ANNEX TO FINAL REPORT

CARICOM Model Biosafety Bill 20[ ]

EXPLANATORY MEMORANDUM

Background

The Biosafety Bill was prepared under the "Review of Biosafety Legislation in CARICOM Member States Project". The Contracting Agency is the University of the West Indies, St Augustine Campus, Trinidad and Tobago, with the Caribbean Agricultural Health and Food Safety Agency (CAHFSA) being the executing entity. The project sought to develop and implement a harmonized biosafety system in CARICOM countries, based on the Cartagena Biosafety Protocol to the Convention on Biological Diversity; and provided support to countries to establish biosafety legislation and regulations based on a harmonized policy. Thirteen CARICOM countries are parties to the Cartagena Protocol on Biosafety.

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 living modified organisms. However, the associated risks to the conservation of biodiversity and agricultural sustainability, and ethical and socio-economic considerations, particularly those that are unknown, have emphasised the need to create a regulatory framework for biosafety, given the risks associated with.

With the exception of St Kitts and Nevis, no other CARICOM Member State at present has a specific law that regulates biosafety. Provisions relating to biosafety are dispersed in laws relating to several sectors, such as environmental management and trade, however, they fail to holistically regulate biosafety.

The legislative drafting approach adopted in the Biosafety Bill is to implement the obligations arising under the Cartagena Protocol on Biosafety without specifically giving the force of law to the Protocol. This approach is utilized, given the Protocol's primary focus on protecting the environment, as opposed to human health, and the advantages to be gained in regulating other matters that the Protocol does not address.

PART I
PRELIMINARY

Clause 1: Short title and commencement
The Bill will commence on a date to be fixed by the Minister by Order published in the *Gazette*.

Clause 2: Interpretation
Clause 2 defines terms used in the Bill. These include "advanced informed agreement procedure" "commercial use or placing on the market", "contained use", "export", "import", "living modified organism", "modern biotechnology".

Clause 3: Scope and application
Clause 3 of the Bill indicates the activities to which the Bill will apply. These are the import; export; transit; contained use; confined field trials; commercial use or placing on the market; direct use as food, feed or for processing of living modified organisms and products of living modified organisms.

Clause 4: Application of precautionary principle
Clause 4 requires persons exercising functions and powers under this Bill to make decisions based on the best available scientific evidence or ecological principles, but where little or no scientific evidence is available, decisions may be based on the precautionary principle

Clause 5: Application of other statutory powers not affected
Clause 5 clarifies that matters arising under any other Act shall not be affected by or be derogated from by the Biosafety Act.

Clause 6: The Crown
Under clause 4 of the Bill, the Bill is binding on the Crown.

PART II
ADMINISTRATION

Division 1
Regional Administration

Division 1 addresses the mechanisms that should be created within the CARICOM Community to allow for the regional support required in promoting a harmonized biosafety framework. This is in recognition that certain human capacity and professional biosafety expertise can be deployed at the regional level for the benefit of CARICOM Member States.

Clause 7 establishes the regional biosafety coordinating network consisting of CAHFSA, the UWI, and any other prescribed organisation or body.

Clause 8 provides for the functions of CAHFSA which include providing an integrated system for supporting biosafety in CARICOM, including by receiving and submitting to the National Competent Authority of the relevant CARICOM Member States applications for the first importation of specified LMOs and products of LMOs; and conducting scientific risk analyses.
.
Clause 9 provides for the functions of the UWI which include providing information on advances in modern biotechnology and biosafety and their impact on risk analysis and decision making;
.
Clause 10 recognises the existence of and provides for the functions of the Regional Biosafety Clearing-House which include hosting biosafety information.

Division 2
National Administration

Division 2 addresses the national mechanisms that should be created to allow for the management of the biosafety framework. Decision making is located within each Member State.

Clause 11 of the Bill establishes a National Competent Authority for the purposes of administering the Bill.

Clauses 12 – 16 provide for the functions of the National Competent Authority, the issuance to it of policy directives by the Minister, terms of appointment and tenure of members of the National Competent Authority, resignations, and termination of appointment of its members.

Clause 17 provides for the Ministry [responsible for the Environment/Sustainable development/ Agriculture] to be National Focal Point and location of National Biosafety Clearing-House.

Clause 18 provides for Secretariat of the National Competent Authority.

Clause 19 establishes the National Biosafety Clearing-House and National Biosafety Register.

Clauses 20-21 establish and define the composition of the National Scientific and Technical Advisory Committee, as well as its functions of National Scientific and Technical Advisory Committee.

Clause 22 establishes and defines the composition and functions of National Socio-Economic Committee.

Clause 23 addresses the Institutional Biosafety Committees which has, inter alia, oversight of laboratory experiments and contained testing of LMOs...

Clause 24 provides for Inspectors and their functions.

Clause 25 requires the submission of an annual report.

PART III

CONTROL MEASURES FOR REGULATED ACTIVITIES

Division 1
Prohibition of activities relating to LMOs, LMOs-FFP and products of LMOs

Clause 26 authorises the Minister to impose prohibitions on activities concerning living modified organisms (LMOs), living modified organisms intended for direct use as food, feed or for processing (LMOs-FFP) and products of LMOs.

Division 2
Approval to import or conduct activity relating to LMOs

Clauses 27 – 30 address the regulatory system for importing or conducting activities relating to LMOs. Approval is required from the National Competent Authority to import or conduct activities relating to LMOs. The procedure provided by law must be followed in making an application, which includes the entity to whom applications are addresses and the information to be submitted. Applications must be processed and decisions on applications relating to LMOs be taken in accordance with the specified provisions. Permits for activities relating to LMOs may be granted to successful applicants. These have standard provisions or may allow for additional conditions to be imposed by the National Competent Authority.

Division 3
Approval to import or conduct activity relating to LMOs-FFP

Clauses 31 – 34 address the regulatory system for approval to import or conduct activities relating to LMOs-FFP. Approval is required from the National Competent Authority to import or conduct activities relating to LMOs-FFP. The procedure provided by law must be followed in making an application, which

includes the entity to whom applications are addresses and the information to be submitted. Applications must be processed and decisions on applications relating to LMOs-FFP be taken in accordance with the specified provisions. Permits for activities relating to LMOs-FFP may be granted to successful applicants. These have standard provisions or may allow for additional conditions to be imposed by the National Competent Authority.

Division 4
Approval for import or conduct of activity relating to products of LMOs for use as food, feed or ingredient

Clauses 35 – 38 address the regulatory system for approval to import or conduct activities relating to products of LMOs for use as food, feed or ingredients (i.e., food and feed commodities). Approval is required from the National Competent Authority to import or conduct activities relating to such products of LMOs. The procedure provided by law must be followed in making an application, which includes the entity to whom applications are addresses and the information to be submitted. Applications must be processed and decisions on applications relating to products of LMOs for use as food, feed or ingredient be taken in accordance with the specified provisions. Permits for activities relating to products of LMOs for use as food, feed or ingredient may be granted to successful applicants. These have standard provisions or may allow for additional conditions to be imposed by the National Competent Authority.

Division 5
Approval for export of LMOs

Clauses 39– 40 address the regulatory system for exporting LMOs. Approval must first be obtained from the country of import. This approval, together with information on the type and nature of LMO to be exported, must be notified to the National Competent Authority.

Division 6
Approval for transit of LMOs

Clauses 41 – 44 address the regulatory system for approval to allow the transit of LMOs through a country. Approval is required from the National Competent Authority to transit the LMOs. The procedure provided by law must be followed in making an application, which includes the entity to whom applications are addresses and the information to be submitted. Applications must be processed and decisions on applications relating to the transit of LMOs be taken in accordance with the specified provisions. Transit permits may be granted to successful applicants. These have standard provisions or may allow for additional conditions to be imposed by the National Competent Authority.

Division 7
Approval for contained use of LMOs

Clauses 45 – 48 address the regulatory system for approval to conduct contained use activities relating to LMOs. Approval is required from the National Competent Authority to conduct contained use activities of LMOs. The procedure provided by law must be followed in making an application, which includes the entity to whom applications are addresses and the information to be submitted. Applications must be processed and decisions on applications relating to contained use of LMOs be taken in accordance with

the specified provisions. Permits for contained use activities may be granted to successful applicants. These have standard provisions or may allow for additional conditions to be imposed by the National Competent Authority, including safety precautions, good microbiological practice and the keeping of records.

Division 8
Approval for confined field trials of LMOs

Clauses 49 – 52 address the regulatory system for approval to conduct confined field trial activities relating to LMOs. Approval is required from the National Competent Authority to conduct confined field trial activities of LMOs. The procedure provided by law must be followed in making an application, which includes the entity to whom applications are addresses and the information to be submitted. Applications must be processed and decisions on applications relating to confined field trials of LMOs be taken in accordance with the specified provisions. Permits for confined field trial activities may be granted to successful applicants. These have standard provisions or may allow for additional conditions to be imposed by the National Competent Authority.

Division 9
Approval for commercial use or release on the market of LMOs

Clauses 53 – 56 address the regulatory system for approval for commercial use or placing on the market of LMOs. Approval is required from the National Competent Authority to commercially use or place on the market LMOs. The procedure provided by law must be followed in making an application, which includes the entity to whom applications are addresses and the information to be submitted. Applications must be processed and decisions on applications relating to commercial use or placing on the market of LMOs be taken in accordance with the specified provisions. Permits for commercial use may be granted to successful applicants. These have standard provisions or may allow for additional conditions to be imposed by the National Competent Authority.

Division 10
General Permit Provisions

Division 10 provides provisions that generally apply to permits.

Clauses 57 – 63 address issues such as withdrawal of applications, cancellation of applications; grant or refusal of permit, standard permit conditions, validity of permits, effect of permit and suspension or revocation of permit.

Division 11
Advance informed application procedure

Clause 64 addresses the advance informed agreement procedure created under the Cartagena Protocol on Biosafety by which applications are made for approval of activities involving different types of LMOs and products of LMOs. Advance informed agreement requires that prior to the first intentional transboundary movement of a specified LMO into its jurisdiction, the Party of import is informed of the proposed import, receives information about the LMO and its proposed use; and is given an opportunity to decide whether or not to allow the import of the LMO, and the conditions for so doing.

Division 12
Simplified application procedure

Clause 65 provides for the use of a simplified application procedure for importing LMOs.

Division 13
Exemptions

Clauses 66 – 68 provide the mechanism by which exemptions from the provisions of the Act can be made, the procedure for applying, and the manner in which applications will be processed and decisions made.

PART IV

PACKAGING, IDENTIFICATION, HANDLING AND TRANSPORT

Clauses 69 – 72 provide for the labeling and packaging of LMOs, the documents to accompany their transport, and the manner in which they should be segregated.

PART V

RISK ANALYSIS

Clauses 73 – 76 provides for the conduct of risk analysis in evaluating the risk associated with LMOs. The process includes risk assessment, risk management and a requirement to disclose new significant risks.

PART VI

UNINTENTIONAL INTRODUCTION INTO THE ENVIRONMENT AND EMERGENCY MEASURES

Clauses 77 – 78 make provisions for unintentional introduction into the environment of LMOs and the emergency measures that should be implemented to address concerns arising therefrom.

PART VII

MECHANISM FOR REVIEW OF DECISIONS

Clauses 79 – 81 provide for the manner in which decisions made under the Act can be reviewed, the right of appeal, and socio-economic considerations that may be considered to influence decisions taken.

PART VIII

ENVIRONMENTAL TRIBUNAL

Clauses 82 – 90 provide for the establishment of Environmental Tribunal to determine matters arising under the Act, its jurisdiction and powers, sittings of the Tribunal, right of appeal to the Tribunal, and the terms and conditions relevant to membership of the Tribunal. and appeals to the High Court.

PART IX

MONITORING, ENFORCEMENT AND COMPLIANCE

Clauses 91 – 97 provide mechanisms for investigation of complaints arising under the Act; measures that can be issued to bring about compliance such as cessation orders and directions to remedy breach; the power of seizure, detention and forfeiture of articles or LMOs; offences and penalties.

PART X

MISCELLANEOUS PROVISIONS

Clause 98 addresses confidentiality of information submitted.
Clause 99 provides for the manner in which conflict of interest should be handled.
Clause 100 provides for the making of Regulations.
Clause 101 provides for transitional provisions to determine the manner in which existing activities should be handled upon the commencement of the Act.

Schedule 1:	Regulatory Agencies
Schedule 2:	Application Form for Approval for Import/Transit/Intentional Introduction into the Environment/Direct Use as Food, Feed or for Processing/Placing on the Market of LMO or Product of LMO
Schedule 3:	Application Form for approval of Contained Use/Confined Field Trial
Schedule 4:	Risk Analysis

CARICOM Biosafety Bill

Version: 21st December 2018

ARRANGEMENT OF SECTIONS

PART III

CONTROL MEASURES FOR REGULATED ACTIVITIES

Division 1
Prohibition of activities relating to LMOs, LMOs-FFP and Products of LMOs

Division 2
Approval to import or conduct activity relating to LMOs

Division 3
Approval to import or conduct activity relating to LMOs-FFP

Division 4
Approval for import or conduct of activity relating to products of LMOs for use as food, feed or ingredient

Division 5
Approval for export of LMOs

Division 6
Approval for transit of LMOs

PART IX

MONITORING, ENFORCEMENT AND COMPLIANCE

PART X

MISCELLANEOUS PROVISIONS

[MEMBER STATE]

No. [ ] of 20[ ]

AN ACT to provide measures to promote the responsible development and use of living modified organisms and products of living modified organisms through approval procedures; to ensure that activities involving the use of living modified organisms and products of living modified organisms, including import, direct use as food, feed or for processing, use for food, feed ingredients, contained use, confined field trials, and commercial use shall be carried out in a manner that prevents or reduces significant adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health and the environment; to provide the basis for ensuring a high level of protection of human life and health, animal health and welfare, environment and consumer interests in relation to food use; to provide criteria for conducting risk analyses; to provide for the harmonisation of legal and administrative mechanisms for biosafety in CARICOM; and to provide for related or incidental matters.

BE IT ENACTED by [ ] as follows -

PART I

PRELIMINARY

1. Short title and commencement.

(1) This Act may be cited as the Biosafety Act, 20[ ].

(2) This Act shall commence on a date fixed by the Minister by Order published in the Gazette.

2. Interpretation.

In this Act, unless the context otherwise requires,

"Advanced informed agreement procedure" means the procedure whereby consent is obtained before an activity is conducted based upon full disclosure of all relevant matters in accordance with section 64;

"Applicant" means a person, whether in [country] or in any other country, who applies for approval of a regulated activity under this Act, and includes an agent residing in (country) who is authorized to act on behalf of that person;

"biological diversity" means the variability among living organisms from all sources including, terrestrial, marine and other aquatic ecosystems, and the ecological complexes of which they are a part, including diversity within species, between species and of ecosystems;

“Biosafety Clearing-House” means the Biosafety Clearing-House established under article 20 of the Cartagena Protocol;

"CARICOM" means the Caribbean Community established by Article 2 of the Revised Treaty of Chaguaramas establishing the Caribbean Community including the CARICOM Single Market and Economy (CSME) done at Nassau, The Bahamas on the 5th day of July 2001;

“CAHFSA” means the Caribbean Agricultural Health and Food Safety Agency established by Article II of the Revised Agreement establishing the Caribbean Agricultural Health and Food Safety Agency signed at St. Georges, Grenada on the 25th day of February 2011;

“Cartagena Protocol” means the Cartagena Protocol on Biosafety to the Convention on Biological Diversity;

“commercial use” or “placing on the market” means **cultivating**, supplying, selling, advertising, donating, or any other form of transfer or making available to a third party, whether in return for payment or free of charge, of a living modified organism, living modified organisms that are intended for direct use as food, feed or for processing, or product of a living modified organism;

“confidential information” means information which has economic value and the economic value is enhanced by the information being secret;

“confined field trial” means a small-scale research activity with a living modified organism that is conducted outdoors and maintained under specific control measures enforced to prevent the escape and environmental persistence of the living modified organism and its progeny;

“contained testing” means experimentation on a living modified organism conducted in an enclosed facility, such as a greenhouse or other restricted structure, that is controlled by specific measures that effectively prevent its contact with the environment;

“contained use” means **commercial or experimental use** conducted within an enclosed facility, such as a greenhouse or other restricted structure, involving a living modified organism or product of a living modified organism, that is controlled by specific measures that effectively prevent its contact with the environment;

“Court” means the High Court;

“designated Competent Authority” means an agency of another country responsible under its national law for the control or regulation of living modified organisms;

“direct use as food or feed or for processing” includes activities that result in –

(a) living modified organisms used for producing food for human consumption;

(b) living modified organisms used for producing feed for animal consumption;

(c) living modified organisms used in industrial processing for producing non-food products such as biofuels and bioplastics;

“ecosystem” means a dynamic complex of plant, animal and micro-organism communities and their non-living systems interacting as a functional unit;

“environment” includes:

(a) ecosystems and their constituent parts;

(b) natural and physical resources; and

(c) the qualities and characteristics of locations, places and areas;

“experimental use” of a living modified organism includes contained use and confined field trials of a living modified organism, but does not include a living modified organism imported for direct use as food, feed or for processing or for placing on the market;

"export” means intentional transboundary movement from the area of national jurisdiction of [country] to the area of national jurisdiction of another country;

“exporter” means any legal or natural person, whether in (country) or any other country, who arranges for a living modified organism to be exported and includes an agent who is authorized to act on behalf of that person;

“feed" means any substance, including additives, whether processed, partially processed or unprocessed, intended to be used for oral feeding to animals;

“food” means a substance, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans and includes —

(a) any substance used for food or drink by humans, other than drugs;

(b) any substance which ordinarily enters into or is used in the production, manufacture, treatment, composition or preparation of food to be ingested by humans; and

(c) any flavouring matters, condiments and chewing substances;

"genetically modified”, in relation to an organism, means an organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology, and includes combinations of living modified organisms;

“import” means intentional transboundary movement into the area of national jurisdiction of [country] from the area of national jurisdiction of another country;

“importer” means any legal or natural person, whether in [country] or any other country, who arranges for a living modified organism to be imported and includes an agent who is authorized to act on behalf of that person;

"ingredient" means a substance, including additives, used in the manufacture or preparation of a food and still present in the finished product, even if in altered form;

“Inspector” means a person appointed under section 24;

"Institutional Biosafety Committee" means a body established under section 23;

“intentional introduction to the environment” means an activity in relation to a living modified organism or its product in which it is deliberately released into the environment for which no specific containment measures are used to limit its contact with the general population and the environment, but does not include living modified organisms intended for direct use as food, feed or for processing;

"International Plant Protection Convention" means the International Plant Protection Convention, done at Rome, Italy on the 6th December, 1951;

“label” means a legend, word, mark, symbol, or design applied to, included in, belonging to, or accompanying a living modified organism, a product of a living modified organism or an article containing any of the foregoing;

"living modified organism" or "LMO" means -

(a) a living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology; or

(b) a living organism that has inherited particular traits from an organism (the initial organism), being traits that occurred in the initial organism because of modern biotechnology;

but does not include:

(c) a human being, including a human being that is covered by paragraph (a) only because the human being has undergone somatic cell gene therapy;

"living organism" means any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids;

“Minister” means the Minister responsible for the [environment] [agriculture] [sustainable development];

"modern biotechnology" means the application of:

(a) in vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or

(b) fusion of cells beyond the taxonomic family;

that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection;

"monitoring" means the maintaining of regular surveillance over, the checking of, the warning about or the recording of a situation or process;

"National Biosafety Clearing-House" means the National Biosafety Clearing-House established under section 19;

"National Biosafety Register" means the register of living modified organisms and other related matters established under section 19;

“National Competent Authority” means the body established under section 11 responsible for implementation and administration of this Act;

“National Focal Point” means the entity designated to be responsible on behalf of [country] for liaison with the Secretariat of the Cartagena Protocol;

“National Scientific and Technical Advisory Committee” means the body established under section 20 to provide scientific advice to the National Competent Authority;

“National Socio-Economic Committee” means the body established under section 22 to provide socio-economic advice to the National Competent Authority;

"OECS" means the Organisation of Eastern Caribbean States established by the Revised Treaty of Basseterre Establishing the OECS Economic Union, done at Gros Islet, Saint Lucia on the 18th June 2010;

“OIE” means the World Organisation for Animal Health;

“package” includes anything in which a living modified organism or product of a living modified organism is wholly or partly placed or packed and includes any basket, pail, tray or receptacle of any kind whether open or closed;

“permit” means a document granted as approval for a regulated activity under Part III;

“permit holder” means a person who is granted a permit under Part III;

“person” includes any company or association or body of persons, corporate or unincorporated;

“person responsible” means a person to whom the responsibilities required by a permit or exemption under this Act are most applicable, including an employer;

“premises” includes a field, building, facility, installation or other physical structure;

“product of a living modified organism” means any substance, material or article consisting of, containing, derived from or produced from a living modified organism by processing or otherwise or from a product of a living modified organism:

(a) if the product contains detectable recombinant deoxyribonucleic acid (DNA); or

(b) where the profile, characteristic or property of the product is no longer equivalent to its conventional counterpart irrespective of the presence of the recombinant deoxyribonucleic acid;

and includes food or feed consisting of, containing, derived from or produced from living modified organisms or ingredients produced from living modified organisms;

“recipient organism” or “parental organism” means the organism into which ‘donor DNA’ or ‘insert’ is being incorporated via a transformation event;

“Regional Biosafety Clearing-House” means the regional document and information portal recognised under section 10;

“regulated activities” means the activities specified under section 3;

“regulatory agency” means a body designated under Schedule 1;

"Revised Treaty of Chaguaramas" means the Revised Treaty of Chaguaramas establishing the Caribbean Community including the CARICOM Single Market and Economy (CSME) done at Nassau, The Bahamas on the 5th day of July 2001;

“risk” means a potential for harm from a regulated activity;

“risk analysis” means the overall process of risk assessment, risk management and risk communication;

“risk assessment” means the process of risk identification, risk characterization and risk evaluation;

“risk communication” means a continual and iterative process to provide, share or obtain information and to engage in dialogue with stakeholders regarding the analysis of risk;

“risk to human health” means the potential adverse impact on human beings and on the conservation and sustainable use of biological diversity as a direct result of -

(a) a living modified organism;

(b) a causal chain of events, through mechanisms such as interactions with other organisms, transfer of genetic material, or changes in use or management;

(c) direct or indirect effects observed on the immediate release of a living modified organism;

(d) direct or indirect effects observed at a later stage of release of a living modified organism or after termination of the release of the living modified organism;

“risk management” mean the process to control and mitigate risk;

“Secretariat", in relation to the National Competent Authority, means the body established by section 18 responsible for assisting the National Competent Authority with the administration of this Act;

“Secretariat of the Protocol” means the Secretariat established by Article 31 of the Cartagena Protocol;

“socio-economic impact” means the direct or indirect effects to the economy, social or cultural practices, livelihoods, indigenous knowledge systems, or indigenous technologies as a result of

the transboundary movement, transit, handling and use of the living modified organism or a product of a living modified organism;

"third party" means any other person not directly involved within a transaction;

"transboundary movement" means a transfer from [country] to another country or into [country] from another country;

"transit" or "transshipment", in relation to the entry of goods, means transit through the state or transshipment with a view to the re-exportation of the goods in question;

"transformation event' means the insertion of a particular transgene into a specific location on a chromosome of a living organism;

"unique identifier" means a simple numeric or alphanumeric code which serves to identify a living modified organism on the basis of the authorised transformation event from which it was developed and provides the means to retrieve specific information pertinent to that living modified organism as generated through the guidance for designating unique identifiers of the Organisation for Economic Cooperation and Development.

3. Scope and application

(1) Subject to the exceptions specified in or prescribed under this Act, this Act shall apply to the following regulated activities:

(a) import;

(b) export;

(c) transit;

(d) contained use;

(e) confined field trials;

(f) commercial use or placing on the market;

(g) direct use as food, feed or for processing;

of living modified organisms and products of living modified organisms.

(2) This Act shall not apply to:

(a) transboundary movement of a living modified organism or product of a living modified organism that is a pharmaceutical for human use and regulated by an enactment or international agreement;

(b) a living modified organism, a product of a living modified organism or an activity relating thereto that is specifically exempted from the operation of this Act under section 66 or prescribed under this Act.

4. Application of precautionary principle

(1) Persons exercising functions and powers under this Act shall, in making a decision, take into account the best available scientific evidence or ecological principles, but where little or no scientific evidence is available, a decision may be based on the precautionary principle.

(2) In this section, "precautionary principle" means that the lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of potential significant adverse effects of a living modified organism on the conservation and sustainable use of biological diversity taking into account risks to human and animal health, shall not prevent or postpone the taking of a decision, as appropriate, with regard to the living modified organism or product of the living modified organism in question, in order to prevent or minimize such potential significant adverse effects.

5. Application of other statutory powers not affected

(1) A power or requirement arising under any other Act shall not be affected by or be derogated from by this Act, and any other approval, permit or licence required to be obtained in relation to a regulated activity under any other Act shall be obtained under that Act, notwithstanding the provisions of this Act.

(2) For the purpose of sub-section (1), a power or requirement arising under any other Act applicable to a regulated activity may include :

(a) plant and animal quarantine and disease control;

(b) the assessment of impacts on the environment;

(c) the use of pesticides;

(d) fisheries and the development of aquaculture;

(e) the carriage of goods by air or sea.

6. Act to bind [Crown] [State]

This Act binds the [Crown] [State].

PART II

ADMINISTRATION

Division 1

Regional Administration

7. Establishment of regional biosafety coordinating network

(1) For the purpose of this Act, there is established a regional biosafety coordinating network which shall consist of:

(a) CAHFSA;

(b) the UWI;

(c) any other organisation or body prescribed under this Act.

(2) The regional biosafety coordinating network shall serve as the central coordinating administrative mechanism for biosafety in CARICOM and shall provide coordinated biosafety services.

8. Functions of CAHFSA

CAHFSA shall provide an integrated system for supporting biosafety in CARICOM, including by:

(a) receiving and submitting to the National Competent Authority of the relevant CARICOM Member States applications for:

(i) the first importation of LMOs [**for a purpose set out in Part III] [for the purpose of cultivation]**;

(ii) the first importation of LMOs intended for direct use as food, feed, or for processing;

(iii) the first importation of products of LMOs for use as food, feed or ingredients;

(b) conducting scientific risk analyses of LMOs, LMOs intended for direct use as food, feed, or for processing and products of LMOs for use as food, feed or ingredients, on behalf of CARICOM Member States and communicating recommendations and reports to CARICOM Member States;

(c) conducting scientific risk analyses and socio-economic risk analyses on behalf of CARICOM Member States, upon their request, of any other regulated activities not falling within paragraph (b), and preparing opinions and communicating recommendations to CARICOM Member States on the analyses conducted;

(d) maintaining under section 10 a regional list of approved LMOs intended for direct use as food, feed, or for processing, other approved LMOs, and products of LMOs for use as food, feed or ingredients exempted from this Act under section 66;

(e) promoting common procedures and standards;

(f) liaising with relevant national bodies and persons in performing its functions under this Act;

(g) establishing administrative mechanisms to support:

(i) the receipt, handling, storage and dissemination of documents;

(ii) decisions taken by the National Competent Authority and designated Competent Authorities;

(h) adopting from international bodies relevant guidelines, decisions, recommendations and standards such as Codex Alimentarius, International Plant Protection Convention and the OIE standards relating to animal health and zoonoses that will be used to support the risk analysis provisions of Schedule 4;

(i) complying with Articles 57 and 74 of Chapter 4 of the Revised Treaty of Chaguaramas.

9. Functions of the UWI

The UWI shall:

(a) provide information on advances in modern biotechnology and biosafety and their impact on risk analysis and decision making;

(b) develop curricula to support the capacity building needs of CARICOM Member States with respect to biosafety;

(c) coordinate a laboratory network throughout CARICOM Member States to facilitate detection of LMOs, products of LMOs and LMOs intended for direct use as food, feed or for processing;

(d) conduct research and development in support of implementing biosafety measures;

(e) coordinate public education programmes to provide information on biosafety in CARICOM.

10. Recognition and functions of Regional Biosafety Clearing-House

(1) The Regional Biosafety Clearing-House is recognised for the purposes of this Act.

(2) The Regional Biosafety Clearing-House shall host information on biosafety in CARICOM, facilitate the exchange of information on biosafety in CARICOM, and provide public access to notices, applications and other information pursuant to the requirements of this Act.

(3) Without limiting the generality of subsection (2), the information that the Regional Biosafety Clearing-House may host include:

(a) a roster of experts of persons with expertise in areas such as -

(i) modern biotechnology;

(ii) biodiversity management and conservation;

(iii) environmental management;

(iv) risk analysis;

(v) any other discipline that may be required in relation to biosafety under this Act;

(b) a regional biosafety register consisting of:

(i) applications for approval received by CAHFSA for the first importation of LMOs, LMOs intended for direct use as food, feed, or for processing, and products of LMOs for use as food, feed or ingredients on behalf of CARICOM Member States;

(ii) decisions on applications made by CARICOM Member States, including approvals under Part III;

(iii) a regional list of approved LMOs intended for direct use as food, feed, or for processing, products of LMOs for use as food, feed or ingredients, other LMOs and other products of LMOs exempted from this Act under section 66;

(iv) applications for and decisions on exemptions from this Act under section 66;

(c) any other information as may be required to give effect to the requirements of this Act.

Division 2

National Administration

11. Establishment and composition of National Competent Authority

(1) For the purposes of this Act, there is established a body known as the National Competent Authority.

(2) The National Competent Authority shall consist of members appointed by the [Minister] as follows:

(a) a representative from the Ministry responsible for health;

(b) a representative from the Ministry responsible for agriculture;

(c) a representative from the Ministry responsible for [environment/sustainable development];

(d) a representative from the Ministry responsible for trade;

(e) a representative from the Ministry responsible for science and technology;

(f) a representative from the Customs Department;

(g) a representative from the Bureau of Standards;

(h) a representative from the Attorney General's Chambers;

(i) a representative from a non-governmental organization whose purpose is to promote commerce;

(j) two representatives from a non-governmental organization whose purpose is to conduct or promote agriculture;

(k) a representative from a non-governmental organization whose purpose is to conduct research.

(3) The Minister may designate a person as an alternative to a person appointed under subsection (2).

(4) The Minister may co-opt, if the circumstances require :

(a) consultants, experts and advisors from national, regional or international organizations;

(b) personnel from other Ministries; or

(c) any other person as the Minister thinks fit;

to assist the National Competent Authority in its functions.

(5) The members of the National Competent Authority shall designate a Chairperson and Deputy Chairperson from among the members.

(6) The Deputy Chairperson shall exercise all the powers and perform all the duties of the Chairperson if the Chairperson is unable to do so.

(7) Subject to this section, the National Competent Authority may regulate its own procedure.

(8) The quorum for any meeting of the National Competent Authority shall be a majority of the members present and voting.

(9) The validity of any proceedings of the National Competent Authority shall not be affected by a vacancy in its membership or by any defect in the appointment or qualification of a member or by reason that a person not entitled, took part in its proceedings.

12. Functions of National Competent Authority

(1) The National Competent Authority shall be the National Biosafety Authority and shall perform the following functions:

(a) monitor developments in the areas of biosafety and modern biotechnology and provide advice and recommendations to the Minister in relation to biosafety and modern biotechnology;

(b) coordinate the roles of and liaise with regulatory agencies specified in Schedule 1 in relation to regulated activities;

(c) promote co-operation between [country] and any other country with regard to research, development and technology transfer in the field of the genetic modification of organisms;

(d) promote public awareness, education and participation concerning the activities regulated under this Act including through the publication of guidance and other materials that explain and elaborate on the risk analysis and approval processes;

(e) receive applications for approval of and provide decisions on**:**

(i) a second or subsequent importation of LMOs intended for direct use as food, feed or processing;

(ii) a second or subsequent importation of products of LMOs for use as food, feed or ingredients; and

(iii) other regulated activities;

(f) co-operate or enter into agreements with CAHFSA to undertake scientific risk analysis of LMOs and products of LMOs required under this Act;

(g) on the recommendation of CAHFSA or the National Scientific and Technical Advisory Committees, make final decisions on applications received under Part III;

(h) carry out any other functions as may be incidental for effective implementation of this Act.

(2) A Secretariat shall be assigned to support the work of the National Competent Authority as provided in section 18.

13. Policy directives to National Competent Authority

The Minister may give directives of a general nature to the National Competent Authority of the policy to be followed in the exercise or discharge of its functions, and the National Competent Authority shall give effect to the directives.

14. Terms of appointment and tenure of members of National Competent Authority

(1) The members of the National Competent Authority shall be appointed by the Minister upon such terms and conditions as may be prescribed.

(2) Members of the National Competent Authority shall be appointed for staggered terms of [two years] each made in a manner that the terms of not more than [ ] members expire at the same time to provide for orderly transition in membership.

(3) Members shall be eligible for re-appointment.

(4) A member who is appointed to fill a vacancy that is created by the death, resignation, or removal from office for a justifiable cause of another member shall hold office only for the unexpired period of the former member.

(5) A member whose period of appointment expires in accordance with subsection (1) shall continue to hold office until his successor is appointed.

15. Resignations from National Competent Authority

(1) The Chairperson may, at any time, in writing, resign his office by addressing the resignation to the [Minister].

(2) A member of the National Competent Authority, other than the Chairperson, may, at any time, in writing, resign his office by addressing the resignation to the Chairperson.

16. Termination of appointment of members

The [Minister] may, after consultation with the Cabinet, terminate the appointment of a member of the National Competent Authority who:

(a) becomes of unsound mind;

(b) becomes incapable of carrying out his or her duties;

(c) becomes bankrupt or compounds with or suspends payment to his creditors;

(d) is sentenced to a term of imprisonment that exceeds six months;

(e) is convicted of an offence involving dishonesty;

(f) is found guilty of misconduct in relation to his duties;

(g) is absent, without the permission of the Minister or the National Competent Authority, from three consecutive meetings of the National Competent Authority;

(h) fails to carry out any duties or functions conferred or imposed on him under this Act; or

(i) is subject to a conflict of interest.

17. Ministry to be National Focal Point and location of National Biosafety Clearing-House

The [Ministry responsible for the Environment/Sustainable development / Agriculture] shall be the National Focal Point in accordance with Article 19 of the Cartagena Protocol and the location of the National Biosafety Clearing-House established under section 19.

18. Secretariat to National Competent Authority

(1) The [Ministry responsible for the environment/sustainable development] [Plant Protection and Quarantine Services] [Ministry responsible for agriculture] shall serve in the capacity of Secretariat to the National Competent Authority with responsibility for the administration of this Act.

(2) The Secretariat to the National Competent Authority may exercise powers and perform duties as may be conferred upon, delegated or assigned under this Act or by the National Competent Authority.

(3) The functions of the Secretariat shall include:

(a) receiving and screening applications for regulated activities for submission to the National Competent Authority;

(b) submitting requests to and receiving opinions, recommendations and reports from CAHFSA on its functions under section 8 relating to scientific risk analyses and socio-economic risk analyses, and on any other regulated activity that the National Competent Authority may request;

(c) submitting requests for socio-economic risk analyses of LMOs or products of LMOs, when required, to the National Socio-Economic Committee, and receiving opinions and reports on the analyses conducted;

(d) causing meetings of the National Competent Authority, the National Scientific and Technical Advisory Committee and the National Socio-economic Committee to be conducted;

(e) communicating decisions of the National Competent Authority to the regulatory agencies;

(f) establishing and maintaining a National Biosafety Clearing-House which shall include a National Biosafety Register;

(g) providing to the National Biosafety Clearing-House and the Regional Biosafety Clearing-House a copy of this Act and other information relevant to the implementation of this Act;

(h) supporting and communicating decisions taken under this Act by making information available to all relevant persons within the times specified by this Act;

(i) supporting the functioning of national biosafety laboratories;

(j) providing a public education and capacity building programmes to increase knowledge about biosafety and biotechnological developments;

(k) registering institutional biosafety committees;

(l) transmitting decisions to the regulatory agencies, CAHFSA and other relevant bodies.

19. Establishment of National Biosafety Clearing-House and National Biosafety Register

(1) There is established the National Biosafety Clearing-House to facilitate the exchange of information on biosafety and modern biotechnology and provide public access to notices, applications and other information under this Act.

(2) The National Biosafety Register is established as a component of the National Biosafety Clearing-House and may include the following:

(a) details of decisions taken on all applications received under this Act or changes of decisions on approvals issued under this Act;

(b) a summary of the contents of the regional approved list of the Regional Biosafety Clearing-House maintained under section 10 (3)(b)(iii) of LMOs;

(c) details of risk analyses submitted by applicants or conducted by other bodies and reviews of the risk analyses;

(d) emergency measures established to manage the unintentional release of living modified organisms into the environment;

(e) information on contraventions of this Act;

(f) a roster of experts of persons in [country] with expertise in:

(i) modern biotechnology;

(ii) biodiversity management and conservation;

(iii) environmental management;

(iv) social and environmental impact assessment; and

(v) risk analysis;

(vi) any other discipline that may be required in relation to biosafety under this Act;

(g) a roster of experts of persons in [country] with expertise in:

(i) social sciences, such as, sociology and anthropology;

(ii) economics;

(iii) land use planning;

(iv) any other discipline that may be required in relation to social and environmental impact assessment under this Act;

(h) national biosafety laws and guidelines.

(3) The public shall have access to any record or document filed in the National Biosafety Clearing-House, except for restricted records or documents designated by the Minister by Notice published in the *Gazette*.

20. Establishment and composition of National Scientific and Technical Advisory Committee

(1) The National Competent Authority shall establish a National Scientific and Technical Advisory Committee selected from the roster of experts included in the National Biosafety Register.

(2) The composition of the National Scientific and Technical Advisory Committee shall be determined by the expertise required in assessing an application and shall consist of not more than [five] persons.

(3) The National Scientific and Technical Advisory Committee may co-opt:

(a) consultants, experts and advisors from national, regional or international organizations;

(b) personnel from other Ministries; or

(c) any other person as it thinks fit;

to assist it in its functions.

(4) The National Competent Authority shall designate a member of the National Scientific and Technical Advisory Committee as Chairperson.

(5) In the absence of the Chairperson the remaining members of the Scientific and Technical Advisory Committee shall elect an acting Chairperson from their members.

(6) The acting Chairperson shall exercise all the powers and perform all the duties of the Chairperson whenever the Chairperson is unable to do so.

(7) Subject to this section, the National Scientific and Technical Advisory Committee may regulate its own procedure.

21. Functions of National Scientific and Technical Advisory Committee

(1) The National Scientific and Technical Advisory Committee shall:

(a) provide expert scientific advice and assistance to the National Competent Authority to enable it to make final decisions on all matters related to scientific risk analyses under this Act;

(b) review scientific risk analyses provided in relation to applications for approval;

(c) conduct scientific risk analyses and take samples of LMOs or products of LMOs for this purpose;

(d) adopt from international bodies relevant decisions, standards, and guidelines such as those of the Codex Alimentarius International, Plant Protection Convention and the OIE standards relating to animal health and zoonoses that will be used to support the risk analysis provisions of Schedule 4;

(e) review risk management measures;

(f) recommend mitigation measures, reporting mechanisms, remedial measures, monitoring procedures and other appropriate and scientifically sound conditions and risk management measures; and

(g) liaise with CAHFSA, the UWI, relevant laboratories and other appropriate bodies on issues relating to biosafety.

(2) The National Scientific and Technical Advisory Committee may, with the approval of the National Competent Authority and in accordance with its directives, appoint subcommittees to assist it with the conduct of its functions.

22. Establishment, composition and functions of National Socio-Economic Committee

(1) The National Competent Authority may establish a National Socio-Economic Committee selected from the roster of experts included in the National Biosafety Register.

(2) The National Socio-Economic Committee shall recommend to the National Competent Authority whether the conduct of a socio-economic analysis for a LMO or product of a LMO is required under this Act having regard to socio-economic and environmental considerations based on the impact of regulated activities on:

(a) the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities; and

(b) the protection of human life and health, animal health and welfare, environment and consumer interests.

23. Institutional Biosafety Committees

(1) An applicant who intends to conduct activities involving contained use of LMOs shall first:

(a) be registered with the Secretariat of the National Competent Authority; and

(b) seek approval for conducting the relevant activity involving contained use of LMOs.

(2) An applicant who receives approval under Part III for conducting contained use of LMOs shall operate under the oversight of an Institutional Biosafety Committee or an equivalent advisory committee.

(3) The particulars of each Institutional Biosafety Committee established under this section shall be submitted to the Secretariat of the National Competent Authority for the registration of the Institutional Biosafety Committee.

(4) An Institutional Biosafety Committee shall consist of not less than five persons, at least three of whom shall have expertise in biosafety.

(5) Two or more persons registered under this Act may establish a joint Institutional Biosafety Committee.

(6) For purpose of forming an Institutional Biosafety Committee, a person registered under this Act may co-opt a person with the relevant expertise.

(7) The Institutional Biosafety Committee shall perform the following functions:

(a) provide guidance for safe use of modern biotechnology undertaken in the facility in which it is located;

(b) regularly review, monitor and supervise laboratory experiments, contained testing and release of LMOs;

(c) through the Secretariat of the National Competent Authority, seek the approval of the National Competent Authority for contained testing, confined field testing, and confined field trial testing;

(d) cause research to be conducted in accordance with this Act or prescribed by this Act and any guidelines or standards issued by the National Competent Authority pursuant to a memorandum of agreement between the Institutional Biosafety Committee and the National Competent Authority.

(8) An Institutional Biosafety Committee shall, every six months or when requested by the National Competent Authority, in the prescribed manner, provide a report to the National Competent Authority containing:

(a) the membership and competence of the Institutional Biosafety Committee;

(b) research and other activities approved by the Institutional Biosafety Committee;

(c) the modern biotechnology and biosafety capacity of the person including the human resources and facilities;

(d) any other matters as may be specified.

24. Inspectors

(1) The [relevant regulatory agency] [Public Service Commission] shall [designate] [appoint] public officers as Inspectors to exercise the functions specified in this Act.

(2) Each Inspector shall be provided with an identity card:

(a) signed by the [relevant regulatory agency] [Public Service Commission] stating that he or she has been appointed as an Inspector under this Act;

(b) that contains a recent photograph of the Inspector.

(3) An Inspector shall, at the request of any person affected by the exercise of a function by the Inspector, exhibit the identity card referred to in subsection (2) to that person.

(4) An Inspector [designated] [appointed] under subsection (1) shall perform the following functions:

(a) inspect any vehicle, land or premises in accordance with the provisions of this Act;

(b) make such examination, inspection, investigation, and inquiries as may be necessary to ascertain whether this Act and the provisions prescribed under this Act are being complied with;

(c) enforce identification, labeling and packaging provisions in or under this Act;

(d) submit to the Secretariat of the National Competent Authority a report on all investigations conducted.

(5) An Inspector may, for the purpose of discharging his or her duties under this Act:

(a) enter, at any reasonable time, any vehicle in which -

(i) a LMO or product of a LMO is about to be, is being, or has been transported; or

(ii) he or she has reasonable cause to believe that a breach of or under this Act is about to be, is being or has been committed;

(b) enter, at any reasonable time, any land or premises:

(i) on which a LMO or product of a LMO is about to be, is being, or has been used or packaged;

(ii) that is being, has been, or is about to be used for a purpose connected with the use or packaging of a LMO or product of a LMO;

(c) require the production of, or seize, inspect and examine, and copy records or other documents kept for the purpose of or required to be kept by or under this Act;

(d) require any person whom he or she finds in a vehicle, on land or premises, to give information as it is in that person's power to give as to who is the occupier or the employer of workers employed to work there;

(e) examine, either alone or in the presence of any other person as the Inspector thinks fit, with respect to compliance with this Act or provisions prescribed under this Act, any person whom he or she finds in such vehicle or on such land or premises as mentioned in sub-section (4);

(f) open and examine any package that on reasonable grounds he or she believes to contain a living modified organism or product of a living modified organism, while ensuring that the LMO does not escape into the environment;

(g) seize and detain for such time as may be necessary, any article by means of which, or in relation to which he or she reasonably believes any provision of this Act or prescribed under this Act has been contravened;

(h) if the Inspector reasonably believes that any provision of this Act or prescribed under this Act has been contravened:

(i) take, without payment, samples of any article being used or transported, and submit them to the laboratory for analysis or examination, ensuring that the sample is packaged and labelled according to the requirements of the Act;

(ii) take, without payment, but with the approval of the Comptroller of Customs, samples of any article imported into the country but not delivered to the importer, out of the charge of Customs, ensuring that the sample is packaged and labelled according to the requirements of the Act, and submit them to a laboratory for analysis or examination.

(6) Subject to subsection (7), an Inspector shall, for the purpose of exercising the powers conferred by subsection (5), first obtain a search warrant issued by a Magistrate.

(7) Where circumstances are such that a living modified organism, living modified organism for direct use as food, feed or for processing, or product of a living modified organism may be removed from the vehicle, land or premises before the Inspector obtains a search warrant, the Inspector may enter the vehicle, land or premises without the warrant, in which case he or she shall produce his or her identification card to the owner, occupier, or person in charge of the vehicle, land or premises, as the case may be.

(8) The Inspector may, if he or she considers it necessary, be accompanied by a member of the police force, a public health inspector, or any person who possesses expert knowledge in the use or effects of a living modified organism for the purposes of discharging his or her functions under this Act.

25. Annual report

(1) In accordance with subsection (2) and not later than three months after the end of each financial year, the National Competent Authority shall submit to the Minister an annual report on its functions for the preceding financial year and the Minister shall not later than one month later lay the same in Parliament.

(2) In this section "financial year" means the twelve months ending on [31 March] in any year.

PART III

CONTROL MEASURES FOR REGULATED ACTIVITIES

Division 1
Prohibition of activities relating to LMOs, LMOs-FFP and Products of LMOs

26. Prohibition concerning LMOs, LMOs-FFP and Products of LMOs

(1) The Minister may, on the recommendation of the National Competent Authority, by Order published in the *Gazette*, prohibit any activity involving a LMO, a LMO intended for direct use as food, feed or processing, or product of a LMO, to prevent or reduce significant risks to biological diversity, the environment and human health.

(2) Prior to publishing an Order under subsection (1), the Minister shall give public notice of the Minister's intention to prohibit the activity concerning the LMO or product of a LMO.

(3) The public notice shall be published in a minimum of two issues of [daily] [weekly] newspapers and shall provide:

(a) a description of the LMO or product of a LMO together with a statement of the intention to prohibit the relevant activity;

(b) that submissions on the proposed prohibition may be made in writing by any person;

(c) the closing date for submissions, which shall not be earlier than [thirty] calendar days after the publication of the notice; and

(d) the address where submissions are to be sent.

(4) A copy of the public notice may be filed with the National Biosafety Clearing-House and the Regional Biosafety Clearing-House.

(5) In addition to the placement of a public notice, the National Competent Authority may establish a consultative process with regulatory agencies, representatives from the farming, academic and business community or the public concerning the proposed prohibition.

(6) Notwithstanding subsections (2) to (4), the Minister may publish an Order in the Gazette without utilizing the public notice process required under this section if there is an environmental or human health emergency.

(7) A person who conducts an activity that is prohibited under subsection (1) commits an offence.

Division 2
Approval to import or conduct activity relating to LMOs

27. Approval required to import or conduct activity relating to LMOs

(1) A person shall not import or conduct an activity relating to a LMO intended for a purpose set out in this Part unless approval is issued in accordance with this Act.

(2) A person who contravenes subsection (1) commits an offence, and is liable on summary conviction:

(a) to a fine not exceeding [ten thousand dollars] or imprisonment for a term not exceeding [two years], or both fine and imprisonment; and

(b) in the case of a second or subsequent conviction, to a fine not exceeding [fifteen thousand dollars] or to imprisonment for a term not exceeding [two years], or to both fine and imprisonment.

(3) Where a person contravenes subsection (1), the National Competent Authority shall:

(a) initiate appropriate actions such as refusal of entry, destruction or repatriation; and

(b) where necessary, inform and advise the public and relevant persons of its actions.

28. Procedure for application to import or conduct activity relating to LMOs

(1) A person who intends to conduct the first importation of or first activity relating to a LMO intended for a purpose set out in this Part in a CARICOM Member State shall submit a written application in the prescribed manner that complies with the following:

(a) is submitted to the relevant CARICOM Member State through CAHFSA using the Regional Biosafety Clearing-House~~;~~

(b) includes:

(i) the information specified in Schedule 2;

(ii) the intended purpose for which the LMO is imported, to the effect that:

(A) where the intended purpose is for direct use as food, feed or for processing, the relevant provisions of Division 3 apply;

(B) where the intended purpose is for use of a product of a LMO as food, feed or ingredient, the relevant provisions of Division 4 apply;

(C) where the intended purpose is for contained use, then the relevant provisions of Division 7 apply;

(C) where the intended purpose is for confined field trials, then the relevant provisions of Division 8 apply;

(D) where the intended purpose is for commercial use or placing on the market, then the relevant provisions of Division 9 apply.

(iii) any information known to the applicant that may be unfavourable to the grant of the application;

(iv) any other information that the applicant or the National Competent Authority may consider necessary for the assessment of the potential significant risk or benefits of the proposed activities or as prescribed under this Act;

(v) the prescribed application fee.

(2) A person who intends to conduct a second or subsequent importation of or activity relating to a LMO for a purpose set out in this Part for which prior approval was given by the National Competent Authority for that or any other CARICOM Member State shall submit a written application in the prescribed manner that complies with the following:

(a) is addressed to the Secretariat of the National Competent Authority;

(b) includes the information specified in subsection (1)(b).

(3) An applicant may:

(a) refer to information contained in the Regional Biosafety Clearing House or National Biosafety Clearing-House;

(b) submit such additional data or information that the applicant considers relevant;

(c) rely on other data or results previously submitted by another applicant, provided that such data or results are not confidential, or where they are confidential the owner of the data or results has given consent in writing to use the data or results.

29. Processing of and decision on application relating to LMO

(1) CAHFSA shall submit applications received under this Division to the National Competent Authority of the relevant CARICOM Member State for its decision.

(2) Where the National Competent Authority receives an application for the first importation of a LMO, the advance informed agreement procedure set out in Division 11 shall be followed in considering the application.

(3) The National Competent Authority in considering an application:

(a) shall have regard to:

(i) any risk analysis conducted by CAHFSA;

(ii) recommendations made by the National Scientific and Technical Advisory Committee in relation to the application;

(iii) protective measures, risk management strategies and other contingency measures required of the applicant to address any emergencies that may occur;

(iv) concerns and views submitted by the public in relation to the propose activity;

(b) may have regard to:

(i) disposal arrangements; and

(ii) any other prescribed matters.

(4) CAHFSA or the National Scientific and Technical Advisory Committee shall submit a recommendation to the National Competent Authority in relation to the application.

(5) The National Competent Authority shall make a final decision on the application and shall:

(a) notify the applicant in writing of its decision to grant a permit, with or without conditions;

(b) notify the applicant in writing of its decision, with reasons, to refuse to grant a permit.

(6) CAHFSA may notify the applicant of the decision made by the relevant CARICOM Member State.

(7) Approvals for the first importation into or first activity conducted in a CARICOM Member State of LMOs shall be placed on the regional approved list of the regional biosafety register and a permit granted may be used for a second or subsequent importation or activity involving the same transformation event and living organism.

(8) Where the National Competent Authority receives an application for a second or subsequent importation of or activity relating to a LMO:

(a) the simplified procedure set out in Division 12 shall be followed in considering the application;

(b) it shall:

(i) approve the application if the LMO is on the regional approved list; and

(ii) allow for the permit granted for the first importation or activity to be used for a second or subsequent importation or activity if it involves the same transformation event and living organism;

(c) if the LMO is not on the regional approved list, the procedure specified in subsections (3) to (6) shall apply.

30. LMO Permit

(1) Where the application for approval is granted, the National Competent Authority shall issue a permit and may impose conditions as it thinks fit, in addition to the standard conditions set out in this Act.

(2) It is a condition of a permit that the permit holder shall, in relation to an import, cause the documentation accompanying a LMO:

(a) be clearly identified as a LMO, referencing information contained in the Regional Biosafety Clearing -House where appropriate, or specifying the following:

(i) a brief description of the LMO, including common and scientific name, relevant traits and genetic modification, including transgenic traits and characteristics such as events of transformation or, where available and applicable, a reference to a system of unique identification;

(ii) where appropriate, further information shall include the commercial names of the LMO, if available, new or modified traits and genetic modification, including transgenic traits and characteristics such as transformation events, risk class, specification of use, any unique identification, where available, as a key to accessing information in the National Biosafety Clearing-House;

(b) specify requirements for safe handling, storage, transport or use as provided under applicable existing international requirements, this Act or prescribed under this Act, or under any agreement entered into by the importer and exporter;

(c) the contact point for further information;

(d) the name, address and contact details of the consignee, importer and exporter.

(3) Where the National Competent Authority grants a permit, it shall, within seven days transmit a copy to the National Biosafety Clearing-House and the Regional Biosafety Clearing-House.

Division 3

Approval to import or conduct activity relating to LMOs-FFP

31. Approval required to import or conduct activity relating to LMOs-FFP

(1) A person shall not import or conduct an activity relating to a LMO intended for direct use as food, feed, or for processing unless approval is issued in accordance with this Act.

(2) A person who contravenes subsection (1) commits an offence, and is liable on summary conviction:

(a) to a fine not exceeding [ ] or imprisonment for a term not exceeding [ ], or both fine and imprisonment; and

(b) in the case of a second or subsequent conviction, to a fine not exceeding [ ] or to imprisonment for a term not exceeding [ ], or to both fine and imprisonment.

(3) Where a person contravenes subsection (1), the National Competent Authority shall:

(a) initiate appropriate actions such as refusal of entry, destruction or repatriation; and

(b) where necessary, inform and advice the public and relevant persons of its actions.

32. Procedure for application to import or conduct activity relating to LMOs-FFP

(1) A person who intends to conduct the first importation of or first activity relating to a LMO intended for direct use as food, feed or processing in a CARICOM Member State shall submit a written application in the prescribed manner that complies with the following:

(a) is submitted to the relevant CARICOM Member State through CAHFSA using the Regional Biosafety Clearing-House;

(b) includes:

(i) the information specified in Schedule 2;

(ii) any other information that the applicant or the National Competent Authority may consider necessary for the assessment of the potential significant risk or benefits of the proposed activities or as prescribed under this Act;

(iii) the prescribed application fee.

(2) A person who intends to conduct a second or subsequent importation of or activity relating to a LMO intended for direct use as food, feed or for processing for which prior approval was given by the National Competent Authority for that or any other CARICOM Member State shall submit a written application in the prescribed manner that complies with the following:

(a) is addressed to the Secretariat of the National Competent Authority;

(b) includes:

(i) the information specified in Schedule 2;

(ii) any information known to the applicant that may be unfavourable to the grant of the application;

(iii) any other information that the applicant or the National Competent Authority may consider necessary for the assessment of the potential significant risk or benefits of the proposed activities or prescribed under this Act;

(iv) the prescribed application fee.

(3) An applicant may:

(a) refer to information contained in the Regional Biosafety Clearing House or National Biosafety Clearing-House;

(b) submit such additional data or information that the applicant considers relevant;

(c) rely on other data or results previously submitted by another applicant, provided that such data or results are not confidential, or where they are confidential the owner of the data or results has given consent in writing to use the data or results.

33. Processing of and decision on application relating to LMO-FFP

(1) CAHFSA shall submit applications received under this Division to the National Competent Authority of the relevant importing CARICOM Member State for its decision.

(2) Where the National Competent Authority receives an application for the first importation of a LMO intended for direct use as food, feed or processing, the simplified procedure set out in Division 12 shall be followed in considering the application.

(3) The National Competent Authority in considering an application:

(a) shall have regard to:

(i) any risk analysis conducted by CAHFSA;

(ii) recommendations made by the National Scientific and Technical Advisory Committee in relation to the application;

(iii) protective measures, risk management strategies and other contingency measures required of the applicant to address any emergencies that may occur;

(b) may have regard to:

(i) disposal arrangements;

(ii) concerns and views submitted by the public in relation to the proposed activity;

(iii) socio-economic considerations; and

(iv) any other prescribed matters.

(4) CAHFSA or the National Scientific and Technical Advisory Committee shall submit a recommendation to the National Competent Authority in relation to the application.

(5) The National Competent Authority shall make a final decision on the application and shall:

(a) notify the applicant in writing of its decision to grant a permit, with or without conditions;

(b) notify the applicant in writing of its decision, with reasons, to refuse to grant a permit.

(6) CAHFSA may notify the applicant of the decision made by the relevant CARICOM Member State.

(7) Approvals for the first importation into or first activity conducted in a CARICOM Member State of LMOs intended for direct use as food, feed, or for processing shall be placed on the regional approved list of the regional biosafety register and a permit granted may be used for a second or subsequent importation or activity involving the same transformation event and living organism.

(8) Where the National Competent Authority receives an application for a second or subsequent importation of or activity relating to a LMO intended for direct use as food, feed or processing –

(a) the simplified procedure set out in Division 12 shall be followed in considering the application;

(b) it shall-

(iii) approve the application if the LMO intended for direct use as food, feed or processing is on the regional approved list; and

(iv) allow for the permit granted for the first importation or activity to be used for a second or subsequent importation or activity if it involves the same transformation event and living organism;

(c) if the LMO is not on the regional approved list, the procedure specified in subsections (3) to (6) shall apply.

34. LMO-FPP permit

(1) Where the application for approval is granted, the National Competent Authority shall issue a permit and may impose conditions as it thinks fit, in addition to the standard conditions set out in this Act.

(2) It is a condition of a permit that the permit holder shall, in relation to an import, cause the documentation accompanying a LMO intended for food, feed or for processing to:

(a) be clearly identified as a LMO intended for food, feed or for processing, referencing information contained in the Regional Biosafety Clearing -House where appropriate, or specifying the following:

(i) a brief description of the LMO intended for food, feed or for processing, including common and scientific name, relevant traits and genetic modification, including transgenic traits and characteristics such as events of transformation or, where available and applicable, a reference to a system of unique identification;

(ii) where appropriate, further information shall include the commercial names of the LMO intended for food, feed or for processing, if available, new or modified traits and genetic modification, including transgenic traits and characteristics such as events of transformation, risk class, specification of use, any unique identification, where available, as a key to accessing information in the National Biosafety Clearing-House;

(b) the contact point for further information;

(c) the name, address and contact details of the consignee, importer and exporter.

(3) Where the National Competent Authority grants a permit, it shall, within seven days transmit a copy to the National Biosafety Clearing-House and the Regional Biosafety Clearing-House.

Division 4
Approval to import or conduct activity relating to products of LMOs for use as food, feed or ingredient

35. Approval to import or conduct activity relating to products of LMOs for use as FFI

(1) A person shall not import or conduct an activity relating to a product of a LMO for use as food, feed or ingredient unless approval is issued in accordance with this Act.

(2) A person who contravenes subsection (1) commits an offence, and is liable on summary conviction:

(a) to a fine not exceeding [ten thousand dollars] or imprisonment for a term not exceeding [two years], or both fine and imprisonment; and

(b) in the case of a second or subsequent conviction, to a fine not exceeding [fifteen thousand dollars] or to imprisonment for a term not exceeding [two years], or to both fine and imprisonment.

(3) Where a person contravenes subsection (1), the National Competent Authority shall:

(a) initiate appropriate actions such as refusal of entry, destruction or repatriation; and

(b) where necessary, inform and advice the public and relevant persons of its actions.

36. Procedure for application to import or conduct activity relating to products of LMOs for use as FFI

(1) A person who intends to conduct the first importation of or first activity relating to a product of a LMO for use as food, feed or ingredient in a CARICOM Member State shall submit a written application in the prescribed manner that complies with the following:

(a) is submitted to the relevant CARICOM Member State through CAHFSA using the Regional Biosafety Clearing-House~~;~~

(b) includes:

(i) the information specified in Schedule 2;

(ii) any other information that the applicant or the National Competent Authority may consider necessary for the assessment of the potential significant risk or benefits of the proposed activities or as prescribed under this Act;

(iii) the prescribed application fee.

(2) A person who intends to conduct a second or subsequent importation of or activity relating to a product of a LMO for use as food, feed or ingredient for which prior approval was given by the National Competent Authority for that or any other CARICOM Member State shall submit a written application in the prescribed manner that complies with the following:

(a) is addressed to the Secretariat of the National Competent Authority;

(b) includes the information specified in subsection (1)(b).

(3) An applicant may:

(a) refer to information contained in the Regional Biosafety Clearing House or National Biosafety Clearing-House;

(b) submit such additional data or information that the applicant considers relevant;

(c) rely on other data or results previously submitted by another applicant, provided that such data or results are not confidential, or where they are confidential the owner of the data or results has given consent in writing to use the data or results.

37. Processing of and decision on application relating to products of LMOs for use as food, feed or ingredient

(1) CAHFSA shall submit applications received under this Division to the National Competent Authority of the relevant importing CARICOM Member State for its decision.

(2) Where the National Competent Authority receives an application for the first importation of a product of a LMO for use as food, feed or ingredient, the simplified procedure set out in Division 12 shall be followed in considering the application.

(3) The National Competent Authority in considering an application:

(a) shall have regard to:

(i) any risk analysis conducted by CAHFSA;

(ii) recommendations made by the National Scientific and Technical Advisory Committee in relation to the application;

(iii) protective measures, risk management strategies, recall, or other measures required of the applicant to address any emergencies that may occur;

(b) may have regard to:

(i) socio-economic considerations; and

(ii) any other prescribed matters.

(4) CAHFSA or the National Scientific and Technical Advisory Committee shall submit a recommendation to the National Competent Authority in relation to the application.

(5) The National Competent Authority shall make a final decision on the application and shall:

(a) notify the applicant in writing of its decision to grant a permit, with or without conditions;

(b) notify the applicant in writing of its decision, with reasons, to refuse to grant a permit.

(6) CAHFSA may notify the applicant of the decision made by the relevant CARICOM Member State.

(7) Approvals for the first importation into or first activity conducted in a CARICOM Member State of products of LMOs for use as food, feed or ingredient shall be placed on the regional approved list of the regional biosafety register and a permit granted may be used for a second or subsequent importation or activity involving the same transformation event and living organism.

(8) Where the National Competent Authority receives an application for a second or subsequent importation of or activity relating to a product of a LMO for use as food, feed or ingredient–

(a) the simplified procedure set out in Division 12 shall be followed in considering the application;

(b) it shall-

(i) approve the application if the product of a LMO for use as food, feed or ingredient is on the regional approved list; and

(ii) allow for the permit granted for the first importation or activity to be used for a second or subsequent importation or activity if it involves the same transformation event and living organism;

(c) if the product of a LMO for use as food, feed or ingredient is not on the regional approved list, the procedure specified in subsections (3) to (6) shall apply.

38. Product of LMOs for use as FFI permit

(1) Where the application for approval is granted, the National Competent Authority shall issue a permit and may impose conditions as it thinks fit, in addition to the standard conditions set out in this Act.

(2) It is a condition of a permit that the permit holder shall, in relation to an import, cause the documentation accompanying a product of a LMO for use as food, feed or ingredient to:

(a) be clearly identified as a product of a LMO for use as food, feed or ingredient, referencing information contained in the Regional Biosafety Clearing-House where appropriate, or specifying its commercial name;

(b) the contact point for further information;

(c) the name, address and contact details of the consignee, importer and exporter.

(3) Where the National Competent Authority grants a permit, it shall, within seven days transmit a copy to the National Biosafety Clearing-House and the Regional Biosafety Clearing-House.

Division 5

Approval for export of LMOs

39. Approval required to export LMOs

A person shall not export a LMO or a product of a LMO unless approval is issued by the designated Competent Authority of the importing country.

40. Procedure for application to export LMO

(1) A person who intends to export a living modified organism or a product of a living modified organism shall comply with the requirements determined by the country of import.

(2) A person who intends to export a living modified organism or a product of a living modified organism shall, prior to the export, provide to the National Competent Authority:

(a) the information specified in Parts A and B of Schedule 2; and

(b) proof of permission to import from the designated Competent Authority of the country of import.

(3) Compliance with subsection (2) does not absolve an exporter from complying with any other laws governing export and foreign trade.

(4) The provision of proof of permission under subsection (2) shall not prevent the National Competent Authority from taking into account other considerations in deciding whether or not to approve the export.

Division 6
Approval for transit of LMOs

41. Approval required for transit of LMO

(1) A person shall not cause the transit of a LMO or a product of a LMO unless approval is issued in accordance with this Act.

(2) A person who contravenes subsection (1) commits an offence, and is liable on summary conviction:

(a) to a fine not exceeding [ ] or imprisonment for a term not exceeding [ ], or both fine and imprisonment; and

(b) in the case of a second or subsequent conviction, to a fine not exceeding [ ] or to imprisonment for a term not exceeding [ ], or to both fine and imprisonment.

(3) Where a person contravenes subsection (1), the National Competent Authority shall:

(a) initiate appropriate actions such as refusal of passage, destruction or repatriation; and

(b) where necessary, inform and advise the public and relevant persons of its actions.

42. Procedure for application to transit LMOs

(1) A person who intends to transit a LMO or a product of a LMO shall submit a written application in the prescribed manner to the National Competent Authority that complies with the following:

(a) is addressed to the Secretariat of the National Competent Authority;

(b) includes:

(i) the information specified in Schedule 2;

(ii) any information known to the applicant that may be unfavourable to the grant of the application;

(iii) the prescribed application fee;

(iv) any other prescribed information.

(2) An applicant may:

(a) refer to information contained in the Regional Biosafety Clearing House or National Biosafety Clearing-House;

(b) submit such additional data or information that the applicant considers relevant;

(c) rely on other data or results previously submitted by another applicant, provided that such data or results are not confidential, or where they are confidential the owner of the data or results has given consent in writing to use the data or results.

43. Processing of and decision on application for transit of LMOs

(1) Where the National Competent Authority receives an application for the transit of a LMO or product of a LMO, it shall follow the simplified procedure set out in Division 12.

(2) The National Scientific and Technical Advisory Committee shall submit a recommendation to the National Competent Authority in relation to the application.

(3) The National Competent Authority shall make a final decision on the application in accordance with the recommendation made under subsection (2), and shall:

(a) notify the applicant in writing of its decision to grant an import permit, with or without conditions;

(b) notify the applicant in writing of its decision, with reasons, to refuse to grant a permit.

44. Transit permit

(1) Where the application for approval is granted, the National Competent Authority shall issue a transit permit and may impose conditions as it thinks fit, in addition to the standard conditions set out in this Act.

(2) It is a condition of a transit permit that the permit holder shall:

(a) provide a copy of the permit at the port of entry and exit to the Comptroller of Customs;

(b) cause the LMO or product of a LMO to be appropriately packaged and labelled for shipment in accordance with this Act or prescribed under this Act;

(c) implement appropriate disposal or destruction measures in case of accidental release while in transit.

Division 7

Approval for contained use of LMOs

45. Approval required for contained use of LMOs

(1) A person shall not conduct an activity that involves contained use of a LMO or a product of a LMO unless approval is issued in accordance with this Act.

(2) A person who contravenes subsection (1) commits an offence, and is liable on summary conviction:

(a) to a fine not exceeding [ ] or imprisonment for a term not exceeding [ ], or both fine and imprisonment; and

(b) in the case of a second or subsequent conviction, to a fine not exceeding [ ] or to imprisonment for a term not exceeding [ ], or to both fine and imprisonment.

46. Procedure for application for contained use of LMOs

(1) A person who intends to conduct an activity that involves contained use of a LMO shall submit a written application in the prescribed manner to the National Competent Authority that complies with the following:

(a) is addressed to the Secretariat of the National Competent Authority;

(b) requests that the premises in which the activity that involves contained use is expected to be conducted be approved for registration;

(c) request that approval for contained use be applicable to a specific modern biotechnology activity for each stage of contained use [on a stage by stage basis];

(d) includes:

(i) the information specified in Schedule 3;

(ii) information about the Institutional Biosafety Committee that is established;

(iii) information about the stages of contained use;

(iv) any information known to the applicant that may be unfavourable to the grant of the application;

(v) any other information that the applicant or the National Competent Authority may consider necessary for the assessment of the potential significant risk or benefits of the proposed activities or prescribed under this Act;

(vi) the prescribed application fee.

(2) An applicant may:

(a) refer to information contained in the Regional Biosafety Clearing House or National Biosafety Clearing-House;

(b) submit such additional data or information that the applicant considers relevant;

(c) rely on other data or results previously submitted by another applicant, provided that such data or results are not confidential, or where they are confidential the owner of the data or results has given consent in writing to use the data or results.

47. Processing of and decision on application for contained use of LMOs

(1)`Where the National Competent Authority receives an application for contained use of a LMO or product of a LMO**,** it shall follow the simplified procedure in Division 12.

(2) The National Competent Authority shall:

(a) consider each application on a case by case basis;

(b) in considering whether the premises should be approved for registration, cause the premises to be inspected and a report prepared by the [relevant regulatory agency];

(c) consider the report of the [relevant regulatory agency] and any representation relating to the report by the applicant;

(d) if it is of the opinion that the premises or personnel employed within the facility need to be modified in order to comply with the requirements made by or under this Act, by notice in

writing, require the applicant to make the necessary modifications before granting approval for a contained use activity;

(e) consider an application on a stage by stage contained use basis in which the containment level is reduced and the scale of release gradually increased based upon an evaluation of each stage and its effects on the environment taking also in account risks to human health;

(f) submit a recommendation to the National Competent Authority for the grant, with or without conditions, or refusal of approval for contained use.

(3) The National Scientific and Technical Advisory Committee shall submit a recommendation to the National Competent Authority in relation to the application.

(4) The National Competent Authority shall make a final decision on the application in accordance with the recommendation made under subsection (3), and shall:

(a) notify the applicant in writing of its decision to grant approval, with or without conditions;

(b) notify the applicant in writing of its decision, with reasons, to refuse to grant approval;

(c) issue approval for each prescribed type or class of contained use activities or stage of contained use on the condition that there is compliance with:

(i) applicable laws, operating procedures, emergency safeguards and other biosafety guidelines, codes of practice and established standards;

(ii) inspection and monitoring requirements for facilities, including any inspection required before commencement of construction;

(iii) directions given by the National Competent Authority, relevant Institutional Biosafety Committees, and relevant regulatory agencies.

48. Contained use approval, oversight and guidelines

(1) Where the application for approval is granted, the National Competent Authority shall:

(a) require the Institutional Biosafety Committee to provide oversight of the contained use activities;

(b) issue a contained use permit form for each prescribed type or class of contained use activities or stage of contained use and may impose conditions as it thinks fit, in addition to the standard conditions set out in this Act.

(2) It is a condition of approval that the person shall:

(a) cause necessary safety precautions to be taken to minimize significant adverse effects on human health, biological diversity, and the environment;

(b) comply with:

(i) applicable laws, operating procedures, emergency safeguards and other biosafety guidelines, codes of practice and established standards to cause the facility to be managed in accordance with good microbiological practices;

(ii) inspection and monitoring requirements for facilities, including any inspection required before commencement of construction;

(iii) directions given by the National Competent Authority, the relevant Institutional Biosafety Committee, or relevant regulatory agencies;

(c) keep and maintain appropriate records.

(3) Where the National Competent Authority grants approval, it shall, within seven days inform the National Biosafety Clearing-House and the Regional Biosafety Clearing-House.

Division 8

Approval for confined field trials of LMOs

49. Approval required for confined field trials of LMOs

(1) A person shall not conduct an activity that involves confined field trials of a LMO unless approval is issued in accordance with this Act.

(2) A person who contravenes subsection (1) commits an offence, and is liable on summary conviction:

(a) to a fine not exceeding [ ] or imprisonment for a term not exceeding [ ], or both fine and imprisonment; and

(b) in the case of a second or subsequent conviction, to a fine not exceeding [ ] or to imprisonment for a term not exceeding [ ], or to both fine and imprisonment.

50. Procedure for application to conduct confined field trial of LMOs

(1) A person who intends to conduct an activity that involves confined field trials of a LMO shall, with the approval of the appropriate Institutional Biosafety Committee, submit a written application in the prescribed manner to the National Competent Authority that complies with the following:

(a) is addressed to the Secretariat of the National Competent Authority;

(b) includes:

(i) the information specified in Schedule 3;

(ii) any information known to the applicant that may be unfavourable to the grant of the application;

(iii) any other information that the applicant or the National Competent Authority may consider necessary for the assessment of the potential significant risk or benefits of the proposed activities or is prescribed under this Act;

(iv) the prescribed application fee.

(2) An applicant may:

(a) refer to information contained in the Regional Biosafety Clearing House or National Biosafety Clearing-House;

(b) submit such additional data or information that the applicant considers relevant;

(c) rely on other data or results previously submitted by another applicant, provided that such data or results are not confidential, or where they are confidential the owner of the data or results has given consent in writing to use the data or results.

51. Processing of and decision on application for confined field trial of LMOs

(1) Where the National Competent Authority receives an application for an activity that involves confined field trials of a living modified organism, the simplified procedure set out in Division 12 shall be followed in considering the application.

(2) The following may be assessed in considering an application:

(a) disposal arrangements and post activity arrangements to ensure that any land used can be utilised for future activities;

(b) protective measures, risk management strategies and other contingency measures required of the applicant to address any emergencies that may occur;

(c) any other prescribed matters.

(3) The National Scientific and Technical Advisory Committee shall submit a recommendation to the National Competent Authority in relation to the application.

(4) The National Competent Authority shall make a final decision on the application in accordance with the recommendation made under subsection (3), and shall:

(a) notify the applicant in writing of its decision to grant a confined field trial permit, with or without conditions;

(b) notify the applicant in writing of its decision, with reasons, to refuse to grant a permit.

52. Confined field trial permit

(1) Where the application for approval is granted, the National Competent Authority shall issue a confined field trial permit and may impose conditions as it thinks fit, in addition to the standard conditions set out in this Act.

(2) It is a condition of a confined field trial permit that the permit holder shall:

(a) cause necessary safety precautions to be taken to minimize significant adverse effects on human health, biological diversity, and the environment;

(b) conduct:

(i) inspection of the site before field testing commences;

(ii) inspection and monitoring of facilities during the field testing; and

(iii) inspection and monitoring of the site, after the field test, to ensure that all material capable of generating live LMOs is removed or destroyed;

(c) comply with:

(i) applicable laws, operating procedures, emergency safeguards and other biosafety guidelines, codes of practice and established standards to cause the facility to be managed in accordance with good microbiological practices;

(ii) directions given by the National Competent Authority, the relevant Institutional Biosafety Committee, and relevant regulatory agencies;

(d) keep and maintain appropriate records.

(3) Where the National Competent Authority grants a permit, it shall, within seven days transmit a copy to the National Biosafety Clearing-House and the Regional Biosafety Clearing-House.

Division 9

Approval for commercial use or placing on the market of LMOs

53. Approval required for commercial use of LMOs etc.

(1) A person shall not conduct an activity that involves commercial use or placing on the market of a LMO, a LMO intended for direct use as food, feed or for processing or a product of a LMO unless approval is issued in accordance with this Act.

(2) A person who contravenes subsection (1) commits an offence, and is liable on summary conviction:

(a) to a fine not exceeding [ ] or imprisonment for a term not exceeding [ ], or both fine and imprisonment; and

(b) in the case of a second or subsequent conviction, to a fine not exceeding [ ] or to imprisonment for a term not exceeding [ ], or to both fine and imprisonment.

54. Procedure for application for commercial use of LMO etc.

(1) A person who intends to conduct an activity that involves commercial use or placing on the market of a LMO, a LMO intended for direct use as food, feed or for processing or a product of a LMO shall submit a written application in the prescribed manner, specifying the activity for which approval is sought, and which complies with the following -

(a) is addressed to the Secretariat of the National Competent Authority;

(b) includes –

(i) the information specified in Schedule **2**;

(ii) any information known to the applicant that may be unfavourable to the grant of the application;

(iii) any other information that the applicant or the National Competent Authority may consider necessary for the assessment of the potential significant risk or benefits of the proposed activities or as prescribed under this Act;

(iv) the prescribed application fee.

(2) An applicant may:

(a) refer to information contained in the Regional Biosafety Clearing House or National Biosafety Clearing-House;

(b) submit additional data or information that the applicant considers relevant;

(c) rely on other data or results previously submitted by another applicant, provided that such data or results are not confidential, or where they are confidential the owner of the data or results has given consent in writing to use the data or results.

55. Processing of and decisions on application for commercial use of LMOs etc.

(1) Where the National Competent Authority receives an application for commercial use or placing on the market of a LMO**,** a LMO intended for direct use as food, feed or for processing or a product of a LMO, **t**he simplified procedure set out in Division 12 shall be followed in considering the application.

(2) The following may be assessed in considering an application:

(a) protective measures, risk management strategies and other contingency measures proposed by the applicant to address any emergencies that may occur during the commercial use or placing on the market;

(b) concerns and views submitted by the public in relation to the proposed activity;

(c) socio-economic consideration;

(d) the benefit of the activity in [country];

(e) any other prescribed matters.

(3) The National Scientific and Technical Advisory Committee shall submit a recommendation to the National Competent Authority in relation to the application.

(4) The National Competent Authority shall make a final decision on the application in accordance with the recommendation made under subsection (2), and shall:

(a) notify the applicant in writing of its decision to grant a commercial use or placing on the market permit, with or without conditions;

(b) notify the applicant in writing of its decision, with reasons, to refuse to grant a permit.

56. Commercial use or placing on the market of LMO permit

(1) Where the application for approval is granted, the National Competent Authority shall issue a commercial use or placing on the market permit and may impose conditions as it thinks fit, in addition to the standard conditions set out in this Act.

(2) A commercial use or placing on the market permit shall specify:

(a) the scope of the approval, including the identity of the living modified organism to be commercially used or placed on the market, and its unique identifier and the location and quantity of land to be used;

(b) any limitations on or conditions for commercial use or placing on the market, including any specific conditions for domestic transport, use, handling, labelling, packaging, monitoring, or export of a LMO, a LMO intended for direct use as food, feed or for processing or a product of a LMO.

(3) Where the National Competent Authority grants a permit, it shall, within seven days transmit a copy to the National Biosafety Clearing-House and the Regional Biosafety Clearing-House.

Division 10
General Permit Provisions

57. Withdrawal of application

An applicant may, without prejudice, withdraw his or her application at any time prior to the issuance of a final decision by the National Competent Authority.

58. Cancellation of application

(1) Where the applicant does not provide any additional information requested by the National Competent Authority within thirty days of the request being made, the National Competent Authority may give the applicant notice that the application cannot be determined and has been cancelled.

(2) Where the National Competent Authority cancels an application under subsection (1), it shall return the cancelled application to the applicant and shall publish notice of the cancellation in a newspaper of general circulation in (country).

59. Grant or refusal of permit

(1) The National Scientific and Technical Advisory Committee shall, where appropriate, submit a recommendation for the granting or refusal of a permit with or without conditions to the National Competent Authority in its consideration of applications.

(2) In accordance with a recommendation made under subsection (1), the National Competent Authority shall make a final decision on the application and shall:

(a) notify the applicant of its decision and give the reasons in writing for the grant, with conditions, or refusal to grant a permit;

(b) issue a permit in the prescribed form.

(3) Where the National Competent Authority grants a permit, it shall, within seven days transmit a copy to the National Biosafety Clearing-House and the Regional Biosafety Clearing-House.

60. Standard permit conditions

(1) A permit granted under this Part shall be subject to the conditions set out by or under this Act.

(2) Subject to section 63, the National Competent Authority may suspend or revoke a condition of a permit if there are grounds that justify the suspension or revocation.

(3) Conditions of a permit that may be imposed or prescribed on regulated activities include:

(a) the scope of the activities authorised by the permit;

(b) the purposes for which the activities authorised by the permit may be conducted;

(c) the geographic area in which the activities authorised by the permit may occur;

(d) compliance with any operating procedures, guidelines, or codes of practice, that may be issued;

(e) documentation and record keeping requirements, including activities involving the LMOs;

(f) the required level of containment in respect of the activities authorised under the permit including the requirements relating to the certification of facilities to specified containment levels;

(g) measures and procedures to manage significant risks posed to the health and safety of persons, or significant risk to the environment;

(h) security requirements, including those in relation to access to facilities and storage of living modified organisms;

(i) supervision, monitoring, auditing and reporting;

(j) actions and measures to be taken in case of unintentional release of the living modified organism in a contained facility or environment;

(k) contingency planning in respect of unintended effects of the activities authorised by the permit;

(l) cleaning up and monitoring of the geographic area (including surrounding areas) for any living modified organism after the activities authorised under the permit are terminated and the permit ceases to have effect;

(m) measures to limit the dissemination or persistence of the living modified organism or its genetic material in the environment;

(n) waste disposal requirements.

(4) It is a condition of a permit that if:

(a) a person is authorised by the permit to deal with a living modified organism;

(b) a particular condition of the permit applies to the activity in relation to a living modified organism by the person;

the person must allow an Inspector to enter premises where the activity is being undertaken for the purposes of auditing or monitoring the compliance of those activities by or under the Act or of the conditions attached to the permit.

(5) It is a condition of a permit that the permit holder inform the National Competent Authority if the permit holder:

(a) becomes aware of additional information as to any significant risks to the health and safety of humans, or the environment, associated or as a consequence of the activities authorised by the permit;

(b) becomes aware of any significant adverse event, such as unintentional release of the living modified organism into the environment, as a consequence of the activities authorised by the permit;

(c) becomes aware of any contraventions of the permit, and any breach of conditions by a person covered by the permit;

(d) any change in circumstance of the permit holder that may affect compliance with the conditions of the permit, and other requirements by or under this Act;

(e) is requested to supply the National Competent Authority with information about activities conducted by the permit holder to enable the National Competent Authority to carry out its functions by or under this Act.

(6) A permit for an activity involving living modified organisms shall be personal to the permit holder, and shall not be transferable or vest by operation of law in any person other than the permit holder.

61. Validity of permit

(1) A permit granted under this Act is valid for the period specified in the permit unless revoked by the National Competent Authority.

(2) Where approval is granted for a regulated activity, the National Competent Authority may allow the first permit granted to be valid for a second or subsequent similar regulated activity involving the same transformational event involving a LMO or product of a LMO by the permit holder.

62. Effect of permit

A permit issued under this Act, unless it provides otherwise, authorizes the permit holder to engage in the activity identified in the permit in relation to the living modified organism identified in the permit.

63. Suspension or revocation of permit

(1) The National Scientific and Technical Advisory Committee may submit a recommendation to the National Competent Authority to suspend or revoke a permit if:

(a) the permit holder:

(i) is convicted of an offence by or under this Act;

(ii) fails to comply with the conditions imposed by the permit;

(b) in the opinion of the National Scientific and Technical Advisory Committee, new information or a review of existing information about the living modified organism establishes significant risks to human or animal health, biological diversity or the environment.

(2) Where the National Scientific and Technical Advisory Committee proposes to suspend or revoke a permit, the National Competent Authority shall give to the permit holder notice in writing of the proposal and the reasons for the proposal and shall invite the person to show cause why the permit should not be suspended or revoked.

(3) A notice to show cause shall state that within twenty-one days, the permit holder may make representations in writing or otherwise, and the National Competent Authority shall not determine the matter without considering the submissions or representations within that period of twenty-one days but may take appropriate action to mitigate any new significant risks that may arise.

(4) Where the National Competent Authority suspends or revokes a permit under this section, it:

(a) shall give the permit holder notice in writing of the suspension or revocation and shall give information concerning the right of appeal under section 80;

(b) shall publish notice of the suspension or revocation in a newspaper of general circulation in (country);

(c) may, where applicable, order the destruction of any LMO and the sterilization of any area in which it is located, in whatever way it considers appropriate and in accordance with appropriate standards.

Division 11
Advance informed application procedure

64. Advance informed agreement procedure

(1) Within ninety days of receiving an application for a regulated activity requiring the use of the advance informed procedure:

(a) CAHFSA shall inform the National Competent Authority of the relevant CARICOM Member State of the application;

(b) the National Competent Authority shall –

(i) publish a summary of the application, in two newspapers of general circulation in [country] for a minimum of two consecutive weeks or if relevant, announce the public notifications by radio and telecast for public guidance;

(ii) screen the application for completeness;

(iii) acknowledge in writing receipt of the application;

(iv) if the application is not complete, request the applicant to submit additional information as may be required.

(2) Where a request for additional information is made under subsection (1), the time taken before receipt of the requested information shall not be included in calculating the time taken prior to making a decision.

(3) Where the application has been screened and found to be complete –

(a) CAHFSA shall do any of the following as the circumstances of an application requires:

(i) prepare a report based on its evaluation of the risk analysis and other relevant technical information submitted by the applicant;

(ii) conduct a scientific risk assessment on behalf of the relevant CARICOM Member State, if requested;

(iii) make a recommendation to the National Competent Authority on applications relating to the first importation of LMOs intended for direct use as food, feed, or for processing or the first importation of products of LMOs for use as food, feed or ingredients;

(iv) submit to the National Competent Authority of the relevant CARICOM Member State on whose behalf the application is received the documents prepared under this paragraph;

(b) the National Competent Authority:

(i) shall transmit the application and accompanying documents to the National Scientific and Technical Advisory Committee for review, which shall prepare a report based on its evaluation of the risk analysis and other relevant technical information and submit the report to the National Competent Authority and submit the report and its recommendations to the National Competent Authority;

(ii) shall consult with relevant regulatory agencies;

(iii) may transmit the application and accompanying documents to the National Socio-Economic Risk Committee for review, which shall prepare a report based on its evaluation of the socio-economic risks;

(iv) shall make a decision based on factors such as the information submitted in the application, scientific risk assessment reports, recommendations and comments made on the application;

(v) shall, within two hundred and seventy days of the date of the receipt of an application by CAHFSA or the Secretariat of the National Competent Authority, communicate in writing, to the applicant, the National Biosafety Clearing-House and the Regional Biosafety Clearing-House its decision;

(vi) shall, where required, issue a permit to the applicant where approval is granted.

(4) A failure by the National Competent Authority to communicate its decision within two hundred and seventy days of the date of receiving the application does not imply its consent to the regulated activity.

Division 12
Simplified application procedure

65. Simplified application procedure

(1) The simplified procedure shall apply to an application for approval of a regulated activity requiring its use.

(2) Upon receipt of an application:

(a) CAHFSA shall:

(i) inform the National Competent Authority of the relevant CARICOM Member State of the application;

(ii) within ten days publish a summary of the application in the Regional Biosafety Clearing-House;

(iii) conduct a scientific risk analysis on behalf of the relevant CARICOM Member State if requested;

(iv) prepare a report based on its evaluation of the risk analysis and other relevant technical information;

(v) submit the report to the National Competent Authority of the relevant CARICOM Member State on whose behalf the application is received;

(vi) submit its recommendations to the National Competent Authority of the relevant CARICOM Member State on whose behalf the application is received;

(b) the National Competent Authority shall:

(i) within ten days of receiving an application publish a summary of the application in the *Gazette* and at least two newspapers in general circulation or any other media in [country]; and

(ii) transmit the application and accompanying documents to the National Scientific and Technical Advisory Committee for review which shall prepare a report based on its evaluation of the risk analysis and other relevant technical information and submit the report to the National Competent Authority;

(iii) make a final decision on the application based on factors such as the information submitted in the application, risk analysis reports, recommendations and comments made on the application approving or denying the application in whole or in part;

(iv) communicate its final decision in writing to the applicant within one hundred-and twenty days of receiving the application and if the application is not granted, provide reasons in writing for the refusal.

Division 13
Exemptions

66. Exemption from Act

A LMO, a product of a LMO or an activity relating thereto may be exempted from this Act if:

(a) it is a LMO intended for food, feed, or for processing that is placed on the regional approved list of the Regional Biosafety Clearing-House under section 10(3)(b)(iii) following a determination by CAHFSA that sufficient experience or information exists to conclude that it is not likely to have significant adverse effects on human health;

(b) it is a product of a LMO for use as food or feed that is placed on the regional approved list of the Regional Biosafety Clearing-House under section 10(3)(b)(iii) following a determination by CAHFSA that that sufficient experience or information exists to conclude that it is not likely to have significant adverse effects on human health;

(c) it is any other living modified organism or product of a living modified organism that is placed on the regional approved list of the Regional Biosafety Clearing-House under section 10(3)(b)(iii) or on the National Biosafety Register under section 19 following a determination by CAHFSA or the National Competent Authority, as the case may be, that sufficient experience or information exists to conclude that it is not likely to have significant adverse effects on the conservation and sustainable use of biological diversity, human health and the environment or is not likely to cause any significant ecological, social or economic harm in [country];

67. Procedure for applying for exemption of LMO

(1) A person may submit an application to the National Competent Authority to exempt a LMO or a product of a LMO from a provision of this Act.

(2) Applications shall:

(a) contain the following:

(i) the grounds upon which an exemption is based;

(ii) the relevant provision of this Act or prescribed under this Act from which an exemption is applied for;

(iii) any information known to the applicant that may be unfavourable to the grant of the application;

(b) be addressed to the Secretariat of the National Competent Authority;

(c) be accompanied by the prescribed application fee.

68. Processing of and decision on application for exemption

(1) In relation to an application for exemption made to CAHFSA the following shall apply –

(a) CAHFSA shall within ten days of receiving an application for exemption publish a summary of the application on its website or by any other means for a minimum of two consecutive weeks;

(b) within one hundred and twenty days of receiving the application, CAHFSA shall immediately notify the applicant of the approval or denial of the application and shall give reasons in writing for the denial of the application for exemption;

(c) where CAHFSA approves an application, it shall issue a certificate of exemption to the applicant.

(2) In relation to an application for exemption made to the National Competent Authority, the following shall apply –

(a) the National Competent Authority shall within ten days of receiving an application for exemption publish a summary of the application in two newspapers of general circulation in [country] for a minimum of two consecutive weeks or if relevant, announce the public notifications by radio and telecast for public guidance;

(b) within one hundred and twenty days of receiving the application, the National Scientific and Technical Advisory Committee shall submit a recommendation to the National Competent Authority to approve or deny the application in whole or in part;

(c) in accordance with the recommendation of the National Scientific and Technical Advisory Committee, the National Competent Authority shall immediately notify the applicant of the approval or denial of the application and shall give reasons in writing for the denial of the application for exemption;

(d) where the National Competent Authority approves an application, it shall issue a certificate of exemption to the applicant.

PART IV

LABELING, PACKAGING AND IDENTIFICATION

69. Labeling of LMOs

LMOs for direct use as food, feed or processing and products of LMOs for use as food, feed or ingredients shall be labelled in accordance with the relevant Codex Alimentarius Standard for labelling of food.

70. Packaging of LMOs

During transit, transport, import or export, living modified organisms and or their products shall be packaged -

(a) under conditions of safety, to avoid significant adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health or animal health;

(b) in the manner prescribed by or under this Act or as required by the National Competent Authority.

71. Documents to accompany the transport of LMOs

LMOs and products of LMOs that are transited, transported, imported, or exported shall be accompanied by documentation that -

(a) clearly identifies the LMOs as LMOs or products of LMOs that "may contain" living modified organisms;

(b) specifies the identity and relevant traits and characteristics;

(c) specifies any requirements for the safe handling, storage, transport and use;

(d) provides the permit number;

(e) provides a contact point for further information, including the name and address of the person to whom the LMOs or products of LMOs are consigned.

72. Segregation

Living modified organisms that are imported or exported by sea or air, or transported by road which could react or interfere with each other, shall be segregated in the manner prescribed under this Act.

PART V

RISK ANALYSIS

73. Risk analysis process

(1) Risk analysis may be conducted by:

(a) an applicant;

(b) CAHFSA;

(c) the National Scientific and Technical Advisory Committee.

(2) Decisions made in relation to regulated activities under Part III shall be based upon risk analyses, which shall:

(a) be carried out in accordance with Schedule 4 with the necessary modifications, where necessary, taking into account recognized risk analysis techniques;

(b) be in accordance with any requirements imposed by CAHFSA or the National Competent Authority, as the case may be, under this Act.

(3) CAHFSA or the National Scientific and Technical Advisory Committee as the case may be, shall provide the National Competent Authority with a risk analysis report after the conclusion of the risk analysis or review of the risk analysis.

74. Risk assessment

(1) CAHFSA or the National Scientific and Technical Advisory Committee shall review the risk assessment submitted by an applicant and shall conduct or cause to be conducted any additional risk assessments to identify and evaluate significant risks posed by a regulated activity to the conservation and sustainable use of biological diversity, taking into account risks to human health or animal health.

(2) The National Competent Authority shall consider the result of a review of a risk assessment report in making a decision on an application.

(3) In any case where the risk assessment shows that significant risks cannot be avoided, the National Competent Authority shall refuse approval of an application for a regulated activity.

(4) The National Competent Authority may require the applicant to bear all or part of the costs for reviewing the risk assessment report or for carrying out the risk assessment, as the case may be.

75. Risk management

(1) The National Competent Authority shall impose risk management measures to the extent necessary to minimise significant adverse effects of a living modified organism on the conservation and sustainable use of biological diversity, when compared to adverse effects from comparable activities not using LMOs, taking into account risks to human health and the environment.

(2) Without limiting the generality of subsection (1), the National Competent Authority may:

(a) subject a LMO to undergo a period of observation commensurate with its life-cycle or generation time, at the cost of the applicant, before it is put to its intended use;

(b) require a person responsible to take measures as may be necessary to prevent or minimise significant harm to the environment, biological diversity, human health, socio-economic conditions or to restore the environment to its previous state as far as is feasible.

(3) A permit holder or person responsible shall implement the risk management measures imposed by the National Competent Authority in a risk management plan that addresses the risk management measures imposed to safely use, prevent, minimise or control the significant risks and adverse effects of a living modified organism on the conservation and sustainable use of biological diversity, taking into account risks to human health and the environment.

(4) For the purpose of assessing or improving the implementation of the risk management plan:

(a) an Inspector may conduct inspections to determine the manner in which a regulated activity is conducted;

(b) a permit holder or person responsible shall submit reports to the National Competent Authority in the manner required by the conditions for approval, in relation to the monitoring and evaluation of significant risks carried out after the approval of the regulated activity;

(c) the National Scientific and Technical Advisory Committee shall evaluate its effectiveness in addressing the significant adverse effects of a LMO on the conservation and sustainable use of biological diversity, taking into account risks to human health and the environment;

(d) the National Competent Authority may order the modification of a risk management plan, including the imposition of additional risk management measures with respect to the regulated activity, if it determines that there is significant danger posed to the conservation and sustainable use of biological diversity, taking into account also risks to human health.

76. Disclosure of significant new risks

(1) A permit holder who becomes aware of any significant new scientific information indicating that regulated activities may significantly adversely affect the conservation and sustainable use of biological diversity, taking into account risks to human health and the environment or pose potential significant risks not previously known or considered, shall immediately advise the National Competent Authority of the new information and newly identified risks and of the measures put in place to ensure the continued safe use of the living modified organism.

(2) CAHFSA, the National Scientific Committee or the applicant, as the case may be, may determine appropriate risk measures.

PART VI

UNINTENTIONAL INTRODUCTION INTO THE ENVIRONMENT `AND EMERGENCY MEASURES

77. Unintentional introduction into the environment

(1) A relevant person who has knowledge of an unintentional introduction into the environment of a LMO shall, upon acquiring knowledge of the unintentional introduction, immediately notify the National Competent Authority of the occurrence.

(2) A notification under subsection (1) shall, to the extent possible, include the following:

(a) available relevant information on the estimated quantities and relevant characteristics or traits of the living modified organism;

(b) information on the circumstances and estimated date of the introduction of the living modified organism;

(c) any available information about the possible significant adverse effect on the conservation and sustainable use of biological diversity or significant risk to human

health and the environment, as well as available information about possible risk management measures;

(d) any other relevant information; and

(e) a point of contact for further information.

(3) The National Competent Authority and the National Scientific and Technical Advisory shall consult with the relevant person to determine whether any action is necessary to minimize any significant adverse effect on the conservation and sustainable use of biological diversity taking into account risks to human health and the environment.

(4) Where the National Competent Authority and the National Scientific and Technical Advisory Committee determine that action is necessary to minimize significant adverse effect on the conservation and sustainable use of biological diversity taking into account risks to human health, the National Competent Authority shall exercise the risk management measures under section 75 and the relevant person ~~s~~hall take the necessary action and shall be liable for the cost of such action.

(5) Where the National Competent Authority knows of an occurrence that leads or may lead to an unintentional introduction into the environment of a living modified organism that is likely to have significant adverse effects on the conservation and sustainable use of biological diversity, taking into account risks to human health, in another country, it shall notify or cause to be notified:

(a) affected or potentially affected countries or persons;

(b) the Regional Biosafety Clearing-House, and the National Biosafety Clearing-House established under the Cartagena Protocol; and

(c) where appropriate, relevant international organizations.

(6) For the purposes of this section, a "relevant person" means a person in direct or indirect control of the living modified organism as authorised under this Act, including *inter alia* the permit holder, producer, exporter, or carrier.

78. Emergency measures

(1) The National Competent Authority shall require an applicant [or permit holder] to prepare an emergency response plan which shall provide:

(a) safety measures and procedures to minimize any significant adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health and the environment; and

(b) all necessary measures to be taken in the event of an emergency.

(2) The National Competent Authority shall make recommendations to the [National Emergency Management Organization] and other regulatory agencies, on appropriate emergency measures to minimize any significant adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health and the environment.

(3) A permit holder who fails to take the necessary measures in an emergency according to the emergency response plan commits an offence and shall, on conviction, be liable:

(a) where the person is an individual, to a fine not exceeding [ ] dollars and, in the case of a continuing offence, to a further fine not exceeding [ ] for each day during which the offence continues after conviction;

(b) where the person is a body corporate, to a fine not exceeding [ ] dollars, in the case of a continuing offence, to a further fine not exceeding [ ] dollars for each day during which the offence continues after conviction.

PART VII

MECHANISM FOR REVIEW OF DECISIONS

79. Review of decision

(1) Decisions made under this Act may be reviewed and changed by the National Competent Authority on its own motion or upon the request of a person on any of the following grounds:

(a) a change in circumstances has occurred that may influence the outcome of the risk analysis upon which the decision was based; or

(b) additional relevant scientific or technical information has become available since `the decision was made.

(2) The National Competent Authority:

(a) shall respond in writing to the request within twenty-one days of its receipt, and may invite the person to make representation in writing or otherwise within a specified time;

(b) indicate whether a further risk analysis is required to be conducted;

(c) may review and change a decision made under this Act on any of the grounds stated in subsection (1);

(d) shall, within ninety days of receipt of the request, provide its decision to the person.

(3) A decision made under this Act is valid until amended or revoked.

(4) Where the National Competent Authority changes a decision under this section, it shall inform the Regional Biosafety Clearing-House and the National Biosafety Clearing House.

80. Right of appeal

[Any person] [An applicant/ A permit holder/ person to whom approval is given] who feels aggrieved by any decision or action taken by the National Competent Authority under this Act may, within the period

and in the manner prescribed by Regulations under the Act, and upon the payment of the prescribed fee, appeal against the decision or action to the Environmental Tribunal.

81. Socio-economic considerations

The National Competent Authority may, in reaching a decision under this Act, take into account socio-economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities.

PART VIII
ENVIRONMENTAL TRIBUNAL

82. Establishment of Tribunal

(1) There is established a tribunal to be known as the Environmental Tribunal.

(2) The Environmental Tribunal shall consist of three members appointed by the [Governor-General], [President] [Executive President], acting in accordance with the recommendation of the Judicial and Legal Services Commission, upon such terms and conditions as may be specified in their instrument of appointment.

(3) A person shall not qualify for appointment as a member of the Environmental Tribunal unless that person has qualifications or experience in law, economics, science or technology.

(4) The [Governor General] [President], [Executive President], acting in accordance with the recommendation of the Judicial and Legal Services Commission, shall appoint a Chairperson of the Environmental Tribunal from among members of the Tribunal who shall be a legal practitioner of not less than seven years standing.

(5) Where a member of the Environmental Tribunal is temporarily absent or is temporarily incapacitated and unable to discharge his or her duty, the [Governor-General] [President] [Executive President], acting in accordance with the recommendation of the Judicial and Legal Service Commission, may, by notice published in the Gazette, appoint a suitable person to act in the member's place.

(6) The Minister shall publish in the Gazette notice of a person appointed as a member of the Environmental Tribunal.

(7) A member of the Environmental Tribunal shall immediately recuse himself or herself if an appeal relates to an issue in which he or she has any direct or indirect interest or if, for any other reason, there is or there is likely to be a conflict of interest as a result of his or her participation in the proceedings.

83. Jurisdiction and powers of the Tribunal

(1) The jurisdiction of the Environmental Tribunal shall be to:

(a) determine disputes arising from -

(i) granting, refusing, suspending or revoking permits under this Act;

(ii) permit conditions;

(c) a failure to treat information in an application as confidential;

(b) make awards and other decisions in accordance with the powers conferred on it by this Act.

(2) The Environmental Tribunal shall not hear and determine a dispute unless it is satisfied that the National Competent Authority has made all reasonable efforts to obtain redress for the complainant and has failed to obtain such redress.

(3) The Environmental Tribunal shall not have jurisdiction to hear and determine any criminal matter that arises out of the contravention of any provision of this Act.

(4) On hearing a matter under this Act, the Environmental Tribunal shall have the powers of a court to summon witnesses, take evidence upon oath or affirmation, and to call for the production of books and other documents.

(5) Where the Environmental Tribunal considers it desirable for the purpose of avoiding expense or delay or any other special reason so to do, it may receive evidence by affidavit and administer interrogatories and require the person to whom interrogatories are administered to make a full and true reply to the interrogatories within the time specified.

(6) In the determination of any matter, the Environmental Tribunal may take into consideration any evidence which it considers relevant to the matter before it, notwithstanding that the evidence is not otherwise admissible under the law relating to evidence.

(7) The Environmental Tribunal shall have the power to award the costs of any proceedings before it and to direct that costs shall be taxed in accordance with any scale prescribed.

(8) All summonses, notices or other documents issued under the hand of the Chairperson of the Environmental Tribunal shall be deemed to be issued by the Environmental Tribunal.

(9) An interested party may be represented before the Environmental Tribunal by an Attorney-at-Law or by any other person whom the Environmental Appeals Tribunal may admit to be heard on behalf of the party.

(10) The Environmental Tribunal may:

(a) confirm, set aside or amend the decision or action concerned which is the subject of the hearing;

(b) refer the relevant matter back to the National Competent Authority for reconsideration; or

(c) make such other order as it considers necessary.

(11) Decisions of the Environmental Tribunal, together with the reasons –

(a) shall be reduced to writing;

(b) shall be provided to the parties to the dispute;

(c) may be published.

84. Sitting of the Tribunal

(1) The Environmental Tribunal shall meet on such occasions as may be expedient for the hearing and determination of disputes, and at such places and times as it may determine.

(2) Regulations may prescribe the procedure to be followed by the Environmental Tribunal in hearing and determining disputes referred to it.

(3) Conflicts of interest shall be addressed in accordance with section 99.

[(4) There shall be appointed a Registrar of the Tribunal who shall be a public officer.]

85. Right of appeal to Tribunal

(1) A person may, within thirty days of receiving notice of a decision made by the National Competent Authority, appeal to the Environmental Tribunal setting out the grounds on which an appeal is made in respect of:

(a) a failure to grant a permit;

(b) a permit that is granted with conditions;

(c) the variation or revocation/suspension of a condition of a permit;

(d) the suspension or revocation of a permit.

(2) Before determining an appeal referred to it under this section, the Environmental Tribunal shall give the applicant, permit holder, or National Competent Authority the opportunity of appearing before and being heard by it.

86. Duration of office

A member of the Environmental Tribunal shall hold office for a period not exceeding three years, and the member shall be eligible for re-appointment.

87. Resignation of a member of the Tribunal

(1) A member of the Environmental Tribunal may, at any time, in writing, resign from the Tribunal and the member's resignation shall be addressed to the [Governor-General] [President] [Executive President].

(2) The Minister shall publish in the Gazette notice of every resignation of a member of the Environmental Tribunal.

88. Termination of membership

(1) The office of a member of the Environmental Tribunal shall become vacant if:

(a) the member dies;

(b) the member's term of office expires;

(c) the member resigns;

(d) the members is convicted of an indictable offence; or

(e) the member is removed from office in accordance with the provisions of subsection (2).

(2) The [Governor-General] [President] [Executive President], acting in accordance with the recommendation of the Judicial and Legal Services Commission, may remove a member from the Environmental Tribunal if the [Governor-General] [[President] [Executive President] is satisfied that the member:

(a) is permanently incapable of performing his or her duties;

(b) has engaged in dishonorable conduct;

(c) is incompetent;

(d) has neglected his or her duty;

(e) is bankrupt;

(f) has a conflict of interest that would prevent providing an unbiased opinion.

89. Remuneration

The members of the Environmental Tribunal shall be paid remuneration as may be appropriated by Parliament for that purpose.

90. Appeals to High Court

A person who is dissatisfied with the decision of the Environmental Tribunal may appeal against the decision to the High Court within fourteen (14) days from the day the decision is made, and the appeal shall be on a question or point of law only.

PART IX

MONITORING, ENFORCEMENT AND COMPLIANCE

91. Investigation of complaints

An Investigator may investigate complaints that fall within his functions under this Act.

92. Cessation orders

(1) The National Competent Authority may issue an order for the immediate cessation of an activity covered by an approval or exemption granted under this Act, if there is a material infringement of an obligation imposed by or under this Act that presents an imminent danger to the conservation and sustainable use of biological diversity, or to human health.

(2) An order issued under subsections (1) shall be withdrawn once the National Competent Authority determines that sufficient information exists to permit the activity to resume or to resume in the absence of additional risk management measures without posing a significant risk to the conservation and sustainable use of biological diversity, or to human health.

93. Direction to remedy breach

(1) If the National Competent Authority is satisfied that a person has conducted an activity relating to a LMO or product of a LMO without or beyond its approval and damage has occurred, it may issue a restoration order or direct the person in writing to remedy the breach.

(2) The restoration order shall specify:

(a) the activity to which the order relates;

(b) the person to whom the order is addressed;

(c) the action which should be taken to remedy the damage and the time, being not more than thirty days or such further period as may be prescribed in the order, within which the action shall be taken; and

(d) the penalty which may be imposed under section 95 if the action specified is not taken.

94. Seizure, detention and forfeiture of article or LMO

(1) Where an Inspector or a Customs officer finds a living modified organism in respect of which no permit was granted by the National Competent Authority in the possession of a person or otherwise in contravention of this Act, the living modified organism or any article in which it is contained shall be seized and detained [and thereafter delivered into the custody of the Secretariat of the National Competent Authority].

(2) Where proceedings are instituted within the time provided under this Act and the Court orders the forfeiture of a LMO or product of a LMO that was seized and detained, it shall be disposed of as the

National Competent Authority may direct or, after consultation with the country from which the LMO was exported, return the LMO at the expense of that country or the owner or person who had possession.

95. Offences

(1) A person who:

(a) in relation to a living modified organism or a product of a living modified organism, conducts a regulated activity without the written approval of the National Competent Authority;

(b) obtains approval by fraud, deception, misrepresentation, misleading or inaccurate information;

(c) contravenes the conditions of the grant of approval, or a direction issued by or under this Act;

(d) resists, obstructs, or hinders an Inspector in the exercise of his powers or duties under this Act;

(e) recklessly or knowingly makes a false or misleading statement that is material, in respect of a regulated activity;

(f) knowingly makes a false entry in a register, record, return, or other document kept or provided by or under this Act, or willfully makes use of such false entry;

(g) fails to keep a record which is required to be kept by or under this Act;

(h) fails to provide information that is required by or under this Act;

(i) removes, alters or interferes in any way with a living modified organism, product of a living modified organism, or an article seized under the provisions of this Act without the authority of an Inspector;

(j) fails to comply with any other requirement for which an offence is imposed by or under this Act;

commits an offence.

(2) A person who commits an offence for which no specific penalty is provided shall be liable,

(a) on summary conviction to a fine not exceeding ten thousand dollars or to imprisonment for a period not exceeding one year or both;

(b) on conviction upon indictment, to a fine not exceeding fifty thousand dollars or to imprisonment for a period not exceeding three years or both.

(3) A prosecution for an offence under this Act may not be commenced more than three years after -

(a) the date on which the offence was committed; or

(b) the date on which evidence of the offence first came to the attention of the Secretariat of the National Competent Authority or a regulatory agency, whichever is the later.

(4) A magistrate or judge may, in his discretion, instead of imposing a fine or term of imprisonment, order a person to remedy the effects of an offence or impose a reduced penalty where the person who committed the offence reported the offence to the National Competent Authority.

(5) Notwithstanding the penalties provided under this Act, the National Competent Authority may, in addition, revoke the approval granted to the person.

96. Continuing offence

Where an offence under this Act is committed or continues on more than one day, the person who committed the offence is liable to be convicted for a separate offence for each day on which the offence is committed or continues.

97. Additional penalties

Where a person has pleaded guilty to, or been convicted of an offence, the Court, in addition to any other punishment that may be imposed under this Act, having regard to the nature of the offence and the circumstances surrounding its commission, may make an order:

(a) prohibiting the offender from doing any act or engaging in any activity that may result in the continuation or repetition of the offence;

(b) disqualifying the offender from obtaining an approval;

(c) directing the offender to take such action as the Court considers appropriate to remedy or avoid any harm to the environment, human health or animal health that results or may result from the act or commission that constituted the offence;

(d) directing the offender to post a bond or pay an amount of money as may be necessary to recover charges associated with an inspection, audit or investigation undertaken in respect of the offence;

(e) directing the offender to post a bond or pay an amount of money as will ensure compliance with any order made pursuant to this section;

(f) directing the offender to compensate any affected party, in whole or in part, for any environmental damage or harm to human health or animal health or the cost of any remedial or preventative action taken or caused to be taken as a result of the act or omission that constituted the offence;

(g) directing the seizure and forfeiture of any vessel, aircraft, vehicle or article used in the commission of an offence;

(h) the sealing off of premises for such period as may be specified in the order: or

(i) requiring the offender to comply with such other reasonable conditions as the Court considers appropriate and just in the circumstances.

PART X

MISCELLANEOUS PROVISIONS

98. Confidentiality

(1) A member of CAHFSA or a person appointed to the National Competent Authority, National Scientific and Technical Advisory Committee, the National Socio-Economic Committee or as an Inspector shall not disclose any information acquired through the exercise of that person's powers or the performance of that person's duties under this Act, except:

(a) in so far as it is necessary for the proper application of the provisions of this Act;

(b) for the purposes of any legal proceedings under this Act;

(c) when ordered to do so by any competent court; or

(d) if he or she is authorised to do so by the Minister.

(2) The National Competent Authority shall decide, after consultation with an applicant under this Act, which information provided pursuant to an application will be kept confidential and shall inform the applicant of its decision.

(3) In this section the following information shall not be confidential information:

(a) the name and address of the applicant;

(b) a general description of the living modified organism;

(c) the risk analysis of foreseeable significant adverse effects performed on the living modified organism; and

(d) any methods and plans for emergency response.

(4) Notwithstanding the provisions of subsection (3), the National Competent Authority may, after consultation with the applicant and if it is satisfied on the grounds of information provided by the applicant that certain information should be withheld in order to protect the intellectual property of the applicant, withhold the information for the period needed to protect such rights.

(5) Notwithstanding if an applicant withdraws an application under this Act, a person to whom subsection (1) applies who has knowledge of the details of the application shall respect the confidentiality of the information supplied.

99. Conflict of interest

(1) A person appointed to the National Competent Authority, National Scientific and Technical Advisory Committee or the National Socio-Economic Committee and whose interest is likely to be affected, directly or indirectly, by a decision of the body of which the person is a member, or on any matter that is likely to evoke an allegation of bias, shall disclose the nature of his interest at the first meeting of the body at which the person is present after the relevant facts have come to his knowledge.

(2) A disclosure made under subsection (1) shall be recorded in the minutes of the relevant body and after the disclosure, the member making the disclosure shall, unless the body otherwise directs, leave the meeting.

(3) Where a person referred to in subsection (2) is allowed by the body to stay in the meeting, the member shall not take part in the deliberations on the matter nor shall the member vote on the matter.

100. Regulations

The Minister may, after consulting the National Competent Authority, make Regulations to give effect to the provisions of this Act, and without prejudice to the generality of the foregoing, for all or any of the following:

(a) application forms for, approval of, format and content of permits and other matters relating to the transboundary movement, transit, handling and use of living modified organisms;

(b) fees, costs, charges and expenses for any permits, risk analysis, investigations, inspections and enforcement;

(a) standards for the identification, transporting, handling, use, labeling, packaging, disposal of waste of living modified organisms,

(b) contents of an emergency response plan;

(c) requirement for the safe handling and disposal of living modified organisms;

(d) evaluation of products of LMOs for use as food, feed or ingredient ;

(e) the procedure for the quarantine of any living modified organism in any place;

(f) the living modified organisms which are prohibited or restricted;

(i) prohibiting or restricting living modified organisms from any area for the conservation and sustainable development of that area;

(j) any matter required to be prescribed under this Act.

101. Transitional provisions

(1) Within two months of the entry into force of this Act, a person responsible for conducting an activity falling within the scope of this Act, or his or her agent located in (county), shall submit an application for approval of the activity in accordance with Part III and indicate the date on which the activity first commenced.

(2) If the application is made within the time period specified in subsection (1), the activity in respect of which the application is made may continue until a decision is made under this Act.

(3) The National Competent Authority shall make a decision in accordance with the relevant section applicable to the application for which approval is required.

(4) An application in relation to an activity falling within the scope of this Act that is pending at the date of entry into force of this Act shall be subject to the provisions of this Act.

(5) Notwithstanding subsections (3) and (4), if an application relates to a LMO intended for direct use as food, feed or processing or a product of a LMO for use as food, feed or ingredient that, prior to the commencement of this Act was placed on the market of a CARICOM Member State, the National Competent Authority may approve the application without the conduct of a scientific risk analysis.

Schedule 1

(Section 12(1)(b))

Regulatory Agencies

Environmental Protection Unit/Agency
Ministry of Agriculture
Ministry of Health
Maritime Administration
Ministry of Trade
Customs and Excise
Bureau of Standards

Schedule 2

(Sections 28; 32; 36; 42; 54)

Application Form for Approval for Import/Transit/Intentional Introduction into the Environment/Direct Use as Food, Feed or for Processing/Placing on the Market of LMO or Product of LMO

To: National Competent Authority of (Country)

A. General Information

1. Name of Applicant:
2. Applying Institution (if relevant):
3. Address of Applicant:
4. Contact details of Applicant: *(telephone, fax, email, website)*
5. Nature of application/regulated activity: *(import, transit,).*
6. Exporting/destination country: *(if applicable)*
7. Expected date of import/transit: *(if known)*

B. Information relating to LMO/Product of LMO/Transformation Event

8. Scientific name:
9. Unique Identification:
10. Taxonomic status, common name, point of collection or acquisition of LMO, and characteristics of
*Parental organism:
*Recipient organism:
11. Centres (country or region) of origin and centres of genetic diversity (wild relatives in the region, if known), of the parental organisms:
12. Description of the habitats where the organisms may persist or proliferate:
13. Description of the nucleic acid or modification introduced, the technique used, and the resulting characteristics of the LMO/product of LMO:
14. Intended use: *(e.g. for direct use as food, feed or processing; use as food, feed or ingredient; contained use; confined field trial; commercial use/placing on the market; intentional introduction into the environment)*
15. Quantity or volume to be imported/transited:
16. Details of previous approval of import into/transit through country (if applicable): (a single approval for multiple activities is applicable only to the same transformation event)

C. Information Relevant to Commercial Use/Placing on the Market

17. Name of product and LMOs contained therein:
18. Name of the manufacturer or distributor and address, including address in the country:
19. Conditions of use of the product (if applicable):
20. Type of expected use: *(e.g. industry, agriculture, consumer use by public at large)*
21. Specific instructions or recommendations for storage and handling (if applicable):

D. Risk Analysis

22. Previous or existing risk analysis report:
23. Methods for the safe handling, storage, transport and use, including packaging, labeling, documentation, disposal and contingency procedures, where appropriate:
24. Regulatory status within the country of export: *(e.g. if it is prohibited in the country of export, faces other restrictions, or has been approved for general release; and, if it is banned in the country of export, the reason for the ban)*
25. Result and purpose of any notification by the exporter to other countries regarding the LMO/product of a LMO to be transferred:
26. Suggested emergency response measures in the event of accidental release:

E. Declaration

I hereby certify that the information provided in this application is to the best of my knowledge and belief, correct and complete.

Signature of Applicant: ……..... Date: …….....

(dd/mm/yy)

Schedule 3

(Section 46; 50)

Application Form for approval of Contained Use/Confined Field Trial

To: National Competent Authority of (Country)

A. General Information

1. Name of Applicant:
2. Applying Institution/Company (if relevant):
3. Address of Applicant:
4. Contact details of Applicant: *(telephone, fax, email, website)*
5. Details of Institutional Biosafety Committee:
6. Registration of Facility:

B. Information relating to LMO/Transformation Event

7. Scientific name:
8. Unique Identification:
9. Taxonomic status, common name, point of collection or acquisition of LMO, and characteristics of
*Parental organism:
*Recipient organism:
10. Centres (country or region) of origin and centres of genetic diversity (wild relatives in the region, if known), of the parental organisms:
11. Description of the habitats where the organisms may persist or proliferate:
12. Description of the nucleic acid or modification introduced, the technique used, and the resulting characteristics of the LMO/:

C. Information on Contained Use/Field Trial Activity

13. Intended use: *(e.g. contained use; confined field trial)*
14. Location of contained use/ field trial activity: *(e.g. size, type of confinement, amount of material proposed, length of study, activities in or around the area)*
15. Legal land use location: *(map with location showing layout of contained use/field trial activity and any other activities within 5 km proximity of plot))*
16. Site description: *((relevant geographic information such as climate/weather/slope/wind/hurricane etc. that might influence field trial effects like dispersal)*
17. Size of facility/field:
18. Nature and purpose of activities:
19. Detailed description of contained use/field trial activity: *(including such activities as laboratory experiments, testing, storing, transporting, producing, processing, disposing or using the LMO in any other way / containment measures, waste disposal plan, post-harvest plan including monitoring)*
20. Start date of planting/activity:
21. Expected date of completion:

D. Administration

22. Details of personnel involved in the activities and their biosafety training/qualifications:
23. Type of data to be collected and method of record keeping.

F. Risk Analysis

24. Summary of potential significant risks:
25. Summary of risk management plan for each significant risk identified:
26. Full risk assessment is attached:
27. Post-testing arrangements for environmental and health monitoring

Declaration

I hereby certify that the information provided in this application is to the best of my knowledge and belief, correct and complete.

Signature of Applicant: ……..... Date: …….....

(dd/mm/yy)

Schedule 4

(Section 73)

Risk Analysis

Objective

1. The objective of the risk analysis, under this Act, is to identify and evaluate the potential significant adverse effects of living modified organisms on the conservation and sustainable use of biological diversity in the likely potential receiving environment, taking into account risks to human health and the environment.

Use of risk analysis

2. Risk analysis is, among other things, used by competent authorities to make informed decisions regarding living modified organisms.

General principles

3. Risk analysis should be carried out in a scientifically sound and transparent manner, and may take into account expert advice of, and guidelines developed by, relevant international organisations.

4. Lack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk, or an acceptable risk.

5. Risk associated with living modified organisms or products thereof, namely, processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology, should be considered in the context of the risks posed by the non-modified parental organisms in the likely potential receiving environment.

6. Risk analysis should be carried out on a case-by-case basis. The required information may vary in nature and level of detail from case to case, depending on the living organism concerned, its intended use and the likely potential receiving environment.

Methodology

7. The process of risk analysis may on the one hand give rise to a need for further information about specific subjects, which may be identified and requested during the analysis process, while on the other hand information on other subjects may not be relevant in some instances.

8. To fulfil its objective, risk analysis entails, as appropriate, the following steps-

(a) an identification of any novel genotypic and phenotypic characteristics associated with the living modified organism that may have significant adverse effects on biological diversity in the likely potential receiving environment, taking into account risks to human health and the environment;

(b) an evaluation of the likelihood of these significant adverse effects being realised, taking into account the level and kind of exposure of the likely potential receiving environment to the living modified organism;

(c) an evaluation of the consequences should these significant adverse effects be realised;

(d) an estimation of the overall risk posed by the living modified organism based on the evaluation of the likelihood and consequences of the identified significant adverse effects being realised;

(e) a recommendation as to whether or not the significant risks are acceptable or manageable, including, where necessary, identification of strategies to manage these risks; and

(f) where there is uncertainty regarding the level of risk, it may be addressed by requesting further information on the specific issues of concern or by implementing appropriate risk management strategies or monitoring the living modified organism in the receiving environment.

Points to consider

9. Depending on the case, risk assessment takes into account the relevant technical and scientific details regarding the characteristics of the following subjects-

(a) Parental organism. The biological characteristics of the parental organisms, including information on taxonomic status, common name, origin, centres of origin and centres of genetic diversity, if known, and a description of the habitat where the organisms may persist or proliferate;

(b) Donor organism(s). Taxonomic status and common name, source and the relevant biological characteristics of the donor organisms;

(c) Vector. Characteristics of the vector, including its identity, if any, and its source of origin, and its host range;

(d) Insert(s) and/or characteristics of the inserted nucleic acid and the function it specifies, and/or characteristics of the modification introduced;

(e) Living modified organism. Identity of the living modified organism, and the differences between the biological characteristics of the living modified organism and those of the parental organism;

(f) Detection and identification of the living modified organism. Suggested detection and identification methods and their specificity, sensitivity and reliability;

(g) Information relating to the intended use. Information relating to the intended use of the living modified organism, including new or changed use compared to the parental organisms; and

(h) Receiving environment. Information on the location, geographical, climatic and ecological characteristics, including relevant information on biological diversity and centres of origin of the likely potential receiving environment.