UNIVERSITY OF THE WEST INDIES

FINAL REPORT

REVIEW OF BIOSAFETY LEGISLATION IN CARICOM MEMBER STATES

submitted by:

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CONTENTS

EXECUTIVE SUMMARY

This Final Report is prepared in accordance with the requirement of the Terms of Reference of the "Review of Biosafety Legislation in CARICOM Member States Project" of the Contracting Agency, The University of the West Indies, St Augustine Campus, Trinidad and Tobago.

It presents the CARICOM Model Biosafety Bill as the Annex to the Report, as well as the methodology used in developing the Bill, lessons learnt, and recommendations for closing gaps found. The methodology entailed the conduct of a gap analysis of the legal framework for biosafety in the participating beneficiary CARICOM Member States.

The major finding of the gap analysis is that existing and proposed biosafety frameworks fail to provide a specific role for regional institutions to carry out functions that are best placed at the regional level. Restraints exist concerning the adequacy of national biosafety capabilities and there are benefits to be gained in creating and implementing a harmonized approach to limit divergence in trade practices relevant to biosafety.

One of the primary recommendations made and reflected in the Model Bill is that the legislation should not specifically give the force of law to the Cartagena Protocol on Biosafety (CPB) to the Convention on Biological Diversity (CBD); but it nevertheless implements its requirements. This approach allows for CARICOM Member States to address additional measures not provided for in the Cartagena Protocol, given that the focus of the Protocol is to address adverse effects of living modified organisms on the environment, as opposed to human health and safety. This approach will therefore allow greater flexibility in responding to advances in modern biotechnology and biosafety which are not addressed by the Cartagena Protocol.

CHAPTER 1 – INTRODUCTION: PROJECT FUNDAMENTALS

1.1 Project Background

The "Review of Biosafety Legislation in CARICOM Member States Project" (herein called “Regional Biosafety Project”) aims to develop and implement a harmonized biosafety system in CARICOM countries, based on the Cartagena Biosafety Protocol and provides support to countries to establish biosafety legislation and regulations based on a harmonized policy.

As much as 90 % of the imports of food and feed into CARICOM countries, particularly those that are derived from commodity crops such as corn, soy, canola and cotton are imported from the Americas, and are predominantly living modified organisms for direct use as food, feed or for processing (LMO-FFP). Furthermore, many of these commodities are imported and converted into a range of manufactured products in Caribbean countries and traded within the CARICOM region. As a result of this, the Council for Trade and Economic Development (COTED) of CARICOM, at its 71st Special Meeting, held in Georgetown, Guyana, from 4th – 6th October, 2017 agreed to the adoption of the Regional Biosafety Policy developed by the University of the West Indies (UWI).

The Contracting Agency is the University of the West Indies, St Augustine Campus, Trinidad and Tobago which is managing the Regional Biosafety Project. The Consultancy is being undertaken by the Caribbean Agricultural Health and Food Safety Agency (CAHFSA).

The Legal Consultant was engaged to review all existing (draft/passed) Biosafety legislation in CARICOM Member States to assess their coherence with the Regional Biosafety Policy. Based on the results, a CARICOM Model Bill was prepared.

1.2 Project Methodology

The contract was signed on 16th February 2018, with the assignment expected to be performed from the 19th February 2018 to 6th April 2018. The Contract was extended to 31st December 2018.

The methodology used for conducting this assignment was directed by the consultancy’s objective and scope of work. The objective of the consultancy is:

(i) to review existing draft or passed legislation to see how they fit with the regional biosafety policy;

(ii) to development a model law for the Region based on the results of the review.

The Terms of Reference specify the following responsibilities of the Consultant -

'The Consultant is expected to:

(i) Attend an initial virtual briefing meeting with the UWI Biosafety Management Team and CAHFSA to discuss the objectives, activities, approach, expected outputs and any other issues related to the execution of the assignment that require clarification;

(ii) Prepare a work plan clearly identifying an outline and timelines within five (5) days of the briefing meeting with the UWI and CAHFSA Technical Team;

(iii) Specifically, develop and present a work-plan, proposal and methodology for developing the review, including a clear understanding of the nature and scope of the assignment, the methodological framework to be employed and the time frame necessary."

The methodology utilised in carrying out the consultancy is as follows -

1. A Kick-off virtual meeting between the UWI Biosafety Management Team, and CAHFSA and the Consultant was held on the 14th March 2018.

   The representatives of CHAFSA and the UWI presented the mandate of the Cartagena Protocol on Biosafety and a synopsis of a UNEP project through which technical assistance was provided to some CARICOM Member States to develop national biosafety policy and legislation. The Consultant sought and received clarification on several issues raised by the Regional Biosafety Policy. These include the structure and powers of the regional biosafety framework and the coordination necessary between national and regional frameworks.

2. Preparation and submission of a Work Plan providing the timeframes for the activities.

3. Conduct of a literature review of documentation relevant to the consultancy.

   The documents reviewed include policies and laws from Antigua and Barbuda, Bahamas, Belize, Dominica, Grenada, Guyana, St Kitts & Nevis, St Lucia, St Vincent & the Grenadines and Trinidad and Tobago; and the Guidelines on Caribbean Biosafety Network Technical Working Group from the Regional Project for Implementing National Biosafety Frameworks in the Caribbean Sub-Region which were submitted by the UWI Biosafety Management Team. Other resource material include "An

Explanatory Guide to the Cartagena Protocol on Biosafety" IUCN Environmental Law Centre, "Cartagena Protocol on Biosafety: A Report on Policy Analysis, Program Design and Implementation" 2004, Columbia University and Biosafety laws from jurisdictions such as The European Union, Africa, India, Pakistan, Malaysia and New Zealand.

4. Preparation of a gap analysis of the national biosafety frameworks, and identifying omissions and weaknesses that affect compliance with the Regional Biosafety Policy. The relevant laws and policies of project beneficiary countries were reviewed and a synopsis created to scope the level of divergence between the national and regional frameworks.

   The findings of the literature review have assisted in identifying the weaknesses of existing laws or draft legislation, and in preparing the CARICOM Model Biosafety law and this Final Report. Permission was provided to the Consultant to forego the preparation of a Progress Report as was required in the Terms of Reference of the project.

5. Preparation of a CARICOM Model Biosafety law that creates the framework necessary to ensure an adequate level of biosafety protection for CARICOM.

   The initial draft of the legislation was revised based on the following inputs-

   - Comments received at the Regional Project for Implementing National Biosafety Frameworks in the Caribbean Sub-Region, Project Closure Meeting, 11th April 2018, Barbados, at which the Consultant provided an overview of the first draft of the CARICOM Model Biosafety Bill. This avenue was used as attempts to convene a specific legislative review meeting of regional biosafety officials and legal representatives failed to materialise due to insufficient confirmation of participation.

   - Meetings of 8th June 2018 and 6th – 7th December 2018 at the St Augustine Campus, Trinidad and Tobago. Attendees comprised officials from CAHFSA, the UWI project team, and the Consultant.

   - Comments submitted by external reviewer, Dr Michael Wach, Consultant with proven research and analytical skills in the fields of science and law.

   (Other post-project revisions are expected to be conducted based upon comments from CARICOM Member States).

6. Preparation of the Final Report.

CHAPTER 2 - ANALYSIS OF BIOSAFETY FRAMEWORKS

2.1 Introduction

Biosafety refers to the safety standards used to handle living modified organisms, which are products of modern biotechnology, given the potential of LMOs to significantly adversely affect the environment and human health. Modern biotechnology involves the use of genetic engineering techniques to transfer useful characteristics beyond the taxonomic family of a living organism. Modern biotechnology has facilitated better ways of growing crops and producing medicines by producing genetically modified organisms. However, the associated risks, particularly those that are unknown, have emphasised the need to create a regulatory framework for biosafety, given the risks associated with the conservation of biodiversity and agricultural sustainability, and ethical and socio-economic considerations.

The international context for biosafety has, as one of its international agreements, the Convention on Biological Diversity (CBD) which entered into force on 29th December 1992. Its objectives are the conservation of biological diversity, the sustainable use of its components, and fair and equitable sharing of benefits arising out of the utilization of genetic resources. The CBD specifically addresses living modified organisms (LMOs), with Article 19(3) requiring the Parties to "consider the need for and modalities of a protocol setting out appropriate procedures, including, in particular, advance informed agreement, in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity".

The Cartagena Protocol on Biosafety (CPB) to the Convention on Biological Diversity (CBD) was therefore negotiated in recognition of "the rapid expansion of modern biotechnology and the growing public concern over its potential adverse effects on biological diversity, taking also into account risks to human health". Thirteen CARICOM countries are parties to the Cartagena Protocol on Biosafety and are committed to implementing the Cartagena Protocol while enhancing their own regulatory framework for addressing LMOs.

UNEP has in the past provided technical assistance to CARICOM Member States in developing biosafety policies and administrative and legal frameworks. For example, National Biosafety Frameworks and Policies have been prepared for countries such as Grenada, Guyana, Saint Lucia, St Kitts and Suriname. Biosafety legislation was enacted in St Kitts and Nevis in 2012, with draft legislation existing in countries such as Saint Lucia, St Vincent and the Grenadines and Grenada. The efforts were however not coordinated and resulted in disparate frameworks that threatened the single market ethos of the Treaty of Chaguaramas with the potential for distortion of trade and investment.

The Regional Biosafety Policy was therefore created to harmonise the regional approach to biosafety. It was adopted by the COTED at its 71st Special Meeting. Its primary focus is to ensure that a regional mechanism is created that will, inter alia, receive applications for import of LMOs and provide them to the

relevant Member States, conduct scientific risk assessments and provide a Regional Biosafety Clearing House that facilitates information sharing.

2.2 Overview of Cartagena Protocol on Biosafety

The Cartagena Protocol on Biosafety contains 40 Article and 3 Annexes. An overview of the Cartagena Protocol on Biosafety is presented.[1]

Purpose
The purpose of the Cartagena Protocol on Biosafety (CPB) is, having regard to the precautionary approach, "to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of LMOs, taking also into account risks to human health, and specifically focusing on transboundary movement" (Article 1).

Scope of the Protocol and Advance Informed Agreement (AIA) procedure (Articles 4–7)

The Protocol applies to "transboundary movement, transit, handling and use of all living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health" (Article 4).

The AIA procedure applies in the first instance that a LMO covered by Article 7 is intentionally moved from the territory of a Party to the Protocol into another.

LMOs subject to AIA provisions
- LMOs intended for intentional introduction into the environment (Article 7(1)).

LMOs excluded from AIA provisions
- LMOs in transit (Article 6(1)).
- LMOs destined for contained use in the Party of import (Article 6(2)).
- LMOs intended for direct use as food or feed, or for processing (LMO-FFPs) (Article 7(2)).
- LMOs identified by the meeting of the Parties to the Protocol as being not likely to have adverse impacts (Article 7(4)).

LMOs excluded from provisions on transboundary movements
- LMOs that are pharmaceuticals for humans that are addressed by other international organizations or agreements (Article 5).

Procedure for LMOs Intended for Direct Use as Food or Feed, or for Processing

[1] Source: Explanatory Guide to the Cartagena Protocol on Biosafety, IUCN, 2003.

Where a Party makes a final decision about domestic use of a LMO (such as placing on the market), and the LMO may be exported for direct use as food or feed, or for processing, then that Party must notify the other Parties through the Biosafety Clearing-House within 15 days of making that decision (Article 11, Annex II).

Review of decisions
An importing Party may review and change a decision on transboundary movement of LMO in light of new scientific information on potential adverse effects on the conservation and sustainable use of biological diversity, taking also into account the risks to human health. An exporting Party or a notifier may request the importing Party to review a decision made under Article 10 if there is change in circumstances that may influence the outcome of risk assessment on which the original decision was based; or additional relevant scientific or technical information has emerged (Article 12).

Simplified Procedure
An importing Party may, by providing advance notice to the Biosafety Clearing-House, allow international transboundary movements of LMOs to it to take place on the basis of a mere notification and allow imports of LMOs to be exempted from the AIAP. The simplified procedure can be used if "adequate measures are applied to ensure the safe intentional transboundary movement of living modified organisms in accordance with the objective of this Protocol (Article 13).

Risk assessment
Risk assessments must be conducted in a scientifically sound manner. (Article 15 and Annex III).

Risk Management
Parties are obliged to set up appropriate mechanisms, measures and strategies to regulate, manage and control risks identified in the risk assessment provisions of the Protocol associated with the use, handling and transboundary movement of
LMOs (Article 16).

Unintentional Transboundary Movements & Emergency Measures
Parties are obligated to notify (potentially) affected States on becoming aware of an occurrence within its jurisdiction that leads or may lead to unintentional transboundary movement of a LMO that is likely to have significant adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health (Article 17).

Handling, Transport, Packaging & Identification
A general duty is imposed on each Party to require LMOs that are subject to intentional transboundary movement within the scope of the Protocol to be handled, packaged and transported under conditions of safety, taking into consideration relevant international rules and standards. (Article 18).

Competent National Authorities & Focal Points

Parties are required to designate one or more national competent authorities, tasked with the administrative responsibilities required by the Protocol (Article 19).

Confidential information
An importing country must allow an applicant to identify which information provided is to be treated as confidential (Article 21).

Public Awareness & Participation
Parties are required to promote and facilitate public awareness, education and awareness regarding LMOs, and must endeavour to ensure public awareness and education on LMOs that may be imported.

Illegal Transboundary Movements
Parties are required to adopt appropriate domestic measures aimed at preventing and penalizing transboundary movements carried out in contravention of domestic measures to implement the Protocol. Such movements shall be deemed illegal transboundary movements (Article 25).

Socio-Economic Considerations
Parties, in reaching a decision on import under the Protocol or under its domestic measures may, consistent with their international obligations, have regard to socio-economic considerations which arise from the impact of LMOs on the conservation and sustainable use of biological diversity especially with regard to the value of biological diversity to indigenous and local communities (Article 26).

Liability & Redress
A process for elaborating international rules for liability and redress for damage resulting from transboundary movement of LMOs must be created (Article 27).

2.3 Overview of Status of Related Biosafety Legislation

With the exception of St Kitts and Nevis' Biosafety Act of 2012, no other participating beneficiary country has a single specific legislation that comprehensively regulates biosafety. Several biosafety related legislation however exist which impact biosafety related functions carried out by various agencies. These government entities, their functions and the laws relevant to their functions are summarised as follows –

1. **Ministry of Agriculture**

   Legislation such as the Fisheries Act, Plant Protection Act, Agricultural Health Act, and Animal Health Act regulate functions relating to the management of agriculture, forestry, fisheries, aquaculture, veterinary services, quarantine, and food safety. A licence/permit must be obtained for research purposes, or for sanitary and phytosanitary purposes when importing or exporting plant and animals to protect against diseases, failing which they can be seized, forfeited and destroyed.

2. **Ministry responsible for the Environment/Sustainable Development**

   Legislation such as the Environmental Management Act establish government bodies responsible for environmental governance, regulate uses of the environment that are likely to endanger public health, provide for the issuance of environmental clearance certificates which authorise activities that may have adverse impacts on the environment, and provide for the management of protected areas.

3. **Physical Planning Department**

   The Physical Planning and Development Act creates a Planning Board charged with oversight of physical planning development for the country. An aspect of this function is to require the conduct of environmental impact assessments for developments that may have significant adverse effects on the environment.

4. **Ministry responsible for Trade/Industry/Commerce**

   The trade of goods is affected by legislation such as the Producers Export Act which requires a licence to export produce, and Import and Export Control Regulations which provide for the use of permits/licences/certificates and other means to control imports and exports. In addition to the functions arising under such legislation, other functions exercised by this Ministry include protecting consumers' interest by ensuring that goods and services are safe and legal (under Consumers Protection Act); promoting cooperation between the public and private sectors to increase business competitiveness; and the monitoring of trade at the local, regional and international levels.

5. **Ministry responsible for Information Technology**

   This Ministry, inter alia, develops information technology policy.

6. **Ministry responsible for Health**

   This Ministry performs functions relevant to the control of drugs, medical research, public health including food safety, and environmental services relating to environmental pollution.

7. **Bureau of Standards**

   Legislation such as the Bureau of Standards Act and Food Safety Act create consumer protection requirements, standards for labelling and food quality.

In summary, the existing laws were created to address specific subject matters and not significant adverse risks associated with LMOs. Some aspects of the laws may be relevant in addressing the use, handling, transfer and

transboundary movement of LMOs as required by the Biosafety Protocol; however, they fail to create a comprehensive regime.

2.4 Regional Biosafety Policy

The CARICOM Biosafety Policy was considered and approved by the COTED in 2017. It seeks to provide a harmonised approach for addressing biosafety within the Community. A synopsis is presented.

1. Principles

Some principles relevant to policy harmonisation include the following –

- Based on the principles and approaches in the Cartagena Protocol on Biosafety of the Convention of Biological Diversity.

- Adhere to the principles and the spirit of the Revised Treaty of Chaguaramas establishing the Caribbean Community including the CARICOM Single Market and the Economy.

- Utilize the collective wisdom and knowledge of the regional scientific community for scientific risk analysis; or for the optional step of socio-economic analysis bringing greater efficiency.

- The risk assessment for LMOs (see Annex-III of CPB) will be science-based using the best science available and using the best scientists available within the CARICOM, with the option of co-opting experts from outside the region, where necessary to reduce cost and improve efficiency (Regional Scientific Risk Assessment). It will however take into consideration the precautionary approach where scientific uncertainty exists (Article 1 of CPB).

- Allow countries the option of having a socio-economic risk assessment (Article 26 of CPB) in addition to the scientific risk assessment of LMOs, where necessary. (National or Sub regional).

- Risk assessment and decision making for LMO-FFPs (Article 11 of CPB) will be based on national legislation but information shall be made available in the Biosafety Clearing-House with copies of any national laws, regulations and guidelines applicable to the import of living modified organisms intended for direct use as food or feed, or for processing (Article 11 of CPB). The risk assessment should be science-based and grounded in the principle of substantial equivalence as espoused by Codex Alimentarius (FAO/WHO). This could be carried out the regional level reducing the regulatory burden of individual countries.

- Decision making for LMOs (intended for intentional introduction into the environment) and LMOs in contained use will be at the country

level and will be on a case-by-case basis and on a stage-by-stage. In the case of LMO-FFP the decision making will be at the regional level[2] possibly coordinated by a regional regulatory organization such as CAHFSA (CARICOM Agriculture, Health and Food Safety Agency).

- The regulatory system for biosafety will be country-based (national) and will at least involve the following agencies; food safety, plant quarantine and the environmental management authority.

- Regulation of LMOs (each event [text-box-4]) will be based on a one-time permit and will be based on the Advanced Informed Agreement (AIA) procedure at the country level (Article 7 of CPB). Regulation of LMO-FFP will be based on a common permitted list on the Regional node of the Biosafety Clearing House. Regulation of LMOs in contained use will be based on a stage-by-stage permit (country level). Regulation of research institutions working on modern biotechnology would be based on a system of guidelines and oversight.

- The policy will establish three tiers of laboratories to support the regulatory agencies – national laboratories, reference laboratories and accredited international laboratories performing the functions of surveillance, monitoring and routine testing; reference testing and capacity building; and validation functions, respectively. The guidelines of operationalising this laboratory network shall be developed and implemented.

- Biosafety information management would be through an internet based biosafety clearing house, with a regional hub and national nodes, ensuring communication and harmonisation between the national biosafety systems and the regional hub.

- The policy will harmonise and streamline the administrative system by building in a gatekeeper function to the Regional node of the Biosafety Clearing House. Setting up a system by parties to the Protocol for receiving applications, notification of decisions and sharing decision documents and other Biosafety information is a requirement of the CPB. A harmonized approach makes it possible to use of the Regional Biosafety Clearing House to receive applications on a common agreed application format and shunt the applications to national nodes and manage the entire application and processing process electronically. An applicant could apply to the regional node indicating which countries that they wish to seek approval for.

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[2] N.B., some refinement of the Regional Biosafety Policy is evidenced in the CARICOM Model Biosafety Bill, including ensuring that decisions taken regarding LMOs must be at the national level, with scientific support in the form of risk assessments being offered at the regional level to enhance efficiencies of scale.

- The food labeling policy will be based on a system of voluntary negative labeling. The critical level for negative labeling will be at the level of 5% LMO content based on best practices around the world.

2. Scope of the Regional Biosafety Policy

The Regional Biosafety Policy deals with the safety of LMOs and LMO-FFP to human and animal health, agriculture and the environment, transboundary movement of LMOs and LMO-FFPs and the mechanisms of harmonization of policies in the CARICOM.

3. Proposed Harmonised Regional Biosafety System

A. Regional harmonization of LMOs intended for intentional introduction into the environment - Administrative System	
Purpose	• Provides the central coordinating functions for biosafety. • Provides a harmonised approach to biosafety by (a) creating an administrative process (application format, timelines with regard to processing of applications) (b) conducting scientific risk assessment and developing opinions (c) conducting socio-economic assessment (if done sub regionally) (d) creating a decision making process (particularly for LMO-FFPs (e) determining the standards, guidelines and methods to be used which may be developed at the regional level and reviewed from time to time by CAHFSA, CROSQ; (f) providing capacity building programmes (g) providing public education; (h) providing biosafety research support thus reducing the regulatory burden of individual countries and fostering an environment of mutual support but which still permits sovereign countries to make their own decisions with regard to LMOs. • Supports the processing of applications (e.g. AIA procedure for LMO) for import into the country, within the stipulated timeframes as specified in the Cartagena protocol. • Maintains a roster of experts from various disciplines. • Commissions scientific risk assessment and socio-economic risk assessment (optional). • Supports the decision making body. • Communicates decisions to interested parties.

	• Makes available the decision documents. • Maintains a list of approved LMOs and LMO-FFP events in the Biosafety Clearing House. • Communicates and coordinates between the regulatory agencies with regard to implementation. • Commissions the development of guidelines, standards, dossiers. • Coordinates public education and engagement programmes to ensure transparency of the system.
Designated Bodies & Specific Functions	• Regional Biosafety Centre (RBC) shall (a) serve as the regional administrative hub; (b) maintain and administer the regional node of the Biosafety Clearing House (R-BCH); (c) cause to be conducted a Scientific Risk Assessment, the Risk Assessment Report and an opinion for submission to the National Competent Authority within the stipulated time; (d) maintain a regional roster of experts; (e) provide capacity building programmes; (f) cause to be conducted biosafety research on behalf of the region, where necessary; (g) support public education programmes; (h) cause to be kept all decisions made in the CARICOM with regards to biosafety. • R-BCH shall (a) receive notifications of LMOs intended for intentional introduction into the environment on an agreed application format on behalf of the region, (b) submit notifications received to the national BCH nodes; (c) manage the electronic processing of applications; (d) ensure that decision timelines are met by issuing reminders the National Biosafety Authorities. • National Competent Authorities will house the national administrative hub and will include a biosafety Secretariat. • Responsibilities include (a) maintain the national node of the Biosafety Clearing-House; (b) upon receiving the scientific risk assessment and opinion from the Regional Biosafety Centre through the R-BCH it may cause to be conducted a socio-economic evaluation nationally or sub regionally (OECS) to determine the socioeconomic cost vs benefit; (c) cause to be conducted meeting/s of the decision making body. • Biosafety Secretariat of the National Competent Authority will (a) support the decision making process by providing all pertinent information to all parties; (b) communicate decisions to all parties including the applicant (for AIA) (within the stipulated time frames as outlined in the Cartagena Biosafety Protocol) and the national regulatory agencies (for implementation of the decisions); (c) maintain an up-to-date

	register of institutional biosafety committees (IBCs); (d) support the functions of the designated National Biosafety Laboratory; (e) providing a public education programme to ensure that the public is educated about new technological developments; (f) provide capacity building on biosafety issues; (g) maintain linkages with all biosafety stakeholders. • National Regulatory Agencies, Food and Drugs Division or its equivalent, Environmental Authority or its equivalent and the Agricultural Quarantine. In some countries the regulatory agencies are coordinated under an umbrella organization (e.g. NAHFSA). • Functions include (a) implement decisions; (b) maintain surveillance at the border (border control) as well as in the environment to ensure that unapproved LMO events are not introduced or have not be introduced unintentionally; (c) provide permits, guidelines and monitor to ensure compliance with the Biosafety Act, Regulations and Guidelines. • The food and drugs or equivalent agency will ensure that labelling complies with relevant laws.
B. Regional harmonization of biosafety systems for Living Modified Organisms intended for direct use as food, feed or processing (LMO-FFP)	
Approach	LMOs-FFP represent LMOs intended for food, feed or processing. Since these are not introduced into the environment, the environmental and agricultural risks are not important or low and hence the Cartagena Protocol recommends that countries regulate these through their local food safety regulations.
Local food safety regulations	Most CARICOM countries are signatory to the Codex Alimentarius Commission of the FAO/WHO. The Regional Biosafety Policy will adhere to the principles and practices recommended by the Commission of the FAO/WHO in relation to LMO-FFPs. According to Codex Alimentarius Commission, risks are assessed solely based only on scientific risk assessment and the decisions made based on the principle of 'substantial equivalence'.
Designated Bodies & Functions	• The regional Biosafety Clearing House (BCH) is responsible for (a) conducting scientific risk assessment, (b) ensuring compliance with the decision making process; and (c) maintaining an updated list of approved events (A LMO 'event' is defined as the insertion of a particular transgene into a specific location on a chromosome. The term "event" is often used to differentiate genetically engineered crop varieties.) • The Caribbean Agricultural Health and Food Safety Agency

	(CAHFSA) will function to (a) make decisions or cause decisions to be made on its behalf in relation to LMO-FFPs; (b) provide decisions on LMO-FFPs to the RBC for submission to countries.
C. Regional harmonisation of labelling of LMO-FFP	
Approach	Mandatory labelling systems given the geospatial position of the Caribbean and its trading relationships and practices will not be pragmatic. It would require that the suppliers of produce grow their crops separately from other LMO crops and with traceability systems in place to preclude the probability of admixture occurring during processing, storage and shipping. This will greatly increase the price of the basic staple goods to the average consumer by at least 20%. On the other hand voluntary negative labelling systems are more pragmatic and easier to implement. In this approach buyers could import product that have been certified as free of GMOs and be able to label them as such. This will allow them to differentiate their product from all other non-labelled products and hence be able to sell it at a higher price to those who prefer products free of LMOs. In all cases the LMO-FFPs imported would have to be first verified as substantially equivalent to the non-LMO counterparts; and therefore would not pose a health risk to the citizenry.
LMO-FFP labelling	The Regional Biosafety Policy brief advocates a system of voluntary negative labelling, with the truthfulness of the labelling verified at a limit of 5% LMO level as the limit for certification processes. Once labelling legislation is approved the regulatory agency responsible for food safety would have to do routine surveillance to ensure that the labels are truthful.
D. Regional harmonization of Biosafety Framework for LMOs in contained use	
Rationale	It is important to deal with application for contained or confined use of LMOs for the following purposes: (a) Support a research and development agenda of an institution or a company by allowing the development of LMOs in the laboratory and testing them in a contained setting in the greenhouse or in confined setting in restricted field trials before an application for commercial release is made. (b) Testing of a LMO in a confined setting before commercial release by a company into the environment. (c) For allowing the production of LMO seeds or products for export within a confined setting with no intention of general introduction into the environment.
Administration	• The countries' biosafety administration system must register

	each of the institutions or companies (Institutional Biosafety Committees, IBCs) that wish to work with LMOs in a contained or confined setting. • The application process and fee can be harmonized. • The IBCs will be authorized to carry on LMO work based on a harmonized signed agreement (with conditionalities) and regionally developed guidelines. • A regulatory agency will be authorized by law to conduct routine monitoring to ensure that institutions or companies are adhering to the guidelines. • Applications for evaluation of LMOs in contained and confined settings before commercial release will be based on a stage-by-stage basis. • Risk assessment and decision making would be at the national level, Regional harmonization of the process is important to allow for the joint development of common guidelines, sharing of best practices, regional support for risk assessment and for providing an even biotechnology development climate throughout the region.
E. Regional harmonization of Biosafety Framework for LMOs in transit	
Rationale	LMOs even if not intended for introduction into the environment from time to time may be transited through one country to the destination country. If proper packaging and labelling standards are not followed then there is a chance that this may lead to unintended introduction into the non-destined environment.
Designated Body & Functions	Regulatory agencies must develop and implement a common standard and guidelines to regulate transiting. These must be informed by Article 19 of the Cartagena Protocol.
F. Liability and redress	
	The region must develop agreed common methods for Liability and Redress based on the Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety.

2.5 Specific Biosafety Legislation

A synopsis is provided of the existing and proposed biosafety legislation of the participating beneficiary countries.

Country	Biosafety Legislation
1. Antigua and Barbuda	**Draft Biosafety Policy; Biosafety & Biotechnology Management Bill 2013; Draft Biosafety Regulations - Biosafety (Environmental Release) Regulations; Biosafety (Labelling) Regulations; Biosafety (Import, Export and Transit) Regulations; Biosafety (Contained Use) Regulations**
	Application/Scope: The Bill is applicable to contained use, intentional introduction into the environment, and import and export of LMOs. It is not applicable to pharmaceuticals for human use; LMOs in transit through but not destined for use in Antigua And Barbuda; any other prescribed exemptions. **Institutional & Administrative arrangements:** The National Biosafety Authority (NBA) is established as the Competent Authority consisting of both public and private sector representatives. A Scientific Advisory Committee is also created with membership drawn from regional bodies. Officials are designated for enforcement purposes. Control, management, authorisation & notification measures for LMOs are imposed. The Minister, on the recommendation of the NBA, may prohibit the handling, transport, use, transfer and release of any LMOs; any activity involving genetically modified organisms, so as to prevent or reduce risks to biological diversity, the environment and human health. Permits/ Authorisations - Persons wishing to conduct contained use activities of LMOs or import LMOs for contained use activities must first submit a notification to the Competent Authority 60 days prior to commencement of contained use activities using a simplified application and review procedure. Authorization is also required for activities involving intentional introduction into the environment and placing on the market (using the advanced informed agreement procedure); import; and export. Provisions are made concerning conditions relating to permits. The NBA may establish a register of LMOs approved for import into the country if satisfied that a risk assessment has been undertaken by an

	accredited regional organisation that is competent to undertake scientific assessments to determine that the LMO does not cause any significant ecological, social or economic harm in the country; there exists information on the interaction between the LMO and natural biodiversity, the environment and human health, including the results of any deliberate release in any other country; and here exists information on any previous approvals of the LMOs in any other country. Any person may apply to the National Biosafety Authority to register a LMO for pre-approval. Other aspects of the legislation address issues such as risk analysis; confidential information; requiring that only licensed and registered facilities can store or process LMOs; development by the NBA of a policy to promote & regulate biotechnology research & development, and the establishment of accidental release control group to create national accidental releases of LMO Risk Management Plan; and enforcement.
2. Bahamas	**Draft National Biosecurity Strategy**
	The vision of the NBS is "to raise awareness of all sectors of society of biosecurity and incorporate biosecurity in national planning and decision-making for the economic, environment and social development of the Bahamas." It addresses priorities and systems for enabling biosecurity and conservation and sustainable use of biodiversity. These are human health, animal health, plant protection, border control, capacity building, risk analysis, monitoring/surveillance and management; and enforcement. The NBS provides that the contents of the draft Biosecurity Act should address, control, eradication and management of organisms that threaten biosecurity. It will provide for the eradication or effective management of unwanted organisms already in the country and regulation of the entry of all alien organisms into the country by a system of permits based on environmental risk analyses. The legislation will establish an administrative framework for its implementation, allow for inter-governmental agency cooperation, NGO and public participation. Regulations for managing GMOs will include designating a National Focal Point, creating and maintaining a national Biosafety Clearing House; administrative system for controlling GMOs such as advanced informed agreement procedure, risk assessment, notifications, information dissemination and processing of applications; information to be provided by applicants; measures to prevent unintentional transboundary movements of GMOs; labelling for GMOs intended for food, feed or processing; designation of confidential information; the process for public participation in decision-making; and ensuring transparency in the decision-making process.

3. Barbados	**National Biosafety Bill 2016**
	Application/Scope: The Bill applies to the import, export, transit, contained use, release or placing on the market of any GMO, whether intended for release into the environment or for use as a pharmaceutical or for food, animal feed or processing. **Institutional & Administrative arrangements:** A National Competent Authority is created to administer the Act. It is supported by other bodies such as a Scientific Advisory Body, Public Information and Education Committee and Decision Making Council. Control, management, authorisation & notification measures for LMOs are imposed. Licences are required for the following activities involving living modified organisms - contained use activities, intentional release into the environment, commercial release, import, export, transit, and emergencies or serious threat to human and animal health, or the environment. The licence is subject to conditions imposed by or under the Act, the Minister etc. Application procedures and the information to be submitted are specified. Provisions specify the manner in which decisions on applications made to the National Competent Authority are made, notifying the decision to the applicant, appealing decisions, and revocation or suspension of licences. Other aspects of the legislation address issues such as risk analysis; confidential information; inspection, monitoring and audit; liability and redress; and transitional provisions.
4. Belize	**Final Draft National Biosafety Policy; Biosafety Bill 2006**
	Application/Scope: The Bill applies to the contained use; intentional introduction into the environment; commercial release on the market; import; export; and use as food, feed or for processing of living modified organisms and products derived from living modified organisms **Institutional & Administrative arrangements:** The Belize Agricultural Health Authority is designated the competent authority to administer the Act. It is supported by other bodies such as the National Biosafety Commission. A National Biosafety Clearing House is established under the management of the Authority which shall be maintained by a Registrar. Authorisation & notification measures for GMOs are imposed for contained use activities, intentional introduction into the environment, placing on the market, export, for direct use as food, and animal feed or processing. A simplified application procedure and the information

	to be submitted are specified. Other aspects of the legislation address issues such as risk assessment and risk management; confidential information; decision-making and communication of decisions; public awareness and participation; labelling for documentation relating to GMO use; and enforcement.
5. Dominica	**Climate Change, Environment and Natural Resource Management Bill 2013**
	Part XVIII addresses Biosafety & Biotechnology Management. **Application:** The development, production, release, transport, use and application of genetically modified organisms (including viruses and bacteriophages); (b) the genetic modification of organisms; and (c) the use of gene therapy. **Institutional & Administrative arrangements** – A National Biosafety Authority is established to administer the law. It is supported by other bodies such as a Secretariat, a Scientific and Technical Advisory Committee, and an Accidental Release Control Group. A National Biosafety Clearing House is established under the management of the National Biosafety Authority. Control, management, authorisation and notification measures for GMOs are imposed. Prohibitions that the Minister may impose concerning GMOs are the importation, handling, transport, use, transfer and release; (b) any activity involving GMOs so as to prevent or reduce risks to biological diversity, the environment and human health. Permits are required for the following activities involving GMOs – import, export, transport, use, store, sell, dispose of or otherwise control. No person may handle, transport, use, transfer, or release any GMO without a permit. Application procedures and the information to be submitted are specified. Allowance is made for the National Biosafety Authority to establish a register of GMOs that have been pre-approved for import into Dominica that have met certain criteria such as risk assessment; there exists information on the interaction between the GMO and natural biodiversity, the environment and human health, including the results of any deliberate release in any other country; and (c) there exists information on any previous approvals of the GMO. Persons may apply to the National Biosafety Authority to register GMOs for pre-approval. Other aspects of the legislation address issues such as risk management; labelling, packaging, segregation, confidential information; appeals, a duty to report threatened releases of GMOs; and enforcement. There are imposed risk management measures for

	import/export, with the person responsible for the import/export required to correctly complete the *Shippers Universal Dangerous Goods Declaration for Air, Sea and Land* and other relevant documentation for the transportation of hazardous substances. Other requirements (which may be impractical and burdensome) relate to the Port Authority being responsible for issuing guidelines and codes of practice concerning: (a) the storage and management of genetically modified organism in a controlled area; (b) the establishment of emergency and response procedures in the event of any accidental of any genetically modified organism in a controlled area; and (c) the establishment of any training requirements or programmes concerning the management, storage or handling of any genetically modified organism in a controlled area; and during the discharge of any cargo containing GMOs ensuring that: (a) the container is inspected to ensure no spillage or residue exists; (b) the berth is secure with access permitted only to authorised personnel and emergency services; (c) suitable warning notices are posted.
6. Grenada	**National Policy on Biosafety; National Biosafety & Biotechnology Management Bill**
	Application/Scope: The requirements of the Act are in addition to, and not in derogation of, the requirements imposed by any other Act. (2) The Act shall not apply to any GMO that is a pharmaceutical for human use, which is the subject of any other enactment or international agreement. **Institutional & Administrative arrangements** – A National Biosafety Board is established to administer the law. It is supported by other bodies such as a Registrar and a Scientific and Technical Advisory Committee. A National Biosafety Clearing House is established under the management of the National Biosafety Authority. Control, management, authorisation & notification measures for GMOs are imposed. Licences are required for the following activities involving GMOs - a contained use activity (the Board has within 90 and 150 days of receipt of the application to issue a licence to the applicant); intentional introduction into the environment, import, export and transit. Provisions are made for the manner in which the Board will assess applications and communicate its decision; conditions attached to licences; suspension, cancellation or revocation of licence. Other aspects of the legislation address issues such as risk assessment and management; packaging, identification and labelling; the use of emergency measures for unintentional release of GMOs; confidential information; public participation; liability and redress;

	inspection and monitoring; appeals; restoration and cessation orders; and offences and penalties..
7. Guyana	**Revised Draft Biosafety/Biotechnology Bill; Draft Biosafety (Labelling) Regulations; Draft Biosafety (Contained Use) Regulations; Draft Biosafety (Environmental Release)Regulations; Draft Biosafety (Environmental Release); Draft Biosafety (Placement on the Market) Regulations**
	Application/Scope: The legislation applies to research, development, production, transport, transboundary movement and transfer use, application and release of genetically modified organisms. **Institutional & Administrative arrangements:** The National Biosafety Authority (NBA) is established as a body corporate. The NBA is the Competent Authority for the purpose of the Cartagena Protocol on Biosafety. The Biosafety Unit within the Environmental Protection Agency acts in the capacity as Secretariat to the NBA and is responsible for administration of the legislation. The Biosafety Unit within the Environmental Protection Agency is responsible for monitoring and ensuring compliance with the law. Inspectors are required to be appointed. The Secretariat must establish and maintain a National Biosafety Clearinghouse. Control, management, authorisation & notification measures for GMOs are imposed. The Minister is empowered to prohibit the handling, transport, use, transfer and release of any GMO; and activities involving GMOs to prevent or reduce risks to biological diversity, the environment, human health or animal health. Persons are restricted from taking several actions - transporting GMOs unless they are registered under the Act; intentionally introducing GMOs into the environment without a permit; manufacturing a GMO for domestic use without a permit; operating a facility, installation or other physical structure for contained use without a permit; importing a GMO for intentional introduction into the environment or domestic use without a permit; importing or exporting a GMO without a permit; conducting biotechnology research and development without a permit. A permit is also required for medical use of GMOs. Provisions are made for the manner in which the NBA will assess applications and communicate its decision; conditions attached to licences; suspension, cancellation or revocation of licence. The NBA may grant a permit for intentional introduction into the environment or for direct use as food, feed or processing of GMOs if it is satisfied that the GMO poses no risk to human and animal health, the environment and biological diversity.

	The NBA must, before approving an application for import of GMO for intentional introduction into the environment, apply the advance information agreement procedure as per article 7 of the Cartagena Protocol. The NBS should establish a register of GMOs that are pre-approved for import into the country based on several factors including the conduct of a risk assessment to determine that they will not cause significant harm and information exists on the interaction between GMOs and the natural biodiversity. The NBA may be petitioned to exempt or apply simplified procedures for GMOs or activities relating to pre-approved GMOs. Labelling of packages of GMOs must be done during transport, import or export; and must state the species of organism and details of the sender and recipient. Packaging of all GMOs must meet several criteria, including being impervious to spores and pollen; watertight, sealed and fracture-proof to prevent unintentional leakage of the contents. In addition to the relevant permit issued for GMOs that are transported, imported or exported, GMOs in transit must also have dangerous goods declaration; a load plan stating where on the ship aircraft or vehicle they are located and an emergency procedures guide providing information on emergency procedures to be employed in accidental release or other emergency. When cargo is being discharged, safety measures should be deployed including ensuring there is no spillage of the container and unloading to be supervised by a qualified person. Other aspects of the legislation address issues such as risk assessment and management systems; taking safeguard measures where there is unintentional or unapproved release of GMOs into the environment; confidential information; mechanisms for review of decisions; establishment of a GMO register; promotion of public awareness and education of the public; monitoring and enforcement.
8. St Kitts and Nevis	**Biosafety Act 2012; Biosafety Amendment Bill; Biosafety Regulations**
	Application/Scope: The Act applies to the movement, transit, handling and use of all GMOs that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health. **Institutional & Administrative arrangements** – The Biosafety Board is established to administer the law. Other officials such as inspectors, analysts, public relations specialist, and

	scientific advisory committee are appointed. Control, management, authorisation & notification measures for GMOs are imposed. GMO products are required to be registered. An application must be made for a licence for various activities relating to GMOs - the intentional introduction into the environment, transport, manufacture, operate; for domestic use, for contained use, import and export. The criteria is whether the GMO would pose absolutely no risk to the health and safety of humans, animals and the environment. A national database is established. Provisions are made for the manner in which the Board will assess applications and communicate its decision; conditions attached to licences; suspension, cancellation or revocation of licence. Other aspects of the legislation address issues such as risk management, confidential information; handling, transport, packaging and identification, and appeals. The Amendment to the Act seeks, inter alia, to modify the definition of GMO to make it less broad to address only those that the country intends to regulate, provides for the appointment and functions of a Registrar for Biosafety, empowers the Board to establish various committees as they become necessary, changes the criteria for granting a licence to whether the benefits of the GMO outweigh the risks to human and animal health, the environment and biological diversity, would empower the Minister to exempt certain persons, classes of persons or category of products from the application of any provisions of the Act. .
9. Saint Lucia	**Biosafety Bill**
	Application/Scope: The Act applies to - (a) the transboundary movement and movements within Saint Lucia, transit, handling, production and use of all genetically modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking into account risks to human health; (b) a genetically modified organism that is a pharmaceutical not covered by an international agreement and that is for human and animal use; (c) fish, insects and other genetically modified animals. **Institutional & Administrative arrangements:** The legislation designates Competent National Authorities for the purposes of administering the Bill (Chief Veterinary Officer, Plant

	Protection and Plant Quarantine Services, Ministry responsible for Health, Ministry responsible for Commerce; and Pesticides and Toxic Chemicals Control Committee); designates the Biodiversity Unit as the national focal point for biosafety; establishes a Biosafety Committee, and a Biosafety Scientific and Technical Advisory Sub-Committee. Control, management, authorisation & notification measures for LMOs are imposed. A licence is required for the following activities - direct use as food, feed or for processing; intentional introduction into the environment; import, export; and transit. The use of the advanced informed procedure is required for the first import of a GMO for contained use; direct use as food, feed or processing; or intentional introduction into the environment. Labelling for direct use as food, feed or processing is required for products or shipments containing GMOs above a limit of 0.9%. Provisions are made for the manner in which the Board will assess applications and communicate its decision; conditions attached to licences; suspension, cancellation or revocation of licence. Other aspects of the legislation address issues such as risk analysis; confidential information; emergency measures for unintentional introduction into the environment; enforcement by inspectors; and the creation of a Biosafety Tribunal.
10. St Vincent & the Grenadines	**Biosafety Bill**
	Application/Scope The Act applies to the movement, transit, handling and use of all genetically modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human and animal health. **Institutional & Administrative arrangements** – The legislation establishes a National Competent National Authority for the purpose of administering the Bill; as well as a Decision Making Council, and a Scientific Advisory Body. It creates a Biosafety Clearing House and Biosafety Fund. Control, management, authorisation & notification measures for GMOs are imposed. Restrictions can be imposed on handling GMOs. A licence is required for the following activities involving GMOs – intentional introduction into the environment; domestic use as food, feed or for processing; contained use; import; export; and research and development. Simplified application and review procedure is created for pre-approved GMOs. Other aspects of the legislation address issues such as labelling,

	packaging; accompanying documentation for transport of GMOs; importation by Sea; procedure for unloading GMOs; procedure for transport; storage other than in Controlled Areas. Provisions are also made for risk assessment and management; confidential information; safeguards to be activated in cases of emergencies with GMOs; handling of complaints; review of decisions; establishment of a Tribunal; and monitoring and enforcement.
11. Trinidad and Tobago	**Biosafety Bill 2016**
	Institutional & Administrative arrangements – The National Biosafety Office (NBO) shall be established in the Ministry responsible for biosafety matters and is designated the competent authority under the Cartagena Protocol. The NBO shall comprise the National Biosafety Secretariat (NBS) and the National Biosafety Committee (NBC). The NBO is the legal authority for decisions regarding all activities using GMOs. Control, management, authorisation & notification measures for GMOs are imposed. Persons are prohibited from carrying out contained activities involving GMOs unless the institution where the person is employed has established an Institutional Biosafety Committee (IBC) and the IBC has been accredited by the NBO. The membership, obligations and responsibilities for the IBC and the requirements for accreditation will be set forth by the NBC in regulations and/or guidelines. Those responsibilities shall include providing the NBO with notice of all contained use activities involving GMOs by any person at the institution. The NBC is required to establish the mechanisms for co-ordination across jurisdictional lines and provide for the implementation of integrated biosafety oversight. There is a general requirement that the conduct of an activity involving a GMO must be done after a determination of safety is made by the NBC and the issuance of a permit by the NBO. However, the use of GMOs in contained research laboratory experiments need not be approved by the NBC as long as they are approved and overseen by the institution's IBC and do not require level B3 or B4 containment. The NBC will issue regulations or guidelines specifying the requirements relevant to carrying out this obligation. The IBC will be responsible for ensuring that contained activities conducted at a registered facility meet all the obligations of the law or guidelines issued pursuant to the law. Other authorisations required are a transit permit, a confined field trial, an intentional introduction into the environment, and a GMO intended for food, feed, and/or processing. For applications submitted for contained use experiments that are not GMOs in contained research laboratory experiments and for confined field trials, the NBC must review the application and conduct any

	necessary risk assessment. Other aspects of the legislation address issues such as appeals; and a voluntary non-GMO labeling system that would allow importers and retailers to label their products as not containing GMOs if less than 5% of the product was derived from a GMO crop or animal.

2.6 Gaps in Specific Biosafety Legislation

The existing and proposed Biosafety legislation examined pre-date the Regional Biosafety Policy which was approved in 2017. They therefore do not reflect the regional integration ethos of the principles and scope of the Policy. Gaps in biosafety framework include the following –

1. Failure to fully utilise the collective wisdom of the regional scientific community in conducting scientific risk analysis.

2. Absence of recognition and role of a regional biosafety administrative system to support the conduct of certain activities that are best conducted at the regional level from which the entire CARICOM Community can benefit.

3. Giving the Cartagena Biosafety Protocol the force of law in Biosafety legislation can be seen as curtailing the ability of the law to be applicable to a wider remit of modern biotechnology issues than those addressed in the Protocol which focuses on adverse effects of LMOs on the environment.

4. Biosafety measures addressing the import of LMO food products and commodities may lack the regulatory focus needed in evaluating their safety level for human consumption. Many such imports are being made on a daily basis. Food safety legislation in the region is not directly applicable to genetically modified food.

5. The availability of national funding to cover the costs of operation of multiple national entities.

6. Different CARICOM Member States focus on regulating different types of LMO activities based on their national priorities. Lack of consistency in the regulatory standards imposed can create a “race to the bottom” if not specifically addressed.

2.7 Recommendations in Revising Specific Biosafety Legislation

A Model Law provides a mechanism for harmonising biosafety legislation in the CARICOM Community. Such a law should be prepared having regard to the following recommendations –

1. Strengthen the legal harmonisation mandate for the agricultural sector in the CARICOM Community contained in Chapter 4 of the Revised Treaty of Chaguaramas by preparing a Model law to address biosafety in the region.

2. Through the instrumentality of the Regional Biosafety Policy, allow for a regional approach to biosafety legislation to be created shaped by the Principles and Scope of the Policy.

   Acknowledge that aspects of the Regional Biosafety Policy, such as decision-making at the regional level, may necessitate some refinement resulting from stakeholder review in creating the legal framework for biosafety. This can enhance its applicability and relevance to regional integration by measures which respect national sovereignty while harnessing the benefits of increasing efficiency in the use of scarce biosafety resources; and which provide a seamless flow between regional and national requirements in dealing with applications for authorisations of LMO activities, notification of decisions, sharing documents and other aspects of information exchange.

3. Create within the Model law a regional administrative mechanism that will allow CAHFSA to serve a crucial role in conducting scientific risk assessments for Member States and provide other services within its functions on the request of Member States.

4. Consider the financial, human resource and legal implications of creating multiple national bodies to perform specific tasks within the national regulatory system.

5. Ensure that the Model law does not introduce unnecessary regulatory burdens that are outside of the respective capabilities of government bodies, companies or other entities to reasonably carry out. Consider its effects on trade – does it hinder, facilitate or attempt to create a new paradigm for imports of LMOs and their products? For example, the content of provisions requiring that documentation relating to the transport of LMOs and products be classified as “dangerous goods”; requirements for special areas to be set aside in the Port Authorities; domestic transport requirements for the carriage of LMOs and their products, all have implications on shipping companies, trucking companies, commodity storage companies, and others.

6. An aspect of the regional administrative structure that already exists in some legislation is the requirement for the national competent body to

establish a register of LMOs approved for import into the country if satisfied that a risk assessment has been undertaken by an accredited regional organisation that is competent to undertake scientific assessments to determine that the LMO does not cause any significant ecological, social or economic harm in the country; there exists information on the interaction between the LMO and natural biodiversity, the environment and human health, including the results of any deliberate release in any other country; and here exists information on any previous approvals of the LMOs in any other country. Although CAHFSA is not specifically named, it can fall within the wording of the text used. This regional outlook should be further built on in creating the regional administrative mechanisms.

7. Ensure that the regulatory cycle set out in the Model law is presented with sufficient clarity to facilitate comprehension and implementation - from pre-authorisation, to authorisation, to post authorisation stages of LMO activities. The structure of the legislation should allocate a separate permit/exemption application process, specify the original recipient of the application and the path the application would take through the regulatory process until authorisation is either granted or denied. It would also describe the data requested to address regulator questions related to granting the permit/exemption. This makes it easier for the public to see that each of the proposed LMO activities poses different levels of risk and requires different associated risk management measures.

8. Consider the implications of specifically providing in the Model law that the Protocol on Biosafety will have the force of law. Such an approach makes subsequent updating difficult where, for example, the Protocol on Biosafety fails to address new techniques but for which it is prudent to regulate in national law. It must be noted that the Protocol was not intended to cover all LMO activities, and the concerns about significant adverse risks to human health are almost tangential to concerns about the environment. At essence is the extent to which parties to the Protocol on Biosafety will be viewed as complying with their international obligations under the Protocol, while making the national law applicable to matters extraneous to, and possibly conflicting with the Protocol.

9. Ensure that references to the taking of action as a result of “risk” to the environment, human health, etc be “significant risk”, as minor or insignificant risks are not of interest in the management of assessed risks. Risk management of activities relating to the use of modern biotechnology should be viewed in a comparative manner to those faced in traditional agriculture.

10. Provide for applicability of the legislation to the import of LMO food products. Significant imports of such food products are already being made into CARICOM Member States. In the absence of Food Safety

legislation that specifically addresses genetically modified food, then a significant source of activities impacting on human health can go unregulated. Although such foods may already be deemed safe for human consumption in various countries, the CARICOM Community must not let unregulated genetically modified material to be imported without scrutiny for human safety.

11. Focus on regulating different types of LMO activities based on national priorities of CARICOM Member States. Consistency in the regulatory standards imposed will lessen trade distortion.

ANNEX - CARICOM MODEL BIOSAFETY BILL