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Report Highlights:

Panama did not make any policy changes on regulating Genetically Engineered (GE) plants, seeds and animals, including for GE microbes, in the past year. Panama has delayed for over ten years the establishment of the implementing regulations of Law 48 of 2002, which created the National Commission of Biosafety for Genetically Modified Organisms. As such, the absence of clear procedures regarding the approval process and coordination among all of the competent government agencies in charge of authorizing the import, research, and commercialization of GE products and animals in Panama causes delays to the official approval of GE events.

Executive Summary:

The Government of Panama (GOP) has delayed establishing the implementing regulations of Law 48 of 2002, which created the National Commission of Biosafety for Genetically Modified Organisms ("GMOs"). As such, the absence of clear procedures regarding the approval process and lack of coordination among multiple competent government agencies in charge of authorizing the import of GE products into Panama causes delays in the approval of biotech events.

TABLE OF CONTENTS

CHAPTER1: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

a) PRODUCTS DEVELOPMENT:

From 2012 to2015 there were a number of field trials for Dupont-Pioneer's "Herculex I" (DAS-01507-1) corn seed variety. However, the company ultimately decided not to move forward with commercialization.

It is important to note that without implementing regulations for the laws on biosafety and biotechnology, with clear rules of procedures for all the GOP agencies involved in this matter, approval delays will continue.

b) COMMERCIAL PRODUCTION:

The only GE product approved for commercial cultivation is the DuPont-Pioneer's "Herculex I" (DAS-01507-1) corn seed variety. However, it has not been commercialized because the Ministry of Health did not grant approval for human consumption. The application sought permission only for animal feed use.

c) EXPORTS:

Panama does not export any GE crops/products.

d) IMPORTS:

Panama approved the DuPont-Pioneer the "Herculex I" (DAS-01507-1) corn variety for import for feed use. Panama imports genetically engineered (GE) corn and soybeans from the United States, Argentina, Brazil, Paraguay, that are intended for animal feed. However, the Panamanian Government does not require notification of these imports.

e) FOOD AID:

Panama is not a currently food aid recipient, nor does it provide food aid. The World Food Programme's Regional Logistics Center for Humanitarian Assistance (CLRAH) is located in Panama City, and uses the logistical facilities of the Panama Canal, maritime ports, highways, railroads, and airlines.

f) **TRADE BARRIERS:**

There are no current biotechnology-related trade barriers affecting U.S. exports to Panama

PART B: Policy

a) REGULATORY FRAMEWORK:

In 2015, Law 8 of March 25, 2015 (in Spanish) was approved, by which the former National Authority of Environment (ANAM) was elevated to Ministry of Environment of the Republic of Panama. It is also the Focal Point of the Cartagena Protocol on Biosafety in Panama.

The absence of clear procedures regarding the approval process, and lack of coordination between all the competent government agencies in charge of authorizing the import of GE products into Panama, causes delays to the approval of GE events when their approval is requested to the government through the National Commission of Biosafety for Genetically Modified Organisms.

The National Commission of Biosafety for Genetically Modified Organisms of Panama is the authority that recommends the approval of GE food and feed and for environmental releases. It is composed of:

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 for Consumer Protection and Defense of the Competition (ACODECO, in Spanish)

The current objectives of the National Commission of Biosafety for Genetically Modified Organisms Commission are:

1. Promote and monitor the implementation of the law that will amend the Law 48 of 2002, which created the National Commission for Biosafety of "GMOs,"
2. Develop, promote, and monitor compliance of the regulations and manuals of procedures for "GMOs,"

3. Strengthen and monitor the Biosafety Clearing House (BCH) of Panama, and
4. Propose the establishment of capacity building in the institutions for Biosafety of Genetically Modified Organisms.

The National legal framework for GMOs is based on the following laws (all in Spanish):
1) Law 72 of December 26, 2001, by which Panama approved the Cartagena Protocol on Biosafety; it entered into force on January 29, 2000.
2) Law 48 of August 8, 2002 that created the National Commission of Biosafety for Genetically Modified Organisms, and dictates other dispositions.
3) Resolution CNB No. 06-2014, established the Internal Regulation for the National Commission of Biosafety for Genetically Modified Organisms.
4) Law 47 of 1996, established 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 approval of the National Director of Plant Health.
5) Law 23 of 1997, which regulates the Animal Health and Agricultural Quarantine.
6) Law Decree 11 of February 22, 2006, which created 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 created 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.

Law 48 of 2002 was implemented on February 26, 2011 with a first meeting of Commissioners. The Commission Presidency rotates among the Ministers. The Commission is in charge of drafting and implementing the regulations for use, import, commercialization, and research of "GMOs," and oversees all aspects of production, introduction, consumption, etc. for all biotech products.

The National Commission of Biosafety for Genetically Modified Organisms of Panama makes a recommendation for the competent authority to authorize the use, production, introduction or consumption of GE events.

There are three Biosafety Committees, under the National Commission of Biosafety for Genetically Modified Organisms of Panama, which conduct risk analysis and risk assessments on a case-by-case basing using science-based evidence:

a) **Biosafety Committee on Agriculture (in Spanish)**: For conducting risk analysis, risk assessments, monitoring and tracking of all activities for use, research, restricted management, laboratory testing,

release to the environment, greenhouse, and experimental batches of GMO for agricultural use (i.e., seeds, feeds consumption).

b) **Biosafety Committee on Public Health (in Spanish):** 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 "GMOs" that may affect human health. (i.e., food consumption, or GE animals to be used for public health research).

c) **Biosafety Committee on Environment (in Spanish)**: 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 following ministries and authorities, along with their respective scope of jurisdiction, are the competent authorities who will make the final decision, depending on the recommendation of the National Commission of Biosafety for Genetically Modified Organisms of Panama:

• 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 "GMOs," 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 "GMOs" and biotechnology developments, conducted in 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 "GMOs" and biotechnology transfer do 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 for 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.

The plethora of GOP agencies making decisions on GE plants and animals creates a management problem and results in stringent, unclear procedures that delay decision-making on biotechnology issues.

b) APPROVALS:

The GOP, under Resolution CNB No. 05-2012 of August 2, 2012 of the National Commission of Biosafety for Genetically Modified Organisms of Panama, authorized cultivation of DuPont-Pioneer's "Herculex I" (DAS-01507-1). However, the company decided not to commercialize this event because the Ministry of Health did not give its approval based on the potential for human consumption. The intended use of the product is for animal feed.

c) STACKED OR PYRAMIDED EVENT APPROVALS: There are no special regulatory treatments for these event approvals. They are treated and reviewed as a regular GE event.

d) FIELD TESTING:

There is no specific policy for managing confined field trials. The National Commission of Biosafety for GMO of Panama will authorize the approval for field trials.

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. These were conducted with the

technical supervision of the Panamanian Agricultural Research Institute (IDIAP, in Spanish) and the assistance of the Panamanian importing company.

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. The second field-trial evaluated biological efficacy.

e) INNOVATIVE BIOTECHNOLOGIES

Panama has not determined the regulatory status or policy for innovative biotechnologies such as genome editing.

f) COEXISTENCE:

Panama applies the following legislation for coexistence regarding organic and GE crops: International standards set by the CODEX Alimentarius and ISO Guide 65 governing organic production and operation process of certifying companies producing organic products. Panama has been increasing the number of farms who are exporting to the European Union using MIDA's National Directorate of Plant Health Organic production certification. MIDA enforces a prohibition on production of GE crops in a radius near organic crops in order to avoid cross pollination between a GE crop and an organic crop. This authority is based on: 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 accepts the CODEX Alimentarius recommendation of voluntary labeling, supporting 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.

h) MONITORING AND TESTING:

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

i) LOW-LEVEL PRESENCE (LLP) POLICY:

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

j) ADDITIONAL REGULATORY REQUIREMENTS

Prior to use for cultivation, the GE seed has to be registered at the National Committee of Seeds for its registration for commercialization. The National Committee of Seeds is under MIDA's structure. https://www.mida.gob.pa/direcciones/direcciones_nacionales/comit-nacional-de-semillas.html. There are currently no GE seeds registered.

k) INTELLECTUAL PROPERTY RIGHTS (IPRs):

Panama is party to other international bodies related to intellectual property rights (IPR), which address plant patents, copyright protection, and 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, has a chapter on Intellectual Property Rights (chapter 15).

l) CARTAGENA PROTOCOL RATIFICATION:

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

m) INTERNATIONAL TREATIES/FORUMS:

To date, Panama has not negotiated any bilateral agreement or memorandum of understanding with any other country regarding GE products.

Panama is a member of the International Plant Protection Convention (IPPC), the CODEX Alimentarius and the World Organization for Animal Health (OIE). Because of a lack of resources to send a GOP representative to international discussions related to GE plants and animals, Panama has not been very active in this area, except for discussions on the Cartagena Protocol.

n) RELATED ISSUES:

None

PART C: Marketing

a) PUBLIC/PRIVATE OPINIONS:

Most agriculture professionals graduate from local universities that lack advanced training in modern developments in biotechnology. This may hurt perceptions of agricultural biotechnology by many in Panama, including those who tend to distrust big industries and new methods of production of food products. There are two private consumers' associations that express concern about a lack of protection from authorities for consumers of medicines and some food products, mainly from Asia. This could lead

to rejection of this technology from consumers and the public sector, depending on the information they receive in the future.

b) MARKET ACCEPTANCE/STUDIES:

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 prepared with "GMOs," and of the supposedly catastrophic impact on the environment if "GMOs" are produced in the country. With less frequency, articles are published that talk about the benefits of GE products. For example, the Serilini study on rats using GE corn caused the Panamanian consumers association to make public statements about not trusting products made from GE corn. When the Serilini study was refuted by the European scientific organizations due to lack of scientific and reliable information, the bad public perception of "GMOs" was reduced.

In Panama there is a consumer trend to look for processed food products with "Non-GMO verified product" labeling.

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

CHAPTER 2: ANIMAL BIOTECHNOLOGY

PART D: PRODUCTION AND TRADE

a) PRODUCT DEVELOPMENT:

The National Commission of Biosafety for Genetically Modified Organisms of Panama, through the Resolution CNB No. 08-2017 of October 5, 2017 granted the approval for the release of GE *Cochliomyia hominivorax* flies into the environment as part of a second phase of research by the Panama – United States Commission for the Eradication and Prevention of Screwworm (COPEG). This phase of research uses a male only strain for the biological control of the Screwworm disease, which will reduce the cost of the program, and benefit Central American and North American livestock production.

There are no other agriculturally - relevant GE or cloned animals in development in Panama that would be commercialized in the next five years.

b) COMMERCIAL PRODUCTION:

On April 16, 2019, AquaBounty, a U.S. company that developed genetically engineered (GE) salmon in Boquete, Panama closed its production and research facilities. AquaBounty left Panama due to the Ministry of Health of Panama's deferred decision on the approval of local consumption. Approval would have required additional studies beyond those already conducted for the Canadian and United States Food and Drug Administration approvals.

c) EXPORTS:
None

d) IMPORTS:
None.

e) TRADE BARRIERS:

There are no trade barriers at this time that would affect U.S. exports for GE animals, cloned animals, or the offspring of cloned animals to Panama.

PART E: Policy

a) REGULATORY FRAMEWORK:

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

b) INNOVATIVE BIOTECHNOLOGIES

Panama has not determined the regulatory status or policy for innovative biotechnologies (such as genome editing, for example). But there are opportunities in animal biotechnology research underway in Panama for innovative GE animals, such as the ongoing research by ARS in COPEG.

c) LABELING AND TRACEABILITY:

Labeling regulations have not been developed for products of animal biotechnology, including for clones or offspring of clones. The new Traceability Law, which is currently under the development of its implementing regulations, may apply in the future for products of animal biotechnology.

d) INTELLECTUAL PROPERTY RIGHTS (IPR):

Panama is a party to international bodies 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).

e) INTERNATIONAL TREATIES/FORUMS:

Panama is not an active participant in discussions related to new animal technologies in international organizations such as the International Organization for Animal Health (OIE) or Organization for Economic Cooperation and Development (OECD).

f) RELATED ISSUES:
None

PART G: Marketing

a) PUBLIC/PRIVATE OPINIONS:

Lawmakers do not think GE animals are a priority for the issuing of new regulations so there have not been any discussions of related regulatory policies for genetic engineering of animals.

Panamanians, after seeing the positive results of the Oxitec's GE mosquitoes, are willing to accept the use of this new technology for the control of Dengue virus. This would also help to control the new Chikungunya and Zika viruses, because the vector is the same species of mosquitoes: *Aedes aegypti*.

b) MARKET ACCEPTANCE/ MARKET STUDIES:

The production of food products from GE animals is not well understood by local consumers. There are no market studies regarding GE animals or cloning acceptance.

CHAPTER 3: MICROBIAL BIOTECHNOLOGY

PART G: PRODUCTION AND TRADE

a) **COMMERCIAL PRODUCTION**
Currently, in Panama there are no research or commercial production projects working on GE microbes in the agricultural sector or in the food industry.

b) **EXPORTS**
c) Panama exports alcoholic beverages and processed products which may contain microbial biotech-derived food ingredients. However, the Government of Panama and the exporters association doesn't have any records of the use of GE microbes in the food industry.

d) **IMPORTS**
Panama does not currently require an import notification of GE microbes for use in the food industry, such as ingredients; or for agricultural production. Therefore, there are no-records of GE microbes. The only microbial biotech-derived food ingredients imported by Panama are those traditionally used in the production of alcoholic beverages, dairy products, and processed products, but they are not registered as GE microbes for food ingredients.

e) TRADE BARRIERS

There are no trade barriers at this time that would affect U.S. exports for GE microbes to Panama.

PART H: POLICY

a) **REGULATORY FRAMEWORK**

No specific regulations have been developed for GE microbes in Panama.

b) APPROVALS

No approvals for GE microbes have been granted, as there has been no request for GE microbes' approval, for research, development, or commercialization in Panama.

c) LABELING and TRACEABILITY

Panama has not determined the regulatory status or policy on labeling for innovative biotechnologies such as GE microbes. The new Traceability Law, which is currently under the development of its implementing regulations, may apply in the future for GE microbes.

d) MONITORING AND TESTING

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

e) ADDITIONAL REGULATORY REQUIREMENTS

None

f) INTELLECTUAL PROPERTY RIGHTS (IPR)

Panama is a party to international bodies 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).

***g)* RELATED ISSUES**

None

PART I: MARKETING

a) PUBLIC/PRIVATE OPINIONS

No public or private opinions has been published in any public media in Panama, regarding GE microbes.

b) MARKET ACCEPTANCE/STUDIES

The production or use of GE microbes for agricultural use or for the food industry is unknown by local consumers. There are no market studies regarding GE microbe's acceptance.

Attachments:

No Attachments

Attachments:

No Attachments