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# GAIN Report

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**Date:** 10/18/2018

**GAIN Report Number:** GT1810

## Guatemala

### Agricultural Biotechnology Annual

**2018**

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**Report Highlights:**

On May 29, 2018, Guatemala sent its draft biotechnology regulation to the World Trade Organization (WTO). The same draft regulation was notified by Honduras on June 5, 2018. Both countries have agreed to harmonize their Genetically Engineered (GE) regulation under the Guatemalan-Honduras Customs Union framework. Both countries have received national and international comments and will be jointly preparing responses. The final regulation will be approved through the Ministry of Economy in Guatemala and the Secretariat of Economic Development in Honduras, as the Customs Union dictates.

**Executive Summary:**

Guatemala presently regulates GE plants through Ministerial Decree 386-2006. This regulation has been in place since 2006 and although it allows for field trials and commercial seed exports, no seed company has ever applied for commercial exports. Four field trial petitions have been made: two for corn, one for cotton, and one for papaya. Corn and cotton were approved for field trials. The field trials for corn were successful. The field trial could not progress to a commercial phase because present regulations do not allow for commercial production.

The draft GE regulation submitted to the WTO by Guatemala and Honduras seeks to harmonize the testing and commercialization of GE plants and animals. Both Guatemala and Honduras are signatories to the Cartagena Protocol, and the draft regulation is a reflection of the text proposed by the Protocol.

The final regulation needs to be approved by the Ministry of Economy in Guatemala and the Secretariat of Economic Development in Honduras. The new regulation is not intended for innovative biotechnologies.

Guatemala, as a WTO member, supported the recent “International Statement on Agricultural Applications of Precision Biotechnology in Geneva at the World Trade Organization (WTO) Committee on the Application of Sanitary and Phytosanitary Measures” on November 2, 2018.

The international statement was led by Argentina, with the support of Australia, Brazil, Canada, Colombia, the Dominican Republic, Honduras, Jordan, Paraguay, the United States, Uruguay, Vietnam and the Secretariat of the Economic Community of West African States. Guatemala looks forward to the possibility of innovate in agriculture through precision biotechnologies, considering those technologies should not be regulated as LMOs.

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## CHAPTER 1: PLANT BIOTECHNOLOGY

### PART A: Production and Trade

a) **PRODUCT DEVELOPMENT:** There is no legal cultivation of commercial GE crops in Guatemala. Local development is not permitted under the current regulations. There are no GE developments in the pipeline. More than 12 years ago, a ringspot resistant papaya was developed in the laboratory, but never received the approval for a greenhouse trial.

b) **COMMERCIAL PRODUCTION:** Guatemala has a de facto ban on GE crop cultivation. Although Guatemalan regulations allow for commercial production of GE seed for export, a difficult approval process for experimental trials has kept the seed industry from pursuing this route. Four traits were evaluated in the past 12 years for pest and herbicide resistance in corn and cotton. These evaluations have not advanced beyond the experimental phase because there is no regulation to approve commercial production. The last evaluation took place back in 2010-2011 for an herbicide and pest-resistant corn that is commercial in Honduras.

c) **EXPORTS:** Though Guatemala allows for GE seed exports, Guatemala has not produced nor exported any GE seeds.

d) **IMPORTS:** Guatemala is a net importer of animal feed. In 2017, Guatemala imported more than 1,055 metric tons (MT) of corn valued at \$214 million, of which 859,000 MT were imported from the United States: 831,000 MT of yellow corn and 27,000 MT of white corn. Corn is the most widely imported grain. All yellow corn goes to the feed industry. The food processing industry imports white corn. In 2017 the feed industry also imported roughly 367,000 MT of soybean meal from the United States. Soybeans and soy products are also used as a dairy-substitute in the food industry.

e) **FOOD AID RECIPIENT COUNTRIES:** Guatemala is a food-aid recipient country. It has the highest rate of chronic malnutrition in Latin America and among the five highest rates in the world. Guatemala receives roughly 1,800 metric tons of food aid from the United States each year. In-kind food donations consist largely of beans, corn-soy blend, rice, and vegetable oil, which are provided as school meals in some of the poorest municipalities.

f) **TRADE BARRIERS:** There is a *de facto moratorium* imposed on research and field trials of GE plants, creating a trade barrier and limiting agricultural productivity. Despite the interest of companies in the past to file petitions for field trials, the slow and bureaucratic procedures which may take more than one year to hear back from the Ministry of Agriculture, asking for more information and studies on local flora, or simply an administrative silence, has negatively impacted any interest on filing petitions. Field trials that have demonstrated effectiveness and shown no greater risk than conventional technologies have nonetheless been denied options for commercialization.

## Part B: Policy

a) REGULATORY FRAMEWORK: The Ministerial Agreement 386-2006 allows for field trials and commercial production of GE seeds for export only. The Guatemalan Ministry of Agriculture, Livestock, and Food (MAGA) is responsible for approving risk analysis conducted by the private sector or academia. The Institute of Agricultural Science and Technology (ICTA) in MAGA is responsible for verifying the on-site trial protocols proposed in the risk analysis. Even though the regulation complies with the Cartagena Protocol, in practice the process is lengthy and demands extensive studies to establish current levels of biodiversity.

Parallel to MAGA's authority, the Council of Protected Areas (CONAP), an office in the executive branch that answers directly to the president, oversees Presidential Decree 207-2014, which established the national policy on GE live organisms<sup>1</sup>. The policy acts as a disincentive to use biotechnology in agriculture and food production. Because of the policy, CONAP continues to assert authority of biotechnology over MAGA. The Stakeholders' Commission discussed the recently proposed regulation under the Guatemala-Honduras Customs Union framework on Biotechnology at the Council of Science and Technology (CST) and comments were submitted.

The proposed regulation to harmonize biotechnology use under the Guatemala-Honduras Customs Union framework is a reflection of the Cartagena Protocol text, focused on Living Modified Organisms, and distant from the former more technical regulation adopted by Honduras. Overall, the draft Biosecurity Technical Regulations of Living Modified Organisms for Agricultural Use appears to be overly restrictive of all living modified organisms (LMOs) when there are no documented adverse effects on biodiversity caused by the transboundary movement of LMOs and no evidence of safety issues in agricultural uses.

The proposal also introduces the need for a confined trial, field experimental, and pre-commercial trial, before attempting a commercial release. The petitions are subject to 270-day period, which are not clear as to the effective time and processes subject to such timeframe. Though an Article is included to consider simplified procedures, there is no explanation of the scope or mechanism. The regulation includes several concepts and criteria, which are not defined and leave ample room for interpretation. In addition, an Article on limitations to release LMOs in restricted areas is included, although there is no definition for restricted areas.

The national revision of the draft regulation is done through the Biotechnology Stakeholders' Committee, within the Secretariat for Science and Technology. This is an Ad Hoc Committee composed by representatives from the private sector, academia, and government. Although the committee's decisions are not binding, members of the Committee participate in other national forums, including the Ministry of Economy, which finally dictates the commercial policy. The draft regulation will go through a national revision with the Biotechnology Stakeholders' Committee and a joint revision with Honduras. The final regulation will go through the Ministers of Economy (COMIECO) resolution body, which is the authority for the approval of technical regulations within

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<sup>1</sup> Decree 207-2014 text in Spanish: <http://www.minfin.gob.gt/index.php/acuerdos-gubernativos/acuerdos-gubernativos-2014/1930-no-207-2014-acuerdo-gubernativo-marn-acuerdase-aprobar-la-politica-nacional-de-bioseguridad-de-los-organismos-vivos-modificados-2013-2023-formulada-por-conap>

the Customs Union and harmonization process within the region. The Ministries of Agriculture in both Guatemala and Honduras are responsible for the implementation.

b) **APPROVALS:** Guatemala has not approved any GE plant event for commercialization. The current regulation does not allow for commercial production of food for the domestic market. Although GE seed production for export is permitted, lack of clarity and a slow process have prevented it.

c) **STACKED or PYRAMIDED EVENT APPROVALS:** Ministerial Decree 386-2006 does not refer to pyramided or stacked events.

d) **FIELD TESTING:** In 2004, MAGA approved field trials of the YieldGard gene in corn for Lepidopteron resistance, and the Liberty gene in cotton for glufosinate-ammonium resistance, which were already deregulated events in the United States. The field trials were carried out successfully, but because of the slow overall regulatory process, the products were no longer of commercial interest to the farmers by the time the experimental field trials were authorized. University Del Valle of Guatemala (UVG) developed ring-spot resistant papaya that never received approval for testing in the field. From 2012 to 2013, Herculex corn (Bt resistance, and herbicide tolerant) was tested on the Southern coast of Guatemala. The Biosafety Committee approved the results of the trials given the reduction in pesticide application and weed control, resulting in positive agricultural impact without negative environmental impacts. Despite the promising results, commercialization is not yet an option. Field trial paperwork approval of the Herculex corn took almost two years.

In order to conduct field trials, interested parties must file a request with MAGA's Direction of Plant and Animal Genetics. The paperwork needs to include a risk analysis for the event and a botanic/biodiversity study for the crop. MAGA may consider additional requirements during the approval process prior to the approval, as it happened with approval of the Herculex field trial in 2012, when MAGA required an extensive study be done on the field-trial plot and surrounding areas to determine current species and risks for biodiversity.

e) **INNOVATIVE BIOTECHNOLOGIES:** Guatemala, as a WTO member, supported the recent "International Statement on Agricultural Applications of Precision Biotechnology in Geneva at the World Trade Organization (WTO) Committee on the Application of Sanitary and Phytosanitary Measures" on November 2, 2018. The international statement was led by Argentina, with the support of Australia, Brazil, Canada, Colombia, the Dominican Republic, Honduras, Jordan, Paraguay, the United States, Uruguay, Vietnam and the Secretariat of the Economic Community of West African States. Guatemala looks forward to the possibility of innovate in agriculture through precision biotechnologies, considering those technologies should not be regulated as LMOs.

f) **COEXISTENCE:** The subject of coexistence has not been addressed by policy or regulatory means though there is a widespread belief that organic agriculture strengthens biodiversity while GE plants harm biodiversity. At present, commercially available GE corn is most suitable for Guatemala's lowlands and not for the Western Highlands due to elevation. The lowland regions of Guatemala, mainly the Southern coast and the Northern department of Petén, have planted hybrid corn varieties for over 30 years and currently see the highest yields in the country. There are currently no GE corn options for the Western Highlands. Corn production in this area is marked by

the use of saved or creole seed, with drastically lower yields compared to hybrids. Guatemala produces non-certified and certified organic agriculture.

g) LABELLING: Guatemala is a member of the World Trade Organization (WTO) and participates in Codex Alimentarius. Guatemala largely implements Codex guidelines regarding food safety and standards. The food processing industry is openly opposed to the labeling of GE food products. The National Council of Protected Areas (CONAP) insists on labeling, but no regulation is in place.

h) MONITORING AND TESTING: Guatemala does not actively test for GE traits in imports or exports.

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

j) ADDITIONAL REGULATORY REQUIREMENTS: There are no additional regulatory requirements beyond GE crop field trial evaluation submissions. As explained in d) Field Testing, a biodiversity baseline can be required as part of the risk analysis.

k) INTELLECTUAL PROPERTY RIGHTS (IPR): IPR in Guatemala has gone through several amendments following the negotiation of free trade agreements. Because of such commercial engagement, Guatemala became a member of the International Union for the Protection of New Varieties of Plants (UPOV) in 2009. In October 2017, UPOV in Geneva reviewed Guatemala's law initiative, which, if approved by the Guatemalan Congress, could spur innovation in agricultural production.

l) CARTAGENA PROTOCOL RATIFICATION: The Guatemalan Congress approved the Cartagena Protocol in 2003 by Legislative Decree 44-03. The Protocol took effect in January 2005.

The point of contact for the Cartagena Protocol in Guatemala is the Technical Office for Biodiversity (OTECBIO), which is part of the Council of Protected Areas (CONAP). CONAP leads the "GMO Biosafety National Policy 2013-2023", officially through Presidential Decree 207-2014.

<sup>[1]</sup> The policy mandates CONAP to coordinate regulatory efforts with the different ministries, such as Ministries of Agriculture, Environment, and Health. CONAP has maintained an active social consultation process related to GE technologies applied to agriculture. Neither the Ministry of Environment nor the Ministry of Health have shown interest in the potential use of the technology.

Although CONAP coordinates the regulatory efforts on LMOs, the ministries keep their corresponding regulatory mandate, as CONAP is not a regulatory authority on agriculture, environment or health. The policy dictates that the Ministries are the competent authorities responsible for the establishment and implementation of their corresponding regulations.

m) INTERNATIONAL TREATIES and FORUMS: Guatemala is a member of the World Trade Organization (WTO), the World Organization for Animal Health (OIE), International Plant Protection Convention (IPPC), CODEX Alimentarius, and the International Union for the Protection of New Varieties of Plants (UPOV). Given budgetary constraints, Guatemala's participation in international fora is limited. Guatemala actively participates in the UN climate change meetings (COP) and CONAP attends the UN conference on biological diversity (COP-MOP). CONAP's position, which does not represent the country's position, is consistently aligned with a restrictive

approach towards GE plants and animals, following the precautionary principle and consistent with the Biodiversity Agreement and other related agreements.

n) **RELATED ISSUES:** Guatemalan farmers support the adoption of biotechnology, especially commercial corn producers. They point to a lack of competitiveness compared to their Honduran neighbors, ever more apparent with the new Guatemalan-Honduran Customs Union. Honduras has been producing higher quality corn (low grain damage with low aflatoxin and mycotoxin levels) and at lower prices for the past twelve years with the help of GE corn. Because of this, the Guatemalan food industry and corn flour producers prefer imported corn. The harmonization of both countries GE regulation will eliminate existing differences related to the access and use of the technology.

Fumonisin and aflatoxin levels in local Guatemalan corn are 10 to 50 times above world average levels. This issue of high mycotoxin levels in Guatemalan corn has not yet become a health concern for some sectors and there is no political will to address it. The World Health Organization recommends planting GE Bt maize for fumonisin control<sup>2</sup>. The Government of Guatemala is not considering this recommendation as an option, despite evidence<sup>3</sup> showing that stunting in Guatemala may be correlated with mycotoxin contamination in corn, the staple of the Guatemalan diet.

### *PART C: Marketing*

a) **PUBLIC/PRIVATE OPINIONS:** Opinions about biotechnology in Guatemala are divided. Science and agriculture faculties at the universities have publicly expressed their support for biotechnology. Political groups at the National University have opposed biotechnology, deferring to conservation and environmental groups. The government has not taken an official position aside from CONAP, whose mandate is for biodiversity conservation and considers biotechnology a threat.

b) **MARKET ACCEPTANCE/STUDIES:** Guatemala has not assessed market acceptance of GE plants or products used in the textile or food industries. The consumers are more concerned with food prices than the technologies used in its production.

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<sup>2</sup> World Health Organization publication No. 158 – “Improving Public Health through Mycotoxin Control”

<sup>3</sup> Ron Riley, USDA Agricultural Research Service, 2014



## CHAPTER 2: Animal Biotechnology

### PART D: Production and Trade

- a) PRODUCT DEVELOPMENT: Guatemala has no GE animal research or development.
- b) COMMERCIAL PRODUCTION: Guatemala has no production of GE animals.
- c) EXPORTS: Guatemala is not a GE animal exporter.
- d) IMPORTS: Guatemala has not imported nor shown interest in importing GE animals.
- e) TRADE BARRIERS: Unknown.

### PART E: Policy

- a) REGULATORY FRAMEWORK: Guatemala has not discussed GE animal regulation at a national level.
- b) APROVALS: Guatemala has not approved any GE animal.
- c) INNOVATIVE BIOTECHNOLOGIES: Guatemala has not discussed innovative biotechnologies.
- d) LABELING AND TRACEABILITY: Guatemala has not started to discuss GE animals, in general.
- e) INTELLECTUAL PROPERTY RIGHTS (IPR): Guatemala has no regulations in place for GE animal IPR.
- f) INTERNATIONAL TREATIES and FORUMS: As member of the WTO, Guatemala reports to the OIE and follows its guidelines. CONAP represents Guatemala at the COP-MOP meetings; MAGA eventually participates.
- g) RELATED ISSUES: Guatemala has a *de facto moratorium* on GE materials, including animals.

### PART F: Marketing

- a) PUBLIC /PRIVATE OPINIONS: Academia has shown interest in GE mosquitoes, in response to malaria control, but has not considered raising the inquiry with the government so far. Active organizations have not raised concerns on GE animals.

b) MARKET ACCEPTANCE/STUDIES: There are no assessments on potential market acceptance of GE animals.