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#### **Report Highlights:**

Genetically engineered crop area planted increased in 2023, though it remained small and limited to cotton for seed and pink pineapples. If approved, area planted could expand further in 2024 as requests for additional pineapple area and the evaluation of new products were pending as of the writing of this report. FAS/San José anticipates a prospective update to agricultural biotechnology regulations could facilitate new research, development, and commercial production of genetically engineered products, including genome edited products, in the near term.

### **EXECUTIVE SUMMARY**

Transgenic seed varieties have been grown in Costa Rica since 1992, primarily for cotton seed reproduction to supply the U.S. planting seed market. Costa Rica has implemented legislation to regulate the import and cultivation of genetically engineered (GE) crops. There is currently no requirement that foods containing GE components be labeled. The composition of the Costa Rican National Technical Biosafety Commission (NTBC) was modified by the Chaves administration after some organizations delayed the nomination of members to the NTBC resulting in delays through 2022 and 2023. Normal operation of the NTBC is expected to resume in October or November of 2023.

Total GE crop area planted has fallen from 1,697 hectares (ha) at the peak of production in 2009, to an estimated 216 ha in 2023. The NTBC evaluated five cotton events in 2020 and approved them in May of 2021; two cotton events were approved in 2022 under a simplified procedure for products with historical use in Costa Rica. Following approval of the new cotton events and the arrival of another cotton seed reproduction entity (Nutrien Ag Solutions), GE cotton seed reproduction area planted could increase in the near term. However, as seed reproduction area planted in Costa Rica ultimately depends on U.S. cotton seed demand, Costa Rican area planted generally does not reflect production capacity.

Costa Rica signed the Cartagena Protocol on Biosafety in 2000. The Costa Rican Legislative Assembly joined the Cartagena Protocol on Biosafety by enacting Law #8537, published in November 2006. Since then, Costa Rica has been working on the national regulatory framework necessary to implement the Protocol. According to local sources, there are some government officials interested in the approval of regulations related to the Cartagena Protocol that would require certain specific information and attestations on imported products derived from biotechnology that are used as animal feed or for human consumption. However, other government officials, animal feed producers, and grain users have expressed concerns about potential effects of the final regulations on GE soybean and GE corn imports.

The only soybean crushing mill in Central America is located in Costa Rica, supporting approximately 255,000 metric tons (MT) of GE soybean imports in 2022. Costa Rican poultry and livestock production drives importation of GE corn for animal feed, reaching a record high of 1,065,000 MT in 2021. All GE soybeans and the majority of GE corn are imported from the United States.

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# **CHAPTER 1: PLANT BIOTECHNOLOGY**

### PART A: PRODUCTION AND TRADE

### **RESEARCH AND PRODUCT DEVELOPMENT**

Costa Rican researchers are working on the development of drought resistant rice and continue to improve upon the GE 'pink' pineapple developed in Costa Rica. The pineapples, genetically engineered to have higher levels of the antioxidant lycopene, obtained U.S. Food and Drug Administration (FDA) approval at the end of 2016. The developer of the pink pineapple produces relatively small volumes exclusively for export – the crop is not approved for commercialization within Costa Rica – and has requested permission to expand production in response to strong global demand; permission is pending review by the NTBC. Other research products being conducted at local public universities include the development of coffee with reduced caffeine, and yeast with tolerance to salinity.

### **COMMERCIAL PRODUCTION**

Costa Rica produces GE cotton seeds for export to the United States. According to the Ministry of Agriculture and Livestock (MAG) Biotechnology Department, total GE crop area planted increased to 216 hectares ha in 2023 (including area planted to GE pineapple), up from 118 ha in 2022.

Cotton events approved for seed production include – Roundup Ready, Roundup Ready Flex, Bollgard, Bollgard II, WideStrike, Cry 1F, Bomoxinil, Liberty Link, Vip 3A, and stacked combinations of approved events. Roundup Ready events have been approved for soybean production, but GE soybeans have not been planted in Costa Rica. The NTBC has not received any requests to date for transgenic plant varieties for human or animal consumption in Costa Rica. According to industry sources, the

procedures to obtain permissions from the NTBC to plant GE varieties are straightforward and do not represent an obstacle to production. A list of approved events can be found <u>here</u> (Spanish only).

### **EXPORTS**

Costa Rica exports GE cotton seeds propagated for the specific purpose of exporting them back to the companies that supplied them. Costa Rica also exports relatively small volumes of GE pineapples, mostly to the United States.

### **IMPORTS**

Costa Rica imports GE corn and GE soybeans from the United States for animal feed production, GE cotton seed for propagation, and a small volume of GE cotton for processing. Imports of GE organisms are limited to those indicated above from the United States. GE Soybeans have previously been imported from Argentina, but in much smaller volumes. Brazil has exported GE corn to Costa Rica since 2012, but the United States remains the preferred supplier due to logistics advantages. In 2022, Costa Rica imported approximately \$400 million of GE products from the United States.

### FOOD AID

The country is neither a recipient nor a donor of food aid.

### **TRADE BARRIERS**

There are no biotechnology trade barriers affecting U.S. exports at this time. Costa Rica is a large importer of GE soybeans and GE corn (primarily yellow corn for animal feed production). Imports of processed products that may contain products of biotechnology are also an important segment of total agricultural imports from the United States.

### PART B: POLICY

#### **REGULATORY FRAMEWORK**

<b>Legal Term</b> (in Spanish)	<b>Legal Term</b> (in English)	Laws and Regulations Where Term is Used	Legal Definition
Organismos genéticamente modificados (OGM)	Genetically modified organisms (GMO)	Regulation 29782	All materials produced by modern methods of biotechnology, and all other techniques that employ cell and/or molecular biology to alter the genetic constitution of living organisms in forms or with results that do not occur in nature or through traditional reproduction.

Legal Term (in Spanish)	Legal Term (in English)	Laws and Regulations Where Term is Used	Legal Definition
Organismo transgénico	Transgenic organism	Regulation 26921	Any modified organism resulting from the insertion, selection, rearrangement, or manipulation of its DNA or RNA, through genetic engineering techniques.
Biotecnología	Biotechnology	Regulation 26921	Any technological application that uses its biological themes and living organisms or its derivatives for the creation or modification of products or processes for specific uses.
Ingeniería genética	Genetic Engineering	Regulation 26921	Set of manipulation techniques of DNA and RNA "in vitro" or under special laboratory conditions.
Material transgénico	Transgenic material	Regulation 26921	Artificially modified genotypes that, due to their multiplication characteristics and permanence in the environment, have the capacity to transfer recombinant genes to other organisms.

In 1990, Costa Rica created the National Technical Biosafety Commission (NTBC), which is attached to MAG by the 1997 <u>Plant Health Protection Law</u> (Spanish only). The law confers upon the NTBC power to regulate imports, exports, research, testing, movement, propagation, industrial production, marketing, and use of transgenic and other "genetically modified" organisms for agricultural use.

On June 13, 2023, the Government of Costa Rica published <u>Executive Decree 44020-MAG</u> (also see attached), which modified articles 111 to 116 of <u>Regulation 26921</u> (Implementing Regulations of the Phytosanitary Protection Law). The decree contained important changes to the purview and functions of the NTBC, as well as the composition of the Commission, and the term that members can serve on the Commission. For instance, point 1 of article 111 indicates that the NTBC will "advise the institutions of the agricultural sector in establishing and executing measures and technical procedures, as well as drafting the necessary technical regulations and executive decrees to regulate organisms that are the product of modern biotechnology, including those obtained from genome editing, as well as modified living organisms or their products, for agricultural use." This modification expanded the scope of the NTBC regulatory purview to include genome editing, which was not included in the previous text.

Adjustments to Article 112 modified the composition of the NTBC by reducing the number of members and changing the organizations that have representation. Although the NTBC composition was set by

the Executive Decree that established the body, it has since been modified several times to incorporate different government and civil society organizations. The latest modification has resulted in the following composition: three representatives from the Ministry of Agriculture, one representative from the Ministry of the Environment and Energy, one representative from the National Seeds Office, one representative from the National Academy of Sciences, one representative from the Ministry of Health, one representative each from the Federation for Environmental Conservation and the Chamber of Agriculture and Agribusiness. NTBC representatives are now appointed for 4-year terms instead of 2-year terms, and there are no term-limits.

Article 117 of the implementing regulations – <u>Reglamento a la Ley de Protección Fitosanitaria No.</u> <u>26921</u> – covers imports and release of GE materials for use in agriculture. The article indicates that a "phytosanitary certificate of release to the environment" is required for importation, as well as compliance with the phytosanitary import requirements. To move the product within the country, the interested party must inform the MAG Biotechnology Department using Form BIO-02. The International Phytosanitary Services Department, in coordination with the NTBC, establishes the import requirements and the biosafety measures for GE material.

Article 118 discusses the process to obtain the certificate for release into the environment of GE materials. The interested party must submit a request to the Biotechnology Department, using Form BIO-02, for NTBC review and approval. Other articles of the regulation (119 through 134) discuss different aspects related to GE materials, such as record keeping, storage, packaging, labeling, movement, accidental release, and others.

An Executive Decree including comprehensive changes to <u>Regulation 26921</u> is now undergoing review by the President's Office of Laws and Decrees and is expected to be published before the end of 2023. The Executive Decree will include changes to technical aspects of the regulation of "living modified organisms" for agricultural use. The Ministry of Agriculture is also in the process of modifying <u>Regulation 32486</u> (Regulation on Agricultural Biosafety Audits of the Ministry of Agriculture and Livestock). This regulation includes technical and administrative aspects of external audits of agricultural biosafety in projects involving "living modified organisms" for agricultural use.

In 2013, environmental groups – including the Federation for Environmental Conservation and the Biodiversity Conservation Network – actively opposed a Monsanto request for approval to plant a new variety of GE corn (production would have been for propagation and re-export of seeds, rather than for commercialization in Costa Rica). Although the NTBC eventually approved Monsanto's request to plant the new corn variety, the environmental groups raised the issue to the Constitutional Court. And though the Constitutional Court upheld the NTBC approval, Monsanto decided not to propagate the variety in Costa Rica.

In 2014-2015, two Constitutional Court cases brought agricultural biotechnology research, production activities, and development plans to a halt. An additional issue of concern, although with unclear legal results, has been the large number of local governments (74 out of a total of 82) that have declared themselves "free of transgenics."

Several bills seeking a moratorium on biotechnology cultivation were introduced in the national legislature during the 2014-2018 session. Although the bills were supported by the Solis Administration (2014-2018), they did not become law. A biotechnology moratorium bill was presented to the Legislative Assembly in 2022 by the leftist party "Frente Amplio," which had presented and supported the previous bills that were defeated. The bill, which called for a moratorium of 5 years, was defeated in the Assembly in September 2023.

Costa Rica has specific legislation in place for the approval of plant biotechnology events for cultivation, import, and export. At this time there is no specific legislation requiring approval of products of biotechnology for food consumption, feed, or processing. Imports of U.S. grains and soybeans for animal feed production enter Costa Rica under procedures identical to the importation of any other agricultural product.

### **APPROVALS / AUTHORIZATIONS**

Requests to obtain approval to plant a biotechnology crop (to be grown commercially, as a field trial, or to be grown for export purposes only) are evaluated by the NTBC. During 2021, the NTBC reviewed and approved five cotton events with different characteristics, including glyphosate tolerance and lepidoptera resistance. A list of approved events can be found <u>here</u> (Spanish only). Two cotton events were approved in December 2022; and one pineapple event and one petunia event are currently under review.

### STACKED or PYRAMIDED EVENT APPROVALS / AUTHORIZATIONS

Cases that present stacked events (plants that combine two or more already approved traits, such as herbicide and insect tolerance) need to undergo the same risk evaluation process as individual events.

#### FIELD TESTING

The country allows field tests of GE crops following appropriate risk analysis and approval from the NTBC. Currently, field testing is limited to a few hectares of pineapples separate from the commercial production area.

#### **INNOVATIVE BIOTECHNOLOGIES**

As indicated earlier, a comprehensive modification of <u>Regulation 26921</u> is expected to be published in the next few months and will include the regulation of innovative biotechnologies, such as genome editing.

#### COEXISTENCE

<u>Regulation 29782</u>, establishing regulations for organic production, indicates in Chapter III Article 24, "Genetically Modified Organisms or those obtained through genetic engineering and the products derived from such organisms, are not compatible with the principles of organic production (understood as production, processing, manufacture or marketing), and their use in organic agriculture is not allowed." The same regulations also indicate, "any person who plants transgenic products, will have to

obtain permission from the Ministry of Agriculture and Livestock, without which, the person will not be allowed to initiate the activity. The permit will be granted if there is a previous study proving that there is no organic production within a reasonable distance, which may be affected by wind or proximity. The procedure to grant the permit will include consultations by the authorities with the organic producer organizations present in the area."

### LABELING AND TRACEABILITY

There is currently no law regarding the use of terms such as "biotech free," "non-biotech," "gmo-free," or "non-gmo" on food package labeling. Anti-biotech as well as consumer protection groups are pushing for mandatory labeling of food products derived from biotechnology.

At this time labeling is required to commercially introduce (either locally produced or imported) GE plant products or other "genetically modified organisms" for use in agriculture in Costa Rica. The product must be identified as GE on a label where the consumer can identify its characteristics. To date, this requirement has been applied only to labeling of planting seeds. Environmentalists continue to call for legislation banning the import of transgenic crops and establishing a labeling system for transgenic foods.

In 2022, Costa Rica imported an estimated \$400 million of biotech commodities from the United States, based on the value of yellow corn, soybean, cotton, and planting seed imports. Processed food imports, many of which contain ingredients derived from biotech commodities, have also increased, reaching nearly \$100 million in 2022.

### MONITORING AND TESTING

The country does not have a monitoring program for GE products and does not actively test for GE products. Rice importers implement a voluntary testing regime for presence of GE rice varieties; testing is conducted in the exporting country of origin.

### LOW LEVEL PRESENCE POLICY

Costa Rica does not have a low-level presence policy at this time.

### ADDITIONAL REGULATORY REQUIREMENTS

There are no additional requirements beyond approval by the NTBC for plant biotechnology events.

### **INTELLECTUAL PROPERTY RIGHTS (IPR)**

Costa Rica has intellectual property rights legislation that protects GE crop intellectual property.

### CARTAGENA PROTOCOL RATIFICATION

Costa Rica signed the Cartagena Protocol on Biosafety in 2000. The Costa Rican Legislative Assembly joined the Cartagena Protocol on Biosafety by enacting Law #8537, published in November 2006. Costa Rica has been working on the national regulatory framework necessary for the implementation of the Protocol. MAG has taken steps to reach agreements with importers and grain users in order to comply

with the protocol. As part of this process, MAG has approached FAS/San José in the past to request a list of all agricultural biotechnology events approved by the United States.

### **INTERNATIONAL TREATIES / FORA**

Costa Rica is a member of the World Trade Organization (WTO), the World Organization for Animal Health (OIE), the International Plant Protection Convention, and the CODEX Alimentarius. In general, Costa Rica has been an active participant in international fora, such as Codex Alimentarius. At times, Costa Rica has shared or supported U.S. positions on issues related to biotechnology. Costa Rica has also participated in the meetings of the parties to the Cartagena Protocol after the country ratified the agreement.

### **RELATED ISSUES**

The Ministry of Environment's National Commission for Management of Biodiversity (CONAGEBIO) requires researchers to register any research project that involves access to Costa Rica's biodiversity and any research project that involves genetic manipulation with the Commission. This requirement has not been an impediment to plant biotechnology activities in Costa Rica.

### PART C: MARKETING

### PUBLIC/PRIVATE OPINIONS

Public relations campaigns against biotechnology – launched over the years by different groups under the Federation for Environmental Conservation and the Biodiversity Conservation Network – have not generally been effective. However, due to a general lack of public scientific knowledge, especially in rural areas where educational attainment is lower, consumer perceptions are susceptible to misinformation from opposition groups. Scientists, government officials, and the press have generally provided accurate information in support of biotechnology and science in response to past biotechnology misinformation campaigns.

The number of highly visible activities organized by opponents of biotechnology has declined in recent years.

### MARKET ACCEPTANCE/STUDIES

Costa Rica is an importer of GE corn and GE soybeans from the United States. There seems to be little concern regarding the process from which these products are derived, whether among users (primarily animal feed producers) or among consumers in the country. Most of the population is not aware that almost all the yellow corn and soybeans imported into the country for animal feed production are derived from biotech varieties. However, anti-biotech groups are trying to build a negative perception of such products among the public, mostly through fear and misinformation.

### **CHAPTER 2: ANIMAL BIOTECHNOLOGY**

# PART D: PRODUCTION AND TRADE

# PRODUCT DEVELOPMENT

There are no GE animals or clones of animals under development in Costa Rica at this time.

# **COMMERCIAL PRODUCTION**

Costa Rica does not commercially produce any livestock clones or GE animals or products derived from GE animals.

# EXPORTS

The country does not export any GE animals, livestock clones, or products from these animals at this time.

#### **IMPORTS**

Costa Rica has not imported GE animals, livestock clones or products from these animals.

#### **TRADE BARRIERS**

There are no specific trade barriers to imports of GE animals, livestock clones, or products from these animals. Imports of any such animals or products would have to go through the established evaluation and approval processes.

### PART E: POLICY

### **REGULATORY FRAMEWORK**

For more information on Costa Rica's biotechnology regulatory framework and terminology, see Chapter 1, Part B.

Animal biotechnology regulations are, generally, not as well-developed as plant biotechnology. MAG has yet to develop specific regulations for animal biotechnology, even though Law 8495 (General Law of the National Animal Health Service) gives the National Animal Health Service (SENASA) legal authority to regulate animal biotechnology in Costa Rica; the text of Law 8495 is available here (Spanish only). SENASA also regulates issues related to food safety for animals and animal products, and animal welfare. Environmental safety issues are regulated by the Ministry of Environment and Energy.

According to SENASA, the regulatory process would involve different Ministries depending on the final use of the product. For example, any animal product would first have to be registered at SENASA. Then if it is going to be released into the environment (e.g., a GE mosquito), it would have to be registered

with the Ministry of Environment and Energy as well. If the product affects human health, it would have to be registered with the Ministry of Health. Also, an animal intended to be used for research purposes would have to be registered with the Ministry of Science and Technology to comply with animal welfare regulations.

### **APPROVALS / AUTHORIZATIONS**

There are no approved or authorized GE animals, livestock clones or products of from these animals at this time.

### **INNOVATIVE BIOTECHNOLOGIES**

Costa Rica has not developed regulations for innovative biotechnologies in animals, in part because the Government of Costa Rica has not yet received applications for innovative biotechnology approval. However, government officials have been working on a comprehensive update and modernization of the national biotechnology regulatory framework that would include provisions for innovative biotechnologies, including genome editing. FAS/San José expects updated regulations to be published before the end of 2023.

### LABELING AND TRACEABILITY

Labeling regulations have not been developed for products of animal biotechnology. However, Article 69 of Law 8495 indicates that any establishment that produces, imports, stores, transports or sells genetic or biotechnology materials of animal origin for human or animal consumption, must have those materials or animals properly identified, must identify the product using appropriate identification materials, must keep the information related to the origin of the animal or product, and must provide the information to SENASA for the operation of the traceability system. The country has traceability regulations in place for live animals, which would apply to GE animals in the eventual case of introduction into the country.

### ADDITIONAL REGULATORY REQUIREMENTS

FAS/San José is not aware of any additional requirements.

### **INTELECTUAL PROPERTY RIGHTS (IPR)**

Although Costa Rica currently does not raise or import GE animals, livestock clones or products from those animals, national intellectual property regulations would protect animal biotechnology intellectual property as well.

### **INTERNATIONAL TREATIES / FORA**

FAS/San José is not aware of specific interventions by Costa Rican officials on the subject of animal biotechnology in international fora. The local Codex Alimentarius Committee is under the Ministry of Economy. According to government representatives, local officials have not participated in animal biotechnology discussions under Codex or the OIE recently.

#### **RELATED ISSUES**

None at this time.

### PART F: MARKETING

#### **PUBLIC/PRIVATE OPINIONS**

Public relations campaigns against biotechnology – launched over the years by different groups under the Federation for Environmental Conservation and the Biodiversity Conservation Network – have not generally been effective. However, due to a general lack of public scientific knowledge, especially in rural areas where educational attainment is lower, consumer perceptions are susceptible to misinformation from opposition groups. Scientists, government officials, and the press have generally provided accurate information in support of biotechnology and science in response to past biotechnology misinformation campaigns.

#### MARKET ACCEPTANCE/STUDIES

The information provided above about acceptance of plant biotechnology generally applies to animal biotechnology. While the issue of animal biotechnology has not received much attention in the local press over the last few years, FAS/San José expects, based on broader cultural attitudes, the issue could be controversial if it became a public topic.

### **CHAPTER 3: MICROBIAL BIOTECHNOLOGY**

#### PART G: PRODUCTION AND TRADE

#### **COMMERCIAL PRODUCTION**

FAS/San José is not aware of commercial production of food ingredients derived from microbial biotechnology in Costa Rica.

#### **EXPORTS**

Costa Rica does not export GE microbes and or products that contain microbial biotech-derived food ingredients to the United States.

#### **IMPORTS**

Costa Rica 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.

#### **TRADE BARRIERS**

There are no trade barriers to the importation of microbial biotech-derived food ingredients and/or processed food products containing microbial biotech-derived food ingredients.

# PART H: POLICY

#### **REGULATORY FRAMEWORK**

Costa Rica does not have a specific regulatory framework for biotech-derived microbes or microbial biotech-derived food ingredients. The Ministry of Health administers regulations for additives and food ingredients, including a mandatory notification process. There is no legislation or regulation pending or under discussion related to microbial biotech at this time.

For more information on Costa Rica's biotechnology regulatory framework and terminology, see Chapter 1, Part B.

#### **APPROVALS / AUTHORIZATIONS**

There is no database or listing of biotech microbes and/or microbial biotech-derived food ingredients approved or registered for use in the country.

#### LABELING AND TRACEABILITY

There are no current or anticipated policies regarding the traceability and labeling of microbial biotechderived food ingredients in Costa Rica.

#### MONITORING AND TESTING

The country does not actively test for evidence of genetic engineering in imports or exports of processed products.

#### ADDITIONAL REGULATORY REQUIREMENTS

FAS/San José is not aware of any additional requirements affecting imports and/or utilization of microbial biotechnology.

#### **INTELLECTUAL PROPERTY RIGHTS (IPR)**

FAS/San José expects Costa Rican IPR regulations would protect microbial biotechnology IPR as well.

#### **RELATED ISSUES**

None at this time.

### PART I: MARKETING

#### PUBLIC PRIVATE OPINIONS

There is very limited knowledge or awareness of microbial biotechnology among the general public. The information/knowledge about the subject is more prevalent among scientists at academic institutions, such as Costa Rica's Technological Institute (TEC), and the University of Costa Rica (UCR), where the general perception among scientists and researchers is mostly positive.

### MARKET ACCEPTANCE/STUDIES

Even though products of microbial biotechnology are being imported and used in research activities in the country, FAS/San José is not aware of any studies on the acceptance (positive or negative) of these products among the general public.

#### Attachments:

No Attachments