was
008-2019;	008-2019;	008-2019	created because the
Procedimiento de	Authorization		advancement of science
autorización para	procedure for		and technology allows
solicitudes relacionadas	applications related to		the development of
somentudes relacionadas			the development of

con el uso de nuevas	the use of new genetic	new varieties of plants
técnicas de	C C	-
	improvement	and organisms through
mejoramiento genético	techniques (precision	new techniques known
(biotecnología de	biotechnology)	as precision breeding
precisión)		techniques, genome
		editing, plant breeding
		innovation or modern
		genetic improvement
		techniques without this
		results in a living
		modified organism.
		The latter is of vital
		importance in the
		application of the
		National regulations,
		since these are genetic
		improvement
		procedures that use
		precise knowledge of
		the relationship
		1
		between the genotype
		and phenotype and the
		tools of molecular
		biology, to develop an
		organism that in most
		cases are equivalent to
		or indistinguishable
		from those that can be
		developed using
		traditional breeding
		techniques.

The Secretariat of Agriculture and Livestock (SAG), through SENASA, oversees the regulation of GE plants. SENASA's Seeds and Plant Genetic Resources 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. These regulations can be found in Spanish here: https://www.senasa.gob.hn/index.php/acuerdos/subdireccion-general-de-sanidad-vegetal

The biosecurity 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 Customs 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 1st, 2019, the rule entered effect for both countries, although most 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.

SENASA would like to further develop Honduras's biotechnology regulations. However, during 2023, there have been no advances on biotechnology regulatory framework development, the manual of procedures for the regulation of animals has been postponed due to the lack of Government consensus with the Ministry of Health.

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

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 to make decisions about field trials, semicommercialization, and commercialization of GE crops.

Honduras does not make distinctions in regulatory treatment for approval between food, feed, processing, and environmental release (cultivation).

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 <u>SENASA Technical Directorate of Plant Health</u>.

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.

The National Committee on Biotechnology and Biosecurity (NCBB) 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.

• *Description 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.

• *Biosecurity 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.

• *Programmed 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).

• *Containment 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.

• *Method of final disposal*: Provide a detailed description of the proposed method for the final disposal of the event.

b) APPROVALS/AUTHORIZATIONS:

In CY 2023, NCBB approved two applications for GM bananas 2 for field testing: i) non-browning banana, ii) extended shelf-life banana. Additionally, The Honduran Government is making progress on creating a procedure manual for regulation of GE animals.

Table 2 shows currently approved events per crop. Authorizations for planting do not have an expiration date.

Approval Year	Company	Сгор		Type of Approval	Usage
2002	Monsanto	Corn	MON 810 + NK 603		Feed, food, and seed production
2010	Pioneer	Corn	TC 1507	Commercial	Feed, food,

Table 2. Approved Crop/Events

					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
2022	Tropic Biosciences	Banana	Non Browning Cavendish Banana	Experimental	Food production
2022	Tropic Biosciences	Banana	Non Browning Cavendish Banana	Commercial	Food production
2022	Tropic Biosciences	Banana	Extended Shelf Life Banana (ESL)	Experimental	Food production
2022	Standard Fruit Company	Banana	Banana resistant to fusarium race 4	Experimental	Food production
2022	Pairwise Plants Services Inc.	Mustard Green	Brassica Juncea with improved flavor profile */	Commercial	Food production
2023	Tropic Biosciences	Banana	Extended Shelf life	Experimental	Field Testing
2023	Tropic Biosciences	Banana	Non-Browning	Experimental	Field Testing

Source: SAG's National Service of Food Safety, Plant and Animal Health (SENASA), Seeds Certification Department. */ The approval follows a simplified procedure if not much modification is done, it is recommended by NCBB as a simplified procedure but also regulated

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 or Gracias a Dios, nor in the municipality of Pespire, Choluteca. GE planting is also restricted in areas near native corn stocks, and in regions higher than 1,000 meters above sea level at the request of native communities.

g) LABELING AND TRACEABILITY: 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 and Plant Genetic Resources Certification Department of SENASA prior to use. Registrations are not overly cumbersome and do not expire.

k) INTELLECTUAL PROPERTY RIGHTS (IPR): The Law for the Protection of New Varieties of Plants protects intellectual property rights of the developer of new varieties and the variety itself. This law was approved by Decree 21-2012 by the Honduran Congress in 2012.

1) 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.

Honduras 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. The Procedural Manual required to implement UPOV has been postponed until further notice by SENASA, due to the new Government administration and some lobbying and dialogue efforts are suggested for it to happen. Honduras phased out in 2022 the *Law for the Protection of New Varieties of Plants* (UPOV) due to pressures from environmental organizations in Honduras.

n) RELATED ISSUES: Expanded use of biotechnology has the potential to benefit Honduran society. There are nearly 200,000 ha. of non-GE corn planted in Honduras, using mostly traditional (non-hybrid) seed. According to PROGRANO (Association of Grains Producers of Honduras in 2023 average corn yield for traditional (creole) seed was 1.5 metric tons per ha., for improved varieties average yield was 4.5 metric tons per ha., for hybrid seed average yield was 5.5 metric tons per ha., and for GE seeds average yield was 7.6 metric tons per ha.

PART C: Marketing

a) PUBLIC/PRIVATE OPINIONS: There are groups that conduct negative campaigns against GE crops. These groups primarily are against all transnational companies that produce and sell seeds, agrochemicals, and mining. The General Public and the Government of Honduras which has an environmental ideology, perceives biotechnology as a technological agricultural tool, the grain producers and the public in general are the ones most supportive about biotechnology in Honduras.

b) MARKET ACCEPTANCE/STUDIES: 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 large farms, which have reduced pesticide use, increased no-tillage cultivation, and increased rotation with legumes to consistently produce high yields.

The Interamerican Bank for development (IADB) has finalized and published a regional market study for agricultural biotechnologies, which was presented in the International Biotechnology Workshop held in Argentina for its socializing stage.

CHAPTER 2: ANIMAL BIOTECHNOLOGY

PART D: Production and Trade

a) RESEARCH AND PRODUCT DEVELOPMENT: Not applicable.

- b) COMMERCIAL PRODUCTION: In discussion and preparation of implementation strategies.
- 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 Customs 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 1st, 2019, the rule entered effect for Guatemala and Honduras.

- b) APPROVALS/AUTHORIZATIONS: 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: FAS Tegucigalpa is not aware of commercial production of food ingredients derived from microbial biotechnology in Honduras.

b) EXPORTS: Not applicable.

c) IMPORTS: Honduras imports food ingredients such as enzymes and additives for different food processing activities. However, the volume or value of these imports, and whether the products are derived from microbial biotechnology could not be determined.

d) TRADE BARRIERS: Not applicable.

PART H: Policy

a) REGULATORY FRAMEWORK: Not applicable.

b) APPROVALS/AUTHORIZATIONS: 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) RELATED ISSUES. Not applicable.

PART I: Marketing

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

Attachments:

No Attachments