NATIONAL BIOSAFETY POLICY

BELIZE

The National Biosafety Policy for the Government of Belize (Approved March 2009)

CONTENT

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 the ability to alter life-forms through applying *in vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or the 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. Combining genes from different organisms is known as recombinant DNA technology, and the resulting organism is said to be “genetically modified”, “genetically engineered”, or “transgenic”; and is often described by the term GMO or Genetically Modified Organism.

Modern biotechnology has the potential to bring about dramatic changes related to food, health and environmental concerns. 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. Such genetic modification procedures have been used to produce crops that are resistant to diseases (and so require less pesticide use for their production), resistant to herbicides, plants that produce fibers of a specific characteristic (such as blue cotton) or pharmaceuticals that have greater precision in their action.

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 overall, must be judicious. An appropriate regulatory framework which provides for credible and effective safeguards must be sustainable and consistently applied across relevant sectors and which must be 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 that manages the biological risks associated with food and agriculture, including relevant environmental risks. **Biosafety** are the biosecurity measures used 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 the fair and equitable sharing of the benefits arising from the use of genetic resources.

Article 28 of the CBD provides for the formulation of Protocols to address the implementation of various aspects of the Agreement. The use of modern biotechnology is an issue of growing international concern due to the need to protect human health and the environment from possible adverse effects. However it is also important to recognize modern biotechnology's potential for addressing the World's critical needs for food and health care. As a result of these concerns the **Cartagena Protocol on Biosafety (CPB**) was adopted in Montreal on the 29th 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 and derived products 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 on to the Convention on Biological Diversity on 13th June 1992 and ratified it on 30th December 1993. With regards to the Cartagena Protocol on Biosafety, Belize ratified this Protocol on 12th February 2004 and is a party by accession since 12th May 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

The Need for Biosafety

Biotechnology brings with it a number of known and unknown risks. 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.

Genetic modification could be used to produce GMO crops that, for example, may be resistant to a specific disease and so provide a significant advantage to the farmer who is producing a food product destined for human or animal consumption. Genetic modification can also be used to produce animal food products. However, the use of products from such sources has a potential risk to human and animal health as well as to the health of the plant or animal modified. This is because such genetic modification alters the naturally occurring expression or production levels of proteins at different stages of growth, as well as in different organs. Such changes have the potential of increasing natural or foreign protein levels in food or food derivatives, and with this the

possibility of creating toxic, pathogenic and/or allergic effects from the use or consumption of the product. Other risks could include unexpected products and effects, and changes in the nutrition, composition or digestibility of the products.

Genetic modification requires the insertion of a gene into a chromosome (DNA) of the recipient organism. The gene inserted may impart a specific character to the recipient organism; such as disease or herbicide resistance in crop plants. However, such modified crop plants may breed naturally with near-by wild relatives and this may lead to the transfer of the inserted gene into natural plant populations. Such an occurrence could have an adverse impact on biodiversity as any wild recipient of such a gene may have a competitive advantage in natural ecosystems. In addition, the unexpected persistence of such a transferred gene and products in the environment, the proliferation of volunteer plants and effects on non-target organisms may occur. Agriculture production sustainability could be compromised by the development of resistant, unmanageable pests (which include weeds) through such a gene transfer process or though natural selection if such risks are not adequately assessed and production protocols that uses GMOs are not strictly regulated. The Government of Belize shall ensure that such risks are adequately assessed and production protocols are adequately regulated.

Ethical and socio-economic concerns include the value of biological diversity to local communities including the preservation of indigenous germplasm and ecosystems. Of particular concern to Belize is the potential loss of export opportunities and access to niche markets that exist for organic and fair trade products. The Government has an obligation to ensure that if the production and use of genetically modified organisms is permitted, it is done in an ethically and socially acceptable manner.

Any development, application and release of GMOs must be conducted in a 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 that 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. This 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 this 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, evaluating and monitoring the development and 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 and mitigate 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 critical 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** and in accordance with other national policies, within the framework of sustainable development of the country for the benefit of present and future generations of Belizeans. 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 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 of modern biotechnology on human health, the environment, food security, biodiversity or existing agricultural activities and markets.

2. Ensure effective mechanisms are established to regulate the importation, management and use of GMOs and GMOs used in FFP.

3. Regulate local production of GMOs with respect to research and development.

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 sustainable social and economic development of Belize;

- Recognizing the human health, environmental and socio-economic risks that may be incurred by careless, illegal, unscrupulous or unethical development or use of modern biotechnology and its products;

- Realizing the need for developing Belize's own capabilities in biosafety through research, development and training;

- Recognizing that niche markets have already been established and are flourishing in Belize for organic and fair-trade products and that these markets expressly forbid the use of or risk of contamination from GMOs or their derivatives;

- Recognizing that the rich natural environment of Belize has one of the highest levels of biodiversity in Central America and that GMOs have the potential to significantly reduce biodiversity levels;

- Recognizing that GMOs have the potential to damage (contaminate, disrupt, destroy) - through gene transfer - indigenous ecosystems (germplasm, landraces, seed sources, agricultural crops, agricultural production practices);

- Recognizing that there are existing traditional alternative methods to be used for sustainable agricultural practices;

- Recognizing that GMOs may have potential benefits with respect to food security and pharmaceuticals. 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. This will include a mechanism to ensure the traceability of GMO products.

4.4.3 Adequate regulations and procedures are established to address national food security needs in the event of an emergency.

4.4.4 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, indigenous cultures and practices, biodiversity or human health.

4.4.5 Risk assessment and management of GMO and GMOs used in FFP shall be carried out according to national biosafety regulations. Decisions shall

be based on evaluation of the risks that may result from a biotechnology product, application or procedure.

4.4.6 Recognition and respect for intellectual property rights with respect to GMOs and their products, will only be granted if it contributes to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and is done in a manner that is conducive to social and economic welfare, and to a balance of rights and obligations (Article 7 of the Agreement on Trade-Related aspects of Intellectual Property Rights (TRIPS).

4.4.7 Obligations under the CBD treaty, Belize shall provide for a mechanism that will allow fair and equitable sharing of the benefits arising from the commercial and other utilization of genetic resources. Access to genetic resources and traditional knowledge for such commercial purpose must fulfill the stated requirements and have the prior informed consent of the Government Ministry responsible for biological resources and the consent of any indigenous communities involved, with both government and indigenous community sharing the proceeds deriving from the commercial exploitation of the material or knowledge concerned. Intellectual property rights can only be obtained if the aforementioned requirements are met

4.4.8 Persons involved in the use or sale of modern biotechnology or its derived products shall ensure that consumers are fully informed of the nature of the technology or product. Data, resulting from safety tests/research on the technology or product, (for agricultural biotechnology, human genetic testing, manipulations or applications, for example), shall be fully disclosed and made public.

4.4.9 Decisions on biosafety issues shall not favor commercial considerations over public health, environmental and safety interests.

4.4.10 Existing and potential markets for organic and fair-trade products are protected.

4.4.11 Labeling of genetically modified products using international norms shall be mandatory so that the consumer may make an informed choice.

4.4.12 The consumer has a right to choose not to consume foods that are derived from GMO and GMO products.

4.4.13 National safety guidelines and implementation practices be adopted by industries using modern biotechnology or their products. The guidelines will cover all related aspects, including material handling, equipment, storage, waste disposal, laboratory safety, etc.

4.4.14 Analytical laboratories legally recognized and proficient for GMO detection be identified, certified, and or established and supported.

4.4.15 Priorities in Human Resource Development in Biosafety are determined, ranked and implemented.

4.4.16 Public awareness of modern biotechnology in relation to assessment of potential risks/benefits/alternatives and management techniques shall be enhanced, involving the community at large, including policy makers, legislators, administrators, the private sector and biotechnology industries.

4.4.17 Research into the risks to the environment and human health that can be caused by modern biotechnology be supported.

4.4.18 A comprehensive regime for liability as well as for adequate and prompt compensation (redress) for damage resulting from the transfer, handling or use (including illegal trafficking) of a GMO or its products under the national jurisdiction of Belize shall be provided for. This regime shall be consistent with the polluter pays principle and shall cover property damage, economic damage (including socio-economic damage to local and indigenous communities) damage to biodiversity, preventive measures, injury or disease and the cost of reinstatement and reinstatement or remediation of an impaired environment.

4.4.19 Given the risk involved this legislation shall have provisions for the implementation of a moratorium on the development or importation of GMOs for planting for commercial purposes into Belize until such time that Belize has this capacity

4.4.20 Persons involved in the production, use or sale of modern biotechnology or its derived products recognize their obligation to ensure that contamination and/or damage to ecosystems, animal and human health does not occur.

4.4.21 This policy is supported by legislation.

4.4.22 In the interim period leading up to the establishment of the infrastructure and capacity necessary to enable full implementation and compliance of the National Policy on Biosafety, appropriate regulations will be drafted under the laws in existence.

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 recognizing the Ministry of Agriculture and Fisheries as the lead Ministry.

5.1 Management and Coordination

5.1.1 **A National Biosafety Council** shall be established. The Council 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, civil society and the private sector. The Council 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 Council shall be supported by a Secretariat and Coordinator, and shall:

   (a) Meet periodically to review the implementation of the policy, legislation and programs and shall report to the Cabinet of Belize;

   (b) Develop and recommend policy improvements, strategic and operational plans, allocate human, technical, financial resources; and

   (c) Monitor and evaluate program operations and achievements.

2. The Council will make decisions with respect to production, importation and use of GMO and GMO derived products in Belize.

5.1.2 The Belize Agricultural Health Authority (BAHA) is the **National Competent Authority** for Biosafety in Belize.

5.1.3 The National Biosafety Council shall establish a **National Biosafety Clearing House** to:

(i) Facilitate the exchange of scientific, technical, environmental and legal information on, and experience with, genetically modified organisms; and

(ii) Assist Belize as a Party, to implement the Protocol in accordance with Article 20 of the Cartagena Protocol on Biosafety.

5.1.4 **National Focal Point (NFP)**: In accordance with Article 19 of the Cartagena Protocol, the National Biosafety Council 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 Council 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 Council shall prepare an annual budget to ensure effective and sustainable implementation of the policy. This will include the use of a cost recovery mechanism along with government and other institutional support.

5.4 Public Awareness, Education and Participation

The Council 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 Council 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 There is an increased public consultation, awareness, education and participation in the biosafety regulatory framework.

6.4 There is an 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 is established.

6.6 An effective monitoring mechanism of GMO use in Belize is established.

6.7 There is an increased public awareness of emerging biosafety issues.

6.8 There is periodic dissemination of information on the state of biosafety in Belize.

ANNEX

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.

'Competent Authority' is the entity responsible for performing the administrative and technical functions required by the Council for the effective implementation of this policy.

'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.

'International Norms' means standards, guidelines or code of practices that is generally agreed on by the international community.

'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.