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Ecuador

Agricultural Biotechnology Annual

Biotechnology Annual 2014: 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 will require mandatory labeling of food and beverage products containing more than 0.9 percent transgenic content. FAS Quito believes this could adversely affect the import of GE-content products. Ecuador justifies its actions claiming that the measure's objectives are to prevent unfair practices that may affect consumer rights. It also aims to prevent unfair competition arising between traders selling products with genetically engineered content and those who do not.

Section I. Executive Summary:

Bilateral agricultural trade between the United States and Ecuador reached \$ 2.4 billion in calendar year (CY) 2013, up nearly 3 percent from the previous year. Ecuador exported a record \$1.9 billion in food and agricultural products to the United States while only importing some \$445 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 indicates that beginning May 15, 2014, mandatory labeling of “contains transgenic” will be enforced. This date has now slipped to August 2014. It nevertheless will still require the mandatory labeling of food and beverage products containing transgenic (also referred to as *cisgenic*) components in excess of 0.9 percent. Ecuador justifies its actions claiming that the measure’s objectives are to prevent unfair practices that may affect consumer rights. It also aims to prevent unfair competition arising between traders selling products with genetically engineered content and those who do not.

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 genetically engineered (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). FAS Quito hears that 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.

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 built up the technical capacity needed to conduct high-level agricultural biotechnology research. Despite continuing to rely on scientific protocols developed elsewhere, it has made progress in those products that are of national interest (e.g., bananas).

Ecuador's Institute for Agricultural Research (INIAP), the country's main agricultural biotechnology research body, claims however that the country lacks the means to conduct GE 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) dispute Ecuador's assertions, attesting that it does have the capability to produce transgenic plants. Ecuador's Polytechnic School of the Coast (ESPOL) – Center for Biotechnology Research (CIBE), a public university, reported in 2012 that it had succeeded in producing a line of transgenic banana plants.

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 (or black leaf streak), 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 \$398 million in bananas and plantains to the United States in CY 2013 alone. 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 Polytechnic School of the Coast 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.

At FAS Quito, we understand that Ecuador's Ministry of Agriculture is working on a draft regulatory framework. Once implemented, it will permit the ministry to assess potential risks associated with the introduction of GE crops. The sense of urgency to finalize regulatory framework procedures is driven by the perception of the country being at competitive disadvantage compared to corn and soybean producers Argentina, Brazil, and Colombia.

- b) **COMMERCIAL PRODUCTION:** Ecuador has no commercial GE plant production.
- c) **EXPORTS:** Ecuador currently does not export GE plant material.
- d) **IMPORTS:** A significant portion of the corn, cotton, soybean meal, and soybean oil for industrial

use in Ecuador is of foreign origin.

- Ecuador imported approximately 98 percent of its cotton needs, or some 15,500 metric tons (MT) in 2013; of which, 94 percent of this volume was GE-derived product.
- Soybean meal and oil imports are rising; the United States is the main supplier of the former. Ecuador in 2013 purchased about 618,000 MT of soybean meal; of which, 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 in place any specific biotechnology requirements for these commodities.

At FAS Quito, we believe that 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. We believe that should Ecuador impose restrictive import measures, these will adversely affect domestic food manufactures; 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 between 1985 and 2006. Thanks to 16 bilateral agreements, Ecuador received 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). FAS Quito hears that 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.

- 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 a dangerous or experimental biotechnology. Concerns have been raised

within the scientific community that this article limits scientific research.

- i. **RESPONSIBLE GOVERNMENT MINISTRIES:** As per the Environmental Management Act (1999), the Ministry of the Environment regulates the production, diffusion, research, use, trade, and import of GE material and products. This act indicates that the Ministry of the Environment oversees the decentralized Environmental Management System while authorizing the Ministries of Agriculture, Commerce, and Health to retain oversight authority on their specific issues.
- ii. **ROLE OF THE BIOSAFETY COMMITTEE/AUTHORITY:** Ecuador Biosafety Committee was created by presidential decree (i.e., an administrative measure) in 2002. The committee has yet to be formed; the position of consumer representative has not been filled. The Correa administration is drafting a new decree that will create both a Biosafety Committee and National Biosafety System. Although biotechnology and biosafety systems are already in place, these lack a regulatory framework. The Environmental Management Act fails to specifically address agricultural biotechnology and biosafety.
- 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. 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 GE 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 is set to commence 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.
- vi. **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.” Enforcement commences in August 2014.

- vii. **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. Similarly article 4 of the Plant Health Law clarifies that the import of plant material for propagation, as well as for research, must count with prior Ministry of Agriculture import approval.
 - viii. **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 exist.
 - ix. **FOOD SOVEREIGNTY LAW:** This (non-technical) 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 however declares the country to be free of GE-material. The introduction of GE-material is permissible only with the president’s explicit authorization. The use of dangerous or 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.
 - x. **THE HEALTH CODE:** In 2006, the Ecuadorian Congress passed a new Health Code. This (general) law includes a food safety provision. The new code however fails to address Ecuador’s lack of capacity for determining the safety of biotechnology-derived food products. The Ministry of Health is drafting enforcement rules for the Health Code.
- b) **APPROVALS:** There is no approval process for genetically engineered traits.
 - 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:** 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 will be enforced by the National Agency for Regulation, Control, and Health Surveillance (ARCSA) starting in 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. RTE INEN 022 – “Labeling of Processed, Packed, and Packaged Food Products” has been modified to clarify how to properly label transgenic product. The relevant articles of RTE INEN 022 included:

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% 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% 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.

- h) TRADE BARRIERS:** Legislation permits the introduction of GE crops under exceptional conditions; which requires presidential intervention on the behalf of the safeguard of national interest. However, imports of GE 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; no royalties are collected. 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 to be implemented; its specifications are not yet public.

- 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 in food is a growing topic of discussion. However, most consumers remain unaware of the existence of GE-content food products.
- b) **PUBLIC/PRIVATE OPINIONS:** Environmental and indigenous groups are well-versed on the issue of biotechnology-derived foods. They have successfully advocated for biotechnology product labeling.
- 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) indicate widespread unfamiliarity with genetically modified and transgenic organisms.

PART D: CAPACITY BUILDING AND OUTREACH

a) ACTIVITIES:

- In 2011, FAS Quito sponsored a mission of Ecuadorian journalists to the United States to learn about GE crops and farmers' experience with this technology.
 - FAS Quito participates in seminars on agricultural biotechnology. Throughout 2010-11, FAS Quito organized "Biotechnology in World Agriculture" conferences at universities.
 - In 2012, FAS Quito partnered with one of Ecuador's regional farm bureaus and co-sponsored training events for 200 farmers, policymakers, and the general public.
 - In 2013, FAS Quito partnered with IICA and INIAP to provide training to Ecuadorian officials and farmers in risk assessment and biodiversity.
 - FAS Quito utilizes Cochran Fellowships and scientific exchanges to educate policymakers, scientists, and others on biotechnology, food safety and biosafety issues.
- i. **GOVERNMENT OF ECUADOR'S OUTREACH EFFORTS:** Ecuadorian researchers at public universities and research institutions often organize seminars on 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 next meeting is in June 2014 and is organized by ESPOL's Center for Biotechnology Research. It will focus on using modern biotechnology to tackle plant diseases in fruit production without risk to Ecuador's biodiversity.

b) STRATEGIES AND NEEDS: We find 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.
- c) **BIOTECHNOLOGY EXPORTS:** None at this time.
- d) **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