

**Required Report:** Required - Public Distribution

**Date:** December 04, 2023

**Report Number:** EC2023-0009

## **Report Name:** Agricultural Biotechnology Annual

**Country:** Ecuador

**Post:** Quito

**Report Category:** Biotechnology and Other New Production Technologies

**Prepared By:** Esteban Espinosa

**Approved By:** Anthony Gilbert

### **Report Highlights:**

On January 20, 2022, the Constitutional Court of Ecuador declared the unconstitutionality of article 56 of the Law on Seeds, Agrobiodiversity and Sustainable Agriculture, which allowed the President of the Republic to authorize the introduction of GE seeds for other purposes than research, now the President should ask for permission to the National Assembly who will evaluate the request. On September 13, 2023, the Minister of Agriculture and Livestock, signed the Ministerial agreement No. 063, approving the “Technical guide for the use of seeds or crops obtained by Precision breeding techniques is approved. This technical guide establishes the procedure for determine whether a seed or crop obtained from precision breeding techniques is capable of registration or marketing as a conventional one, in accordance with the provisions of the Organic Law on Agrobiodiversity, Seeds and Promotion of Sustainable Agriculture and its Regulations.

## EXECUTIVE SUMMARY

In October 2016, Ecuador's Minister of Agriculture and Minister of Industries announced that the National Institute for Agricultural Research "INIAP", one of the country's main agricultural biotechnology research institutions, would start field trials of genetically engineered (GE) corn from major seed companies for research purposes. On June 1, 2017, Ecuador's National Assembly approved The Organic Law on Agrobiodiversity, Seeds, and Promotion of Sustainable Agriculture that side-stepped the constitutional ban on the cultivation of GE crops by permitting GE crop cultivation for research purposes. Experimental trials were expected to start in 2018 but remain delayed due to legal issues. There have been several challenges to the constitutionality of the law, some of which were brought to Ecuador's Constitutional Court. No ruling has been made to date, as all of Ecuador's Constitutional Court justices were removed from their appointments in August 2018, and the new Constitutional Court judges were only appointed in January 2019. Also, in January 2019, a lower local court in Los Rios province ruled in favor of the plaintiffs in a case where farmers claimed that the Government of Ecuador (GOE) had allowed the commercial cultivation of GE crops.

Ecuador's Biosafety Committee was created by presidential decree in 2002, but only formally seated in 2015. The National Biosecurity Commission (Comisión Nacional de Bioseguridad: CONABIO) was established and held its first formal meeting in 2015, however it has failed to establish itself as the entity with jurisdiction over biotechnology issues.

On May 21, 2019, Ecuador's Office of the President issued the implementing regulation for the Omnibus Bill on the Environment. Article 16 mandates the formation of a National Biosafety Committee. Article 30 provides exceptions to the use of biosafety protocols. Among the exceptions are those organisms resulting from the genetic improvement of species that do not have recombinant or foreign DNA in the genome.

Although Article 401 of Ecuador's 2008 Constitution declares the country to be free of transgenic crops and seeds, it also granted the President the sole authority to authorize the entry of genetically modified agricultural products and seeds, which was modified in 2022. Article 281 of the Constitution provides the regulatory foundation for the introduction of GE crops. Article 281 establishes as a role and responsibility of the State: "to ensure the development of the appropriate scientific research and technological innovations to ensure food sovereignty" and "regulate under biosafety standards the use and development of modern biotechnology, as well as its experimentation, use, and commercialization".

On January 20, 2022, the Constitutional Court of Ecuador declared the unconstitutionality of article 56 of the Law on Seeds, Agrobiodiversity and Sustainable Agriculture, which placed an exception: "entry can be allowed through the Presidency of the Republic"; thus, it was challenged through 6 unconstitutionality lawsuits and modified to the following text: "The Plenum of the National Assembly, in two debates and through a special resolution, will approve or reject, with the favorable vote of the qualified majority of its members the request of the President of the Republic, in relation to the introduction of genetically modified seeds and crops."

On September 13, 2023, the Minister of Agriculture and Livestock, signed the Ministerial agreement No. 063, approving the "Technical guide for the use of seeds or crops obtained by Precision breeding techniques is

approved. This technical guide establishes the procedure for determine whether a seed or crop obtained from precision breeding techniques is capable of registration or marketing as a conventional one, in accordance with the provisions of the Organic Law on Agrobiodiversity, Seeds and Promotion of Sustainable Agriculture and its Regulations.

Bilateral agricultural trade between the United States and Ecuador in 2022, was more than 4.2 billion, up eleven percent from the previous year. Ecuador exported \$3.2 billion in food and agricultural products to the United States, while importing \$740 million in U.S.-origin product, an increase of twenty two percent comparing with 2021. Major U.S. agriculture exports to Ecuador include soybean meal, wheat, cotton, corn, beef, feeds & fodders, prepared foods, and fresh fruits. This guide will broad the option of seeds and genetics for the agricultural sector and increase US exports.

**TABLE OF CONTENTS**

**CHAPTER 1: PLANT BIOTECHNOLOGY.....3**  
**PART A: PRODUCTION AND TRADE .....3**  
**PART B: POLICY .....5**  
**PART C: MARKETING .....12**

**CHAPTER 2: ANIMAL BIOTECHNOLOGY .....13**  
**PART D: PRODUCTION AND TRADE .....13**  
**PART E: POLICY .....13**  
**PART F: MARKETING .....14**

**CHAPTER 3: MICROBIAL BIOTECHNOLOGY.....14**  
**PART G: PRODUCTION AND TRADE .....14**  
**PART H: POLICY.....14**  
**Part I: MARKETING.....15**

## CHAPTER 1: PLANT BIOTECHNOLOGY

### PART A: PRODUCTION AND TRADE

a) **RESEARCH AND PRODUCT DEVELOPMENT:** Over the past seventeen years, Ecuador has invested in infrastructure and developed the technical capacity needed to conduct high-level agricultural biotechnology research. Despite relying on scientific protocols developed elsewhere, it has made progress on products of national interest such as bananas and potatoes.

In October 2016, Ecuador's Minister of Agriculture, and the Minister of Industries both announced that INIAP, the country's main agricultural biotechnology research body, would start field trials of GE corn from major seed companies for research purposes; trials that as of now, have not begun. During 2019, INIAP held several rounds of meetings with the local industry and the government officials to promote and provide inform on biotechnology. INIAP requested USDA support in these meetings and trainings, but due to the COVID-19 pandemic, Ministry budget reduction, the appointment of new authorities in May 2021 and the changes of the Ministry of Agriculture in September 2021 and May 2022, institute's ability to conduct events has been delayed.

On June 1, 2017, Ecuador's National Assembly voted to permit the cultivation of GE crops and seeds for research purposes through the Organic Law on Agrobiodiversity, Seeds, and Promotion of Sustainable Agriculture. Shortly after the law's passage, five challenges against it were brought to Ecuador's Constitutional Court. No ruling has been made at the time of writing, as all Constitutional Court justices were removed from their appointments in August 2018, and new Constitutional Court judges were appointed in January 2019. This new Court had a backlog of over 15,000 cases when seated, thus it is difficult to determine when challenges to the law will be brought in front of the justices.

Ecuador has the technical capacity to develop GE plant varieties. The Polytechnic School of the Coast's (ESPOL) Center for Biotechnology Research (CIBE) reported in 2012 that it succeeded in producing lines of cisgenic and transgenic banana plants that are resistant to black sigatoka (or black leaf streak). It has also developed a line of plants bio-fortified with higher concentrations of folates, which are types of B-vitamins. Ecuador is not developing antibiotics, foods, or pharmaceuticals using GE techniques or plants. In 2020, ESPOL organized the Fifth International Congress of Biotechnology and Biodiversity (V CIBB-2020), which brought together 270 virtual attendees. During the event, participants learned about the latest scientific and research advances in banana and cacao, as well as topics of interest in the areas of biotechnology, biodiversity, clean technologies and bioproducts.

b) **COMMERCIAL PRODUCTION:** GOE's regulatory agencies assert that Ecuador has no commercial GE plants in production. Some local farmers are requesting a change in the constitution to be able to plant GE plants to improve yields and reduce productions costs, which allow them to be more competitive.

In January 2019, a Lower Local Court located in a county from Los Rios province ruled in favor of plaintiffs in a case where farmers claimed that the Government of Ecuador had allowed the commercial cultivation of GE soybeans, in violation of the constitutional ban on GE plant cultivation. Ecuador's

Office of the Ombudsman, a government agency, initiated the case on behalf of local producers. The GOE has not officially recognized that Ecuador produces GE crops. It is also not clear how/if the case argued in the Los Rios court will advance.

c) EXPORT: Ecuador currently does not export GE plant material.

d) IMPORTS: Imports of corn, cotton, soybean meal, and soybean oil for industrial use in Ecuador are largely of foreign origin.

Ecuador imported approximately ninety five percent of its cotton needs, roughly 7,000 metric tons, (MT) in 2021. Of these imports, an estimated 90 percent consisted of GE-derived product.

Soybean meal and oil imports are rising. Argentina, Bolivia, Paraguay, and the United States are the main suppliers. In 2020, Ecuador purchased roughly 1,570,000 MT of soybean meal, of which an estimated 99 percent was GE-derived product.

Despite Ecuador's claims to be a food sovereign country, the country is not competitive in the production of certain commodities. It is import dependent on foreign sources (e.g., the United States, Argentina, and Bolivia) to meet its cotton and soybean meal needs. It currently does not have specific biotechnology requirements for these imported commodities. A requirement of Ecuador's Food Sovereignty Law is that foods can only be imported after health and safety requirements have been met.

Ecuador is unlikely to become self-sufficient in the short- to medium-term in the production of cotton and soybean meal. On the contrary, Ecuador will likely continue to source cotton and soybeans from foreign countries, accordingly with information received in 2021 the last cotton production areas were abandoned. Cotton and soybean products are used as ingredients for animal feed in shrimp, poultry, and pork production and as cooking oil for human consumption.

e) FOOD AID: Ecuador continues to be a beneficiary of a USDA Food for Progress program focused on cacao production. Through this program Ecuador does not receive in-kind donations of agricultural products but receives the proceeds of monetization taking place in a third country. Ecuador on occasion provides food aid to other countries with non-GE commodities, such as rice and lentils and receives food aid from the U.N. World Food Program.

f) TRADE BARRIERS: The current constitutional challenge to experimentation with GE crops does not permit the import of GE plants for research purposes, and the constitutional ban prevents imports of GE seeds used for commercial cultivation. Imports of GE commodities intended for food, feed, or processing do not require special authorizations and U.S. exports of harvested crops have not experienced barriers based on their GE nature.

## **PART B: POLICY**

Ecuador's constitution prohibits the commercial cultivation of GE crops. At the same time, the import of GE products intended for food, feed, and processing is permitted. In June 2017, on direction from the President, Ecuador's National Assembly passed a law permitting the cultivation of GE crops for research purposes. A summary of this regulatory framework follows. Approvals are not required for the importation of food with GE content for human consumption, but these foods must include a label.

Other than labeling, there are no regulatory requirements for GE ingredients. GE-related labeling is not required for foods destined for animal consumption. In 2019, Ecuador's Office of the President issued the implementing regulation for the Omnibus Bill on the Environment. The implications of this Regulatory Ruling for biotechnology applications in agriculture are also included below.

a) REGULATORY FRAMEWORK:

Legal term (in official language)	Legal Term (in English)	Laws and Regulations where term is used	Legal Definition (in English)
Ingeniería genética (IG): Manipulación de la composición genética mediante la introducción o eliminación de genes específicos a través de técnicas modernas de biología molecular y ADN recombinante.	Genetic Engineering (GE): Manipulation of genetic makeup by introducing or removing specific genes through modern molecular biology techniques and recombinant DNA.	Ecuadorian Constitution 2008 Organic Law on Agro-biodiversity, Seeds, and Promotion of Sustainable Agriculture	Genetic engineering: Manipulation of an organism's genes by introducing, eliminating, or rearranging specific genes using the methods of modern molecular biology, particularly those techniques referred to as recombinant DNA techniques.
Organismo Transgénico: Organismo (animal, vegetal o microorganismo) en el cual un gen foráneo, o una secuencia de ADN foránea ha sido incorporada a su genoma durante su desarrollo inicial	Transgenic Organism: An organism (animal, plant, or microorganism) in which a foreign gene, or a foreign DNA sequence, has been incorporated into its genome during its initial development	Ecuadorian Constitution 2008 Organic Law on Agro-biodiversity, Seeds, and Promotion of Sustainable Agriculture	Transgenic organism: An organism resulting from the insertion of genetic material from another organism using recombinant DNA techniques.
TECNOLOGÍA DE ADN RECOMBINANTE. Es el proceso de cortar y recombinar fragmentos de ADN de diferentes fuentes como medio para el aislamiento de genes o para alterar su estructura o función.	RECOMBINANT DNA TECHNOLOGY. It is the process of cutting and recombining fragments of DNA from different sources as a means for isolating genes or altering their structure or function.	Omnibus Bill on the Environment May 21, 2019	Recombinant DNA technology: Procedures used to join together DNA segments in a cell-free system (e.g., in a test tube outside living cells or organisms). Under appropriate conditions, a recombinant DNA molecule can be introduced into a cell and copy itself (replicate), either as an independent entity (autonomously) or as an integral part of a cellular chromosome.

**Ecuadorian Constitution:** Article 401 of Ecuador's 2008 Constitution declares the country to be free of transgenic crops and seeds and prohibits the commercial cultivation of GE crops. This article of the Constitution also grants the President sole authority to authorize the entry of GE agricultural products

and seeds intended for purposes other than commercial cultivation, but not the authority to authorize commercial cultivation of GE crops. Section two of Article 401 affirms that the state reserves the right to regulate the use and development of biotechnology and its products, as well as its experimentation, use, and commercialization. It prohibits the use of dangerous, experimental biotechnology, but guidelines for defining what constitutes dangerous or experimental biotechnology do not exist.

Article 281 of Ecuador's 2008 Constitution provides the regulatory foundation to the introduction of GE crops. Article 281 establishes as a role and responsibility of the State, "to ensure the development of the appropriate scientific research and technological innovations to ensure food sovereignty" and "regulate under biosafety standards the use and development of modern biotechnology, as well as its experimentation, use, and commercialization".

Commercial GE production would require a presidential intervention citing national interests such as food security concerns, followed by ratification of the intervention by Ecuador's National Assembly that such national interest exists, and a ruling by the Constitutional Court attesting that such national interest does not contradict the Constitution's declaration of Ecuador as a country free of transgenic crops.

### **Organic Law on Agrobiodiversity, Seeds, and Promotion of Sustainable Agriculture**

The National Assembly approved the "Organic Law on Agro-biodiversity, Seeds, and Promotion of Sustainable Agriculture" on June 1, 2017. This Law permits the cultivation of GE crops for research purposes. It should be noted that in the section with the glossary and definition of terms, there is no mention of "transgenic crops" or related terms. Also, the Law does not define the National Agrarian Authority. FAS Quito understands that the National Agrarian Authority is the Ministry of Agriculture and Livestock. FAS Quito expects that the rules that the Ministry of Agriculture and Livestock are drafting will describe the relationship of the Law to the Constitution's provisions regarding transgenic crops. Key articles from the Law are translated into English below:

- **Article 56 - Seeds and transgenic crops** – "Transgenic seeds and crops can enter the national territory, only to be used for research purposes. In cases when entry is required for other purposes, the procedure established in the Constitution must be followed for that purpose. Transgenic seeds and crops. They constitute very serious special offenses, the unauthorized entry or use of genetically modified seeds and crops."
- **Article 57 - Destruction of seeds and transgenic crops** – "In case of illegal entry or use of transgenic seeds or crops, the National Agrarian Authority, upon due verification, will Ex-officio with its confiscation, destruction, and incineration, as well as the definitive cancellation of the respective registration, on a case-by-case basis. The application of the sanctions will be carried out without affecting the initiation of criminal or civil actions that may arise, in accordance with the Law. If officials are responsible for the illegal introduction or use of transgenic seeds or crops, they will be removed in accordance with the procedure established by law, without affecting the integral reparation of damages that may occur. Public action is granted to denounce the entry or use of transgenic seeds or crops, in accordance with current regulations."
- **Article 58 – Sanctions** – "Individuals or legal entities that violate this law and its regulations, regardless of any civil or criminal actions to which they may be subject, shall be punished with

a) Written warning, b) Fine, c) Suspension of registration and d) Cancellation of registration. In case of concurrence of infractions, the sanction corresponding to the most serious infraction will apply.”

### **Technical guide for the use of seeds or crops obtained by Precision breeding techniques.**

The Ministry of Agriculture and Livestock approved the Agreement No. 063 "Technical guide for the use of seeds or crops obtained by Precision breeding techniques", on September 13, 2023. This technical guide establishes the procedure for determine whether a seed or crop obtained from precision breeding techniques is capable of registration or marketing as a conventional one, in accordance with the provisions of the Organic Law on Agrobiodiversity, Seeds and Promotion of Sustainable Agriculture and its Regulations - LOASFAS.

Examples of precision enhancement or gene editing techniques are: Zn Finger Nucleases (ZFN), Transcription Activator Similar Activity Nuclease (TALEN), Clustered and Regularly Interspaced Short Palindromic Repeats – CRISPR-Associated System (CRISPR-Cas).

### **Implementing regulation for the Omnibus Bill on the Environment**

Article 16 of this ruling was signed on May 21, 2019, and mandates the formation of a National Biosafety Committee. Amongst other responsibilities, the Committee will assess requests for research in modern biotechnology and its products and could advise the government and the public on the possible environmental, agricultural, and socioeconomic impacts of GE products to public health, ancestral knowledge, innovations, practices of rural communities, and indigenous peoples. Article 30 provides exceptions to the use of biosafety protocols. Among the exceptions are those organisms resulting from the genetic improvement of species that do not have recombinant or foreign DNA in the genome. This article could open the possibility of conducting research in the area of genome editing. An unofficial translation of this Article is below:

- Art. 230. Exceptions:
  - a) “Organisms that are the result of gene flow (sic movement) among species that do not have recombinant or foreign DNA in the resulting genome.”
  - b) “Human genome analysis, stem cell culture of human beings, modification of human germ cells, diagnostic tests of human, animal and plant diseases, genetic manipulation of human germ cells and gene therapy; as well as hospital biosafety. In addition to these three key pieces of the regulatory framework, the following entities and policies make up Ecuador’s biotechnology regulatory framework. Unfortunately, as can be seen from the descriptions of activities included below, there are isolated and sometimes contradicting efforts of different government agencies towards a clear and long-term national policy regarding the use of modern biotechnologies. The Government of Ecuador has yet to express a position regarding innovative biotechnologies such as genome editing.”

**Competent Government Authorities:** The 2017 Organic Law on Agrobiodiversity, Seeds, and Promotion of Sustainable Agriculture designates all authority regarding transgenic crops to the National Agrarian Authority. It is assumed that the Ministry of Agriculture and Livestock is the authoritative



entity for controlling, approving, and regulating all aspects related to the use of GE crops in the country. The 2019 implementing regulation for the Omnibus Bill on the Environment reinforces the authority designated to the Ministry of Agriculture and Livestock as the National Agrarian Authority.

**Role of The Biosafety Committee/Authority:** Ecuador's Biosafety Committee was created by presidential decree (i.e., an administrative measure) in 2002, and formally seated in 2015. The National Biosecurity Commission (Comisión Nacional de Bioseguridad – CONABIO) was established in 2015 but never received any official authority. The 2019 implementing regulation for the Omnibus Bill on the Environment calls for the formation of a National Biosafety Committee.

**Assessment of Political Factors:** Ecuador's government does not look favorably on the country's dependence on foreign sources for several imports (e.g., animal feed ingredients and planting seeds) and technologies, as well as the impact of this dependence on its balance of payments.

On the production side, some farmers believe that the introduction of GE seeds and plant varieties produced with innovative biotechnologies will make them more productive and allow them to lower their cost of production. New breeding innovations are a popular topic amongst government bodies since they present an opportunity to expedite development of new crop varieties and bypass the opposition of some groups to transgenic crops.

Seed companies and growers expect that the Law's rules will address and clarify these topics once the Constitutional Court rules in the pending case on transgenic crops.

#### **Other Pertinent and Pending Legislation:**

Consumer Rights Protection Law (July 10, 2000): This law regulates supplier-consumer relations and promotes consumer awareness and protection of consumer rights. It contains a clause that declares that in the case of ambiguity in official dispositions, these should be interpreted in favor of the consumer. The Office of the Ombudsman enforces this law. Commencing in 2014, the Consumer Protection Law has been utilized to enforce the mandatory labeling of GE-content foods. Articles 13 and 14 state that “in the case of products sold for human or animal consumption, produced with biotechnology or any type of genetic manipulation, labels must warn of this fact using highlighted characters.”

Imports of Animal and Plant Material: The Animal and Plant Health Law of 2017 established import requirements for genetic material in accordance with Andean Community of Nations' (CAN) regulations. Article 13 stipulates that the import of plant material for propagation, as well as for research, must have prior import approval from the Ministry of Agriculture and Livestock's sanitary and phytosanitary regulatory agency, AGROCALIDAD.

Rules for Sanitary Registration and Control: This regulation establishes the sanitary registration requirements for imports and domestic products. Article 50 refers to sanction mechanisms. Article 54 clarifies that imports of biotechnology and GE-content products are permissible if these products meet Ministry of Health requirements. A positive list of authorized transgenic products does not exist.

Food Sovereignty Law: This law declares food sovereignty as a national policy. It creates the inter-ministerial National System for Food Sovereignty and Nutrition, as well as the National Food

Sovereignty Conference. Article 26, mirroring the national constitution, declares the country to be free of GE material. Although not specifically stated, it is understood that this declaration does not include food. The introduction of GE material for commercial cultivation is permissible only with the president's explicit authorization and with approval of the National Assembly. The introduction of GE materials for research purposes is allowed. The use of "dangerous, experimental application" of biotechnology is forbidden. No definition of "dangerous" or "experimental" is provided. Commodities that contain transgenic components can be imported only after health and safety requirements are ensured. These commodities cannot be reproductively viable.

Implementing regulation for the Organic Law on Agrobiodiversity, Seeds, and Promotion of Sustainable Agriculture: At the time of writing this report, the Ministry of Agriculture and Livestock has completed a final draft of these Rules but is awaiting the ruling on the constitutionality of the law by the Constitutional Court before publishing.

**Timeline for Approvals:** Ecuador's INIAP is expected to provide a technical recommendation on the introduction of GE corn and soybeans for planting by the end of 2022. Completion of this recommendation is pending and will be subject to the rulings of Ecuador's Constitutional Court.

b) **APPROVALS/AUTHORIZATIONS:** There is no list of GE derived plants or crops approved or registered in the country for cultivation, import, or export.

c) **STACKED OR PYRAMIDED EVENT APPROVALS/AUTHORIZATIONS:** There are no mechanisms in place for dealing with stacked events, nor are any being developed.

d) **FIELD TESTING:** Ecuador authorizes transgenic plant development under controlled laboratory conditions. Field-testing for research purposes was authorized in 2017. The Ministry of Agriculture and Livestock is currently drafting specific guidelines for field-testing of GE crops as part of a group of several other guidelines that will ensure compliance with the new Law of Seeds, pending the verdict of the Constitutional Court.

e) **INNOVATIVE BIOTECHNOLOGIES:** Existing laws and regulations make explicit references to transgenic crops and techniques. However, there are no references to new breeding innovations or the use of genome editing to produce new crop varieties.

f) **COEXISTENCE:** No coexistence policy exists.

g) **LABELING:** The Consumer Protection Law mandates the labeling of GE foods. Articles 13 and 14 state that "in the case of products sold for human or animal consumption, produced with biotechnology or any type of genetic manipulation, labels must warn of this fact using highlighted characters." Labeling requirements have been enforced by the National Agency for Regulation, Control, and Health Surveillance (ARCSA) since August 2014. So far, these requirements have not impacted agricultural trade. Note: this requirement does not seem to apply to sales of products that will be used as inputs in animal feed and livestock production.

Similarly, in 2013, the Antitrust Secretariat issued Technical Norm SCPMNT-2013-001 "Unfair Practices that Mislead and Violate Regulations Related to Labeling and Promotion of Food Products

(Foods and Beverages).” This norm establishes that food and beverage products produced and traded in Ecuador must include a label identifying the product as “transgenic” or “non-transgenic.” The rationale behind this regulation is that non-GE products compete at a disadvantage with GE products. RTE INEN 022, “Labeling of Processed, Packed, and Packaged Food Products,” has been modified to clarify how to properly label transgenic products and allow the enforcement of regulations that had been previously enacted but never implemented. The relevant articles of RTE INEN 022 include:

- **Article 3.1.6:** The term “transgenic component” is used to refer to a living organism that has been modified by the addition of exogenous genes to achieve new properties.
- **Article 5.2:** For processed foods containing transgenic ingredients, the product label must state, in the main panel, in highlighted letters as provided for in Annex B of the NTE INEN 1334-1 standard, "CONTAINS TRANSGENIC COMPONENTS," provided that the transgenic content exceeds 0.9 percent in the product.
- **Article 5.3:** When transgenic ingredients are used, the list of ingredients must state the name of the ingredient, followed by the word "TRANSGENIC," provided that the content of the transgenic component exceeds 0.9 percent in the product.
- **Article 5.4:** For purposes of traceability, the manufacturer must request that the supplier state that the ingredient is or is not a transgenic component. Ecuador INEN RTE 022 norm requires that, as of August 2014, all products containing GE-content be labeled with a declaration stating that they contain transgenic ingredients. This labeling requirement is, however, only applicable to products intended for direct sales to consumers. To date there are 365 products labeled in this manner. Ecuador does not consider animals fed with GE ingredients as GE/transgenic animals.

Ecuador’s food manufacturers are required to certify that they are not utilizing GE ingredients in their products. Manufacturers are also required to obtain from their ingredient suppliers sworn statements attesting that the ingredients supplied are not genetically engineered. Suppliers, many of which are merely intermediary brokers, are hesitant to front costly lab testing needed to certify ingredients as being free of GE content.

Food manufacturers consequently often opt to label their products as containing GE content as a precautionary measure to mitigate their liability in the case of positive GE content detection during testing. Existing regulations do not penalize this precautionary measure. Some manufacturers on their own initiative are marketing their products as GE free. Ecuador does not require a GE free labeling statement.

h) **MONITORING AND TESTING:** Although some protocols might be employed on an ad-hoc basis, FAS Quito is not aware of the GOE actively testing for GE traits in imports and exports. FAS Quito is also not aware of the GOE actively testing for GE traits in fields.

i) **LOW-LEVEL PRESENCE (LLP) POLICY:** Ecuador has not established a low-level presence (LLP) rule for processed food products. The Ministry of Agriculture is interested in establishing an LLP rule and opposes a zero-tolerance level approach in the case of imported planting seeds. Ecuador has yet to officially state in a law or regulation what the threshold will be for LLP in imported planting seeds.

j) **ADDITIONAL REGULATORY REQUIREMENTS:** None.

k) **INTELLECTUAL PROPERTY RIGHTS (IPR):** Legislation permits the registration of new plant varieties. State-funded new plant varieties are deemed public goods and while no royalties are currently being collected, Ecuador reserves the right to collect royalties. Private breeding and seed companies, however, can register new varieties and charge royalties. FAS Quito will monitor any IPR issues related to GE crops as these new seed varieties could be introduced in years to come.

l) **CARTAGENA PROTOCOL RATIFICATION:** Ecuador is a signatory of the Convention on Biological Diversity and the Cartagena Protocol on Biosafety; policies and regulations issued must be in accordance with these agreements. However, under Ecuador's Constitution, no international protocol or agreement can be above the Constitution.

m) **INTERNATIONAL TREATIES/FORUM:** Ecuador is "somewhat" bound by Andean Community of Nations Decision 523 that requires its biosafety regulations follow the Andean Strategy on Biodiversity. It does not currently participate in other biotechnology fora.

n) **RELATED ISSUES:** Risks to agricultural production associated with climate change have triggered additional interest in exploring GE crops and new breeding innovations as part of Ecuador's climate change adaptation and mitigation strategies. The need to take adaptation and mitigation measures is also embedded in the new implementing regulation for the Omnibus Bill on the Environment.

## **PART C: MARKETING**

a) **PUBLIC/PRIVATE OPINIONS:** In general, small producers in the highland provinces still oppose biotechnology. These farmers primarily grow native crops, such as potatoes, Andean corn, Andean grains, and quinoa. Larger producers from the coast seem to favor the introduction of GE crops. These farmers largely produce yellow corn and rice. Thus, among farmers, views are often at odds. Several environmental groups opposed to GE crops have been effective in shaping public opinion.

b) **MARKET ACCEPTANCE/STUDIES:** Biotechnology is a growing topic of discussion. Most Ecuadorian farmers and food manufacturers do not oppose GE products. The last public opinion poll was conducted in 2008 by Ecuador's Ministry of Environment (Organismos genéticamente modificados, biotecnología y bioseguridad: estudio de percepción pública, Quito, Ecuador: Ministerio del Ambiente, Programa de Bioseguridad; Jarrín, G. and V. Solís, 2008). FAS Quito speculates that the public is not opposed to the production or consumption of GE foods. For example, food manufacturers have stated that after mandatory labeling of GE foods was enforced, consumption did not decrease. In contrast, when nutritional labeling was enforced, consumption of foods with high sugar and fat content went down.

## **CHAPTER 2: ANIMAL BIOTECHNOLOGY**

### **PART D: PRODUCTION AND TRADE**

- a) RESEARCH AND PRODUCT DEVELOPMENT: None at this time.
- b) COMMERCIAL PRODUCTION: None at this time.
- c) EXPORTS: None at this time.
- d) IMPORTS: None at this time.
- e) TRADE BARRIERS: None at this time. Ecuador does not have a system for monitoring imports of GE animals, offspring of clones, or genetics from cloned animals.

#### **PART E: POLICY**

- a) REGULATORY FRAMEWORK: There is no regulatory framework for GE animals or cloning; and/or products derived from these animals or their offspring.
- b) APPROVALS: None at this time.
- c) INNOVATIVE BIOTECHNOLOGIES: Ecuador has yet to decide if and how to regulate innovative biotechnologies such as genome editing in animals and cloning.
- d) LABELING AND TRACEABILITY: No specific labeling or traceability requirements exist other than the labeling requirements that apply to food products containing GE plants. FAS Quito is not aware of any traceability requirements. However, as in the case of plants, the responsibility over traceability falls to the trader who must be able to certify that an ingredient is not “transgenic”.
- e) INTELLECTUAL PROPERTY RIGHTS (IPR): There are no biotechnology specific IPR regulations.
- f) INTERNATIONAL TREATIES/FORUMS: Ecuador does not officially support international groups that support or oppose GE animals or cloning. Ecuador is a very active member of the Codex Alimentarius. Ecuador is a member of the World Organization for Animal Health (OIE). Ecuador has not been active in discussions related to animal biotechnologies.
- g) RELATED ISSUES: None at this time.

#### **PART F: MARKETING**

- a) PUBLIC/PRIVATE OPINIONS: None available.
- b) MARKET ACCEPTANCE/STUDIES: None available.

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

#### **PART G: PRODUCTION AND TRADE**

- a) COMMERCIAL PRODUCTION: None at this time.
- b) EXPORTS: None at this time.
- c) IMPORTS: None at this time.
- d) TRADE BARRIERS: None at this time. Ecuador does not have a system for monitoring imports of GE microbes.

## **PART H: POLICY**

- a) REGULATORY FRAMEWORK: There is no regulatory framework for GE microbes.
- b) APPROVALS/AUTHORIZATIONS: None at this time.
- c) LABELING AND TRACEABILITY: No specific labeling or traceability requirements exist other than the labeling requirements that apply to food products containing GE plants.
- d) MONITORING AND TESTING: None at this time
- e) ADDITIONAL REGULATORY REQUIREMENTS: None at this time
- f) INTELLECTUAL PROPERTY RIGHTS (IPR): There are no biotechnology specific IPR regulations.
- g) INTERNATIONAL TREATIES/FORUMS: Ecuador does not officially support international groups that support or oppose GE microbes. Ecuador is a very active member of the Codex Alimentarius. Ecuador is a member of the World Organization for Animal Health (OIE).
- h) RELATED ISSUES: None at this time.

## **PART I: MARKETING**

- a) PUBLIC/PRIVATE OPINIONS: None available.
- b) MARKET ACCEPTANCE/STUDIES: None available.

**Attachments:**

No Attachments