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El Salvador

Agricultural Biotechnology Annual

Regulatory Framework for Genetically Engineered Plants Completed

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Report Highlights:

On April 30th 2008, El Salvador abolished Article 30 of the Planting Seed Law that required imported seeds to have a phytosanitary certificate with an additional declaration stating that the seeds did not contain GE organisms. El Salvador ratified the Cartagena Protocol in 2003. The Environment Law, effective since 1998 provides guidance on assessing the environmental impact of GE organisms.

There is no legal impediment to use of biotechnology. Genetically engineered (GE) corn field trials have been successfully completed. The Ministry of Environment has completed the regulatory framework for their safe use and commercialization after working on it for the past 8 years.

However, the current government administration so far has shown little interest in advancing biotechnology mainly due to ideological positions against it.

Section I. Executive Summary:

El Salvador is a net food importer. White corn, red kidney beans, and rice are the major food staples. The United States is the main supplier of yellow corn for animal feed, rice, wheat, vegetable oil, tallow, soybean meal and cotton, among other products.

Currently there are no restrictions on imports of agricultural biotech products. The only law that regulated trade of biotech products was the Planting Seed Law that went into effect in 2001. Title IV of the Law (Chapter I, Article 30) stated that it was prohibited to import, investigate, produce or commercialize GE seeds. Due to pressure from the private sector and to rising food costs, the Government of El Salvador (GOES) abolished Article 30 in 2008 (Please see Chapter 1, Part B: Plant Biotechnology Policy).

The other law that addresses biotechnology is the Environment Law, effective since May 1998. Article 21 Paragraph " \tilde{N} " of this law provides regulations for carrying out environmental impact studies to determine if GE organisms are harmful to the environment and Article 68 provides guidance on procedures to create bio-safety norms. El Salvador ratified the Cartagena Protocol in 2003.

El Salvador has a developed biotechnology regulatory system. From 2002 to 2004, the Ministry of Environment conducted a project to define the legal framework to regulate GE organisms and to define intergovernmental coordination between the Ministries of Agriculture, Environment, and Health. The project was financed by the Global Environment Fund (GEF) and the United Nations Environment Program. In 2011, the Ministry of Environment launched the second phase of the GEF program with a four-year project on "Safety of Modern Biotechnology". The implementation of this project has been extended until March 2018 (Refer to Chapter 1, Part B: Plant Biotechnology Policy).

The GOES administration that was in office from 2004 to 2009 made a proposal for a Special Ruling for the safe use and commercialization of GE organisms that was to be presented to the National Assembly for approval and ratification. Once this step was accomplished, a Biosecurity Committee was to be created to assure compliance with the ruling (Please see Section III. Plant Biotechnology Policy). Thus far, progress has been made and the Special Ruling is only pending a revision of Article 26 (Imports and Transfer of GE organisms destined for human consumption or animal feed, or for further processing) by the Ministries of Agriculture and Health.

The main applications for biotechnology have been in the cultivation of vegetable tissue and propagation of in-vitro vegetable materials. The National Center for Agricultural and Forestry Technology (CENTA) of the Ministry of Agriculture (MAG) is the main government institution offering tools to develop improved crop varieties. CENTA has mainly focused on creating improved white corn, rice, and red kidney bean varieties to increase productivity.

The National Food Commission composed of the Ministries of Agriculture, Environment and Health has formulated a proposal for the "Special Ruling for Food Safety of Modern Biotechnology Derived Products" with the objective of complying with Article 11 of the Cartagena Protocol. MAG created an Institutional Biosafety Commission to formulate proposals for the registration of agricultural inputs derived from biotechnology, including the creation of proposals for special rulings.

The Ministry of Environment created the Scientific Committee for Biosecurity in 2009. The committee will serve an advisory role and is composed of representatives from the Ministries of Agriculture, Environment, and Health, the Chamber of Agriculture (CAMAGRO), the Agricultural Input Association (APA) and the National University. However, this Committee has not met in the eight years of its existence because of a lack of regulations outlining the function of the committee.

Even though the current GOES administration (2014-2019) is working on getting all the procedures completed, there is political and ideologically-inclined opposition to the use of the technology.

Section II. Author Defined: Section II. PLANT AND ANIMAL BIOTECHNOLOGY

CHAPTER 1: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

a) PRODUCT DEVELOPMENT: Not applicable.

b) COMMERCIAL PRODUCTION:

El Salvador does not produce any biotech crops and there are no crops under development that would be in the market in the coming year. El Salvador does not produce biotech crops developed outside the United States that have not passed through the U. S. regulatory system. El Salvador, however, does import biotech products mainly from the United States: yellow corn, white corn, soybean meal, cotton, and corn-soy blend.

c) EXPORTS: Not applicable.

d) IMPORTS:

There are no obstacles to importing/marketing genetically engineered (GE) crops and processed products in El Salvador at this time. Being a densely populated developing nation, El Salvador must rely on imported food to satisfy local demand. El Salvador is dependent upon imported soybeans, soybean meal and yellow corn as feed protein sources. The United States is the main trading partner for El Salvador and U.S. products are regarded as being of higher quality and safer than others available in the market.

e) FOOD AID:

El Salvador has been a food aid recipient for the past decade and continues to receive food assistance from the United States and Europe. Wheat, soybean meal, yellow corn, rice and vegetable oil are the main commodities sent to El Salvador as food assistance.

f) TRADE BARRIERS:

In 2012 and again in 2013, El Salvador's National Assembly passed Decree 198 "Special transitional provisions to develop the production of certified corn and bean seeds" for seed used in the Presidential Agricultural Package Giveaway Program.

This decree stated that only local producers can participate in the provision of certified corn and bean seeds for the Package Giveaway Program managed by the Ministry of Agriculture.

The primary concern was that a number of provisions in the decree were not consistent with the government procurement obligations of the CAFTA-DR, specifically Chapter 9.

Since the 2015 program, the GOES made the necessary changes to the decree in order to comply with CAFTA-DR procurement provisions.

There are no other additional biotechnology-related trade barriers that negatively affect U.S. exports.

PART B: POLICY

a) REGULATORY FRAMEWORK:

The regulatory framework for agricultural biotechnology has been completed. Through the first phase of the GEF-funded project, the GOES wrote a proposal for a regulatory framework that includes national policy for biotechnology and bio-safety, an administrative and regulatory system for imports of GE products, a decision making support system, and a mechanism for social participation and consultation. Public consultations concluded nine years ago and a "Special Ruling for the Safe Handling of GMOs," to provide an environmental permit for any activity or project that implies genetic handling or production of GE products was published in the Official Gazette on July 1, 2008.

The initiative is a complement to the creation in 2003 of the National Bio-safety Commission composed of members of the Ministries of Agriculture (MAG), Environment and Public Health (MSPAS), the National Commission for Science and Technology (CONACYT), and private sector representatives. An additional effort has been the creation of El Salvador's Biotechnology Clearing House (BCH-El Salvador), available at the MARN's web site <u>http://www.marn.gob.sv/</u>.

A \$1.0 million second phase of the GEF program that started in 2011 and was supposed to last 4 years has now been extended and is expected to be concluded by March 2018. The objective of this program is to implement a regulatory framework and strengthen the capacity of government agencies involved directly or indirectly with the implementation of the Cartagena Protocol. This program is expected to provide the following: a document with the results of an institutional capacity evaluation and proposal for an institutional framework, an instructive for application of the framework, including guidelines for technical rulings regarding consumption of GE organisms (for direct use as human food, animal feed, or for processing), a proposal for conformation and ruling of operation of the Scientific Committee for Biotech Safety, a flow chart for institutional channels, user guides and forms; and a proposal for a

digital information and administrative system.

Under the proposed regulatory framework, the Ministry of Environment would be the institution in charge of enforcing the safe handling of GE organisms and coordinating with MAG and MSPAS on appropriate bio-safety applications. Currently there is no list of approved biotech crops for food, processing, feed or environment.

b) APPROVALS:

There are no approved plants or crops for cultivation or exports in El Salvador. Imports of GE crops or processed products are not restricted.

c) STACKED or PYRAMIDED EVENT APPROVALS: Not applicable.

d) FIELD TESTING:

Field-testing of GE crops has been conducted. In 2008, two companies were authorized to import two varieties of GE corn for experimental field testing. A cost/benefit analysis carried out by the National Center for Agricultural Technology (CENTA) and by the Ministry of Environment was made public and provided positive findings. But there was no subsequent follow-up.

e) INNOVATIVE BIOTECHNOLOGIES: Not applicable.

f) COEXISTANCE: Not applicable.

g) LABELING:

El Salvador requires labeling for packaged foods mainly for health and consumer information. Nutrition facts and ingredient lists are part of the label. Labeling for food products that contain GEs is required under Article 128 of the Consumer Law; however, this rule is currently not being enforced. For additional information on labeling regulations please refer to El Salvador's Food and Import Regulations and Standards report at <u>www.fas.usda.gov</u>.

h) MONITORING AND TESTING: No testing at this time. MARN is monitoring planting fields in the North to discard involuntary introduction of GE corn from neighboring Honduras.

i) LOW LEVEL PRESENCE (LLP) POLICY: No LLP policy.

j) ADDITIONAL REGULATORY REQUIREMENTS: Not applicable.

k) INTELLECTUAL PROPERTY RIGHTS (IPR): Not applicable.

1) CARTAGENA PROTOCOL RATIFICATION:

El Salvador signed and ratified the Cartagena Protocol on April 23, 2003. There is no impact on trade at this time because of Protocol rules.

Progress towards implementing biotechnology laws and regulations has been slowed by a lack of access by the legislative branch to scientific information about biotechnology. Until recently, political party agendas affected the ability of the government to obtain approval from the National Assembly for new government policies.

In addition, El Salvador still has many gaps in the National Administrative and Regulatory System to be able to respond to the current challenges presented by the movement across borders of modern biotech products, especially with respect to the permit requests, their movement through the proper channels and the authorizations to carry out activities with biotechnology.

At this time, only the Ministry of Environment is partially complying with the obligations of the Cartagena Protocol and there is lack of coordination among competent institutions to respond to permit requests for the access of GE plants and animals to the country.

m) INTERNATIONAL TREATIES/FORA:

Due to lack of resources El Salvador does not participate in international fora such as the International Plant Protection Convention (IPPC) or the Codex Alimentarius (Codex) discussions related to GE plants.

n) RELATED ISSUES:

CropLife has been active in El Salvador to raise public awareness of biotechnology in general. In 2012, this institution carried out an outreach activity where members of the National Assembly's agricultural commission had the opportunity to get a presentation form an expert on GE crops and how introducing the technology would assist El Salvador to deal with issues such as pests, low yields and lack of profitability for farmers.

CropLife has also held meetings with Salvadoran academia, Ministry of Education's Science and Technology Division, Ministry of Agriculture Technology Transfer Division (CENTA) and legal advisors of the Ministry of Environment. The objectives of these meetings were to raise awareness of GE crops and products and also to present the progress made in Central America regarding biotechnology.

PART C: MARKETING

a) PUBLIC/PRIVATE OPINIONS:

Sometimes local environmental NGOs publish articles in written media to oppose GE products. Lack of general public familiarity with the GE technology or science does not help to improve the public perception.

b) MARKET ACCEPTANCE/STUDIES:

There are no obstacles to marketing biotech products in El Salvador at this time. Being a densely populated developing nation, El Salvador must rely on imported food to satisfy local demand. The United States is the main trading partner for El Salvador and U.S. products are regarded as being of higher quality and safer than others available in the market.

Biotechnology is not a main priority of the government and consuming public, and food safety issues that could affect product marketing are more related to food borne diseases.

CHAPTER 2: ANIMAL BIOTECHNOLOGY

PART D: PRODUCTION AND TRADE

a) PRODUCT DEVELOPMENT:

There is no legislation or regulations in place at this time related to the development, commercial use, import and/or disposal of genetically-engineered animals or products derived from these animals. The relevant government entities that might have a role in the regulation of the genetic engineering of animals would be the Ministry of Agriculture, the Ministry of Environment, and the standard setting body National Center for Science and Technology (CENTA). There are no active organizations that lobby for or against the genetic engineering of agriculturally-relevant animals. However, there is a group of NGOs such as CESTA and UNES that generally oppose any type of genetic engineering or biotechnology. El Salvador does not actively participate in discussions related to the genetic engineering of agriculturally-relevant animals in international organizations mainly due to the lack of funds for this type of activities.

- b) COMMERCIAL PRODUCTION: Not applicable.
- c) EXPORTS: Not applicable.
- d) IMPORTS: Not applicable.
- e) TRADE BARRIERS: Not applicable.

PART E: POLICY

- a. REGULATORY FRAMEWORK: Not applicable.
- a. INNOVATIVE BIOTECHNOLOGIES: No regulation at this time.
- c) LABELING AND TRACEABILITY: Not applicable.

- d) INTELECTUAL PROPERTY RIGHTS (IPR): Not applicable.
- e) INTERNATIONAL TREATIES/FOR A: Not applicable.

PART F: MARKETING

a. PUBLIC/PRIVATE OPINIONS:

See part C: Plant Biotechnology Marketing.

a. MARKET ACCEPTANCE/STUDIES:

There is little to no awareness of GE animals among the Salvadoran public. GE animal biotechnology is not a high priority in the local political agenda.