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Ecuador to Permit Field Trials of Genetically Engineered Crops

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Report Highlights:

On June 1, 2017, Ecuador's National Assembly approved the "Organic Law on Agrobiodiversity, Seeds and Promotion of Sustainable Agriculture." This law side-steps the constitutional ban on the cultivation of GE crops by permitting GE crop cultivation for research purposes. The Ministry of Agriculture and Livestock is drafting specific guidelines for the implementation of this law at this time.

EXECUTIVE SUMMARY

In October 2016, Ecuador’s Minister of Agriculture and the Minister of Industries both announced that the National Institute for Agricultural Research (INIAP), the country’s main agricultural biotechnology research body, would start field trials of GE corn from major seed companies for research purposes. The trials are expected to last two years.

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. While the Commission held its first formal meeting on May 6, 2015, it has failed to establish itself as the entity with jurisdiction over all biotechnology issues.

On June 1, 2017, Ecuador’s National Assembly approved *The Organic Law on Agrobiodiversity, Seeds and Promotion of Sustainable Agriculture*. Ecuador now allows the cultivation of GE crops for research purposes. As a result of the new Law of Seeds, the Government of Ecuador has now effectively placed all responsibility for research and commercialization of GE plants in the hands of Ecuador’s Ministry of Agriculture and Livestock (MAG). MAG officials are currently considering language for a ruling that would specify functions for different MAG offices; such as INIAP or the Undersecretary of Agriculture, regarding GE crops. The policy position of offices within MAG are not always aligned. It should be noted that the glossary and definition of terms section of the “Seeds Law” makes no mention of the term “transgenic crops” or related terms. Similarly, the “Seeds Law” does not define which government office is the National Agrarian Authority. It is assumed that the MAG is the authoritative entity that the Law refers to.

Although Article 401 of Ecuador’s 2008 Constitution declares the country to be free of transgenic crops and seeds, it also grants the President the sole authority to authorize the entry of genetically modified agricultural products and seeds. 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”.

Bilateral agricultural trade between the United States and Ecuador reached \$2.39 billion in calendar year (CY) 2016, down about 6.3 percent from the previous year. Ecuador exported \$2.08 billion in food and agricultural products to the United States, while only importing \$310 million in U.S.-origin product.

Major U.S. agriculture exports to Ecuador include soybean meal, wheat, cotton, prepared food and fresh fruits.

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PLANT & ANIMAL BIOTECHNOLOGY

CHAPTER 1: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

- a) Product development:** Over the past few 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 (e.g., bananas).

In October 2016, Ecuador's Minister of Agriculture and the Minister of Industries both announced that the National Institute for Agricultural Research (INIAP), the country's main agricultural biotechnology research body, will start field trials of GE corn from major seed companies with research purposes.

On June 1, 2017, Ecuador's National Assembly voted to permit the cultivation of genetically engineered crops and seeds for research purposes.

Regarding domestic capabilities, Ecuador has 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.

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.

Ecuador is not developing antibiotics, foods or pharmaceuticals using GE techniques or plants.

- b) Commercial production:** Ecuador has no commercial GE plants in 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 are largely of foreign origin.
- Ecuador imported approximately 98 percent of its cotton needs, or some 11,000 metric tons (MT) in 2016. Of these imports, at least 87 percent of this volume was GE-derived product.
 - Soybean meal and oil imports are rising. The United States and Bolivia are the main suppliers. In 2016, Ecuador purchased about 920,000 MT of soybean meal, of which, at least 97 percent was GE-derived product.

Ecuador is import dependent on foreign sources (e.g., the United States, Argentina, and Bolivia) 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, Ecuador will likely continue to source from foreign countries some of the ingredients for 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 will adversely affect feed manufacturing. This would jeopardize employment and undermine both food security and the government's own efforts at combating malnutrition. The Government of Ecuador is likely to import GE corn seed for research purposes in the year 2018.

- e) **Food aid:** Ecuador is not a food-aid recipient country.
- f) **Trade barriers:** Legislation permits the introduction of GE crops for research purposes and under exceptional conditions for commercial purposes. Commercial production requires presidential intervention citing national interests such as food sovereignty concerns, ratification by Ecuador's National Assembly that such national interest exist, and possibly 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. Imports of raw commodities 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 constitutional mandate on the cultivation of GE crops prohibits the commercial cultivation of GE crops, while at the same time permitting the import of GE-content food and agricultural products. 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 imports 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.

a) Regulatory Framework

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 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.

Keeping the content of Article 401 in mind, it is Article 281 of Ecuador's 2008 Constitution that 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”.

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 MAG. FAS Quito expects that the guidelines that are currently being drafted by MAG 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 are allowed to 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. Very serious special infractions are the unauthorized entry or use of genetically modified seeds and crops for any purpose other than scientific research.

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 proceed 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 aforementioned 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.

In addition to these two 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.

- i. **Responsible Government Ministries:** Until the approval of the Organic Law on Agrobiodiversity, Seeds and Promotion of Sustainable Agriculture, the Environmental

Management Act (1999) established that the Ministry of the Environment regulate the production, diffusion, research, use, trade, and import of GE material and products. The act states that the Ministry of the Environment oversee the decentralized Environmental Management System, while the Ministries of Agriculture, Commerce, and Health retain oversight over specific issues. However, the 2017 Organic Law on Agrobiodiversity, Seeds and Promotion of Sustainable Agriculture vests all authority regarding transgenic crops onto the National Agrarian Authority. It is assumed that the MAG is the authoritative entity for controlling, approving and regulating all aspects related to the use of GE crops in the country.

- 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 Biosecurity Commission has failed at organizing itself and being vested with official authority. Therefore, as stated by the Food Sovereignty Law, and the Seeds Law, for purposes of introduction of GE crops in Ecuador, the authority over such endeavors falls under the portfolio of the MAG and its research arm INIAP.
- 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 impact of this dependence on its balance-of-payments. On the production side, farmers believe that the introduction of genetically engineered seeds will make them more productive and allow them to lower their cost of production. New Breeding Technologies appear to be a hot 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 guidelines will address and clarify these topics.
- 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. **Other Pertinent and Pending Legislation:**
 - [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 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 establishes 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 MAG's 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 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. 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.
 - **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.
 - **Rules for the Organic Law on Agrobiodiversity, Seeds and Promotion of Sustainable Agriculture:** At the time of writing this report, MAG is in the process of revising a final draft of these Rules.
- vi. **Time Line for Approvals:** Ecuador's INIAP is expected to provide a technical recommendation on the introduction of GE corn and soybean in the next two years.
- b) **Approvals:** There is no list of GE-derived plants or crops approved or registered in the country for cultivation, import, or export. For research purposes, MAG officials have publicly stated that crops of interest include: corn, cotton, and soybeans.
- c) **Stacked or pyramided event approvals:** There are no mechanisms in place for dealing with stacked events.
- d) **Field testing:** Ecuador authorizes transgenic plant development under controlled laboratory conditions. Field testing for research purposes was authorized in 2017. MAG 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.
- e) **Innovative biotechnologies:** Not applicable. Existing laws and regulations make explicit references to transgenic crops and techniques. However, there are no references to new breeding techniques or the use of modern biotechnology to produce cisgenic crops.
- f) **Coexistence:** No coexistence policy exists.

g) Labeling: The Consumer Protection Law mandates the 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.” 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 free of GE content. 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) **Monitoring and testing:** Although some protocols might be employed on an ad-hoc basis, FAS/Quito is not aware of Ecuador actively testing for GE traits in imports and exports. FAS/Quito is not aware of Ecuador actively testing for GE traits in fields either.
- i) **Low-level presence (LLP) policy:** Ecuador has a low-level presence (LLP) policy for processed food products. It favors the establishment of a LLP policy and in conversations opposes a zero-tolerance level approach in the case of planting seeds. However, Ecuador has yet to officially state in a law or regulation what the threshold will be for LLP.
- 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; 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 are introduced in the next years.

- 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; requiring that its biosafety regulations be in compliance with 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 as part of Ecuador's climate change adaptation and mitigation strategies.

PART C: MARKETING

- a) **Public/private opinions:** A few environmental and indigenous groups still oppose biotechnology but much less so than a few years ago. Farmers of other minority groups on the other hand seem to favor the introduction of GE crops, particularly along the Coast. Thus, amongst farmers views are often at odds.
- 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 the 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).

CHAPTER 2: ANIMAL BIOTECHNOLOGY

PART D: PRODUCTION AND TRADE

- a) **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.
- b) **Innovative biotechnologies:** Ecuador has yet to decide, or not, how to regulate innovative biotechnologies such as genome editing in animals.
- c) **Labeling and traceability:** No specific 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 under the trader who must be able to certify that an ingredient is not “transgenic”.
- d) **Intellectual property rights (ipr):** There are no biotechnology-specific IPR regulations.
- e) **International treaties/forums:** Ecuador does not officially support international groups that back or oppose GE animals or cloning.
- f) **Related issues:** None at this time.

PART F: MARKETING

- a) **Public/private opinions:** None.
- b) **Market acceptance/studies:** None.