Teni Eric Housty

Project Methodology

GY-NBF CONSULTANCY # 01
Development of the Biosafety/ Biotechnology Bill for Guyana

"Private and Confidential"

Teni Eric Housty
Attorney-at-Law, Mediator and Legal Consultant

11th February, 2014

Ms. Jenniffer Bentick,
National Project Coordinator,
National Biosafety Framework (NBF) Project
Environmental Protection Agency,
Ganges Street,
Sophia,
Georgetown.

Dear Ms. Bentick,

GY-NBF CONSULTANCY # 01
Development of the Biosafety/ Biotechnology Bill for Guyana

I have attached hereto as Attachment A, a further revised First Draft of the Biosafety/Biotechnology Bill. The adjustments are based on the comments received thus far. I look forward to meeting with you and your team to work on the further finalisation of the text of Attachment A.

Yours faithfully,

Original Signed by

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Attachment A

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Arrangement of Sections

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PART I

PRELIMINARY

Short Title.

Interpretation. 2 "accident" means

*[**any incident by which any genetically modified organism may be introduced, either directly or indirectly, into the environment, which results, or is likely to result in significant harm to biological diversity, the environment, human health or animal health or safety**]*

[any incident involving an unintended general release of biotechnological products which could have an immediate or delayed adverse impact on the environment]

[any incident involving an unintentional environmental release of genetically modified organisms that is likely to have an immediate or delayed adverse impact on the environment or on animal health within the Republic].

[any incident involving an unintended release of biotechnology products into the environment which may have an immediate or delayed adverse impact on the environment.]

"advanced informed agreement [Procedure]" means

[*the procedure whereby consent is obtained before any activity is undertaken based upon full disclosure of all relevant matters in accordance with [section ....]*

or

[*consent given by the Competent Authority based upon the full disclosure and taking responsibility for the accuracy of all relevant information by the applicant before any import, export, transit is undertaken on any genetically modified organism or a product of a genetically modified organism.]*

or

[the consent obtained before any activity is undertaken based upon full

disclosure of all relevant information and the taking of full responsibility by the supplier of the information for its accuracy and completeness]

"analyst" means *a person appointed under [section ...] of this Act to be an analyst for the purposes of this Act*

"Appeal Tribunal" means *the Biosafety Appeals Tribunal established under [section ..]"*

"Applicant" means

a person submitting an application pursuant to the provisions of this Act

or

any person making an application for the approval of the National Biosafety Authority, or the person to whom the approval is given;

or

any legal or natural person, whether in [Guyana] or any other State, who applies for any permit or approval for the handling, transport, use, transfer or release of any genetically modified organisms pursuant to the provisions of this Act;

"Biodiversity" means

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

or

"the variability among genetically modified organisms from all sources including, inter alia, terrestrial, marine and other aquatic ecosystems, and the ecological complexes of which they are part this includes diversity within species, between species and of ecosystems;

or

"Biosafety" means
The level of safety when risk management measures must be taken to avoid potential risk to human and animal health and safety and to the conservation of the environment as a result of exposure to activities with genetically modified organisms and biological safety shall have a corresponding meaning.

or

set of measures, policies and procedures used or established for assessing, preventing, monitoring and managing any risk associated with genetically modified organisms to human health or animal health and safety and to the environment;

or

the avoidance of risk to human health or animal health and safety, and the conservation of the environment, as a result of the use of genetically modified organisms;

"Biosafety Clearing-house" means *the Biosafety Clearing-House established under article 20 of the [Cartagena] Protocol;*

"Biotechnology" means

the development of products by exploiting biological processes or substances using intact original or modified organism or by using active cell components;

or

Any technique that uses living organisms or parts of organisms to made or modify products, to improve plants or animals, or develop micro-organisms for specific purposes

"Cartagena Protocol" means the

Cartagena Protocol on Biosafety to the Convention on Biological Diversity

or

Cartagena Protocol on Biosafety the text of which is set out in the [Fifth Schedule] to this Act

"Cell technology" means *techniques for the production of living cells with new combinations of genetic material by the fusion of two or more cells*

"Code" means (a) in respect of any genetically modified organism transported by sea, the International Maritime Dangerous Goods (IMDG) Code relating to the carriage of dangerous goods by sea, as amended from time to time, approved by the Maritime Safety Committee of the International Maritime Organisation (IMO); or

(b) in respect of any genetically modified organism transported by air, the Dangerous Goods Regulations relating to the carriage of dangerous goods by air, as amended from time to time, approved by the International Civil Aviation Organisation (ICAO) or the Dangerous Goods Board of the International Air Transport Association (IATA);

Competent Authority means

the [National Biosafety Authority] established under Part II of the Act.

or

means the entity responsible for the implementation of this [Law]
or

an agency of another country responsible under its national law for the control or regulation of genetically modified organisms

"contained use" means

any operation in which genetically modified organisms are produced, grown, stored, destroyed or used in some other way in a closed system in which physical barriers are employed, either alone or together with chemical and/or biological barriers, to limit contact between the organism on the one hand and humans and the environment on the other hand

"Controlled area" means *as provided in [Part 5] means any declared*

port of entry by air or sea, and includes any area occupied or controlled by the [Maritime Administration Department];

"Deliberate release" means *any intentional introduction into the environment of a genetically modified organism, or a combination of genetically modified organisms or products thereof, and includes releases for – (i) commercial purposes; (ii) research purposes in field experimentation; (iii) use in greenhouses, aquaculture facilities, or animal accommodation unless the facility is approved for contained use or disposal of genetically modified organisms;*

"Designated Competent Authority" means an agency of another country responsible under its national law for the control or regulation of genetically modified organisms

"domestic use" means

Includes placing on the market for direct us as food, feed or processing

or

The use of a genetically modified organism exclusively for household purposes such as cooking

"Ecosystem" means *a dynamic complex of plant, animal and micro-organism communities and their non-living systems interacting as a functional unit*

"Environment" means

includes atmosphere, land, soil, water and all living organisms

or

includes the physical factors of the surroundings of human beings, including land, water, atmosphere, soil, vegetation, climate, sound odour, aesthetics, fish and wildlife

the aggregate of surrounding objects, conditions and influences that affect the life and habits of [human beings] man or any other organisms or collection of organisms

"Export" means

the intentional transboundary movement of any genetically modified organism or a product of a genetically modified organism from one country to another country

or
means intentional transboundary movement of any genetically modified organism to [Guyana]

"exporter" means

any legal or natural person, whether in [Guyana] or any other State, who arranges for a genetically modified organism to be exported"

or

any person who arranges for any genetically modified organism or a product of a genetically modified organism to be exported;

or

any legal or natural person who arranges for a *genetically modified* organism to be exported;

"Facility" means any physical structure where activities involving genetically modified organisms are carried out, including -
(a) a building or part of a building;
(b) a laboratory;
(c) a greenhouse;
(d) an animal house;
(e) an aquarium or tank;
(f) a fermentor;
(g) any other place;

"food" means any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans;

"Gene technology" means *techniques that involve the isolation, characterization, modification and introduction of deoxyribonucleic [DNA] acid into cells or viruses;*

Genetically engineered (organism) means
any organism, excluding humans, that is a product of modern biotechnology

"genetically modified" means 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 genetically modified organisms

"Genetically modified food" means Food containing, consisting of or produced from genetically modified organisms

"Genetically modified organism" means

micro-organisms, plants and animals whose genetic composition has been modified by the use of gene or cell technology, more specifically -
(i) an organism derived from the formation of a combination of genetic material by artificial techniques, or
(ii) an organism inheriting such combination of genetic material, or
(iii) an organism that results from the replication of an organism described in paragraph (i), and
and includes living modified organisms, or such other matter as may be prescribed by the Minister.

or

any biological entity including plants, animals, bacteria and all other kinds of micro-organisms, cell cultures (prokaryotic or eukaryotic) created and propagated as such, virus, and plasmids and other kinds of vectors, in which the genetic material has been altered in a way that does not occur naturally, by means of cell or gene technology

or

means any organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology techniques

or

(a) means an organism whose genetic material has been modified by the activity of manipulating recombinant deoxyribonucleic acid (DNA) or Ribonucleic acid (RNA) molecules; and
(b) includes – (i) a living modified organism;
(ii) a product of a genetically modified organism;

(c) does not include organisms arising from techniques that imply the direct introduction into an organism, or hereditary material, when this does not involve the use a recombinant DNA or RNA molecules or genetically modified organisms, modified by processes, such as, in vitro insemination, conjugation, transduction or any other natural process

"import" means

i*ntentional transboundary movement of any genetically modified organism to [Guyana]*

or

the intentional transboundary movement of any genetically modified organism or a product of a genetically modified organism into one country from another country

"importer" means

any legal or natural person who arranges for any genetically modified organism or a product of a genetically modified organism to be imported

or

any legal or natural person who arranges for a genetically modified organism to be imported.

or

any legal or natural person, whether in [Guyana] or any other State, who arranges for a genetically modified organism to be imported

"Institutional Biosafety committee " means The committee constituted under [section …]

"inspector" means Any person appointed as an inspector under this Act

" Inspectorate" means the [unit] constituted under [section..]

"Intentional introduction into the environment"

(i) *in vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or*
(ii) fusion of cells beyond the taxonomic family, that overcomes natural physiological reproductive or recombination barriers and that are not techniques used in natural breeding and selection;

or

" (*a) in vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of the 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;

or

(a) means any deliberate release of a genetically modified organism for which no specific containment measures are used to limit their contact with and to provide a high level of safety for the general population and the environment; and
(b) includes the following activities -
(i) the deliberate release of a genetically modified organism for research purposes, such as, field trials;
(ii) the deliberate release of a genetically modified organism for commercial purposes, remedial purposes or such other purposes;
(iii) the use of a genetically modified organism in a greenhouse, aquaculture facility, animal accommodation or other facility, unless the facility in question is approved for contained use as part of an approved laboratory or other installation;
(iv) routine release from contained use;
(v) the disposal of waste containing a genetically modified organism;
(vi) placing on the market of a product consisting of or containing genetically modified organisms;
(vii) transport of a genetically modified organism;
(c) does not include a genetically modified organism imported for direct use for food, feed or for processing;

or

"*means any release into the environment, including any production or use that is not contained use of genetically modified organisms or products; this includes releases for: commercial purposes, remediation, research purposes in field experiments, use of genetically modified*

organisms or products in greenhouses, aquaculture facilities, animal accommodation unless the facility is approved for contained use as part of an approved laboratory or other installation, disposal of waste containing genetically modified organisms or products, and transport of genetically modified organisms or product; SKN

includes (a) any production or use that is not contained use; (b) releases for (i) commercial purposes; (ii) remediation; (iii) research purposes in field experiments; (iv) use of genetically modified organisms in greenhouses, aquaculture facilities, animal accommodation unless the facility is approved for contained use as part of an approved laboratory or other installation; (v) disposal of waste containing genetically modified organisms; but does not include genetically modified organisms intended for direct use as food, feed or processing.

or

means any deliberate use of genetically modified organisms other than not contained use

"label" means *any legend, word, mark, symbol, or design applied to, included in, belonging to, or accompanying any genetically modified organism or a package thereof;*

"living modified organism" means *any living organisms that possesses a novel combination of genetic material obtained through the use of modern biotechnology*

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

"Modern biotechnology" means

(i*) in vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or*
(ii) fusion of cells beyond the taxonomic family, that overcomes natural physiological reproductive or recombination barriers and that are not techniques used in natural breeding and selection;

or

[(a) in vitro nucleic acid techniques, including recombinant

deoxyribonucleic acid (DNA) and direct injection of the 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;]

"Minister" means the minister responsible for [the environment]/[Biosafety

National Competent Authority means an agency of another country responsible under its national law for the control or regulation of genetically modified organisms

"National Focal Point" means the entity designated to be responsible on behalf of Guyana for liaising with the Secretariat of the Cartagena Protocol;

"notification" means *a notification made pursuant to this Act*

"notifier" means *a person who makes a notification pursuant to this Act*

"Operator" means any person conducting activities authorized or otherwise allowed under this Act

"organisms" mean

[any multicellular, uncellular, subcellular or cellular entity capable of replication or of transferring genetic material whether by natural or artificial processes, or such other entity or matter as may be prescribed by the Minister].

or

[a biological entity, cellular or noncellular, capable of metabolism, replication, reproduction or transferring genetic material and includes a icroorganism];

or

[any biological entity capable of transferring or replicating genetic material including sterile biological entities, viruses, viroids and plasmids]

"packaging" means *all products made of any materials of any nature to be used for the containment, protection, handling, delivery and preservation of genetically modified organisms from one place to another*

"permit" means a *permit issued under this Act;*

"person" i*ncludes corporate bodies and unincorporated bodies;*

"placing on the market" means ***supplying, selling, advertising, donating, making available to any third party,*** *or any other form of transfer, whether free of charge or not,* ***of any genetically modified organism or product of a genetically modified organism***

"product" means

any material derived by processing or otherwise from genetically modified organisms

or

a preparation consisting of, or containing a genetically modified organism

or

any material derived by processing, or howsoever, from any genetically modified organisms

"register" means the register established in terms of [section ..]

"registry" means the compilation of genetically modified organisms or activities that are authorized, exempted or subject to simplified procedures in accordance with this Act and regularly published by the Competent Authority

"Relevant regulatory agency" means a regulatory agency as set out in the First Schedule to the Act, or such other agency as the Minister may, by Order in
the *Gazette*, determine

"risk assessment" means

the use of scientific and other appropriate methods to identify and

characterise the nature, likelihood of occurrence, and potential magnitude of any hazards, with due regard to the precautionary principle as articulated in [section 5];
or

the evaluation of the direct and indirect risks to human and animal health, the environment, biological diversity and to the socio-economic conditions and ethical values of the country or its populace, which may be posed by the import, contained use, intentional introduction into the environment or domestic use and includes the evaluation of secondary and long-term effects

or

the process for dealing with uncertainties and incomplete data in order that decisions may be made in full consideration of potential consequences;

or

the identification and evaluation of the direct and indirect potential impacts of a genetically modified organism or a product of a genetically modified organism on the biological diversity, human and animal health, socio-economic consideration and ethical values of the country which may be posed by the making, import, transit, contained use, release or placing on the market of a genetically modified organism or a product of a genetically modified organism. This may include the evaluation of secondary and long-term effects;

"risks to environment" mean *the potential impact on the environment as a direct result of -*
(a) a genetically 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 the genetically modified organism;
(d) direct or indirect effects observed at a later stage of release of the genetically modified organism or after termination of the release of the genetically modified organism

"risks to human health" mean *the potential impact on human beings and on the conservation and sustainable use of biological diversity as a direct result of -*

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

"Secretariat" means the Secretariat of the Cartagena 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 intentional introduction into the environment, domestic use, contained use or import of the genetically modified organism or product*

"Unique Identifier" means a combination of alphabets and numbers used to distinguish one organism from the other, and allow for attaching and retrieving specific information on the organism developed by the Biosafety Clearing House.

Scope and application of Act

3 (1) This Act applies to the research, development, production, transport, transboundary movement and transfer use, application and release of genetically modified organisms.

(2) The requirements of this Act are in addition to, and not in derogation to, the requirements imposed by any other law.

(3) This Act shall not apply to genetically modified organisms that are pharmaceuticals for human use.

(4) This Act shall be binding on the State.

Objectives of Act

4 The objectives of this Act are -

(a) to provide a framework for the research, development, production, transport, use, application and release of genetically modified organisms resulting from modern biotechnology that may have adverse effects on conservation and sustainable use of biological diversity, taking also into account risks to human health or animal health;

(b) to establish a transparent, science-based and predictable process for reviewing and making decisions on the research, development, production, transport, use, application and release of genetically modified organisms;

(c) to provide for the establishment of the National Biosafety Authority;

(d) to implement the Cartagena Protocol on Biosafety; and

(e) to provide for related or incidental matters.

Precautionary Principle

5. (1) The National Biosafety Authority in reaching a decision shall take into account the best available scientific evidence or ecological principles, but where little or no scientific evidence is available, the Biosafety National Biosafety Authority reach a decision based on the precautionary principle.

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

PART 2

ADMINISTRATION

Establishment of National Biosafety Authority

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

(2) the National Biosafety Authority shall consist of seventeen members appointed by the Minister representing the following -

(a) Two Representatives of the Environmental Protection Agency drawn from:

(b) Director of Food and Drugs Department of the Ministry of Health or his or her legal designate;

(c) Chief Executive Officer of National Agricultural Research and Extension Institute or his or her legal designate;

(d) Director of Institute of Applied Science and Technology or his or her legal designate;

(e) Chairman of the Pesticides and Toxic Chemicals Control Board or his or her legal designate;

(f) Representative of the Guyana National Bureau of Standards;

(g) Chief Executive Officer of the Guyana Livestock Development Authority;

(h) Chairman of the National Commission of Codex Alimentarius or his or her legal designate;

(i) Representative of the Private Sector Commission;

(j) Representative of the Ministry with responsibility for Amerindian Affairs or National Toshaos Council;

(k) Representative of the University of Guyana;

(l) Representative of the Guyana Consumers Association;

(m) Representative of the Minister with responsibility for Industry, Commerce and Tourism;

(n) Representative of the Minister with responsibility of Foreign Trade and International Cooperation;

(o) Representative of the Customs and Trade Administration of the Guyana Revenue Authority; and

(p) Representative of the Joint Services – Coast Guard.

National Biosafety Authority as National Competent Authority

7. The National Biosafety Authority shall be the National Competent Authority in connection with the *Cartagena Protocol on Biosafety to the Convention on Biological Diversity.*

Functions of the National Biosafety Authority

8. The National Biosafety Authority shall -

(a) advise the Minister, other Ministries and appropriate bodies, on all aspects concerning the development, production, transport, use, application and release of genetically modified organisms;

(b) ensure that all activities with regard to the development, production, transport, use, application and release of genetically modified organisms are performed in accordance with the provisions of this Act;

[co-ordinate, monitor, assess and provide guidelines with respect to activities relating to the safe transfer, handling, storage, containment and use of genetically modified organisms in order to ensure that such activities do not have adverse effect on human health or the environment];

(c) perform such other duties and responsibilities as required by the Minister to provide for the implementation of the *Cartagena Protocol on Biosafety to the Convention on Biological Diversity.*

(e) promote awareness and education among the general public in matters relating to Biosafety;

(f) ensure capacity-building including scientific and technical training in the proper and safe management of Biosafety, and in the use of risk assessment and risk management for Biosafety, and the enhancement of technological and institutional capacities in Biosafety;

(g) monitor developments in the area of biotechnology and provide advice and recommendations to the Minister in relation to policy, strategic plans, trade, economic development, environmental management, research and development, science and technology development.

[co-ordinate research and surveys in matters relating to the safe development, transfer, handling and use of genetically modified organisms, and to collect, collate and disseminate information about the findings of such research, investigation or survey;]

[initiate and manage consultation and review processes on the development of national strategies, plans, policies and programmes on biotechnology and Biosafety in Guyana;]

[advise the Government on legislative and other measures relating to the safe transfer, handling and use of genetically modified organisms;]

consult and collaborate with other regulatory agencies in the discharge of its functions under this Act;

(h) perform any other function which is incidental to the performance of any of the foregoing functions.

Duties of the National Biosafety Authority

9. In order to perform the functions provided in [section 8], the National Biosafety Authority may -

(a) require any applicant to -

(i) provide such information as may be necessary to undertake any risk assessment or risk management process required under the Act;

(ii) use designated facilities for the development, production, storage, containment, use or application of genetically modified organisms or to release such organisms into the environment;

(iii) submit to the National Biosafety Authority through the Secretariat, an assessment of the risk and, where required, an assessment of the impact on national biodiversity, the environment, human health or animal health of such development, production, use, application or release, as the case may be;

(b) require the Secretariat or the [Scientific Advisory Committee] established pursuant to [section 24] to examine the conformity of an application to the requirements of this Act;

(c) require the Secretariat to maintain a register of -

(i) all applications made pursuant to the requirements of this Act;

(ii) the particulars of all genetically modified organisms that have been approved pursuant to the requirements of this Act;

(iii) the particulars of all facilities involved in the contained use or the trial release of genetically modified organisms;

(iv) the names and addresses of persons concerned with the contained use or trial release of genetically modified organisms;

(v) the names and addresses of persons listed on the Roster of Experts established pursuant to [section 31].

(d) require notification by the applicant of any intended change in the type of activities or release involving genetic modification of organisms being undertaken at facilities for which approval was granted under the provisions of this Act, in which case the National Biosafety Authority may require the applicant to apply for a new permit;

(e) require the Secretariat to arrange for the inspection of facilities where activities with or the release of genetically modified organisms are being undertaken;

(f) require the Secretariat to arrange for the inspection of all activities that may be necessary, including contained use, trial release and general release to ensure compliance with that all terms and conditions attached to a permit issued under this Act;

(g) after consideration of the risk assessment, and in consultation with the Scientific Advisory Committee established pursuant to [section 31], approve, subject to the provisions of this Act and any other law and in accordance with such terms and conditions as the National Biosafety Authority may deem necessary, the use of the facilities concerned for the purpose for which the application was made, or the handling, transport, use, transfer or release of genetically modified organisms into the environment, and authorize the Secretariat to issue a permit accordingly;

(h) require that the applicant or any user immediately notify the Secretariat both orally and in writing of any accident involving genetically modified organisms and require that the Secretariat be supplied with information on the circumstances of the accident, the identity and quantity of genetically modified organisms released, any information necessary to assess the impact of the accident on national biodiversity, the environment, human health or animal health, and the emergency measures taken to avoid or

mitigate any adverse impact of such accident;

(i) require the Secretariat to appoint a panel to enquire into and report on the causes of an accident, and to make recommendations to the Minister with a view to avoiding similar accidents in the future and with a view to limiting the adverse impact of such accidents;

(j) inform any other country of any accident that may have an impact on that country's national biodiversity, environment, human health or animal health;

(k) co-operate or enter into agreements with any person or institution to undertake any risk assessment or risk management process required under this Act upon such conditions as the National Biosafety Authority and the person or institution concerned may agree upon;

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

(m) with the consent of the Minister approve and publish guidelines for all uses of genetically modified organisms;

(n) advise the Minister on -

(i) restrictions and prohibitions that should be established on the handling, transport, use, transfer and release of any genetically modified organisms;

(ii) the exercise of the necessary control of imports or transboundary movement of any genetically modified organisms;

(iii) the development, production, use, application, release and distribution of genetically modified organisms;

(iv) the authorisation or notification of contained uses of any genetically modified organisms;

(v) the authorisation of trial or general releases of any genetically modified organisms;

(vi) the control measures to be taken in the event of an accident of any genetically modified organisms;

(vii) the intellectual property implications arising from the development, production, use, application, release and distribution of genetically modified organisms;

(viii) any other matter with regard to genetically modified organisms;

(o) make recommendations to the Minister on the appointment of members to the Scientific Advisory Committee pursuant to [section 31.

Tenure of members of National Biosafety Authority

10. (1) Subject to the provisions of subsections (2) and (3) of this section, a member of the National Biosafety Authority shall, unless he or she vacates office earlier, hold office for a period of three years, except that such a member shall be eligible for re-appointment.

(2) A member who is appointed to fill a vacancy that is created by the death, resignation, or removal from office for a justifiable cause shall hold office only for the unexpired period of the former member, except that such member may be eligible for re-appointment.

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

Resignation

11. (1) The Chairperson may, at any time, in writing, resign his office and the resignation shall be addressed to the Minister.

(2) A member of the National Biosafety Authority, other than the Chairperson, may, in writing, resign from office and the resignation shall be addressed to the Chairperson. by giving at least three months notice in writing to the Chairperson of his or her resignation

Revocation/Termination of Appointment

12. The Minister may at any time, in writing, revoke the appointment of any member of the National Biosafety 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 or her 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 or her duties;

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

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

Alternate Members

13. (1) The Minister may appoint a person to be an alternate member for a specified member of the National Biosafety Authority, other than the Chairperson.

(2) The Minister may at any time, in writing, revoke the appointment of an alternate member in the same way as the revocation for a member may be revoked pursuant to [section 12].

(3) The alternate member appointed pursuant to subsection (1) may act temporarily in the place of that member if that member is absent or incapable of performing the duties of a member.

Vacancy

14. (1) The office of a member of the National Biosafety Authority is vacated -

(a) on the death of the member;

(a) ceases to be an officer within the agencies listed in **section 6**;

(b) is absent without leave from more than three consecutive meetings of the National Biosafety Authority;

(b) if the member becomes disqualified pursuant to [section 12];

(c) if the member resigns from membership pursuant to [section 11];

(d) if the Minister revokes the appointment of that member pursuant to [section 12]; or

(e) if the member fails to attend three consecutive meetings of the

National Biosafety Authority without being excused by the Minister in writing.

(2) If a vacancy occurs in the membership of the National Biosafety Authority, the Minister shall appoint a person to fill the vacancy in a manner that respects the requirements in [section 15] for the constitution of the National Biosafety Authority.

(3) A member appointed to fill a vacancy shall hold office only for the unexpired portion of the term of the former member.

(4) Whenever the Minister is satisfied that any member of the National Biosafety Authority is prevented by illness or any other reason from performing the duties required under the Act, the Minister may appoint any other person suitable to act as the deputy of that member while such member is so prevented, and such deputy shall during the period he or she so acts, perform the functions of the member in whose stead he or she has been appointed so to act.

Decisions not Invalidated

15. (1) A vacancy in the membership of the National Biosafety Authority shall not invalidate a decision of the National Biosafety Authority made at a meeting with the quorum required pursuant to [section 23].

(2) Where a disqualified member sits at a meeting of the National Biosafety Authority, the National Biosafety Authority may review and amend its decision within two months of that decision being made.

Keeping Accounts of the National Biosafety Authority

16. The National Biosafety Authority shall keep proper records of accounts in accordance with generally accepted international standards and principles and shall prepare and retain financial statements in respect of each financial year.

Signing of Documents and Decisions

17. All documents made by, and the decisions of the National Biosafety Authority may be signified under the hand of the Chairperson or any member of the National Biosafety Authority authorised by the Chairperson to act in that behalf, or by the Secretary of the National Biosafety Authority.

Funds of the National Biosafety Authority

18. The funds of the National Biosafety Authority shall consist of -

(1) annual grants appropriated by the National Assembly;

(2) fees charged under the provisions of this Act for applications and Permits;

(3) donations and grants from international organisations and other agencies;

(4) loans;

(5) any other sums received by the National Biosafety Authority.

Audit of the National Biosafety Authority

19. The accounts of the National Biosafety Authority shall be audited annually.

Annual Report by Authority
No. 20 of 2003

20. Subject to the provisions of Part XII of the Fiscal Management and Accountability Act 2003, the National Biosafety Authority shall, not later than four months after the end of each financial year, submit to the Minister and annual report containing -

(a) an account of its functions for the proceeding financial year in the detail as the Minister may direct;

(b) an audited statement of accounts of the National Biosafety audited under section 19.

(c) such other matters as the Minister my determine.

Appointment of the Chair of the National Biosafety Authority

21. The Minister shall designate a chairperson and deputy chairperson from among them members of the National Biosafety Authority.

Appointment of the Deputy Chair of the National Biosafety Authority

22. The deputy chairperson appointed by the Minister under [section 21] shall exercise all the powers and perform all the duties of the chairperson whenever the chairperson is unable to perform such functions

Meetings of the National Biosafety Authority

23. (1) The National Biosafety Authority shall meet at such times as may be necessary to carry out the tasks, functions and responsibilities as required under this Act, and in any event shall meet at least four times in a calendar year.

(2) The National Biosafety Authority may convene special working groups for the purpose of preparing any document, policy or programme that shall be submitted for the consideration of the Minister.

(3) At least two weeks prior to convening a meeting of the National Biosafety Authority, the Secretariat established pursuant to section 14 shall prepare and circulate to members an agenda outlining items for discussion and approval, which may include policies and programmes that promote Biosafety of biotechnology, and initiatives that focus on finance, science and technology, education, training and public awareness, capacity building and support for the *Cartagena Protocol on Biosafety to the Convention on Biological Diversity*

(4) The quorum for any meeting of the National Biosafety Authority shall be a majority of the members.

(5) The National Biosafety Authority may determine its own procedures to be followed at its meetings and cause minutes to be kept of its proceedings.

(6) The National Biosafety Authority may co-opt other knowledgeable persons to serve on the National Biosafety Authority in order to provide advise whenever the National Biosafety Authority deems it necessary.

(7) The National Biosafety Authority may invite written comment from knowledgeable persons on any aspect of Biosafety or biotechnology which lies within the National Biosafety Authority's mandate.

(8) Formal approval of any policy, programme or initiative by the National Biosafety Authority shall be by general consensus of those members present at a meeting, providing that matter may be approved unless at least fifty percent of appointed members are present at the meeting.

(9) Any matter that has been approved by the National Biosafety Authority shall be transmitted by the Chairperson to the Minister for consideration.

The Secretariat

24. (1) The **Biosafety** Unit within the **Environmental Protection Agency** acting in the capacity as Secretariat to the National Biosafety Authority, is charged with the administration of this Act.

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

Functions of the Secretariat

25. The Secretariat shall subject to the instructions of and the conditions laid down by the National Biosafety Authority -

(a) issue a permit as required or prescribed under this Act or Regulations;

(b) where it has been ascertained or there are reasonable grounds for believing that genetically modified organisms are being imported or locally produced or used contrary to the provisions of this Act or the conditions of a permit issued hereunder -

(i) serve a notice upon any person by whom or on whose behalf genetically modified organisms are being so imported into, produced or used in Guyana for the removal of such genetically modified organisms to a place or facility and in a manner prescribed by the National Biosafety Authority; and

(ii) authorize an inspector to destroy such genetically modified organisms or cause it to be destroyed, subject to procedures and other provisions as set out in Regulations under this Act;

(c) with just cause, amend or withdraw a permit issued under this Act;

(d) furnish an inspector with a certificate of appointment;

(e) require the cessation of any genetic modification activity at facilities where the provisions of this Act or the conditions of a permit have not been or are not being complied with; and

(f) ensure that appropriate measures are undertaken by all users at all times with a view to the protection of the national biodiversity, the environment, human health or animal health from hazards.

Functions of the Biosafety Inspectorate Unit.

26. The **Biosafety** Unit within the **Environmental Protection Agency** shall -

(a) monitor and ensure compliance with the provisions of this Act and the Regulations made hereunder; and

(b) perform such functions as may be assigned to it by the National Biosafety Authority from time to time.

Appointment of Biosafety Inspectors

27. (1) The Biosafety Unit may appoint any officer, or with the approval of the Minister, any person who is not an officer, as an inspector to exercise and perform the functions referred to in [section 28].

(2) Every inspector shall be furnished with –

(i) a certificate signed by the Secretariat stating that he or she has been appointed as inspector under this Act; and

(ii) an identity card containing a recent photograph of the inspector.

(3) An inspector shall, at the request of any person affected by the exercise or performance of a function by such an inspector, exhibit the certificate and identity card referred to in sub-section (2) to such a person.

(4) The Instrument of Appointment for any inspector appointed under the provisions of this Act shall be published by way of notice in the *Gazette*.

Powers of Biosafety Inspectors

28. (1) An inspector appointed under subsection (1) of section [27] of this Act shall perform the following functions, that is to say -

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

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

(c) enforce identification, labeling and packaging provisions in this Act.

(2) 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) it is reasonably suspected that a genetically modified organism is about to be, is being, or has been

transported, or

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

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

(i) it is reasonably suspected that a genetically modified organism is about to be, is being, or has been used or packaged;

(ii) it is reasonably suspected that is being, has been, or is about to be used for a purpose connected with the use or packaging of a genetically modified organism;

(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 the regulations;

(d) require any person whom he finds in a vehicle, on land or premises, as the case may be, to give such information as it is in his power to give as to who is occupier thereof or the employer of workers employed to work thereon;

(e) examine, either alone or in the presence of any other person as the inspector thinks fit, with respect to the observance of the provisions of this Act or the regulations, any person whom

(i) he or she finds in such vehicle or on such land or premises as mentioned in subsection (1) of this section, or

(ii) he or she has reasonable cause to believe to be, or to have been within the preceding two months, employed thereon,

and to require any such person to be questioned and to sign a declaration of the truth of the matters respecting which he or she is questioned; so, however, that no person shall be required under this provision to answer any question or to give evidence tending to incriminate himself;

(f) open and examine any package that on reasonable grounds he or she believes to contain a genetically modified organism;

(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 provisions of this Act or the regulations made under this Act has been contravened;

(h) if the Inspector reasonably believes that any provisions of this Act or the regulations made under this Act has been contravened

(i) take, without payment, samples of any article being used or transported, and submit them to the analyst for analysis or examination;

(ii) take, without payment, but with the approval of the Commissioner General of the Guyana Revenue Authority samples of any article imported into the country but not delivered to the importer, out of the charge of customs, and submit them to an analyst appointed under this Act for analyst or examination

(3) Subject to subsection (4) of this section, an inspector shall, for the purpose of exercising the powers conferred upon them by subsection (2) of this section, first obtain a search warrant issued by a court of Summary Jurisdiction.

(4) Where circumstances are such that a genetically modified organism may be removed from the vehicle, land or premises before the inspector obtains the search warrant pursuant to (3), 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.

(5) The inspector may, if he or she deems 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 any genetically modified organism for the purposes of discharging his functions under this Act.

Or

(1) An inspector may, on the authority of a warrant issued in terms of sub-section (2), conduct an investigation to determine whether the provisions of this Act are being or have been complied with, and may, for that purpose during normal office hours and without giving prior notice, enter any place or facility in respect of which he or she has reason to believe that a contravention of the provisions of this Act is taking place -

(a) to inspect any activity or process carried out in or upon such place or facility in connection with any activities referred to in this Act;

(b) to request any information regarding such an activity or process from the owner or person in charge of such place or facility or from any person carrying out or in charge of the carrying out of such activities;

(c) to seize any appliance, book, statement or document and take samples of material or substances which appear to provide proof of a contravention of any provision of this Act; and

(d) to give notice to the owner of any material, substance, appliance, book, statement or document seized under paragraph (c) or to the person who had control over it immediately before any seizure under subparagraph (c) to remove the seized items at such person's own cost within a period and to a place specified in such notice.

(2) A warrant referred to in sub-section (1) shall be issued by a magistrate or other judicial officer who has jurisdiction in the area in which the place or facility in question is situated, and shall only be issued if it appears from information on oath that there are reasonable grounds to believe that any material, substance, appliance, book, statement or document that may relate to a contravention of this Act, is upon or in such place or facility.

(3) A warrant issued in terms of this sub-section (2) shall be executed with strict regard to decency and order.

(4) If no criminal proceedings are instituted in connection with any item referred to in sub-section (2), seized in terms of sub-section (1)(c), or if it appears that such item is not required at any trial for the purpose of evidence or an order of court, that item shall be returned as soon as possible to the person from whom it was seized.

(5) After the conclusion of criminal proceedings any item seized in terms of sub-section (1)(c) and which served as an exhibit in proceedings in which a person was convicted, shall be handed over to the inspector to be destroyed or otherwise dealt with as instructed by the Secretariat.

(6) Where any person obstructs, assaults, threatens or delays any officer in the execution of his duties under the Act or Regulations, the officer may arrest that person without a warrant.

(7) Any person arrested under the provisions of sub-section (6) shall be taken with all practicable speed before a magistrate and shall not be detained without a warrant longer than is necessary.

(8) An inspector may, at any time, order that any -

(a) genetically modified organism; or

(b) any organism suspected of being a genetically modified organism, that is imported into Guyana, be held at a particular place until an inspection, examination, analysis or risk assessment, as applicable, is conducted.

(9) Where an inspector suspects that any genetically modified organism presents a risk of harm to Guyana's biodiversity, the environment, human health or animal health, he shall:

(a) seize the genetically modified organism and take such steps as are necessary to reduce the risk of harm;

(b) immediately notify the National Biosafety Authority.

(10) No action shall be brought against any inspector in respect of anything done or omitted to be done by him in good faith in the execution of his powers and duties under this Act or any regulations made hereunder.

or

(1) Where an inspector reasonably suspects that there is an imminent danger posed to the conservation and sustainable use of biological diversity, taking into account risks to human health or animal health, or has to conduct an investigation into a complaint, he or she may -

(a) enter and inspect any premises; and

(b) take with him or her any equipment or material required for the purpose of the inspection;

(c) carry out or cause to be carried out such tests and inspections, and make such recordings, as may in the circumstances be necessary;

(d) direct that any, or any part of, the premises, or anything in or on such premises, shall be left undisturbed, whether generally or in particular respects, for so long as is reasonable necessary for the purpose of any test or inspection;

(e) take samples of any organisms, articles or substances found in or on the premises and of the air, water or land in, on, or in the vicinity of, the premises;

(f) in the case of anything found in or on the premises, which appears to him or her to contain or to have contained a genetically modified organism which have adversely affected or is likely to adversely affect the conservation and sustainable use of biological diversity, taking into account risks to human health or animal health, to cause it to be dismantled or subjected to any process or test, but not so as to damage or destroy it unless this is necessary;

(g) to take possession of a genetically modified organism and detain it for so long as is necessary for all or any of the following purposes, namely -

(i) to examine it;

(ii) to ensure that it is available for use as evidence in any proceedings for an offence against this Act;

(h) to require the production of, or where the information is recorded in computerised form, the furnishing of extracts from, any records which are required to be kept under this Act or it is necessary for him or her to see for the purposes of any test or inspection under this section and to inspect, and take copies of, or of any entry in, the records;

(i) to require any person to afford him or her such facilities and assistance with respect to any matters or things within that person's control or in relation to which that person has responsibilities as are necessary to enable the inspector to exercise any of the powers conferred on him or her by this section;

(j) do any other act or thing necessary or convenient to be done to carry out an inspection.

(2) An inspector may only exercise the powers under subsection (1) if the inspector shows proof of identity and the occupier of the premises consents or a warrant is issued under section 77.

Search warrant

29. (1) An inspector may apply to a court of Summary Jurisdiction for a warrant to enter, search and seize.

(2) A magistrate may issue a warrant for entry, search and seizure, if the magistrate is satisfied by information on oath that such inspection is reasonably necessary.

(3) A warrant issued under this section shall -

(a) describe the place to which the warrant relates;

(b) state the name of the Inspector responsible for executing the warrant;

(c) specify the period for which the warrant remains in force, which must not be more than seven days;

(d) state whether the entry is authorised to be made at any time of the day or night or during specified hours of the day or night;

(e) state the purpose for which the warrant is issued.

(4) In executing a warrant an inspector shall not use force unless accompanied by a police officer and the use of force is specifically authorised in the warrant.

Establishment of National Biosafety Clearing-house

30. (1) The Secretariat shall establish and maintain a National Biosafety Clearinghouse in order to facilitate the exchange of information on Biosafety and modern biotechnology in Guyana, and provide public access to notices, applications and other information pursuant to the requirements of this Act.

(2) The National Biosafety Clearinghouse, shall include, *inter alia*, the following -

(a) a roster of experts that shall include the names, contact particulars and relevant biographical information of all individuals in Guyana with expertise in:

(i) genetically modified organisms;

(ii) biodiversity management and conservation;

(iii) environmental management;

(iv) social and environmental impact assessment; and

(v) risk assessment and management.

(b) national Biosafety laws and guidelines;

(c) a list of genetically modified organisms that have been approved for import or export;

(d) all applications lodged pursuant to the provisions of this Act;

(e) a summary of emergency measures that have been established to manage the accidental release of any genetically modified organism into the environment;

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

(3) While not in any manner limiting the requirements of sub-section (2) above, the National Biosafety Clearinghouse shall contain:

(a) current guidelines and codes of practice concerning the handling, transport, use, transfer and release of any genetically modified organisms;

(b) any national emergency response plans for genetically modified organisms;

(c) all documents produced, collected or submitted with respect to:

(i) the handling, transport, use, transfer and release of any genetically modified organisms;

(ii) the registration of any facility involved in modern biotechnology, and shall be capable of providing immediate information concerning any guideline, code of practice or response plan in the event of any enquiry

(4) The public shall have access to any record or document filed in the National Biosafety Clearinghouse, except for such documents or records as may be restricted for reasons of public security by the Minister by publication of a notice in the Gazette.

Establishment of Biosafety Scientific Advisory Committee

31. (1) The National Biosafety Authority may establish a Scientific Advisory Committee to assist in the performance of its functions.

(2) Persons to be appointed as members of the Scientific Advisory Committee under this section shall be suitably qualified and shall be appointed from such disciplines as the National Biosafety Authority may deem fit, which disciplines may include the following,

(a) ecology;

(b) molecular genetics;

(c) population genetics;

(d) microbial physiology;

(e) pathology;

(f) entomology;

(g) atmospheric physics;

(h) veterinary science;

(i) laboratory applications;

(j) industrial processes;

(k) food safety;

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

(m) economics;

(n) land use planning; and

(o) plant breeding.

(3) The Scientific Advisory Committee may co-opt -

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

(b) personnel from other Ministries; or

(c) persons, whether or not they are connected with the National Biosafety Authority, as it thinks fit, to be members of the Scientific Advisory Committee.

(4) A member of the Scientific Advisory Committee whose interest is likely to be affected, directly or indirectly, by the decision of the Scientific Advisory Committee on any matter or is likely to evoke an allegation of bias, shall disclose the nature of his interest at the first meeting of the Scientific Advisory Committee at which he is present after the relevant facts have come to his knowledge

(5) A disclosure made under subsection (4) of this section shall be recorded in the minutes of the Scientific Advisory Committee and after the disclosure the member making the disclosure shall, unless the Scientific Advisory Committee otherwise directs, leave the meeting.

(6) Where a member referred to in subsection (5) of this section is allowed by the Scientific Advisory Committee to stay in the meeting, the member shall not take part in the deliberations on the matter by the Scientific Advisory Committee nor shall the member vote on the matter.

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

Functions of scientific advisory committee

32. (1) The Biosafety Scientific Advisory Committee shall -

(a) act as the national scientific and technical advisory body on all matters concerning or related to the genetic modification of organisms;

(b) advise, on request of the Minister, the National Biosafety Authority, other Ministries and appropriate bodies, on matters concerning the genetic modification of organisms and, inter alia, advise them on-

(i) all aspects relating to the introduction of genetically modified organisms into the environment;

(ii) proposals for specific activities or projects concerning the genetic modification of organisms;

(iii) all aspects concerning the contained use of genetically modified organisms;

(iv) the importation and exportation of genetically modified organisms; and

(v) proposed regulations and written guidelines;

(c) liaise through the relevant national departments with international groups or organisations concerned with Biosafety; and

(d) invite written comments from knowledgeable persons on any aspect of the genetic modification of organisms which lies within the Committee's brief.

(2) The Committee may appoint subcommittees to deal with specific matters as required.

Public disclosure of possible conflicts of interest

33. (1) A member of the National Biosafety Authority who is any way, either directly or indirectly, interested in a matter before the National Biosafety Authority shall declare the nature of his or her interest at the first meeting of the National Biosafety Authority at which it is practicable to do so and shall leave the meeting on the matter coming up for discussion.

(2) A declaration and the departure of a member of the National Biosafety Authority from the meeting in accordance with subsection (1) shall be noted in the minutes of the meeting.

(3) A member of the National Biosafety Authority shall not -

(a) vote in respect of a matter before the National Biosafety Authority in which he or she is in any way interested, whether directly or indirectly; or

(b) seek to influence the vote of any other member of the National Biosafety Authority in relation to the matter.

(4) A member of the National Biosafety Authority who fails to comply with subsection (3) shall be promptly removed from the National Biosafety Authority.

Code of Ethics

34 (1) The National Biosafety Authority shall in consultation with regulatory agencies develop a code of ethical conduct to guide the activities of the National Biosafety Authority and any other person acting by virtue of any the provisions contained in this Act.

(2) A code of ethical conduct developed by virtue of the provision of subsection (1) shall provide for the following elements:

(a) the highest standards of integrity and conduct;

(b) the proactive promotion ethical behaviour;

(c) the use of sound biological, scientific, technical, physical, and social science information in decision-making;

(d) respect for human dignity, human rights and fundamental freedoms;

(e) promotion of professionalism, honesty, impartiality, integrity, non-discrimination and transparency in decision-making;

(f) respect for privacy and confidentiality of information;

(g) prohibiting corrupt practices;

(h) respect for intellectual property rights and traditional knowledge; and

(i) any other relevant and appropriate tenet.

PART 3

CONTROL OF GENETICALLY MODIFIED ORGANISMS

Prohibition concerning genetically modified organisms

35. The Minister shall, guided by any existing National Biosafety Policy and on the recommendation of the National Biosafety Authority, by notice in the Gazette, prohibit –

(a) the handling, transport, use, transfer and release of any genetically modified organisms.

(b) any activity involving genetically modified organisms,

so as to prevent or reduce risks to biological diversity, the environment, human health or animal health.

Public notice on intent to prohibit importation

36. (1) [Prior to issuing any notice prohibiting the import of any genetically modified organism under the provisions of [section 35] above, the Minister shall give public notice of his or her intention to prohibit the import of such organism].

(2) The public notice outlined in sub-section (1) above shall be published in local newspapers and shall provide -

(i) a description of the organism together with a statement that it is government's intention to prohibit the import of such organism;

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

(iii) the closing date for submissions, which shall not be earlier than thirty calendar days after public notification; and

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

(3) A copy of the public notice as provided under sub-sections (1) and (2) shall be lodged with the National Biosafety Clearinghouse maintained by the Secretariat.

(4) In addition to the placement of any public notice as provided under sub-sections (1) and (2), the National Biosafety Authority may establish a consultative process with other government ministries, departments or statutory bodies, or with representatives from the academic and business community or the public concerning the proposed prohibition.

(5) Any person who imports any genetically modified organism that has been prohibited under the provisions of **[section 35]** shall be guilty of an offence and liable to the penalties provided in [Schedule 6] of the Act.

Control of genetically modified organisms

37. No person shall -

(a) transport a genetically modified organism unless that genetically modified organism is registered in accordance with the provisions or the regulations made under this Act;

(b) intentionally introduce into the environment a genetically modified organism without a permit issued in that respect in accordance with the provisions of this Act or regulations made under this Act;

(c) manufacture a genetically modified organism for domestic use without a permit issued in that respect in accordance with the provisions of this Act or regulations made under this Act

(d) operate any facility, installation or other physical structure for contained use without a permit issued in that respect in accordance with the provisions of this Act or regulations made under this Act;

(e) import a genetically modified organism for intentional introduction into the environment or domestic use without a permit issued in that respect in accordance with the provisions of this Act or regulations made under this Act;

(f) export a genetically modified organism without a permit issued in that respect in accordance with the provisions of this Act or the regulations made under this Act;

(g) conduct biotechnology research and development without a permit issued in that respect in accordance with the provisions of this Act or the regulations made under this Act.

PART 4

MANAGEMENT OF GENETICALLY MODIFIED ORGANISMS

Intentional Introduction Into The Environment

Permit for intentional introduction into the environment

38. (1) A person who wishes to apply for a permit for intentional introduction into the environment as required by this Act or regulations made under this Act shall apply, in the prescribed form, to the National Biosafety Authority.

(2) An application referred to in subsection (1) of this section shall be accompanied by the prescribed fee, which fee shall be payable to the [National Biosafety Authority].

(3) The National Biosafety Authority shall, upon receipt of the application, cause to be published in at least one newspaper [of general circulation in Guyana] for two consecutive weeks, a notice containing the scientific name, common name and intended use of the genetically modified organism for the purpose of inviting public comments on the application.

[(4) An application made pursuant to subsection (1) shall contain -

(a) the information set out in the [Fourth Schedule] to this Act; and

(b) such other information that the applicant or the National Biosafety Authority may consider necessary.]

Objection to permitting.

39. (1) A person may object to the permitting of a genetically modified organism for intentional introduction into the environment on any ground that may be prescribed by regulations made under this Act.

(2) Any objection to the permitting of a genetically modified organism for intentional introduction into the environment shall be lodged with the National Biosafety Authority within twenty one days of the publication of the notice referred to in subsection (3) of [section 38].

Consideration of Application

40. The National Biosafety Authority , before approving an application for intentional introduction into the environment

(a) shall consider all objections and information made available to it;

(b) shall consult with the relevant regulatory agency;

(c) may, request additional information from the applicant.

Refusal to approve application.

41. (1) The National Biosafety Authority may refuse to approve an application for a Permit for intentional introduction into the environment on any of the following grounds, that is to say,

(a) if the application is not accompanied by all the information required to be submitted along with it;

(b) if the application contains information that is misleading, false, deceptive, or likely to deceive or create an erroneous impression on the National Biosafety Authority;

(c) if the genetically modified organism or product is likely to have an adverse effect on conservation and sustainable use of biological diversity, taking into account risks to human health or animal health;

(2) Where the National Biosafety Authority refuses to approve an application in accordance with the provisions of subsection (1) of this section, it shall, as soon as practicable, notify the applicant of its decision and the reasons for the decision.

Grant of Permit for intentional introduction in into the environment

42. (1) Where the National Biosafety Authority is satisfied that there is firm and sufficient evidence that the genetically modified organism poses no risk to human and animal health, the environment and biological diversity, the National Biosafety Authority may grant the permit.

(2) Upon the grant of the permit for intentional introduction into the environment the applicant shall be issued an appropriate permit upon payment of the prescribed fee and the permit shall contain such contents as may be prescribed by the regulations made under this Act.

(3) The permit for intentional introduction into the environment may be subject to the following conditions -

(a) that the permit holder carry out monitoring and evaluation of risks;

(b) the condition that the permit holder take out a policy of insurance against liability to pay compensation for damages; or

(c) such other conditions as the National Biosafety Authority considers necessary for the protection of the conservation of biological diversity or sustainable use of biological organisms, taking into account risks to human health or animal health.

(4) The National Biosafety Authority may impose new conditions if, in the opinion of the National Biosafety Authority, new information or a review of existing information about the genetically modified organism establishes risks to human or animal health, biological diversity or the environment, based on the precautionary principle.

(5) Where the National Biosafety Authority grants a permit in accordance with the provisions of this section, the National Biosafety Authority shall enter the particulars of the permit in the Register of Permits which shall be open to inspection by the public on payment of the prescribed fee.

Variation or Cancellation of Permit

43. (1) The National Biosafety Authority, shall may, at any time, cancel a permit issued under the provisions of subsection (2) of **section [42]** of this Act on any of the following grounds, that is to say,

(a) upon a breach of a condition to which the permit was granted;

(b) where the permit holder contravenes any provision of this Act or the regulations made under this Act;

(c) where, after the issue of the permit, it comes to the knowledge of the National Biosafety Authority that information which was submitted in support of the application for the grant of a permit for domestic use misled or created an erroneous impression on the National Biosafety Authority by reason of being false or deceptive;

(d) if, in the opinion of the National Biosafety Authority, new information or a review of existing information about the genetically modified organism establishes risks to human or animal health, biological diversity or the environment, based on the precautionary principle;

(e) for any other justifiable reason the National Biosafety Authority may think proper to do so by reason of protecting the conservation and sustainable use of biological diversity, taking into account the risks to human health or animal health.

(2) Where the National Biosafety Authority cancels a permit in accordance with the provisions of this section, the National Biosafety Authority shall, within seven days, by notice published in the Gazette and at least two newspapers of general circulation in Guyana to inform the public of the cancellation of the permit.

(3) No compensation shall be payable as a consequence of the cancellation of a permit

Domestic Use As Food, Feed Or Processing

Direct use as food, feed or processing (domestic use)

44. (1) A person who wishes to apply for a permit for [domestic use as food, feed or processing] of [**genetically modified food or genetically modified organisms]** use as required by this Act or regulations made under this Act shall apply, in the prescribed form, to the National Biosafety Authority.

(2) An application referred to in subsection (1) of this section shall be accompanied by the prescribed fee, which fee shall be payable to the [National Biosafety Authority].

(3) The National Biosafety Authority shall, upon receipt of the application, cause to be published in at least one newspaper [of general circulation in Guyana] for two consecutive weeks, a notice containing the scientific name, common name and intended use of the genetically modified organism for the purpose of inviting public comments on the application.

[(4) An application made pursuant to subsection (1) shall contain -

(a) the information set out in the [Fourth Schedule] to this Act; and

(b) such other information that the applicant or the National Biosafety Authority may consider necessary.]

Objection to permitting.

45. (1) A person may object to the permitting of a genetically modified organism for **[domestic use/direct use as food, feed, or processing]** on any ground that may be prescribed by regulations made under this Act.

(2) Any objection to the permitting of a genetically modified organism for **[domestic use/direct use as food, feed, or processing]** shall be lodged with the National Biosafety Authority within twenty one days of the publication of the notice referred to in subsection (3) of [section 44].

Consideration of Application

46. The National Biosafety Authority , before approving an application for a permit for **[domestic use/direct use as food, feed, or processing] -**

(a) shall consider all objections and information made available to it;

(b) shall consult with the relevant regulatory agency;

(c) may, request additional information from the applicant.

Refusal to approve application.

47. (1) The National Biosafety Authority may refuse to approve an application for a Permit **[domestic use/direct use as food, feed, or processing]** on any of the following grounds, that is to say,

(a) if the application is not accompanied by all the information required to be submitted along with it;

(b) if the application contains information that is misleading, false, deceptive, or likely to deceive or create an erroneous impression on the National Biosafety Authority;

(c) if the genetically modified organism or product is likely to have an adverse effect on conservation and sustainable use of biological diversity, taking into account risks to human health or animal health;

(2) Where the National Biosafety Authority refuses to approve an application in accordance with the provisions of subsection (1) of this section, it shall, as soon as practicable, notify the applicant of its decision and the reasons for the decision.

Grant of Permit for Domestic Use [food, feed and processing]

48. (1) Where the National Biosafety Authority is satisfied that there is firm and sufficient evidence that the genetically modified organism poses no risk to human and animal health, the environment and biological diversity, the National Biosafety Authority may grant the permit.

(2) Upon the grant of the permit for domestic use the applicant shall be issued an appropriate permit upon payment of the prescribed fee and the permit shall contain such contents as may be prescribed by the regulations made under this Act.

(3) The permit **[domestic use/direct use as food, feed, or processing]** may be subject to -

(a) the condition that the licensee take out a policy of insurance against liability to pay compensation for damages; or

(b) such other conditions as the National Biosafety Authority considers necessary for the protection of the conservation of biological diversity or sustainable use of biological organisms, taking into account risks to human health or animal health.

(4) Where the National Biosafety Authority grants a permit in accordance with the provisions of this section, the National Biosafety Authority shall enter the particulars of the permit in the Register of Permits which shall be open to inspection by the public on payment of the prescribed fee.

Variation or Cancellation of Permit

49. (1) The National Biosafety Authority, shall, at any time, cancel a permit issued under the provisions of subsection (2) of **section [48]** of this Act on any of the following grounds, that is to say,

(a) upon a breach of a condition to which the permit was granted;

(b) where the permit holder contravenes any provision of this Act or the regulations made under this Act;

(c) where, after the issue of the permit, it comes to the knowledge of the National Biosafety Authority that information which was submitted in support of the application for the grant of a permit for domestic use misled or created an erroneous impression on the National

Biosafety Authority by reason of being false or deceptive;

(d) if, in the opinion of the National Biosafety Authority, new information or a review of existing information about the genetically modified organism establishes risks to human or animal health, biological diversity or the environment, based on the precautionary principle;

(e) for any other justifiable reason the National Biosafety Authority may think proper to do so by reason of protecting the conservation and sustainable use of biological diversity, taking into account the risks to human health or animal health.

(2) Where the National Biosafety Authority cancels a permit in accordance with the provisions of this section, the National Biosafety Authority shall, within seven days, by notice published in the Gazette and at least two newspapers of general circulation in Guyana to inform the public of the cancellation of the permit.

(3) No compensation shall be payable as a consequence of the cancellation of a permit

Contained Use

Permit for Contained Use

50. (1) A person who wishes to use any facility or other space for contained use shall apply, in the prescribed form, to the National Biosafety Authority to have the premises [licensed/authorised] by the National Biosafety Authority in accordance with the provisions of this Act or regulations made under this Act.

(2) An application referred to in subsection (1) of this section shall be accompanied by the prescribed fee, which fee shall be payable to the [National Biosafety Authority].

(3) The National Biosafety Authority shall, upon receipt of the application cause to be published in at least one newspaper of general circulation in Guyana for two consecutive weeks, a notice containing the scientific name, common name and intended use of the genetically modified organism for the purpose of inviting public comments on the application.

(4) An application made pursuant to subsection (1) shall contain -

(a) the information set out in the [**Third Schedule**] to this Act; and

(b) such other information that the applicant or the National Biosafety Authority may consider necessary for the assessment of the potential risk or benefits of the particular contained use activity.

Objection to Application

51. (1) A person may object to the licensing of a facility, installation or other physical structure for contained use on any ground that may be prescribed by regulations made under this Act.

(2) Any objection to the licensing of a facility, installation or other physical structure for contained use shall be lodged with the National Biosafety Authority within twenty one days of the publication of the notice referred to in subsection (2) of [section 50] of this Act.

Inspection of facility

52. Where an application is made to the National Biosafety Authority as required by [section 50] of this Act, the National Biosafety Authority shall arrange for an inspection of the facility, installation or other physical structure by an inspector, analyst or a member of the National Biosafety Authority, as the case may be, who shall prepare a report and submit it to the National Biosafety Authority as early as possible**.**

Consideration of Application

53. The National Biosafety Authority shall, upon receipt of the report submitted to it pursuant to the provisions of [section 50] of this Act, consider the application, and in so doing shall -

(a) take into account the construction, facilities and the staff that is used or is to be used in the facility, installation or other physical structure; and

(b) consult with the relevant regulatory agency;

Grant of Permit

54. (1) Where, upon consideration of the application referred to in [section 50], the National Biosafety Authority is satisfied that the requirements of this Act and any regulations made under this Act are complied with the National Biosafety Authority may grant a Permit to the applicant on such terms and conditions as the National Biosafety Authority may deem fit, and the Permit may be issued on payment of the prescribed fee and shall be in the prescribed form.

(2) Where the National Biosafety Authority grants a Permit in accordance with the provisions of this section, the National Biosafety Authority shall enter the particulars of the Permit in the Register of Permits which shall be open to inspection by the public

on payment of the prescribed fee.

(3) Where the National Biosafety Authority is of the opinion that the facility, installation or other physical structure, facilities or staffing of the applicant need to be altered or modified in order to comply with the provisions of this Act or regulations made under this Act, the National Biosafety Authority shall, by notice in writing, require the applicant to make the necessary alterations or modifications before a Permit is granted.

Variation or Cancellation of Permit

55. (1) The National Biosafety Authority shall, where a [permit holder /licensee] to whom a permit has been granted under this Part is convicted of an offence under this Act or the regulations made under this Act, or contravenes any condition attached to the permit, vary or cancel the permit.

(2) Notice of variation or cancellation shall be sent to the [permit holder/licensee] or person in charge of the facility, installation or other physical structure to which the permit relate, and the variation or cancellation shall have effect upon receipt of the notice.

(3) Where the National Biosafety Authority varies or cancels a permit in accordance with the provisions of this section, the National Biosafety Authority shall, within seven days, by notice published in the Gazette and at least two newspapers [in Guyana], inform the public of the variation or cancellation of the permit

Publication of list of facilities

56. The National Biosafety Authority shall publish in the Gazette, as necessary, a list of facilities, installations or other physical structures that are [permitted/licensed] for contained use and shall do likewise in the case of any facility, installation or other physical structure in respect of which any [permit/licence] is varied or cancelled.

Import Permit

Application Import Permit

57. (1) A person who wishes to apply for a [Permit] for the import of a genetically modified organism as required by this Act shall apply to the National Biosafety Authority, and the application shall be in a prescribed form and shall include the following information, that is to say,

(b) in the case of a genetically modified organism imported for [domestic use], the information in Annex II of the [Cartagena Protocol]l/[Schedule …];

(2) The application referred to in subsection (1) of this section shall be accompanied by the prescribed fee in respect of the grant of permit, which fee shall be paid to the [National Biosafety Authority.]

(3) The National Biosafety Authority shall, upon receipt of the application, cause to be published in at least one newspaper [of general circulation in Guyana] for two consecutive weeks, a notice containing the scientific name, common name and intended use of the genetically modified organism for the purpose of inviting public comments on the application.

[(4) An application made pursuant to subsection (1) shall contain -

(a) the information set out in the [Fourth Schedule] to this Act; and

(b) such other information that the applicant or the National Biosafety Authority may consider necessary.]

Objection to application for import permit

58. (1) A person may object to the permitting of a genetically modified organism for import.

(2) Any objection to the permitting of a genetically modified organism for import shall be lodged with the National Biosafety Authority within twenty one days of the publication of the notice referred to in subsection (3) of [section 57].

Decision on Importation for intentional introduction

59. (1) The National Biosafety Authority shall -

(a) before approving an application for the import for intentional introduction, apply the advance informed agreement procedure in accordance with Article 7 of the Cartagena Protocol; and

(b) consult with the relevant regulatory agency;

(2) The National Biosafety Authority shall within ninety days of receipt of an application submitted to it pursuant [section 57] of this Act, acknowledge receipt of the application.

(3) The acknowledgement referred to in subsection (1) of this section shall be in writing in the prescribed form and shall include the following information, that is to say,

(a) the date of receipt of the application;

(b) whether the application, *prima facie* contains the information referred to in [section 50];

(c) that the import is to proceed in accordance with the provisions of this Act.

(4) A failure by the National Biosafety Authority to acknowledge receipt of an application for import for intentional introduction into the environment does not imply its consent to the import.

(5) Subject to the provisions of [section 62] of this Act, the National Biosafety Authority shall, consider the application, and in so doing shall take into account a risk assessment report submitted by the applicant or undertaken by the National Biosafety Authority.

(6) Within [ninety days/ **two hundred and seventy days**] of the date of receipt of the application, the National Biosafety Authority shall communicate, in writing, to the applicant and to the Biosafety-Clearing House its decision as follows -

(a) approving the import for intentional introduction into the environment;

(b) prohibiting the import;

(c) requesting additional relevant information; or

(d) informing the applicant that the period specified in this subsection is extended by a defined period of time.

(7) In calculating the time within which the National Biosafety Authority is to respond in paragraph (c) of subsection (7) of this section, the number of days the National Biosafety Authority has to wait for additional relevant information shall not be taken into account.

(8) The National Biosafety Authority may refuse to approve an application for a Permit to import for intentional introduction into the environment on any of the following grounds, that is to say,

(a) if the application is not accompanied by all the information required to be submitted along with the application;

(b) if the application contains information that is misleading, false, deceptive, or likely to deceive or create an erroneous impression on the National Biosafety Authority;

(c) if the genetically modified organism is likely to have an adverse effect on conservation and sustainable use of biological diversity, taking into account risks to human health or animal health.

(9) Where the National Biosafety Authority refuses to approve an application in accordance with the provisions of subsection (9) of this section, it shall, as soon as practicable, notify the applicant of its decision and the reasons for the decision.

(10) Where the National Biosafety Authority refuses to approve an application in accordance with the provisions of this section, the National Biosafety Authority shall, by notice published in the Gazette and at least one newspaper in Guyana for two consecutive weeks, inform the public of the refusal of the Permit.

Decision procedure for imports for domestic use

60. (1) The National Biosafety Authority before approving an application for a Permit for import for domestic use -

(a) shall, consider all objections and information made available to it;

(b) consult with the relevant regulatory agency;

(c) may, request additional information from the authority referred to in paragraph (b) of Annex I of the Protocol.

(2) The National Biosafety Authority may refuse to approve an application for a Permit for import for domestic use on any of the following grounds, that is to say,

(a) if the application is not accompanied by all the information required to be submitted along with the application;

(b) if the application contains information that is misleading, false, deceptive, or likely to deceive or create an erroneous impression on the National Biosafety Authority;

(c) if the use of the genetically modified organism is likely to produce adverse effects on conservation and sustainable use on biological diversity, taking into account risks to human health or animal health.

(3) Where the National Biosafety Authority refuses to approve an application in accordance with the provisions of subsection (2) of this section, it shall, as soon as practicable, notify the applicant of its decision and the reasons for the decision.

Grant of permit for import

61. (1) Where the National Biosafety Authority approves an import or a permit for importation in accordance with **section [59] or section [60]** of this Act and it is satisfied that there is firm and sufficient evidence that the genetically modified organism to be imported poses no risk to human and animal health, the environment and biological diversity, the National Biosafety Authority may grant the permit subject to the provisions of subsection (2) of this section.

(2) The permit granted under this section

(a) shall be issued upon payment of the prescribed fee;

(b) may include information on how the decisions will apply to subsequent imports of the same genetically modified organism;

(c) **[may/shall]** be subject to the condition that

(i) the applicant shall carry out monitoring and evaluation of risks after the genetically modified organism has been imported for intentional introduction into the environment;

(ii) the applicant take out a policy of insurance against liability to pay compensation for damages;

(iii) or such other condition as the National Biosafety Authority may consider necessary; and

(iv) shall be in the prescribed form.

(3) Where the National Biosafety Authority grants a permit subject to conditions it shall, as soon as practicable inform the applicant of its decision and the reasons for the decision.

(4) A permit may be subjected to new conditions, if in the opinion of the National Biosafety Authority, new information or a review of existing information about the genetically modified organism establishes risks to human or animal health, biological diversity or the environment, based on the precautionary principle.

(5) Where the National Biosafety Authority grants a permit in accordance with the provisions of this section, the National Biosafety Authority shall, by notice published in the Gazette and at least two newspapers of general circulation in Guyana to inform the public of the grant of the permit.

(6) Where the National Biosafety Authority grants a permit in accordance with the provisions of this section, the National Biosafety Authority shall enter the particulars of the permit in the Register of Permits which shall be open to inspection by the public on payment of the prescribed fee.

Variation or Cancellation of Permit

62. (1) The National Biosafety Authority, may, at any time, cancel a permit issued under the provisions of **section [50]** of this Act on any of the following grounds, that is to say,

(a) upon a breach of a condition to which the permit was granted;

(b) where the permit holder contravenes any provision of this Act or the regulations made under this Act;

(c) if, in the opinion of the National Biosafety Authority, new information or a review of existing information about the genetically modified organism establishes risks to human or animal health, biological diversity or the environment, based on the precautionary principle;

(d) for any other justifiable reason the National Biosafety Authority may think proper to do so by reason of protecting the conservation and sustainable use of biological diversity, taking into account the risks to human health or animal health.

(2) Where the National Biosafety Authority cancels a permit in accordance with the provisions of this section, the National Biosafety Authority shall, by notice published in the Gazette and at least two newspapers of general circulation in Guyana to inform the public of the cancellation of the permit.

Export Permit

Application for Export Permit

63. **(1) A person who wishes to apply for a [Permit] for the export of a genetically modified organism as required by this Act shall apply to the National Biosafety Authority, and the application shall be in such form and shall contain such particulars as may be prescribed.**

(2) The application referred to in subsection (1) of this section shall be accompanied by the prescribed fee in respect of the grant of Permit, which fee shall be paid to the [National Biosafety Authority].

(3) **The National Biosafety Authority shall, upon receipt of the application,**

(a) **cause to be published in at least two newspapers of general circulation in Guyana for two consecutive weeks, a notice containing the scientific name, common name and intended use of the genetically modified organism for the purpose of inviting public comments on the application;**

(b) **notify, or require the applicant to notify the competent national authority of the country of import.**

(c) consult with the relevant regulatory agency;

(4) **The notification referred to in paragraph (b) of subsection (3) of this section shall be in writing and shall contain -**

(a) the information set out in the [**Fourth Schedule**] to this Act; and

(b) such other information that the applicant or the National Biosafety Authority may consider necessary.

Or

Export Permit

63. (1) Any person who wishes to export any genetically modified organism under the provisions of Part 6 shall notify -

(a) the National Biosafety Authority in Guyana; or

(b) the State that is to import the genetically modified organism; and request written consent to export such organisms to Guyana or such State, as the case may be

(2) The notification transmitted under the provisions of sub-section (1) above shall contain -

(a) a full and accurate description of the genetically modified organisms to be exported, which shall include the technical and common name and a statement of the quantities to be exported;

(b) information relating to the conditions of release, contained use, or placing on the market, and where appropriate, the receiving environment for the genetically modified organism;

(c) the name of the State that is to receive the genetically modified organisms and documentary proof that such State possesses the technical capacity and the facilities and suitable risk assessment and risk management systems to ensure that the handling, transport, use, transfer and release of any genetically modified organisms does not cause any significant ecological, social or economic harm;

(d) confirmation of the existence of a contract between the applicant and the recipient in the State to which the genetically modified organism is to be exported, specifying the environmentally sound manner in which the genetically modified organisms in question is to be handled;

(e) a report documenting any risk assessment that has been undertaken in the country of export to determine that the genetically modified organisms does not cause any significant ecological, social or economic harm;

(f) information on the interaction between the genetically modified organism and natural biodiversity, the environment, human health or animal health, including the results of any deliberate release in the country of export or other country;

(g) information on any previous approvals or rejections of the genetically modified organisms;

(h) a description of any risk management measures that are required for the safe transport, use, handling of such genetically modified organism, including -

(i) information concerning marking, labelling, packaging, storage and segregation requirements;

(ii) information on monitoring, control, disposal and waste management procedures;

(iii) emergency response plans to address any unintentional release.

(3) Any person who submits an application under the provisions of sub-section (2) above which to his knowledge contains any false or mis-leading information, shall be guilty of an offence and liable on conviction to the penalties provided under [Schedule 6] of the Act.

(4) Upon receipt of any application under the provisions of sub-section (1) (a) above, the National Biosafety Authority shall -

(a) determine whether the genetically modified organisms has been pre-approved for import pursuant to the provisions of [section 81];

(b) consult with the Scientific and Advisory Committee;

(c) consult with the relevant regulatory agency;

(d) determine that a comprehensive risk assessment be undertaken pursuant to the provisions of Part 6 at the expense of the applicant; and

(e) give public notice of the application under this Part.

(5) The public notice required in sub-section (4)(d) above shall be published in local newspapers and shall provide -

(a) a description of the nature of the application;

(b) a full and accurate description of the genetically modified organism that is to imported;

(c) information concerning the location, time and method of use of the genetically modified organism that is to be imported;

(d) a statement concerning any significant impact on natural biodiversity, the environment, human health or animal health that may result from the use of the genetically modified organism that is to be imported;

(e) any risk management or environmental monitoring or management plans that are to be established;

(f) that submissions on the application may be made in writing by any person;

(g) the closing date for submissions, which shall not be earlier than thirty calendar days after public notification; and

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

(6) A copy of the public notice as provided under sub-sections (4) (d) shall be lodged with the National Biosafety Clearinghouse established pursuant to [section 30].

Objection to permitting.

64. (1) A person may object to the permitting of a genetically modified organism for export.

(2) Any objection to the permitting of a genetically modified organism for import shall be lodged with the National Biosafety Authority within twenty one days of the publication of the notice referred to in subsection (3) of [section 63].

Consideration of application.

65. The National Biosafety Authority shall, before approving an application for export, consult with the relevant regulatory agency, consider all objections and information made available to it, and the National Biosafety Authority may, where it is satisfied that there is an advance informed agreement with the competent authority of the country of import, approve the application.

Refusal to approve application.

66. (1) The National Biosafety Authority may refuse to approve an application for a Permit to export on any of the following grounds, that is to say,

(a) if the application is not accompanied by all the information required to be submitted along with it;

(b) if the application contains information that is misleading, false, deceptive, or likely to deceive or create an erroneous impression on the National Biosafety Authority;

(c) if the genetically modified organism or product is likely to have an adverse effect on conservation and sustainable use of biological diversity, taking into account risks to human health or animal health;

(d) if the genetically modified organism or product is banned by the laws of the country of import.

(2) Where the National Biosafety Authority refuses to approve an application in accordance with the provisions of subsection (1) of this section, it shall, as soon as practicable, notify the applicant of its decision and the reasons for the decision.

Grant of Permit for export.

67. (1) Where the National Biosafety Authority is satisfied that the export may proceed, the National Biosafety Authority may grant the Permit subject to the provisions of subsection (2) of this section.

(2) The Permit granted under this section -

(a) shall be issued upon payment of the prescribed fee;

(b) may be subject to such conditions as the National Biosafety Authority may consider necessary; and

(c) shall be in the prescribed form.

(3) Where the National Biosafety Authority grants a Permit subject to conditions it shall, as soon as practicable inform the applicant of its decision and the reasons for the decision.

Biotechnology Research And Development

Biotechnology Research & Development Permit

68. (1) A person who wishes to apply for a permit for biotechnology research and development as required by this Act or regulations made under this Act shall apply, in the prescribed form, to the National Biosafety Authority.

(2) An application referred to in subsection (1) of this section shall be accompanied by the prescribed fee, which fee shall be payable to the [National Biosafety Authority].

(3) The National Biosafety Authority shall, upon receipt of the application, cause to be published in at least one newspaper [of general circulation in Guyana] for two consecutive weeks, a notice containing the scientific name, common name and intended use of the genetically modified organism for the purpose of inviting public comments on the application.

[(4) An application made pursuant to subsection (1) shall contain -

(a) the information set out in the [Fourth Schedule] to this Act; and

(b) such other information that the applicant or the National Biosafety Authority may consider necessary.]

Objection to permitting.

69. (1) A person may object to the permitting of a genetically modified organism for biotechnology research and development on any ground that may be prescribed by regulations made under this Act.

(2) Any objection to the permitting of a genetically modified organism for biotechnology research and development shall be lodged with the National Biosafety Authority within twenty one days of the publication of the notice referred to in subsection (3) of **[section 68**].

Consideration of Application

70. The National Biosafety Authority , before approving an application for a permit for biotechnology research and development -

(a) shall consider all objections and information made available to it;

(b) shall consult with the relevant regulatory agency;

(c) may, request additional information from the applicant.

Refusal to approve application.

71. (1) The National Biosafety Authority may refuse to approve an application for a biotechnology research and development on any of the following grounds, that is to say,

(a) if the application is not accompanied by all the information required to be submitted along with it;

(b) if the application contains information that is misleading, false, deceptive, or likely to deceive or create an erroneous impression on the National Biosafety Authority;

(c) if the genetically modified organism or product is likely to have an adverse effect on conservation and sustainable use of biological diversity, taking into account risks to human health or animal health;

(2) Where the National Biosafety Authority refuses to approve an application in accordance with the provisions of subsection (1) of this section, it shall, as soon as practicable, notify the applicant of its decision and the reasons for the decision.

Grant of Permit for biotechnology Research and Development

72. (1) Where the National Biosafety Authority is satisfied that there is firm and sufficient evidence that the genetically modified organism poses no risk to human and animal health, the environment and biological diversity, the National Biosafety Authority may grant the permit.

(2) Upon the grant of the permit for biotechnology research and development the applicant shall be issued an appropriate permit upon payment of the prescribed fee and the permit shall contain such contents as may be prescribed by the regulations made under this Act.

(3) The permit biotechnology research and development may be subject to -

(a) the condition that the permit holder take out a policy of insurance against liability to pay compensation for damages; or

(b) such conditions regarding collaboration, cooperation and access to information; or

(c) fair sharing and transfer of knowledge and monetary and non-monetary benefits arising from the research; or

(d) such other conditions as the National Biosafety Authority considers necessary for the protection of the conservation of biological diversity or sustainable use of biological organisms, taking into account risks to human health or animal health.

(4) Where the National Biosafety Authority grants a permit in accordance with the provisions of this section, the National Biosafety Authority shall enter the particulars of the permit in the Register of Permits which shall be open to inspection by the public on payment of the prescribed fee.

Cancellation of Permit

73. (1) The National Biosafety Authority, may, at any time, cancel a permit issued under the provisions of subsection (2) of **section [72]** of this Act on any of the following grounds, that is to say,

(a) upon a breach of a condition to which the permit was granted;

(b) where the permit holder contravenes any provision of this Act or the regulations made under this Act;

(c) where, after the issue of the permit, it comes to the knowledge of the National Biosafety Authority that information which was submitted in support of the application for the grant of a permit for domestic use misled or created an erroneous impression on the National Biosafety Authority by reason of being false or deceptive;

(d) if, in the opinion of the National Biosafety Authority, new information or a review of existing information about the genetically modified organism establishes risks to human or animal health, biological diversity or the environment, based on the precautionary principle;

(e) for any other justifiable reason the National Biosafety Authority may think proper to do so by reason of protecting the conservation and sustainable use of biological diversity, taking into account the risks to human health or animal health.

(2) Where the National Biosafety Authority cancels a permit in accordance with the provisions of this section, the National Biosafety Authority shall, within seven days, by notice published in the Gazette and at least two newspapers of general circulation in Guyana to inform the public of the cancellation of the permit.

(3) No compensation shall be payable as a consequence of the cancellation of a permit

Permit for medical use

74. (1) A person who wishes to apply for a permit for **medical use** as required by this Act or regulations made under this Act shall apply, in the prescribed form, to the National Biosafety Authority.

(2) An application referred to in subsection (1) of this section shall be accompanied by the prescribed fee, which fee shall be payable to the [National Biosafety Authority].

(3) The National Biosafety Authority shall, upon receipt of the application, cause to be published in at least one newspaper [of general circulation in Guyana] for two consecutive weeks, a notice containing the scientific name, common name and intended use of the genetically modified organism for the purpose of inviting public comments on the application.

[(4) An application made pursuant to subsection (1) shall contain -

(a) the information set out in the [Fourth Schedule] to this Act; and

(b) such other information that the applicant or the National Biosafety Authority may consider necessary.]

Objection to permitting.

75. (1) A person may object to the permitting of a genetically modified organism for [**medical use]** on any ground that may be prescribed by regulations made under this Act.

(2) Any objection to the permitting of a genetically modified organism for **[medical use]** shall be lodged with the National Biosafety Authority within twenty one days of the publication of the notice referred to in subsection (3) **of [section74].**

Consideration of Application

76. The National Biosafety Authority , before approving an application for a permit for **[medical use]** -

(a) shall consider all objections and information made available to it;

(b) shall consult with the relevant regulatory agency;

(c) may, request additional information from the applicant.

Refusal to approve application.

77. (1) The National Biosafety Authority may refuse to approve an application for a Permit **[medical use]** on any of the following grounds, that is to say,

(a) if the application is not accompanied by all the information required to be submitted along with it;

(b) if the application contains information that is misleading, false, deceptive, or likely to deceive or create an erroneous impression on the National Biosafety Authority;

(c) if the genetically modified organism or product is likely to have an adverse effect on conservation and sustainable use of biological diversity, taking into account risks to human health or animal health;

(2) Where the National Biosafety Authority refuses to approve an application in accordance with the provisions of subsection (1) of this section, it shall, as soon as practicable, notify the applicant of its decision and the reasons for the decision.

Grant of Permit for medical use

78. (1) Where the National Biosafety Authority is satisfied that there is firm and sufficient evidence that the genetically modified organism poses no risk to human and animal health, the environment and biological diversity, the National Biosafety Authority may grant the permit.

(2) Upon the grant of the permit for medical use the applicant shall be issued an appropriate permit upon payment of the prescribed fee and the permit shall contain such contents as may be prescribed by the regulations made under this Act.

(3) The permit **[medical use]** may be subject to -

(a) the condition that the licensee take out a policy of insurance against liability to pay compensation for damages; or

(b) such other conditions as the National Biosafety Authority considers necessary for the protection of the conservation of biological diversity or sustainable use of biological organisms, taking into account risks to human health or animal health.

(4) Where the National Biosafety Authority grants a permit in accordance with the provisions of this section, the National Biosafety Authority shall enter the particulars of the permit in the Register of Permits which shall be open to inspection by the public on payment of the prescribed fee.

Cancellation of Permit

79. (1) The National Biosafety Authority, may, at any time, cancel a permit issued under the provisions of subsection (2) of **section [78]** of this Act on any of the following grounds, that is to say,

(a) upon a breach of a condition to which the permit was granted;

(b) where the permit holder contravenes any provision of this Act or the regulations made under this Act;

(c) where, after the issue of the permit, it comes to the knowledge of the National Biosafety Authority that information which was submitted in support of the application for the grant of a permit for domestic use misled or created an erroneous impression on the National Biosafety Authority by reason of being false or deceptive;

(d) if, in the opinion of the National Biosafety Authority, new information or a review of existing information about the genetically modified organism establishes risks to human or animal health, biological diversity or the environment, based on the precautionary principle;

(e) for any other justifiable reason the National Biosafety Authority may think proper to do so by reason of protecting the conservation and sustainable use of biological diversity, taking into account the risks to human health or animal health.

(2) Where the National Biosafety Authority cancels a permit in accordance with the provisions of this section, the National Biosafety Authority shall, within seven days, by notice published in the Gazette and at least two newspapers of general circulation in Guyana to inform the public of the cancellation of the permit.

(3) No compensation shall be payable as a consequence of the cancellation of a permit

Confidential Information

80. (1) The National Biosafety Authority shall permit the applicant to identify information submitted under this Act that is to be treated as confidential and justification shall be given in such cases upon request.

(2) The National Biosafety Authority shall consult the applicant if it decides that information identified by the applicant as confidential does not qualify for such treatment and shall, prior to any disclosure, inform the applicant of its decision, providing reasons on request, as well as an opportunity for consultation and for an internal review of the decision prior to disclosure.

(3) The National Biosafety Authority shall protect confidential information received under this Act.

(4) The National Biosafety Authority shall not use such information for a commercial purpose, except with the written consent of the applicant.

(5) Where an applicant withdraws or has withdrawn an application, the National Biosafety Authority shall respect the confidentiality of commercial and industrial information, including research and development information as well as information on which the applicant disagrees as to its confidentiality.

(6) Without prejudice to subsection (5) of this section, the following information shall not be considered confidential

(a) the name and address of the applicant;

(b) a general description of the genetically modified organism;

(c) a summary of the risk assessment of the effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health or animal health; and

(d) any methods and plans for emergency response.

Or

(1) The National Biosafety Authority shall -

(a) allow an applicant to identify information provided to the National Biosafety Authority in accordance with the requirements of this Act and any regulations made hereunder, that is to be treated as confidential, with justification for claims of confidentiality to be provided upon request;

(b) decide whether it accepts as confidential the information designated by the applicant;

(c) inform the applicant of any rejection of the claim of confidentiality, providing reasons on request, as well as an opportunity for consultation; and

(d) in the event that an applicant withdraws an application in accordance with [section ,…], respect the applicant's claims of confidentiality.

(2) The National Biosafety Authority shall not use confidential information for any purpose not authorized under this Act, and shall ensure that such information is protected by any person involved in handling applications under this Act.

PART 5

PRE-APPROVED ORGANISMS

Simplified Application and review procedures for Pre-approved genetically modified organisms

81. (1) The National Biosafety Authority [may/shall] establish a register of genetically modified organisms that have been pre-approved for import into Guyana.

(2) No genetically modified organism may be registered pursuant to sub-section (1) unless the National Biosafety Authority is satisfied:

(a) a risk assessment has been undertaken by an accredited organisation that is competent to undertake scientific assessments to determine that the genetically modified organisms does not cause any significant ecological, social or economic harm in Guyana;

(b) there exists information on the interaction between the genetically modified organism and natural biodiversity, the environment, human health or animal health, including the results of any deliberate release in any other country;

(c) there exists information on any previous approvals of the genetically modified organisms in any other country;

(3) The register of genetically modified organisms that have been pre-approved for import into Guyana shall be lodged with the National Biosafety Clearinghouse established pursuant to [section **30**].

(4) No application for import shall be required under the provisions of [**section 57**] for any genetically modified organism that has been registered pursuant to sub-section (1).

Public Notification of Pre-Approved genetically modified organisms

82. The National Biosafety Authority shall be required to provide periodic public notifications in two local newspapers, in both print and electronic forms, on the list of all Pre-approved genetically modified organisms. Where relevant such notifications shall be announced by radio and telecast for public guidance to complete information retrieval sources from the print media.

Petition for exemption or simplified procedures for Pre-approved genetically modified organisms.

83. (1) Any person may petition the National Biosafety Authority to exempt or to apply simplified procedures for genetically modified organisms or activities under [**section 81]** at any time.

(2) Petitions shall contain the following information -

(a) Name and address of the Applicant;

(b) Name and description of the genetically modified organisms or types and classes of genetically modified organisms and/or activities for which exemption or simplified procedures are sought;

(c) A comprehensive discussion of the scientific basis for the requested action accompanied by supporting documentation;

(d) Any information known to the Applicant that would be unfavourable to the petition.

(3) Within ten (10) days of receipt, the National Biosafety Authority shall publish the petition and transmit the petition to the Scientific Advisory Committee for review.

(4) The National Biosafety Authority shall make a final decision on the petition based upon the scientific review conducted by Scientific Advisory Committee and relevant comments submitted by the public. The final decision may either approve or deny the petition in whole or in part and shall be communicated in writing to the Applicant within one hundred-twenty (120) days of receipt of the petition by the Competent Authority.

Labelling of genetically modified organisms and related products

84. (1) During transport, import or export each package shall be clearly labelled in English as containing genetically modified organisms.

(2) The labelling shall also state the species of organism and the name, address and telephone number of both the sender and the recipient.

(3) Any label affixed in accordance with the provisions of sub-section (1) and (2) above must be positioned in the following manner:

(a) on cartons and boxes - at least one label on the side or end;

(b) on drums and similar containers - at least one label on the side on the upper half;

(c) on jerricans and similar containers - at least one label on one of the largest surfaces;

(d) on gas cylinders and small pressure vessels - at least one label positioned near or on the shoulder, and for larger cylinders and pressure vessels where the size or slope makes the label difficult to read a second label should be positioned on the opposite sides of the container

(e) on pallet loads and open-top containers - except where the class label on the packaging is clearly visible, the label or labels should be positioned in the upper half of each of the two opposite sides of the load, and where the pallet contains a mixed load then all class labels must be placed on both sides.

(4) Every label affixed under the provisions of sub-section (3) above shall be in such a manner that when the genetically modified organisms are transported the nature of the consignment is readily recognisable.

(5) **Labelling shall be carried out in accordance with regulations made under this Act.**

Packaging of genetically modified organisms

85. (1) The packaging of all genetically modified organisms shall be –

(a) impervious to both spores and pollen;

(b) watertight, sealed and fracture-proof, so as to prevent any unintentional leakage of the contents.

(2) There shall always be an inner and an outer container, which shall both be waterproof.

(3) Between the inner and the outer container, there shall be fluid-absorbent material capable of absorbing a quantity of fluid equivalent to that in the container.

(4) If two or more inner containers are carried in the same outer container -

(a) each inner container shall be separately packaged in shock-absorbent and fluid-absorbent material;

(b) the outer container shall be watertight, sealed, fracture proof, etc. so as to prevent any unintentional leakage of the contents.

or

(1) The National Biosafety Authority shall take necessary measures to require that genetically modified organisms that are subject to import or export are handled, packaged and transported under conditions of safety, in order to avoid adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health or animal health.

(2) A licensee or a holder of a certificate shall ensure that documentation accompanying -

(a) genetically modified organisms that are intended for direct use as food, feed or processing, clearly identifies that they "may contain" genetically modified organisms and are not intended for intentional introduction into the environment, as well as a contact point for further information;

(b) genetically modified organisms that are destined for contained use -

(i) clearly identifies them as genetically modified organisms; and

(ii) specifies any requirements for the safe handling, storage, transport and use, the contact point for further information, including the name and address of the individual and institution to whom the genetically modified organisms are consigned

(c) genetically modified organisms that are intended for intentional introduction into the environment of the country and any other genetically modified organism -

(i) clearly identifies them as genetically modified organisms;

(ii) specifies the identity and relevant traits or characteristics, any requirements for the safe handling, storage, transport and use, the contact point for further information and, as appropriate, the name and address of the licensee or holder of the certificate; and

(iii) contains a declaration that the import or export is in conformity with the requirements of this Act applicable to the licensee or a holder of a certificate.

Accompanying Documentation for transport of genetically modified organisms

86. (1) All genetically modified organisms that are transported, imported, or exported shall be accompanied by the permit issued pursuant to **[Part 4]** which shall at all times be available for inspection by an inspector.

(2) In addition to any delivery slips or invoices that are required for the commercial transaction, the following documents must accompany genetically modified organisms in **transit** -

(a) a *Shippers Universal Dangerous Goods Declaration for Air, Sea and Land*, which shall -

(i) bear a declaration signed by the person who offers the genetically modified organisms for transportation indicating that the goods are fully and accurately described by their proper shipping names and that they are classified, packed, marked, labelled and in proper condition for transport in accordance with the provisions of, where appropriate, the Code or this Part; and

(ii) contain, inter alia, the following particulars for each individual genetically modified organism, and in the following order:

(A) the Proper Shipping Name;

(B) the Class or organism;

(C) where applicable, the scientific and common name, taxonomic classification, characteristics, such additional information and where appropriate the unique identifier;

(D) the packaging group;

(E) the number and type of packages and the total quantity covered by the description;

(F) Additional Handling Information, including the control and emergency temperatures and any other information necessary to ensure that the substance will be segregated correctly and to indicate and additional precautions that must be taken under special circumstance;

(G) the delivery addresses of the consignor and consignee, and contact phone numbers where available.

(b) a *Consolidated Packing Certificate for Dangerous Goods*, containing information about the packing of the genetically modified organism goods, except for goods carried in bulk;

(c) a *Load Plan*, stating where the genetically modified organisms are located on the ship, aircraft or vehicle, which must be signed by the person loading the goods; and

(d) an *Emergency Procedures Guide*, providing information concerning emergency procedures that are to be employed in the event of any accidental release or other emergency.

(3) The documents referred to in sub-section (2)(a) and (2)(b) above must have a characteristic striped border, in red and white.

(4) The documents referred to in sub-section (2) above must be attached to each other while accompanying any genetically modified organism in transit.

Importation by sea

87. (1) Where any genetically modified organism is to be imported into

Guyana by sea, the owner or master of the vessel shall, at least 48 hours before the genetically modified organisms are to be landed, or if this is not practicable, as soon as practicable thereafter, give written notice to the [Maritime Administration Department at the port in which the genetically modified organism is to be landed.

(2) The written notice given in compliance with the provisions of sub-section (1) above shall specify -

(a) the identity of every genetically modified organism;

(b) where applicable, the number on the container transporting the genetically modified organism;

(c) the quantity of each the genetically modified organism being imported;

(d) the vessel on which each the genetically modified organism is to be carried to Guyana;

(e) the seaport at which the vessel is to arrive;

(f) the estimated time and date of arrival of the vessel; and

(g) any special cargo transportation or storage requirements pertaining to any the genetically modified organism aboard the vessel that is to be imported into Guyana.

(3) The shipping agent for the vessel that will carry the genetically modified organism to Guyana shall, at least two working days prior to the vessels arrival, lodge with the Maritime Administration Department and the National Biosafety Authority a copy of the Shippers Universal Dangerous Goods Declaration for Air, Sea and Land, or where appropriate, the Dangerous Goods Declaration.

(4) On receipt of the Shippers Universal Dangerous Goods Declaration for Air, Sea and Land, the Maritime Administration Department shall -

(a) confer with the National Biosafety Authority to verify accuracy with any permit issued under this Act; and thereafter:

(b) allocate transit or storage areas according to the classification and criteria stipulated in the document, and shall advise the responsible shipping agent of the allocated location.

(5) The master of any vessel arriving at any controlled area shall surrender to the shipping agent all original Shippers Universal Dangerous Goods Declaration for Air, Sea and Land pertaining to any genetically modified organism aboard the vessel that is to be imported into Guyana.

(6) Where the National Biosafety Authority is satisfied that there has been a failure on the part of the master of any vessel in a prescribed port area to comply with a requirement of this Act or the regulations, or with a condition imposed pursuant thereto, the National Biosafety Authority may cause the vessel to be detained until compliance with any requirements specified by the National Biosafety Authority.

(7) The National Biosafety Authority shall forthwith deliver, in writing, to the captain of the vessel particulars of the non-compliance;

(8) Upon receipt of the original Shippers Universal Dangerous Goods Declaration for Air, Sea and Land, the shipping agent shall, before any genetically modified organism is discharged from the vessel -

(a) hand the documents to the stevedore responsible for unloading the vessel; and where appropriate

(b) discuss with the stevedore any special cargo requirements.

(9) It shall be the responsibility of the stevedore to take all appropriate precautions when unloading any genetically modified organism, and -

(a) ensure that the genetically modified organism are stowed in the transit or storage areas allocated by the Maritime Administration Department under the provisions of any permit issued under this Act, or according to the classification and criteria stipulated in the permit; and

(b) place all documentation pertaining to the genetically modified organism in a location adjacent to where the organisms are to be stored within the controlled area.

(10) The Maritime Administration Department may, in consultation with the National Biosafety Authority, issues guidelines and codes of practice concerning -

(a) the storage and management of genetically modified organism in a controlled area;

(b) the establishment of emergency and response procedures in the event of any accidental release of any genetically modified organism in a controlled area;

(c) the establishment of any training requirements or programmes concerning the management, storage or handling of any genetically modified organism in a controlled area;

(d) the establishment of any training requirements or programmes concerning emergency and response procedures in the event of an accidental release of any genetically modified organism in a controlled area.

(11) In making any guidelines or codes of practice under the provisions of sub-section (10) above, the National Biosafety Authority shall ensure the broadest possible consultation.

(12) Upon concluding any guidelines or codes of practice under the provisions of sub-section (11) above, the National Biosafety Authority shall lodge a copy with the National Biosafety Clearinghouse.

(13) Any person who fails to comply with the requirements of any guideline or code of practice issued by the Maritime Administration Department pursuant to the provisions of sub-section (12) above, shall be guilty of an offence and liable to the penalties provided in [Schedule 6] of the Act.

(14) The appropriate authority will carry-out inspections to ensure compliance with any permit, standard and procedures established in this Part, and for this purpose is empowered to execute spot checks to ensure compliance with any such requirements.

Procedures for unloading genetically modified organisms

88. (1) During the discharge of any cargo containing genetically modified organism the appropriate regulatory authority shall ensure that -

(a) the container is inspected to ensure no spillage or residue exists;

(b) the berth is secure with access permitted only to authorised personnel and emergency services;

(c) suitable warning notices are posted.

(2) During the discharge from a vessel of any cargo containing genetically modified organism the shipping agent and the stevedore shall ensure that -

(a) unloading operations are supervised by a properly qualified and trained person; and

(b) any mechanical machinery being used to move genetically modified organisms is operated by a competent operator.

(3) During the discharge from a vessel of any genetically modified organism it shall be the responsibility of the ship's master, the shipping agent and the stevedore to ensure that the discharging vessel operates no more than one crane at any one time.

(4) In the event of an accidental release or spillage of genetically modified organism in a controlled area, the Maritime Administration Department is to take appropriate action, which shall include -

(a) determining the identity of the genetically modified organism and the quantity of any accidental release or spillage;

(b) securing the area to prevent unauthorised access;

(c) determining whether emergency services are to be called; and

(d) determining, in consultation with the National Biosafety Authority, the appropriate method of clean up and disposal.

(5) During the unloading of any cargo containing genetically modified organisms, the relevant Shippers Universal Dangerous Goods Declaration for Air, Sea and Land, or where appropriate the Dangerous Goods Declaration, shall be inspected by the shipping agent and the stevedore to ensure that the declaration accurately reflects the nature and quantity of genetically modified organism being unloaded.

(6) The shipping agent and stevedore undertaking the unloading of any cargo containing genetically modified organism shall ensure that any consignments that are not to be immediately dispatched to the consignee shall be stored according to conditions and directions given by the National Biosafety Authority.

Procedures for transport of genetically modified organisms by road

89. (1) The provisions of this section shall come into force and effect no later than twelve months after the enactment of this Act.

(2) Only licensed and certified drivers shall transport genetically modified organisms on any road.

(3) The [Environmental Protection Agency] will undertake the licensing and registration of drivers under the provisions of sub-section (2), and for this purpose shall, in consultation with the National Biosafety Authority, establish procedures and requirements for licensing, registration and training, and for the endorsement of Permits for any registered driver.

(4) Any driver licensed to transport genetically modified organisms shall have his or her Permit endorsed to this effect, and shall be required to carry their Permit and genetically modified organism transport permit at all times when carrying such organisms.

(5) The [Environmental Protection Agency], in undertaking the licensing and registration of drivers under the provisions of sub-section (3), shall –

(a) limit the number of drivers that will be registered to transport genetically modified organisms; and

(b) require such drivers to carry adequate insurance to cover any foreseen harm to human health or animal health or the environment that may result from an accidental release of any genetically modified organisms that is being transported by road.

(6) The [Environmental Protection Agency] will only issue a Permit under the provisions of sub-section (3) once the driver has satisfactorily passed an established training program on the handling and transportation of genetically modified organisms, which shall be undertaken every two years.

(7) Any person who wishes to transport any genetically modified organisms in bulk upon any road shall apply in writing to the [Environmental Protection Agency].

(8) Any application for a permit that is submitted under the provisions of sub-section (7) shall contain -

(a) a full and accurate description of the genetically modified organisms to be transported including the scientific and common name, taxonomic classification, characteristics, such additional information and where appropriate the Unique Identifier.;

(b) a statement of the quantities to be transported;

(c) the name and location of the place from where the genetically modified organisms is to be transported; and

(d) the name and location of the place to where the genetically modified organisms is to be transported.

(9) Upon receipt of any application under the provisions of sub-section (7), the [Environmental Protection Agency], shall verify that the location to where the genetically modified organisms are to be transported is, as appropriate, a controlled area, or is licensed pursuant to the requirements of this Act, and thereafter may, in consultation with the National Biosafety Authority -

(a) refuse permission for the transportation of any organism; or

(b) issue a permit, which may specify conditions.

(10) Any permit issued under sub-section (9) shall contain the following information -

(a) the identity of every genetically modified organism being transported, including the scientific and common name, taxonomic classification, characteristics, such additional information and where appropriate the Unique Identifier.

(b) the quantity of each genetically modified organism being transported;

(c) the vehicle on which each genetically modified organism is to be transported;

(d) the route which shall be used for the transportation of the genetically modified organisms;

(e) any special transportation or storage requirements pertaining to any genetically modified organism that is to be transported by road; and

(f) the particulars of the person to whom the permit is issued.

(11) Any route specified in terms of sub-section (10) (d) should, where practicable, be planned to minimise risk to human health, animal health and the environment.

(12) The Environmental Protection Agency may for just cause, at any time, cancel a permit that has been issued under sub-section (9) (b).

(13) If any requirement or conditions contained in a permit are not strictly complied with, the Environmental Protection Agency may issue such directions as may be considered appropriate for the immediate cessation of the transportation of the genetically modified organism.

(14) Any person who fails to comply with the direction, requirement or condition imposed by the Environmental Protection Agency is guilty of an offence and liable upon conviction to the penalties provided in [Schedule 6] of the Act.

(15) Within seven days of issuing any permit under the provisions of subsection (9), the Environmental Protection Agency shall lodge a copy of the permit with the National Biosafety Clearinghouse established pursuant to [section 30].

(16) The Environmental Protection Agency will carry-out inspections of drivers and vehicles to ensure compliance with any permit, standard and procedures established in this Part, and for this purpose is empowered to execute spot checks to ensure compliance with any such requirements.

(17) Any person who transports on any road any genetically modified organisms other than in compliance with the requirements of this section is guilty of an offence and liable upon conviction to the penalties provided in [Schedule 6] of the Act.

(18) Any driver convicted under the provisions of subsection (17), in addition to any other penalty imposed, may be prohibited from carrying out the business of transporting genetically modified organisms for a period of time.

(19) Any application or permit that may be required under the provisions of this section may be sent by means of a faxed copy, on condition that the original is immediately dispatched by the quickest possible means.

(20) Once a permit has been issued for the transport of any genetically modified organism under the provisions of this Act, the person responsible for the transportation of the consignment shall provide the driver that is to transport the genetically modified organism with a copy of:

(a) the permit issued under the provisions of this Act and

(b) a copy of the Shippers Universal Dangerous Goods Declaration for Air, Sea and Land.

(21) The driver who is to transport the genetically modified organism shall, upon receiving the documentation specified in sub-section (20) above, inspect the load and documentation to ensure that the consignment complies with the description contained in the documentation.

(22) The driver shall ensure that any required separations are adhered to when loading the genetically modified organism, and shall ensure that the documentation provided in terms of the provisions of sub-section (20) above is placed in the cab of the vehicle.

(23) When a vehicle is loaded with genetically modified organisms, such organism must be packed, labelled and segregated in accordance with the requirements of this Part.

(24) All genetically modified organisms in transit by road must be secured with load restraints to prevent movement of the load during normal operating conditions.

(25) At least one 2 kilogram dry powder fire extinguisher must be carried on any vehicle that transports genetically modified organism, in addition to any other equipment that may be specified by the Environmental Protection Agency.

(26) In the event of any spill or accident during the transportation of any genetically modified organism by road, and where appropriate, it shall be the responsibility of the driver to -

(a) secure the area around the vehicle or spill;

(b) determining whether emergency services are to be called;

(c) assess the situation and respond in an appropriate manner; and

(d) notify the consignor and consignee of the nature of the spill or accident.

Storage other than in Controlled Areas

90. (1) Only licensed and registered facilities shall store or process any genetically modified organism.

(2) The National Biosafety Authority, in consultation with regulatory agencies, will undertake the licensing and registration of premises under the provisions of sub-section (2) above, and for this purpose may establish:

(a) standards pertaining to the storage or processing of genetically modified organism on any premises;

(b) procedures and requirements for the licensing and registration of premises;

(c) requirements for the training of employees in the safe handling of genetically modified organism.

(3) [National Biosafety Authority], in undertaking the licensing and registration of premises under the provisions of sub-section (3) above, shall require such premises to carry adequate insurance to cover any foreseeable liability for harm to human health, animal health or the environment.

(4) The person in charge of any premises that is to be used for the storage or processing of any genetically modified organism shall apply in writing to the National Biosafety Authority for permission to use such premises for such purpose.

(5) Any application for a permit that is submitted under the provisions of sub-section (1) above shall contain:

(a) a full and accurate description of the genetically modified organism that are to be stored or processed, including the scientific and common name, taxonomic classification, characteristics, such additional information and where appropriate the Unique Identifier.; and

(b) a statement of the quantities of genetically modified organisms to be stored or processed and the duration of such storage;

(c) the name and location of the place where the genetically modified organism is to be stored or processed;

(d) a description of the processing that is to be undertaken on any genetically modified organism;

(e) a copy of the risk management protocols and emergency measures that operate within the facility.

(6) Upon receipt of any application under the provisions of sub-section (5) above, the National Biosafety Authority shall inspect the premises to determine if:

(a) adequate facilities exist for the safe storage or processing of genetically modified organism;

(b) adequate security, segregation and safety measures exists at the premises; and

(c) employee training in the management of genetically modified organism has been undertaken.

(7) Upon completion of any inspection undertaken under the provisions of sub-section (6) above, the National Biosafety Authority shall:

(a) refuse permission for the storage or processing of

genetically modified organism in such premises; or

(b) issue a permit, which may specify conditions.

(8) Any permit issued under sub-section (7) (ii) above shall contain the following information:

(a) the name and location of the place where the genetically modified organism is to be stored or processed;

(b) a full and accurate description of the genetically modified organism that are to be stored or processed, including the technical and common name;

(c) a statement of the quantities to be stored or processed, and the duration of such storage or processing;

(d) [any special risk management measures pertaining the transport of any genetically modified organism that is to be stored or processed.]

(e) any special risk management measures pertaining to any genetically modified organism that is to be stored or processed.

(9) The National Biosafety Authority may for just cause, at any time, cancel a permit that has been issued under sub-section (7) (ii) above.

(10) If any requirement or condition contained in a permit is not strictly complied with, the National Biosafety Authority may issue such directions as may be considered appropriate for the immediate cessation of the storage or processing of the genetically modified organism.

(11) Any person who fails to comply with the direction, requirement or condition imposed by the National Biosafety Authority shall be guilty of an offence and liable to the penalties provided in [Schedule 6] of the Act.

(12) Within seven days of issuing any permit under the provisions of sub-section (7) (ii) above, the National Biosafety Authority shall lodge a copy of the permit with the National Biosafety Clearinghouse established under [**section 30**].

(13) Any premises used for the storage or processing of genetically modified organism must ensure that all such organisms on the premises are packed, labelled and segregated in accordance with the requirements of this Part, and any direction issued by the National Biosafety Authority.

(14) The person in charge of any premises used for the storage or processing of genetically modified organism shall ensure that genetically modified organism storage areas or processing areas are secured against unauthorised access.

(15) The person in charge of any premises used for the storage or processing of genetically modified organism shall maintain material data sheets on any genetically modified organism stored or processed on the premises and shall ensure that these sheets are readily accessible in the event of an emergency.

(16) The person in charge of any premises used for the storage or processing of genetically modified organisms shall ensure that an Emergency Procedures Guide providing information concerning emergency procedures that are to be employed in the event of any accidental release or other emergency, is kept on the premises and that all employees are trained in emergency procedures.

(17) The person in charge of any premises used for the storage or processing of genetically modified organism shall ensure that a daily inspection is undertaken by a responsible person of the genetically modified organism store areas to assure no accidental release or leakage is occurring.

(18) Any person who stores or processes any genetically modified organism other than in compliance with the requirements of this section, or in violation of any direction, order or requirement imposed by the National Biosafety Authority, shall be guilty of an offence.

Monitoring and submission of new information

91. All registered applicants engaged in approved activities relating to the development, release, transport and use of genetically modified organisms and related products with viable transmissible DNA, RNA, oncogenes and viral vectors, either for research, commercial purposes or human health, animal health, plant health and veterinary use, shall be required to submit to the National Biosafety Authority any new information requiring early disclosure within forty-eight hours of the access of that information if the information increases the level of risk

beyond what was previously determined.

PART 6

RISK ASSESSMENT AND RISK MANAGEMENT

Risk assessment process

92. (1) The National Biosafety Authority shall establish and maintain an effective risk assessment and risk management system to ensure that:

(a) the handling, transport, use, transfer and release of any genetically modified organisms in Guyana does not cause any significant ecological, social or economic harm;

(b) the promotion of any biotechnology research or development does not cause any undesirable impact upon Guyana's natural biodiversity, environment, human health or animal health.

(2) Any risk assessment or risk management system that shall be established pursuant to the provisions of sub-section (1) shall, be, be based on standards recommended by the National Biosafety Authority, where possible.

or

(1) A risk assessment conducted by -

(a) an applicant or the Scientific Advisory Committee; or

(b) review of a risk assessment conducted by the Scientific Advisory Committee

Risk assessment requirements shall be as stipulated in [Schedule 2]

93. (1) Risk Assessment shall be carried out in accordance with the [Fifth Schedule] taking into account recognised risk assessment techniques.

(2) In order to effectively assess all risks posed by the use of a genetically modified organism, the Scientific Advisory Committee [**shall/may]** require an applicant to provide the following -

(a) characteristics of the vector;

(b) characteristics of the genetically modified organism or

product of the genetically modified organism;

(c) safety considerations for human and animal health;

(d) environmental considerations;

(e) socio-economic considerations;

(f) management plan;

(g) monitoring plan;

(h) control of release;

(i) waste treatment;

(j) emergency response plan; and

(k) other available scientific evidence;

in order to identify and evaluate the possible adverse effects of a genetically modified organism on the conservation and sustainable use of biological diversity, taking into account risks to human health or animal health.

(3) The cost of risk assessment or review of risk assessment shall be borne by the applicant.

(4) On conclusion of the risk assessment or review of the risk assessment, the Advisory Committee shall provide the National Biosafety Authority with a risk assessment report.

(5) A risk assessment report provided pursuant to subsection (4) shall give the opinion, with justifications, on the disposition of the application and indicates any measures or actions that need to be taken to ensure the safe use of the genetically modified organism.

Evaluation of Risk Management system

94. The National Biosafety Authority shall monitor and review the risk management process provided in accordance with the requirements of this Act and regulations made hereunder.

Review of risk assessment report

95. (1) The National Biosafety Authority shall review the risk assessment report that has been submitted in pursuance of the requirements of this Act.

(2) Within two weeks of the receipt of any report mentioned in sub-

section (1) above, the National Biosafety Authority shall publish, during two subsequent weeks, in two issues of the local newspaper circulating in the area where the undertaking would likely be carried out, and in the Gazette, a notice to advise the public that copies of the risk assessment report are available for public scrutiny

(3) A notice published under the provisions of sub-section (1) above shall state -

(a) a summary description of the activity or undertaking involving genetically modified organism;

(b) the address where the activity or undertaking is to be carried out;

(c) the place where the report may be inspected;

(d) the time limit for the submission of public comments in writing to the National Biosafety Authority.

(4) A risk assessment report submitted under [section 92] shall be open at all reasonable hours for public inspection for a period of not less than one calendar month.

(5) The National Biosafety Authority shall consider all comments and observations that may be submitted as a result of the public review.

(6) The National Biosafety Authority may, for the purposes of the review of any report -

(a) request any ministry, department, statutory body, non-governmental organisations, or any other person to submit their observations or recommendations in writing concerning any matter contained in a report;

(b) require the applicant to carry out any further study or to submit additional information for the purpose of evaluating any potential for significant risk to Guyana's natural biodiversity, the environment, human health or animal health

Responsibility for risk management measures

96. (1) It shall be the responsibility of the applicant to implement any risk management measures, including any monitoring programme, protection plan, or mitigation measure that shall constitute the conditions of any permit granted under this Part.

(2) The Secretariat shall cause to be conducted any inspection that may

be necessary to determine whether any undertaking or activity involving genetically modified organisms are undertaken in accordance with any risk management measures that shall constitute the conditions of any approval granted under this Act.

(3) The Secretariat, upon undertaking any inspection as required under the provisions of sub-section (2) above, may cause an action to be initiated before any competent court, where it has been determined that any undertaking or activity involving genetically modified organisms has not been undertaken in accordance with any risk management plan that shall constitute the conditions of any approval granted under this Act.

Risk Communication

97. A licensee or permit holder who becomes aware of any significant new scientific information indicating that permitted activities may -

(a) adversely affect the conservation and sustainable use of biological diversity, taking into account risks to human health or animal health; or

(b) pose potential risks not previously known or considered; shall immediately advise the National Biosafety Authority of the new information and newly identified risks and of the measures put in place to ensure the continued safe use of the genetically modified organism.

Risk management measures

98. (1) The National Biosafety Authority shall establish and maintain appropriate mechanisms, measures and strategies to regulate, manage and control risks identified in the risk assessment associated with the use, handling and import or export of genetically modified organisms

(2) Without prejudice to the generality of subsection (1) of this section, the National Biosafety Authority may take the following measures:

(a) subject any genetically modified organism to a period of observation commensurate with its life-cycle or generation time, at the cost of the original applicant, before it is put to its intended use, provided that this does not result in continuous trials in the field or contained use;

(b) restrict or prohibit the import, intentional introduction into the environment, contained use or domestic use;

(c) order the cessation of any activity that is being undertaken in violation of any of the provisions of this Act or any decisions

made under this Act;

(d) order the cessation of any activity that is shown to cause risk to human or animal health, biological diversity or the environment;

(e) subject to subsection (3), require a licensee to take such measures as may be necessary to prevent or limit any harm or damage to human or animal health, biological diversity or the environment, or to restore the environment to its previous state as far as feasible;

(f) in case of imminent and serious danger to human or animal health, biological diversity or the environment, and where immediate intervention is required, the National Biosafety Authority shall take such measures as are necessary without prior notice, and all costs and expenses shall be borne by, or be recoverable from, the licensee;

(g) require the applicant to submit reports periodically in respect of monitoring and evaluation of risks carried out after the grant of a Permit under the provisions of this Act;

(h) prohibit the import, intentional introduction into the environment or placing on the market of the genetically modified organism if the National Biosafety Authority is satisfied that it contains characteristics or specific traits which pose risks to human, animal or plant health, the environment, or biological diversity.

(3) If no action is taken within a reasonable time after notification by the licensee under paragraph (3) of subsection (2) of this section, the National Biosafety Authority may undertake the necessary measures and all costs and expenses shall be borne by, or be recoverable from the licensee.

(4) Measures based on risk assessment shall be imposed to the extent necessary to prevent adverse effects of the genetically modified organism on the conservation and sustainable use of biological diversity, taking into account risks to human health or animal health, within the country.

(5) The National Biosafety Authority shall endeavour to ensure that any genetically modified organism, whether imported or locally developed, has undergone an appropriate period of observation that

is commensurate with its life-cycle or generation time before it is put to its intended use.

Or

(1) The National Biosafety Authority shall ensure that appropriate mechanisms, measures or strategies are in place to regulate, manage and control risks identified –

(a) during the risk assessment process; or

(b) under [section….];

and shall impose such mechanisms, measures or strategies to the extent necessary to prevent adverse effects of a genetically modified organism on the conservation and sustainable use of biological diversity, taking into account risks to human health or animal health.

(2) Without prejudice to the generality of subsection (1), where on the advice of the National Biosafety Authority, the Minister is satisfied that the regulating of the discharge of genetically modified organisms into an area is necessary to prevent the adverse effects of a genetically modified organism on the conservation and sustainable use of biological diversity, taking into account risks to human health or animal health, the Minister shall by Order published in the *Gazette* declare the area to be a genetically modified control area or a genetic resource centre.

(3) An Order pursuant to subsection (2) shall specify the boundaries of the genetically modified organism control area and the genetically modified organism required to be regulated.

(4) The National Biosafety Authority shall notify the public through the media of the risk management measures taken under this section.

PART 7

EMERGENCY MEASURES AND SAFEGUARDS

Duty to Report Threatened releases of genetically modified organisms

99. (1) Where there is any significant threat that an accidental release of any genetically modified organism may occur, the owner or master of the ship, or the owner or person in charge of the facility, or the occupier of the place on land, as the case may be, shall immediately and by the quickest available means report the threatened occurrence to the National Biosafety Authority.

(2) The report required to be made under sub-sections (1) shall contain the following information -

(a) the event to which the threat is attributable;

(b) the weather, and where applicable, sea conditions at the time the report is made;

(c) the description and quantity of any genetically modified organism that may be accidentally released or may escape;

(d) the measures being taken to minimise the threat of damage that may occur.

(3) Any person who fails to comply with the requirement of sub-section (1) and (2) above, shall be guilty of an offence and liable to the penalties provided in [**Schedule 6]** of the Act.

Unintentional introduction into the environment

100. (1) A [regulatory agency] or any other person with knowledge of an unintentional or unapproved introduction into the environment of a genetically modified organism that is likely to pose [**Biosafety risks**] shall, within twenty-four hours of knowledge of the introduction, notify the National Biosafety Authority of the occurrence.

(2) A notification under this section shall include such adequate information as would enable the National Biosafety Authority to mitigate any adverse effects to both human beings and the environment.

(3) The National Biosafety Authority shall, in consultation with the regulatory agency concerned, determine whether any action is necessary to minimize any Biosafety risks.

(4) A permit holder [or any other person], with knowledge of an unintentional or unapproved introduction into the environment of a genetically 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 or animal health, shall within twenty four hours of knowing of the introduction, notify the National Biosafety Authority of the occurrence.

(5) A notification under subsection (4) shall include the following -

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

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

(c) any available information about the possible adverse effect on the conservation and sustainable use of biological diversity or risk to human health or animal health, as well as available information about possible risk management measures;

(d) any other relevant information; and

(e) a point of contact for further information.

(6) The National Biosafety Authority shall consult with the notifier to determine whether any action is necessary to minimize any adverse effect on the conservation and sustainable use of biological diversity taking into account risks to human health or animal health.

(7) Where the National Biosafety Authority determines determine that action is necessary to minimize adverse effect on the conservation and sustainable use of biological diversity taking into account risks to human health or animal health, the National Biosafety Authority shall exercise the risk management measures under Part 6 and the notifier shall take the necessary action and shall be liable for the cost of such action.

National genetically modified organisms Disaster and Risk Management Plan

101. (1) A National Accidental Release of Genetically Modified Organisms Risk Management Plan shall be drawn up by the National Biosafety Authority in collaboration with the Civil Defence Commission and additional regulatory agencies, in accordance with the provisions of any law regarding disaster risk management.

PART 8

MECHANISM FOR REVIEW OF DECISIONS

Review of decisions

102. (1) The National Biosafety Authority may, at any time, in light of new scientific information on potential adverse effects on the conservation and sustainable use of biological diversity, taking into account the risks to human health or animal health, review and change a decision regarding an import or export.

(2) Where the National Biosafety Authority reviews and changes a decision pursuant to subsection (1) of this section, the National Biosafety Authority shall, within thirty days, inform any applicant that had previously notified the import or export of the genetically modified organism referred to in such decision, as well as, the Biosafety Clearing-House, and shall set out the reasons for its decision.

(3) An applicant may request the National Biosafety Authority to review a decision it has made where the applicant considers that:

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

(b) additional relevant scientific or technical information has become available.

(4) Where a request is made pursuant to subsection (3) of this section, the National Biosafety Authority shall respond in writing to such a request within ninety days and set out the reasons for its decision.

(5) The National Biosafety Authority may, at its discretion, require a risk assessment for subsequent imports.

Applicant's Right of Appeal.

103. A person who feels aggrieved by any decision or action taken by the National Biosafety Authority, the Secretariat or an inspector in terms of 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 such decision or action to the [Environmental Appeals Tribunal established under Part VIII of the Environmental Protected Act No.11 of 1996].

Powers of the Environmental Appeals Tribunal

104. (1) On hearing an appeal under this Act, the Environmental Appeals 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.

(2) Where the Environmental Appeals 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 by the Appeals Board.

(3) In the determination of any matter, the Environmental Appeals Tribunal may take into consideration any evidence which it considers relevant to the subject of an appeal before it, notwithstanding that such evidence would not otherwise be admissible under the law relating to evidence.

(4) The Environmental Appeals 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.

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

(6) Any interested party may be represented before the Environmental Appeals 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.

(7) Environmental Appeals Tribunal may:

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

(b) refer the relevant matter back to the Secretariat for reconsideration by the National Biosafety Authority; or

(c) make such other order as it may deem fit.

(8) If a decision or action which is the subject of an appeal -

(a) is set aside, the fee referred to in sub-section (1) shall be refunded to the appellant concerned; or

(b) is amended, such portion of the fee referred to in sub-section (1) as the Environmental Appeals Tribunal concerned may determine, shall be refunded to the appellant.

(9) The decision of an Environmental Appeals Tribunal, together with the reasons therefor, shall be reduced to writing, and copies thereof shall be furnished to the Minister, whereupon the Minister may take such further action as he or she may deem necessary.

Socio-economic considerations

105. The National Biosafety Authority may in reaching a decision under this Act, take into account socio-economic considerations arising from the impact of genetically 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 9

REGISTER

Register of genetically modified organisms

106. The register of genetically modified organisms maintained by the National Biosafety Authority shall include:

(a) Name and identity of the genetically modified organism;

(b) Unique identification of the living modified organism/genetically modified organism;

(c) Transformation event;

(d) Introduced or Modified Traits;

(e) Techniques used for modification;

(f) Description of gene modification;

(g) Vector characteristics of the modification;

(h) Insert or inserts;

(i) Taxonomic name/status of recipient organism or parental organisms;

(j) Common name of recipient organism or parental organisms;

(k) Point of collection or acquisition of recipient or parental organisms;

(l) Characteristics of recipient organism or parental organisms related to Biosafety;

(m) Centre(s) of origin of recipient organism or parental organisms;

(n) Centres of genetic diversity, if known, of recipient organism or parental organisms;

(o) Habitats where the recipient organism or parental organisms may persist or proliferate;

(p) Taxonomic name/status of donor organism(s);

(q) Common name of donor organism(s);

(r) Point of collection or acquisition of donor organism(s);

(s) Characteristics of donor organism(s) related to Biosafety;

(t) Intended use of the genetically modified organism in Guyana;

(u) Receiving environment;

(v) Summary of risk assessment or environmental review;

(w) Detection/Identification method of the genetically modified organism;

(x) Evaluation of the likelihood of adverse effects;

(y) Evaluation of the consequences;

(z) Overall risk;

(aa) Recommendation on level of risk;

(bb) Actions to address uncertainty regarding the level of risk;

(cc) Availability of detailed risk assessment information; and

(dd) Any other relevant information.

Molecular/diagnostic identification of /genetically modified organisms

107. Where disputation on the accurate determination of the genetically modified trait may arise, the National Biosafety Authority may determine the minimum appropriate tests as recommended by the Biosafety Advisory Scientific Committee for independent validation or authentication of the identification of the genetically modified organism at the cost of the applicant.

PART 10

BIOTECHNOLOGY RESEARCH, INNOVATION AND DEVELOPMENT

National Policy

108. The National Biosafety Authority shall coordinate the development of a national policy to promote and regulate research and development in the field of biotechnology.

PART 11

PUBLIC ACCESS TO INFORMATION, AWARENESS AND PARTICIPATION

Public awareness and participation

109. (1) The National Biosafety Authority shall promote public awareness and education of the public and those conducting the activities subject to the Act, concerning Biosafety matters, through the publication of guidance documents and other material aimed at improving the understanding of Biosafety.

(2) The National Biosafety Authority shall give notice in the Gazette of all decisions made regarding applications for approval.

(3) Upon request, the National Biosafety Authority shall, upon payment of the prescribed fee, avail to any person copies of records kept under **[section 106**], including details of any application that do not qualify as confidential information.

(4) Any person may submit written comments on a proposed decision for any application for placing a genetically modified organism on the market, within thirty days from the date the note is posted.

Or

(1) The National Biosafety Authority shall to develop procedures to engage the public through education and awareness, through the issuance of public participation and regulatory guidelines and strategies on public engagement.

(2) The National Biosafety Authority shall promote awareness, participation and education of the public and those conducting activities concerning Biosafety matters through the publication and dissemination these Regulations and the Guidelines as well as guidance documents and any other material aimed at improving understanding of Biosafety and related authorization an notification requirements.

(3) The National Biosafety Authority shall publish, on a regular basis,

(a) notices concerning proposals on exemptions and simplified procedures, and

(b) proposed decisions on applications and petitions filed pursuant to applications for intentional introduction into the environment.

(4) On a request made by any person the National Biosafety Authority shall make available to that person, portions of an application or petition which does not qualify as confidential information.

(5) A person may submit a written comment on a proposed decision for an application for placing genetically modified organisms on the market or a petition for an exemption within sixty days from the date the notice is posted.

(6) The comments shall be considered as part of the decision-making process.

(7) A comment received by the National Biosafety Authority and a response to the comment shall be made available to the public on request.

(8) The National Biosafety Authority shall publish notices of final decision concerning the applications or petitions and notices concerning the final resolution of compliance in cases involving non-compliance with any of the provisions of these Regulations.

(9) The National Biosafety Authority shall establish and maintain a registry of

(a) genetically modified organisms for which authorization is granted by the Committee including whether the organization has been authorized for placing them on the market; and

(b) genetically modified organisms and activities which are exempted or subject to simplified procedures as determined by the National Biosafety Authority.

(10) the comments received by the National Biosafety Authority and the response shall be made available to the public on request

Regional Information sharing

110. The National Biosafety Authority shall be required to regularly update all national Biosafety information through its national and regional Biosafety Clearing-house mechanisms, at least quarterly.

International information sharing

111. (1) The National Biosafety Authority shall notify the Biosafety Clearing House that its domestic regulations shall apply with respect to any imports of genetically modified organisms to the area of national jurisdiction of Guyana.

(2) The National Biosafety Authority shall provide to the Biosafety Clearing House:

(a) A copy of this Act, including any amendments, decisions , or regulations promulgated hereunder, and any other legislation or national guidelines of relevance to the implementation of the Cartagena Protocol or the management of genetically modified organisms;

(b) Summaries of risk assessments generated;

(c) Final decisions regarding the importation or intentional introduction into the environment of genetically modified organisms;

(d) Reports concerning national implementation of the Cartagena Protocol in accordance with Article 33 of the Cartagena Protocol;

(e) Within thirty (30) days of taking a decision, a copy of the decision describing the changes to the previous decision and the reasons for the decision; and

(f) Any other information required under the Cartagena Protocol or other international agreements concerning the subject matter addressed by this Act.

(3) Where the National Biosafety Authority renders a final decision regarding domestic use, including placing on the market, of an genetically modified organism that may be subject to export for direct use as food or feed or for processing, it shall ensure that information concerning the authorization of that genetically modified organism, as specified in Annex III, is provided to the Biosafety Clearing House established under the Cartagena Protocol within fifteen (15) days of making the decision.

PART 12

MONITORING, ENFORCEMENT AND COMPLIANCE MECHANISMS

Inspections at Ports of Entry or Exit

112. (1) Every person in possession of any genetically modified organism as part of his or her personal effects or baggage, shall on arrival in or departure from [Guyana]**,** declare such possession to the Customs Officer or inspector on duty at the port of entry or exit, and shall:

(a) permit such officer to inspect and examine any genetically modified organism in their possession;

(b) afford all reasonable facilities and assistance in carrying out any inspection and examination of any genetically modified organism; and

(c) produce all permits or relevant documents in respect of the genetically modified organism.

(2) Where any person is found to be in possession of any organism that a Customs Officer or inspector has reasonable cause to believe or suspect may be a genetically modified organism, and for which there is no valid permit, that person shall surrender such organism

to the officer.

(3) Any person who fails to comply with any of the requirements of sub-sections (1) and (2) above, shall be guilty of an offence and liable on conviction to the penalties provided under [S**chedule 6]** of the Act.

(4) Any organism surrendered to a Customs Officer or inspector pursuant to the requirements of sub-section (2) above shall be immediately conveyed to the National Biosafety Authority.

(5) Should any organism surrendered to a Customs Officer or inspector pursuant to the requirements of sub-section (2) above be determined by the National Biosafety Authority not to be a genetically modified organism, such organism shall forthwith be released to the person who surrendered the specimen.

(6) Any person who has surrendered an organism pursuant to the provisions of sub-section (2) above, may apply for a permit to re-export genetically modified organism.

Confiscation of genetically modified organisms and related products

113. *(*1) Where a Customs Officer or inspector finds any genetically modified organism:

(a) in or on any ship or aircraft;

(b) at any port of entry or exit; or

(c) within any parcel, container, packing case, crate, box or package intended for import, export or transshipment, and which is being transported otherwise than in accordance with the provisions of this Act, the genetically modified organism shall be seized and forfeit to State by the Customs Officer or authorised agent, and thereafter delivered into the custody of the Secretariat of the National Biosafety Authority.

(2) Any officer or inspector seizing any genetically modified organism pursuant to the provisions of sub-section (1) above, may also seize:

(a) any container, packing case, crate, box, or other form of receptacle holding such genetically modified organism; and

(b) anything which the officer has reason to believe may be used as evidence of a breach of the provisions of this Act,

provided that the owner of the items seized under this sub-section may apply to the National Biosafety Authority for the return of any seized item that is not required for evidentiary purposes, and which does not pose any harm to Guyana's biodiversity, the environment, human health or animal health.

(3) Where proceedings are instituted within the time provided under this Act, and at the final conclusion of those proceedings the court orders the forfeiture of any genetically modified organism that was seized and detained, it shall be disposed of as the National Biosafety Authority may direct.

(4) Where the seizure and confiscation of any living modified organism has been ordered, the National Biosafety Authority shall ensure that the organism is properly cared for and housed in such a fashion such as to minimise the risk of harm to `Guyana's natural biodiversity, the environment, human health or animal health.

(5) Where the confiscation of any illegally imported genetically modified organism has been ordered, the National Biosafety Authority may, after consultation with the State where the specimen was obtained, return the genetically modified organism at the expense of such State.

(6) In any case where a genetically modified organism has been seized pursuant to the provisions of sub-section (1) above, and:

(a) the owner cannot be determined; or

(b) the specimen may die, rot, spoil or otherwise perish, the Secretariat of the National Biosafety Authority may dispose of the genetically modified organism as if it was forfeited to State.

(7) All costs and expenses of and attendant upon any disposal, housing, safe-keeping, or re-export of any genetically modified organism that has been seized shall be borne by the owner or the person who had possession thereof, and shall be recoverable from him or her as a debt due to the State, and no compensation shall be payable in respect of such seizure.

Offences and Penalties

114. (1) Any person who -

(a) contravenes or fails to comply with any condition, restriction, prohibition, reservation or directive imposed or issued in terms of this Act;

(b) obstructs or hinders any inspector in the exercise of his or her powers or the performance of his or her duties in terms of this Act or refuses to furnish information as required in terms of this Act to the Secretariat or the National Biosafety Authority;

(c) refuses or fails to furnish information or give an explanation or to reply to the best of his or her ability to a question lawfully demanded from or put to him or her by any inspector in the performance of his or her functions in terms of this Act, or furnishes information, an explanation or a reply to any inspector which is false or misleading, knowing that it is false or misleading; or

(d) falsely holds himself or herself out to be an inspector or any other officer appointed in terms of this Act, shall be guilty of an offence.

(2) A person who exports or imports any genetically modified organism in contravention of any requirement or condition specified under the Act, is guilty of an offence and liable upon conviction [**to a fine not exceeding [$1,000,000] or to imprisonment for a period of not exceeding five years, or to both such fine and imprisonment or as specified in Schedule …]**.

(3) A person who knowingly, intentionally, or with reckless disregard to human health or animal health, safety or the environment:

(a) releases any genetically modified organism that results in harm to human health or animal health or safety, or severe damage to Guyana's natural biodiversity or the environment;

(b) permits or participates in the transboundary movement of any genetically modified organism that results in harm to human health or animal health or safety, or severe damage to the environment; is guilty of an offence and liable upon conviction [**to a fine not exceeding [$1,000,000] or to imprisonment for a period of not exceeding five years, or**

to both such fine and imprisonment or as specified in Schedule …].

(4) Any person convicted of an offence under the Act and not provided under sub-sections (2) and (3) , shall-

(a) on a first conviction be liable [**to a fine not exceeding [$1,000,000] or to imprisonment for a period of not exceeding five years, or to both such fine and imprisonment or as specified in Schedule …]**.and

(b) on a second or subsequent conviction be liable [**to a fine not exceeding [$1,000,000] or to imprisonment for a period of not exceeding five years, or to both such fine and imprisonment or as specified in Schedule …]**..

Limitation period of Offences

115. 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 for the attention of the Secretariat to the National Biosafety Authority, or any regulatory agency, whichever is the later.

Continuing Offence

116. 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.

Additional Penalties

117. Where an offender has pleaded guilty to, or been convicted of an offence, the court may, 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, 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) 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;

(c) directing the offender to post such bond or pay such amount of money as may be necessary to recover charges associated with any inspection, audit or investigation undertaken in respect of the offence;

(d) directing the offender to post such bond or pay such amount of money as will ensure compliance with any order made pursuant to this section;

(e) 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;

(f) directing the seizure and forfeiture of any vessel, aircraft, or vehicle used in the commission of any offence;

(g) requiring the offender to comply with such other reasonable conditions as the court considers appropriate and just in the circumstances.

Civil Claims for Environmental Damage

118. Notwithstanding the results of any criminal proceedings arising under this Act, the Secretariat to the National Biosafety Authority, or a person who has suffered loss or harm as a result of any release of genetically modified organism may institute a civil claim for damages in any court, which may include a claim for:

(a) economic loss resulting from the release of genetically modified organisms or from activities undertaken to prevent, mitigate, manage, clean up or remediate any harm from such release;

(b) medical costs and loss of earnings associated with any human health or animal health impact;

(c) loss of earnings arising from damage to any natural resource;

(d) loss to, or of any natural environment or resource;

(e) costs incurred in any inspection, audit or investigation undertaken to determine the nature of any release of genetically modified organism, or to investigate response and risk management options.

Liability of Corporations and Corporate Directors

119. (1) Where a corporation commits an offence under this Act, any officer, director, employee or agent of the corporation who directed, authorised, assented to, acquiesced in or participated in the commission of the offence is a party to and guilty of the offence, and is liable to the punishment provided for the offence, whether or not the corporation has been prosecuted or convicted.

(2) A corporation that -

(a) has caused or contributed to any release of genetically modified organism; or

(b) owns, manages, or exercises control over any facility or land that has caused or contributed to any release of genetically modified organism, may, in addition to any penalty that may be imposed under this Act or regulations, be liable to a claim for civil damages as provided in [section 118].

Where an offence is committed by a body corporate, a person who at the time of the commission of the offence was a director, manager, secretary, or other officer of the body corporate, shall be deemed to have committed the offence, unless they prove that the offence was committed without their consent or connivance and that they exercised such due diligence as they ought to have exercised having regard to the nature of their duties to prevent the commission of the offence.

Corporate Liability in Case of Bankruptcy

120. Where any corporation commits an offence under this Act, any penalty or award of damages against that corporation shall take precedence over any secured or preferred claim lodged in any action for bankruptcy against that corporation.

Liability of Research Institutes and Board Directors

121. Where an offence is committed by a [Research Institute], a person who at the time of the commission of the offence was a director, manager, secretary, or other officer of the [Research Institute], shall be deemed to have committed the offence, unless they prove that the offence was committed without their consent or connivance and that they exercised such due diligence as they ought to have exercised having regard to the nature of their duties to prevent the commission of the offence.

Liability of Educational Institutions and Board Directors

122. Where an offence is committed by an [Educational Institution], a person who at the time of the commission of the offence was a director, manager, secretary, or other officer of the [Educational Institution], shall be deemed to have committed the offence, unless they prove that the offence was committed without their consent or connivance and that they exercised such due diligence as they ought to have exercised having regard to the nature of their duties to prevent the commission of the offence.

Proof of Offence

123. Where the inspection report of the inspector or person carrying out any inspection pursuant to the requirements of this Act, verifies that:

(a) the condition of the facility or its equipment; or

(b) the risk management measures, do not substantially meet the requirements of this Act or Regulations, or the conditions of any permit issued under the Act, and there are clear grounds for believing that the facility has caused any release of genetically modified organism, such report shall be admissible in evidence as prima facie proof of the commission of the offence, and the burden of proving, on a balance of probabilities, that the facility has not caused the release shall be upon the owner or person in charge of the facility.

Procedural aspects

124. (1) In any prosecution of an offence under this Act it is sufficient proof of the offence to establish that it was committed by an employee or agent of the accused, whether or not the employee or agent is identified or prosecuted for the offence.

(2) A certificate of an analyst stating that the analyst has analysed or examined an organism or substance and stating the result of the analysis or examination is admissible in evidence in any prosecution for an offence under this Act and, in the absence of evidence to the contrary, is proof of the facts contained in the certificate.

(3) Notwithstanding the provisions of sub-section (2), the party against whom a certificate of an analyst is produced may, with the leave of the court, require the attendance of the analysts for the purposes of cross-examination.

(4) No certificate of an analysts shall be received in evidence unless the party intending to produce it has given to the party against whom it is intended to be produced reasonable.

Cessation orders

125. (1) The National Biosafety Authority, in consultation with the **Environmental Protection Agency**, may issue an order for the immediate cessation of an approved activity, or for the immediate imposition of additional risk management measures with respect to such activity, if the National Biosafety Authority, in consultation with the relevant regulatory agency, determines that there is an imminent danger posed to the conservation and sustainable use of biological diversity, taking into account risks to the human health or animal health on the basis of -

(a) one or more tests conducted and evaluated in a manner consistent with acceptable scientific procedures;

(b) other validated scientific evidence.

(2) The National Biosafety Authority may issue a cessation order -

(a) upon the failure of any person issued with an approval to demonstrate compliance with such approval after a reasonable period of time; or

(b) in the event of non-compliance with the provisions of this Act or regulations made hereunder.

(3) A cessation order issued under this Act may be withdrawn once the National Biosafety Authority determines that sufficient information exists to permit the activity concerned to resume, or to resume in the presence of additional risk management measures, without posing a significant risk to human health or the environment.

Compensation

126 (1) The Minister may, in consultation with the National Biosafety Authority out of money voted for that purpose by Parliament, order compensation to be paid to occupiers or owners of premises in respect of healthy genetically modified organisms destroyed in order to restrict the risk to human and animal health.

(2) No compensation is payable to a person who commits an offence under this Act and claims compensation in respect of any premises or thing by means of or in relation to which the offence was committed.

PART 13

IMPLEMENTATION MEASURES

Regulations

127. (1) The Minister may make regulations to give effect to any provision of this Act, and in particular and without prejudice to the generality of the foregoing, for all or any of the following:

(a) the application and approval of, and other matters relating to the import, release, contained use, intentional release, placing on the market, of any genetically modified organism;

(b) designating any organism to which this Act applies;

(c) for the variation of any risk management regime as provided in this Act;

(d) establishing criteria, procedures and protocols for the safe destruction, temporary storage or disposal of any genetically modified organisms;

(e) establishing criteria for accreditation or approval of any biotechnology research facility;

(f) establishing the storage, handling, and laboratory practices of any biotechnology research facility;

(g) establishing sampling and analytical procedures and protocols for any risk assessment regime as provided in the Act;

(h) prescribing fees, costs, or expenses for any approvals, risk assessments, investigations, inspections, enforcement done under the Act;

(i) prescribing the labelling, identification, packaging requirements of any genetically modified organism;

(j) respecting the format or contents of any permit;

(k) to give effect to any Policy to Promote and Regulate Biotechnology Research and Development approved under the provisions of Part 8;

(l) prescribing information to be contained in an order to stop work on any development activity or undertaking;

(m) prescribing the procedures for appeal in accordance with Part 9 of this Act; and

(n) with respect to any matter necessary to carry out the intent and purpose of this Part of this Act.

(2) Regulations made under this section shall be subject to negative resolution of the National Assembly.

Transitional Provisions

128. (1) After the date of the entry into force of this Act, any activity regulated under the provisions of this Act, shall submit an application for approval of the activity in accordance with the provisions of this Act.

(2) The application referred to in subsection (1) of this section shall be submitted to the National Biosafety Authority within two months of the coming into force of this Act.

(3) If the application has been made within the time period specified in subsection (2) of this section, the activity in respect of which the application is made may continue until a decision is made by the [National Biosafety Authority] under this Act.

(4) Any application pending at the date of entry into force of this Act shall be subject to the provisions of this Act.

Amendment of Schedules

129. (1) The Minister may, by Order, from time to time amend the Schedules to this Act.

(2) [**Every Order made under this section shall be subject to negative resolution of the National Assembly.]**

Schedule 1 Regulatory Agencies

Schedule 2 Information Required In Applications For Approval Of Contained Use Activity

Schedule 3 Information Required In Applications For Intentional Release Into The Environment

Schedule 4 Information Required In Applications For Import And Export

First Schedule

Regulatory Agencies

No.11 of 1996	Environmental Protection Agency
No. 31 of 2010	National Agricultural Research and Extension Institute
No.1 of 2010	The Guyana Livestock Development Authority
No.8 of 2011	The Seed Quality Control and Certification Agency
	The Revenue Authority of Guyana
	The Guyana National Bureau of Standards
	The Civil Defence Commission
	Maritime Administration Department

INFORMATION REQUIRED IN APPLICATIONS FOR APPROVAL OF CONTAINED USE ACTIVITY

1. *Name, address and contact details of the applicant.*

2. The location where contained use activities are to be undertaken.

3. The nature and identity of genetically modified organisms to be involved.

4. The nature and purpose of the contained use activities [including such activities as storing, transporting, producing, processing, disposing or using the genetically modified organisms in any other way]

5. A description of the containment measures to be provided and the suitability of those measures for the genetically modified organisms and activities to be undertaken.

6. A description of any potential risks associated with the genetically modified organisms or the activities to be undertaken;

7. A description of remedial measures to be undertaken in the event of any accident [any unintentional introduction into the environment of the genetically modified organism that may occur as a result of the contained use].

8. country of origin;

9. place where the genetically modified organism was produced;

10. *A sworn declaration of the applicant that the above mentioned information is factually correct.*

INFORMATION REQUIRED IN APPLICATIONS FOR **Intentional Release Into the Environment**

(a) the name, address and contact details of the applicant;

(b) the name and identity of the genetically modified organism or product;

(c) the taxonomic status, common name, point of collection or acquisition, and characteristics of the recipient organism or parental organisms related to Biosafety;

(d) centres of origin and centres of genetic diversity, if known, of the recipient organism or the parental organisms and a description of the habitats where the organisms may persist or proliferate;

(e) taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism related to Biosafety;

(f) description of the nucleic acid or the modification introduced, the technique used, and the resulting characteristics of the genetically modified organism;

(g) intended use of the genetically modified organism or product, namely, processed materials that are of genetically modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology;

(h) a risk assessment report consistent with Part 6 of this Act;

(i) **any additional information the applicant deems relevant to an assessment of the potential risks or benefits of the requested activity.**

(j) suggested methods for the safe handling, storage, transport and use, including packaging, labeling, documentation, disposal and contingency procedures, where appropriate;

(k) a declaration in the prescribed form that the information in paragraphs (a)-(j) is factually correct.

INFORMATION REQUIRED IN APPLICATIONS FOR Importation or Exportation of Genetically Modified Organism

1. Name, address and contact details of the exporter.

2. Name, address and contact details of the importer.

3. Name and identity of the genetically modified organism, as well as the domestic classification, if any, of the Biosafety level of the genetically modified organism in the State of export.

4. Intended date or dates of the import or export, if known.

5. Taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or parental organisms related to Biosafety.

6. Centres of origin and centres of genetic diversity, if known, of the recipient organism or the parental organisms and a description of the habitats where the organisms may persist or proliferate.

7. Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms related to Biosafety.

8. Description of the nucleic acid or the modification introduced, the technique used, and the resulting characteristics of the genetically modified organism.

9. Intended use of the genetically modified organism, namely, processed materials that are of genetically modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology.

11. Quantity or volume of the genetically modified organism to be transferred.

12. a previous and existing risk assessment report consistent with the provisions of this Act.

13. Suggested methods for the safe handling, storage, transport and use, including packaging, labelling, documentation, disposal and contingency procedures, where appropriate.

14. Regulatory status of the genetically modified organism within the State of export (for example, whether it is prohibited in the State of export, whether there are other restrictions, or whether it has been approved for general release) and, if the genetically modified organism is banned in the State of export, the reason for the ban.

15. Result and purpose of any notification by the exporter to other States regarding the genetically modified organism to be transferred.

16. A declaration that the above-mentioned information is factually correct.

Fines and Penalties