



Required Report: Required - Public Distribution

Date: November 20,2020

Report Number: CS2020-0027

Report Name: Agricultural Biotechnology Annual

Country: Costa Rica

Post: San Jose

Report Category: Biotechnology and Other New Production Technologies

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Report Highlights:

Transgenic seed varieties have been grown in Costa Rica since 1992. All of the seeds are exported to the United States. 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 Costa Rican National Technical Biosafety Commission (NTBC) has been meeting regularly this year and has approved several cotton events for seed reproduction.

SECTION I. EXECUTIVE SUMMARY

Transgenic seed varieties have been grown in Costa Rica since 1992. All of the seeds are exported to the United States. Costa Rica has implemented legislation to regulate the import and cultivation of GE crops. There is currently no requirement that foods containing GE components be labeled. The Costa Rican National Technical Biosafety Commission (NTBC) has been meeting regularly this year and has approved several cotton events for seed reproduction.

Total area planted of GE crops dropped from 1,697 ha. at the peak of production in 2009, to less than 300 ha. in 2019. Legal challenges to GE cultivation have continued. In 2018, a member of the NTBC challenged the approval of a cotton event and took the case to the Constitutional Court. Although the Court did not cancel the approval of the event, it ruled that in the future, requests for approval must be made public so that the public is aware that the event is under review by the Biosafety Commission.

The NTBC has been meeting regularly and approved a total of four cotton events in 2019 and 2020. The NTBC will also begin the evaluation of five cotton events at its next meeting. As a result of the approval of new cotton events and the arrival of a new player in the seed reproduction business, area planted of GE cotton for seed reproduction is expected to increase in the next few years.

Costa Rica signed the Cartagena Protocol on Biosafety in May 2000 and it became law in November 2006. Since then, Costa Rica has been working on the national regulatory framework necessary to implement the Protocol.

SECTION II: PLANT AND ANIMAL BIOTECHNOLOGY

Contents

CHAPTER 1: PLANT BIOTECHNOLOGY	3
PART A: PRODUCTION AND TRADE	3
PART B: POLICY	4
PART C: MARKETING	7
CHAPTER 2: ANIMAL BIOTECHNOLOGY	8
PART D: PRODUCTION AND TRADE	8
PART E: POLICY	9
PART F: MARKETING	10
CHAPTER 3: MICROBIAL BIOTECHNOLOGY	10
PART G: PRODUCTION AND TRADE	
PART H: POLICY	11
PART I: MARKETING	12

CHAPTER 1: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

a) PRODUCT DEVELOPMENT: Costa Rican researchers are working on the development of drought resistant rice as well as pineapples with a higher content of antioxidants. Although GE pineapples obtained FDA approval at the end of 2016, they are not currently being produced commercially in Costa Rica.

b) COMMERCIAL PRODUCTION: Costa Rica produces GE cottonseeds entirely for export to the United States. According to the Ministry of Agriculture's Biotechnology Department, area planted with GE crops reached 229.5 hectors (ha.) in 2019, including area planted to pineapple production. It is expected to increase in 2020 due to the approval of new events and new investment.

The events approved for seed production include - Roundup Ready, Roundup Ready Flex, Bollgard, Bollgard II, WideStrike, Cry 1F, Bomoxinil, Liberty Link, Vip 3A, and some combinations of approved events for cotton. For soybeans, only Roundup Ready has been planted in the past. The Costa Rican Government (CRG) has not received any requests to date for approval to plant transgenic varieties for human or animal food consumption in Costa Rica. According to industry sources, the procedures to obtain permissions from the CRG to plant GE varieties are straightforward and do not represent an obstacle to production. A list of approved events can be found here: <u>http://cr.biosafetyclearinghouse.net/decisions.shtml</u>

c) EXPORTS: Costa Rica exports cottonseeds propagated for the specific purpose of exporting them back to the companies that supplied them.

d) IMPORTS: Costa Rica imports GE corn and soybeans from the United States for animal feed production, and a small volume of cotton for processing. Imports of GE organisms are limited to those indicated above from the United States. The same products (corn and soybeans) have been imported from Brazil and Argentina. In 2019, Costa Rica imported \$236.7 million of biotech commodities from the United States, based on the value of corn and soybean imports.

e) FOOD AID: The country is not a recipient of food aid and is not likely to become a food aid recipient.

f) TRADE BARRIERS: There are no biotechnology trade barriers that affect U.S. exports at this time. Costa Rica is a large importer of soybeans and 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 products imported from the United States.

PART B: POLICY

a) REGULATORY FRAMEWORK: In 1990, Costa Rica created the National Technical Biosafety Commission (NTBC), which is attached to the Ministry of Agriculture by law (Plant Health Protection Law 7664 of April 1997, (see text in Spanish) <u>Phytosanitary Protection Law</u>. 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.

Implementing regulations (Reglamento a la Ley de Protección Fitosanitaria No. 26921-MAG) can be found at the following link <u>Reglamento</u>. Article 117 of the regulation covers imports and release of genetically engineered materials for use in agriculture. The regulation 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 Biotechnology Department of the Ministry of Agriculture and Livestock, using Form BIO-02. The International Phytosanitary Services Department, in coordination with the NTBC will issue the import requirements and the biosafety measures for genetically engineered material. Article 118 discusses the process to obtain the certificate for release into the environment of genetically engineered materials. The interested party must submit a request to the Biotechnology Department using "Form BIO-02". This request will be forwarded for review and approval to the NTBC. Other articles of the

regulation (119 through 134) discuss different aspects related to genetically engineered materials, such as record keeping, storage, packaging, labeling, movement, accidental release, and others.

In the past, the composition of the NTBC has had a more political than scientific learning. The current NTBC is made up of one representative of the Science and Technology Ministry, two representatives from the Ministry of Agriculture, two representatives from the Ministry of the Environment, one representative from the National Seeds Office, two representatives from the National Academy of Sciences, two representatives from the Ministry of Health, one representative from the Federation for Environmental Conservation, and one representative from the Biodiversity Conservation Network.

In 2013, in response to a request by Monsanto for approval to plant a new variety of genetically engineered corn (production would be for propagation and re-export of the seeds - not for commercial production), groups opposed to biotechnology became very active. Although the NTBC eventually approved Monsanto's request to plant the new corn variety, the environmental groups raised the issue to the Constitutional Court (Sala Cuarta). **Note**: Although the Monsanto corn variety has been approved, the company decided not to plant in Costa Rica at this time. **End Note**.

In 2014-2015, two Constitutional Court cases resulted in major setbacks for companies involved in biotechnology activities. Research, production activities and development plans were stopped as a result. An additional issue of concern, although with unclear legal results, is the decision of a large number of municipalities or local governments (74 out of a total of 81) to declare themselves "free of transgenics".

During the previous legislature, there were several bills that sought a moratorium on biotechnology cultivation. Although the bills were supported by the previous Administration, they did not become law.

Costa Rica has specific legislation in place for the approval of plant biotechnology events for cultivation, import, and export. However, 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

b) APPROVALS: 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 2019 the NTBC reviewed and approved two cotton events, with different characteristics, one with resistance to glyphosate and isoxaflutol, and the other with tolerance to hemiptera and thysanoptera.

A list of approved events can be found here: http://cr.biosafetyclearinghouse.net/decisions.shtml

c) STACKED or PYRAMIDED EVENT APPROVALS: 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.

d) FIELD TESTING: The country allows field tests of GE crops, following appropriate risk analysis. Currently, field testing is limited to a few hectares of pineapples.

e) INNOVATIVE BIOTECHNOLOGIES: Costa Rica has not developed regulations for innovative biotechnologies. Government officials with regulatory responsibilities in the biotechnology field have held meetings to discuss the need for regulation of such biotechnologies but they acknowledge that it would involve political compromise by different government sectors (Ministry of Science and Technology, Ministry of the Environment and Energy, Ministry of Health, and Ministry of Agriculture and Livestock), which has not been possible at this point. Also, according to government officials, they have not received any requests for approval of innovative biotechnologies in the country. Costa Rica is in the process of drafting regulations for gene editing. According to government officials, the draft regulation may be completed in 2021.

f) COEXISTENCE: Regarding the coexistence of biotechnology and non-biotechnology crops (including organic agriculture), Executive Decree 29782 – MAG of September 18, 2000 (Organic Production Regulation), indicates in Chapter III, Article 24: "Genetically Engineered 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 law can be found in the following link under "Leyes" (see Ley 8591):

http://www.sfe.go.cr/SitePages/Normativa/InicioNormativa.aspx

Costa Rica has legislation in effect to promote the production of organic crops. Article 24 of the legislation indicates the following: "any person who plants transgenic products, will have to obtain permission from the Ministry of Agriculture, 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."

g) LABELING: There is no law regarding the use of labels such as "biotech free", "non-biotech", "gmo-free" or "non-gmo" right now. Anti-biotech as well as consumer protection groups are pushing for mandatory labeling of food products derived from modern biotechnology. According to government officials, an inter-agency commission is reviewing a draft regulation for the evaluation of the safety of genetically engineered products for human and/or animal consumption. The need to label genetically engineered products authorized for consumption will be considered after the draft regulation mentioned above is approved. At this time labeling is required to introduce and/or trade plant products or other genetically modified organisms (GMOs) for use in agriculture in Costa Rica. In this case the product must be identified as such on a label where the consumer can identify its characteristics. To date, this requirement has been applied only to labeling of planting seeds. Environmentalists have called in the recent past for legislation to ban the import of transgenic grains and to establish a labeling system for transgenic foods.

In 2019, Costa Rica imported \$236.7 million of biotech commodities from the United States, based on the value of corn and soybean imports. Processed food imports, many of which contain ingredients derived from biotech commodities, have also increased over time.

h) MONITORING AND TESTING: The country does not have a monitoring program for GE products and does not actively test for GE products.

i) LOW LEVEL PRESENCE POLICY: Costa Rica does not have a Low-Level Presence policy at this time.

j) ADDITIONAL REGULATORY REQUIREMENTS: There are no additional requirements beyond approval by the NTBC for plant biotechnology events.

k) INTELLECTUAL PROPERTY RIGHTS (IPR): Although the country currently does not plant GE crops commercially, there is legislation in effect that would protect intellectual property rights for such products.

I) CARTAGENA PROTOCOL RATIFICATION: Costa Rica signed the Cartagena Protocol on Biosafety in 2000. It was published in the Official Diary, "La Gaceta" on November 2006, thus becoming law. Costa Rica has been working on the national regulatory framework necessary for the implementation of the Protocol. The Ministry of Agriculture (MAG) has taken steps to reach agreements with importers and grain users in order to comply with the protocol. As part of this process, the Ministry of Agriculture approached Post in the past to request a list of all agricultural biotechnology events approved by the United States.

m) INTERNATIONAL TREATIES/FORA: In general, Costa Rica has been an active participant in international forums such as Codex Alimentarius. At times, Costa Rica has shared or supported U.S. positions on issues related to biotechnology. Costa Rica also has participated in the meetings of the parties to the Cartagena Protocol after the country ratified the agreement.

n) RELATED ISSUES: Not applicable.

PART C: MARKETING

a) PUBLIC/PRIVATE OPINIONS: The anti-biotech campaign, created by different groups under the Federation for Environmental Conservation and the Biodiversity Conservation Network, did not have a significant negative impact among consumers in the past. However, because of the lack of scientific education of the public and the widespread use of misinformation by groups opposed to biotechnology, the perception and attitudes toward GE products may be changing amongst the general population. The general public has limited knowledge of the topic and can be easily influenced by these groups, especially in rural areas, where the educational level of the population tends to be lower. On the other side, these groups' statements and actions have given scientists, Ministry of Agriculture officials, and the press the opportunity to express points of view favorable to biotechnology.

There have been activities organized by environmental groups in support of the biotech moratorium bill. For instance, in March 2016, an organization called "Pax Natura" brought to Costa Rica anti-biotech writer Steven M. Drucker who wrote, "Altered Genes, Twisted Truth." During their visit, they met with legislators to promote the moratorium bill. In addition, the left wing party "Frente Amplio" organized an event in June 2015 at the Legislative Assembly with the participation of Dr. Ray Siedler, a former Environmental Protection Agency researcher and vocal opponent to biotechnology. However, the number of activities organized by opponents of biotechnology has declined in recent years.

b) MARKET ACCEPTANCE/STUDIES: Costa Rica is an importer of corn and soybeans from the United States. There seems to be little, if any, concern regarding the process from which these products are derived, be it among users (primarily animal feed producers) or among consumers in the country. The majority of the population is not aware that almost all the yellow corn and soybeans imported into the country for animal feed production is 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

a) **PRODUCT DEVELOPMENT:** There are no GE animals or clones of animals under development in the country at this time.

b) COMMERCIAL PRODUCTION: Costa Rica does not commercially produce any livestock clones or GE animals or products derived from GE animals.

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

d) IMPORTS: Costa Rica has not imported GE animals or livestock clones or products from these animals.

e) TRADE BARRIERS: There are no specific trade barriers to imports of genetically engineered products. Imports of any such products would have to go through the evaluation procedures established by the local authorities.

PART E: POLICY

a) REGULATORY FRAMEWORK: Law #8495 (General Law of the National Animal Health Service) provides SENASA with the legal authority to regulate animal biotechnology in Costa Rica. The following is the link to the text of the law:

SENASA Law (English version)

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 the Environment (MINAET). The field of animal biotechnology regulation is not as developed as plant biotechnology. The Ministry of Agriculture has yet to develop specific regulations for animal biotechnology, even though the General Law makes SENASA responsible for regulating this specific area of biotechnology.

According to SENASA, the regulatory process would involve different Ministries depending on the final use of the product. For instance, any animal product would have to be registered at SENASA first; if it is going to be liberated into the environment (for instance a GE mosquito), it would have to be registered with the Ministry of the Environment as well. If the product could influence 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.

b) INNOVATIVE BIOTECHNOLOGIES: Costa Rica has not developed regulations for innovative biotechnologies. Government officials with regulatory responsibilities in the biotechnology field have held meetings to discuss the need for regulation of innovative biotechnologies, but they acknowledge that the development of such regulations involves a political compromise of several Government sectors (Ministry of Science and Technology, Ministry of the Environment and Energy, Ministry of Health, and Ministry of Agriculture and Livestock), and such agreement has not been reached at this point.

c) LABELING AND TRACEABILITY: Labeling regulations have not been developed for products of animal biotechnology. However, Article 69 of SENASA's Law 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.

d) INTELECTUAL PROPERTY RIGHTS (IPR): There is legislation in effect that would protect intellectual property rights for such products.

e) INTERNATIONAL TREATIES/FORA: Post 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 located at the Ministry of Economy. According to government representatives, local officials have not participated in animal biotechnology discussions under Codex or the OIE recently.

f) RELATED ISSUES: Not applicable

PART F: MARKETING

a) PUBLIC/PRIVATE OPINIONS: Please see the section on plant biotechnology.

b) MARKET ACCEPTANCE/STUDIES: The information provided above about acceptance of plant biotechnology generally applies to animal biotechnology. However, the issue of animal biotechnology has not received much attention over the last few years in the local press. Post would expect the issue to be controversial if it becomes a public discussion topic.

CHAPTER 3: MICROBIAL BIOTECHNOLOGY

PART G: PRODUCTION AND TRADE

- a) COMMERCIAL PRODUCTION: Post is not aware of commercial production of food ingredients derived from microbial biotechnology in Costa Rica. Post contacts in the field of biotechnology did not have sufficient knowledge or information regarding this area to appropriately respond to our questions.
- b) EXPORTS: Costa Rica does not export GE microbes and or products that contain microbial biotech-derived food ingredients to the United States.
- c) 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.
- d) TRADE BARRIERS: There are no trade barriers for the importation of microbial biotechderived food ingredients and/or processed food products containing microbial biotech-derived food ingredients.

PART H: POLICY

- a) REGULATORY FRAMEWORK: Except for the requirement to notify the use of additives and other food ingredients to the Ministry of Health, Costa Rica does not have a specific regulatory framework for biotech-derived microbes or microbial biotech-derived food ingredients specifically. There are regulations in place for the notification of additives and food ingredients. The agency in charge of this process is the Ministry of Health. However, we were not able to determine any difference in the process of additive notification for products derived from biotechnology or by different methods. There is no pending legislation or regulation waiting for approval or under discussion in relation to microbial biotech-derived food ingredients at this time.
- b) APPROVALS: There is no database or listing of approved biotech microbes and/or derived food ingredients approved or registered for use in the country.
- c) LABELING AND TRACEABILITY: There is no current or predicted policies regarding the traceability and labeling of microbial biotech-derived food ingredients at this time in Costa Rica.
- d) MONITORING AND TESTING: The country does not actively test for evidence of genetic engineering in imports or exports of processed products. An exception to this rule is that rice importers, as a matter of marketing strategy/product image, require that rice imports be nonbiotech, and product testing is conducted at the country of origin. However, this is not government mandated or required testing.
- e) ADDITIONAL REGULATORY REQUIREMENTS: There are no additional regulatory requirements at this time affecting U.S. exports of microbial biotech products.
- f) INTELLECTUAL PROPERTY RIGHTS (IPR): Costa Rica has IPR legislation in effect that would protect intellectual property rights for such products if an exporter or producer decided to register its intellectual property rights.
- g) RELATED ISSUES: The Ministry of Environment's National Commission for Management of Biodiversity (CONAGEBIO) requires researchers to register with the Commission, any research project that involves access to Costa Rica's biodiversity and any research project that involves genetic manipulation. This requirement applies to research projects that use local plants for medical applications for instance.

PART I: MARKETING

- a) PUBLIC PRIVATE OPINIONS: Currently there is very limited knowledge and awareness of microbial biotech among the general public. The information/knowledge about the subject is more widespread among scientists at the different academic institutions such as Costa Rica's Technological Institute (TEC), and the University of Costa Rica (UCR), where the general perception among scientists and part of the student body is generally positive.
- b) MARKET ACCEPTANCE/STUDIES: Even though microbial biotechnology products are being imported and used in research activities in the country, there is basically no information on the acceptance (positive or negative) of these products among the general public.

Attachments:

No Attachments