

DRAFT

# NATIONAL BIOSAFETY POLICY

Prepared By

National Biosafety Committee

**Dated: 08 October 2006**

**CONTENT**

	<b>Section</b>	<b>Page</b>
<b>1</b>	<b>INTRODUCTION</b>	<b>3</b>
<b>2</b>	<b>JUSTIFICATION</b>	<b>4</b>
<b>3</b>	<b>SCOPE</b>	<b>5</b>
<b>4</b>	<b>POLICY FRAMEWORK</b>	<b>6</b>
<b>5</b>	<b>STRATEGY</b>	<b>8</b>
<b>6</b>	<b>INDICATORS OF PERFORMANCE</b>	<b>10</b>
	<b>ANNEX: DEFINITIONS/GLOSSARY OF TERMS</b>	<b>11</b>

## 1 INTRODUCTION

Biotechnology refers to any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use. It has been used to describe the use of biology in industrial processes such as agriculture, brewing and drug development. Traditional applications include plant and animal breeding, brewing beer with yeast and cheese making with bacteria and meristem plant production through tissue culture. Over recent years, however, **modern biotechnology** has revolutionized ability to alter life-forms through applying *in vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cell or organelles, or fusion of cell beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection. Combining genes from different organisms is known as recombinant DNA technology, and the resulting organism is said “genetically modified”, “genetically engineered”, or “transgenic”.

Modern biotechnology has the potential to bring about dramatic changes to address food and health related issues. While conventional biotechnology has been in use for a long time, modern biotechnology (**genetic modification**) is relatively new and is being increasingly used in the production of food, fibers, fuel, food stocks and pharmaceuticals.

Despite its potential for addressing agricultural, environmental and health issues, the need to detect and to protect humans and other natural resources from possible adverse effects of modern biotechnology have made it an issue of growing international concern. The use of genetic modification therefore must be weighed against all known and unknown risks, and must be overall judicious. An appropriate regulatory framework which provides for credible and effective safeguards, sustainable, consistent across relevant sectors and which is practical to implement is thus the only prudent means of maximizing the benefits of biotechnology while minimizing the risks.

**Biosecurity** is generally understood to mean all policies and regulatory framework to manage the biological risks associated with food and agriculture, including relevant environmental risks. **Biosafety** is a biosecurity measure to protect human health and the environment from the possible adverse effects of the products of modern biotechnology.

At the 1992 Earth Summit in Rio de Janeiro, Brazil, world leaders agreed on a comprehensive strategy for "sustainable development" - meeting our needs for health, environment and biodiversity while ensuring that we leave a healthy and viable world for future generations. One of the key agreements adopted at Rio was **Convention on Biological Diversity (CBD)** which establishes three main goals: the conservation of biological diversity, the sustainable use of its components, and fair and equitable sharing of the benefits arising from the use of genetic resources.

Article 28 of the Convention on **Biological Diversity** provides for the formulation of Protocols to address the implementation of various aspects of the Agreement. Modern

biotechnology is an issue of growing international concern related to the need to protect human health and the environment from its possible adverse effects, whilst recognizing its great potential for addressing the World's critical needs for food, agriculture and health care. As a result **Cartagena Protocol on Biosafety (CPB)** was adopted in Montreal on the 29<sup>th</sup> January 2000 at an extraordinary meeting of the Conference of the Parties to the Convention on Biological Diversity.

The Cartagena Protocol on Biosafety makes provisions to regulate, manage or control risks associated with transfer, handling and use of organisms resulting from modern biotechnology that may have adverse effects on conservation and sustainable use of biological diversity focusing on their trans-boundary movement.

Belize signed to the Convention on Biological Diversity on June 13<sup>th</sup> 1992 and ratified it on December 30<sup>th</sup> 1993. With regards to the Cartagena Protocol on Biosafety, Belize ratified to this Protocol on February 12<sup>th</sup> 2004 and is a party by accession since May 12<sup>th</sup> 2004. As a signatory to the CBD and CPB Belize is obliged to implement the articles of the CPB and develop its own national regulatory framework for the safe transfer, handling, use and release of **genetically modified organisms (GMOs)** and products resulting from modern biotechnology.

## 2 JUSTIFICATION

Biotechnology brings with it a number of potential risks. However, it should not be construed that because there is potential risk that the problem associated with the risks will materialize. With our current knowledge, the potential risks associated with the application of modern biotechnology can be categorized into human, plant and animal health risks, risks associated with the conservation of biodiversity and agricultural sustainability, and ethical and socio-economic risks.

Potential risks associated with human, animal and plant health include expression levels of the protein at different growth stages as well as different organs, foreign protein levels in food derivatives, the potential for toxicity, pathogenicity and allergenicity. Other factors would include unexpected products and effects, changes in nutrition, composition, digestibility and digestion products.

Factors that could have an adverse impact on biodiversity are unexpected persistence of the gene or transgene in the environment, volunteers, transgene products, susceptibility of non-target organisms. Agriculture production sustainability could be compromised by the development of resistant, unmanageable pests through gene transfer or natural selection if production protocols are not strictly regulated.

Ethical and socio-economic issues include the value of biological diversity including indigenous germplasm to local communities as well as potential loss of export opportunities vis a vis the regulatory trade environment. The government has the obligation to ensure that the production and use of genetically modified organisms and

the production of cloned animals take place in an ethically and socially acceptable manner.

Any development, application and release of GMOs must be conducted in manner that will ensure the conservation and sustainable use of natural resources. Biosafety is therefore not only an international obligation in terms of the Cartagena Protocol but also a desired endeavor that the Government of Belize wants to ensure for its people.

There is an urgent need to establish biosafety measures for Belize, not only for the genetically modified organisms (GMOs) or **genetically modified products used in food, feed and processing (FFP)** that may be produced locally in the future, but also for those may be imported into the country. There remains considerable uncertainty about potential risks associated with modern biotechnology. The possible costs of mitigating or reversing any harm that may occur as a result of the use of modern biotechnology may also prove to be immense, and far-reaching, especially to the government which is ultimately responsible for assuring the health status and food security of the Belizean population.

This policy sets the overall framework in which adequate safety measures will be developed and put into force, so that Belize can minimize possible risks to human health and the environment while extracting maximum benefit from any potential that modern biotechnology may offer. The National Policy on Biosafety is also an important tool to ensure that the knowledge, practices and benefits of Belize's traditional techniques are safeguarded.

The establishment of a National Policy on Biosafety is also an important step in meeting Belize's obligations to the Convention on Biological Diversity (CBD) and the Cartagena Protocol on Biosafety.

### 3 SCOPE

This policy provides the framework to protect the natural resources of Belize and the health of the people living in the country from the adverse effects that may arise from the development and application of GMOs and its derived products including pharmaceuticals. This will be achieved by:

- (i) regulating and monitoring the use of GMOs in Belize;
- (ii) establishing criteria for assessing the risks associated with GMO use;
- (iii) developing the capacity in Belize to effectively manage such risks;
- (iv) promoting the establishment of collaborative links with regional countries and institutions on biosafety;

- (v) establishing mechanisms for assessing the benefits to be derived from GMO use; and
- (vi) ensuring that public education, participation and consultation is key in the implementation of this policy.

## **4 POLICY FRAMEWORK**

### **4.1 Policy Statement**

The Biosafety Policy reflects the commitment of the Government of Belize in ensuring appropriate levels of protection in the safe use of modern biotechnology based on **the precautionary principle**, within the framework of sustainable development for the benefit of present and future generations. All matters related to the handling and/or use of GMOs and its products in Belize shall be in accordance with the goal and objectives as expressed in this policy.

### **4.2 Goal**

To ensure an appropriate level of protection of human, animal and plant health and life in the development and application of modern biotechnology, while ensuring that it contributes to the well-being of the country of Belize.

### **4.3 Policy Objectives**

1. Implementation of biosafety measures in order to ensure that there will be no adverse effects on human health, the environment and biodiversity.
2. Ensure effective regulation and management of GMO and GMOs used in FFP that might be imported to Belize, based on the Advanced Informed Agreement and signing of which should be guided by the Precautionary Principle.
3. Regulate any locally produced GMO or GMOs used in FFP.
4. Support and facilitate capacity building in Biosafety, with particular reference to regulatory management, risk assessment, risk management, risk mitigation and risk communication, including the development of a roster of experts in biosafety.
5. Promote dissemination of knowledge in the safe use and probable hazards of modern biotechnology.

6. Provide an institutional framework for national decision making, networking, monitoring R&D, and international cooperation in all matters relating to biosafety.

#### **4.4 Policy Principles**

- Recognizing the importance of protecting its people, environment and biodiversity while promoting a sustainable social and economic development through the implementation of biosafety measures;
- Recognizing the human health, environmental and socio-economic risks that may be incurred by careless or unscrupulous or unethical development of modern biotechnology and the use of its products;
- Realizing the need for developing our own capabilities in biosafety through research and development and training; and
- Reaffirming the commitment to the obligations of CBD and CPB.

##### **Belize shall ensure that:**

- 4.4.1 Biosafety regulations are established based on the precautionary principle and the advanced informed agreements;
- 4.4.2 The production, use, import, export, sale or trans-boundary movements of modern biotechnology applications, practices and products conform fully to all relevant national legislations and international agreements and obligations to which Belize is signatory to;
- 4.4.3 Public awareness, education and participation in the decision-making processes are made essential for ensuring the ethical and judicious use of modern biotechnological applications, practices and products for socio-economic development, without jeopardizing the environment, biodiversity and human health;
- 4.4.4 Risk assessment and management of GMO and GMOs used in FFP shall be carried out according to national biosafety regulations. Where scientific risk evaluations of a biotechnology product, application or procedure give rise to a negative recommendation, this shall not be overruled;
- 4.4.5 The industries involved in the use of modern biotechnology shall reveal information on organisms used and all other relevant data in order that consumers are aware of the substances they are exposed to. Safety test data, especially for agricultural biotechnology and human genetic testing, manipulations and applications, shall be fully disclosed and made public;

- 4.4.6 Decisions on biosafety issues are not biased to favor commercial consideration over public health, environmental and safety interests;
- 4.4.7 Labeling of genetically modified products is made mandatory so that the consumer may make an informed choice;
- 4.4.8 National safety guidelines and implementation practices be adopted by industries using modern biotechnology. The guidelines will cover all related aspects, including material handling, equipment, storage, waste disposal, laboratory safety, etc.;
- 4.4.9 Analytical laboratories legally recognized and proficient for GM detection be identified and or established and supported;
- 4.4.10 Priorities in Human Resource Development in Biosafety be assessed, identified and developed;
- 4.4.11 Public awareness of modern biotechnology in relation to assessment of potential risks/benefits and management techniques shall be enhanced, involving the community at large, including policy makers, legislators, administrators, the private sector and biotechnology industries;
- 4.4.12 Research into the risks to the environment and human health that can be caused by modern biotechnology be supported;
- 4.4.13 In the interim period leading up to the establishment of the infrastructure necessary to enable full implementation and compliance of the National Policy on Biosafety, appropriate regulations be drafted and enforced as a matter of urgency under the laws in existence at present, particularly in the case of GMO and GMOs derived products used as FFP.

## **5 STRATEGY**

To achieve the goal and objectives and facilitate adherence to the policy principles, Belize will use the following organizational arrangements and mechanisms for implementation.

### **5.1 Management and Coordination**

- 5.1.1 **A National Biosafety Commission** shall be established. The Commission shall be comprised of technical representatives from the Ministries of Agriculture, Health, Natural Resources and Environment, Regulatory agencies/bodies involved in agricultural health, food safety and standards, International and Regional Organizations, the NGO community and the

private sector. The Commission will oversee the management and coordination process for production, importation and use of GMO material in Belize. A multi-sectoral approach will be used.

1. The Commission will meet periodically to review the implementation of the policy, legislation and programs and shall report to the Cabinet of Belize.
2. The Commission shall be supported by a Secretariat and Coordinator, and shall:
  - (a) Develop and recommend policy improvements, strategic and operational plans, allocate human, technical, financial resources; and
  - (b) Monitor and evaluate program operations and achievements.

5.1.2 **A National Biosafety Clearing House** shall be established to:

- (i) Facilitate the exchange of scientific, technical, environmental and legal information on, and experience with, genetically modified organisms; and
- (ii) Assist Parties to implement the Protocol in accordance with Article 20 of the Cartagena Protocol on Biosafety.

5.1.3 **National Focal Point (NFP):** In accordance with Article 19 of the Cartagena Protocol, Belize shall designate a NFP responsible to liaise with international institutions, government and the public. . The Focal Point of the Cartagena Protocol on Biosafety will be under the Belize Agricultural Health Authority (BAHA).

## **5.2 Capacity Building**

The Commission will support and facilitate capacity building in biosafety (risk assessment, risk management, risk communication etc.) to ensure the effective regulatory management of GMOs in Belize.

## **5.3 Financial Implications**

The Commission shall prepare an annual budget to sustain its operations using a cost recovery program along with government and other institutional support.

## **5.4 Public Awareness, Education and Participation**

The Commission will establish a Public Education Committee with the responsibility to ensure public awareness and participation through periodic

public consultation and the dissemination of up to date information on GMO issues, using all available media.

### **5.5 National and Global Security**

The Commission will keep abreast of international developments/systems and agreements related to biosafety issues with a view of updating and enhancing Belize's policy and regulatory framework.

## **6 INDICATORS OF PERFORMANCE**

- 6.1 The biosafety regulatory framework is in accordance with national, regional and international requirements.
- 6.2 All activities with GMOs are conducted in accordance with the goals, objectives and principles of this policy and the provisions of the Biosafety regulations.
- 6.3 Increased public consultation awareness, education and participation in the biosafety regulatory framework.
- 6.4 Increased capacity in the field of GMOs especially with regard to risk assessment, risk management and risk communication.
- 6.5 An updated database of current biosafety issues in other countries, especially countries in the region.
- 6.6 An effective monitoring mechanism of GMO use in Belize.
- 6.7 Increase awareness of emerging biosafety issues.
- 6.8 Periodic dissemination of information on the state of biosafety in Belize.

## DEFINITIONS/GLOSSARY OF TERMS

**‘Biosafety’ or ‘biological safety’** means the management of risks to human and animal health and safety, and to the conservation of the environment, as a result of activities with genetically modified organisms.

**‘Biosafety Clearing House’** means a clearing house mechanism as established under the article 18 (3) of the convention

**‘Biosecurity’** encompasses all policy and regulatory frameworks (including instruments and activities) to manage risks associated with food and agriculture (including relevant environmental risks), including fisheries and forestry.

**‘Biotechnology’** refers to any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for a specific use.

**‘Convention’** means the Convention on Biological Diversity (CBD)

**‘Environment’** means the aggregate of surrounding objects, conditions and influences that influence the life and habits of man or any other organisms or collection of organisms.

**‘Genetically Modified Organism’** means any living organism, the genes or genetic material of which has been modified in a way that does not occur naturally through mating or natural recombination or both, and ‘genetic modification’ shall have a corresponding meaning. For the purpose of the policy reference to GMOs includes products and processes of GMOs.

**‘Modern biotechnology’** means the application of: (a) In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or (b) Fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection.

**‘Monitoring’** means the maintaining of regular surveillance over, the checking of, the warning about or the recording of a solution or process.

**‘Precautionary principle’**, as provided for in the Cartagena Protocol on Biosafety, “Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of potential adverse effects of genetically modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health shall not prevent that Party taking a

decision, as appropriate, with regard to the import of the GMO in question, in order to avoid or minimize such potential adverse effects.”

**‘Risk’** means the probability of causing or incurring a loss or damage or an adverse impact or a misfortune.