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## Ecuador

### Agricultural Biotechnology Annual

### Biotechnology Annual 2015: Genetically Engineered Crops and Transgenic Labeling

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**Report Highlights:**

Ecuador maintains anti-biotechnology laws and regulations. Trade of genetically engineered (GE) products (i.e., soybean and soybean products, cotton, and corn) however continues. Beginning in August 2014, Ecuador requires mandatory labeling of food and beverage products containing more than 0.9 percent transgenic content. This year's report provides an overview of the implementation of the new labeling requirement. The National Biosecurity Commission (*Comisión Nacional de Bioseguridad* – CONABIO) was established in 2015. The commission held its first formal meeting on May 6, 2015. CONABIO is expected to exercise jurisdiction over all biotechnology issues.

## **Section I. Executive Summary:**

Bilateral agricultural trade between the United States and Ecuador reached \$2.75 billion in calendar year (CY) 2014, up nearly 14 percent from the previous year. Ecuador exported a record \$2.3 billion in food and agricultural products to the United States while only importing \$437 million in U.S.-origin product. Major U.S. agriculture exports to Ecuador include soybean meal, wheat, cotton, prepared food and fresh fruits.

On October 15, 2013, Ecuador published an amendment to Technical Regulation RTE INEN 022 “Labeling of Processed, Packed, and Packaged Food Products,” which requires mandatory labeling of processed food products containing genetically engineered (GE) ingredients. Enforcement commenced in August 2014.

Ecuador’s Biosafety Committee was created by presidential decree (i.e., an administrative measure) in 2002, but only formally seated in 2015. The National Biosecurity Commission (*Comisión Nacional de Bioseguridad* – CONABIO) was established in 2015. The Ministries of the Environment, Agriculture, and Public Health along with the Secretariat of Higher Education, Science, Technology and Innovation form CONABIO. The commission held its first formal meeting on May 6, 2015. CONABIO is expected to exercise jurisdiction over all biotechnology issues.

President Rafael Correa in September 2012 criticized opponents of biotechnology, labeling these as “fundamentalists who are afraid of the truth.” Sources report that Mr. Correa believes that having enshrined the GE issue within the 2008 Constitution has been a “major mistake.” Mr. Correa recently clarified ([Enlace Ciudadano Number 147](#)) that public and private biotechnology research is permissible; stressing that what is not permissible is GE productive cultivation (that is without the approval of the National Assembly).

## Section II. Plant Biotechnology

### CHAPTER 1: PLANT BIOTECHNOLOGY

#### PART A: PRODUCTION AND TRADE

- a) **PRODUCT DEVELOPMENT:** Ecuador over the past few years has invested in infrastructure, as well as 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 (e.g., bananas).

Ecuador's Institute for Agricultural Research (INIAP), the country's main agricultural biotechnology research body, sustains however that the country lacks the means for conducting biotechnology related research. INIAP confirms nonetheless that Ecuador's first biotechnology laboratory opened in 1978; since then, at least 53 (as of March 2009) additional labs have been established nationwide. Sources at the Inter-American Institute for Cooperation in Agriculture (IICA) indicate that Ecuador does indeed have the capability to produce transgenic plants. Ecuador's Polytechnic School of the Coast (ESPOL) – Center for Biotechnology Research (CIBE), a public university, reports that in 2012 it succeeded in producing lines of cisgenic and transgenic banana plants resistant to black sigatoka (or black leaf streak); as well as a line of plants bio-fortified with higher concentrations of folates. Plantings remain however under laboratory-controlled conditions, field trials are forbidden due to Ecuador's constitutional ban on growing genetically engineered (GE) crops.

At FAS Quito, we find that there is strong agribusiness interest in biotechnology; particularly in tissue culture and somatic embryogenesis and molecular biological applications and diagnosis. Driving producer interest is the need to overcome growing black sigatoka fungicide resistance in Ecuador's banana plantations. Black sigatoka is caused by the ascomycete fungus *Mycosphaerella fijiensis*; plants with leaves damaged by the disease may have up to 50 percent lower fruit yields. Ecuador exported nearly \$394 million in bananas and plantains to the United States in CY 2014 alone, a major export accomplishment. Sources allege that Ecuador's cut-flower, cacao, and aquaculture industries already actively utilize biotechnology.

We understand that future research aims to focus on the production of in-vitro plants, in-vitro conservation, molecular markers, cryopreservation, diagnostic methods, assisted plant breeding, genetic transformation, genomics, bio-informatics, and biosafety among others. Ecuador's ESPOL has commented to FAS Quito its desire to collaborate with the United States on cacao DNA sequencing and the adaptation of banana and cacao plants to disease and climate change.

- b) **COMMERCIAL PRODUCTION:** Ecuador has no commercial GE plant production.
- c) **EXPORTS:** Ecuador currently does not export GE plant material.
- d) **IMPORTS:** Corn, cotton, soybean meal, and soybean oil for industrial use in Ecuador is largely of foreign origin.

- Ecuador imported approximately 98 percent of its cotton needs, or some 13,000 metric tons (MT) in 2014; of which, 94 percent of this volume was GE-derived product.
- Soybean meal and oil imports are rising; the United States and Argentina are the main suppliers. Ecuador in 2014 purchased about 752,000 MT of soybean meal; of which, around 96 percent was GE-derived product.

Ecuador is import dependent on foreign sources (i.e., the United States, Argentina, and Brazil) for its cotton and soybean meal needs. It currently does not have specific biotechnology requirements for these commodities.

Ecuador is unlikely to become self-sufficient in the short- to medium-term in the production of cotton and soybean meal. On the contrary, it will likely become increasingly dependent on foreign sources to supply the growing needs of the local animal feed, poultry, pork, cooking oil, aquaculture (i.e., shrimp and tilapia), tuna canning, and snack food industries. Sources comment that should Ecuador impose restrictive import measures, these may adversely affect domestic food manufacturing; jeopardizing employment and undermine both food security and the government's own efforts at combating malnutrition.

- e) **FOOD AID RECIPIENT COUNTRIES:** Ecuador benefited from Food for Progress assistance programs between 1985 and 2006, receiving in-kind donations of wheat, powder milk, soybean oil, soybean meal, and sorghum. Ecuador is no longer eligible for PL-480 Food for Progress programs. Under the Food for Peace Program and the Food Security Program, Ecuador received in 2008-13 in-kind donations of wheat flour, beans, lentils and soybean oil, as well as cash donations. Ecuador has not objected to these donations based on GE considerations.

## **PART B: POLICY**

President Rafael Correa in September 2012 criticized opponents of biotechnology, labeling these as “fundamentalists who are afraid of the truth.” Sources report that Mr. Correa believes that having enshrined the GE issue within the 2008 Constitution has been a “major mistake.” He has clarified that constitutional mandate is contradictory; for it prohibits the local development and cultivation of GE crops while at the same time permitting the import of GE-content food and agricultural products (i.e., soybean meal and corn). Reportedly the National Assembly (i.e., Ecuador's legislative branch), where Mr. Correa's party (Alianza País) holds an absolute majority, may amend the constitution to permit GE research and cultivation. Mr. Correa recently clarified ([Enlace Ciudadano Number 147](#)) that public and private biotechnology research is permissible; stressing that what is not permissible is GE productive cultivation (without the approval of the National Assembly).

- a) **REGULATORY FRAMEWORK:** Article 401 of Ecuador's 2008 Constitution declares the country to be free of transgenic crops and seeds. This article does however grant the President sole authority to authorize the entry of genetically modified agricultural products and seeds. Section two of Article 401 affirms that the state reserves for itself 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; guidelines however do not exist for defining what constitutes dangerous or experimental biotechnology. Concerns have been raised that this article limits scientific research.

- i. **RESPONSIBLE GOVERNMENT MINISTRIES:** The Environmental Management Act (1999) establishes that the Ministry of the Environment regulates the production, diffusion, research, use, trade, and import of GE material and products. The act states that the Ministry of the Environment oversees the decentralized Environmental Management System, while the Ministries of Agriculture, Commerce, and Health retain oversight over specific issues.
- ii. **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. The Ministries of the Environment, Agriculture, and Public Health along with the Secretariat of Higher Education, Science, Technology and Innovation form CONABIO. The commission held its first formal meeting on May 6, 2015. CONABIO's is responsible for: 1) policy formulation; 2) proposing the national biosecurity agenda for genetically modified organisms; 3) biosecurity management projects and activities; 4) the approval of norms relating to GE products, their byproducts, and GE-content products; 5) recommending the authorization and or the de-authorization of GE products, their byproducts, and GE-content products, including their introduction, propagation, storage, cultivation, transportation, export and import, and development; 6) supervising GE product evaluation procedures, its risk management, control and monitoring mechanisms; 7) reporting violations; 8) gathering groups of experts; 9) registering individuals and institutions working with genetically modified organisms; 10) requesting national and or international assistance on behalf of related activities; and 11) promoting capacity development.
- iii. **ASSESSMENT OF POLITICAL FACTORS:** Ecuador's government is reportedly perturbed by the country's dependence on foreign sources for a number of imports (e.g., animal feed ingredients and planting seeds) and technologies, as well as the effect of this dependence on its balance-of-payments. Some farmers believe that the introduction of genetically engineered seeds will make them dependent on foreign multi-national corporations. Senior government leadership, as well as the country's larger agricultural producers, recognizes that genetically engineered seeds provide higher yields and other benefits. The National Plan for Healthy Living (2013-17) includes biotechnology as one of the fourteen priority sectors targeted by the government as critical for transforming Ecuador's production matrix. This plan advocates the establishment of (research) alliances with countries in possession of advanced biotechnology capabilities. CONABIO's establishment permits a more technical assessment of biotechnology. Sources indicate that with participation limited to government officials, CONABIO's determinations could potentially be subjected to political expediency.
- iv. **DISTINCTION BETWEEN FOOD AND FEED REGULATIONS:** Current regulations require that GE-content in food for human consumption must be declared on the product label. Enforcement commenced in the second-half of 2014. There is no similar requirement for animal feed.
- v. **PERTINENT AND PENDING LEGISLATION:** The National Assembly in February 2009 approved the Food Sovereignty Law; regulating the use of biotechnology in Ecuador. The law however is vague, failing to provide clarifications for the utilization of biotechnology in

agricultural production. Existing legislation, such as the country's Health Code, the Consumer Rights Protection Law, the Agricultural Development Law, the Seed Law, and the Animal and Plant Health Laws fail to provide specific guidance on biosafety issues. The Ministry of Agriculture in 2013 drafted a bill aimed at protecting biodiversity through the regulation of planting seeds production. The bill normalizes research, as well as the production and the import of planting seeds.

- **Consumer Rights Protection Law (July 10, 2000):** The law regulates supplier-consumer relations; promoting consumer awareness and protection of consumer rights. It contains a clause that declares that in 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 mandate the mandatory labeling of GE-content foods. Articles 13 and 14 state “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 Health Law establishes import requirements for genetic material in accordance with Andean Community of Nations' (CAN) regulations. Article 4 stipulates that the import of plant material for propagation, as well as for research must count with prior Ministry of Agriculture import approval.
- **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 is permissible if these products meet Ministry of Health requirements. A positive list of authorized transgenic products does not however exist.
- **Food Sovereignty Law:** This law declares food security 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. The introduction of GE-material is permissible only with the president's explicit authorization (and with approval of the National Assembly). 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.
- **The Health Code:** In 2006, the Ecuadorian Congress passed a new Health Code. This (general) law includes a food safety provision. The Ministry of Health is drafting enforcement rules for the Health Code.

vi. **TIME LINE FOR APPROVALS:** Ecuador has not developed an approval process.

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

- c) **FIELD TESTING:** Ecuador authorizes transgenic plant development under controlled laboratory conditions. Field testing is not authorized.
- d) **STACKED EVENTS:** There are no mechanisms in place for dealing with stacked events.
- e) **ADDITIONAL REQUIREMENTS:** Still pending.
- f) **COEXISTENCE:** No coexistence policy exists.
- g) **LABELING:** In defense of consumers' right to know, the Consumer Protection Law mandates the labeling of GE-content foods. Articles 13 and 14 state "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 are enforced by the National Agency for Regulation, Control, and Health Surveillance (ARCSA) since August 2014.

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 product 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 all products containing GE-content as of August 2014 be labeled declaring that they contain genetically engineered/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 genetically engineered ingredients as genetically engineered/transgenic animals.



OBS: Package labeling before and after implementation of INEN RTE 022.

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 GE-free. Food manufacturers are consequently often opting to label their products as containing GE-content as 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) **TRADE BARRIERS:** Legislation permits the introduction of GE crops under exceptional conditions; introduction requires presidential intervention citing national interest. However, imports of GE-content commodities occur with frequency.
- i) **INTELLECTUAL PROPERTY RIGHTS:** Legislation permits the registration of new plant varieties. State funded new plant varieties are deemed public goods; 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.
- j) **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.

- k) **INTERNATIONAL TREATIES/FORA:** Ecuador is bound by Andean Community of Nations Decision 523; requiring that its biosafety regulations be in compliance with the Andean Strategy on Biodiversity. It does not currently participate in other biotechnology fora.
- l) **RELATED ISSUES:** Ecuador's Precautionary Principle creates trade controversies.
- m) **MONITORING AND TESTING:** Monitoring and testing protocols are being implemented.
- n) **LOW-LEVEL PRESENCE POLICY (LLP):** Ecuador has a low-level presence policy for processed food products. It favors the establishment of a LLP, but opposes a zero-tolerance level approach in the case of planting seeds.

### **PART C: MARKETING**

- a) **MARKET ACCEPTANCE:** Biotechnology is a growing topic of discussion. Most Ecuadorian farmers and food manufacturers do not oppose GE products. Consumers, most of which often hold conflicting views on biotechnology, need to be properly educated.
- b) **PUBLIC/PRIVATE OPINIONS:** Environmental and indigenous groups oppose biotechnology. They have successfully advocated for biotechnology product labeling. In a recent survey, 87 percent of respondents indicated that they read food product labels; with 63 percent of these indicating that they are also aware they are purchasing GE-content products.
- c) **MARKETING STUDIES:** Results of the Ministry of the Environment's 2008 Genetically Modified Organisms, Biotechnology, and Biosecurity study (Jarrín, G. and V. Solís, *Organismos genéticamente modificados, biotecnología y bioseguridad: estudio de percepción pública*, Quito, Ecuador: Ministerio del Ambiente, Programa de Bioseguridad) highlight widespread consumer unfamiliarity with genetically modified and transgenic organisms.

### **PART D: CAPACITY BUILDING AND OUTREACH**

#### **a) ACTIVITIES:**

- In 2013, FAS Quito partnered with IICA and INIAP to provide training to Ecuadorian officials and farmers in risk assessment and biodiversity.
- In March 2015, FAS Quito supported the organization of the First Latin America Food Summit, focusing on the challenges of feeding a growing global population.
- FAS Quito utilizes Cochran Fellowships and scientific exchanges to educate policymakers, scientists, and others on biotechnology, food safety and biosafety issues.

- b) **GOVERNMENT OF ECUADOR'S OUTREACH EFFORTS:** Ecuadorian researchers at public universities and research institutions routinely organize biotechnology seminars, as well advocate in the press the benefits of biotechnology. Seminars are attended by farmers, exporters, agribusiness, technicians, academics, and producer association representatives. Ecuador's ESPOL International

Congress on Biotechnology and Biodiversity is likely to become the main venue for discussing scientific advances in the country. The last meeting held was organized by ESPOL's Center for Biotechnology Research in June 2014.

- c) **STRATEGIES AND NEEDS:** Opportunities exist for assisting Ecuador in strengthening institutional capacities related to the establishment and enforcement of science-based regulations and international standards. Opportunities include scientific exchanges, training and capacity building, as well as technology transfer.

## **CHAPTER 2: ANIMAL BIOTECHNOLOGY**

### **PART E: PRODUCTION AND TRADE**

- a) **BIOTECHNOLOGY PRODUCT DEVELOPMENT:** None at this time.
- b) **COMMERCIAL PRODUCTION:** None at this time.
- d) **BIOTECHNOLOGY EXPORTS:** None at this time.
- e) **BIOTECHNOLOGY IMPORTS:** 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 F: POLICY**

- a) **REGULATION:** Ecuador's constitution limits the possibilities of cultivating GE plants or of conducting research on GE plants. We are unaware of limitations on biotech animals.
- b) **LABELING AND TRACEABILITY:** No labeling and traceability requirements.

- c) **TRADE BARRIERS:** No trade barriers have been identified.
- d) **INTELLECTUAL PROPERTY RIGHTS (IPR):** There are no biotechnology IPR regulations.
- e) **INTERNATIONAL TREATIES/FORA:** Ecuador does not officially support international groups that back or oppose GE animals or cloning.

#### **PART G: MARKETING**

- a) **MARKET ACCEPTANCE:** There are no studies assessing consumer acceptance.
- b) **PUBLIC/PRIVATE OPINIONS:** None.
- c) **MARKET STUDIES:** None.

#### **PART H: CAPACITY BUILDING AND OUTREACH**

- a) **ACTIVITIES:** None preformed.
- b) **STRATEGIES AND NEEDS:** None preformed.