

# National Biosafety Policy

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## Messages

## List of Acronyms and Abbreviations

AIA	Advance Informed Agreement
BCH	Biodiversity Clearing House
BSJ	Bureau of Standards Jamaica
CARICOM	Caribbean Community and Common Market
CBD	Convention on Biological Diversity
CSME	Caribbean Single Market Economy
GEF	Global Environmental Facility
GMO	Genetically Modified Organism
GMO	Genetically Modified Organism
JADF	Jamaica Agricultural Development Foundation
MICI	Ministry of Industry, Commerce and Investment
MOA	Ministry of Agriculture
MOE	Ministry of Education
MOHE	Ministry of Health and Environment
MRE	Ministry with Responsibility for the Environment
NBC	National Biosafety Committee
NEPA	National Environment and Planning Agency
NCST	National Commission on Science and Technology
NRCA	Natural Resources Conservation Authority
PCA	Pesticides Control Authority
RBA	Regional Biosafety Authority
SPS	Sanitary and Phytosanitary Measures
SRC	Scientific Research Council
TBT	Technical Barriers to Trade
TRIPS	Trade Related Aspects of Intellectual Property Rights
UNEP	United Nations Environment Programme
UWI	University of the West Indies
WTO	World Trade Organisation

## INTRODUCTION

Human kind has for centuries utilised the principles of biotechnology in the food and agricultural industries. Biotechnology – which is defined as technological applications that use biological systems and living organisms to make or modify products for human use – has generated advances in the development of medicines, foods, textiles and other every day products. With scientific advances, such as the development of DNA technology, biotechnology processes have progressed beyond traditional cross-breeding of closely related species to Modern Biotechnology. Modern Biotechnology involves the application of in vitro nucleic acid techniques and facilitates the use of genes from any class of organism as well as the development of genetically modified organisms.

Through Modern Biotechnology research new genetically modified plant or animal life forms are continually being developed for use in agriculture, horticulture, the food industry, medical research, the pharmaceutical industry etc. While these **Genetically Modified Organisms** or **GMOs**<sup>1</sup> have the potential to advance human development, the risks attendant to their use must be carefully identified and managed. These risks include possible threats to biodiversity, risks to human, plant and animal health as well as the socio-economic consequences of introducing GMOs and their derivatives into the environment or the marketplace. The process of managing these risks can be referred to as **Biosafety**.

In June 2001, Jamaica signed the Cartagena Protocol on Biosafety, a supplementary agreement to the Convention on Biological Diversity. The Protocol aims to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of Genetically Modified Organisms (GMOs), specifically focusing on transboundary movements through planned or accidental import/export.

This document constitutes the National Biosafety Policy for Jamaica. It is the product of deliberations by a range of state and non-state agencies, many of whom are represented on the National Biosafety Committee, as well as consultations with stakeholders. It sets out objectives, strategies and implementation procedures for a range of state-led activities, which together create the framework for a national biosafety regime. It addresses the safe use, transportation, storage and handling of Genetically Modified Organisms – including requirements for transboundary movement – and sets a policy framework for supporting research and public education on modern biotechnology. The policy is designed to meet not only international obligations, specifically those set out in the Cartagena Protocol on Biosafety, but also the peculiar needs and requirements of Jamaica as it seeks to benefit from the advantages of the technology.

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<sup>1</sup> These may also be referred to as Living Modified Organisms or LMOs

This policy is to be read and implemented in conjunction with a range of complementary national laws and policies<sup>2</sup>, including the National Biotechnology Policy, which creates a wider regulatory framework for the biotechnology industry. It will be further supplemented by a Biosafety Law, which is in its early stages of development.

In addition to the inputs and expertise of local stakeholders, the preparation of this policy was facilitated through technical support from the Global Environment Facility and the United Nations Environment Programme.

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<sup>2</sup> A summary of the main corollary laws is included below.

## **SITUATIONAL ANALYSIS**

### **Historical Context**

The introduction of Biosafety issues in the Jamaican policy agenda occurred in 1997 when the Jamaica Agricultural Development Foundation (JADF) requested permission for the importation of plants that were genetically engineered by a Jamaican studying in the United States. The plant was the transgenic papaya, on which research is still being conducted at the Biotechnology Centre at the University of the West Indies. The request brought awareness to the fact that there was no legislative or regulatory mechanism under which such applications could be processed.

As a precursor to the initiation of local transgenic research trials, the National Biosafety Committee (NBC) was formed as a multi-sectoral team operating under the auspices of the National Commission on Science and Technology (NCST). The NBC was given a statutory mandate under the Plants (Importation) Control Regulations (1997) and oversight responsibilities for the importation and research on transgenic plants.

Jamaica became party to the Convention on Biological Diversity on January 6, 1995 and signed the Cartagena Protocol on Biosafety on June 4, 2001. Jamaica was integrally involved in the negotiations of the text of the Cartagena Protocol, which recognizes the potential benefits of modern biotechnology while seeking to ensure the safe use, transfer and handling of its outputs, with a particular focus on the transboundary movement of Genetically Modified Organisms.

In Jamaica's preparation to ratify the Cartagena Protocol, the development of National Biosafety Framework, a National Biosafety Policy and a National Biosafety Act was initiated. The work of the NBC has been integral to this process. Its initiatives have included:

- The development of Draft Guidelines for the Release of GMOs into the Environment;
- The implementation of a public education programme on biosafety from 2001 to 2002;
- The development of a Draft Booklet on Frequently Asked Questions (FAQs) on GMOs;
- The establishment of a National Biosafety Clearing House;
- The ongoing monitoring of field trials on transgenic papaya; and
- Guiding the development of this policy.

## **Regional Context**

The process of developing and implementing Biosafety frameworks in Caribbean countries is being driven by the regional political and economic agenda and common concerns, including issues related to capacity. The agenda for Biosafety in the Caribbean region is being set by the Caribbean Community and Common Market (CARICOM), which comprises Antigua and Barbuda, Barbados, the Bahamas, Belize, Dominica, Grenada, Guyana, Haiti, Jamaica, St. Kitts and Nevis, St. Vincent and the Grenadines, St. Lucia, Suriname and Trinidad and Tobago, and also covers the Dominican Republic, which has observer status. Through the establishment of the Caribbean Single Market Economy (CSME) a legal foundation will be provided for the movement of goods, services, capital and skills among member states. The impact of the CSME will require eventual harmonization of national biosafety frameworks in CARICOM member states. CARICOM's commitment has been demonstrated in the establishment of a Working Group on Biotechnology, which will address biosafety.

Biosafety concerns throughout the Caribbean region include:

1. Threats to the small, fragile ecosystems of the small island developing states (12 of the 15 regional countries)
2. Threats to large areas of rich biodiversity (Belize, Guyana and Suriname)
3. Threats to sustainable livelihoods by agriculture and wildlife
4. Minimal capacity in biosafety
5. Inadequacy of immediate technical skills needed to implement and operate Biosafety regimes
6. Absence of Centres of Excellence in biosafety or biotechnology
7. Cross-border control
8. Public awareness and public perception

The majority of the countries of the Caribbean have endorsed a cooperative plan for the implementation of their National Biosafety Frameworks. An early component of this regional effort is expected to be the establishment of a Regional Biosafety Authority (RBA) to assist with the implementation and harmonization of national biosafety frameworks.

## **International Context**

There are several international agreements that have an impact on global Biosafety policy. While not all of these agreements have been ratified by Jamaica, they set the tone for Biosafety regulation at the national level.

### *1. The Cartagena Protocol on Biosafety*

Emerging from a Conference of Parties to the Convention on Biodiversity, it was decided by parties – including Jamaica – to develop a protocol on biosafety. The



specific emphasis of this protocol was on the transboundary movement of GMOs. This became known as the Cartagena Protocol on Biosafety and has its main objective as ensuring an adequate level of protection in the safe transfer, handling and use of Genetically Modified Organisms<sup>3</sup> that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health and specifically focusing on transboundary movements.

The protocol sets an enabling environment for regulating transboundary movement by establishing a set of procedures that both exporting and importing countries can follow. This is referred to as the Advance Informed Agreement (AIA) procedure. The Cartagena Protocol also underscores the applicability of the precautionary principle, which allows countries to take conservative, risk prevention measures in the absence of detailed scientific data on the impact that a GMO may have on human health and biodiversity.

The Cartagena Protocol does not address issues regarding national biosafety development and monitoring.

## 2. The Basel Convention

The Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal is a comprehensive global environmental agreement on hazardous and other wastes. It aims to protect human health and the environment from the adverse effects of the generation, management, transboundary movements and disposal of such wastes. The Convention came into force in 1992 and has 170 parties.

## 3. The International Plant Protection Convention

This convention sets a framework for protecting plant health by assessing and managing the risks of plant pests. This includes risks associated with GMOs and invasive species. The IPPC allows governments to take action to prevent the introduction and spread of such pests, and can thus affect the transboundary movement of any GMO that could be considered a plant pest.

## 4. The World Trade Organisation Agreements

A number of agreements under the World Trade Organization (WTO) contain provisions that are relevant to biosafety, including:

- Agreement on the Application of Sanitary and Phytosanitary Measures
- Agreement on Technical Barriers to Trade

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<sup>3</sup> Note however that the Cartagena Protocol uses the alternate term 'Living Modified Organisms'

- Agreement on Trade-Related Aspects of Intellectual Property Rights

### *Related International Organisations*

In addition to the treaty bodies monitoring each of the above agreements, there are other global entities whose work impacts on Biosafety issues. These include the following:

#### 1. The Codex Alimentarius Commission

This commission addresses food safety and consumer health, and has established an ad hoc Intergovernmental Task Force on Foods derived from Biotechnologies. The Task Force develops standards and guidelines for GMOs in food products, including the issues of labelling and consumer information.

#### 2. The World Organization for Animal Health

This organisation addresses the international trade in animals, animal genetic material and animal products, and seeks to prevent the introduction of infectious agents and diseases in the course of such trade.

## **Legislative and Policy Environment**

There are several pieces of legislation that currently affect some aspects of biosafety. The following national polices, laws and regulations are relevant.

### *Laws*

**The Plants (Quarantine) Act, 1994:** This law regulates the importation of plant species and establishes controls on plant pests. In addition to quarantine procedures, the Act empowers the Minister to prohibit the importation of any plant, article or thing from any country, where he is satisfied that plant pests may be introduced into the island. This would apply to any GMO that can be classified as a 'plant pest'.

**Plants (Importation) Control Regulations, 1997 under the Plants (Quarantine) Act, 1994:** This is currently the only legal instrument that directly addresses the issues of biosafety. This was enacted in 1997 and amended in 2005. Under these regulations the National Biosafety Committee is legislated to monitor the importation of any plant, seed, cutting or slip, which has been genetically modified and imported into Jamaica for the purpose of experimentation. The NBC has thus been monitoring both the importation of transgenic material as well as experimental transgenic trials being conducted in Jamaica.

**The Animals (Diseases and Importation) Act, 1948:** This act subjects imported animals, birds, reptiles and insects to a quarantine procedure.

**The National Resources Conservation Authority (NRCA) Act, 1991:** This Act establishes the NRCA, which has among its functions the capacity to take necessary steps to manage the physical environment of Jamaica so as to ensure the conservation, protection and proper use of its natural resources. The scope of its statutory mandate is sufficiently broad to cover Biosafety issues and the possible impact of GMOs on human health and biodiversity.

Through the Environmental Permit and Licence system, the NRCA monitors the impact of industry on the environment. One category of activity that the NRCA is thus required to regulate is the introduction of species of flora, fauna and genetic material into the environment.

Related laws include the Wildlife Protection Act, 1945 and the Endangered Species (Protection, Conservation and Regulation of Trade) Act, 2000.

**The Food and Drugs Act, 1975:** This law regulates the importation, sale, labelling, packaging and advertising of food and drug products. Through this law, as well as the **Pharmacy Act, 1975** the importation or sale of GMOs in the form of pharmaceutical products may be restricted.

**The Pesticides Act, 1975:** This law regulates the importation, manufacture, sale, labelling and use of pesticides, and may thus affect GMOs being utilised for pest control purposes.

### *Policies*

**Biotechnology for Socio-economic Development: A Policy for Jamaica (Draft 2006):** This policy focuses exclusively on biotechnology, including research and development activities. The Draft Biotechnology Policy is currently at the stage of Public Consultations.

**Science and Technology Policy (1990):** This policy recognizes biotechnology as a priority area, particularly as regards agricultural, crop and animal production as well as research and development activities. It recognizes the need to manage the use of the island's biological resources and to build additional capacity in biotechnology. The Science and Technology Policy is currently being revised for upgrading to reflect current issues.

**The National Biosafety Act (proposed):** Drafting instructions are being prepared for legislation on biosafety to complement this policy.

In addition to those listed above, there are other laws and policy that are indirectly relevant to a biosafety framework. These laws, and the departments that implement or enforce them, are listed in Table A.

## **Current Programmes & Institutional Arrangements**

The National Biosafety Committee is the core local institution with direct oversight on biosafety issues. The institutions that are represented on the Committee include government ministries and agencies, as well as academic and research institutions.

The Ministry of Health and Environment has policy oversight on environmental issues including the protection of biodiversity.

The National Commission on Science and Technology has responsibilities for various aspects of the field of science, and provides oversight to the NBC.

*Table A: Ministries and Agencies Implementing Biosafety-Related Laws and Policies*

<b>Ministry and/or Agency</b>	<b>Instrument</b>
The Ministry of Agriculture	<ol style="list-style-type: none"> <li>1. Plant Quarantine Act</li> <li>2. Animals (Disease and Importation) Act</li> </ol>
The National Environment and Planning Agency	<ol style="list-style-type: none"> <li>1. Natural Resources and Conservation Authority Act.</li> </ol>
The Ministry of Health <ul style="list-style-type: none"> <li>➤ Pharmacy Council</li> <li>➤ Pesticides Authority</li> </ul>	<ol style="list-style-type: none"> <li>1. Food and Drugs Act</li> <li>2. The Pharmacy Act</li> <li>3. The Pesticides Act</li> <li>4. The Public Health Act</li> </ol>
The Ministry of Industry, Commerce and Investment <ul style="list-style-type: none"> <li>➤ Scientific Research Council</li> </ul>	<ol style="list-style-type: none"> <li>1. The Standards Act</li> <li>2. The National Science and Technology Policy</li> </ol>
The Ministry of Foreign Affairs and Foreign Trade	<ol style="list-style-type: none"> <li>1. Cartagena Protocol on Biosafety</li> <li>2. Convention on Biological Diversity</li> <li>3. WTO Agreements</li> <li>4. Other related conventions</li> </ol>
Customs Department	<ol style="list-style-type: none"> <li>1. Plant Quarantine Act</li> <li>2. Animals (Disease and Importation) Act</li> </ol>

The Ministry of Agriculture, through its Plant Quarantine Division, is engaged in the monitoring and enforcement of existing biosafety-related laws and policies. Its Veterinary Services Division regulates the importation of animal species. Both divisions – in collaboration with the Customs Department – are indirectly involved in regulating the transboundary movement of Genetically Modified Organisms.

The National Environment and Planning Agency assists in the implementation of the regulatory framework for environmental protection under the Natural Resources Conservation Authority.

Various tertiary and research units, including departments within the University of the West Indies, the Scientific Research Council, the College of Arts, Science and Education, Northern Caribbean University, the Dairy Industries and the Coconut Industry Board are engaged in or connected with the development or application of biotechnology research.

The Jamaica Bureau of Standards and the Consumer Affairs Commission, respectively regulate and monitor the application of standards to different aspects of trade and commerce.

The Institute of Jamaica currently manages a national Biosafety Clearing House, which interfaces with the international Biosafety Clearing-House established under the Cartagena Protocol and facilitates the exchange of Biosafety information among countries.

## VISION AND VALUES

### *Vision Statement*

Jamaica is provided with an enabling environment for the safe development, use and application of modern biotechnology, resulting in minimal risks to human health and biodiversity and maximum benefits to agricultural, scientific and industrial development.

### *Principles and Values*

As the vision statement suggests, this policy is premised on an approach to biotechnological development that balances possible risks against potential benefits. The principles and values that will underlie the interpretation and implementation of this policy are outlined as follows:

**The Precautionary Approach:** Where there are threats of serious or irreversible damage to human health or the environment, lack of scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.

**Primacy of Public Health:** The economic benefits that could potentially result from the development or importation of GMOs and derived products will be weighed against their impact on public health. The primacy of public health considerations should translate into the imposition of conditions and restrictions where necessary and the strict enforcement of all aspects of this policy.

**Enabling Environment for Resource Development:** The local development and promotion of modern biotechnology is critical to Jamaica's advancement and its future positioning in an evolving global marketplace. The local biotechnology industry will be facilitated to the extent of available resources. The implementation and monitoring of biosafety standards will assist in creating an enabling environment for biotechnology.

**Shared and Accessible Benefits:** Measures will be established to ensure the equitable sharing of benefits arising from the use of modern biotechnology across various sectors and industries.

**Public Awareness and Participation:** The right of the public to make informed choices on their level of exposure to or consumption of GMOs and derived products will be fulfilled and protected. The public's civic right to participate in policy development and transparency in decision-making will also be accommodated.

## **POLICY GOAL AND OBJECTIVES**

### ***Goal***

To provide, through the establishment and monitoring of standards, a safe and enabling environment for the development, transboundary movement, handling and use of genetically modified organisms, while managing risks to human health and biodiversity.

### ***Objectives***

The main objectives of the National Biosafety Policy are:

1. To ensure the effective regulation and management of the importation, exportation and transboundary movement of GMOs, in keeping with international standards.
2. To ensure that the possible negative effects of GMOs on human health and biodiversity are effectively managed.
3. To regulate the labeling of GMOs.
4. To facilitate public awareness and participation in biosafety policy implementation and transparency in decision-making.
5. To increase the capacity of national institutions to implement and monitor a national framework for biosafety.

## **IMPLEMENTATION STRATEGIES**

The approach to implementation will be multi-sectoral, involving the collaboration and input of the Ministry with Responsibility for the Environment (MRE), which at the time of preparing his policy is the Ministry of Health and Environment (MOHE), the Ministry of Agriculture (MOA), the Ministry of Industry, Commerce and Investment (MICI), the Ministry of Education (MOE) as well as the Customs Departments and ports of entry.

The lead implementing agency will be the Ministry with Responsibility for the Environment. Coordination, enforcement and monitoring will be overseen by the National Biosafety Committee, a multi-sector body in which many of the other implementing agencies are represented. Other specific implementation functions will be integrated into the related mandates of a range of government entities. Organisations that benefit from government funding and/or regulation, in particular universities and research entities, will also be involved in implementing the relevant biosafety strategies. Particulars of implementation are further outlined in the next section.

The strategies for implementing each objective are set out as follows.



**Objective 1: Ensure the effective regulation and management of the importation, exportation and transboundary movement of GMOs, in keeping with international standards.**

The Cartagena Protocol provides global standards for regulating the transboundary movement of GMOs. The implementation of its provisions facilitates synchronicity between the local regulatory environment and that which exists in other markets/jurisdictions. In the identification of strategies to fulfill this objective, aspects of the Cartagena Protocol related to the following areas will be applied:

- Transboundary movement of GMOs
- Notification procedures
- Decision-making procedures
- Unintentional and illegal transboundary movement
- GMOs in transit
- Information sharing

*Implementation Strategies and Procedures*

1. **The MRE** is the policy authority that establishes procedures for regulating the trade and transboundary movement of GMOs, and may expand or amend the following policies and procedures from time to time.
2. **The NBC** will recommend, monitor and keep under review procedures for regulating the transboundary movement of GMOs, including but not limited to the procedures set forth below.
3. Prior to the first intentional transboundary movement (i.e. exportation or importation) of a GMO, the following requirements must be fulfilled, in keeping with the 'Advance Informed Agreement' (AIA) requirements under the Cartagena Protocol :
  - a. **The exporter** shall submit written notification to the competent national authority of the destination country. The written notification shall be in the format required by the country of destination, and shall contain all the information required by the Cartagena Protocol<sup>4</sup>.
  - b. For a product being exported from Jamaica, the information given in a notification must be verified by **the MRE** prior to submission to the country of destination.
  - c. For products being imported to Jamaica, the 'competent national authority' for receiving and reviewing notifications shall be the **MRE**, or its designate.

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<sup>4</sup> See Annex 1 of the Cartagena Protocol

- d. Having received a notification from a prospective importer, the **MRE** will acknowledge receipt in writing within 90 days, stating:
    - i. The date of receipt
    - ii. Whether the notification contains the required information
    - iii. The decision-making procedure for consenting to or prohibiting the importation of the GMO
  
  - e. Within 270 days of acknowledging such notification, **the MRE** shall submit its written decision, which may fall within any of the following categories:
    - i. Unconditional approval.
    - ii. Conditional approval, including, where applicable, requirements, guidelines or timelines for meeting such conditions.
    - iii. Prohibition of the importation of the GMO.
    - iv. A request for additional information.
    - v. An extension of the review period by a stated number of days.Except in the case of an unconditional approval, **the MRE** shall submit reasons with its decision.
  
  - f. **The MRE**, with the advice of **the NBC** and with reference to the Cartagena Protocol, shall determine the range of factors to be considered in reviewing an application for the importation of an GMO. Such factors shall include, but not be limited to, the available scientific data on the GMO, the possible adverse effects on biodiversity and the potential socio-economic impact of introducing the GMO into the environment. Conditions may be imposed (among other things) to mitigate or control potential risks.
  
  - g. **The MRE** may delegate some or all of its functions in this section to a competent agency within the public sector, provided that it shall maintain oversight over such delegated functions.
4. **The MRE** retains the right to waive the 270 day waiting period and to allow immediate importation of a GMO pending the consideration of a notification. The MRE may also designate GMOs that are exempt from its Advance Informed Agreement procedure. Such waiver or statement of exemption must be made in writing and shall, for the purposes of importation, serve the same function as an approval.
5. Subsequent transboundary movements of the GMO must be in compliance with the provisions of this policy, as well as the conditions (if any) imposed on its approval.

6. No GMO shall be allowed entry into the island without documentary evidence of the relevant ministerial approval. **The Customs Department** shall put measures in place to facilitate and enforce this prohibition.
7. **Notwithstanding** any statement made in this policy or in a grant of approval, waiver or statement of exemption, **the MRE** retains the right to suspend or prohibit the further importation of any GMO on any of the following grounds:
  - a. New scientific evidence has revealed potential harm that was not considered at the time of approval.
  - b. The importer's persistent non-compliance with conditions of approval.
  - c. The importer's failure to give full and frank disclosure in the notification.
  - d. The importer's attempt to import additional GMOs without ministerial approval.

In every such case, **the MRE** shall notify the affected importer or importers, giving reasons for the Minister's decision.

8. The approval procedures governing importation of GMOs shall not apply to GMOs being held in transit to another destination country, provided that procedures for the use, handling, storage and transportation of such GMOs shall comply with the requirements of this policy.
9. In the event that there is a significant risk or occurrence of unintentional or illegal transboundary movement of GMOs outside of Jamaica, **the MRE** shall inform **the Biosafety Clearing-House** housed within the **Institute of Jamaica** (see below) as well as each national competent authority of the likely destination countries.
10. All decisions made under these procedures shall be recorded by **the Institute of Jamaica**, which shall perform the function of a national biosafety information clearing-house. The Institute shall, in compliance with the Cartagena Protocol, forward relevant information to the international Biosafety Clearing-House, in such format as is required.

**Objective 2: Ensure that the possible negative effects of GMOs on human health and biodiversity are effectively managed.**

*Overview*

The potential adverse effects that GMOs may have on biodiversity and natural ecosystems must be identified, evaluated and risks mitigated. Such evaluations will take into account the possible effects of use or exposure on human health, and will reflect the standards and guidelines developed by international organisations. The management of risks is related not only to the external trade and transboundary movement of GMOs, but to activities within the local biotechnology industry.

In addition to the biodiversity impact of introducing a GMO into the environment, changes wrought by such an introduction can have strong effects on local communities and industries. These effects can be of great consequence and should guide the framework for introducing a GMO into the environment and/or market.

In order to manage the interface between GMOs and the human and physical environment, safety procedures must be observed by every organisation whose personnel come into physical contact with GMOs. These should include general guidelines applicable across different industries, as well as specific procedures tailored to each individual organisation.

This policy objective will be implemented under three main headings:

- A. Risk Management
- B. Assessment of Socio-Economic Impact
- C. Promotion of Safe Practices

*Implementation Strategies*

**A. Risk Management**

1. **The NBC** will develop, and continually update, risk assessment procedures applicable to the importation, use, handling, research and development of GMOs. Risk assessment procedures will be developed and implemented in a scientifically sound manner and will reflect international standards, particularly those set out in the Cartagena Protocol.
2. A risk assessment shall be undertaken by the **MRE** (or a designated agency), prior to granting any approval related to the use, handling or transboundary movement of a GMO. This shall for the time being include approvals regarding the importation of GMOs.
3. Risk assessments may also be undertaken at any time on the subject matter of modern biotechnology research being conducted by locally-based tertiary or

scientific institutions. Notwithstanding the existence or outcomes of previous assessments, a risk assessment should always be conducted immediately prior to the first release of a GMO into the environment.

4. In making its determination in relation to granting any approval related to the use, handling or transboundary movement of a GMO, the MRE (or its designate) will weigh the outcomes of a risk assessment against:
  - a. The relative impact of or risks associated with similar, non-modified organisms; and
  - b. The social or economic impact that is likely to result from the introduction of the GMO into the environment.
5. The cost of conducting a risk assessment shall be borne by the party whose products, research or systems are being assessed.
6. The risk assessment may, at the request or on the approval of the MRE, be conducted by any competent public or private entity.
7. Where there is insufficient data to carry out a thorough assessment of risks, the MRE may apply the 'precautionary principle' in its decision-making.

## **B. Assessment of Socio-Economic Impact**

1. **The MRE** may restrict, prohibit or attach conditions to the use or introduction of a GMO into the environment and/or market where it appears that such use or introduction is likely to result in significant, adverse socio-economic impact.
2. **The NBC** shall set parameters for the socio-economic impact assessment of a GMO. In so doing the NBC shall be guided by, among other factors, the extent to which the use (including illicit or off-label uses) or introduction of the GMO poses a threat to:
  - a. The livelihood of a local community;
  - b. A practice that is considered part of the national culture or heritage; or
  - c. Human health.
3. Any organisation, community or group of persons claiming the adverse potential or actual effects of the use or introduction of a GMO shall make a submission to the MRE that clearly sets out:
  - a. The nature of the adverse effects of the use or introduction of the GMO;
  - b. Evidence of the causal links between the GMO and such effects; and
  - c. Recommended restrictions on the use or introduction of the GMO.

### C. Promotion of Safe Practices

1. **The NBC** will develop guidelines for the development and implementation of internal safety procedures for public or private organisations engaged in modern biotechnology research or the use, transportation, storage or handling of GMOs.
2. Every **publicly funded programme** engaged in modern biotechnology research or whose personnel are engaged in the use, transportation, storage or handling of GMOs shall develop and implement internal safety procedures. Programmes to which this section is applicable shall include, but not be limited to, the following:
  - a. Tertiary institutions receiving government grants or subventions
  - b. Departments and agencies under the **MOHE, MICI, MOA, MOE** or any other line ministry, in which personnel are directly exposed to GMOs.
  - c. **Customs Department** and ports of entry.
3. As a precondition to the approval of grants, incentives or other forms of state support to **private organisations** or the entry into public-private partnership with any **tertiary or scientific research institution**, such organisations or institutions shall be required to develop internal safety procedures reflecting the guidelines developed by the NBC.
4. Safety procedures should, among other things, provide for the accurate labeling and identification of GMOs (as further detailed below) and should endeavour to limit the possibility of accidental introduction of the GMO into the environment.
5. Safety procedures must also set guidelines for their monitoring, enforcement and compliance management. These should include:
  - a. Provisions for the wide dissemination of the procedures among personnel;
  - b. Orientation protocols for new personnel;
  - c. Intermittent process audits; and
  - d. Penalties for procedural breaches.

### Objective 3: Regulate the labeling of GMOs.

In keeping with the requirement for safe use and handling of GMOs, as well as the requirement of keeping the public informed on the nature and characteristics of GMOs to which it is exposed, standards for the labeling of GMOs must be carefully developed and monitored. Such information is important, not only for GMOs being introduced to the market, but also for GMOs being stored, transported or displayed for research or informational purposes, as well as GMOs being brought into the island for aid relief.

#### *Implementation Strategies and Procedures*

1. **The NBC** in collaboration with **the Bureau of Standards** will put in place from time to time standards for the labeling and identification of GMOs. In developing these standards, the NBC will take into account the labeling and packaging requirements under the Cartagena Protocol, as well as those proffered by other international bodies. The NBC will from time to time consult with **the Bureau of Standards** and **the Consumer Affairs Commission** to keep such standards updated and relevant.
2. All relevant monitoring bodies, including **the Bureau of Standards, the Consumer Affairs Commission, the National Environment and Planning Agency, the Customs Department** and departments under **the Ministry of Agriculture** shall incorporate such labeling and identification standards in their ongoing monitoring regimes.
3. At a minimum, the standards for labeling GMOs will include the following requirements:
  - a. All GMOs, whether in storage, in contained use, being transported, on the market, on display or which may otherwise be exposed to the public, should be clearly marked with language to the effect that it:
    - i. Contains or may contain Genetically Modified Organisms
    - ii. (Unless such release has been approved) is not intended for release into the environment.This information should be included in labels, packaging and signage, as well as in documentation accompanying the GMO.
  - b. Labels, packaging and signage for GMOs being stored, transported, displayed or distributed should also contain the following information:
    - i. The identity and relevant traits or characteristics of the GMO;
    - ii. Instructions for safe use, storage, transportation or handling;
    - iii. Instructions for preventing the unintentional release of the GMO into the environment; and

- iv. The name and contact information of the owner, distributor, importer, exporter, any party having custody of or responsibility for the GMO or any party authorised to give further information on the GMO.
- c. A GMO that is being imported or exported should also be labeled with a declaration that the transboundary movement of the GMO is in compliance with the standards of the Cartagena Protocol.
- d. All labels, packaging and signage for GMOs shall be:
  - i. In English;
  - ii. Written or typed in a clear, legible font; and
  - iii. Conspicuously placed.



**Objective 4: Facilitate public awareness and participation in biosafety policy implementation and transparency in decision-making.**

As one of the principles on which any national biosafety regime is based, the responsibility for informing the public on biosafety and modern biotechnology must be executed through ongoing and multi-sectoral initiatives. In keeping with the policy of the Government of Jamaica to integrate public consultations on all major policy decisions, the participation of the public in biosafety policy and decision-making will also be accommodated to ensure transparency.

*Implementation Strategies and Procedures*

1. The **MRE**, through **the National Environment and Planning Agency** and in collaboration with **the NBC** will develop and implement a Public Education Campaign on Biosafety, which shall include but not be limited to:
  - a. FAQs, brochures and other easily distributed materials explaining the characteristics and principles of biosafety and biosafety policy in simplified language.
  - b. Publication of this Biosafety Policy and related information in booklet format, to facilitate wide distribution throughout the public sector and among tertiary and scientific organisations engaged in modern biotechnology research.
  - c. Documentation of all forms, standards, guidelines and protocols related to biosafety and modern biotechnology, for print and electronic access by the public.
  - d. Stakeholder awareness-building fora, to be conducted islandwide.
  - e. Personnel training sessions to be conducted within all public and private entities that will have direct input in the implementation of this Biosafety Policy.
2. The **MOA**, **the MOE**, **the MICI**, **the Bureau of Standards**, **the Consumer Affairs Commission** and **the Customs Department** will, where relevant, incorporate relevant information from this Biosafety Policy in their public education materials or activities.
3. The **MRE** and **the NBC** will lobby for the inclusion of information on modern biotechnology and this Biosafety Policy in:
  - a. The public education campaigns of all public and private entities involved in public awareness building on issues related to science, the environment, agriculture and consumer protection.
  - b. The curricula of vocational or tertiary institutions conducting training in the science, environmental or agricultural fields.

**Objective 5: Increase the capacity of national institutions to implement and monitor a national framework for biosafety**

The effective implementation of this policy will require the upgrading of technology and human resources in all government entities involved in the process. This will require the commitment of the heads of such ministries and agencies to build internal capacity, to the extent of available resources.

While several agencies may integrate this policy into existing operations through adjustments to procedures and training of staff, investment in equipment and technology is required for other responsibilities. In particular, the capacity to identify GMOs in food, plant, animal and other products that are being imported, or which are the subject of research, will require such investment.

*Implementation Strategies and Procedures*

1. **The MRE** and all implementing agencies will include in their annual plans and programmes strategies to support and facilitate biosafety, through capacity development, knowledge transfer and the acquisition of technological resources and equipment, requisite to their respective mandates under this policy.
2. **The MRE** as the policy authority with responsibility for biosafety, and in conjunction with the **National Council for Science and Technology**, shall strengthen the capacity of **the NBC** to monitor and oversee the implementation of this policy.
3. The implementation of this policy requires the capacity to test food, plant, animal and similar products which are being imported *or* the subject of research in order to identify the existence of GMOs. **The MRE**, in conjunction with **the MOA** and **the Customs Department** shall build the capacity for such testing, through the acquisition of equipment and the training of staff.
4. **The NBC** will maintain a database of all projects and initiatives involving modern biotechnology research or the use of GMOs.

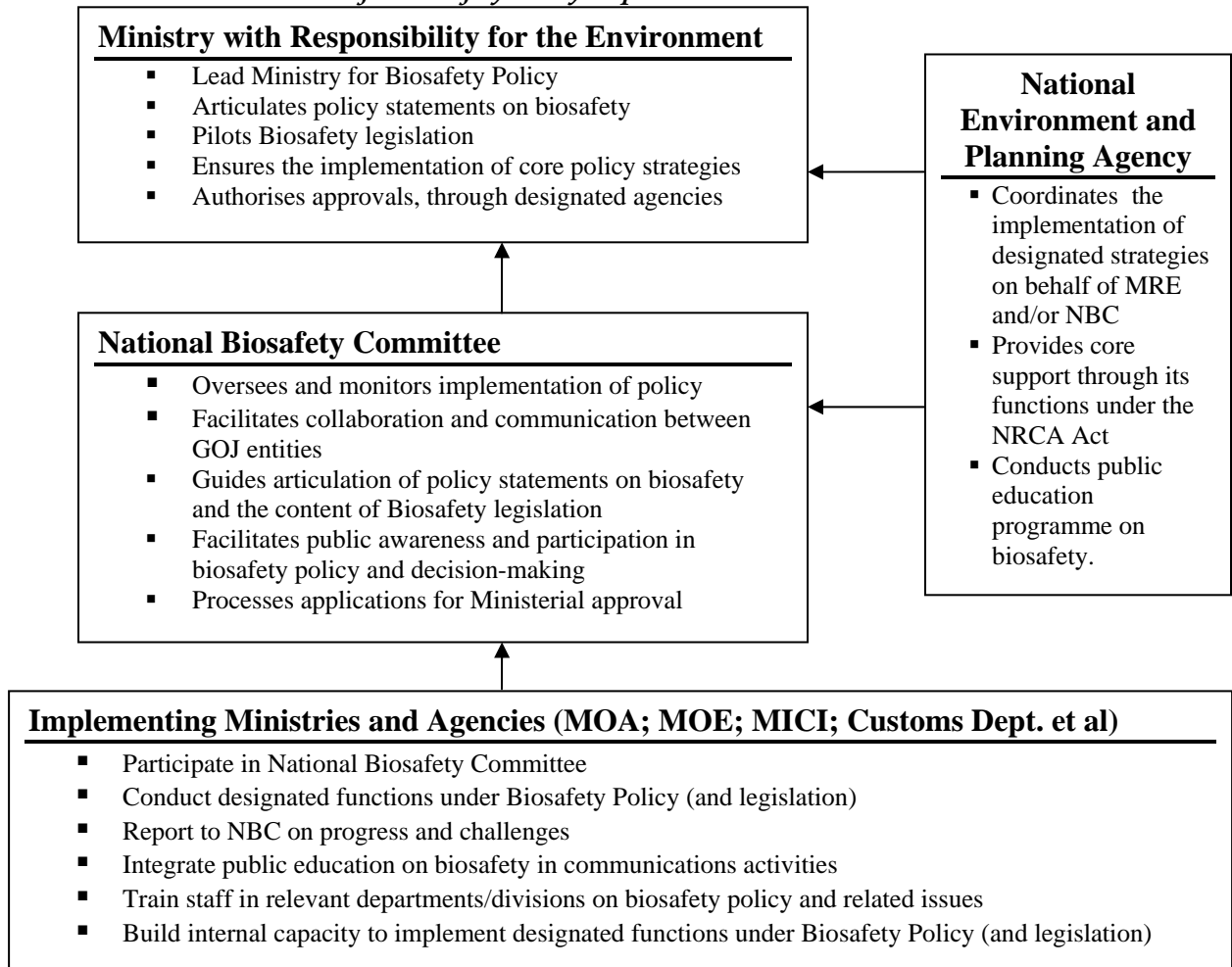
## FRAMEWORK FOR IMPLEMENTATION AND MONITORING

The full implementation of this policy requires the clear delineation of responsibilities and the cross-departmental coordination of a range of public sector agencies.

### Implementation Framework

Figure 2 below sets out the institutional framework within which this policy will be implemented.

*Figure 2: Institutional Framework for Biosafety Policy Implementation*



As Figure 2 shows, there are three levels of implementation. The Ministry with Responsibility for the Environment, currently the Ministry of Health and Environment, is the lead policy authority on biosafety issues. The National Biosafety Committee gives more direct oversight to the implementation process, and is directly involved in the implementation of some activities, such as public education or

processing approvals. The Implementing Agencies fall within the third level. Collectively they form the NBC; individually they each have implementation responsibilities for the aspect of this policy that intersects with their mandate. Figure 3 gives a summary of the agencies named as implementers of this policy and the objectives with which each is associated.

The National Environment and Planning Agency plays a critical part in the process. While being an implementing agency in its own right, NEPA provides support to the leading roles performed by the MRE and the NBC respectively.

*Figure 3: Implementing Agencies for Biosafety Policy Objectives*

IMPLEMENTING AGENCY	OBJECTIVES				
	1	2	3	4	5
Agriculture, Min.					
Agriculture, Min.: Plant Quarantine Division					
Agriculture, Min.: Veterinary Services Division					
Agriculture, Min.: Bodles Research Station					
Bureau of Standards					
Consumer Affairs Commission					
Customs Department					
Education, Min.					
Health and Environment, Min.					
Industry Commerce and Investment, Min.					
Institute of Jamaica					
National Biosafety Committee					
National Environment and Planning Agency					
Scientific Research Council					

**Implementation Mechanisms**

The following measures will be used to facilitate and monitor the seamless implementation of this policy. Their implementation will be led by the NBC, but will involve consultation with key implementation agencies and stakeholders, as needed.

1. **Annual Implementation Plans** will be developed by the NBC, in consultation with all implementing agencies and departments. This will involve the identification of priority activities, projected targets and measurement indicators for each policy objective.
2. **Monthly Reports** will be submitted to the NBC by each implementing agency, summarising progress achieved as well as challenges encountered.

The NBC will facilitate collaboration between departments to remove roadblocks and improve efficiency.

3. **Guidelines** will be developed as needed by the NBC, in consultation with relevant implementing agencies and stakeholders, to clarify any aspect of this policy that requires further elaboration in order to streamline the implementation process.
4. **Knowledge Management** remains a part of the NBC's coordinative function, as it facilitates the cross-departmental dissemination of information, sharing of best practices etc.
5. **Law and Policy Reviews** will be conducted by the NBC on a biannual basis, to assess the adequacy of the legal and policy framework for Biosafety and make submissions to relevant Ministries regarding the laws and policies to be amended or updated. This shall include submissions to the Ministry of Finance regarding the adequacy of budgetary allocations to relevant public sector agencies/initiatives.