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Court Challenge to Ecuadorian Proposal 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-stepped the constitutional ban on the cultivation of genetically engineered (GE) crops by permitting GE crop cultivation for research purposes. Anti-GMO groups subsequently brought the case to Ecuador's highest court. To date, no ruling has been made.

EXECUTIVE SUMMARY

On October 2016, Ecuador's Minister of Agriculture and the Minister of Industries jointly announced that the National Institute for Agricultural Research (INIAP), the country's main agricultural biotechnology research body, would start field trials of genetically engineered (GE) corn from major seed companies for research purposes. This statement was backed up on June 1, 2017 when 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 genetically engineered (GE) crops by permitting GE crop cultivation for research purposes. Experimental trials were expected to start in 2018. However, this did not happen due to several (five) challenges to the constitutionality of the law that were brought to Ecuador's Constitutional Court. No rulings have been made to date.

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 biotechnology issues.

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 \$2.19 billion in calendar year (CY) 2017, down 8.4 percent from the previous year. Ecuador exported \$1.89 billion in food and agricultural products to the United States, while only importing \$297 million in U.S.-origin product.

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

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PLANT & ANIMAL BIOTECHNOLOGY

CHAPTER 1: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

- a) Product development:** Over the past decade, 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, would start field trials of GE corn from major seed companies for research purposes.

On June 1, 2017, Ecuador's National Assembly voted to permit the cultivation of genetically engineered crops and seeds for research purposes. Shortly after passage, five challenges were brought to Ecuador's Constitutional Court. No ruling has been made as all justices were removed from their appointments in August 2018. Ecuador is currently in the middle of a process to appoint new justices. At the time of writing, there is no clear timeline for the appointment of new permanent justices. It is estimated that the process will take about three months. It is also unclear how much of a priority the cases against *The Organic Law on Agrobiodiversity, Seeds and Promotion of Sustainable Agriculture* will be for new court. The Court has over 15,000 cases pending and over 3,000 cases under consideration.

Regarding domestic capabilities, Ecuador has the capability to produce transgenic plants. Ecuador's Polytechnic School of the Coast's (ESPOL) Center for Biotechnology Research (CIBE), reports that in 2012 it succeeded in producing lines of cisgenic and transgenic banana plants that are resistant to black sigatoka (or black leaf streak). It has also reported 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 99 percent of its cotton needs, or some 11,500 metric tons (MT) in 2017. Of these imports, at least 93 percent of this volume was GE-derived product.

- Soybean meal and oil imports are rising. Argentina, Bolivia, Paraguay and the United States are the main suppliers. In 2017, Ecuador purchased about 850,000 MT of soybean meal, of which, at least 95 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; and, it is therefore 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 commodities. It is safe to assume that the Government of Ecuador considers them safe, as it is a requirement of the Food Sovereignty Law 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 from foreign countries some of the ingredients for animal feed used in shrimp, poultry and pork production; cooking oil for human consumption; and other food ingredients produced using modern biotechnology. Sources comment that should Ecuador impose restrictive import measures, these will adversely affect feed manufacturing and processed food manufacturing. This would jeopardize employment and undermine both food security and the government's own efforts at combating malnutrition.

- e) **Food aid:** Ecuador is not a food-aid recipient country.
- f) **Trade barriers:** The current constitutional challenge to experimentation with GE crops does not permit the introduction of GE crops for research purposes, even under exceptional conditions for commercial purposes. Commercial production would require presidential intervention citing national interests such as food security 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 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 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. The Government of Ecuador has yet to express a position regarding innovative biotechnologies such as genome editing.

- i. **Competent Government Authorities:** 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 oversees 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 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.
- 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 but was never vested with any official authority. Therefore, as stated by the current 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 Ministry of Agriculture and Livestock and its research arm INIAP.
- iii. **Assessment of Political Factors:** Ecuador's government does not look favorably on 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, 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 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 rules will address and clarify these topics, once the Constitutional Court rules in the pending case about transgenic crops.
- 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 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 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 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.
- Rules 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 of the Constitutional Court before publishing.

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, Ministry of Agriculture and Livestock 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 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:** Not applicable. 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-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 have been 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 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 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 not established a low-level presence (LLP) rule for processed food products. It favors such establishment though, and 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 and new breeding innovations as part of Ecuador's climate change adaptation and mitigation strategies.

PART C: MARKETING

- a) **Public/private opinions:** Only a handful of environmental and indigenous groups still oppose biotechnology in the highland provinces. Farmers of other minority groups seem to favor the introduction of GE crops, particularly along the Coast. Thus, amongst farmers views are often at odds, with opposition being small and concentrated in certain groups of the Ecuadorian population.

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). FAS Quito estimates that the general 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) **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.
- 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 under 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 back or oppose GE animals or cloning.
- g) **Related issues:** None at this time.

PART F: MARKETING

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