

Section 1

Introduction to the Trinidad and Tobago National Biosafety Framework Project

Trinidad and Tobago, like many other countries, has identified biotechnology¹ as an important technology option to address issues such as food security, development of the agricultural sector and environmental protection. The use of biotechnology is also seen as a means of achieving leadership in tropical medicine and diagnostics, specifically in HIV/AIDS research and therapeutics to assist in improving the health care available to the citizens of Trinidad and Tobago. T&T however is aware that of ‘genetic engineering’, which produces Genetically Modified Organisms (GMOs)² or LMOs³ is one of the most controversial tools in modern biotechnology.

With respect to LMOs, regulatory systems differ widely in terms of the rule of origin (product vs. process), the legal framework and the decision-making process. As a result of the transboundary impacts of international trade in LMOs, a number of international policies and legal regulations, both binding and non-binding have been developed to address the issue of biosafety at the global level. T&T is signatory to several of these international agreements and protocols (listed below), which have been developed to treat with variations in national policies as it relates to trade and which either encompasses or deals specifically with the concept of LMOs.

The country-specific policy options towards LMOs range among Promotional, Permissive, Precautionary and Preventive. In order to provide a practical trade solution in the face of these differences, it has been generally agreed that products of modern biotechnology should be subject to rules, within a policy and regulatory framework that recognizes the importance of managing any potential risks associated with the technology. This safeguard is termed ‘biosafety’⁴ and the objective of a biosafety system is to provide a transparent and safe environment for biotechnology development and use. Despite the differences in the philosophical and /or political approaches, the scientific and technical approaches are similar in terms of assessing the potential environmental and food-safety risks posed by LMOs.

¹ The term ‘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.

² GMOs are organisms in which the genetic material (DNA) has been altered in a way that does not occur naturally. The technology is often called “modern biotechnology” or “gene technology”, sometimes also “recombinant DNA technology” or “genetic engineering”. Such methods are used to create GM plants – which are then used to grow GM food crops.

³ A Living Modified Organism (LMO) is defined in the Cartagena Protocol on Biosafety as any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology. In everyday usage LMOs are usually considered to be the same as GMOs (Genetically Modified Organisms), but definitions and interpretations of the term GMO vary widely.

⁴ Biosafety is a term used to describe efforts to reduce and eliminate the potential risks resulting from biotechnology and its products.

Trinidad and Tobago and The Cartagena Protocol on Biosafety

In January 2000, agreement was reached on the Cartagena Protocol on Biosafety to the Convention on Biodiversity. The objective of the Protocol is “to ensure an adequate level of protection in the field of the safe transfer, handling and use of Living Modified Organisms (LMOs) resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risk to human health, specifically focusing on transboundary movements” (Article 1). The Protocol applies to the transboundary movement, transit, handling and use of all LMOs that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health (Article 4). However, LMOs that are pharmaceuticals for humans are excluded from the scope of the Protocol if they are covered by other international agreements or arrangements (Article 5).

In November 2000, the 16th GEF (Global Environmental Facility) Council approved the "Initial strategy for assisting countries to prepare for the entry into force of the Cartagena Protocol on Biosafety"(GEF/C.16/4) as well as the UNEP/GEF Global Project entitled "Development of National Biosafety Frameworks." The overall objective of these initiatives is the preparation of countries for the entry into force of the Protocol, which came into effect on September 11, 2003.

Trinidad and Tobago acceded to this Protocol on October 5th 2000. The Ministry of Public Utilities and the Environment is the National Focal Point for this Protocol. As a signatory to the CPB, T&T is obligated by the rules of the Protocol to put in place a National Biosafety System which is an enabling mechanism for making decisions on the safe transfer, handling and use of LMOs. The biosafety system will comprise policies, regulations, guidelines and systems that seek to harmonize the interests of all members and components of society inclusive of the general public, innovators and the State. The biosafety system should take into account the rules that govern human and animal health, food safety, agriculture, environmental protection and production sustainability, science and technology as well as domestic, regional and international trade, among others. The obligations of Trinidad and Tobago under this Protocol fall under the following three main categories:

- (i) Administrative Measures
- (ii) Legal Measures
- (iii) Procedural Measures

Regulation of biosafety is obviously very complex, involving numerous stakeholders and issues, and for which there are a variety of conceptual approaches to deal with the issue. Trinidad and Tobago, as signatory to the CPB has decided to take a precautionary approach and assess risk on each application for development and use of LMOs on a case by case basis using the NBF. As such, risk assessment and regulatory requirements are an integral part of the development and use of any LMO. The regulations will be based on administrative instruments set up by governmental agencies and on laws that provide the basic and enforceable guidelines. The information from the Biosafety Clearing House will be an integral part of any risk assessment although the risk assessment will depend on the country, region and ecosystem where the LMO is intended to be released.

Presently in Trinidad and Tobago, there are regulations in place for the import of live organisms for any purpose as well as materials to be used as food. The Competent National Authorities (where the administrative function resides) are The Ministry of Agriculture, Land and Marine Resources (MALMR), the Ministry of Health (MOH) and the Ministry of Finance (through the Customs and Excise Division). Safety, in the present system, is regulated by several governmental pieces of legislation mainly:

- Food & Drugs - Food and Drugs Division of the Ministry of Health which enforces Food and Drugs Act. Chapter 30:01. Regulations 7(1), 14(h), (i), (j), 15.
- Environment - Environmental Management Authority within the Ministry of Public Utilities and the Environment which is governed by the EMA Act 2000.
- Plant & Animal Protection - Plant & Animal Quarantine Services, Ministry of Agriculture, Land & Marine Resources which enforces Plant Protection Regulations 1997.
- Customs and Excise Division of the Ministry of Finance. Chapter 78:01 of the Customs Act which governs importations.

Trinidad and Tobago occupies a unique position within the Caribbean region. It has a predominant oil and gas sector with secondary sectors in agriculture and manufacturing and processing. While tourism is a secondary sector in Trinidad, it is the primary economic activity in Tobago. Visitors for business or tourism come from across the globe but with the majority from North America and Europe. In addition, T&T has recently been developing stronger linkages with the Latin American regional and South America. Much of the agricultural products T&T consumes, along with processed foods and animal feeds are imports from the USA or through US distributors. Interestingly however, most of the fresh agricultural produce and processed foods are exported to Europe. This places Trinidad and Tobago in a difficult position since the countries of imports and exports have basic ideological and philosophical differences in their approach to the issue of Genetically Modified Organisms (GMOs). As such the NBF for T&T must take into consideration any special requirements that T&T may have to protect the local as well as regional and international export markets.

Status of Biotechnology in Trinidad and Tobago

The under mentioned is a status report on the biotechnology activities in Trinidad and Tobago.

Research

The Biotechnology Laboratory of the Department of Life Sciences of The University of the West Indies (UWI), the Cocoa Research Unit, **CAB International**, and the Central Experimental Station (**C.E.S.** of the Ministry of Agriculture, Land and Marine Resources) are engaged in biotechnology research but it is the only UWI laboratory that currently is involved in genetic engineering (Table 1). Two other laboratories, **CAB International**, and the Central Experimental Station (**C.E.S.** of the Ministry of

Agriculture, Land and Marine Resources) have stated their intentions to initiate work in the area in the future⁵.

⁵ Biosafety Regulations in Latin America and the Caribbean under the International Biosafety Protocol, CamBio Tech-Chile/OAS Project 2003. Report by Prof. E.J. Duncan on Legislation and Capacity-building needed in the republic of Trinidad & Tobago to meet the requirements of the Cartagena Protocol on Biosafety. Pg 10..

Table 1 Current uses of biotechnology in research and development in Trinidad and Tobago

Institution		Crop	Biotechnology activity		Modern Biotechnology
UWI	The Biotechnology Laboratory, Department of Life Sciences	Anthurium	Work on novel bloom colours and patterns; disease resistance; horticultural attributes; productivity	Laboratory research work for development of new varieties with selected traits; micropropagation; confined field trials	Recombinant vectors in bacteria and modified agrobacteria for transformation
		Tomato	Gemini virus		
		Bananas and plantains		Micropropagation techniques	
		Root crops		Micropropagation techniques	
		Hot peppers	Genetic screening		
	Cocoa Research Unit	Cocoa	DNA fingerprinting	To identify mislabelled trees in the international cocoa gene bank; construction of a genetic linkage map for cocoa; identification of markers linked to disease resistance;	
CAB International (Global project)			Molecular biology	To identify and characterize groups within species and to develop molecular markers; conducts tests of GM plants e.g. Transgenic rice lines with resistance to viruses and nematodes	There is no work being conducted in the local centre (The Caribbean and Latin American Regional Centre) to date but there is intent for the future

(Extracted from 'Biosafety in Trinidad and Tobago' – Jocelyn Lee Young, 2004)

Facilities for testing

At present the 'Department of Life Sciences of The University of the West Indies possesses the only laboratory in which genetic modification is in progress. While personnel at the University are capable of testing for constructs in material, they are unable to do quantitative estimates. Further while the laboratory is ideally suited for training young scientists in the practical aspects of genetic engineering, it cannot be looked upon as a source for testing⁶.

Two possibilities were identified as laboratories, which with some upgrading and appropriately trained personnel can serve as testing facilities. These are the laboratories of the Food and Drugs Division of the Ministry of Health, and the Caribbean Industrial Research Institute (CARIRI). A new laboratory, a part of a laboratory complex proposed by the Government, is shortly to be built for the Food and Drugs Division. Such a laboratory apparently now under planning could be upgraded to allow for testing of GMOs. The Director of CARIRI has indicated that the organisation has plans for building a fully equipped laboratory for testing of GMOs. CARIRI at present has quite a few testing laboratories, which have full accreditation internationally. There should be little problem in a laboratory they set up getting accreditation as a testing facility.

Capacity in availability and development of human skills

Within Trinidad and Tobago there are few experts in the specific area of modern biotechnology. Several databases have been compiled during this project including: experts in biotechnology and those with training in risk assessment and management and other resource persons who have been trained in support areas such as Animal and Plant Science, Environmental Sciences, Microbiology, Fisheries and Extension etc. The database provides information about the type of resources that are currently available within the country in related sectors.

Existence of dedicated centres or programmes

The main dedicated centre which also houses programmes for biotechnology is within the framework of the University of the West Indies (UWI). The University of the West Indies is divided into three campuses across the region - Barbados, Jamaica and Trinidad and Tobago.

UWI provides technical support in biotechnology and biosafety in addition to biodiversity, education, environment, regulatory work, national standards and legislation, invasive and alien species and risk assessment and management. Previously there were no established programmes for scientific and technical training in biotechnology and biosafety. However there has been a recent reassessment of the programmes with a resulting thrust towards harmonization of the education programmes across the three campuses (Trinidad and Tobago, Barbados and Jamaica). UWI is now committed to a Masters of Science in Biotechnology, which will provide training for scientists, policy

⁶ Ibid, pg.11.

makers and regulators in biotechnology. The programme has inherent flexibility which allows students to pursue diploma programmes within specific areas in these fields (Professor Umaharan, 2004). In addition it is possible to introduce the topics of modern biotechnology and biosafety within the traditional programmes.

Formulation of systemic and long-term policies

Whilst biotechnology and biosafety are recent areas of interest for Trinidad and Tobago, there are no policies presently in place with respect to biosafety issues. There are therefore no formal and specific measures taken to regulate, manage or control the risks associated with the use and release of LMOs resulting from biotechnological activities.

There are, however, systemic and long-term policies that are used for other issues that have similar requirements as LMOs. Examples of these include the use of the ecosystem, precautionary and bio-geographical approaches for work being done on Alien Invasive Species. Also, Trinidad and Tobago has, to a limited extent, established and maintained facilities for the ex-situ conservation of and research on plants that represent genetic resources originating elsewhere so as not to threaten ecosystem and in situ population of species. It is also a government policy to require an Environmental Impact Assessment for developmental projects. Biodiversity considerations are an integral part of the Environmental Impact Assessment process. This is the main mechanism by which biological resources and their sustainable use are considered and addressed. Those activities that can adversely affect biological resources are discouraged and mitigation measures are promoted for conservation of biodiversity.

These tools, that are already used nationally, can also be used in the development of a National Biosafety Plan. To some extent therefore there are associated long-term policies in place.

It should be noted that the formulation of long term policies should also include the availability of sustained financing to ensure that all the policies and strategies can be implemented in a timely and sustainable manner.

Existence of scientific infrastructure

Trinidad and Tobago, like other countries in the LAC region, requires appropriate infrastructures that will allow the proper absorption, development and use of biotechnology. There is a need to ensure proper management of the technology and to systematically build up local scientific, technological and regulatory competence. The existence of appropriate scientific infrastructure is critical to ensure efficient and effective conduct of this technology transfer. This scientific infrastructure deals with physical infrastructure and not human resources, which was dealt with in 8.1.

Trinidad and Tobago has the general laboratory facilities that are necessary for the conduct of routine tests within the country. The major laboratories are located within the medical sector in the main hospitals (Port of Spain and San Fernando) as well as the teaching hospital facility (Mount Hope Medical Sciences Complex). There are other institutions where laboratory services are available such as private laboratories.

In addition, there are two other possible laboratories, which with some upgrading and appropriately trained personnel can serve as testing facilities

- Laboratories of the Food and Drugs Division of the Ministry of Health
- The Caribbean Industrial Research Institute (CARIRI) - CARIRI at present has quite a few testing laboratories, which have full accreditation internationally(*OAS Report, 2004*)

Appropriate institutional structures and linkages

Because of the nature of the issue of biosafety, for an effective and efficient Biosafety Framework, it is essential that there be national linkages within the agencies/ government departments involved in the development and operation of a National Biosafety Framework. The National Committee for development of a Biosafety Policy and Framework (NCC) is one such committee where there is such cross-sectoral representation and as such the potential for cross-sectoral action. In addition to having formal stakeholder relationships, the NCC is also becoming actively involved in relationship building within specific groups in relevant sectors for example, manufacturing associations.

Trade in GMOs and LMOs

The 2003 survey conducted by Prof. Duncan for the Cambio- Chile/OAS project included 14 laboratories and local food and agro-chemical companies. Only the UWI and CABI reported to import GMOs/LMOs. The non-research organizations all claim not to import GMOs/LMOs⁷.

The National Biosafety Framework for Trinidad and Tobago

The main element of the NBF for T&T is the biosafety policy which will provide the national vision for biosafety which is consistent with other policy objectives related to food, agriculture, the environment and trade and sustainable development. This vision will then be operationalized through the other components of the NBF, which include, the regulatory, administrative and decision making systems(includes risk assessment and management options) as well as mechanisms for public participation and information. This task (development of the biosafety policy, regulations and framework) is being managed through the cross-sectoral membership of a National Coordinating Committee (NCC), which was established in 2000 by the Government of Trinidad and Tobago with the assistance of the UNEP-GEF Global NBF Project.

Given the wide scope of biosafety, the potential for growth and the uncertainty of long-term risk, the NCC has recommended the drafting of new legislation pertaining exclusively to biosafety. The new laws will regulate research and development as well as import and direct use of products of biotechnology. In addition, since legislation also affects the success and access to the benefits of biotechnology the guidelines will include those that regulate investment opportunities, conflict resolution mechanisms, intellectual property rights and opportunities for redress and liability. In addition to this regulatory

⁷ Ibid, pg. 10 and Table 1 on pg. 13.

component, the proposed administrative system for biosafety management within the NBF will comprise the following:

1. The institutional framework which includes a Competent Authority (decision-making entity) and supporting departments responsible for receiving, processing and issuing requests and permits, risk assessments as well as monitoring and enforcement.
2. Procedures and guidelines for handling notifications and requests and permits (according to various Articles in the Cartagena Protocol)
3. Procedures and guidelines for Risk Assessment and Characterization
4. A decision-making system which takes into account public opinion

The regulatory framework of the NBF for T&T must be structured to have an inherent flexibility that can allow introduction of adjustments to existing legislation and creation of additional rules since biotechnology is a fast evolving field. In addition, the efficiency of the national biosafety system will depend largely on the way the rules are administratively organized and factors in the administrative-technical bodies and the GMO release application process. The decision-making mechanism will be the core of the system and will be based on the analysis of potential adverse effects deriving from living modified organism releases (risk assessment). In that sense, it is necessary to apply risk assessment methodologies, what implies an inter-disciplinary task (including molecular biologists, ecologists, agronomists, vets, chemists, toxicologists). The NBF is intended to handle requests for: import for direct use as food, feed or processing, intentional introduction into the environment, propagation, field test, contained use, transit, export and other uses as they are identified.

T&T recognizes that biotechnology, which is inherently neither good nor bad (a neutral technology), is providing powerful tools for sustainable development in a wide range of activities. The rapid rate of advances and development in R&D indicates that this will be the century for biotechnology. Biotechnology can combine with other technologies such as IT and nanotechnologies to transform industry and provide novel ways to produce new medicines, food, processes, materials etc. The National Biosafety Policy and Framework along with the National Biotechnology Policy, which is presently being developed, will afford T&T the opportunity to be a part of this new reality and reap the benefits of this new technology and possibly other technologies as they emerge. The potential for the beneficial use of biotechnology in T&T include:

- Better agricultural production – improved diagnostic tools and remedies such as biopesticides / biofertilizers to assist with food security
- Improved competitiveness in agriculture via better quality – e.g. novel colours (horticulture), reduction in post harvest losses, greater stability of yield, better seeds, value-added products e.g. food technology, product differentiation
- Provision of biotechnology services such as micropropagation, embryo transfer, fingerprinting, disease diagnosis, recombinant vaccines/ edible vaccines, gene therapy, smart drug therapy/ nanodrug delivery, fertility

therapy, bioremediation of polluted soils, composting of wastes, quantifying the loss of biodiversity and assessing conservation strategies, development of biodegradable plastics and biosensors etc.

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Methodology

The methods used to obtain information included technical, scientific and legal reviews by experts within the NCC; taking of inventories from relevant government and other national agencies; surveys of opinions and knowledge among experts and within the general public via direct interviews and stakeholder consultations.

The information gathered was used to produce a working draft of the NBF which was then subject to expert review by members of the NCC.

The progression of work for the development of the NBF basically followed the outline provided by the UNEP-GEF Global NBF Project which took an approach that divided the project into four stages.

Stage 1: Definition of its governing principles

This began with the definition of a national biosafety strategy since it provided the principles to guide the development and implementation of the biosafety system and regulations regarding the safe and appropriate use of biotechnology tools and products. The policy was intended to articulate a national approach to biosafety needs and regulations that integrated all aspects of life in T&T e.g. political, social, ethical, health, economic and environmental considerations. While it was the first stage in the process, a draft policy was not completed until the end of the project. However, the guiding principles were used to provide direction for the NBF.

Stage 2: Surveys and inventories and creation of databases

The inventory and evaluation of national priorities and policies as it relates to agriculture, health, environment, social welfare and trade was the second stage of the development process. In addition there was a national appraisal of the status of biotechnology and biosafety which served to identify the available resources and regulatory framework and allowed an assessment on the adequacy of the current system for supporting the proposed NBF. Databases listing national experts in the general sciences as well as fields related to biotechnology, biosafety and risk assessment and risk management of LMOs were created.

Stage 3: Consultation with stakeholder and interested parties

Given the high degree of illiteracy as it related to biotechnology and biosafety there was great emphasis on public education and engagement during the third stage. This was important since ideally the process used to develop the NBF and its operation requires transparency and public involvement.

In this stage there was also an analysis to identify priorities and parameters for the preparation of a draft National Biosafety Framework (NBF).

Stage 4: Preparation of the NBF draft

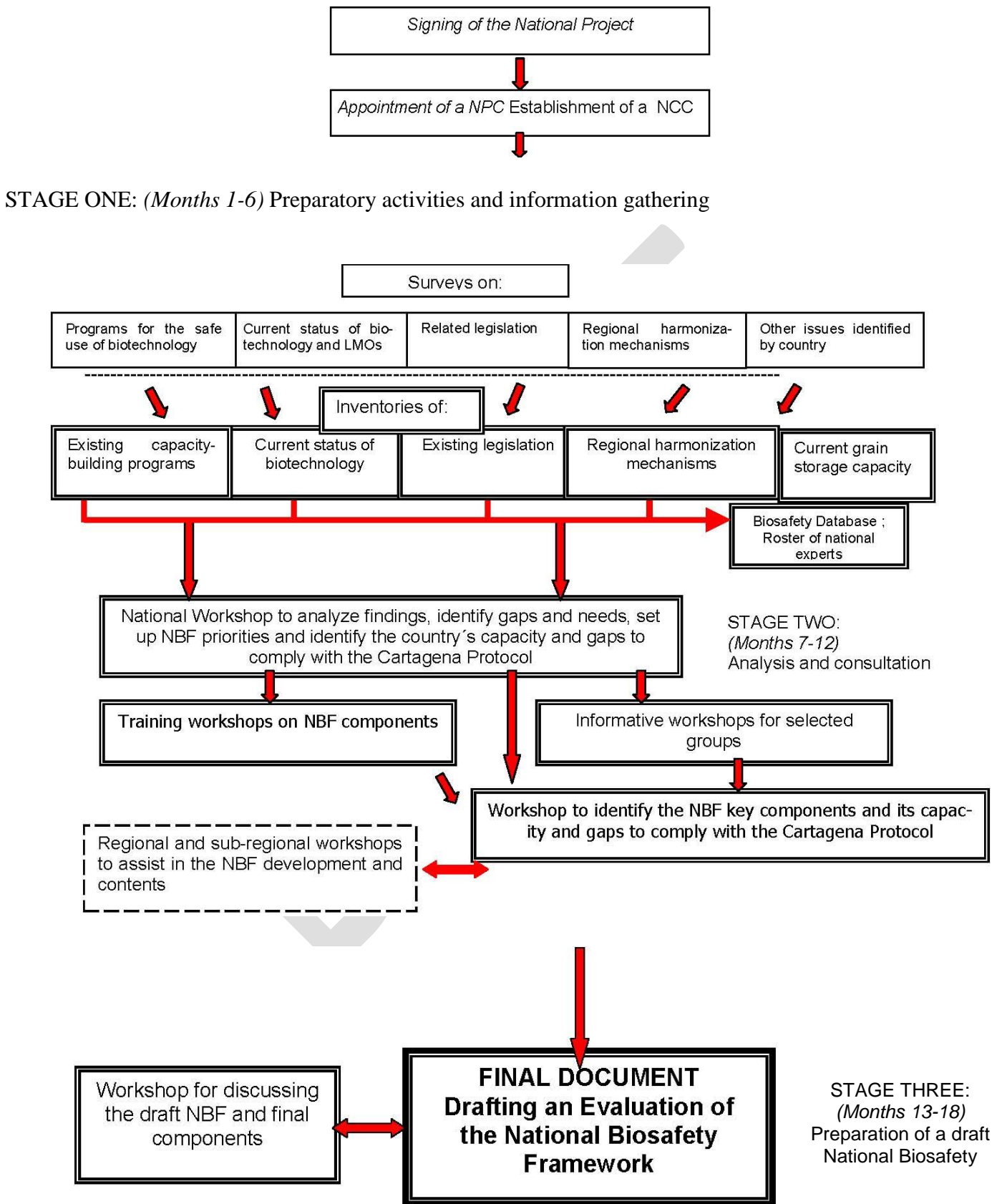
This final stage involved the preparation of the draft NBF along with an implementation plan. The present draft of the NBF for T&T is therefore a product of consultative meetings with the members of the NCC who provided input as representatives of the key

government departments as well as national and regional agencies and institutes. The final draft has been endorsed by the NCC. The key elements of the development of the National Biosafety Framework for T&T are outlined in Figure 1.

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Key Elements in the Procedure for the Development of the National Biosafety Framework (NBF)

Figure 1



Section 2
National Policy on Biosafety (Jan 07)

Article I. LIST OF ACRONYMS

AIA	Advanced Informed Agreement
BCH	Biosafety Clearing House
BL	Biosafety Level
CARICOM	Caribbean Community
CARDI	Caribbean Agricultural Research and Development Institute
CBD	Convention on Biological Diversity
CPB	Cartagena Protocol on Biosafety
CSME	CARICOM Single Market and Economy
CSO	Central Statistical Office
DNA	Deoxyribonucleic Acid
FAO	Food and Agriculture Organisation of the United Nations
FDD	Food and Drugs Division
GM	Genetically Modified
GMO	Genetically Modified Organism
IBC	Institutional Biosafety Committee
IICA	Inter-American Institute for Co-operation on Agriculture
IPPC	International Plant Protection Convention
LMO	Living Modified Organism
LMO-FFP	LMOs intended for Food, Feed and Processing
MALMR	Ministry of Agriculture, Land and Marine Resources
MPUE	Ministry of Public Utilities and the Environment
MOH	Ministry of Health
NBA	National Biosafety Authority
NBC	National Biosafety Committee
NBS	National Biosafety Secretariat
NBSAP	National Biodiversity Strategy and Action Plan
NIH	National Institute of Health
NIHERST	National Institute of Higher Education Research Science and Technology
OIE	World Organisation for Animal Health
RAM	Risk Assessment and Management
RBAC	Regional Biosafety Advisory Committee
SIDS	Small Island Developing State
SPS	Sanitary and Phytosanitary
TBT	Technical Barriers to Trade
THA	Tobago House of Assembly
TRIPS	Trade-Related Aspects of Intellectual Property Rights
UNCHR	United Nations Convention on Human Rights
WHO	World Health Organisation
WTO	World Trade Organisation

GLOSSARY OF TERMS AND CONCEPTS

Allergen	An antigen that provokes an immune response.
Alternative dispute resolution	Any mechanism for resolving disputes other than by way of litigation.
Antinutrient	Compounds that inhibit the normal uptake or utilisation of nutrients.
Biological diversity	The variability among living organisms from all sources including, <i>inter alia</i> , terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this includes diversity within species, between species and of ecosystems.
Biosafety	Policies and procedures adopted to ensure that products of modern biotechnology do not negatively affect plant, animal or human health; genetic resources; or the environment.
Biosafety Clearing House (BCH)	Established under Article 20 of the Cartagena Protocol on Biosafety to facilitate the exchange of scientific, technical, environmental and legal information on, and experience with, living modified organisms, as well as to assist Parties to implement the Protocol.
Biotechnology	Any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use.
Biosafety level	<p>In the conduct of contained experiments involving recombinant DNA molecules, four biosafety levels have been identified as follows:</p> <ul style="list-style-type: none">• BL1 - provides for a low level of containment for experiments involving transgenic plants in which there is no evidence that the modified organisms would be able to survive and spread in the environment, and if accidentally released, would not pose an environmental risk.• BL2 - assigned to experiments with transgenic plants and associated organisms, which, if released outside the greenhouse, could be viable in the surrounding environment, but would have a negligible impact or could be readily managed.• BL3 - facilities are designed to prevent the accidental release of transgenic plants, plant pathogens, or other organisms that have a recognised potential for significant detrimental impact on the environment.• BL4 – refers to containment conditions for research with plants

and certain pathogens and other organisms that require special containment because of their recognised potential for significant detrimental impact on managed or natural ecosystems.

Confined research	Includes field trials, clinical trials and industrial trials.
Contained research	Includes activities in laboratories, greenhouses, cages, production in fermenters or indoor facilities.
DNA	Deoxyribonucleic acid, which constitutes the genetic material of most known organisms and organelles.
Environmental Commission	A superior court of record, established under the Environmental Management Act of 2000, which has jurisdiction to hear and determine appeals from decisions or actions taken by the EMA. It has the same power to punish contempts as the High Court of Justice.
Form C-82	An internationally accepted instrument used by Customs to regulate imports and exports.
Genetic resources	Genetic material of actual or potential value.
Genetically modified organisms (GMOs)	Organisms, whose genetic makeup has been altered by recombinant DNA or cell fusion technologies in way that does not occur naturally by mating or natural recombination.
Germline	Refers to the body's reproductive cells that generate the eggs or sperms, as opposed to the other cells that contribute the structure of the body.
GM event	A specific genetic modification carried out on a particular crop
Greenhouse	Includes structures erected to conduct confined Recombinant-DNA research or testing.
Limited trial	A research step that precedes unconfined commercial release into the environment.
Living modified organisms (LMOs)	Any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology and is capable of transferring or replicating genetic material.
Marginalisation	The state of being considered unimportant, undesirable, unworthy, insignificant and different resulting in inequity, unfairness, deprivation and enforced lack of access to mainstream power.
Modern biotechnology	The use of cell fusion technologies or recombinant DNA technology

(genetic engineering) to alter the genetic makeup of living organisms.

Precautionary approach

The approach whereby any possible risk associated with the introduction of a new technology is avoided, until a full understanding of its impact on health and environment is available.

Recombinant DNA

The result of combining DNA fragments from different sources.

Regional Biosafety Advisory Committee (RBAC)

The committee envisaged as being the regional harmonisation mechanism under the CARICOM (yet to be established).

Substantial equivalence

Embodies the idea that existing organisms used as food or as a source of food can be used as a basis for comparison when assessing the safety of human consumption of a food or a food component that has been modified or is new.

Sustainable use

The use of components of biological diversity in a way and at a rate that does not lead to the long-term decline of biological diversity, thereby maintaining its potential to meet the needs and aspirations of present and future generations.

Transboundary movement

The movement of a living modified organism from one Party to another Party, save that for the purposes of Articles 17 and 24 of the Cartagena Protocol on Biosafety, transboundary movement extends to movement between Parties and non-Parties.

1) Transgene

An isolated gene sequence used to transform an organism.

2) Unconfined use

Includes general production, outside of a confined facility. Unconfined use may be carried out under a conditional approval that sets specific risk management conditions for a set period of time.

**Article II. Vision
2020**

A multi-sectoral National Strategic Development Plan to guide Trinidad and Tobago's achievement of developed country status by the year 2020.

Article III. Executive Summary

Biosafety refers to the policies and procedures adopted to ensure that products of modern biotechnology do not negatively affect plant, animal or human health; genetic resources; or the environment. Biosafety became a consumer protection issue with the placing of commercial products of modern biotechnology such as genetically modified organisms (GMOs) or products derived from them, for example, soybean and corn, into the environment and the food chain in the mid 1990s.

The National Biosafety Policy of Trinidad and Tobago ("the Policy") was developed within the context of international agreements such as the Cartagena Protocol on Biosafety (CPB) under the Convention of Biological Diversity, (CBD), *Codex Alimentarius* Commission of the Food and Agriculture Organisation/World Health Organisation (FAO/WHO), the Sanitary and Phytosanitary (SPS), Technical Barriers to Trade (TBT), and Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreements of the World Trade Organisation and the United Nations Convention on Human Rights (UNCHR). It is also in accord with the requirements for implementation of the CARICOM Single Market and Economy (CSME) as well as national policies on agriculture, human and animal health, food safety, and the environment.

The Policy articulates a national approach to biosafety that integrates political, social, ethical, health, economic, and environmental policies and considerations into decisions regarding the safe and appropriate use of modern biotechnology and its products. It is balanced, transparent and participatory and promotes the precautionary approach to decision-making. Trinidad and Tobago has identified modern biotechnology as an important technology option to address issues such as food security, agricultural sector development, bioresource development, and environmental protection.

The Policy's overall objectives are to guide the:

- (i) Development of an appropriate and transparent administrative, regulatory and legislative framework to govern the safe development and use of products of modern biotechnology, including Living Modified Organisms (LMOs) and LMOs intended for use in food, feed and processing (LMO-FFPs);
- (ii) Establishment and maintenance of appropriate mechanisms and strategies to assess and manage risk to ensure the protection of plant, animal or human health; genetic resources; or the environment;

- (iii) Development of an appropriate system for the labelling of products resulting from modern biotechnology in keeping with national consumer opinions and regional and international trade obligations;
- (iv) Promotion and facilitation of public awareness, public education and access to relevant information related to the development and use of modern biotechnology as well as systems for participatory decision making; and
- (v) Development of a national biosafety capacity-building plan to effectively implement the Policy.

The Policy is based on the following principles:

- (i) **Balanced approach to biosafety** - The Policy advocates a balanced approach so that procedures for biosafety do not unduly restrict biotechnology development and trade, which are important for achieving the sustainable developmental goals of the National Strategic Development Plan (Vision 20/20).
- (ii) **Decision-making process based on cost-benefit analysis** - Acknowledging the importance of biotechnology as a developmental tool, Trinidad and Tobago will use scientific risk analysis and socio-economic analysis for decision-making. Where scientific uncertainty exists the precautionary approach to decision making will be used.
- (iii) **‘Precautionary’ and ‘substantial equivalence’ approaches to scientific risk analysis** - Recognising its commitments to the CPB, WTO (SPS and TBT Agreements) and *Codex Alimentarius* Commission, Trinidad and Tobago will use the precautionary approach for environmental safety assessments and substantial equivalence for food safety assessments, which are enshrined in the national environmental and health policies respectively.
- (iv) **Case-by-case approach** - Decision-making will be based on risk analysis of the individual biotechnological applications, rather than a general approach.
- (v) **Stage-by-stage approach** - Decision-making will be based on risk analysis at the different stages of application of biotechnology (i.e. contained use, greenhouse, limited field release and commercial release).
- (vi) **Flexibility in decision-making** - Recognising that decisions are based on current, scientific information, the decision-making process will be flexible, to take into account advances in scientific knowledge. Decisions also have to be pragmatic to enable easy implementation.

- (vii) **Participatory approach to decision-making** - Recognising the wide-ranging implications of the Policy on various sectors, it provides for a mechanism to incorporate sectoral interests in the decision-making process.
- (viii) **Transparency in decision-making** - The decision-making process will provide opportunities for public participation and the results of such decisions will be made available in a timely and accessible manner. The Policy supports a public education and awareness campaign that seeks to inform the public of new developments on a timely basis.
- (ix) **Cognisance of intellectual property rights** - The Policy will recognise the confidentiality of information contained in the applications. In addition, biosafety clearance granted by relevant authorities should not be construed as permission to import, stockpile, and market, as these rights may belong to industrial property owners.
- (x) **Pragmatic approach to labelling** - Given our trading relationships, the Policy also outlines a pragmatic approach to food labelling, which is pro-choice, fair and at the same time intended to have minimal effect on food prices.
- (xi) **Regional harmonisation** - The Policy facilitates the regional harmonisation of biosafety standards and procedures, joint capacity-building efforts, public education efforts, labelling and risk analysis efforts to ensure smooth implementation of the CSME.
- (xii) **Human rights-based approach** - The Policy supports a human rights-based approach as enshrined in the 'Rights-Based Approach' of the United Nations, recognising that human rights and development are not distinct.

The Policy proposes a system, which consists of the following components:

- (i) An institutional framework, which includes:
 - The National Biosafety Authority (NBA), which comprises the National Biosafety Secretariat (NBS) and Committee (NBC), is the legal authority for decisions relating to the safe transfer, handling and use of LMOs resulting from modern biotechnology, and products derived from them, that may have adverse effects on plant, animal or human health, genetic resources or the environment.
 - Institutional Biosafety Committees (IBCs), which will be responsible for keeping an accurate and up-to-date record of biotechnology activities in institutions, ensuring that these activities comply with the guidelines provided by the NBA, and submitting applications to

the NBA for confined or unconfined release of products of modern biotechnology including LMOs into the environment.

- Supporting regulatory agencies, including the Environment Management Authority (EMA), Ministry of Agriculture, Land and Marine Resources (MALMR), Food and Drugs Division (FDD), Customs and Excise Division, and the Tobago House of Assembly (THA).
- (ii) An administrative system which includes procedures and guidelines for:
- Decision-making, including scientific risk analysis (risk assessment, management and communication), socio-economic evaluation and public participation;
 - Regulatory mechanisms such as permits, notifications and guidelines/oversight;
 - Transboundary movement of LMOs and LMO-FFPs, contained LMO research at various biosafety levels, confined greenhouse or field research, deregulated status and export of LMOs;
 - Compliance monitoring and oversight;
 - Liability and redress, mitigation of risks, and managing intellectual property and confidential information;
 - Public participation and transparency;
 - Penalties; and
 - Appeal processes.
- (iii) A legislative framework that will provide the legal authority to the relevant institutions and regulatory agencies, and harmonisation with existing legislation.
- (iv) A plan for the promotion and facilitation of public awareness, education and information access
- (v) A National Biosafety Capacity-Building Plan. The Government also recognises that in order to effectively implement the Policy, human resources and institutional capacity will have to be strengthened especially in the areas of risk analysis, public awareness, IT and communication technology, laboratory facilities for LMO testing, law enforcement and compliance monitoring.

The Policy underscores the importance of the development of the national biosafety framework with appropriate legislation and regulations to enforce it, and stresses the need for capacity-building as an imperative for the effective implementation of regulations.

Introduction

Consumer protection is a core component of the national objective of the Government of the Republic of Trinidad and Tobago (“the Government”) to improve the quality of life for all citizens. Biosafety became a consumer protection issue with the placing of commercial products of modern biotechnology⁸ (e.g. genetically modified organisms (GMOs)⁹ or products derived from them) into the environment and into the food chain in the mid 1990s. Biosafety refers to the policies and procedures adopted to ensure that GMOs and products made from them do not negatively affect plant, animal or human health, genetic resources or the environment. Establishing credible and effective safeguards for GMOs is critical for maximising the benefits of biotechnology while minimising risks.

Acknowledging biosafety as an important consumer protection issue, the Government established in August 2000 a Cabinet-Appointed Committee, chaired by the Ministry responsible for Consumer Affairs (the Ministry of Legal Affairs), to develop a National Policy and Regulations on Biosafety. Recognising the wide-ranging implications of such a policy on public health and safety, environmental management, international relations, trade, intellectual property rights and the innovation climate, the Committee was constituted with a wider representation involving various Government ministries, national and regional research and development institutions and civil society. The National Biosafety Policy of Trinidad and Tobago (“the Policy”) articulates a national approach to biosafety and integrates political, social, ethical, health, economic, and environmental policies and considerations of the Government into decisions regarding the safe and appropriate use of modern biotechnology and its products.

The Policy was developed within the context of international agreements to which Trinidad and Tobago is a signatory, and is in harmony with the requirements for implementation of the CARICOM Single Market and Economy (CSME). The most important international protocol addressing biosafety issues is the Cartagena Protocol on Biosafety (CPB) to the Convention on Biological Diversity (CBD), to which Trinidad and Tobago acceded on October 5th 2000. The objective of CPB is to ensure an adequate level of protection in the field of safe transfer, handling and use of living modified organisms (LMOs)¹⁰ resulting from modern biotechnology, which may have adverse effects on the conservation and sustainable use of biological diversity or on human and animal health. Other international commitments that may impinge on the policy and framework arise out of the Sanitary and Phytosanitary (SPS), Technical Barriers to Trade (TBT) and Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreements of the World Trade Organisation (WTO), food safety standards and protocols developed by

⁸Modern biotechnology refers to the use of cell fusion technologies or recombinant DNA technology (genetic engineering) to alter the genetic makeup of living organisms.

⁹Genetically modified organisms refer to organisms, whose genetic makeup has been altered by recombinant DNA or cell fusion technologies in way that does not occur naturally by mating or natural recombination.

¹⁰Living modified organisms means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology and is capable of transferring or replicating genetic material.

the *Codex Alimentarius* Commission of the Food and Agriculture Organization/World Health Organisation (FAO/WHO), and international plant and animal health protocols of the International Plant Protection Convention (IPPC) and World Organisation for Animal Health (OIE). In addition, the principles of the United Nations Convention on Human Rights (UNCHR) underlie the development of the Policy.

Globally, biotechnology is regarded as the dominant general-purpose technology of the 21st century. Trinidad and Tobago, like many other developing countries, has identified modern biotechnology as an important technology option to address issues such as food security and the development of the agricultural sector, bioresource development, and environmental protection. The use of modern biotechnology is also seen as a means of achieving leadership in tropical medicine and diagnostics, specifically in HIV/AIDS research and therapeutics to assist in improving the health care available to the citizens of Trinidad and Tobago. Products of modern biotechnology however should be subject to rules to ensure that they are developed and used in a way that they do not pose an unacceptable risk to plant, animal or human health; genetic resources; or the environment. The Policy provides a balanced policy environment so that biotechnology development can be nurtured within an environment where the potential risks associated with the technology are appropriately managed.

In light of the impact of such a policy on citizens, its development was informed by the widest possible public consultation across sectors, stakeholders and civil society. Towards this end, extensive stakeholder and public consultations, opinion surveys and public education campaigns to raise awareness of biotechnology and biosafety were conducted.

The main purpose of this document therefore is to establish a biosafety policy for consumer protection while ensuring that biotechnology development and use are not unduly restricted.

Setting The Context

This section summarises the issues raised at various fora and discussions held at the committee level in arriving at the policy objectives and policy directions and provides the contextual basis for the Policy.

Biotechnology, Innovation And Biosafety

The biotechnology revolution is influencing every sphere of human activity, including agriculture, human and animal health, biodiversity conservation, environmental remediation, industrial applications and forensics, and has significant implications for humankind. Widely regarded as a scale-neutral technology, it is of particular interest to Small Island Developing States (SIDS) in so far as it can provide innovative solutions to achieving development goals. The governing council of the Inter-American Institute for Co-operation on Agriculture (IICA), in its hemispheric plan for the next decade has identified biotechnological tools as critical to revitalising agriculture and in the sustainable exploitation of the region's bioresources. In addition, biotechnology is contributing to health care through novel therapeutics and vaccines. Recognising the importance of this technology, CARICOM established a regional working group to develop a policy on biotechnology and biosafety. Trinidad and Tobago, like many other

Caribbean nations, is also developing a biotechnology policy as part of the science and technology policy with the objective of encouraging innovation, research and development.

Biosafety policies ensure that products of modern biotechnology, such as GMOs, do not pose an unacceptable risk to plant, animal or human health; genetic resources; or the environment. A biosafety policy also provides an enabling environment for biotechnology development by ensuring that the interface between technology and society is carefully managed. The Policy will ensure that the environment, along with plant, animal and human health, is managed at the highest safety standards without being unduly restrictive to biotechnology development and trade. Given the importance of achieving the sustainable development goals of the National Strategic Development Plan (Vision 20/20),¹¹ separate policies are required for biotechnology and biosafety. This two-pronged approach will ensure that perceived conflicts of interest, as they relate to biosafety, do not hamper biotechnology development and implementation or impinge on human rights. However, this approach requires that there is articulation between the two policies so that neither adversely affects the distinct goals of the other.

International Perspectives

Internationally, GMOs and products derived from them have been the subject of great controversy. The proponents of the technology argue that genetic engineering can help feed the increasing world population with more nutritious food at a reduced cost. They also claim that it is critical to establishing a sustainable global agriculture system. Opponents on the other hand argue that the technology carries along with it numerous risks to the society. They maintain that the long-term impact of the technology on plant, animal or human health; genetic resources; or the environment is not well understood. Environmental concerns include the cross-pollination of the transferred gene ('trans gene') from the GM crop to other related plants, referred to as 'gene transfer', and the possible influence of the 'trans gene' on non-target organisms. Human and animal health concerns include the possible toxicity or allergenicity of products of the 'trans gene' and the transfer of antibiotic-resistant genes.

The controversy is also influenced by issues, which are often outside the realm of simple costs and benefits of the technology. These include international trade obligations, socio-economic concerns, intellectual property rights and patenting issues (genes and living organisms), accessibility of technologies by developing countries and marginalised¹² groups (rural farmers, women and indigenous persons), public trust in the regulatory agencies, moral and ethical issues, culture and heritage, and consumer rights.

¹¹Vision 2020 is a multi-sectoral National Strategic Development Plan to guide Trinidad and Tobago's achievement of developed country status by the year 2020.

¹²Marginalisation refers to the state of being considered unimportant, undesirable, unworthy, insignificant and different resulting in inequity, unfairness, deprivation and enforced lack of access to mainstream power.
<http://www.undp.org/rbec/nhdr/1996/georgia/glossary.htm> (16/2/06)

Scientific risk analysis is the generally accepted method for assessing the acceptability of GMOs, but there is disagreement with respect to the decision-making process. One view argues for the use of the precautionary approach whilst the other advocates substantial equivalence¹³. The proponents of the use of the precautionary approach argue that the technology is in its infancy and carries with it scientific uncertainties and justifies a cautious approach. The application of the precautionary principle allows countries to:

- (i) take preventative action in the face of scientific uncertainty;
- (ii) shift the burden of proof to the proponents of an activity;
- (iii) explore a wide range of alternatives to possibly harmful actions; and
- (iv) increase public participation in decision-making.

The proponents of substantial equivalence argue that the use of the precautionary approach can lead to arbitrary decision-making the creation of unjustifiable trade barriers, and the stifling of innovation. They regard the precautionary approach as an ill-defined and nebulous concept, which is open to abuse and could serve as a front to further protectionist or competitiveness-driven trade agendas. Proper application of the precautionary approach requires an understanding of the magnitude, distribution and uncertainty of risks, the extent of exposure, and the trade-offs and lost benefits in foregoing the risk. The proponents of substantial equivalence therefore contend that it is a more pragmatic decision-making tool. Moreover, they point out that sound science as a basis of decision-making is enshrined in the WTO agreements such as SPS and TBT.

The Government is signatory to the CPB as well as the SPS and TBT agreements of the WTO and is a member of the *Codex Alimentarius* Commission. The precautionary approach is a basic tenet of the CPB whilst the *Codex Alimentarius* Commission of the FAO/WHO uses substantial equivalence in its food safety assessments. The precautionary approach is enshrined in the National Environmental Policy of Trinidad and Tobago whilst substantial equivalence is used as the basis for food safety assessments in Trinidad and Tobago. The Policy therefore adopts a dual approach to biosafety decision-making, in keeping with its international commitments.

Trinidad and Tobago acknowledges the potential risks associated with the technology, but recognises that if these are properly managed, modern biotechnology can benefit society and can contribute to achieving national development goals (Vision 20/20). Like any other technology, the costs and benefits to the society depend on how the technology is used. A biosafety policy that evaluates biotechnology products on a case-by-case basis and takes into consideration both the risks and benefits would be able to harness the good of the technology, while avoiding the ills. Such an approach requires a flexible regulatory regime providing for notification and permits, and guidelines and oversight. The Policy will also allow the flexibility to alter decisions as new information becomes available.

The Policy therefore advocates independent and rigorous scientific risk assessment as a

¹³The concept of substantial equivalence embodies the idea that existing organisms used as food or as a source of food can be used as a basis for comparison when assessing the safety of human consumption of a food or a food component that has been modified or is new.

basis for decision-making, but provides the flexibility to commission an independent socio-economic assessment, as required, to support the decision-making process and to safeguard the national interests of Trinidad and Tobago.

International Trade And Implications For Biosafety

Internationally, it has been estimated that 70-100% of processed foods are derived from GMOs. Based on trade data for the period January to September 2005, North America (USA and Canada) supplied 31% of the imports into Trinidad and Tobago and attracted 61% of the total domestic export volume out of Trinidad and Tobago. The USA alone accounted for 29% of the imports into, and 60% of the domestic exports out of, Trinidad and Tobago, and can therefore be regarded as Trinidad and Tobago's main trading partner. In comparison, although the European Union supplied 13% of the total imports into Trinidad and Tobago, it only attracted 7% of the domestic exports. With specific reference to food imports and exports, the trade data for January to September 2005 indicated that the USA accounted for 45% and 6% respectively, compared to 11% and 22% in trade with EU.

Based on data from the Central Statistical Office (CSO, 2006), more than 95% of corn, soybean, cotton and canola products are imported into Trinidad and Tobago from the key producers of GM crops such as USA, Canada and Australia. Therefore, it follows that GM foods already exist on the Trinidad and Tobago market.

The Policy therefore ensures that trade between Trinidad and Tobago's major trading partners is not unduly affected.

Regional Perspectives

The establishment of the CSME requires harmonisation of biosafety policies and legislation among CARICOM countries. To this end, CARICOM established a regional working group on GMOs, which has been mandated to develop a regional biotechnology and biosafety policy. Regional harmonisation of biosafety was first addressed in a regional biosafety capacity-building workshop organised by NIHERST in January 2004. Subsequently, a second meeting was organised by CARDI in April 2005 to move the agenda forward. More recently, the issue was further elaborated in a regional biotechnology and biosafety needs assessment workshop organised by IICA in November 2005. Deliberations at these workshops concluded that the following should be reflected in the regional policy document and implementation mechanism:

- (i) The technical capacity to evaluate notifications is limited particularly in the smaller CARICOM territories and a mechanism should be developed to address this.
- (ii) A database of CARICOM expertise should be developed to ensure that the scattered human resources in the region can be used to maximum benefit in regulatory decision-making, particularly in cases where conflicts of interests arise. A joint database of approved GMO events in food for consumption can be developed.

- (iii) A regional biosafety information system should be established to provide information transfer between CARICOM member states to ensure that countries within CARICOM avoid duplication of efforts.
- (iv) Copies of notifications/applications for GMO release made to national authorities should be sent to the regional biosafety authorities so that countries can benefit from feedback from other CARICOM member countries. Common application requirements and administrative systems adopted by countries will allow experiences to be readily transferred to other CARICOM states.
- (v) The region should establish common biosafety standards and guidelines so that trade between CARICOM member countries will not be affected.
- (vi) Joint capacity-building programmes and common testing facilities will reduce the cost of biosafety implementation and should be supported wherever possible.
- (vii) Regional public education campaigns and curriculum improvement efforts at primary, secondary and tertiary levels should be encouraged to reduce cost and bring greater harmonisation of efforts.
- (viii) A common policy on labelling of foods modified by modern biotechnology should be developed towards supporting regional trade.
- (ix) A mechanism should be established for the national biosafety authorities to collaborate with the regional biosafety authority.

The Policy should therefore reflect the aforementioned regional policy guidelines.

National Perspectives

Agriculture

Important advances in modern agro-biotechnology can positively affect production and germplasm enhancement. However, they also bring with them biosafety concerns particularly in the areas of gene transfer and the coexistence of GM crops with organic agriculture. Gene transfer can negatively impact trade with traditional export markets for commodities such as cocoa and honey. There is also the potential impact of gene transfer which can result in unintended harmful effects on plants, insects and micro-organisms.

The objectives of the Sector Policy for Food Production and Marine Resources (2001-2005) are to increase and sustain agricultural productivity and competitiveness. The Sector Policy promotes the application of new technologies such as biotechnology for achieving these stated objectives. As such, in order to ensure that Trinidad and Tobago successfully exploits the biotechnology revolution, the Ministry of Agriculture, Land and Marine Resources (MALMR) will collaborate with appropriate agencies, and promote the

development of the necessary institutional capacity and other resources for the effective implementation of the stated policy. In addition, there will be the development of mechanisms for the use, regulation and control of biotechnology and biotechnological products.

The MALMR is empowered under the Plant Protection Act of 1975 (with amendments of 2001) and the Animal Diseases and Importation Act of 1954 (with amendments of 15/1955; 6/1963; 102/1977 and 45/1979) respectively, to regulate the importation of plants, plant products including seeds, and any other propagative materials, soil, animal and animal products. As a member of the International Plant Protection Convention (IPPC), guidelines for the introduction of LMOs as detailed in International Standard of Phytosanitary Measures No. 11 are used to guide the conduct of pest risk analyses.

Food and Health

The introduction of foods produced through modern biotechnology potentially brings new issues for food safety such as changes to macro- and micronutrients, and introduction or altered levels of anti-nutrients, endogenous toxicants, allergens, and physiologically active substances. Safety assessments of food produced from GMOs should include their health and nutrition effects on the whole population as well as special groups (including immuno-compromised individuals, infants and the elderly); through direct and indirect exposure of humans to the food or to the GMO itself.

The National Health Policy makes reference to the safe and wholesome food supply to the population of Trinidad and Tobago. Although legislation regarding public health and food safety is being reviewed and updated, there is no specific reference to foods produced through modern biotechnology. Accordingly, the existing National Health Policy has to be revised to reflect technological changes in modern food production without compromising food safety and wholesomeness.

The *Codex Alimentarius* Commission of the FAO/WHO is a standing international commission on food safety standards, which is constantly evaluating emerging issues and contributing to the development of international standards and protocols for food safety and food labelling. The biosafety policy and legislation should therefore be flexible enough to incorporate the emerging and continually evolving world views on food safety.

The Food and Drugs Division is empowered under the Food and Drugs Act 8 of 1960, Chapter 30:01 to regulate the importation, manufacture, storage, sale, distribution and destruction of food, drugs, cosmetics and medical devices in Trinidad and Tobago. The Act however does not specifically address the importation, use and placement in the market of LMOs intended for food, feed and processing (LMO-FFPs).

Environment

The environmental concerns that relate to the intentional introduction of GMOs into the natural environment of Trinidad and Tobago are:

- (i) unintended changes in the competitiveness or virulence of the target species;
- (ii) possible adverse impacts of the transgenic products on non-target species;
- (iii) potential of transgenes being transferred to wild relatives; and
- (iv) possibility that an existing non-target gene may lose its effectiveness.

The Revised National Environmental Policy of Trinidad and Tobago provides in Section 3.2 that “GMOs shall not be imported or acquired, marketed or released into the environment of Trinidad and Tobago without authorisation from the relevant government authority”. This policy, however, does not provide sufficient guidance for the decision-making process. In this regard, a specific policy on biosafety is required. Such a policy should incorporate the precautionary approach a basic tenet of the National Environmental Policy, and include provisions for fulfilling the country’s obligations under the CPB. Additionally, the policy governing the development and use of GMOs should not adversely affect the conservation and use of the country’s biological resources in keeping with the National Biodiversity Strategy and Action Plan (NBSAP).

The management and protection of the environment of Trinidad and Tobago is effected primarily through the Environmental Management Act of 2000, which established an Environmental Management Authority responsible for, *inter alia*:

- (i) developing and implementing policies and programmes for the effective management and wise use of the environment;
- (ii) co-ordinating environmental management functions;
- (iii) promoting education and public awareness programmes on the environment;
- (iv) developing and establishing national environmental standards and criteria;
- (v) monitoring compliance with the standards criteria and programme relating to the environment; and
- (vi) taking all action for the prevention and control of pollution and conservation of the environment.

The Environmental Management Act however, does not provide specific provisions for the protection of the environment from possible threats posed by the intentional introduction of LMOs into the environment.

Research Agenda

Research in Trinidad and Tobago is currently carried out in the areas of agricultural, medical, industrial and environmental biotechnology. Such research is critical to achieving competitiveness and sustainable development. Most research to date on GMOs is carried out in laboratories and none has been released into the environment. Since there are no national guidelines governing laboratory research, most research on recombinant-DNA is conducted based on the “National Institute of Health (NIH) Guidelines for Recombinant-DNA Research” of the USA on a voluntary basis. It is important that specific guidelines similar to the ‘NIH Guidelines of Recombinant-DNA Research’ are developed to govern research, and an oversight mechanism put in place to ensure that such guidelines are strictly adhered to.

At various stages of the research programme, recombinant-DNA research is conducted either in the laboratory, greenhouse¹⁴ or under field conditions. The level of potential risk to the environment increases from the laboratory to the field and so should the stringency of biosafety requirements. The Policy should provide a step-by-step approach to biosafety regulation of laboratory, greenhouse and field research, and provides guidelines, with the national regulatory agencies providing oversight for the laboratory and greenhouse steps. For the field research step, mandatory notification and a permit will be required prior to engaging in any field experimentation.

Additionally, the Policy should contain provisos that no work involving modification of germlines¹⁵ of the human being will be carried out. It will also ensure that intellectual property rights and confidentiality of information are respected.

Public Perception and Opinions

Although there was a general awareness of the term GMO among the population of Trinidad and Tobago, most people had an inaccurate perception of the concept. There was also uncertainty regarding the presence of GMOs in supermarkets and their safety. In Tobago, there was a particular concern about the presence of GMOs negatively impacting competitiveness in the international tourist market, given Tobago's image as being a 'Clean, Green, Safe and Serene' destination.

Some members of the public indicated that GM food would be desirable if the level of pesticides applied to crops could be reduced or if it were more nutritious than non-GM food. Most persons indicated that benefits along with risks of the technology should be considered in determining the suitability of the technology.

The important factors identified as affecting consumer choice of GM as against non-GM food are price, ethics and religion. Most persons were of the view that mandatory labelling of GM products is required, but they were not prepared to pay the increased cost associated with labelling.

There was general dissatisfaction with the level of public education on GMOs, and the government was seen as having the responsibility for providing such information. The media (especially television), along with pamphlets and flyers were considered the most effective means of information dissemination.

With respect to other potential applications of biotechnology in Trinidad and Tobago, medicine and medical research and environmental management were identified as areas most suited to the application of the technology, provided that adequate measures are put in place to protect plant, animal and human health and the environment.

¹⁴Greenhouse is used in its widest sense to include structures erected to conduct confined Recombinant-DNA research or testing.

¹⁵Germline refers to the body's reproductive cells that generate the eggs or sperms, as opposed to the other cells that contribute the structure of the body.

Labelling

The two major approaches to labelling GM products involve:

- (i) process labelling, whereby all products derived from the GM process are labelled as genetically modified, whether or not they contain components of the transgene or its products; or
- (ii) product labelling, which involves labelling products that have GM ingredients at detectable levels.

Another approach involves mandatory positive labelling (EU, Japan), where any product that contains GM ingredients is labelled as such, while with voluntary negative labelling (USA), retailers have the option of labelling their products as ‘not containing GM ingredients’. Among countries that use mandatory positive labelling the percentage of GM content that triggers labelling varies (EU: 0.9%; Japan: 5%).

In Trinidad and Tobago, public opinion favours a mandatory labelling approach. This approach will indicate that the product is or has been derived from GMOs and, where applicable, whether it may cause reactions, allergies or other side effects.

However, the USA, the major trading partner of Trinidad and Tobago, does not have a mandatory labelling scheme, and so implementing such a proposal would require that each consignment be identified, segregated, traced and tested in order to implement such a labelling regime. Apart from being onerous, this will considerably increase the cost of food by approximately 10-15%.

Given that the purpose of any implemented policy is to effectively, efficiently and safely serve the public and promote public good, the costs versus benefits of labelling should be carefully considered.

This Policy adopts a pragmatic approach, where approved GM events¹⁶ will be placed on the Biosafety Clearing House (BCH),¹⁷ after appropriate food safety testing has been carried out. Such information will also be placed in supermarkets and other food outlets. The Policy requires that all unapproved events be notified and subjected to risk analysis. LMO-FFPs will be subjected to routine surveillance to ensure that unapproved GM events do not enter the food chain. The Policy allows voluntary negative labelling of approved GM events, where importers and retailers will be permitted to label their products as not containing GMOs. This is a more pragmatic approach that is less tedious, pro-choice and will not result in a general increase in the cost of food, or restrict trade with our major trading partner.

¹⁶GM event refers to a specific genetic modification carried out on a particular crop.

¹⁷The Biosafety Clearing House is an internet-based system for information sharing under the CPB, which makes available national decisions on approved GM products and events.

Regulatory Systems And Legislative Framework

The Republic of Trinidad and Tobago has existing laws and regulations upon which a strong legal framework pertaining to biosafety can be built. These include:

- (i) Plant Protection Act of 1975 and Regulations 1997 - 3(1), 9, 14, 18
- (ii) Animal Diseases and Importation Act of 1954 (with amendments of 15/1955; 6/1963; 102/1977 and 45/1979)
- (iii) Food and Drugs Act, Chapter 30:01, sections 6 (1), (2), 25(1), (2)
- (iv) Customs Act, Chapter 78:01 and
- (v) Environmental Management Act of 2000
- (vi) The Consumer Protection and Safety Act of 1985

Amendment of these existing Acts and Regulations is possible, but given the wide scope of biosafety, the potential for growth, and the uncertainty of long-term risk, amending several statutes can create ambiguities and lead to problems with enforcement. Therefore holistic standalone legislation on biosafety is desired. This may require the amendment of the existing legislation in order to ensure harmonisation.

The proposed biosafety legislation will include:

- (i) “Precautionary” and “substantial equivalence” approaches to decision-making
- (ii) Entry status (imported and in transit goods)
- (iii) Roles and powers of regulatory agencies, inspectorates, monitoring bodies and oversight mechanisms
- (iv) Process for handling applications
- (v) Establishment of the National Biosafety Committee, Risk Assessment and Management Committee, Institutional Biosafety Committees, and Assessment of Damage Committee
- (vi) Decision-making process and authority
- (vii) Certification upon approval
- (viii) Revocation of approval
- (ix) Right of appeal by Applicant
- (x) Labelling requirements
- (xi) Penalties to be imposed
- (xii) Redress and compensation
- (xiii) Notices and notifications including timeframes
- (xiv) Provision for destruction of material in lieu of returning material to the country of origin
- (xv) Exemptions
- (xvi) Forms for required information

Policy - Scope, Objectives And Guiding Principles

Due to the expanding global market, products of modern biotechnology are becoming increasingly available in Trinidad and Tobago. It is therefore imperative that a clear policy be developed to govern the safe handling, transfer, and use of such products.

Scope Of The Policy

The Policy governs the safe development and use of products of modern biotechnology including LMOs and LMO-FFPs. It also encompasses activities such as import, export and transit through national ports of entry; contained laboratory, greenhouse or field research and contained use; placing on the market; deliberate release into the environment; unintended releases labelling and contingency measures as well as treatment and disposal of wastes associated with products of modern biotechnology.

Policy Objectives

The Policy's overall objectives are to guide the:

- (i) Development of an appropriate and transparent administrative, regulatory and legislative framework to govern the safe development and use of products of modern biotechnology, including Living Modified Organisms (LMOs) and LMOs intended for use in food, feed and processing (LMO-FFPs);
- (ii) Establishment and maintenance of appropriate mechanisms and strategies to assess and manage risk to ensure the protection of plant, animal or human health; genetic resources; or the environment;
- (iii) Development of an appropriate system for the labelling of products resulting from modern biotechnology in keeping with national consumer opinions and regional and international trade obligations;
- (iv) Promotion and facilitation of public awareness, public education and access to relevant information related to the development and use of modern biotechnology as well as systems for participatory decision making; and
- (v) Development of a national biosafety capacity-building plan to effectively implement the Policy.

Guiding Principles

The Policy is based on the following principles:

- (i) **Balanced approach to biosafety** - The Policy advocates a balanced approach so that procedures for biosafety do not unduly restrict biotechnology development and trade, which are important for achieving the sustainable developmental goals of the National Strategic Development Plan (Vision 20/20).
- (ii) **Decision-making process based on cost-benefit analysis** - Acknowledging the importance of biotechnology as a developmental tool, Trinidad and Tobago will use scientific risk analysis and socio-economic analysis. Where scientific uncertainty exists the precautionary approach to decision making will be used.
- (iii) **'Precautionary' and 'substantial equivalence' approaches to scientific risk analysis** - Recognising its commitments to the CPB, WTO (SPS and TBT Agreements) and *Codex Alimentarius* Commission, Trinidad and Tobago will use the precautionary approach for environmental safety assessments and substantial equivalence for food safety assessments, enshrined in the national environmental and health policies respectively.
- (iv) **Case-by-case approach** - Decision-making will be based on risk analysis of the individual biotechnological applications, rather than a general approach.
- (v) **Stage-by-stage approach** - Decision-making will be based on risk analysis at the different stages of application of biotechnology (i.e. contained use, greenhouse, limited field release and commercial release).
- (vi) **Flexibility in decision-making** - Recognising that decisions are based on current, scientific information, the decision-making process will be flexible, to take into account advances in scientific knowledge. Decisions also have to be pragmatic to enable easy implementation.
- (vii) **Participatory approach to decision-making** - Recognising the wide-ranging implications of the Policy on various sectors, it provides for a mechanism to incorporate sectoral interests in the decision-making process.
- (viii) **Transparency in decision-making** - the decision-making process will provide opportunities for public participation, and the results of such decisions will be made available in a timely and accessible manner. The

Policy supports a public education and awareness campaign that seeks to inform the public of new developments on a timely basis.

- (ix) **Cognisance of intellectual property rights** - the Policy will recognise the confidentiality of information contained in the applications. In addition, biosafety clearance granted by relevant authorities should not be construed as permission to import, stockpile, and market, as these rights may belong to industrial property owners.
- (x) **Pragmatic approach to labelling** - Given our trading relationships, the Policy also outlines a pragmatic approach to food labelling, which is pro-choice, fair and at the same time intended to have minimal effect on food prices.
- (xi) **Regional harmonisation** - The Policy facilitates the regional harmonisation of biosafety standards and procedures, joint capacity-building efforts, public education efforts, labelling and risk analysis efforts to ensure smooth implementation of the CSME.
- (xii) **Human rights-based approach** - the Policy supports a human rights-based approach as enshrined in the 'Rights-Based Approach' of the United Nations, recognising that human rights and development are not distinct.

The National Biosafety System

The national biosafety system entails:

- (i) An institutional framework, which includes the National Biosafety Authority (NBA) comprising the National Biosafety Secretariat (NBS) and Committee (NBC), Institutional Biosafety Committees (IBCs) and supporting regulatory agencies.
- (ii) An administrative system which includes procedures and guidelines for:
 - Applicants and the application process;
 - Decision-making, including scientific risk analysis (risk assessment, management and communication), socio-economic evaluation and public participation;
 - Regulatory mechanisms such as licenses, permits, notifications and guidelines/oversight;
 - Transboundary movement of LMOs and LMO-FFPs, contained LMO research at various biosafety levels, confined greenhouse or field research, deregulated status, transit, import and export of LMOs;
 - Compliance monitoring and oversight;
 - Liability and redress, mitigation of risks, and managing intellectual property and confidential information;
 - Public participation and transparency;
 - Penalties; and
 - Appeal processes.
- (iii) A legislative framework that will provide legal authorities to the relevant institutions and regulatory agencies, and harmonisation with existing legislation.
- (iv) A plan for public awareness, education, and information access.
- (v) A National Biosafety Capacity-building Plan

Institutional Framework

The National Biosafety Authority (NBA)

The Government will establish an NBA, under the Ministry responsible for Biosafety, as the legal authority for decisions relating to the safe transfer, handling and use of LMOs resulting from modern biotechnology, and products derived from them that may have adverse effects on the conservation and sustainable use of biological diversity or on human and animal health.

The NBA will comprise a National Biosafety Secretariat and a National Biosafety Committee and will act as the competent authority as defined under the CPB. The NBA will serve as a coordinating mechanism to ensure that biosafety regulations are implemented by the relevant regulatory agencies.

National Biosafety Secretariat (NBS)

Functions of the NBS will include:

- (i) Receiving and preliminary screening of notifications/applications related to:
 - importation; transit and placing on the market of products of modern biotechnology including LMOs (except LMO-FFPs which will be the responsibility of the Food and Drugs Division, Ministry of Health) contained (greenhouse, BL3 and BL4¹⁸ research) or confined use for research or other purposes; and
 - deliberate release into the environment of LMOs
- (ii) Acknowledging receipt of the notification/application;
- (iii) Requesting further information from the notifier/applicant necessary for the decision-making process;
- (iv) Undertaking a risk assessment review of a proposed activity;
- (v) Establishing minimal risk management requirements to help inform decision-making;
- (vi) Communicating decisions to the notifier/applicant, regulatory authorities, Regional Biosafety Advisory Committee (RBAC)¹⁹ and the public;
- (vii) Responding to requests by the notifier/applicant to review decisions, including queries regarding approved applications;

¹⁸Guidelines for biosafety are categorised into four levels. BL3 and BL4 represent the highest levels of biosafety, requiring more stringent containment.

¹⁹Regional Biosafety Advisory Committee (RBAC): This committee is envisaged as being the regional harmonisation mechanism under the CARICOM, but is yet to be established.

- (viii) Consulting with the notifier/applicant on treatment of confidential information;
- (ix) Supporting the decision-making processes;
- (x) Responsible for the establishment and maintenance of a BCH, a mechanism for documentation and information exchange;
- (xi) Maintaining a register of institutional biosafety committees and points of contact, LMO and LMO-FFP exporters and importers, notifications received and decisions; and a management information system;
- (xii) Co-ordinating capacity-building programmes related to biosafety implementation and public education campaigns;
- (xiii) Co-ordinating with regulatory agencies, which are responsible for implementing decisions taken by the NBC;
- (xiv) Interaction with the BCH and CPB mechanisms; and
- (xv) Interaction with regional and other national biosafety entities.

The National Biosafety Committee (NBC)

The NBC will be appointed by the Cabinet based on the recommendation of the Minister responsible for Biosafety for a fixed term and would include representatives from Ministries of Health, Agriculture, Environment, Finance (Customs and Excise Division) Trade and Legal Affairs; Office of the Attorney General, Tobago House of Assembly, Environment Management Authority, research institutions, Universities, relevant NGOs and the private sector. The Cabinet will also approve the terms of reference for the Committee. The NBC on behalf of the NBA will be responsible for the decision-making process. It will be authorised to establish sub-committees for scientific risk analysis, socio-economic evaluation and soliciting public opinion; and for co-opting expertise for these committees, as necessary.

The NBC will be responsible for establishing procedures to avoid conflicts of interests arising within the appointed committees. It will also commission the development and updating of biosafety guidelines and, along with the regulatory agencies, develop a contingency plan for unexpected eventualities.

Institutional Biosafety Committees (IBCs)

Each institution involved with products of modern biotechnology including LMOs will establish an IBC, and both the institution and the committee will be registered with the NBA. Institutions conducting research at the BL3, BL4 levels or commercial-scale research will require a designated biological safety officer, who will also be a member of the IBC. The IBC will be responsible for keeping an accurate and up-to-date record of biotechnology activities in the institution, ensuring that the activities of the institution comply with the guidelines provided by the NBA and submitting applications to the NBC for confined (greenhouse, BL3 and BL4 research) or unconfined release of products of modern biotechnology including LMOs into the environment.

Regulatory Agencies

Environmental Management Authority (EMA)

On behalf of the NBA, the EMA, in conjunction with the MALMR, will have the responsibility for monitoring, on a periodic basis, field trials (both restricted and commercial scale trials) conducted by the IBCs for adherence to environmental safety standards stipulated by the NBA. In addition, the EMA will be responsible for periodic monitoring and certifying that laboratory facilities involved in BL1 and BL2 research are compliant with the guidelines of the NBAs. The EMA will be responsible for monitoring the compliance of laboratories to the conditions under which the NBA approved research at the BL3 and BL4 levels, especially with regard to containment and waste disposal. It will ensure that the IBCs have adequate contingency plans in place in case of unintended breach of containment, and will serve as the first line of contact when such breaches occur.

The EMA will have periodic reporting requirements to the NBA on all monitoring services performed.

Agricultural Health (Plant and Animal)

Plant and animal health are the responsibility of the MALMR which will monitor plant and animal health issues arising out of the recommendations made by the NBA. Monitoring all agricultural trials for agricultural impacts and transportation of GM planting material will fall under the purview of the division responsible for agricultural health on behalf of the NBA. It has a periodic reporting requirement to the NBA of all monitoring services performed. In addition, the division responsible for agricultural health on behalf of the NBA shall be responsible for regulating the importation of products of modern biotechnology including LMOs into Trinidad and Tobago.

Food and Drugs Division (FDD)

The FDD of the Ministry of Health (MOH) shall be responsible for regulating the importation and placement on the market of LMOs-FFPs. The FDD shall have authority to ensure that the food safety standards relating to GM foods approved by the NBA are adhered to, with respect to both imported and locally produced LMO-FFPs. It shall receive applications for the first time importation of LMO-FFPs and will conduct confirmatory tests using its facilities or, where necessary, through the network of affiliated food testing laboratories in the region, and convey the results with a recommendation to the NBC. The NBC can either commission a further thorough scientific review through the Risk Assessment and Management (RAM) sub-committee and/ or simply obtain feedback from the public forum, prior to approval. Approved GM events will be placed on the BCH. Furthermore, the FDD shall be responsible for developing labelling, food safety and quality standards for LMO-FFPs and a contingency plan for unexpected eventualities consistent with recommendations from the NBC.

Customs and Excise Division

The Customs and Excise Division of the Ministry of Finance will process and verify all documents relating to all goods, imported and exported (Form C-82)²⁰. In the case of imported goods, these forms must first be endorsed by the relevant regulatory agency. The regulatory agency will indicate at the time of endorsement, whether delivery could be authorised or whether the goods need to be held for examination, examined and released, or released to premises for subsequent examination.

In the case of exports, including transshipments, the minimum procedural requirement is that prior approval from the NBA must be received by the exporter before any goods are brought to the Customs.

Tobago House of Assembly (THA)

The Assembly shall be responsible for implementing in Tobago, Government policy relating to biosafety²¹. To effectively fulfil this mandate, all regulatory agencies must have a presence in Tobago.

²⁰Form C-82 is an internationally accepted instrument used by Customs to regulate imports and exports.

²¹Tobago House of Assembly Act, Chap.25:03

Administrative System

The administrative system (Appendix) will be based on guidelines and oversight, notification and permits, and will utilise, as far as possible, existing systems for importation of food and feed, pharmaceuticals and agricultural commodities including seeds. The system will establish functional links between the NBA and the regulatory agencies through Memoranda of Understanding. The administrative system will be supported by a legislative framework that will give legal authority to the various institutions within the National Biosafety System.

Applicants and the Application Process

- 1) The NBA requires that all persons, local or foreign, apply for permission for the following activities:
 - Import, export or transit of unapproved LMOs and LMO-FFPs
 - Contained research or use²² involving unapproved LMOs
 - Confined research or use²³ involving unapproved LMOs
 - Placing on the market of unapproved LMOs or LMO-FFPs (unconfined use²⁴)

All applicants, foreign or local, requesting permission for transboundary movement of LMOs for research or use must apply through a registered national IBC, prior to undertaking the activity.

Applications are to be made to the NBA using the prescribed forms for each activity. The applications will be reviewed by the NBA and decisions communicated to the applicant within stipulated timeframes.

²²Includes activities in laboratories, greenhouses, cages, production in fermenters or indoor facilities.

²³Includes field trials, clinical trials and industrial trials.

²⁴Includes general production, outside of a confined facility. Unconfined use may be carried out under a conditional approval that sets specific risk management conditions for a set period of time.

Decision-Making Process and Procedures

Decision-Making Authority and Decision-Making Guidelines

The NBA will ultimately be responsible for all decisions with regard to the importation, exportation, transit and placing on the market of LMOs (except LMO-FFPs which will be the responsibility of FDD) as well as for the contained use, contained or confined research, and the deliberate release of LMOs into the environment. The decision-making process, however, will take place at the level of the NBC, supported, if necessary, by the ‘Risk Assessment and Management’ (RAM) sub-committee and a ‘Socio-Economic Assessment’ (SEA) sub-committee’, and will be based on guidelines developed by the NBA.

Basis of Decision-Making

Decision-making will be on a case-by-case basis, with each case evaluated at each stage of development. The application for a permit to conduct greenhouse trials with a specific LMO will, for instance, be treated as distinct from an application for a field trial or for the deliberate commercial release of that same LMO. Furthermore, decisions will be on an event-by-event basis, such that a genetic modification in a specific host will be treated as distinct from the same genetic modification in a different host.

Decisions for the deliberate release of LMOs into the environment will be based primarily on ‘science-based risk analysis’ and ‘cost-benefit’ analysis. The principles and procedures of scientific risk analysis will incorporate risk assessment, risk management and risk communication. When scientific uncertainty exists with regard to the potential environmental risks associated with the release of LMOs into the environment, the precautionary approach may be invoked to minimise the potential risks associated with the introduction of LMOs into the environment. Precautionary decisions, however, shall be instituted in proportion to the likelihood and magnitude of the potential risk.

With regard to the introduction of LMO-FFPs into the food chain, decisions shall be based on ‘scientific risk analysis’ guided by international standards developed by the *Codex Alimentarius* Commission of the FAO/WHO and adopted by the Government. The decision-making process for the deliberate introduction of LMO-FFPs into the food chain shall be based on the principle of ‘substantial equivalence’.

Decision-Making and Decision Communication

The NBC shall strive to arrive at a consensus decision. However, when it is divided with respect to a decision, the majority decision shall prevail. Decisions will be made in a timely manner within stipulated timeframes. All decisions will be communicated to applicants and regulatory agencies entrusted with the implementation and monitoring functions. Decisions will also be provided to the RBAC, BCH and made available to the public.

The NBA will establish systems to ensure that conflicts of interest do not arise which may compromise the decision-making process, and ensure that intellectual property rights and confidential information are respected and withheld in public documents.

Review of Decisions/ Revoking Decisions

Applicants shall be permitted to request a review of decisions of the NBA if:

- (i) a change in circumstances has occurred (for example a change in the proposed receiving environment of the LMO, availability of improved detection and identification methods for the LMO, change in the intended use of the LMO) which may influence the outcome of the risk assessment upon which the decision was based; or
- (ii) additional relevant scientific or technical information has become available.

Similarly, the NBA is authorised to revoke a decision if new scientific information indicates that the approved LMOs may pose a risk to plant, animal or human health; genetic resources; or the environment.

Applicants, as well as third parties, will also be afforded the opportunity to appeal decisions of the NBA to the Environmental Commission²⁵. The NBA will however, make every effort to encourage and promote alternative dispute resolution²⁶.

Transparency in Decision-Making

All decisions shall be accompanied by decision documents, which will outline the decisions, the conditions attached to the decisions, and the basis for arriving at the decisions. Decision documents (excluding proprietary and confidential information) will be gazetted and placed in the media and the BCH to ensure transparency.

In addition to having access to decisions, the public will participate in decision-making through representation of various NGOs/stakeholders on the Sub-Committees of the NBA. Permits issued will also be published in the media, the gazette and the BCH.

²⁵Environmental Commission is a superior court of record, established under the Environmental Management Act of 2000, which has jurisdiction to hear and determine appeals from decisions or actions taken by the EMA. It has the same power to punish contempts as the High Court of Justice.

²⁶Alternative dispute resolution is any mechanism for resolving disputes other than by way of litigation.

Procedures for Transboundary Movement of LMOs and LMO-FFPs

- (b) All transboundary movement (import, export and transit) of LMOs and unapproved events of LMOs-FFPs will require approval from the NBA and a permit from the relevant regulatory authorities.

Importation of LMOs Intended for Deliberate Release into the Environment

Applications for the first intentional transboundary movement of LMOs (specific LMO events) for deliberate introduction into the environment will require the Advanced Informed Agreement (AIA) of the NBA and a permit from the relevant regulatory agency. The procedure for obtaining approval will include a scientific risk analysis and a socio-economic analysis when necessary. Approved events will be placed on the BCH and will be exempt from the AIA procedure.

Importation of LMOs destined for contained use will not be subjected to the AIA procedure. However, they should, at a minimum, be clearly identified as LMOs, with specifications for their safe handling, storage, transport and use. The contact point for further information, including the name and address of the consignee, must also be provided.

Importation of LMO-FFPs

Applications for the first time importation of an LMO-FFP will be received and processed by the FDD and a recommendation forwarded to the NBA for approval. Decisions shall be taken by the NBA based on scientific risk analysis and the principle of substantial equivalence. The decisions will be communicated to the FDD and the public, and placed on the BCH. Subsequent imports of approved LMO-FFPs placed on the BCH will proceed through the regular import procedures.

The support system for this procedure will consist of a food registry that will include a list of importers and approved GM events by crop, and which will be made available on the BCH. However, there will be a system of random verification of the imported LMOs-FFP, which will be conducted by the FDD through approved laboratories (either locally or regionally), to determine if there are any unapproved GM events present.

Export of LMOs or LMO-FFPs

Each exporter will be required to obtain prior approval from the NBA, and adhere to the following minimum documentation requirements governing all LMOs and/or LMO-FFPs:

- (i) LMO-FFPs must be clearly identified as “may contain LMOs” and “not intended for intentional introduction into the environment”. A contact point for further information must also be included with the name and address of the consignee.

- (ii) LMOs destined for contained use must be clearly identified as such, with specifications for their safe handling, storage, transport and use. A contact point for further information, including the name and address of the consignee, must also be included.
- (iii) LMOs which are intended for intentional introduction into the environment of the country of import must be clearly identified as such, with specifications on the identity and relevant traits and/or characteristics, and requirements for safe handling, storage, transport and use. The contact point for further information and the name and address of the importer and exporter must also be specified.

LMOs or LMO-FFPs in Transit

Transboundary movement of LMOs not destined for use in Trinidad and Tobago (i.e. LMOs in transit) must fulfil the notification requirements of the NBA. Notification requirements should include among others: country of export, country of import, country of final destination and the nature of genetic modification. This notification will be placed on the BCH.

Procedures for Conducting Research Involving LMOs

Recombinant-DNA research is conducted in stages (laboratory, greenhouse or under field conditions) toward the eventual development of an LMO that will be commercially released into the environment. The level of exposure increases from the laboratory to the field and may require more stringent biosafety requirements. The biosafety knowledge of an LMO may increase through field trial data collection. This knowledge may alter the required levels of biosafety management.

Contained Research at BL1 or BL2 Levels

- (i) Contained laboratory research in modern biotechnology at the BL1 and BL2 levels shall be conducted in NBA-registered institutions, on the condition that all research activities strictly adhere to the 'National Biosafety Guidelines for Recombinant DNA Research' developed by the NBA. The IBC will be responsible for ensuring that the principal investigators responsible for laboratories in the various institutions adhere to the guidelines. The EMA will provide oversight to ensure that laboratories and the IBC follow the guidelines strictly.

Contained Research at BL3 or BL4 Levels

Principal investigators pursuing research or commercial activities at the BL3 and/or BL4 levels involving LMOs must apply to the NBA, through the IBC, for permits to pursue such activities. NBA approvals for all BL3 and BL4 research will require that specialised facilities are in place, along with adherence to the specific guidelines for Recombinant-DNA research.

The EMA will be responsible for oversight and compliance monitoring of the guidelines provided by the NBA.

Confined Greenhouse Research

Regulatory permits from the NBA will be required for all categories of greenhouse experiments involving LMOs. Principal investigators will be required to apply, through the IBC, to the NBA for permits for greenhouse trials. The NBA will require a risk analysis prior to issuing permits, if it regards the work as high-risk or is not satisfied with confinement standards. Permits issued by the NBA will be accompanied by guidelines for greenhouse research (depending on the biosafety level of the study), which provide a set of rules to ensure that the work carried out in greenhouses does not pose an unacceptable risk to plant, animal or human health; genetic resources; or the environment. Permits may also

have special conditions and monitoring requirements attached to them. Oversight and compliance monitoring shall be carried out by the EMA.

The IBC will serve as the institutional authority with responsibility for oversight, to ensure that work within the institution is carried out according to the specified rules. The greenhouse manager will assume full responsibility for implementation of the biosafety procedures developed on a daily basis, including access, maintenance of records, transfers, signage, pest management, security and contingencies.

Limited Release Trials (Field Trial)

A permit from the NBA is mandatory for all categories of field experiments involving unapproved LMOs. Since a limited release trial is an intentional release into the environment, the NBA will commission a preliminary scientific risk analysis prior to issuance of a permit, which will detail any risk management conditions for the trial. Along with the permit, the NBA will provide guidelines for research carried out on LMOs in limited-scale field trials. Routine compliance monitoring of such trials will fall within the purview of one or more of the regulatory agencies.

Applications should be submitted by principal investigators to the NBA through the relevant IBCs. The IBC will serve as the institutional authority with responsibility for oversight, to ensure that work within the institution is carried out according to the permit conditions and general guidelines. The field station manager will assume full responsibility for implementation of the biosafety procedures, including storage, access, maintenance of records, transfers, growing season, harvest, destruction, post-harvest monitoring, accidental releases, reporting, signage, pest management, security and contingencies.

Commercial Release or Application for Deregulation

This represents the last regulatory step prior to attaining unregulated status for an LMO. The objective of this regulatory step is to provide comprehensive risk assessment and appropriate risk management to ensure that the commercial release does not pose an unacceptable risk to plant, animal or human health; genetic resources; or the environment. At this stage, in addition to risk analysis, a Socio-Economic Impact Assessment, including a cost-benefit analysis and assessment of public opinion may be required.

The safety risk assessment guidelines should address concerns such as invasiveness, gene flow to compatible species, effects on existing agricultural systems and crop genetic diversity, long-term ecological effects, in addition to human health issues such as allergenicity, toxicity and nutritional quality and any other issue deemed important by the NBC.

A permit from the NBA is required to obtain deregulated status. The permit may have conditions for implementation and monitoring. There may be reporting requirements. A permit could be terminated upon evidence of any negative impacts on plant, animal or human health; genetic resources; or the environment. Applications arising from local research shall be submitted, through a National IBC to the NBA. Simultaneously, the application will be forwarded to the RBAC, which will make it available to all member countries. The member states may express any concerns to the RBAC and support these with further recommendations within given time frames.

Procedures for Compliance Monitoring and Oversight

The NBA will develop Memoranda of Understanding with the relevant regulatory agencies that will perform compliance monitoring and oversight functions on behalf of the NBA. The regulatory agencies will be required to report on such activities to the NBA on a regular basis.

Administrative Costs of Decision-Making and Compliance Monitoring

The NBA will factor in the cost of decision-making and compliance monitoring in the application fee for permits, so that the cost can be recovered from the applicant. The NBA may charge a differential fee for local and foreign applicants in an effort to stimulate local research and innovations in the area of biotechnology.

Liability and Redress

In the event that damage is caused to biodiversity, human life or health, property, or the environment under the jurisdiction of Trinidad and Tobago, the applicant will be liable for compensation and all costs incurred in mitigation and rehabilitation. This liability can result from either unapproved use of a LMO, or through LMOs for which false or misleading information was provided by applicants when approvals were granted.

Contingencies

Contingency plans will be instituted to mitigate against breaches of containment/confinement due to natural disasters, fire, negligence, industrial action, eco-terrorism, vandalism and other forms of terrorism. The NBA will require that all individuals/institutions undertaking research or commercial activities involving unregulated LMOs put in place the necessary contingency measures in cases of emergencies or unexpected events which may result in the breach of containment or confinement facilities. Any breach in containment/confinement should immediately be brought to the attention of the NBA.

In order to minimize any significant adverse effects on the conservation and sustainable use of biological diversity, and also taking into account risks to human health, the NBA will initiate, through the relevant regulatory agencies, the necessary action, including emergency measures and sensitising the public.

Management of Proprietary and Confidential Information

The NBA will allow the applicant to identify information submitted which is to be treated as confidential, and which will not be divulged, except with the written consent of the applicant.

The NBA will consult with the applicant if it decides that the specified information does not qualify for such treatment and shall, prior to any disclosure, inform the applicant of its decision. The NBA will provide the applicant with an opportunity for consultation, and for an internal review where necessary, and will provide reasons for its decision on request.

If an applicant withdraws an application, the confidentiality of commercial and industrial information, including research and development information, will be respected.

Permission granted for commercial exploitation of products of modern biotechnology including LMOs or LMO-FFPs should not be construed as permission to infringe upon the rights of industrial property owners. Applicants should be advised to contact Intellectual Property Office in this regard.

Public Awareness and Public Education

The Government will promote and facilitate public awareness and education, including access to information, concerning the development, introduction and use of products of modern biotechnology on an on-going basis, through the NBA.

The decision to allow or disallow the commercial release of a LMO will be gazetted and the public informed through the media. The NBA will publish a yearly summary of LMOs approved for commercial release, and will commission public awareness and risk communication campaigns as deemed necessary by the NBC.

Non-Compliance and Penalties

It will be the duty of the applicant to ensure that all the information provided is truthful and valid. Furthermore, the applicant will be responsible for implementing the conditions applied to the approval of any application.

The regulatory agencies will be authorised by law to impose penalties according to the seriousness of the infraction, which can range from warnings, fines, injunctive relief, seizure and destruction, withdrawal of permits, or criminal proceedings.

Appeal Process

The NBA shall institute an appeal process, which will provide a mechanism to appeal any national decision, without the need for litigation. This will be conducted within a stipulated time frame that is short and involves a second review totally independent of the

first review. The appeal process will be enshrined in the Biosafety legislation and the decision is final.

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Legislative Framework

The Government will develop appropriate and effective legislation to give the force of law nationally for the implementation of the Policy. Such legislation will regulate research and development as well as direct import, export and use of products of biotechnology, and support the existing laws and regulations governing intellectual property rights, consumer rights, the environment, agriculture and health. The enabling legislation will provide for liability and redress for damages caused by unexpected events, penalties and a permit/oversight system that would give legal force to the necessary terms and conditions recommended by the NBA for activities with products of modern biotechnology including LMOs and LMO-FFPs.

Plan For The Promotion And Facilitation Of Public Awareness, Education And Information Access

The Government shall promote and facilitate public awareness, education and information access concerning the safe transfer, handling and use of products of modern biotechnology including LMOs, guided by a rights-based approach to accountability and citizen participation. This will be achieved through the formation of partnerships between the Government, national and regional research and development institutions, academic institutions and civil society aimed at the development and implementation of effective and sustainable public awareness and education programmes on products of modern biotechnology, including LMOs.

Methods of engagement will include the mass media, public open days, printed information, internet groups, public databases, information hotline, school and community programmes, workshops, seminars and continued biosafety presence at all relevant national events.

Public consultations will be held if required, for applications at various biosafety levels as determined by the NBC, which in turn will be informed by scientific risk assessment. In all these cases where there is controlled use of products of modern biotechnology, the final decision for the approval of the applications will rest with the NBA. The results of such decisions will be made available to the public, while respecting confidential information in accordance with Article 21 of the CPB.

National Biosafety Capacity - Building Plan

The Government recognises that, in order to effectively implement the Policy, human resources and institutional capacity will have to be strengthened, especially in the areas of risk analysis, public awareness, IT and communication technology, laboratory facilities for LMO testing, law enforcement and compliance monitoring. In order to ascertain these requirements, the NBA will commission a needs assessment with respect to human resource, training, institutional strengthening, and legislative requirements. This

assessment will form the basis for a National Biosafety Capacity-Building Plan that will guide future capacity-building activities.

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Section 3 The Regulatory System

General Principles

As a signatory to the CPB, Trinidad and Tobago has to establish a domestic biosafety system in the form of a biosafety policy, strategy, legislation and administrative set up to provide the foundation for subsequent technical and regulatory implementation. These measures should aim at ensuring that the development, handling, transport, use, transfer and release of living modified organisms are undertaken in a manner that prevents or reduces the risks to biological diversity, taking into account risks to human health (Article 3). The main principles that are embodied in the regulatory system for biosafety are based on precaution and transparency. The development of an effective and transparent regulatory system for T&T entails:

1. Establishment of a regulatory authority and legal framework and,
2. Development of a system for the implementation of biosafety along with the necessary guidelines and procedures.

Regulatory guidelines in T&T

An analysis of the legislative requirements of the Cartagena Protocol on Biosafety (Article 1), which focused on the: *the precautionary approach and the need for adequate protection* was conducted to identify what national legislation was required for implementation of the CPB. To support this, an inventory and analysis of the legislation that exists within Trinidad and Tobago revealed that legislation relevant to the CPB could be found within those that regulate Plant Protection and Food and Drugs.

Existing Regulatory Bodies and Laws

Safety issues in Trinidad and Tobago are regulated by several governmental organisations. They include:

- Food & Drugs - Food and Drugs Division of the Ministry of Health. Enforces Food and Drugs Act. Chapter 30:01. Regulations 7(1), 14(h), (i), (j), 15.
- Environment - Environmental Management Authority within the Ministry of Public Utilities and the Environment. Governed by the EMA Act 2000.
- Plant & Animal Protection - Plant & Animal Quarantine Services, Ministry of Agriculture, Land & Marine Resources. Enforces Plant Protection Regulations 1997.
- Importations - Customs and Excise Division of the Ministry of Finance.

There is established legislation in these areas, which however, in most instances is old and in need of revision, enhancement and harmonization. In addition, although there are established positions in some of the above-mentioned divisions, personnel have not been trained specifically in biosafety relating to GMOs and LMOs. Biosafety is neither established in legislation nor is there established bodies that address the issue. An examination of the existing legislation indicated that the provisions of the Plant

Quarantine Act and the Food and Drugs Act, and their accompanying regulations may be amended to address immediate concerns relative to GMOs and LMOs.²⁷

The Plant Protection Regulations 7(1), 14 (h), (i), (j), 15 offers some protection prior to the arrival of a GMO/LMO. The Regulations state that: “*all planting material is subject to such inspection and treatment as may be necessary, as a condition of entry into Trinidad and Tobago.*” A provision such as this would facilitate the precautionary approach by allowing for inspection and treatment where necessary. Also the provision allowing for the entry status of fruits or vegetables to be determined “*according to pests present in the exporting country*” can be used in a precautionary way where there is difficulty in determining the risk of a particular LMO but the biosafety record of the exporting country is documented and known. However, roles of the existing regulatory agencies and personnel must be clearly defined in order for these pieces of legislation to be used efficiently and effectively²⁸.

The Regulations also require that “*The Plant Quarantine Service shall issue Phytosanitary certificates based on inspections performed at the request of exporters to aid them in meeting the entry requirements for Trinidad and Tobago*”. A similar certificate could be issued following a risk assessment by the responsible agencies and persons.

Regulations 3 (1), 7 (1),9, and 14 stipulate that the entry in the country of any restricted articles which may present a pest risk to the agriculture must be subject to examination upon arrival by a Plant Quarantine Officer and if necessary subject to treatment, destruction or re-export as needed. The provision allows for some assessment to take place and where an article is deemed a biosafety risk, the recourse would be destruction or re-export as treatment would not be applicable. The Regulations allow for the entry of plant pests provided a permit is issued to a recognised scientific and research institution where it is destined for use. The safeguards specified in the Regulations for permit requirements should apply to these institutions and their permits should specifically state that the materials is to be used exclusively for research²⁹.

Regulation 18 recognizes that Trinidad and Tobago are separated by water and specifically provides that “*all fruit, vegetable or plant material which is subject of an order made by the Minister shall be carried to Tobago, unless... accompanied by a Phytosanitary Certificate.*” This provision can be used in biosafety regulations.

Sections 6(1), (2) of the Food & Drug Act states that:

- *‘Any person who labels, packages, treats, processes, sells or advertises any food in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding character, value, quantity, consumption merit or safety is guilty of an offence.’*

²⁷ Prof. Julian Duncan, pgs. 2 and 12.

²⁸ Ibid, pg. 4.

²⁹ Ibid pg.6.

‘An article of food that is not labelled or packaged as required by the Regulation or is labelled contrary to the Regulations shall be deemed to be labelled or packaged contrary to subsection (1)’.

These provisions are relevant to the labelling of goods containing GMOs and would require more specificity after taking due regard to trade impacts. The Minister also has ample powers to make regulations concerning food and drugs in respect of labelling, packaging, condition of sale, standards of composition, importation, method of preparation, packing, storing, testing, the powers and duties of inspectors and analysts, among other things. On the advice of the biosafety committee, the Minister can exercise these powers to promote biosafety.

It is to be noted that the country’s food labelling regulations are currently being updated. The draft revised regulations states in section 10.012 (6) that the *“presence in any food or food ingredients obtained through biotechnology of an allergen transferred from any of the products listed in sub section (5) shall be declared”*. The listed products are those known to cause hypersensitivity such as cereals containing gluten, crustacea, eggs and egg products, fish and fish products, peanuts, soybean and such products, all of which must be declared. Proposed sections 16.036 (2) and (3) can supply a measure of protection against the possible harmful effects of genetically engineered plants containing agricultural chemicals and drugs. A food would not comply with the regulations if it contains *“an agricultural chemical or any of its derivatives...in an amount that exceeds the maximum residue limit set out in column III of that item.”* There is provision for the *“results of tests and scientific analysis that demonstrate that the use of the food will not be detrimental to the health of the purchaser or user.”*

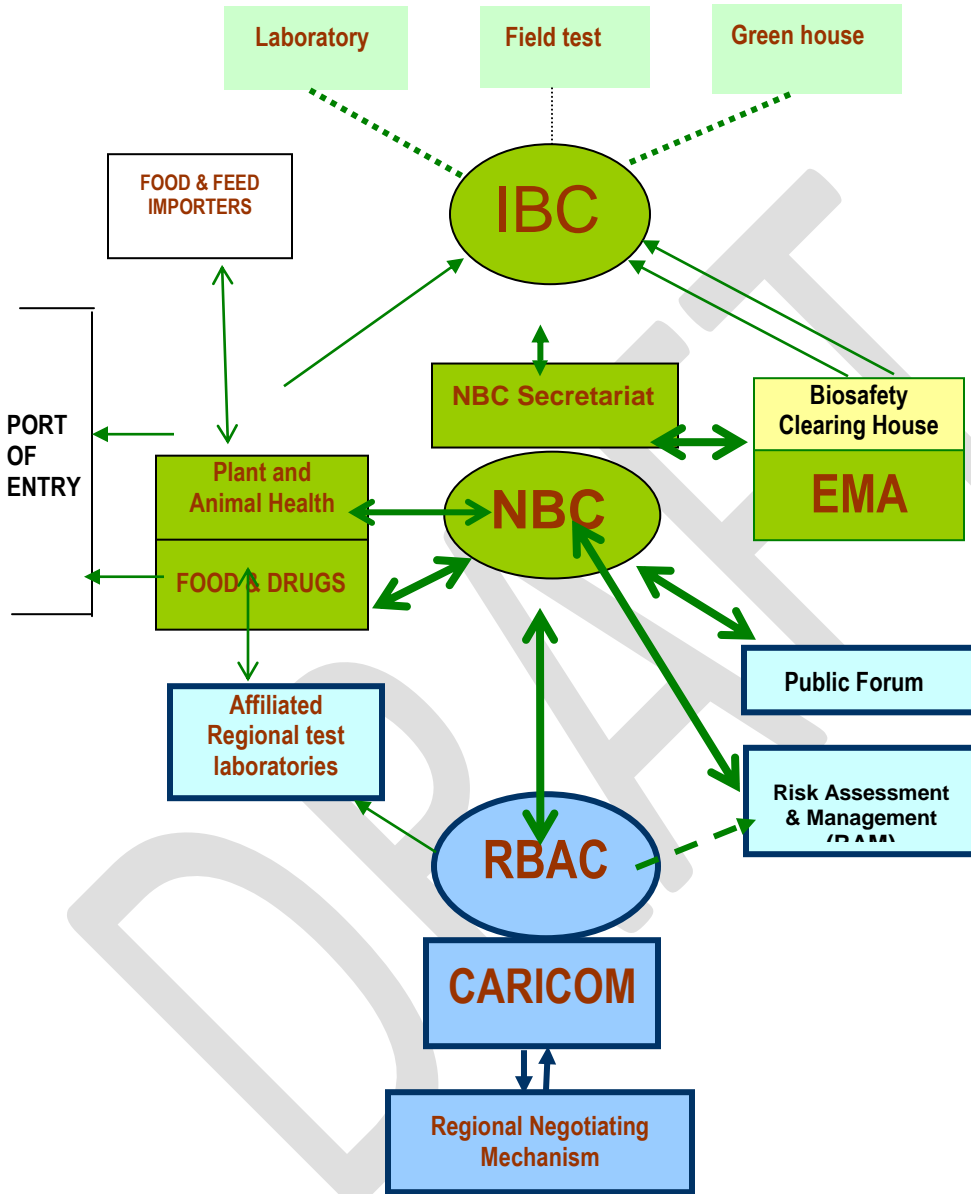
Proposed Regulatory Laws

As can be seen from the above inventory and analysis, there are no laws in Trinidad and Tobago that deals specifically with products of modern biotechnology and biosafety. Given the wide scope of biosafety, the potential for growth and the uncertainty of long-term risk, the GOTT has decided to draft new legislation pertaining exclusively to biosafety (Section 2.0). The new laws will regulate research and development as well as direct import and use of products of biotechnology and support the existing laws and regulations.

Proposed Regulatory Bodies (Diagram 3.1, Table 3.1)

The institutional framework to manage biosafety in T&T will be based on existing institutions with modified roles and functions. The proposed model for the regulatory and institutional framework borrows features from the Australian, European and US regimes but has been modified to suit the national requirements using existing national structures as the framework foundation.

Diagram 3.1 Biosafety regulatory system in Trinidad and Tobago
(P. Umaharan, 2005)



NBC - National Biosafety Committee
 IBC - Institutional Biosafety Committee
 RBAC - Regional Biosafety Advisory Committee
 EMA - Environmental Management Authority
 BCH - Biosafety Clearing House - T&T

Table 3.1

Committee/ Agency	Responsibilities
<p>National Biosafety Committee (NBC)</p> <ul style="list-style-type: none"> ▪ Competent and legal authority for decision making³⁰ which operates through a Secretariat 	<ul style="list-style-type: none"> ▪ The lead body for the coordination and harmonization of the NBF which will be inter-agency and multi-sectoral ▪ Develop/ commission the continued development and updating of biosafety guidelines ▪ Distribute guidelines to stakeholders and interested parties ▪ Set the scientific and technical guidelines as well as operational procedures and standards for the other agencies involved in the NBF ▪ Oversee the implementation of the NBF ▪ Maintain consensus documents on issues which will guide the decision making process ▪ Receive, review and make final decision on applications for: <ul style="list-style-type: none"> - <i>conduct of research on LMOs</i> - <i>limited or commercial release of LMOs into the environment</i> - <i>import of GM food, feed or seed material, for field testing</i> - <i>production of GM food</i> - <i>placement of GMOs on local market</i> <p><i>(Note: this takes into account the confidentiality requirement)</i></p> <ul style="list-style-type: none"> ▪ Collect application fees ▪ Resolve conflicts of interests and appeals when they arise ▪ Inform the decision to applicants ▪ Maintain decision documents at every step of the decision making process with rationales ▪ Place the decisions on gazette ▪ Coordinate with the regional biosafety advisory committee (RBAC) ▪ Develop and monitor the implementation of contingency plans for unexpected eventualities ▪ Ensure the development and implementation of a Management Information System (MIS) ▪ Ensure the development and implementation of a labeling policy in collaboration with the Food and Drugs Division (FDD)

³⁰ Decision making for biosafety as it relates to modern biotechnology in the following areas: plants and plant products, fisheries and other aquatic resources, domesticated animals and biological products used for animal husbandry or veterinary purposes and biological agents for biocontrol; research and development; pharmaceuticals that are not addressed by other international agreements or organizations; regulated organisms intended for bioremediation, improvement of forest and wildlife genetic resources; and those applications that can potentially have an impact on conservation and sustainable use of biodiversity.

	<ul style="list-style-type: none"> ▪ Ensure the development and implementation of systems for traceability of GMOs or unique identification of GMOs ▪ Registration of IBCs, based on predetermined set of criteria ▪ Revocation of IBC membership based on evidence of non-compliance ▪ Human resource development for regulatory implementation through commissioning of training programmes ▪ Ensure public transparency ▪ Publish a yearly summary of GMOs approved for commercial release ▪ Conduct public awareness and risk communication campaigns. ▪ Maintain an internet accessible database of all applications received and what stage they are in, and which ones have received approval ▪ Receive reports from all subcommittees (RAM, public opinion) and regulatory authorities (FDD, PAHI and EMA) in a timely fashion and use for continued decision-making ▪ Certification of Registered Institutional Biosafety Committees through a National Regulatory Authority. <p>The NBC will be authorized by law to apply penalties according to the seriousness of the infraction and can range from warnings, fines, activities delayed, permits withdrawn, seizure and destruction or criminal proceedings</p>
<p><i>Environmental Management Authority (EMA)</i> Monitoring and enforcement</p>	<ul style="list-style-type: none"> ▪ Monitor greenhouse and field trials for adherence to environmental safety standards, risk management strategies and long-term monitoring recommendations by visits to greenhouse and field trial stages as well as commercial fields ▪ Scheduled reporting to the NBC of all services performed monitoring
<p><i>Plant and Animal Health Inspectorate of the Ministry of Agriculture (PAHI)</i> <ul style="list-style-type: none"> ▪ Monitoring and enforcement </p>	<ul style="list-style-type: none"> ▪ Monitor plant and animal health issues arising out of the recommendations made by the NBC. ▪ Monitor all agricultural trials for agricultural impacts, transportation of GM planting material, suitability of site or greenhouse. ▪ Scheduled reporting to the NBC of all monitoring services performed ▪ Responsible for regulating the importation of GMOs into Trinidad and Tobago
<p><i>Food and Drugs Division of</i></p>	<ul style="list-style-type: none"> ▪ Receive applications for first time import of GM material

<p><i>the Ministry of Agriculture (FDD)</i></p> <ul style="list-style-type: none"> ▪ Monitoring and enforcement agency 	<p>intended for use as food or feed</p> <ul style="list-style-type: none"> ▪ Conduct confirmatory tests using its facilities or through the network of affiliated food testing laboratories in the region ▪ Communicate the results with a recommendation to the NBC ▪ Develop a labeling policy consistent with recommendations from the NBC ▪ Ensure that the food safety standards developed by the NBC along with RBAC are adhered to, with respect to both imported and locally produced GMOs
<p><i>Regional biosafety Advisory Committee (RBAC)</i></p> <ul style="list-style-type: none"> ▪ Constituted by the CARICOM Secretariat and maintains an advisory role. 	<ul style="list-style-type: none"> ▪ Develop regional positions for negotiations at international harmonization fora ▪ Develop food safety standards that are consistent among member countries ▪ Assist in the establishment of a regional network of food testing laboratories ▪ Commission the development of consensus documents on crops and genetic modifications ▪ Maintain a website that summarizes decisions taken by individual countries to ensure transparency ▪ Maintain a database of human resource and biotechnology capacity within the region ▪ Mediate trade disputes arising from non-harmonious decisions taken by member countries ▪ Mount coordinated public education campaigns
<p><i>Institutional Biosafety Committee (IBC)³¹</i></p> <p>Criteria for needing and IBC:</p> <ul style="list-style-type: none"> ▪ Possession of a laboratory facility that can manage at least a Biosafety Level 2 experiment. ▪ The Principal Investigator must have at least a Master’s Degree in Biotechnology or a related discipline. ▪ Additional training must include biosafety and risk assessment and management. ▪ Unit must have a 	<ul style="list-style-type: none"> ▪ Review recombinant DNA research conducted at or sponsored by the institution for compliance with the NBC Guidelines ▪ Conduct of the necessary evaluation of the project and communicate results with conditions to the NBC and the Principal Investigator ▪ Ensure compliance at laboratories by surveillance, data reporting, and adverse event reporting. ▪ Pursue applications for trials with the NBC on behalf of the PI ▪ Provide technical advice to PI ▪ Develop and implement emergency plans covering breach of containment, accidental spills and personnel contamination resulting from recombinant DNA research ▪ Develop a mechanism to resolve conflict of interests as well as maintain confidentiality ▪ Provide advice and training on laboratory, greenhouse and field safety procedures for institute staff

³¹ Current facilities that require an IBC include: UWI, CARIRI, CARDI, CAREC, MOH, MALMR

sufficiently large body of work related to modern biotechnology	<ul style="list-style-type: none">▪ Appoint a Site Manager to oversee and be responsible for operations and to observe adherence to NBC stipulated guidelines for conducting the field trial.
Risk Assessment and Management Committee (RAM)	<ul style="list-style-type: none">▪ Conducting of thorough scientific review of the applications on behalf of the NBC▪ Transmit result of study to NBC with recommendation
NBC Secretariat	<ul style="list-style-type: none">▪ Facilitates the operation of the NBC

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Proposed Management Tools

The management tools for the proposed regulatory system comprise mechanisms and guidelines to facilitate research, development and commercialization of LMOs to ensure that the work carried out does not pose an unacceptable risk to human health or the environment. These mechanisms are meant to ensure that:

- The procedures for biosafety unify the management and supervision roles and functions of all the authorities that are involved in regulation of LMOs
- There are clear requirements for research, pilot testing, environmental release, commercialisation, application and transboundary movements to go through the procedure of risk assessment
- The developers/ importers of biotechnology and its products report to the relevant authorities and follow relevant procedures according to their different risk level activities
- Specifications are provided for risk management and that different risk management measures will be adopted for different phases of activities.

Accreditation of IBCs

Regulatory approvals and permits

Regulatory approvals required vary with type of experiments. Depending on the assignment of biosafety level they may require different sets of regulatory approvals prior to commencement of experiments based on the type of activity (Table 3.2)

Table 3.2

Contained testing which is a research step preceding confined trials and is conducted in restricted conditions.
Confined trial which is a research step preceding unconfined commercial release into the environment.
Unconfined release which is a commercial step that allows unconfined release into the environment.

Guidelines and oversight

Guidelines and oversight as a management tool will operate through the allocation of responsibilities (Table 3.3) and reporting requirements (Table 3.4).

Table 3.3 Roles and responsibilities

	Responsibility
<p>IBC</p> <ul style="list-style-type: none"> - Local authority - Include at least one scientist with experience in plants and plant pathogens - Biosafety officer may be assigned 	<ul style="list-style-type: none"> - Local authority - Project approval (dependent on biosafety level) - Responsible for oversight pertaining to specified rules of containment within greenhouses
<p>Principal Investigator</p> <ul style="list-style-type: none"> - PIs (and Greenhouse managers) should be trained on biosafety procedures and containment principles 	<ul style="list-style-type: none"> - safe handling of GMOs - coordinates with greenhouse manager, other researchers and technicians to develop a containment and contingency plan for each experiment according to the assigned biosafety level and international standards/ guidelines (plan to include all steps in the experimental protocol including transport, record keeping, pest management, equipment maintenance, termination etc.) - submit plan to IBC for approval - prepare a policy and procedures manual should be prepared and shared with everyone involved in the research - training of all researchers and technicians on biosafety procedures - implementation of an appropriate labeling system - maintenance of an activity log for each experiment and termination procedures used in destroying material.
<p>Site Manager</p>	<p>The site manager assumes full responsibility for implementation of the biosafety procedures on a day-to-day basis at the trial site. He/she will put in place procedures for restricting and recording access, keep a record of all experiments being carried out, maintain records of all items moved in as well as moved out or destroyed, manage all the workers to ensure that safety standards are adhered to during all operations (transport, harvesting, decontamination) ensure appropriate signage are posted, maintain the site to the required safety level, implement a routine rodent control programme, implement a process of post-trial monitoring if required to remove volunteers, to ensure that the site is secure from possible intruders, supervise all harvesting and termination operations and develop and implement a contingency plan in case of emergencies. The site manager will also take responsibility for training all laborers employed on safety procedures.</p>

The NBC however has the ultimate regulatory authority through EMA and PAHI to ensure that rDNA work (at BL2-P or above) is carried out in institutions according to the guidelines. This shall be done through unannounced spot checks or announced checks at critical points of the experiment.

Table 3.4 Reporting requirements

Personnel	Responsibilities
<p>Greenhouse manager (Reports to Principal Investigator)</p>	<p>Responsible for all procedural matters at the greenhouse level</p> <p>*Monthly reports to PI will include:</p> <ul style="list-style-type: none"> - facility integrity - security issues - access issues - signage - labeling issues - rodent and pest control - other greenhouse management issues - immediate report of containment breaches
<p>Principal investigator (Reports to IBC)</p>	<p>Responsible for the safety of the research activities</p> <ul style="list-style-type: none"> - *comprehensive report on transportation, harvest and seed control, pollen control, termination procedures, labeling issues and technical issues etc. relating to the experiment to the IBC with the aid of other researchers and technicians.
<p>IBC (Reports to NBC where high biosafety level experiments are conducted)</p>	<ul style="list-style-type: none"> - *Monthly reports on the progress of the experiment - Progress may be monitored by the **biosafety officer on behalf of the IBC and PAHI on behalf of NBC.

*A report template will be provided (hard copy and by email) for easy reporting and data management

** The biosafety officer will send independent reports to the IBC, while PAHI will report to the NBC independently. The reporting ensures that when higher biosafety level experiments are carried out at least two independent sources of reporting to the IBC and two independent sources of reporting to the NBC exists.

Risk management

The use of specific procedures to reduce to an acceptable level, the negative consequences of an assessed risk is one of the management tools that will be used in the NBF. These procedures include containment and confinement using physical, biological or other strategies. Other risk management procedures include termination and follow-up procedures. These strategies will be based on the case-by-case risk assessment and will depend on the types of organisms, their natural means of spread and the environment in which the tests are conducted.

Remedies

In case of non-compliance and violations, the NBF through the legislation will propose a system of liability and appropriate redress.

Inspection, Monitoring and Enforcement

Inspection and monitoring are management tools that will be used to ensure compliance with the terms and conditions of the approval given by the NBC, Regulatory Authority or IBC. In addition, it will also serve to confirm that the risk assessment was accurate and can identify any unanticipated events. With respect to laboratory studies, the IBC will be responsible for oversight. Containment and confinement trials as well as commercial release of LMOs will require inspection and monitoring by the National Regulatory Authorities in addition to the IBC with the NBC responsible for oversight and identifying the responsibilities of the inspection and monitoring agencies. The National Regulatory Authorities responsible for inspection and monitoring are:

1. Environmental Management Authority (EMA)
2. Plant and Animal Health Inspectorate of the Ministry of Agriculture (PAHI)
3. Food and Drugs Inspectorate of the Ministry of Agriculture (FDI)

Assigning biosafety levels

The level of biosafety regulation applied to the above activities depends on the relative level of risk. T&T will follow the internationally accepted NIH guidelines which identify four biosafety levels, BL1 - BL4, with Biosafety Level 4 requiring the most stringent containment conditions and Biosafety Level 1 the least stringent. Assigning a biosafety level is important for recommending regulatory guidelines to manage the associated risks of research and development using modern biotechnology.

The following criteria are considered in assigning a biosafety level:

- (a) Source and nature of introduced DNA, whether from an exotic infectious agent, or pathogen; whether a fragment of DNA or complete genome is involved
- (b) Recipient organism: mode and ease of dissemination; breeding system; invasiveness; noxious weed or one capable of interbreeding with a noxious weed; potential for gene flow; potential for detrimental impact on natural or managed ecosystems.
- (c) Nature of expressed protein: whether a vertebrate toxin or potential or known allergen; whether toxic to biodiversity.
- (d) Local environment: vulnerability of ecosystem; nature and importance of nearby crops; presence of sexually compatible weedy species and
- (e) Experimental procedures: that may require transfer to and from greenhouse or special containment measures.

Biosafety Levels

- 1) BL1-P is designed to provide a moderate level of containment for experiments for which there is convincing biological evidence that precludes the possibility of survival, transfer, or dissemination of recombinant DNA into the environment, or in which there is no recognizable and predictable risk to the environment in the event of accidental release.
- 2) BL2-P is designed to provide a greater level of containment for experiments involving plants and certain associated organisms in which there is a recognized possibility of survival, transmission, or dissemination of recombinant DNA containing organisms, but the consequence of such an inadvertent release has a predictably minimal biological impact.
- 3) BL3-P and BL4-P describe additional containment conditions for research with plants and certain pathogens and other organisms that require special containment because of their recognized potential for significant detrimental impact on managed or natural ecosystems.

Experiments may:

1. Require only IBC approval (BL1),
2. Require IBC approval, RAM review and NBC approval (BL2)
3. Require IBC approval, RAM and Public forum review and NBC approval.
4. Be exempt from any approval

I. Experiment that require only IBC approval

The BL1 designation provides for a low level of containment for experiments involving LMOs, in which there is no evidence that the modified organism would be able to survive and spread in the environment and if accidentally released, would not pose an environmental risk. eg transgenic potato plants containing cloned insect resistant genes from primitive potato cultivars.

The **Institutional Biosafety Committee** shall review and approve all experiments in this category prior to their initiation. Requests to decrease the level of containment specified for experiments in this category will be considered by the NBC.

II. Experiments that require IBC approval, RAM subcommittee review and NBC approval

BL2 is assigned to experiments involving rDNA, which, if released into the environment could be viable in the surrounding environment but will have a negligible impact or could be readily managed. For such experiments the containment conditions or stipulation requirements will be recommended by RAM and set by NBC at the time of approval. Such experiments will also require IBC approval before initiation. e.g. The deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire the trait.

III. Experiments that require IBC approval, RAM subcommittee and public forum review and NBC approval

BL3 and 4 designations are for experiments involving exotic infectious agents or production of toxins that can cause serious environmental harm. e.g. experiments involving the cloning of toxin molecules with LD50 of less than 100 ng per kg body weight, botulinum toxins, tetanus toxin, diphtheria toxin, and *Shigella dysenteriae* neurotoxin.

IV. Experiments that are exempt from regulatory approvals

Those that do not present a significant risk to health or the environment, as determined by the NBC, based on the advice of RAM or consensus documents developed, internationally, will be exempt, for example:

- Recombinant-DNA (rDNA) molecules that are not in organisms or viruses;
- rDNA consisting of segments of viral DNA or a synthetic DNA segment;
- rDNA molecules containing DNA segment from a prokaryotic source or its plasmid, when propagated only in that host or transferred to other host by well established physiological means;
- rDNA molecules that consist entirely of DNA from an eukaryotic host including its chloroplasts, mitochondria, or plasmids (but excluding viruses) when propagated only in that host (or a closely related strain of the same species),
- Any others that will not present any threat to the environment as determined by the NBC.

The NBC will maintain a list of certified host-vector systems.

Section 4

Administrative System of the NBF

General Principles

As a signatory to the CPB, T&T must designate one national focal point and one or more competent national authorities, or one entity to act as both. (Article 19) and identify a point of contact for notifications on unintentional transboundary movements and emergency measures (Article 17). In addition to these requirements, the NBF includes an administrative system for handling notifications or requests for authorization.

The proposed administrative system for the management of biosafety in T&T will comprise:

5. The institutional framework which includes the Competent Authority and the supporting departments responsible for receiving, processing and issuing requests and permits
6. The procedures and guidelines for handling notifications and requests and permits
7. The procedures and guidelines for Risk Assessment and Characterization
8. The decision-making system

Current systems of application

There are well defined systems in place at this time for the import of living organisms for any purpose as well as articles to be used as food. These systems reside within the Ministry of Health and the Ministry of Agriculture, Land and Marine Resources, both of which have an integral relationship with the Ministry of Finance through the Customs and Excise Division.

The Food and Drugs Inspectorate of the Ministry of Health

The Food and Drugs Inspectorate (FDI) is a Regulatory and Standards Monitoring Agency found within the Chemistry Food and Drugs Division of the Ministry of Health (MOH) (Figure 4.1). It is the authorized government agency responsible for the administration and enforcement of the Food and Drugs Regulations promulgated under the Act. The FDI is responsible for issues relating to the quality, purity and safety of food, drugs, cosmetics and medical devices. This involves monitoring of all aspects of importation, manufacture, storage, distribution, sale, fraud and deception in labelling and advertising and disposal of the same, in order to ensure compliance with the provisions of the Food and Drugs Act and Regulations. The import process can be seen in Figure 4.2. The Inspectorate is accessible to the general public, manufacturers, importers, distributors etc. for guidance and information on all aspects relating to these articles.

**Figure 4.1 Present Structure Chemistry Food and Drugs Division of the Ministry of Health
(Selected areas relevant to Biosafety)**

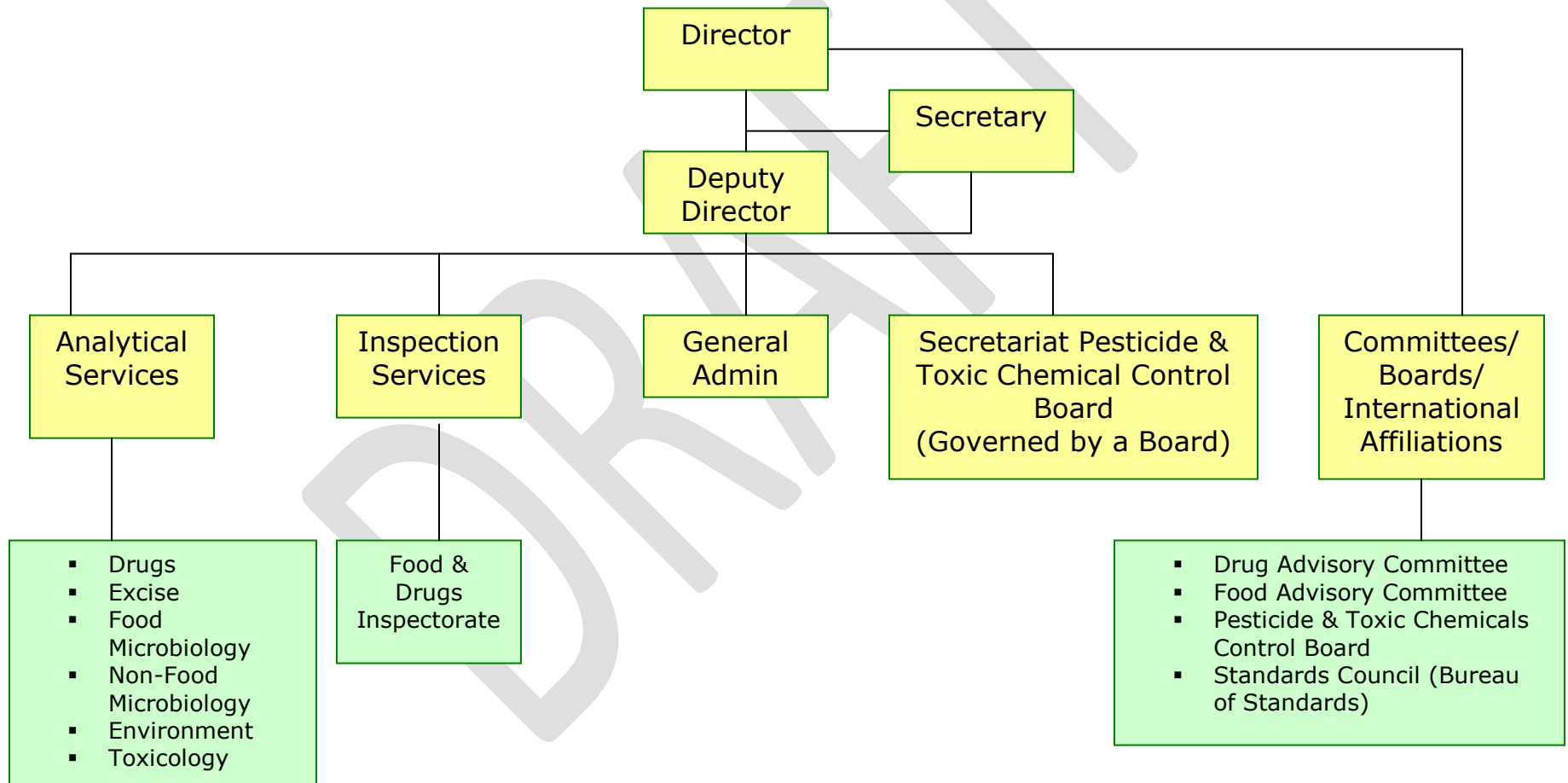


Figure 4.2 Current System for import of food, drugs, cosmetics and medical devices

SCHEMATIC TO BE SCANNED IN

DRAFT

4.2.2 Ministry of Agriculture, Land and Marine Resources systems

Figures 4.3

Present Structures of the relevant sections of MALMR as it relates to biosafety and imports as a Regulatory Authority (Selected areas relevant to Biosafety)

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Figure 4.4 Current System for imports (plants, animals, seeds, microorganisms, fish)

SCHEMATIC TO BE SCANNED IN

DRAFT

Proposed application system

It was not the intention to create a new administrative system but rather to find mechanisms for biosafety management to fit into already established and operational structures and systems. At present the National Competent Authorities and the systems for import and use of articles that may potentially GM reside within the Ministry of Agriculture, Land and Marine Resources and the Ministry of Health with support from the Ministry of Finance through the Customs and Excise Division. Other relevant systems already established and operational include the procedures for application of a Certificate of Environmental Clearance (CEC)³² and Environmental Impact Assessment (EIA)³³ from the Environmental Management Authority of T&T.

The administrative system outlined here as a component of the NBF (Figure 4.5) dovetails into the current systems listed above. The functional links between the current competent authorities and the NBC will be established through Memoranda of Understanding. The final output to the applicant will be a license/ permit to import or develop a LMO with the necessary terms and conditions which will be recommended by the NBC but implemented by the National Regulatory Authority currently responsible for that article. There is also the option to refuse to grant the license/ permit for import or use but an explanation must be provided by the NBC.

All requests for the development of local LMOs or imports of articles that may be GM, regardless of the intended use (with the exception of LMOs to be used in laboratory research), must be done through a National Regulatory Authorities as listed in Table X.

Table 4.1 National Regulatory Authorities in Trinidad and Tobago

Food and Drugs Division of the Ministry of Health	<ul style="list-style-type: none"> ▪ articles of food, drugs, cosmetics and medical devices for direct use ▪ include LMOs to be used for food, feed or processing
Plant Quarantine Division of the Ministry of Agriculture, Land and Marine Resources	Need to fill this out for imports of plants, animals, fish, microorganisms or other

Where it is a commercial outfit that is seeking regulatory approval, such applications should still be directed through a Regulatory Authority or a registered IBC with a clear description of the relationship and responsibilities of all parties.

The application process that will be used for import and research and development of LMOs is outlined **Figure 4.5.** This is an **Advanced Informed Agreement (AIA) Procedure** which applies to the first intentional transboundary movement of LMOs for intentional introduction into the environment of the Party of import. The purpose of this procedure is to ensure that T&T has the opportunity and the capacity to assess risks that may be associated with the LMO before agreeing to its import. Specifically, the Party of

³² Certificate of Environmental Clearance (CEC) process is a measure adopted primarily for environmental protection and the application process facilitates ongoing interaction between applicants and relevant authorities. One of the concepts behind the CEC application process is the consideration of all possible impacts on human health and the environment in order to prevent or minimize such impacts.

³³ Environment Impact Assessment (EIA) is an invaluable tool in planning and environmental management which may be used in the CEC process depending on the proposed activity. EIA is the process for identifying the likely effects on the environment of carrying out particular activities and for conveying this information to members of the public and for those responsible for making decisions on the proposed activities. The use of the EIA facilitates public participation and seeks to address and minimize potential adverse impacts as well as contributes to environmental management through monitoring.

export or the exporter must notify the Party of import by providing a detailed, written description of the LMO in advance of the first shipment. The AIA includes the following three (3) components:

- Notification by the Party of export or the exporter
- Acknowledgment of receipt of notification by the Party of import
- Decision procedure and review of decisions

The Party of import is to acknowledge receipt of this information within 90 days. Then, within 270 days of the date of receipt of notification, the Party of import must communicate its decision either:

- (i) approving the import
- (ii) prohibiting the import
- (iii) requesting additional relevant information, or
- (iv) extending the 270 days by a defined period of time

Except in a case in which consent is unconditional, the Party of import must indicate the reasons on which its decisions are based. (Article 7, Article 8, Article 9 and Article 10)

A Party of import may, also at any time, in light of new scientific information, review and change a decision. A Party of export or a notifier may also request the Party of import to review its decisions (Article 12). AIA procedure does not apply to the following categories of LMOs:

- LMOs in transit (Article 6)
- LMOs destined for contained use (Article 6)
- LMOs intended for direct use as food or feed or for processing (Article 7.3)

While the Protocol's AIA procedure does not apply to certain categories of LMOs, T&T retains the right to regulate the importation on the basis of domestic legislation. In addition, the Party of import may also specify in advance to the BCH that it will exempt certain imports of LMOs from the AIA procedure (Article 13).

Requirements for the application for intentional release of an LMO into the environment or for contained for field studies

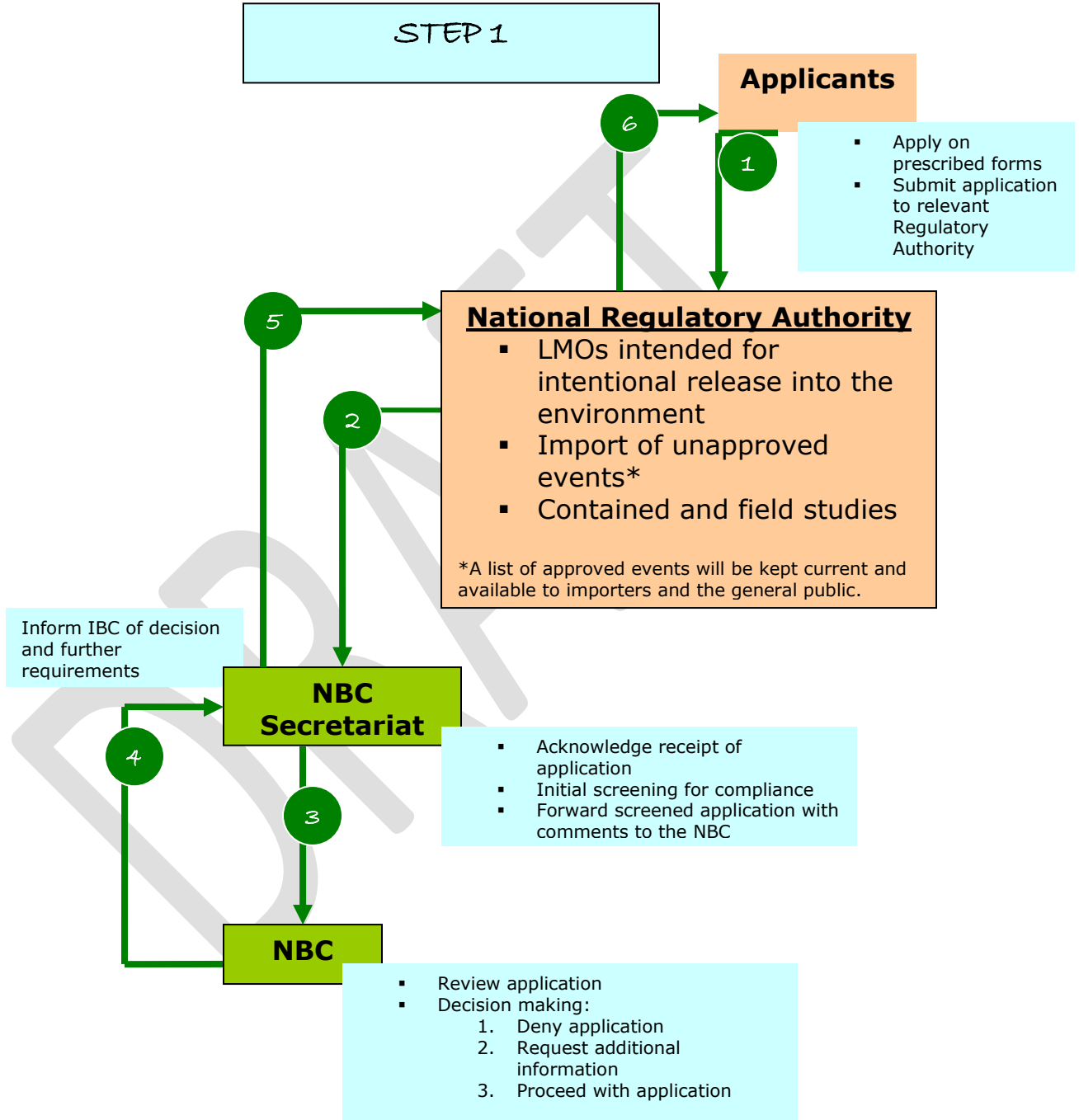
The requirements for the application for intentional release of an LMO into the environment or for contained for field studies (which require the AIA procedure) are listed in **Boxes 4.1 and 4.2** whilst some information is provided on the proposed application fee structure in **Box 4.3**.

The Applicant is responsible for providing information completely and truthfully and for providing supporting scientific data and rationale. The Applicant can request for information to be kept confidential since the NBC will have a policy to deal with confidential information (CBI). All the procedures and prescribed application forms will be available at registered IBC offices, NBC secretariat and on relevant websites. Completed application forms can be submitted either by registered mail or via the online facility. There will be an information services line available within the NBC secretariat.

The review process is detailed in **Figure 4.6** and **Box 4.4**.

Figure 4.5

Application for the intentional release of a LMO into the environment and contained and field studies



Note:
For the application where additional information is needed, the applicant can resubmit and re-enter the system at ...

1

Box 4.1

Application for intentional release of a LMO into the environment and contained and field studies

- The NBC secretariat shall receive FOUR copies of the applications for intentional release of a LMO into the environment along with the application fee.
- The NBC shall assess the eligibility of the applicant and the completeness of the application form and if unsuitable return it to the National Regulatory Authority or IBC within 10 working days indicating the reason for rejection.
- The National Regulatory Authority or IBC will then forward the information to the applicant.
- The applicant has the right to resubmit with additional information, without an additional fee.
- If application is accepted then an acknowledgement to the National Regulatory Authority or IBC is forwarded indicating that the process takes a maximum of 90 days.
- Simultaneously the application is forwarded to RBAC, which will make it available to all member countries through its website and notify member states within 7 working days.
- The member states have the right to express any concerns to the RBAC within 30 working days, and support it with further recommendations within 60 days.

The application forms will be sent for subcommittee reviews and RBAC after confidential business information is removed if requested by the applicant.

Box 4.2

Application forms intentional release of a LMO into the environment and contained and field studies require:

- complete contact information of the applicant
- information on whether the LMO in question was imported or locally developed
- description of the organism with respect to its taxonomy
- pedigree of variety used
- biology of the organism, habit, life cycle traits
- related species in the environment
- interactions of LMO in the environment with sexually compatible species and non-target species
- novelty of LMO, novel product
- selective advantage with respect to life history traits
- outcrossing frequency, weediness, and stress adaptations
- volunteers effects
- description of the modification for the LMO, including genes, constructs, transformation vectors and methods used
- characterization of inserted DNA (copy number, partial copies, junction sequences), protein and RNA characterization and expression profiles,
- description of the inheritance and stability of introduced traits that are functional in the organism
- description of the parental genome
- description of the novel trait (metabolic pathways, breakdown products, tissue specific and developmental specific expression, toxicity and allergenicity of novel products
- residual effects and toxicity on non-target organisms
- number of generations removed from the original as well as the objective of modification
- description of cultivation practices associated with the LMO, residual effects and toxicity
- risks identified and how the risk would be managed
- outline of a monitoring arrangement to assess the long-term impacts of the introduction

Additional requirements may include:

- The impact on cultural heritage and indigenous systems
- An evaluation of the alternatives to this activity, giving consideration to concerns of the environment, alternative sites, designs, approaches and processes
- contingency plan which includes measures proposed to avoid, reduce, mitigate or remedy any of the significant adverse effects identified

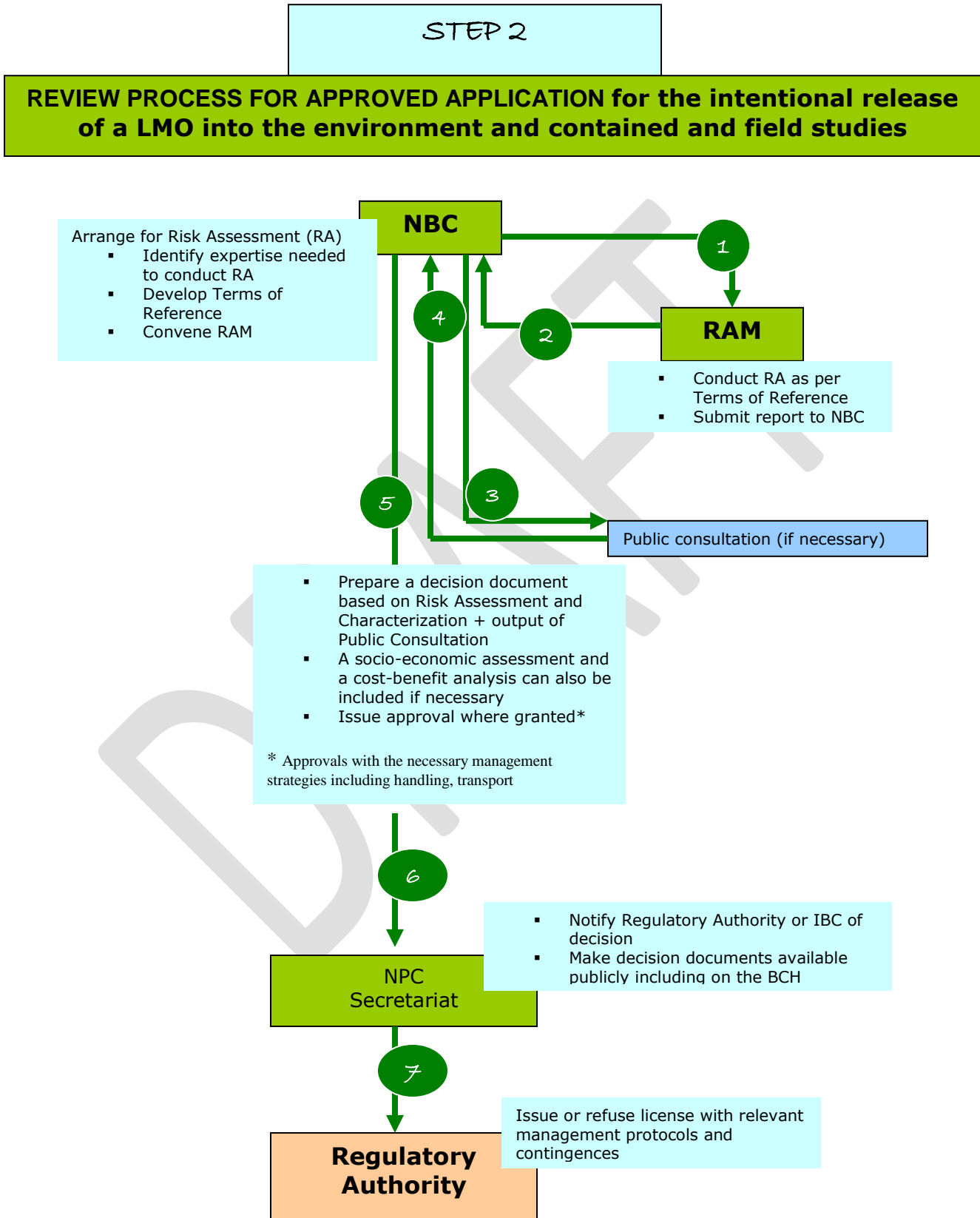
Box 4.3

Information on Proposed Application Fees*

- There will be a charge for the processing of applications by the NBC (this is in addition to the existing charge by the current National Authority).
- The applicant for the license/ certificate will pay all the associated fees and charges.
- A minimum and maximum charge will be set depending on the type of activity.
- A schedule of fees will be developed based on the types of activities anticipated (e.g. (direct use, laboratory studies, greenhouse studies, field studies, and commercialization)).
- In the case of extracts from Registers, the party requesting the extract must pay the fee.

* The fee structure will be developed as a part of the implementation phase of the project.

Figure 4.6



Box 4.4

Review Process

- The NBC shall commission a scientific review by the RAM subcommittee and a public consultation through the public opinion subcommittee.
- The NBC shall also allow a two month period for any other public comments during the application review process.
- The RAM subcommittee may co-opt expertise to evaluate the application, but would be required to submit its recommendation within 30 days to the NBC secretariat.
- The RAM subcommittee through the NBC may request FDI to carry out a complete food safety assessment, prior to making a decision.



In such cases, the clock may be stopped.

- The NBC shall superimpose the scientific risk assessment and public opinion on to a socio-economic assessment and a cost-benefit analysis that the NBC will be mandated to carry out.
- The NBC shall make recommendations within 120 days of acceptance of application.



The clock may be stopped if the applicant needs to submit further information at any of the evaluation steps.

- The NBC may accept the application, as is, or accept it with conditionalities, request further information or reject the application with reasons.
- When additional information is required, the Regulatory Authority or IBC will be notified and that information forwarded to the applicant who will be given a stipulated time depending on the nature of request.
- If long-term monitoring is mandated in the recommendation, NBC shall specify, clearly, what will be monitored and for how long and by whom.
- The costs of the monitoring exercise shall be borne by the applicant.
- NBC may request the IBC to develop a DNA based identification system to track specific releases of LMOs.
- NBC may also set in motion an oversight mechanism through the EMA or FDI or both.

Application for LMOs intended for direct use as Food or Feed, or Processing

Living Modified Organisms intended for direct use as Food or Feed or Processing (Imos-FFP) represent a large category of agricultural commodities that are imported into T&T. The Protocol, instead of using the AIA procedure for these commodities, establishes a more simplified procedure for the transboundary movement of Imos-FFP. Under this procedure, a Party must inform other Parties through the BCH, within 15 days, of its decision regarding domestic use of Imos that may be subject to transboundary movement.

Decisions by T&T on whether or not to accept the import of Imos-FFP will be taken under its domestic regulatory framework and will be consistent with the objective of the Protocol. In case of insufficient relevant scientific information and knowledge, T&T retains the right to use precaution in making its decisions on the import of Imos-FFP.

The applications for these imports will fall under the FDI of the MOH and will proceed through the regular import procedures as outlined in Figure 4.2. The support system for this procedure includes the maintenance of a list of importers as well as a list of approved GM events by crop and the development of a food registry. This information will be made available to the importers as well as the general public through the various communication channels available, including direct information to importers via meetings and notices, newspaper advertisements etc. Approved GM events for Imos-FFP commodities will be allowed into T&T through this system. However, there will be a system of random checks of the imported Imos-FFP, which will be conducted by the FDI through approved laboratories (either locally or regionally), to determine if there are any unapproved GM events present. In the event that this occurs, there will be fines for non-compliance.

A summary of all the certificates required by the MALMR and the MOH is outlined in Table 4.2.

Table 4.2
Certificate Requirement for Import of LMOs for intentional release into the environment, contained and field studies and LMOS-FFP into Trinidad and Tobago

Products	Title of Certificate	Purpose	Requesting Ministry
All foods	Certificate of Free Sale	Food Safety	Ministry of Health Chemistry Food and Drugs Division
All foods	Certificate of analysis	Food Safety Food Quality Heavy metals/ Inorganic Organic standards	Ministry of Health Chemistry Food and Drugs Division
All animal and fish products	Health Certificate	Food Safety Food Quality	Ministry of Health Chemistry Food and Drugs Division
All meat and poultry products including pet foods	Meat/ Poultry Certificate of Wholesomeness	Food Safety Food Quality	Ministry of Health Chemistry Food and Drugs Division
All unprocessed plant products <ul style="list-style-type: none"> ▪ Fresh fruits, vegetables, rice, flour, peas, beans, plants, lumber 	Phytosanitary Certificate	Food Safety Plant Protection	Ministry of Health Chemistry Food and Drugs Division Ministry of Agriculture, Land and Marine Resources; Plant Quarantine Service
Processed foods	Certificate of Quality and Condition	Food Safety	Ministry of Health Chemistry Food and Drugs Division
All canned and packaged meats	Cooking/ Processing Certificate	Food Safety	Ministry of Health Chemistry Food and Drugs Division
Fish	Mercury/ Heavy Metals Certificate of Analysis	Food Safety	Ministry of Health Chemistry Food and Drugs Division
Peanuts, corn	Aflatoxin Certificate	Food Safety	Ministry of Health Chemistry Food and Drugs Division
Meat products	Halal/ Kosher Certificate	Religious Beliefs	Ministry of Health Chemistry Food and Drugs Division
	Others: <ul style="list-style-type: none"> ▪ Organically Grown Foods ▪ Irradiated Foods ▪ Genetically Modified Foods 		Ministry of Health Chemistry Food and Drugs Division

Data Storage Mechanisms

National Registries

A vital component of the administrative system of the NBF is the development and use of national registers. Presently, there is a Register for ‘New Drugs Submission’ which is housed within the FDI. To apply for the import of a new drug, the applicant must fill out a ‘New Drug Submission Form’ which requires information on clinical studies, product description, product formulation/ specification, toxicity data, methods of analysis etc. along with the relevant certification and samples. Similar Registers are recommended for the import of LMOs for intentional release into the environment, contained and field studies and LMOs-FFP. These Registries will be available on the websites of the NBC and other relevant agencies as well as the Regional Biosafety Clearing House (BCH) which will be a node of the global BCH.

There will also be National Registers of Licenses and/or Certificates of Clearance which will include the application including the information supplied (without the confidential information), the certificate/ license including the recommended measures and other terms and conditions subject to which the certificate/ license was issued or the reasons for refusal of the certification.

These Registers are open to examination by members of the public and will be available via the internet on several websites:

- The Biosafety Clearing House
- The Environmental Management Authority
- Ministry of Public Utilities and the Environment
- Ministry of Agriculture, Land and Marine Resources
- Ministry of Health
- Ministry of Information

Comment forms (which will be developed) will be available at each site (land location and website). This will allow submission of positions, comments, analyses and other information from the general public and specific stakeholders.

The public will also be informed of the final decision in a timely manner in addition to having access to the decision documents which will include the rationale for the decision and other information.

Biosafety Clearing House

The CPB established the Biosafety Clearing-House (BCH) since it is critical to the implementation of the Protocol and is intended to be a repository of information on LMOs and Biosafety by:

- Facilitating the exchange of scientific, technical, environmental and legal information on, and experience with, living modified organisms; and
- Assisting Parties to implement the Protocol, taking into account the special needs of developing country Parties, in particular the least developed and small island

developing States among them, and countries with economies in transition as well as countries that are centres of origin and centres of genetic diversity.

The national focal point for the BCH will be the **Environmental Management Authority** and T&T will make available to the BCH the information specified under paragraph 3 of Article 20 which are as follows:

- (i) Any existing laws, regulations and guidelines for implementation of the Protocol, as well as information required for the Advanced Informed Agreement (AIA) procedure under the Protocol
- (ii) Any bilateral, regional and multilateral agreements and arrangements
- (iii) Summaries of risk assessments or environmental reviews of LMOs, including relevant information regarding processed products of LMO origin
- (iv) Final decisions regarding the importation or release of LMOs
- (v) Reports submitted pursuant to Article 33, including those on the implementation of the AIA procedure

In addition, Trinidad and Tobago is required to make the following information available to the BCH:

- (i) Information on a final decision regarding domestic use, including placing on the market of a LMO that may be subject to transboundary movement for direct use as food or feed, or for processing (paragraph 1, Article 11)
- (ii) Copies of national laws, regulation and guidelines applicable to the import of LMOs intended for direct use as food or feed, or for processing (paragraph 5, Article 11)
- (iii) A declaration that a decision will be made prior to the first import of LMOs intended for direct use as food or feed, or for processing, by a developing country Party or a Party with an economy in transition that does not have a domestic regulatory framework in place (paragraph 6, Article 11)
- (iv) Information on review and change of a decision by a Party of import regarding intentional transboundary movement, as a result of new scientific information about the impacts of the LMO concerned (paragraph 1, Article 12)
- (v) Information from a Party of import regarding simplified procedures (Article 13)
- (vi) A decision on whether that Party's domestic regulations shall apply with respect to specific imports to it (paragraph 4, Article 14)
- (vii) Notification of an occurrence under one's jurisdiction resulting in a release that leads, or may lead, to an unintentional transboundary movement of a living modified organism that is likely to have significant adverse effects on the conservation and sustainable use of biological diversity (paragraph 1, Article 17)
- (viii) Relevant details setting out point of contact for the purpose of notifications of occurrence of accidental release of LMOs (paragraph 2, Article 17)
- (ix) Information concerning cases of illegal transboundary movements (paragraph 3, Article 25)

Access to information and the issue of confidentiality

The NBF recognizes the right of the general public and specific stakeholders to have access to information as it relates to biosafety decisions in a timely manner. The following information will be made available to the general public:

- the application (with the confidential business information deleted³⁴)
- a non-technical summary of the findings of the assessors on Risk Assessment and Characterization comprising:
 - the key issues
 - a brief evaluation of the potential hazards of the proposed activity
 - the measures and recommendations proposed for addressing the findings
 - background readings/ references for further research on the issue

The information will be made available for public comment via the following methods:

1. Publication of a Notice in the Gazette and in one or more of the daily newspaper of general circulation
2. Information supplied through the channels developed through the partnership programme outlined above
3. Through the route already established by the Environmental Management Authority for 'Application for a Certificate of Environmental Clearance'. Through this system the information will be lodged at:
 - The various entities responsible for town and country planning (North, East, South and Tobago Regional Offices)
 - The Environmental Management Authority
 - Ministry of Public Utilities and the Environment
 - Various offices of the Ministry of Agriculture, Land and Marine Resources
 - Various offices of the Ministry of Health
 - Ministry of Information
 - Web pages of relevant Ministries

³⁴ Confidential information will be withheld from the general public unless the NBC declares that the confidentiality of such information is not in the interest of the public.

Capacity building requirements

The implementation of the NBF requires a particular set of capacity building in various sectors such as policy/ decision makers, regulatory agencies, research institutes, general public etc. Capacity building can be articulated within the following categories:

- Human skills
- Existence of dedicated centres or programmes
- Formulation of systemic and long-term policies
- Existence of scientific infrastructure
- Appropriate institutional structures and linkages

With respect to training, the following areas were identified in an OAS report compiled by Professor Julian Duncan (2004):

- Testing procedures for GMOs /LMOs for certifying labels, if labelling becomes mandatory
- Training in biotechnology risk assessment and management as well as international trends in regulation, for persons who are in and will function in regulatory roles in the area of safety.
- Training in the area of risk-benefit analysis as a basis for assessment of applications, as well as training on the impact of biotechnology on biological models and emerging theoretical perspectives, research guidelines and procedures
- Training for a panel in reviewing applications consistent with international standards and trends as regards assessment of ecological effects; assessment of human health impacts and assessment of agricultural impacts.
- Training on topics relative to the release of genetically modified organisms

In addition to training of personnel, there is need for upgrading of physical facilities to meet the challenges of testing. There is also the issue of linkages within the region and internationally with the following:

- Donor agencies
- Development partners
- International organizations
- Sub-regional agencies
- Regional agencies
- International agencies

Capacity building in these and other areas will facilitate the following:

- Enactment of appropriate policies and regulations
- Accurate safety assessments and compliance monitoring
- Safe research and development
- Public trust

Section 5 The Decision Making System

Guiding principles

The NBF decision making system will be based on laws and guidelines that already exist and that will be drafted with respect to the Biosafety Act. It is based on the standards of precaution in accordance with the CPB (Articles 10 and 11) and includes the principles of **risk assessment, management and communication within a transparent and participatory framework on a case-by case basis**. The impact on socio-economic, ethical, cultural and other considerations (consistent with Article 26 of the CPB) will be considered in the final decision making process especially as it relates to the sustainable use of biological diversity and the value of the same to indigenous and local communities.

Risk Assessment

Risk assessment is defined as a scientific method to assess the risks posed by any new technology that may have potential adverse effects on human, animal or environmental health. It serves as the basis for the decision-making process, which is also influenced by the regulatory framework, the national priorities, development strategies, public policies, potential socioeconomic and trade impacts, public perception, scientific capacities and international duties. In accordance with Article 10 and 11 of the CPB, the standard of precaution is **iterated** such that concerned government departments and agencies can take the necessary action to protect the public interest and welfare.

A generally accepted method for biotechnology risk assessment includes the following steps:

1. Identification of the potential adverse effects on human and environmental health
2. Estimation of the likelihood of these adverse effects being realized
3. Evaluation of the consequences should the risk be realized
4. Consideration of the appropriate risk-management strategies
5. Estimation of the overall potential environmental impact, including a consideration of potential impacts that may be beneficial to human health or the environment.

Risk Assessment will be a mandatory component of the NBF and the procedure will demand three types of information:

- 1) Biology of the non-genetically modified counterpart organism,
 - 2) Traits of the GMO phenotype expression and
 - 3) GMO molecular genetic traits.
- (All of this information will be supplied by the applicant on the application forms)

The procedure will follow a set format and follow the following principles:

- Risk Assessment will be conducted in a scientifically sound and transparent manner based on available scientific and technical information. This will be conducted by members of the RAM (See Section **2.0**) where expertise can be can

- co-opted as needed.
- Analysis will be conducted on a case-by-case basis and on the basis of the transformation event.
- If new relevant and significant information becomes available the risk assessment can be readdressed to identify whether the risk has changed.

Trinidad and Tobago is a member of the multilateral treaty ‘The International Plant Protection Convention’ (IPPC) which has always played an important role in international trade through its WTO recognized standards on food and agriculture (including relevant environmental risks), fisheries and forestry. The standards cover three sectors - food safety, plant life and health and animal life and health. These sectors include food production in relation to food safety, the introduction of plant pests, animal pests and diseases, and zoonoses, the introduction and release of genetically modified organisms (GMOs) and their products, and the introduction and safe management of invasive alien species and genotypes.

As such the Risk Assessment guidelines for the NBF will be based on Annex III of the CPB and the procedure that is currently being used by the MALMR i.e. ISPM 11 (International Standards for Phytosanitary Measures #11) – Pest Risk Analysis for quarantine pests including analysis of environmental risks and Living Modified Organisms³⁵. This is one of a set of standards, guidelines and recommendations which are used as the basis for Phytosanitary measures and applied by the Members of the World Trade Organization under the Agreement on the Application of Sanitary and Phytosanitary Measures. Whilst the use of ISPM 11 will be the core of the Risk Assessment procedure, the other relevant standards, guidelines and recommendations of other relevant ISPMs will be used for the NBF. The supporting ISPMs are listed in Table 5.1.

Table 5.1 International Standards for Phytosanitary Measures (ISPM) that will be used in the NBF

ISPM #	
1	Principles of Plant Quarantine as it relates to international trade (1995)
2	Guidelines for pest risk analysis (1996)
3	<ul style="list-style-type: none"> ▪ Code of conduct for the import and release of exotic biological control agents (1996) ▪ Guidelines for the export, shipment, import and release of biological control agents and other beneficial organisms (as appendix to the report of ICPM-7; published version will be available later) (2005)
4	Requirements for the establishment of Pest Free Areas (1996)
6	Guidelines for surveillance (2004)
7	Export certification system (1997)
8	Determination of pest status in an area (1998)
9	Guidelines for pest eradication programmes (1998)
10	Requirements for the establishment of pest free places of production and

³⁵ [Website address](#)

	pest free production sites (1999)
12	Guidelines for Phytosanitary certificates (2001)
13	Guidelines for the notification of non-compliance and emergency action (2001)
14	The use of integrated measures in a systems approach for pest risk management (2002)
15	<ul style="list-style-type: none"> ▪ Certification mark (2003) ▪ Guidelines for regulating wood packaging material in international trade (2002)
16	Regulated non-quarantine pests: concept and application (2002)
17	Pest reporting (2002)
19	Guidelines on lists of regulated pests (2003)
20	Guidelines for a Phytosanitary import regulatory system (2004)

Risk assessment

This includes the categorization of the organism to determine whether the criteria for being a risk is are satisfied. The process continues with the evaluation of the probability of spread and establishment and other potential risks associated with LMOs and potential economic consequences including environmental consequences.

The impact on market activity is a key part of the LMO regulatory process and consists of verifying that the commercial approval will not have a negative impact on foreign trade. This specific assessment will be carried out by the RAM and it includes an analysis of the current status of regulatory systems and public acceptance in the countries that buy our exports. The situation of our commercial competitors, potential markets, the crop proportion in our trade with each country and the proportion of our imports in their total purchases are also taken into account.

Risk management

This includes the implementation of a variety of measures, such as: crop isolation distances, non-LMO borders, control of volunteer plants, physical barriers, land use restrictions, hybrid management (pollen containing the inserted DNA), special protocols (for specific crops or situations), the establishment of release scales (experimental scales) and specific inspections and monitoring.

Risk communication

This is a part of risk assessment that is growing in relevance. It is a complex area where many factors play an important role. Such factors are: access to information (including type, level, means of communication and management of confidential information), effects of information communication (qualified objections, impacts on decision-making, local effects), educational campaigns (considering target audiences, their level, the means and educational strategies), programmes for building a rational public perception, how general arguments and specific issues are dealt with, socioeconomic impacts, and the effects that all these factors have on the decision-making process.

Finally, it is relevant to analyze how to implementing regulations. This is also a complex issue, which includes risk assessment, management, communication and mitigation

mechanisms, involved costs, law enforcement control and guarantee as well as initiatives on international co-operation and harmonization.

It is paramount that all these processes ensure transparency in decision-making, the implementation of public participation mechanisms (a very complex issue), the monitoring and post-marketing control (possible long-term effects and specific programmes, such as those on insect-resistance and herbicide-tolerance management, when needed). Putting this complete system into practice will require appropriate regulations, a clear definition of the biosafety system structure, highly-qualified professionals to carry out the assessment process based on updated scientific information, as well as mechanisms to access new information and update the system when necessary.

DRAFT

Section 6

Mechanisms for promoting and facilitating public awareness, education and participation

Trinidad and Tobago intends to abide by the Cartagena Protocol on Biosafety as it relates to public awareness and participation as outlined in Box 1. In addition to the stated LMOs, T&T will use the same principles for all products of modern biotechnology as it is defined in the National Biosafety Policy (Section 2.0).

Box 1

Article 23 of the Cartagena Protocol on Biosafety

- 1. Parties (to the Protocol) shall:**
 - (a) Promote and facilitate public awareness, education and participation concerning the safe transfer, handling and use of living modified organisms in relation to the conservation and sustainable use of biological diversity, taking also into account risks to human health. In so doing Parties should cooperate, as appropriate, with other states and international bodies;**
 - (b) Endeavour to ensure that public awareness and education encompass access to information on living modified organisms identified in accordance with this Protocol that may be imported.**
- 2. The Parties shall, in accordance with their respective**

Based on the above agreement, three (3) activities are anticipated to be a part of the public awareness operational procedures of the NBF.

- (a) An ongoing education and awareness programme on biotechnology and biosafety as well as the rights of citizens to have access to information and be a part of relevant decision-making processes.
- (b) Develop and implement a system to provide relevant and current information in a timely manner to the public.
- (c) Develop and implement a system to allow public consultation which will inform the actual decision-making process as it relates to the development, introduction and use of products of modern biotechnology in Trinidad and Tobago.

As a background to developing the Biosafety Policy and other components of the NBF, a series of public awareness activities were conducted. The activities, methods and results are detailed below.

Objectives of the public education and awareness campaign

These activities were initiated promoted and facilitated by the NCC via a Public Education and Awareness Subcommittee. The mandate of the subcommittee was to develop and execute a Public Education Programme that included both information sharing and gathering, within the time confines of the 18-month NBF Project.

The subcommittee acknowledged that public participation was needed in the establishment of the NBF for the following reasons:

- (a) To provide the public with all the arguments which promote or caution against full acceptance of biotechnology, specifically LMOs with the intention to facilitate development of an informed public
- (b) To provide an opportunity to obtain public feedback, comments and advice for the vision for national biosafety as articulated by the development of the Biosafety Policy
- (c) For transparency and accountability of the decision-making process that will be used in the NBF
- (d) To protect the public interest and adequately reflect the interests of different groups which would enable parties to share in the responsibility and have a sense of ownership of the final decision
- (e) To enable socio-economic and other non-scientific issues to be taken into account
- (f) To inspire public trust and make the NBF workable and sustainable
- (g) To maintain the international standards and an ongoing global trend of public engagement in decision-making processes

In developing the campaign several challenges (listed below) were taken into consideration.

- The complexity of the process of stakeholder identification which takes into consideration the non-homogeneity of the national public and the need to accurately identify potential stakeholders and their stakes
- The occurrence of different degrees of participation including information-sharing, consultation, joint-decision making and citizen-led initiatives and the potential scepticism if the public considers the participatory consultation process illegitimate as it relates to the real value placed on their contribution.
- The need to be a credible source of information (without bias on the issue) and to provide participants with the opportunity to discuss issues related to biosafety on their own terms.
- The ‘high science’ nature of the topic combined with the largely ‘illiterate’ population as it relates to biotechnology, biosafety and the general topic of science combined with the short time available to conduct effective public education on this new topic.
- Insufficient time for evaluation of the success of implementation.

Method used for conduct of the public education and awareness campaign

In all instances, the government of T&T (through the UNEP-GEF NBF Project) initiated the activities conducted in the public awareness and education campaign. While the organizing committee acknowledged that this was not the ideal, attempts were made to encompass all stakeholder groups so that the maximum amount of relevant knowledge could be included in the process, in addition to helping to ensure credibility so that stakeholders could feel more ownership and by extension, commitment to the process.

The stakeholder groups included the following:

- 1) Sector stakeholders
 - Trade and Legislation
 - Environment, Agriculture and Research and,
 - Health
- 2) Specific focus groups
 - Commercial businesses and private farmers in Agriculture – crop production, small ruminants and livestock, poultry, horticulture, beekeeping
 - Manufacturers and food distributors
- 3) Youth
- 4) General public

Activities

Several activities were conducted during an intensive six-month period of public awareness activities which are listed below:

Targeted stakeholder consultations:

- (a) Three separate sector stakeholder consultations in;
 - i. Trade and Legislation
 - ii. Environment, Agriculture and Research, and
 - iii. Health
- (b) Three general stakeholder (public) meetings in Trinidad.
- (c) Two general stakeholder (public) meetings in Tobago.
- (d) One youth forum with participants from secondary school (ages 14-16 years) in Trinidad.
- (e) One youth forum with participants from secondary school (ages 11-16 years) in Tobago.

The intention of these formal programmes was to provide information on the basics of modern biotechnology and its application in agriculture, health and research as well as the links with legislation and regional and international trade issues. These sessions also provided the opportunity for discussions, feedback, information gathering and input into the development of the National Biosafety Policy

Each participant was provided with an information packages containing:

- A questionnaire which served to provide a clear record of the input of each group/ participant as it related to the Biosafety Policy as well as feedback and evaluation of the programme.
- A brief of the Cartagena Protocol on Biosafety
- A summary of the status of biotechnology in Trinidad & Tobago
- A list of general definitions on biotechnology and biosafety

Mobile Biosafety Exhibition:

In an attempt to reach as many members of the public in various parts of Trinidad and Tobago, 5 public education campaigns were held at venues so selected to achieve this objective. These included:

- (a) Brian Lara Promenade (North Trinidad)
- (b) Trincity Mall (East Trinidad)
- (c) Tourism Park, Centre of Excellence (East Trinidad)
- (d) Gulf City Mall (South Trinidad)
- (e) Tobago

The Biosafety Exhibition consisted of an information booth where literature on biosafety could be obtained. There were numerous posters on display along with food items containing labels indicating that certain imported processed foods available in the local supermarkets ‘may contain genetically modified products’ as well as others which did not contain genetically modified products.’

At the Public Biosafety Exhibitions, the official mascot of the Consumer Affairs Division, ‘Curtis the Consumer Cat’, provided entertainment for children so that the parents were able to obtain information from the booth.

At the Youth Fora as well as the Public Biosafety Exhibitions small tokens were gifted to the students and booth visitors respectively. The tokens consisted of pencil cases and pencils for the students of the Youth Fora and pens and rulers for booth visitors. All tokens carried a biosafety message.

Survey on the “Assessment of consumer knowledge of genetically modified organisms (GMOs)”

Survey Materials and Methods

The survey, “Assessment of consumer knowledge of genetically modified organisms (GMOs)” was conducted during the period July – September 2005 at a number of institutions and among members of the public during the education forums held. In all, a total of 545 persons were surveyed.

Institutions

The questionnaire was sent primarily to the institutions represented on the National

Biosafety Committee (NBC), namely:

- The Ministries of Legal Affairs (Consumer Affairs Division) Trade, Health, Finance (Customs & Excise Division), Public Utilities and the Environment, Foreign Affairs, Agriculture, Land and Marine Resources, and the Attorney General
- The University of the West Indies (UWI)
- Environmental Management Authority (EMA)
- Caribbean Association for Feminist Research and Action (CAFRA)
- Inter-American Institute for Co-operation on Agriculture (IICA)
- Tobago House of Assembly (Division of Tourism and Division of Agriculture)
- Ministry of Education, Administrative Complex and Community Development in Tobago
- Caribbean Agricultural Research and Development Institute (CARDI),
- Caribbean Industrial Research Institute (CARIRI), and
- National Institute for Higher Education Research Science and Technology (NIHERST)

In addition to these above-mentioned institutions, surveys were also conducted at the College of Science, Technology and Applied Arts of Trinidad and Tobago (COSTAATT), CARONI Research Division and Consumers International (Trinidad and Tobago Branch). Individuals at these institutions were randomly selected, and each institution was asked to complete a total of 20 questionnaires. There were variations in the total number of questionnaires actually completed.

The fora were used to not only provide members of the public with general information on GMOs, but to also conduct the survey. Members of the NCC as well as students from the UWI facilitated both of these activities.

Processed items and local fruits and vegetables were placed on display at all venues with the exception of the Tourism Park in order to relate the issue of GMOs to everyday life. The processed foodstuff was used to provide examples of items that 'may contain GMOs', while the fruits and vegetables were items that were regarded as 'GM-free'. In addition to this display, posters and factsheets were also used to inform the public on the issue of GMOs.

In all fora attempts were made to convey comprehensive unbiased information on the nature and consequences of GMOs. It was clearly stated at the beginning of each meeting as well as to individuals during the exhibitions that the purpose of the event/ display was not solely to provide accurate information and allow for consultation but also to provide an opportunity for individuals to ask questions and express their opinions freely and comfortably knowing that their opinion will feed into the broader policy process of the development of the National Biosafety Policy.

In addition to the above planned activities several other promotional activities were conducted as follows:

1. Many opportunities were grasped to display the Biosafety exhibition at related activities such as:
 - Tourism Park

- World Consumer Day
 - World Food Day
 - Trinidad and Tobago Agricultural Society Annual Exhibition
2. Several information columns were placed in the various national newspapers to provide general information on biotechnology and biosafety.
 3. An official media briefing was conducted where the persons from all the media houses were invited to view and participate in a structured programme similar to that outlined in Appendix 2.

All the activities were extensively publicized in the print and electronic media (via advertisements and interviews) in advance of the events. In addition, it was explained that feedback will be provided at the end of the activity via public meetings, internet information, and use of the media as well as lodging documents in easily accessible areas which would be specified. Contact information for the Consumer Affairs Division as well as the NPC (UNEP-GEF NBF Project) was given so that additional comments could be sent at a later date although a deadline for the receipt of public comments was specified.

Best Practices and Lessons Learned

- i. The science was difficult to grasp in many instances although attempts were made to make it manageable. However, the format of the formal programmes, where there were several presenters and an allowance for discussions and questions, assisted in overcoming this to some extent. The committee however acknowledged the stakeholders' stated difficulty of getting quality feedback within such a short time after introduction of this 'new' topic and the short time available. As such a genuine and thoughtful participatory deliberation was not possible to the degree that was desired.
- ii. Although targeted efforts were made to extend information and to provide opportunities for consultation and participation to a previously identified stakeholder audience, there were some inequalities throughout the campaign which could be based mainly on location and economic parameters since all the events were located in easily accessible urban areas.
- iii. Repeatedly during all events the presenters had to reiterate that they had no stance on the matter and that the exercise was to present a neutral platform for information provision and gathering.
- iv. The culture of the country and even sub-cultures within the country played an important part in the interactions. The presence of a mascot for entertainment of the children (and adults); the use of music and a public address system to attract and invite persons into the booth; the action of providing literature as well as small tokens to the visitors and the availability of a knowledgeable group of

persons to answer questions without a time limit, all played significant roles in having a good public awareness campaign within the short time period.

- v. There was more participatory activity during the public exhibition than the formal meetings. Perhaps the nature of the informal setting and the availability of an ‘expert’ who provided individual attention without a time limit provided the comfort needed to deal with a new topic.

The campaign was also highly resource intensive requiring a great commitment of funds and personnel. These requirements were due to the ‘new’ nature of the topic and the need to generate interest in a very short timeframe.

Future Plans for promoting and facilitating national public awareness, education and participation

T&T intends to continue to use a pro-active approach to information dissemination and public participation. The range of views with respect to the degree and extent to which public involvement and consultation should be implemented was taken into consideration in development of future plans.

Trinidad and Tobago, in planning the future work as it relates to public education, awareness and active engagement in the decision-making process as it relates to the Cartagena Protocol on Biosafety, intends to abide by the international obligations that it has agreed to which is best reflected by:

1. Principle Ten of the Rio Declaration (as outlined in **Box 2**) and
2. Relying on the underlying principle being that participation and access to information affecting one’s life is a basic human right regardless of the level of education of literacy and despite the general consumer being unaware of this fundamental right.

Box 2

Principle 10 of the Rio Declaration

‘Environmental issues are best handled with the participation of all concerned citizens, at the relevant level. At the national level each individual shall have appropriate access to information concerning the environment...and the opportunity to participate in decision-making processes. States shall facilitate and encourage public awareness and participation by making information widely available. Effective access to judicial and administrative proceedings, including redress and remedy, shall be provided.’

The government is aware of the multiple roles that it must play in the public awareness campaign. The main roles are:

- i. To initiate awareness and participatory activities
- ii. To provide the enabling environment for other agencies to take the initiative
- iii. To provide an efficient system to allow public participation in decision making as it relates to LMOs and GMOs.

Public awareness and education

With respect to public engagement, the initiation activities were conducted in this phase of the project. An analysis of the activities conducted indicates that the challenges mentioned earlier must be taken into consideration when attempting to provide the enabling environment for other agencies to take over the initiative of public engagement. These are:

- Accurate identification of stakeholders and their stakes
- Understanding and catering for the non-homogeneity of the national public
- Understanding the different degrees of participation that are required
- Being able to target the non-urban and functionally illiterate
- The need to be a credible source of information
- The ‘high science’ nature of the topics of biotechnology, GMOs, LMOs and biosafety
- The ‘high degree of illiteracy’ as it relates to these topics (biotechnology and biosafety)

The future plan is based on the development of an enabling environment for other agencies to take the initiative. The main recommendation is for the formation of partnerships between government and civil societies to overcome the challenges that have been identified and provide effective and sustainable public awareness and education programmes such that there is the potential for all citizens to benefit from the information provided. Table 5.2 outlines what is required to design and implement the national public education/awareness campaign for biosafety.

Table 5.2 Requirements to conduct effective and sustainable public engagement in the area of Biotechnology and Biosafety

Activities	Action needed	Resources needed
Identify additional stakeholders to be a part of the Public Awareness Subcommittee of the National Biosafety Committee	<ul style="list-style-type: none"> ▪ Discussion at the level of the National Biosafety Committee to decide on additional stakeholders 	<ul style="list-style-type: none"> ▪ No additional resources required
Formalize the Public Awareness Subcommittee of the National Biosafety Committee	<ul style="list-style-type: none"> ▪ Develop Terms of Reference ▪ Obtain Government approval 	<ul style="list-style-type: none"> ▪ Stipend for each member ▪ Meeting accommodations
*Hire a coordinator to ensure the activities planned by the subcommittee are conducted in a timely manner.	<ul style="list-style-type: none"> ▪ Develop Terms of Reference ▪ Obtain Government approval ▪ Advertise, interview and hire 	<ul style="list-style-type: none"> ▪ Salary package with necessary allowances (travel, phone etc.) ▪ Office space outfitted with necessary requirements (phone, fax, copier, computer, high speed internet)

		access etc.)
<p>Identify civil society actors to be involved in the partnership programme</p> <p>- this includes women as a functional group of stakeholders because of women's multiple responsibilities make them key consumers, decision makers and educators</p>	<ul style="list-style-type: none"> ▪ Research on the existing civil societies ▪ Selection of civil societies based on previously identified criteria ▪ Discussion at the subcommittee level to choose the societies for partnership programme ▪ Discuss with NBC 	
<p>A. Develop a plan of public engagement</p> <p>B. Develop a plan for education of government departments/ agencies especially those whose portfolios are implicated by this issue</p>	<ul style="list-style-type: none"> ▪ Meetings among the selected civil societies representatives and members of the Subcommittee to develop a strategic plan for effective engagement of the national public ▪ Submission of plan to NBC for approval ▪ Develop the tools that will be used in the campaign (i.e. tools for public engagement)** ▪ Identify what resources will be needed (including source of funds) 	<ul style="list-style-type: none"> ▪ Project planning skills
<p>Implementation of plan</p>	<ul style="list-style-type: none"> ▪ Training as needed for implementation ▪ Implementation with the necessary evaluation and opportunity for continuous improvement 	<ul style="list-style-type: none"> ▪ Finances ▪ Personnel ▪ Transport ▪ Training facilities ▪ Project management skills ▪ Office infrastructure

**The methods of engagement will include the following:

- Public open days and demonstration projects
- Theatre
- Printed information
- Internet groups
- Media (all forms)
- Public databases
- Information hotline/ center
- Continued biosafety presence at all related / celebrations
- School programmes – students, teachers
- Workshops and seminars
- Media awareness
- The NBC Secretariat as a knowledge centre for Biosafety with resident expertise and telephone help line.

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Table 2 Requirements to conduct effective and sustainable public participation in the decision making process

Activities	Action needed	Resources needed
Development of the partnership channels	<ul style="list-style-type: none"> ▪ See Table 1 	<ul style="list-style-type: none"> ▪ No additional resources
Adopt the EMA channels of information flow	<ul style="list-style-type: none"> ▪ Identify if these established channels are functional and effective ▪ Devise the necessary regulations to be able to use these channels if deemed fit 	<ul style="list-style-type: none"> ▪ Legal assistance ▪ Assistance from EMA
Implement system	<ul style="list-style-type: none"> ▪ Develop the necessary comment forms for comments at land locations and websites ▪ Publicize the format in the daily newspaper ▪ Ensure that there is a method for recovery of this information and integration into the decision making process ▪ Transmission of final decisions through the same information channels 	<ul style="list-style-type: none"> ▪ Personnel to develop data forms ▪ Financial resources ▪ Computer resources ▪ IT

This system for public participation in decision making will only be used for applications for:

1. Commercial release and
2. Importation for direct use of products of modern biotechnology.

No public consultations will be required for laboratory or greenhouse testing stages although some public notification may be made for field trials if the risk management committee decides that it will be needed. In all these cases where there is controlled use of products of biotechnology, the final decision will rest with the NBC which will be informed by the scientific risk assessment and characterization and management recommendations. The conduct of the trials will be the responsibility of the main investigator who will be managed by the IBC along with enforcement and monitoring agencies that will report to the NBC (see institutional framework).

Section 8 Conclusion

It is known that there is difficulty within the international community to find a mechanism which can lead to a satisfactory degree of interaction that is agreeable to all the stakeholders (companies, scientists, NGOs, general public). T&T prefers to adopt the position that the public has fundamental rights, even if members are unaware of it. The public engagement systems outlined above are designed to develop an informed public to ensure that their rights can be exercised within an appropriate framework for decision-making. The final decision on an application will be based on the risk assessment procedure and collation of public comments (within the stipulated time frame). The final decision will be done by a majority vote by members of the NBC.

The public education and participation systems will be designed to be transparent with inherent mechanisms for quality control and continuous improvement as required along with the necessary regulations/legislation, in combination with a resourced and effective administrative framework.

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Section 9 Implementation of the Proposed Regulatory System

Activities	Action needed	Resources needed
Identify additional stakeholders to be a part of the NBC and the NBC Secretariat	<ul style="list-style-type: none"> ▪ Identify what additional skills/ resources are needed on the NBC which is the core committee 	No additional resources required
Formalize the National Biosafety Committee and the NBC Secretariat	<ul style="list-style-type: none"> ▪ Develop Terms of Reference for National Biosafety Committee identifying the Committee as the legal decision-making body ▪ Identify site for the NBC and secretariat to be located ▪ Obtain Government approval - appointment by the Cabinet based on the recommendation of an advisory committee ▪ Include a mechanism to co-opt experts (with the relevant ToRs) as needed since all applications will be dealt with on a case-by-case basis ▪ Include a mechanism to allow excuse of members if there is conflict of interest 	<ul style="list-style-type: none"> ▪ Stipend/ salary for each member ▪ Office space / site location outfitted with necessary requirements – conference room, library facilities and secretariat facilities (phone, fax, copier, computer, high speed internet access etc.)
Confirm/ modify the institutional framework for the NBF	<ul style="list-style-type: none"> ▪ NBC Committee meetings to decide if plans are adequate of if modifications are needed 	<ul style="list-style-type: none"> ▪ Office facilities ▪ Project management skills
Develop detailed plan for implementation	<ul style="list-style-type: none"> ▪ Develop plan for implementation with timelines and resources needed ▪ Identify training needs at all levels 	<ul style="list-style-type: none"> ▪ Office facilities ▪ Project management skills
<p>Implementation of plan to facilitate the operation of all the components of the NBF</p> <ol style="list-style-type: none"> i. regulatory system ii. administrative system iii. decision-making system includes: (risk assessment & characterization, decision- making, communication & public engagement) <p><i>Plan implemented with the necessary evaluation and opportunity for continuous improvement</i></p>	<ul style="list-style-type: none"> ▪ Advise relevant personnel in all agencies (Table 3.2) involved about the proposed institutional framework ▪ Put infrastructure in place ▪ Hire staff as needed ▪ Meetings of all relevant personnel in all agencies to outline roles and responsibilities ▪ Training staff at all levels and in all agencies involved in the NBF (holistic and specific responsibilities) ▪ Institutionalize the necessary databases and commodity registers (Section 4.4) ▪ Put the necessary infrastructure systems in place 	<ul style="list-style-type: none"> ▪ Finances ▪ Personnel ▪ Transport ▪ Training facilities ▪ Project management skills ▪ Office infrastructure ▪ IT

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Test run of system	Receipt of an application for each category of use: (a) Laboratory (b) Greenhouse (c) Limited field trial (d) Full field trial (e) Commercial release	Full system resources
System modification as needed	This will be determined by the outcome of the test runs	Full system resources
*Enact legislation	<ul style="list-style-type: none"> ▪ Identify the specific legislation needed to allow effective functioning of the regulatory and institutional systems ▪ Draft legislation ▪ Approve legislation 	<ul style="list-style-type: none"> ▪ Legal expertise ▪ Government commitment

*Since legislation also affects the success and access to the benefits of biotechnology the guidelines include those that regulate investment opportunities along with conflict resolution mechanisms that may arise from contractual agreements and intellectual property rights.

Certification scheme for IBC

Developing a monitoring plan including indicators, performance measures and timelines and resources needed