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Ecuador's INIAP Set to Start Field Trials of Genetically Engineered Corn

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Report Highlights:

In October 2016, Ecuador's Ministries of Agriculture and Industries announced that the National Institute for Agricultural Research INIAP will start field trials of GE corn with research purposes. The trials are expected to last two years. Adoption of modern biotechnology in Ecuador will respond to the State's Constitutional mandate to ensure food sovereignty. A recent increase in phytosanitary problems and adverse weather have significantly reduced agricultural productivity.

SECTION I. 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, will start field trials of GE corn from major seed companies with research purposes. The trials are expected to last two years.

Although Article 401 of Ecuador's 2008 Constitution declares the country to be free of transgenic crops and seeds, while granting the President sole authority to authorize the entry of genetically modified agricultural products and seeds, Article 281 of the same 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".

President Rafael Correa, on more than one occasion, has clarified ([Enlace Ciudadano Number 147](#)) that public and private biotechnology research is permissible; stressing that what is not permissible is GE commercial cultivation (that is without the approval of the National Assembly).

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 Commission, although it held its first formal meeting on May 6, 2015, has failed at establishing itself as the entity with jurisdiction over all biotechnology issues. As a result, the Government of Ecuador has placed all responsibility over research and commercialization of GE plants in the hands of Ecuador's Ministry of Agriculture, Livestock, Aquaculture and Fisheries (MAGAP).

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.

Bilateral agricultural trade between the United States and Ecuador reached \$2.55 billion in calendar year (CY) 2015, down about 7.5 percent from the previous year. Ecuador exported \$2.2 billion in food and agricultural products to the United States, while only importing \$365 million in U.S.-origin product.

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

SECTION II. PLANT & ANIMAL BIOTECHNOLOGY

CHAPTER 1: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

- a) **PRODUCT DEVELOPMENT:** Ecuador over the past few years 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. The trials are expected to last two years. After that period, the Ecuadorian Government will determine the feasibility of allowing the commercialization of GE corn seeds. Public interviews, in Spanish, about this subject can be found here:

<http://expreso.ec/economia/produccion-transgenicos-gobierno-economia-AG769020>
<http://expreso.ec/actualidad/semillas-transgenicos-agricultura-produccion-LC774269>

Regarding domestic capabilities, 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.

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.

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 is largely of foreign origin.
- Ecuador imported approximately 98 percent of its cotton needs, or some 13,000 metric tons (MT) in 2015. Of these imports, at least 72 percent of this volume was GE-derived product.
 - Soybean meal and oil imports are rising. The United States and Argentina are the main suppliers. In 2015, Ecuador purchased about 850,000 MT of soybean meal, of which, at least 94 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. 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 2016.

- e) **FOOD AID:** Ecuador is not a food-aid recipient country.
- f) **TRADE BARRIERS:** Legislation permits the introduction of GE crops under exceptional conditions. Introduction requires presidential intervention citing national interest such as food sovereignty concerns.

PART B: POLICY

President Rafael Correa in September 2012 criticized opponents of biotechnology, labeling these as “fundamentalists who are afraid of the truth.” Mr. Correa himself has stated publicly 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), despite Mr. Correa's party (Alianza País) holding an absolute majority, might not amend the constitution to permit GE research and cultivation. However, such a step seems not to be a necessary condition to allow experimentation with GE crops for research purposes. Indeed, Mr. Correa has clarified ([Enlace Ciudadano Number 147](#)) that public and private biotechnology research is permissible; stressing that what is not permissible is GE commercial 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.

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

- 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 Biosecurity Commission has failed at organizing itself and being vested with official authority. Therefore, as stated by the Food Sovereignty Law, for purposes of introduction of GE crops in Ecuador, the authority over such endeavors falls under the portfolio of the MAGAP 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 effect 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. The following video, in Spanish, highlights the position of the major stakeholders regarding the adoption of GE crops:

El Productor TV: Biotechnology - Transgenic Crops, A Positive or Negative Impact?
<https://youtu.be/gViDWDTFW4k>

Senior government leadership, in addition to the country’s agricultural producers, have recognized 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.

- 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 which regulates the use of biotechnology in Ecuador. The law however is vague, failing to provide clarifications for the utilization of biotechnology in agricultural production.
 - **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 MAGAP 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 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.

vi. **Time Line for Approvals:** Ecuador’s INIAP is expected to provide a technical recommendation on the introduction of GE corn 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, MAGAP officials have publicly stated that crops of interest include: corn, cotton and soybeans.
- c) STACKED EVENTS:** 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 has also been authorized but only for those GE varieties for which the same variety is already being commercialized in-country without the GE event or events.

- e) **INNOVATIVE BIOTECHNOLOGIES:** Not applicable.
- 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) **MONITORING AND TESTING:** Although some protocols might be employed on an ad-hoc basis, FAS/Quito is not aware if Ecuador actively tests for GE traits in imports and exports. FAS/Quito is not aware if Ecuador actively tests for GE traits in fields either.
- i) **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.
- j) **ADDITIONAL REGULATORY REQUIREMENTS:** None.
- k) **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. FAS/Quito will monitor any IPR issues

related to GE crops as these new seed varieties are introduced in the next two 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.
- m) INTERNATIONAL TREATIES/FORA:** 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:** Ecuador’s Precautionary Principle creates trade controversies. 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:** Some environmental and indigenous groups oppose biotechnology but much less so than a few years ago. They have successfully advocated for biotechnology product labeling and this fact seems to have eased the pressure on banning GE technologies in favor of letting the end consumer choose and influence the market.
- 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 applied 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/FORA:** 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.