USDA Foreign Agricultural Service
GAIN Report
Global Agricultural Information Network

Required Report - public distribution

Date: 6/29/2012

GAIN Report Number: EC1209

Ecuador

Agricultural Biotechnology Annual

2012 Ecuador Biotechnology Report: Policy, Trade, Marketing of Genetically Engineered (GE) Crops

Approved By:
Emiko Purdy
Prepared By:
Henry Vega

Report Highlights:
Ecuador maintains a number of anti-biotech laws and regulations, but there is no enforcement and trade in corn and soybean products continues. However, this situation can change quickly. Ecuador's National Assembly will likely consider a controversial Bill of Agri-Biodiversity during the second half of 2012, which could effectively restrict imports of genetically modified crops. Efforts are needed to strengthen the institutional capacities to establish and enforce regulations based on science and international standards. On the other hand, in recent years, Ecuadorian public and private research institutions have increased their activities related to agri-biotechnology.

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. 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 National Assembly will consider a very controversial Bill of Agri-Biodiversity in the second half of 2012. In the interim, imports have continued normally.

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 organisms (GEOs). The regulation initially created trade problems with soybean meal and soybean oil imports, but backlash from the industries that use these products as inputs has led the government to drop any enforcement measures. As Ecuador imports about 30 percent of its corn demand, 90 percent of cotton, and 95 percent of soybean meal and oil, these products have been entering with no restrictions or review.

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 has made some progress toward the implementation of National Biosafety Framework. The design of an awareness program, which falls under the framework that Cartagena Protocol signatories agreed in Nagoya last year, has started.

In the last few years, Ecuador's public research institutions, due to increased levels of government funding, and private university 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. BIOTECHNOLOGY TRADE AND PRODUCTION

Traditionally, Ecuador's Institute for Agricultural Research (INIAP), the main venue for agri-biotechnology research, has claimed that given the incipient technology and infrastructure available, Ecuador does not have the capacity to conduct any GEO-related research. As a consequence, INIAP's research has focused on improving the quality of seeds through hybrids for cocoa, potatoes, tomato, corn, rice and soybeans. However, a 2008 Inter-American Institute for Cooperation in Agriculture (IICA) assessment of agri-biotechnology in Latin America suggested that Ecuadorian laboratories have the capability to produce transgenic plants. Indeed, a 2009 INIAP assessment of its own capacities as well as other biotechnology laboratories across Ecuador suggests that public and private interest in biotechnology research has increased tremendously in the last few years. According to INIAP, the first biotechnology laboratory in Ecuador opened in 1978. From then until 1998 the number of biotechnology labs has 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.

The increase in the interest in biotechnology likely responds to demand conditions for tissue culture and somatic embryogenesis, molecular biology applications and diagnosis. In the last year, 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 larger extent include the flower sector, the banana and cacao sectors, as well as the aquaculture industry.

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, biosafety, among others. Ecuador's ESPOL has expressed interest to Post in collaborating 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.

Given the nonexistence of a framework to regulate biotechnology, Ecuador does not allow the importation of seeds containing GEOs. According to the Ministry of Agriculture, all seeds used for corn, soybean and other crops are either hybrids developed by the INIAP or other certified imported seeds that do not contain GEOs, and which must have passed through a rigorous in-country certification process. Existing law, however, does not properly specify or authorize any government agency to conduct such certification process due to a typo in the text of the law appearing in the National Register.

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

- Presently, Ecuador imports 30 percent of its corn demand. Imports reached more than 500,000 MT in 2011.
- Ecuador purchased more than ninety percent of its cotton needs from foreign sources in 2010, of which 75 percent came from the United States.
- Soybean meal and oil imports are also rising, with Argentina as the traditional main supplier. However, depending on prices, Ecuador purchases significant volumes of soybean meal from the United States. Imports of soybean meal reached more than 550,000 MT in 2011.

As seen from the figures above, Ecuador currently sources high percentages of its corn, cotton and soybean requirements to fulfill its meal 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 self supply this demand 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.

SECTION III. BIOTECHNOLOGY POLICY

Ecuador has developed in recent years 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 a product of national interest such as is the case of bananas. In the biosafety debate over genetically engineered crops, Ecuador has remained incapable of submitting enough scientific evidence about the possible risks of the use of biotechnology as a way to justify restrictive trade measures against biotech foods. However, it is clear that Ecuadorian authorities are worried about the issue of "dependence" from foreign technologies and imports of certain products, such as planting seeds and oilseeds. There is also an increased fear from 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, Post understands that producers are highly aware of the benefits of improved seeds, brought illegally into the country from Argentina and Brazil, which may have already been planted by some farmers.

Regulatory Framework Background and Ecuador's 2008 New Constitution

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 GEOs. 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. However, 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. 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. This law is vague and does not provide any specifics on the use of biotechnology in agriculture. It is expected that Ecuador's National Assembly will consider at least one additional law or ruling regarding seeds and agricultural research in the framework of protecting the country's biodiversity. In the interim, imports

continue normally. Interested private sector industries continue to work with Ecuadorian authorities to develop implementing regulations that would not impede trade in products derived from biotechnology.

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 could be significantly reduced.

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. Many of these laws are to be revised and approved by Ecuador's National Assembly in the future.

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. Also, as a member of the Andean Community of Nations, Ecuador is subject to Andean Decision 523, which states an Andean Strategy on Biodiversity that must be taken into account by all members when issuing their regulations on biosafety.

In 2012 Ecuador's National Assembly's Intercultural Council on Food Sovereignty has proposed language for a "Law of Agri-Biodiversity" that would mandate control of products derived from biotechnology, ban research efforts, and unjustifiably block imports. The proposed law will be introduced for consideration of the National Assembly's Commission on Food Sovereignty in mid July.

Specific Laws dealing with Biosafety and Biotechnology

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, article 13 and article 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.

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.

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 GEO 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. It is not apparent when Ecuador's National Assembly will address the issue.

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 GEOs. 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 transgenics 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. Industry groups are expected to continue to exert pressure on the Government of Ecuador to ensure any additional norms address their concerns and that trade will not be disrupted.

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. Affected private sector industries plan to work with Ecuadorian authorities to develop implementing regulations that would not impede trade in products derived from biotechnology.

Recent Developments

In the last year, Ecuador's Ministry of Environment has started initial work toward developing a regulatory framework to address the use of biotechnology. However, due to administrative and operational limitations, progress has been delayed. In 2011 the Ministry advanced the design of an awareness program which falls under the framework that Cartagena Protocol signatories agreed to in Nagoya last year. This program includes several activities aimed at strengthening and developing communication and information tools. Government agencies have also started the process of hiring experts to assist in the reorganization and definition of the National Biosafety Framework. There are five government agencies involved in this effort: Ministry of Industries and Productivity, Ministry of Foreign Affairs through its Office of the Environment, the Secretariat of Science and Technology, Ministry of Public Health, and the Ministry of Agriculture through its Animal Health and Plant Inspection Service (AGROCALIDAD) and INIAP.

The National Assembly's Intercultural Council on Food Sovereignty has just submitted the Agri-Biodiversity Bill that will start being debated by the National Assembly's Commission on Food Sovereignty in mid July. A vote would be expected 45 days later. A revision process is possible but the law could be finalized by November 2012. The draft bill proposes the creation of The National System for Ecuador Free of Transgenic Crops and Seeds, entity that will coordinate with customs and border controls, ports and airports, to provide logistical and operational mechanisms needed to prevent entry to the country of transgenic crops and seeds. The bill as very serious criminal offenses: a) To have, exchange, produce, market genetically modified seeds and crops; b) To import or export genetically modified seeds and crops. Those who engage in these activities either by action or omission will be punished with a fine equivalent to 2,000 times Ecuador's mandatory monthly wage ($292) and the offender will be subject to civil or criminal action as appropriate.

SECTION IV. MARKETING ISSUES

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. However, environmental and indigenous groups are fully aware of the issue, and although they lack scientific evidence on the implications of biotechnology, 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." Ecuador's National Standards Institute only includes the labeling of GEOs as a voluntary requirement. In addition, continued application of the Precautionary Principle in Ecuador is likely to create further trade controversies.

There is no specific information related to the market acceptance of biotech foods. However, it is believed that if the existing regulation is enforced requiring biotech products special labels "alerting" of presumable harmful characteristics, a considerable portion of Ecuadorian consumers will certainly reject them. There are no products in the Ecuadorian market, whether imported or locally produced, that contain labels declaring GEO content. In the last year, however, a producer of "organic" and "all natural" products including breakfast cereals, syrups, baked products and other ready-to-eat snacks has started using labels to refer to the content of GEOs in its products, basically labeling them as "non-GEO."

SECTION V. CAPACITY BUILDING AND OUTREACH

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.

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.

Further efforts are being made to continue with this type of assistance.

Government of Ecuador's Outreach Efforts

INIAP researchers organized a seminar on biotechnology in the Amazon region in June 2011. The objective of the seminar was to promote and assess the opportunities for using biotechnology in the agricultural sector of the Amazon region. The seminar was attended by farmers, exporters, agribusiness leaders, technicians, academics, and producers associations of the Amazon region. The seminar did not include the applicability of genetic engineering to improve the region's crops.

Ecuador's ESPOL hosted the I International Congress on Biotechnology and Biodiversity in May 2012. The meeting was 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. Three USDA scientists attended. The Congress was sponsored by Ecuador's Association of Banana Exporters and was held simultaneously with the IX International Banana Forum, the Western Hemisphere's largest gathering of the banana industry. Both events had participants from more than 20 countries. CIBE scientists presented their first cisgenic plant produced using genetic engineering techniques to transfer specific genes from disease-resistant banana varieties into the commercial Cavendish banana.