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Caribbean Biosafety and Biotechnology

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Report Highlights:

Many Caribbean Community (CARICOM) Member States have engaged in efforts to comply with their obligations under the Cartagena Protocol on Biosafety (CPB) to the Convention on Biological Diversity (CBD) since they became parties to the agreement. While progress has lagged over the years, regulatory structures are beginning to take shape in some countries and a harmonized regional policy has been set forth in an effort to regulate transboundary movement of products from modern plant biotechnology in a cohesive manner throughout the region.

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Section I: Executive Summary:

Several institutions within the Caribbean Basin Agricultural Trade Office's (CBATO) region of coverage are conducting biotech research on crops such as sugarcane, cassava, papaya, rice, coconuts, cocoa, coffee, peppers, and spices and to a lesser extent on ornamentals and animals [1]. This research has yielded a number of advances, including developing transgenic papaya varieties resistant to devastating papaya viruses as well as the development of biochemical compounds suitable for use as bio-pesticides. However, the actual commercial production of genetically engineered (GE) products will take many years. The Caribbean region is not yet at the stage where animal genetic engineering or cloning of animals is being developed.

The CBATO is not aware of any specific requirements related to the importation of GE products in its region. Currently, the United States is the region's main supplier of food and agricultural products. Approximately two thirds of all corn, soybean, cotton and canola products are imported from the United States.

Suppliers may encounter greater regulation of GE products as well as increased consumer awareness in the years ahead. Over the past several years most of the countries within CARICOM have worked at developing their own draft National Biosafety Framework (NBF); a combination of policy, legal, administrative and technical instruments geared toward addressing safety for the environment and human health in relation to modern biotechnology [2]. This was being done with the support of the United Nations/Global Environment Facility (UNEP/GEF), which is helping these countries meet their obligations under the CPB [3]. To date, only St. Kitts and Nevis and St. Lucia have enacted any biosafety legislation and no country in the region has a fully functional biosafety framework in place.

[1] The CBATO islands of coverage are: Anguilla, Antigua & Barbuda, Aruba, The Bahamas, Barbados, Bermuda, British Virgin Islands, Cayman Islands, Cuba, Dominica, Guadeloupe, Martinique, Grenada, Montserrat, the former Netherlands Antilles (Curaçao, Bonaire, Sint Maarten, Saba & St. Eustatius), St. Kitts & Nevis, St. Lucia, Saint Martin, St. Barthélemy, St. Vincent & the Grenadines, Trinidad & Tobago, and Turks & Caicos Islands. For purposes of this report, Cuba is excluded from the CBATO's region of coverage.

[2] CARICOM Member States are: Antigua and Barbuda, The Bahamas, Barbados, Belize, Dominica, Grenada, Guyana, Haiti, Jamaica, Montserrat, St. Lucia, St. Kitts and Nevis, St. Vincent and the Grenadines, Suriname, and Trinidad and Tobago (CARICOM Associate Members are: Anguilla, Bermuda, British Virgin Islands, Cayman Islands, Turks and Caicos Islands).

[3] CARICOM Member States that are Parties to the CPB are: Antigua and Barbuda, The Bahamas, Barbados, Belize, Dominica, Grenada, Guyana, Jamaica, St. Kitts and Nevis, St. Lucia, St. Vincent and the Grenadines, Suriname, and Trinidad and Tobago. It should be noted that Jamaica is not part of the UNEP/GEF Regional Project for Implementing NBFs in the Caribbean because it did not ratify the CPB until after the project was initiated. Instead, Jamaica is carrying out its own NBF project.

Section II: Plant and Animal Biotechnology

CHAPTER 1: PLANT BIOTECHNOLOGY

PART A: Production and Trade

a) Product Development:

There are no GE plants or crops under development in the CBATO region that are poised to be commercialized in the near future. Overall, agricultural production throughout the region is minimal, and most countries import the majority of their agricultural product needs. Total land area is 23,783 sq. km. (9,183 sq. miles), roughly the size of New Hampshire. Of this area, only about seven percent is arable, and an even smaller percentage is farmed.

Nonetheless, research institutions throughout the Caribbean have recognized that production of GE plants and crops could lead to increased yields and reduced use of water and inputs. These institutions have identified several local products (sugarcane, cotton, rice, coconuts, cocoa, coffee, peppers, spices, and anthuriums among others) that could be improved using agricultural biotechnology. Some of the institutions leading the way with research on some of these plants and crops are: the University of the West Indies (UWI), the Caribbean Agricultural and Development Institute (CARDI), and the National Agriculture Research Institute (NARI) in Guyana.

b) Commercial Production:

In the absence of a fully functioning biosafety legal framework in place to oversee the production or release of Living Modified Organisms (LMOs), countries in the region are being cautious when it comes to GE crop cultivation. In essence, there are no known field trials or commercial production of GE products taking place in the CBATO region.

c) Exports:

Not applicable.

d) Imports:

Currently, the United States is the region's main supplier of food and agricultural products. In some cases, particularly for imports of the consumer-oriented products category, products from third countries are transshipped through the United States. The following tables show the region's imports of some key GE products, including the consumer-oriented products category, which largely represents products derived from, or containing GE corn, soybean and/or canola.

Reporting Countries Export Statistics (Partner: CBATO Islands Participating in Biosafety Project), Corn

Country	Unit	2017	Market Share (%)
United States	Tons	124,790	94.13
Brazil	Tons	6,524	4.92
Other	Tons	1,253	0.95
Total	Tons	132,567	100.00

Source: Global Trade Atlas

Reporting Countries Export Statistics (Partner: CBATO Islands Participating in Biosafety Project),
Soybeans

Country	Unit	2017	Market Share (%)
United States	Tons	26,436	66.94
Brazil	Tons	13,000	32.92
Other	Tons	55	0.14
Total	Tons	39,491	100.0

Source: Global Trade Atlas

Reporting Countries Export Statistics (Partner: CBATO Islands Participating in Biosafety Project),
Soybean Meal

Country	Unit	2017	Market Share (%)
United States	Tons	38,699	45.29
Brazil	Tons	46,476	54.39
Other	Tons	273	0.32
Total	Tons	85,448	100.0

Source: Global Trade Atlas

Reporting Countries Export Statistics (Partner: CBATO Islands Participating in Biosafety Project),
Soybean Oil and Its Fractions, Whether Or Not Refined, But Not Chemically Modified

Country	Unit	2017	Market Share (%)
United States	Tons	12,140	60.01
Argentina	Tons	5,061	25.02
Brazil	Tons	1,510	7.46
Other	Tons	1,520	7.51
Total	Tons	20,231	100.00

Source: Global Trade Atlas

Reporting Countries Export Statistics (Partner: CBATO Islands Participating in Biosafety Project),
Rapeseed, Colza or Mustard Oil and their fractions

Country	Unit	2017	Market Share (%)
United States	Tons	523	78.53
Canada	Tons	130	19.52
Other	Tons	13	1.95
Total	Tons	666	100.00

Source: Global Trade Atlas

Reporting Countries Export Statistics (Partner: CBATO Islands Participating in Biosafety Project),
Cotton

Country	Unit	2017	Market Share (%)
United States	Tons	137	100.00
Other	Tons	0	0.00
Total	Tons	137	100.00

Source: Global Trade Atlas

Reporting Countries Export Statistics (Partner: CBATO Islands Participating in Biosafety Project),
Consumer-Oriented Products

Country	Unit	2017	Market Share (%)
United States	US Dollars	601,751,969	53.68

New Zealand	US Dollars	72,070,426	6.43
Brazil	US Dollars	48,030,496	4.29
U.K.	US Dollars	45,115,353	4.02
Canada	US Dollars	45,060,822	4.02
Netherlands	US Dollars	41,792,399	3.73
Costa Rica	US Dollars	38,758,656	3.46
France	US Dollars	21,412,625	1.91
Other	US Dollars	206,902,955	18.46
Total	US Dollars	1,120,895,701	100.00

Note: Export numbers shown in US dollars to avoid inconsistencies created by different units of measure for quantity.

Source: Global Trade Atlas

e) Food Aid:

The CBATO region is not a regular food aid recipient. However, due to the devastating 2017 hurricane season, some islands (e.g. Dominica) may receive some food aid. It is unknown whether any GE products have been part of any food aid programs in the region.

f) Trade Barriers:

Post is not aware of any specific requirements related to the importation of GE products in its region [1]. Within the Caribbean region, CARICOM is focused on establishing the Caribbean Single Market and Economy to facilitate the free movement of CARICOM-origin products between Member States. It remains to be seen whether CARICOM will develop regional rules affecting trade in GE products.

PART B: Policy

a) Regulatory Framework:

Most of the countries within CARICOM are seeking to address their plant biotechnology requirements through a NBF. To date, only St. Kitts and Nevis and St. Lucia have enacted any biosafety legislation. While an important first step toward establishing their comprehensive NBFs, implementing regulations have yet to be finalized and thus the regulatory and institutional structures are not yet operational. None of the other CARICOM countries has enacted any biosafety legislation.

The Regional Project for Implementing NBFs

The \$13 million UNEP/GEF Regional Project for Implementing NBFs in the Caribbean, which is being executed by UWI, is assisting the 12 CARICOM countries that are parties to the CPB with implementation of their obligations [2]. This project is a continuation of previous UNEP/GEF biosafety capacity building efforts in the region dating back to 2001.

[1] Guadeloupe and Martinique, as overseas departments of France, may be exceptions to this statement.

[2] CBATO Islands participating in the UNEP/GEF project are Antigua and Barbuda, The Bahamas, Barbados, Dominica, Grenada, St. Kitts and Nevis, St. Lucia, St. Vincent and the Grenadines, and Trinidad and Tobago. The other CARICOM participants are Belize, Guyana, and Suriname.

The overall goal of the UNEP/GEF project is to implement effective, operable, transparent and sustainable NBFs, and deliver global benefits that are compliant with the CPB in the Caribbean sub-region countries while also protecting against any potential risks from the introduction of LMOs. The four project aims are to:

- “Establish institutional (policy/legal) frameworks for biosafety at both the national and regional levels that will allow Parties to the CPB to utilize modern biotechnology in compliance with this Protocol;
- Facilitate the establishment, enhancement and operation of institutional capacities as well as technical and technological resources among the participating Caribbean Member States for the detection, assessment and management of potential risks from modern biotechnology (in combination with invasive alien species (IAS) where appropriate) at the national and regional levels;
- Develop and strengthen the human resource base and level of expertise in biosafety on a national and regional scale, in support of biosafety management and national biosafety systems in the Caribbean;
- Improve and consolidate biosafety information management within the Caribbean project countries in a way that can promote transparency, raise public awareness and facilitate biosafety decision making, and be up scaled to provide broader regional information services as needed, and if possible, establish links to information sources.”

The regional portion of the project aims to support the establishment of a region-wide mechanism for coordinating and supporting countries in biosafety management by providing them with training on biosafety risk assessment and the management of LMOs. A key component of this will be a Regional Biosafety Clearing House (R-BCH), which will include an electronic information hub to communicate with similar BCHs at the national level. The R-BCH will be responsible for:

- managing the entire application process of LMOs intended for introduction into the environment, including distributing the information to the appropriate national BCH nodes. It will also maintain the timeline with prompts to the National Biosafety Authorities to ensure that decisions are made within the stipulated timeframe.
- maintaining a regional roster of experts to provide assistance to countries where expertise does not exist, and to harmonize risk assessment processes in the region by pooling existing resources.
- supporting the regional network of laboratories to provide assistance to the national regulatory agencies in monitoring and testing activities.
- providing capacity building and carrying out public education programs.

National activities of the project will also support the establishment of the necessary legal and institutional frameworks, public education programs, and training necessary for effective and sustained implementation of the CPB. Projected country-specific outcomes include establishing:

- Functional NBFs in line with the CPB and the national and regional needs of each country;
- Functional national systems able to detect LMOs and perform risk assessments;
- Functional systems to monitor the environment and enforce regulations;
- National systems for biosafety information management while stimulating public awareness, biosafety education, and participation in the decision-making process.

The project, which began in November 2012, was originally scheduled to be completed by December 2015. However, due to various factors, the project deadline was postponed. According to UWI’s project management, country level activities have concluded and regional level activities are expected to wrap up by December 2018. In addition to the project’s conclusion being pushed back, the realization that the timeline for enacting biosafety legislation in each country could not be fully controlled led to the redefinition of an important project output. Rather than countries being expected to enact biosafety legislation, the current expectation is that the draft legislation will be ready for Parliamentary approval. To date, only St. Kitts and Nevis and St. Lucia have passed their respective biosafety legislation while all others are working to make their draft legislation “Parliament-ready.” It is important to note that Barbados and The Bahamas never signed the project partnership agreement with UWI, and Suriname signed the agreement quite late into the project. This precluded these countries from drawing on any project funds for national level activities and thus fully participating in the project. These countries

opted toward transferring their project country funds to the regional component of the project in order to reap some tangential benefits from the project.

UWI's project management is currently working with a consultant to develop a proposal to be presented to UNEP/GEF for a follow-up project to help participating countries enact their biosafety legislation. If fully approved, UNEP/GEF will consult with participating countries to assign an Executing Agency for the project. Once the legislative framework is in place, the expectation is that the Caribbean Agricultural Health and Food Safety Agency (CAHFSA), a CARICOM organization, would be charged with regional follow-up, harmonization, and sustainability of biosafety regulatory efforts. UWI's responsibilities will focus on assisting the R-BCH, capacity building, and supporting the laboratory network.

The following table shows the general status of the biosafety legislation of the CBATO countries participating in the UNEP/GEF project.

Country	Status of Legislation (as of September 2018)
Antigua and Barbuda	Draft legislation is not "Parliament-Ready"
The Bahamas	Draft legislation has yet to be developed
Barbados	Draft legislation has yet to be developed
Grenada	Draft legislation is "Parliament-Ready"
Dominica	Draft legislation is not "Parliament-Ready"
St. Kitts and Nevis	Legislation passed.
St. Lucia	Legislation passed.
St. Vincent and the Grenadines	Draft legislation is not "Parliament-Ready"
Trinidad and Tobago	Draft legislation is not "Parliament-Ready"

Note: Although not part of the CBATO region, Belize and Guyana are also reported to have their draft legislation "Parliament-Ready", on the other hand Suriname's draft legislation is not.

Source: UWI project management.

In addition to the UNEP/GEF project efforts, CARICOM's Council for Trade and Economic Development (COTED) has reportedly passed a "Regional Biosafety Harmonization Policy." Key elements of this policy include:

- The regulatory system for biosafety will be country-based and at a minimum will involve the agencies responsible for food safety, plant quarantine and environmental management in each country.
- Some biosafety activities, such as risk assessment, capacity building, public education, information management, and reference laboratory testing, are to be handled at the regional level.
- Risk assessment for LMO's will be science-based.

- Risk assessment and decision making for LMO-FFPs will be science-based and grounded in the principle of *substantial equivalence* [1] as espoused by Codex Alimentarius. This will be done at the regional level.
- Decision-making for LMO's intended for intentional introduction into the environment and LMO's intended for contained use will be handled on a case-by-case and stage-by-stage basis. This will be done at the country level.
- Regulation of LMOs (each event) will be based on a one-time permit and will be based on the *Advance Informed Agreement (AIA) procedure* [2] at the country level.
- Biosafety information management will be conducted through an internet-based BCH, with a regional hub and national nodes, ensuring communication and harmonization between the two levels.
- Food labeling policy will be based on a system of voluntary negative labeling. The critical level for negative labeling will be at five percent LMO content.

b) Approvals:

Without all the legal and regulatory frameworks being in place, no GE plants or crops have been approved or registered in the region for cultivation, import, or export.

c) Stacked or pyramided event approvals:

The same holds true for stacked or pyramided events. Moreover, such events are not contemplated in CARICOM's regional policy. A scientific risk assessment would need to be conducted before any approval or registration would be considered.

d) Field Testing:

No field-testing of GE crops is currently taking place.

e) Innovative Biotechnologies:

The use of innovative biotechnologies (such as genome editing) in plants or plant products has not been fully contemplated in national legislation or regional policy. Thus, even when proposed biosafety regulatory systems become operational, the regulatory status of such biotechnologies will be undetermined and will likely require further assessment.

f) Coexistence:

[1] In food safety, the concept of substantial equivalence holds that the safety of a new food, particularly one that has been genetically engineered, may be assessed by comparing it with a similar traditional food that has proven safe in normal use over time.

[2] Under the CPB, the AIA procedure applies to the first intentional transboundary movement of LMOs for intentional introduction into the environment of the Party of import. It includes four components: notification by the Party of export or the exporter, acknowledgment of receipt of notification by the Party of import, decision procedure and review of decisions. The purpose of this procedure is to ensure that importing countries have both the opportunity and the capacity to assess risks that may be associated with the LMO before agreeing to its import.

Although no rules are currently in place for coexistence of GE and non-GE crops, it is worth noting that individual countries in the region have indicated that once biosafety regulatory systems become operational, they will want to retain decision-making on this matter at the national level rather than at the regional level.

g) Labeling:

As a general pragmatic approach to trade (in recognition of the large volume of food imports from the United States), project participants have reportedly agreed to implement voluntary rather than compulsory negative labeling requirements for foods containing GE ingredients. Labeling legislation would need to be approved before implementation could take place by the appropriate labeling enforcement authority in each country.

h) Monitoring and Testing:

As part of the UNEP/GEF project, the region has developed testing capability for LMO events. At the country level, participating countries have acquired lab equipment and trained lab personnel to conduct basic testing. UWI also has three regional labs with more advanced equipment, which national labs can use to conduct more advanced tests or validate their results. As a third option, the region would rely on accredited U.S. reference labs. To date, no trade has been affected by any monitoring or testing.

i) Low Level Presence (LLP) Policy:

The draft regional biosafety policy calls for countries to implement a five percent LLP.

j) Additional Regulatory Requirements:

Not applicable.

k) Intellectual Property Rights (IPR):

Given the lack of commercial production of GE crops in the region, Post is not aware of any GE-related IPR issues.

l) Cartagena Protocol Ratification:

Nine of the countries in the CBATO region are parties to the CPB, and while they are all in the process of trying to meet their obligations under the protocol, none has fully implemented it to date.

Status of Ratification and Entry into Force of the CPB

	Date of Signature	Date instrument of ratification or accession was deposited	Accession Mode	Date of entry into force
Antigua and Barbuda	May 24, 2000	Sep 10, 2003	Ratification	Dec 9, 2003
The Bahamas	May 24, 2000	Jan 15, 2004	Ratification	Apr 14, 2004
Barbados		Sep 6, 2002	Accession	Sep 11,

				2003
Dominica		Jul 13, 2004	Accession	Oct 11, 2004
Grenada	May 24, 2000	Feb 5, 2004	Ratification	May 5, 2004
St. Kitts and Nevis		May 23, 2001	Accession	Sep 11, 2003
St. Lucia		Jun 16, 2005	Accession	Sep 14, 2005
St. Vincent and the Grenadines		Aug 27, 2003	Accession	Nov 25, 2003
Trinidad and Tobago		Oct 5, 2000	Accession	Sep 11, 2003

Source: Convention on Biological Diversity website (<http://bch.cbd.int/protocol/parties/#tab=0>).

Please refer to the table in PART B, sub-paragraph a, for information on the status of each country's biosafety legislation. As part of the UNEP/GEF regional project for implementing NBFs in the region, UWI is working with a consultant from the International Centre for Genetic Engineering and Biotechnology (ICGEB) in Trieste, Italy, to develop implementing regulations based on each country's draft legislation. Model legislation has also been developed to assist those countries lagging behind in their effort to produce draft biosafety legislation that is to be passed by their respective Parliament.

m) International Treaties/Forums:

We are not aware of the region or any individual CBATO islands of coverage taking positions pertaining to agricultural biotechnologies, the use of such technologies, and products thereof in other international treaties/fora.

n) Related issues:

None.

PART C: Marketing

a) Public/private opinions:

As part of the UNEP/GEF project, participating countries engaged in "awareness raising activities" at the national level to educate the public on biosafety, biotechnology, bio-security and invasive species. The project also supported stakeholder consultations as part of the national processes to enact biosafety regulations. Nonetheless, overall awareness of agricultural biotechnology and GE products is quite limited. There is no public discussion on the matter and there are no NGO's or public campaigns lobbying for or against agricultural biotechnology, albeit for planting GE crops or consuming foods derived from GE crops.

b) Market acceptance/studies:

There are no significant marketing issues that currently affect U.S. agricultural products.

CHAPTER 2. ANIMAL BIOTECHNOLOGY:

PART D: Production and Trade

a) Product Development:

The Caribbean region is not yet developing animal genetic engineering or cloning of animals. Although there has been some biotech research in Barbados on Blackbelly sheep, the region is far from having the capability to engage on specific animal biotechnology projects. However, experts in the region believe that an expansion of animal breeding using conventional and new embryo techniques as well as DNA techniques to characterize regional species would be a positive development. The use of molecular techniques to identify genes for breeding purposes will be high on the research agendas of several countries in coming years.

On a related topic, in 2016 the Government of the Cayman Islands, through its Mosquito Research & Control Unit (MRCU), partnered with the UK based biotechnology firm, Oxitec, to collaborate on a “Friendly *Aedes aegypti* Mosquito Project.” *Aedes aegypti* is a vector for Dengue Fever, Chikungunya, Zika (which has been linked to nervous system disorders and birth defects such as microcephaly), and Yellow Fever. The project uses a pioneering technique involving GE male mosquitos to fight *Aedes aegypti*. The GE males, which cannot bite, are released into the wild to mate with female *Aedes aegypti*, producing offspring that die before reaching maturity. The GE males also die within a few days. The result of the project was a greatly reduced *Aedes aegypti* population. MRCU’s collaboration with Oxitec goes back to 2009, when field releases of the GE mosquitos were conducted in Grand Cayman to test the safety and efficiency of the technique. According to the MRCU’s June 2017 Annual Report on the project, the operational deployment of GE mosquitos (which began in July 2016) yielded a 62 percent suppression of *Aedes aegypti* in the release area. Moreover, the release area has shown consistent lower levels of infestation for the whole of 2017, confirming that the population has been suppressed. So far, the Cayman Islands is the only country within the CBATO region of coverage employing biotechnology in its fight against mosquito-borne disease.

b) Commercial Production:

Not applicable.

c) Exports:

Not applicable.

d) Imports:

Not applicable.

e) Trade Barriers:

Although there are no known barriers to trade, it is believed that animal health and food safety authorities would treat requests for imports of GE animals, livestock clones, and offspring of clones or products from these animals, with an abundance of caution prior to granting import approval.

PART E: Policy

a) Regulatory Framework:

The UNEP/GEF Regional Project for Implementing NBFs in the Caribbean pertains to plant biotechnology only. There is no regulatory framework for animal biotechnology.

b) Innovative Biotechnologies:

Not applicable.

c) Labeling and Traceability:

Not applicable.

d) Intellectual Property Rights (IPR):

Not applicable.

e) International Treaties/Forums:

Not applicable.

f) Related Issues:

None.

PART F: Marketing

a) Public/Private Opinions:

As mentioned earlier, overall awareness of agricultural biotechnology and animal biotechnology specifically, is quite limited. There is no public discussion on the matter and there are no NGO's or public campaigns lobbying for or against agricultural biotechnology. However, it is believed that the public is more sensitive to animal biotechnology and would treat issues related with livestock clones, offspring of clones, and GE animals with greater caution.

b) Market Acceptance/Studies:

There are no studies that we are aware of regarding marketing of animal biotechnology products in the region. Overall acceptance of animal biotechnology by government regulators, producers, the trade and consumers remains unknown, but as mentioned above the subject is likely to be treated with a great deal of caution.