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## **Ecuador**

### **Agricultural Biotechnology Annual**

#### **2013 Ecuador Biotechnology Situation: Policy, Trade, Marketing of Genetically Engineered (GE) Crops and Animals**

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**Report Highlights:**

Although Ecuador maintains a number of anti-biotech laws and regulations, there is minimal enforcement, and trade in cotton and soybean products continues. Ecuador's Ministry of Agriculture is expected to send the National Assembly a new draft of a Bill of Agri-Biodiversity. However, there is no specific timeline for this. Ecuador needs to strengthen its institutional capacities to establish and enforce regulations based on science and international standards. On the positive side, in recent years, Ecuadorian public and private research institutions have increased their activities related to agricultural biotechnology.

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### **SECTION I. EXECUTIVE SUMMARY**

Ecuador has a number of laws and regulations that could impact the importation, distribution and use of products derived from biotechnology, but it lacks a specific law that directly regulates biotechnology, biodiversity, and trade of seeds. Article 401 of the 2008 Constitution declares Ecuador free of transgenic crops and seeds. However, the same article grants the President the exclusive authority to allow imports of agricultural crops and seeds that may have been produced using genetic modification. In February 2009, Ecuador's legislative body approved a Food Sovereignty Law aimed at regulating the use of biotechnology. The law was published in the National Register on May 5, 2009. This law is very vague and does not provide any specifics on the use of biotechnology in agriculture. It is expected that Ecuador's Ministry of Agriculture will be sending a new draft bill on biodiversity and seeds to the National Assembly where President Correa's party holds an absolute majority. The bill is expected to be aligned with President Correa's positive appraisal of technology and innovation. There is no specific timeline for this, either. In the meantime, imports of biotech crops continue.

In April 2006, Ecuador enacted the Food and Nutrition Security law that invokes the precautionary principle and calls for prohibitions on the use, handling, trade or importation of any food products that are, or contain, genetically engineered (GE) materials. The regulation initially created trade problems with soybean meal and soybean oil imports, but a backlash from the industries that use these products as inputs has led the government to drop any enforcement measures.

Ecuador ratified the Cartagena Protocol on Biosafety in November 2002, and its general policies on biosafety are expressed in several existing laws, including the Constitution. During 2011, the Ministry of Environment made some progress toward the implementation of the National Biosafety Framework.

In the last few years, Ecuador's public research institutions, private universities, and research centers,

have notably increased their human and infrastructure capabilities making Ecuador a country with a high potential to develop its biotechnology sector.

## **SECTION II. PLANT AND ANIMAL BIOTECHNOLOGY**

### **CHAPTER 1: PLANT BIOTECHNOLOGY**

#### **PART A: Production and Trade**

##### *a) Product Development:*

In recent year, Ecuador has developed the human and infrastructure resources to conduct high-level research on agricultural biotechnology. Although it still relies on scientific protocols developed elsewhere, it has made progress in products of national interest, such as bananas.

Traditionally, Ecuador's Institute for Agricultural Research (INIAP), the main venue for agricultural biotechnology research, has claimed that given the incipient technology and infrastructure available, Ecuador does not have the capacity to conduct any GE-related research. However, according to the Inter-American Institute for Cooperation in Agriculture (IICA)'s assessment of agricultural biotechnology in Latin America in 2008, Ecuadorian laboratories have the capability to produce transgenic plants. According to INIAP, the first biotechnology laboratory in Ecuador opened in 1978. As of 1998, the number of biotechnology labs had increased to 11. As of March 2009, there were 53 laboratories. In 2012, Ecuador's Center for Biotechnology Research (CIBE) at Ecuador's Polytechnic School of the Coast (ESPOL), a public university, reported that it had successfully produced a line of cisgenic banana plants.

Interest in biotechnology has increased as agribusiness responds to increased demands for tissue culture and somatic embryogenesis, molecular biology applications and diagnosis. In the last two years, Ecuador's banana sector has shown a strong interest in exploring the use of modern biotechnology to tackle the problem of fungicide resistance for black sigatoka in banana plantations. Agricultural sectors that seem to be using biotechnology to a relatively significant extent include the flower sector, the banana and cacao sectors, and the aquaculture industry.

In September 2012, President Rafael Correa came out very strongly against what he called opposition to GE by "fundamentalists who are afraid of the truth". He has insisted that it was a "big mistake" to include the GE issue in the Constitution. He has also pointed out that the Constitutional mandate is contradictory as it prohibits the development and cultivation of GE crops while at the same time Ecuador imports GE foods including grains and soybean meal. There is speculation that the current National Assembly, in which President Correa's party Alianza País holds an absolute majority, might consider amending the constitution to allow GE research and cultivation.

Areas of future research interest among Ecuadorian biotechnology laboratories and professionals include efficiency in the production of in-vitro plants, in-vitro conservation, molecular markers, cryopreservation, diagnosis methods, assisted plant breeding, genetic transformation, genomics, bioinformatics, and biosafety, among others. Ecuador's ESPOL has expressed interest to the U.S.

Foreign Agricultural Service office in Quito (FAS/Quito) facilitating collaboration with U.S. scientists in two areas: (1) cacao's DNA sequencing, and (2) adaptation of banana and cacao plants to diseases and the effects of climate.

In addition, given the lack of a framework to regulate biotechnology, Ecuador's Ministry of Agriculture is reportedly working on a draft regulatory framework that will allow it to assess any potential risks related to the introduction of GE crops. There is an urgent need to accomplish this as the country is at a competitive disadvantage with respect to its South American neighbors such as Brazil, Colombia, and Argentina in the production of corn and soybeans.

b) *Commercial Production:*

There is no commercial production of GE-plants in Ecuador at this time.

c) *Exports:*

Ecuador does not export GE-plant materials at this time.

d) *Imports:*

A growing proportion of the supply of corn, cotton, soybean meal, and soybean oil for industrial use is of foreign origin. Brief descriptions of the commercial situation of these products are as follows:

- Ecuador purchased approximately 98 percent of its cotton needs (11,000 MT) from foreign sources in 2011, of which 94 percent was GE.
- Soybean meal and oil imports are rising, with the United States as the main supplier. Ecuador purchased more than 517,000 MT of soybean meal in 2012, of which 99.8 percent was GE.

As seen from the figures above, Ecuador currently sources high percentages of its cotton and soybean meal requirements to fulfill its needs from foreign buyers – mainly the United States, Brazil, and Argentina – without any specific biotechnology requirements. The animal feed as well as the poultry, pork, cooking oil, tilapia, shrimp, tuna canning, feed manufacturing and snacks industries currently use these products in their formulas, and it is unlikely that Ecuador would have the capacity to become self-sufficient in the near future. Therefore, the issuance of additional restrictive rules would not only hurt U.S. export interests, but it would complicate the survival of large local industries, further jeopardizing Ecuador's efforts to generate jobs, achieve food security, and combat malnutrition.

e) *Food Aid Recipient Countries*

Ecuador benefited from Food for Progress assistance between 1985 and 2006. Through 16 bilateral agreements, Ecuador received in-kind donations of wheat, powder milk, soybean oil, soybean meal, and sorghum. Ecuador is no longer an eligible country to receive food aid under PL-480 Food for Progress. Under the Food for Peace Program and the Food Security Program, Ecuador has received in-kind donations of wheat flour, beans, lentils and soybean oil, as well as cash donations between 2008 and 2013. Ecuador has never objected to these donations based on GE considerations.

## **PART B: Policy**

## *a) Regulatory Framework*

### i. Background and Ecuador's 2008 New Constitution

A general national policy on biosafety is expressed in existing laws. Article 401 of the 2008 Constitution declares Ecuador free of transgenic crops and seeds. The same article grants the President the exclusive authority to allow imports of agricultural crops and seeds that may have been produced using genetic modification.

The second section of Article 401 contains implications that might affect the development of biotechnology in Ecuador. This section states that the State will regulate, under strict norms of biosafety, the use and development of modern biotechnology and its products, as well as biotechnology experimentation, use, and commercialization. It further states that the application of risky or experimental biotechnology is forbidden. This last part has awakened a lot of controversy among Ecuador's scientific community as it is not clear under what parameters risky or experimental will be defined. Overall, the scientific community is concerned that the scope of work of highly trained scientists is significantly limited at this time.

### ii. Responsible Government Ministries:

According to the Environmental Management Act from 1999, the Ministry of Environment is the entity in charge of regulating the production, propagation, research, use, trade, and importation of GE materials. The same law establishes the Ministry of Environment's coordination authority over the decentralized Environmental Management System and allows for other institutions, such as the Ministries of Agriculture, Health, and Commerce to have direct authority over their own issues.

Although the institutions are in place, there is no specific law to regulate biotechnology and biosafety. The Environmental Management Act is very broad and does not deal with specific issues of agricultural biotechnology and biosafety.

### iii. Role of the Biosafety Committee/Authority:

Ecuador issued a presidential decree creating a Biosafety Committee back in 2002. However, the Committee could not be formed due to a legal issue as no proper representative of the consumers could be identified. Currently, the Correa administration is working on a new degree that will create a Biosafety Committee and establish a National Biosafety System.

### iv. Assessment of Political Factors:

In the debate over genetically engineered crops, Ecuadorian authorities seem worried about the issue of "dependence" on foreign technologies and imports of certain products, such as planting seeds. There is also increased fear among farmers that allowing biotech seeds will hurt their plantings, and that using these products will turn their production capacity into a dependency relationship with multinational corporations. Nevertheless, FAS/Quito understands that President Correa's officials in leadership positions and most importantly producers are highly aware of the benefits of improved seeds. Moreover, Ecuador's National Plan for Good Living in its latest edition (2013-2017) continues to include biotechnology as one of the fourteen priority sectors that needs government support to change Ecuador's production matrix. The Plan also calls for developing alliances with foreign countries that have a scientific competitive advantage in innovation and includes bio-sciences (genetics, biology, biotechnology) and bioengineering as areas to be prioritized.

v. Distinctions between Food and Feed Regulations:

According to existing regulations, food for human consumption containing GE-materials must be labeled but this is not enforced. There are no similar regulations for animal feed.

vi. Pertinent and Pending Legislation:

In February 2009, Ecuador's legislative body approved a Food Sovereignty Law aimed at regulating the use of biotechnology. This law is vague and does not provide any specifics on the use of biotechnology in agriculture. It is expected that Ecuador's new National Assembly will consider a new draft law to be sent by the Office of the President in the next several months.

Other national laws such as the Health Code, the Consumer Rights Protection Law, the Agricultural Development Law, the Law of Seeds, and the Plant and Animal Health Law are of general applicability but do not provide specific guidance on biosafety issues.

In 2013, Ecuador's Ministry of Agriculture has started drafting its own bill to protect biodiversity and regulate production of crop seeds. The bill will norm research, production and imports of seeds. In 2011 the Ministry of Environment advanced the design of an awareness program which falls under the framework that Cartagena Protocol signatories agreed to in Nagoya. This program included several activities aimed at strengthening and developing communication and information tools.

b) Labeling: The Law for Protection of Consumer's Rights

This law, enacted on July 10, 2000, regulates the supplier-consumer relationship by promoting knowledge and protection of consumer's rights. It has a clause by which ambiguous dispositions should be interpreted to favor the consumer. The public entity in charge of enforcing this law is the Office of the Ombudsman. However, little or nothing has been done to exercise such enforcement. This Law leaves room for specific laws to regulate health and safety issues. This is currently the only law in place that deals with biotechnology labeling.

Regarding Biotechnology, articles 13 and 14 of this law state that "in the case of products sold for human or animal consumption that had been produced using biotechnology or any type of genetic manipulation, labels must warn of this fact using highlighted characters" and provide labeling requirements for genetically engineered food products. This regulation is not being enforced.

c) Imports of Vegetable Materials and Animals: Laws of Animal and Plant Health

Article 4 of the Plant Health Law establishes that any import of plant materials for propagation, including those used for research, must be authorized by the Ministry of Agriculture. In the case of animals used for genetic improvement, the Animal Health Law provides requirements and authorizations from the Ministry of Agriculture, and establishes the obligation to comply with Andean regulations.

#### d) Authorized Biotech Foods: Rules for Sanitary Registration and Control

This regulation deals with the sanitary registration of national and imported food and beverage products for human consumption in Ecuador. Article 50 of this regulation makes reference to fines and penalties, which will be applied according to the dispositions of the Consumers Rights Protection Law.

Furthermore, article 54 mentions that biotech and/or GE foods will only be authorized to enter Ecuador when such products comply with the requirements of the Ministry of Health, which would issue a positive list of transgenic products authorized for import. Such a list does not exist.

#### e) Food Sovereignty Law 2009

The main objective of this law is to promote and provide access to food and nutrition and agricultural land. It declares food security as a primary national policy and creates the inter-ministerial “National System of Food Sovereignty and Nutrition” and the “National Food Sovereignty Conference.” The Law is based on Constitutional principles that guarantee people’s rights. The Law is not technical and limits its ruling to broad and vague principles.

Article 26 declares Ecuador free of GE materials. It mentions that the introduction of GE seeds and crops will only be possible in the case of national interest which must be recognized by the Office of the Presidency. The state is given the authority to regulate the use and development of modern biotechnology and its products, as well as experimentation, use, and commercialization. The use of risky or experimental application of biotechnology is forbidden, although no definition of risky or experimental is given.

Article 26 also mentions that raw materials that contain transgenic ingredients can be imported and processed only when they fulfill health and safety requirements, and that they are not able to reproduce, while respecting the precautionary principle so that they do not threaten human health, food sovereignty and the ecosystem. It adds that products processed using GE materials must be labeled according to the law that regulates consumer rights. This is the most controversial part of this law. While it requires importers to only bring in material that cannot be reproduced, it also requires that food sovereignty and ecosystems be taken into consideration. Additional laws and regulations on biodiversity, biotechnology, usage and commercialization of biotechnology products, animal health, seeds, plant health are mentioned as the set of norms that will establish the mechanisms of food safety and the instruments that will guarantee respect to the Rights of Nature and the production of safe foods while establishing preferred treatment to micro-entrepreneurs, microenterprises or micro and small and medium size producers.

This is not the first time that a law like this has been issued. In May 2005, after the passage of a similar law, the Ministry of Agriculture stopped imports of soybean meal and soybean oil for three weeks. This caused great difficulties for the poultry, animal feed, cooking oil, and tuna canning industries. Even though the provisions of this law were initially enforced, a technical error found in the text gave Ecuador’s Attorney General enough reason to declare the bill unenforceable. Since then, trade has flowed normally and there have not been any reports of shipments being stopped or import permits being denied as a result of this regulation.

f) *The Health Code*

As a continuation of the push against biotechnology, Ecuador's Congress passed a new Health Code law in December 2006. This is a general law dealing with the protection of human health, and includes provision on matters of food safety. This bill literally reintroduced the provisions of the Food and Nutrition Security Law and corrected its technical errors. However, it does not resolve the issue of Ecuador's lack of capacity to determine the safety of food products derived from biotechnology. The Law also leaves the implementation of its biotechnology-related dispositions to the application of rules that are still to be issued.

The Ministry of Health has the lead in drafting rules for this law, which cannot be fully enforced without them. For this reason, imports of food products have continued normally, and the Ministry of Agriculture has not issued a position on the matter. These rules are not likely to be available anytime soon.

g) *Timelines for Approvals:*

No approval process exists at this time.

h) *Approvals:*

Ecuador's regulations have not framed the process to approve GE traits. Anecdotally, Ecuador's Ministry of Agriculture conducted a favorable risk analysis for the introduction of GE carnations for cultivation in greenhouses in the mid-1990s. However, no records exist that imports of GE-carnations actually took place.

i) *Field Testing:*

Ecuador has allowed the development of cisgenic plants in controlled laboratory conditions only. There is no authorization for field testing at this time.

j) *Stacked Events:*

Ecuador has not determined how to deal with stacked events at this time.

k) *Additional Requirements:*

The establishment of requirements is still pending.



l) *Coexistence:*

Ecuador does not have a coexistence policy.

m) *Labeling:*

In accordance with the Law for Protection of Consumer's Rights, enacted on July 10, 2000, products sold for human or animal consumption that had been produced using biotechnology or any type of genetic manipulation must be labeled as GE-products using highlighted characters." This regulation is not being enforced. There are no products in the Ecuadorian market, whether imported or locally produced, that contain labels declaring GE content. In the last few years, however, a producer of "organic" and "all natural" products including breakfast cereals, syrups, baked products and other ready-to-eat snacks has used labels to refer to the content of GE materials in its products, basically labeling them as "non-GE." Ecuador's National Standards Institute only includes the labeling of GE materials as a voluntary requirement.

n) *Trade Barriers:*

Although existing legislation makes the introduction of GE crops possible only under exceptional circumstances to the discretion of the President of Ecuador and when it is of national interest, imports of GE crops have taken place normally.

o) *Intellectual Property Rights (IPR):*

Ecuador's legislation allows the registration of plant varieties. New varieties developed using public funds are considered public goods and no royalties are collected. Private breeding and seed companies can register their varieties and charge royalties to growers. From time to time, government officials come out publicly against growers having to pay royalties to foreign breeding companies but their intention to abolish royalty payments has not materialized as they realize it would be detrimental to the export sector.

p) *Cartagena Protocol Ratification:*

On the international front, as a signatory of the Convention on Biological Diversity and the Cartagena Protocol on Biosafety, Ecuador is obliged to issue policies and regulations in accordance with the precepts of these international agreements.

q) *International Treaties/Fora:*

As a member of the Andean Community of Nations, Ecuador is subject to Andean Decision 523, which

states an Andean Strategy on Biodiversity must be taken into account by all members when issuing their regulations on biosafety. There are no other internationally recognized fora in which Ecuador participates at this time.

r) *Related Issues:*

Continued application of the Precautionary Principle in Ecuador is likely to create further trade controversies.

s) *Monitoring and Testing:*

Ecuador does not have any official monitoring and testing protocols. In the last few years, environmentalist groups have taken on testing corn fields and soybeans at grocery stores using rapid band-type tests. Results from corn fields have shown that there are not GE materials. Results for soybeans have not been made public yet.

t) *Low-Level Presence Policy (LLP):*

Ecuador does not have a low-level presence policy. Government officials have indicated that they favor the establishment of a LLP but oppose a zero-tolerance approach.

## **PART C: Marketing**

a) *Market Acceptance:*

The use of biotechnology in food is a new topic for discussion in Ecuador. The majority of consumers are not aware of the existence of food products derived from the use of biotechnology, and in a country with abundant patches of food insecure regions, this may not be an issue of major concern to the poor and struggling majority.

b) *Public/Private Opinions:*

Environmental and indigenous groups are fully aware of the issue of foods derived from biotechnology, and although they lack scientific evidence on the implications of such technology, they have pushed and succeeded, at least in paper, that biotech-related products be either labeled or advertised as such, as a “requirement to preserve this country’s mega-biodiversity.”

c) *Marketing Studies:*

In 2008, Ecuador’s Ministry of Environment published a study of public acceptance of GE organisms,

biotechnology and biosafety. The survey results showed that 76 percent of the population were not familiar with the concept of genetically modified organism and 88 percent were not familiar with the concept of transgenic organism. The report can be found here:

<http://web.ambiente.gob.ec/sites/default/files/archivos/PUBLICACIONES/BIOSEGURIDAD/Documentos/tostecnicos/percepcionpublica-orggeneticamentemodificadosbiote.pdf>

## **PART D: Capacity Building and Outreach**

### *a) Activities:*

Even with the lack of accurate information about biotechnology within Ecuador, several activities related to biotech capacity building and outreach has been carried out by government institutions and industry. FAS/Quito has also been active in the past few years on issues related to promoting biotechnology and agricultural research. In October 2008, FAS Quito representatives attended a conference on agricultural biotechnology which intended to start the process to define a strategy to address biotechnology and environmental issues on agriculture. In August 2009, FAS/Quito organized six outreach conferences on biotechnology. Attendees included government officials and academics, as well as university students. In 2010 FAS/Quito organized two workshops, one in Quito and one in Guayaquil, for journalists on how to communicate to the public biotechnology-related topics.

In 2011, FAS/Quito sponsored a mission of Ecuadorian journalists to the United States to learn more about the process to reengineer crops and the experience of farmers using this technology.

FAS/Quito often participates in seminars on biotechnology in agriculture to college students and faculty. In 2010 and 2011, FAS Quito continued its series of conferences at higher education institutions on the issue of Biotechnology in World Agriculture.

In 2012, FAS/Quito partnered with one of Ecuador's regional Farm Bureaus and co-sponsored training events directed to more than 200 farmers, policymakers, and general public with the participation of two well-known scientists, one from Brazil and one from the United States.

In 2013, FAS/Quito is partnering with IICA and INIAP to provide training to Ecuadorian technical officials and farmers on risk assessment and biodiversity.

FAS/Quito has also made use of Cochran Fellowships and scientific exchanges to educate policymakers, scientists, and others through short training courses on biotechnology, food safety and biosafety issues.

### 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 leaders, technicians, academics, and producer association representatives.

Ecuador's ESPOL International Congress on Biotechnology and Biodiversity is likely to become the main venue to discuss scientific advances in Ecuador. The first Congress took place in May 2012 and

the second edition is scheduled for mid 2014. The meeting is organized by ESPOL's Biotechnology Center (CIBE). The scientific Congress focused on using modern biotechnology to tackle plant diseases in fruit production without risk to Ecuador's biodiversity. CIBE has authorization from the Office of the President to conduct research that uses biotechnology.

b) *Strategies and Needs:*

Opportunities exist to assist Ecuador in strengthening the institutional capacities to establish and enforce regulations based on science and international standards. These opportunities include scientific exchanges, training and capacity building, as well as technology transfer.

## **CHAPTER 2: ANIMAL BIOTECHNOLOGY**

### **Part E: 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. Regarding cloned animals, Ecuador does not currently have a system to monitor the imports of GE animals, the offspring of clones, or genetics from cloned animals.

### **Part F: Policy**

a) *Regulation:*

It is important to note that Ecuador's 2008 Constitution severely limits the possibilities to grow GE plants or conduct research on GE plants. However there is no mention of limitations on biotech animals.

b) *Labeling and Traceability:*

No labeling and traceability requirements have been established at this time.

c) *Trade Barriers:*

No trade barriers have been identified at this time.

d) *Intellectual Property Rights (IPR):*

Ecuador does not currently have IPR regulation specific to biotechnology.

e) *International Treaties/Fora:*

Ecuador does not officially support international groups that either support or oppose GE animals or cloning.

## **PART G: Marketing**

a) *Market Acceptance:*

There are no studies assessing consumer acceptance available at this time.

b) *Public/Private Opinions:*

Neither government nor private opinions have been made public.

c) *Market Studies:*

There are no market studies available at this time.

## **PART H: Capacity Building and Outreach**

a) *Activities:*

No activities have been performed.

*Strategies And Needs:*

No strategies or needs assessment has been performed.