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## **Panama**

### **Agricultural Biotechnology Annual**

#### **2016 Agricultural Biotechnology Report for Panama**

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**Report Highlights:**

Panama has made progress in animal biotechnology with the development of genetically enhanced (GE) salmon and has conducted field trials for GE mosquitoes to fight the Dengue virus and GE *Cochliomyia hominivorax* flies to fight Screwworm. Panama has also approved imports of GE corn seed for local production although none is currently being planted. Biotech development in Panama is not a current government priority which explains why there are still no established official regulations/policies on biosafety and biotechnology.

## Section I. Executive Summary:

Panama is a net food importer and the United States is by far its main supplier. In 2016, exports of U.S. agricultural, fish & forestry products to Panama exceeded \$694.1 million. The U.S-Panama Trade Promotion Agreement (TPA) entered into force on October 31, 2012. USDA estimates that the agreement, when fully implemented, will boost U.S. agricultural exports to Panama annually.

The most important U.S. products exported to Panama in 2016 were [i]:

Consumer Oriented foods.....	\$384.9 million
Grains in Bulk.....	\$132.1 million
Intermediate products (soybean meal, oil, flour, and seeds).....	\$129.4 million
Distilled Spirits.....	\$19.4 million
Forest products.....	\$16.5 million
Fish products.....	\$4.8 million

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[i] Data Source: U.S. Census Bureau Trade Data, Foreign Trade Statistics

The future looks bright for exports of U.S. food products as Panama's 2016 Gross Domestic Product (GDP) is \$52.13 billion with a growth rate of 4.4 percent. Panama has shown robust growth in a sustainable manner averaging 7.3 percent over the past 10 years. Due to the TPA between the United States and Panama, U.S. food products will have increased access to the Panamanian market at zero percent duties once tariff phase-outs run their course completely. The United States currently has a 60 percent market share of food products imported into Panama.

Panamanian consumers are demanding more “ready to eat products” or specialty food products such as confections, cheese, coffee, wines, beers, snacks, spices, ethnic, natural, organic, fat free, low sodium, lactose free, gluten free and more, which are the best prospects of U.S. exporters. Bulk agricultural products are also important particularly yellow corn and soybean meal for animal feed and wheat and rice for human consumption. Panama also imports a large amount of rice (approximately 182,388 metric tons annually) and, in recent years, the United States has held 97 percent of the imported rice market.

Domestic production and exports to the rest of the world has declined dramatically in the last 5 years due to overall contraction in the agricultural sector. Panama lacks a national agricultural policy although most agricultural associations and organizations are now urging the government to establish one so the sector can compete with growing imports.

Panama is a party to the Cartagena Protocol on Biosafety, as adopted by Law 72 of 2001. Panama signed the agreement on May 3, 2011 the Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress.

The Government of Panama (GOP) has delayed establishing regulations of the Law 48 of 2002, which created the National Commission of Biosafety for Genetically Modified Organisms (GMOs). Currently, the absence of clear procedures regarding the approval process and coordination among all the competent government agencies in charge of authorizing the import of GMOs into Panama has been

causing delays on the approval of four GMO events, requested through the National Commission of Biosafety for Genetically Modified Organisms. The Government Administration, led by President Juan Carlos Varela, has the challenge of establishing the implementing regulations for the laws on biosafety and biotechnology. However, biotech development in Panama is not a top priority.

## **CHAPTER 1: PLANT BIOTECHNOLOGY**

### **PART A: PRODUCTION AND TRADE**

#### **A) PRODUCTS DEVELOPMENT:**

The GOP, through Resolution CNB No. 05-2012 of August 2, 2012 of the National Commission of Biosafety for Genetically Modified Organisms of Panama (Official Gazette No. 27105-A), has authorized cultivation with DuPont-Pioneer's "Herculex I" (DAS-01507-1) Corn seed for local producers but require the use of the Biosafety and Management Plan for controlled planting. This plan was published in the Official Gazette No. 27340-B through the Ministry of Agricultural Development Resolution DAL -024-ADM-2013 of June 20, 2013. Previously, the GOP conducted two official field trials during agricultural crop year 2012-2013 in the province of Los Santos, Panama using 2,011 bags of the Herculex I corn seed under the technical supervision of the Panamanian Agricultural Research Institute (IDIAP, in Spanish) and the assistance of a Panamanian importing company.

On the first field trial the GOP evaluated a) pollen dispersal and the insect population on crops of corn Herculex I; b) biological efficacy; and c) agronomic validation. During the second field trial the GOP made another evaluation on biological efficacy. However, in 2015, DuPont – Pioneer decided not to ship the 2,500 bags (with 60,000 seeds per bag) because the Herculex I corn seed was only approved for controlled planting for animal feed consumption, not for human consumption. Additionally, there was an absence of clear procedures regarding the approval process and coordination among the Ministry of Agricultural Development's Plant Health National Direction and the National Committee of Seeds for authorizing the Registration of a genetically modified seed, which is a legal requirement for the commercialization of all seed varieties in Panama. The Panamanian importing company will continue its efforts with the Biosafety Committee on Public Health to achieve full approval of Herculex I for food consumption and with the National Committee of Seeds for its registration for commercialization.

In May 2010, the National Commission of Biosafety for Genetically Modified Organisms of Panama received the formal request for the approval of GM rice for human consumption from Bayer's Crop Science LLRice62. However, Bayer Crop Science decided in 2016 to back away apparently in frustration due to the extremely long approval process in place. It is important to note that without clear regulations on biosafety and biotechnology and established rules and procedures for all the GOP agencies involved in this matter, such long delays in approval will likely continue.

#### **B) COMMERCIAL PRODUCTION:**

The only GE product approved for commercial cultivation is the DuPont-Pioneer's "Herculex I" (DAS-01507-1) corn seed. However, it has not been commercialized yet, due to the reason explained above.

### **C) EXPORTS:**

Panama does not export any GE crops/products to any country.

### **D) IMPORTS:**

Panama is waiting to receive “Herculex I” (DAS-01507-1) corn seed from DuPont-Pioneer once all local legal requirements are fulfilled, as explained in paragraph A).

### **E) FOOD AID RECIPIENT COUNTRY:**

Panama is not a currently food aid recipient.

## **PART B: POLICY**

### **A) REGULATORY FRAMEWORK:**

The Ministry of the Environment ([www.miambiente.gob.pa](http://www.miambiente.gob.pa)) is the Focal Point of the Cartagena Protocol on Biosafety in Panama.

This year, [Law 8 of March 25, 2015](#) was approved, by which the former National Authority of Environment (ANAM) was elevated to Ministry of Environment of the Republic of Panama.

The National Commission of Biosafety for Genetically Modified Organisms of Panama is composed of the following organizations:

#### 1) Competent National Authorities:

- Ministry of Agricultural Development (MIDA, in Spanish)
- Ministry of Health (MINSA, in Spanish)
- Ministry of Commerce and Industry (MICI, in Spanish)
- Ministry of Foreign Relations (MIRE, in Spanish)
- Ministry of Environment (MIAMBIENTE, in Spanish)
- Panamanian Food Safety Authority (AUPSA, in Spanish)
- Authority of the Aquatic Resources of Panama (ARAP, in Spanish)

#### 2) Institutions for Technical Support:

- National Secretariat for Science, Technology and Innovation. (SENACYT, in Spanish)
- Institute of Scientific Research and High Technology Services (INDICASAT AIP.)
- Agricultural Research Institute of Panama (IDIAP, in Spanish)
- Technological University of Panama (UTP, in Spanish)
- University of Panama
- Gorgas Memorial Institute for Health Studies (ICGES, in Spanish).
- Authority of Free Competition and Consumer Rights (ACODECO, in Spanish)

The current objectives of the Commission are to:

1. Promote and monitor the implementation of the law that will amend the Law 48 of 2002, which creates the National Commission for Biosafety of genetically modified organisms.
2. Develop, promote and monitor the compliance of the regulations and manuals of procedures for the genetically modified organisms.
3. Strengthen and monitor the [Biosafety Clearing House \(BCH\) of Panama](#)
4. Propose the establishment of capacity building in the institutions for Biosafety of Genetically Modified Organisms.

The National legal framework for GMO's is based on the following laws:

- 1) [Law 72 of December 26, 2001](#), by which Panama approved the Cartagena Protocol on Biosafety entered into force on January 29, 2000.
- 2) [Law 48 of August 8, 2002](#) that creates the National Commission of Biosafety for Genetically Modified Organisms, and dictates other dispositions.
- 3) [Resolution CNB No. 06-2014](#), establishing the Internal Regulation for the National Commission of Biosafety for Genetically Modified Organisms.
- 4) [Law 47 of 1996](#), establishing that for the import, export, research, experiment, release to the environment, reproduction and commercialization of transgenic plants, bio-control agents and seeds for production, and the National Direction of Plant Health has approval.
- 5) [Law 23 of 1997](#), which regulates the Animal Health and Agricultural Quarantine.
- 6) [Law Decree 11 of February 22, 2006](#), which creates the Panamanian Food Safety Authority (AUPSA) and the dispositions for the import, transit and trans-boundary movement of food and feed into Panama.
- 7) [Law 8 of March 25, 2015](#), which creates the Ministry of Environment of the Republic of Panama.

The Law 72 of 2001, being an international agreement, is in force but has not been fully implemented.

The Law 48 of 2002 was implemented on February 26, 2011 with a first meeting of Commissioners. The Commission Presidency is to be rotated among the Ministers with 2016's Presidency of the Commission being Minister of Agricultural Development (MIDA) Dr. Jorge Arango. The Commission is in charge to draft and implement the regulations for use, import, commercialization, and research of genetically modified organisms, and oversight of all aspects of production, introduction, consumption, etc. of all biotech products, and is to make a priority of the Cartagena Protocol and the precautionary principle.

The National Commission of Biosafety for Genetically Modified Organisms of Panama will not directly authorize the use, production, introduction or consumption of a genetically modified organisms (GMO) in Panama, but it will recommend the competent authority to approve or not the use, production, introduction, research or consumption of a GMO in Panama, and will recommend the adoption of Biosafety and Management Plan for genetically modified organisms.

Under the National Commission of Biosafety for Genetically Modified Organisms of Panama, are three Biosafety Committees, which have to conduct risk analysis and risk assessments, case by case and step by step, with science-based evidence. Depending on the type and use of the GMO, the respective

Committee will be in charge to pursue the analysis and assessments:

- a) **Biosafety Committee on Agriculture**: For conducting risk analysis, risk assessments, monitoring and tracking of all activities for use, research, restricted management, laboratory testing, release to the environment, greenhouse, net house and experimental batches of GMO for agricultural use (i.e. seeds, feeds consumption).
- b) **Biosafety Committee on Public Health**: For conducting risk analysis, risk assessments, monitoring and tracking of all activities for use, research, restricted management, laboratory testing, release to the environment, technological development of genetically modified organisms that may affect human health. (i.e. food consumption, or GM animals to be used on Public Health research).
- c) **Biosafety Committee on Environment**: For conducting risk analysis, risk assessments, monitoring and tracking of all activities for use, research, restricted management, laboratory testing, release to the environment, greenhouse, net house and experimental batches of GMO for research; and use of raw material for feed consumption, ornament and bioremediation through microorganisms.

The competent authorities who will have to make the final decision, depending on the recommendation of the National Commission of Biosafety for Genetically Modified Organisms of Panama, are the following ministries and authorities, with their respective scope of jurisdiction:

- The **Ministry of Agricultural Development (MIDA)** is the competent national authority to regulate, control, approve and monitor the use, import, export, research, experiment, release to the environment, reproduction and commercialization and management of genetically modified organisms, such as live animals, semen and embryos, transgenic plants, bio-control agents and seeds for agricultural production.
- The **Ministry of Health (MINSA)** is the competent national authority to regulate, control, approve and monitor the use and management of genetically modified organisms and biotechnology developments, conducted on national territory, affecting human health and the establishment of biosafety standards required for human protection.
- The **Ministry of Commerce and Industry (MICI)** is the competent national authority responsible for ensuring that negotiations and international trade agreements that involve the use of genetically modified organisms and biotechnology transfer, does not affect domestic production and investment, the environment, biodiversity and human health, and ensures the best interests of Panama.
- The **Ministry of Environment (MIAMBIENTE)** is the competent national authority for the implementation of the Cartagena Protocol on Biosafety and of the Convention on Biological Diversity, as the focal point of Panama, as well as management and environmental management of natural heritage and biodiversity of Panama. MIAMBIENTE has the power to regulate and control access to and use of biogenetic resources in general, and establish, approve and monitor compliance with the rules risk assessment procedures for the release into the environment, and monitor mitigation impacts on biodiversity and the environment, including the protected areas.
- The **Panamanian Food Safety Authority (AUPSA)** is the competent national authority that regulates

and enforces compliance of sanitary and phytosanitary measures and quality standards related to the import, transit and transboundary movement of food and feed into Panama.

- The **National Secretariat of Science, Technology and Innovation (SENACYT)**, is the competent national authority for the promotion of research for the development and transfer of biotechnology in general, and for the regulation of LMO's for use in scientific research.
- The **Authority of Aquatic Resources of Panama (ARAP)** is the entity with responsibility for the authorization, control, supervision, monitoring, and release to the aquatic environment of marine and genetically modified aquatic organisms that are located outside of protected areas.
- The **Authority for Consumer Protection and Defense of the Competition (ACODECO)** is the entity responsible for protecting and ensuring the process of free economic competition, eliminating monopolistic practices and other restrictions in the efficient functioning of markets for goods and services, monitoring food labeling compliance and preserving the best interests of consumers in Panama.

Also, MIAMBIENTE, as the focal point for the Cartagena Protocol, received the second phase of non-reimbursable funds from the United Nations Environmental Program (UNEP) Global Environment Funds (GEF) to help Panama in the implementation of the Cartagena Protocol on Biosafety in Panama and its national legal framework. However, these funds have not been used due to the lack of an administrator or project manager.

## **B) APPROVALS:**

As mentioned previously, under Resolution CNB No. 05-2012 of August 2, 2012 of the National Commission of Biosafety for Genetically Modified Organisms of Panama, published in the Official Gazette No. 27105-A, has authorized cultivation with DuPont-Pioneer's "Herculex I" (DAS-01507-1) Corn seeds for local corn producers but using the Biosafety and Management Plan for controlled planting. This plan was published in the Official Gazette No. 27340-B through the Ministry of Agricultural Development Resolution DAL -024-ADM-2013 of June 20, 2013.

## **C) FIELD TESTING:**

The GOP conducted two official field trials during agricultural crop year 2012-2013 in the province of Los Santos, Panama, using 2,011 bags of Herculex I corn seed with the technical supervision of the Panamanian Agricultural Research Institute (IDIAP, in Spanish) and the assistance of the Panamanian importing company.

On the first field trial the GOP evaluated: an assessment of pollen dispersal; assessment of populations of insects on crops of corn Herculex I; evaluation of biological efficacy; and agronomic validation. And on the second field-testing the GOP made another evaluation of biological efficacy.

## **D) STACKED EVENT APPROVALS:**

None

**E) ADDITIONAL REQUIREMENTS:**

Prior to use GE corn seed or any other seed, it must be registered at the National Committee of Seeds prior to commercialization. The National Committee of Seeds is under MIDA's structure.

[http://www.mida.gob.pa/direcciones/direcciones\\_nacionales/comite-nacional-de-semillas.html](http://www.mida.gob.pa/direcciones/direcciones_nacionales/comite-nacional-de-semillas.html)

**F) COEXISTENCE:**

Panama applies the following legislation for coexistence: Non-GE crops (Organic Products): International standards set by the CODEX Alimentarius and ISO Guide 65 governing organic production and operation process of certifying companies producing organic products. National Legislation for Organic production: Law 8 of January 24, 2002; Executive Decree of August 11, 2004; and Ministerial Resolution No. DAL-067.ADM-05 of December 9, 2005.

**G) LABELING:**

At the international level, Panama supports a policy of not requiring specific mandatory labeling for biotech products, a principle also applied in Panama for all food products, as established in Article 36 of Law 45 of October 31, 2007. Panama accepts the CODEX Alimentarius recommendation of voluntary labeling.

However, there are on-going discussions on labeling as the result of the first hearing of Draft Bill No. 157 of 2015 for regulating the food labeling of food derived of genetically modified organisms.

**H) TRADE BARRIERS:**

There are no biotechnology-related trade barriers affecting U.S. exports, currently.

**I) INTELLECTUAL PROPERTY RIGHTS (IPRs):**

Panama is also a party to other International Bodies related to Intellectual Property Rights (IPR), which addresses plant patents, copyright protection, registration requirements; it is also a member of the UPOV Convention, and the International Treaty on Plant Genetic Resources for Food Agriculture, among others. The U.S-Panama Trade Promotion Agreement which entered into force on October 31, 2012 also has a chapter on Intellectual Property Rights (chapter 15).

**J) CARTAGENA PROTOCOL RATIFICATION:**

Panama is an active party of the Cartagena Protocol on Biosafety, under the Convention of Biological Diversity. And Panama signed on May 3, 2011 the Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress.

**K) INTERNATIONAL TREATIES/FORA:**



To date, Panama has not negotiated any type of Bilateral Agreement or Memorandum of Understanding with any other country regarding GMOs or LMOs. Panama is a member of the International Plant Protection Convention (IPPC), the CODEX Alimentarius and the World Organization for Animal Health (OIE). Panama has not been very active in international discussions related to GE plants and animals except for discussions on the Cartagena Protocol.

**L) RELATED ISSUES:**

None

**M) MONITORING AND TESTING:**

Panama does not currently have a monitoring and testing program for GE products.

**N) LOW-LEVEL PRESENCE POLICY:**

Panama does not currently have a Low Level Presence (LLP) policy.

**PART C: MARKETING**

**A) MARKET ACCEPTANCE:**

From time to time, local newspapers publish articles (that appear to come from foreign sources) advising of the alleged dangers to humans posed by foods that include GE materials along with the supposedly catastrophic impact on the environment. With less frequency, articles are published that highlight the benefits of GE crops and their products. For example, the “Serilini” study on rats using GE corn caused the Panamanian consumers association to make public statements about not trusting products that included GE corn material. When the “Serilini” study was refuted by European scientific organizations due to the lack of scientific and reliable information, the bad public perception of GMOs was reduced somewhat. There is a growing trend of consumers looking for processed food products with the “Non-GMO verified product” labeling on them.

**B) PUBLIC/PRIVATE OPINIONS:**

Most agriculture professionals graduate from local universities that lack advanced training in modern developments in biotechnology. This may hurt perceptions of GMOs by many, including those who tend to distrust big industries and new methods of mass production of food products. There are two private consumers’ associations that are expressing concern about lack of protection from authorities for consumers of medicines and of some imported food products, mainly from Asia. This could lead to rejection of this technology from the consumers and the public sector, depending on the information they receive in the future.

**C) MARKETING STUDIES:**

There have been no market studies in Panama to assess consumer acceptance of GMOs.

## **CHAPTER 2: ANIMAL BIOTECHNOLOGY**

### **PART E: PRODUCTION AND TRADE**

#### **A) BIOTECHNOLOGY PRODUCT DEVELOPMENT:**

In Panama, genetic engineering in animals has been used for salmon production in Boquete, Province of Chiriqui, of AquaBounty's AquaAdvantage® Salmon. These salmon include a gene that helps the fish grow to market size in half the time of conventional salmon. The research undertaken by a private company and supervised by the National Commission of Biosafety for Genetically Modified Organisms of Panama, has been noting positive results. However, the GOP has still not authorized GE salmon for commercialization.

On November 19, 2015n the United States Food and Drug Administration (FDA) approved AquaBounty Technologies' application for AquaAdvantage Salmon - an Atlantic salmon that reaches market size faster than non-GE farm-raised Atlantic salmon. The FDA regulates GE animals under the new animal drug provisions of the Federal Food, Drug, and Cosmetic Act, because the recombinant DNA (rDNA) construct introduced into the animal meets the definition of a drug. In this case, the rDNA construct introduces a trait that makes the AquaAdvantage Salmon grow faster. FDA has determined that the AquaAdvantage Salmon meet all regulatory requirements for approval, including that food from the fish is safe to eat for human consumption. FDA will soon release guidance for labeling of food derived from Atlantic salmon that has or has not been genetically engineered to help those manufacturers who wish to voluntarily make the distinction on the labeling of their food products.

The Gorgas Memorial Institute of Tropical and Preventive Health Studies (ICGES) in Panama requested authorization for research and release into the environment of Oxitec's GE mosquitoes *Aedes aegypti* to control Dengue virus in Panama. ICGES released over 300,000 GE sterile males *A. aegypti* mosquitoes in Araján district, 18 kilometers west of Panama City, as an evaluation project. Unlike females, *Aedes* males do not feed on blood but flower nectar. The purpose of this project is for the transgenic male *Aedes* to copulate with native female laying 80 to 100 eggs. Coupling with sterile males will prevent mosquitoes from reproducing and decrease their population. This biological control is safer than fumigating the entire country with insecticides.

The National Commission of Biosafety for Genetically Modified Organisms of Panama is conducting the approval process for GE *Cochliomyia hominivorax* flies as was requested by the Panama – United States Commission for the Eradication and Prevention of Screwworm (COPEG). There are no other agriculturally-relevant animals genetically engineered in Panama.

#### **B) COMMERCIAL PRODUCTION:**

The Government of Panama will have the challenge of approving GE AquaAdvantage® Salmon for commercialization now that it has been approved by the FDA.

### **C) BIOTECHNOLOGY EXPORTS:**

None

### **D) BIOTECHNOLOGY IMPORTS:**

GE mosquitoes and salmon were imported in their first stages and they grew until their final stages in Panama. On the other hand, COPEG's GE *Cochliomyia hominivorax* flies are produced in a laboratory located in Pacora, Panama city, Panama.

## **PART F: POLICY**

### **A) REGULATION:**

No specific regulations have been developed for products of animal biotechnology. General biosafety and biotechnology laws apply for animal biotechnology in Panama.

### **B) LABELING AND TRACEABILITY:**

Labeling regulations have not been developed for products of animal biotechnology. A new traceability law, which is currently under the development, may apply in the future to animal biotechnology products.

### **C) TRADE BARRIERS:**

There are no trade barriers at this time that would affect U.S. exports.

### **D) INTELLECTUAL PROPERTY RIGHTS (IPR):**

Panama is a party to international organizations related to Intellectual Property Rights (IPR), which addresses plant patents, copyright protection, registration requirements.

The U.S-Panama Trade Promotion Agreement entered into force on October 31, 2012 also has a chapter on Intellectual Property Rights (chapter 15). Therefore, the above will also apply for products of animal biotechnology.

### **E) INTERNATIONAL TREATIES/FORA:**

Panama is not an active participant in discussions related to new technologies in international organizations such as OIE or OECD.

## **PART G: Marketing**

## **A) MARKET ACCEPTANCE AND B) PUBLIC/PRIVATE OPINIONS:**

The production of food products from genetic engineered animals is not well understood by local consumers. This reflects in the fact that lawmakers do not think this is a priority in the issuing of new regulations and, therefore, there have not been any discussions of related regulatory policies for genetic engineering of animals.

Panamanians, after seen the positive results of the Oxitec's GE mosquitoes, are willing to accept the use of new technologies for the control of Dengue virus, which could also help with controlling Chikungunya and Zika viruses since the vector is the same species of mosquitoes: *Aedes aegypti*.

## **MARKET STUDIES:**

None