CAPACITY-BUILDING WORKSHOP ON BIOSAFETY FOR THE CARIBBEAN

The capacity-building workshop on biosafety for the Caribbean was successfully conducted over the period January 19th -30th 2004 in Port of Spain, Trinidad. The workshop exemplified collaboration at its best engendering as it did the co-operation of several national, regional and international bodies. National collaborators included NIHERST, the Ministry of Public Utilities and the Environment, the Ministry of Legal and Consumer Affairs and the Environment Management Authority in Trinidad and Tobago. External partners comprised the Caribbean Council for Science & Technology (CCST), the United Nations Development Programme through its Perrez Guerrero Trust Fund, the Technical Centre for Agricultural and Rural Co-operation ACP-EU (CTA), the Caribbean Agricultural Research and Development Institute (CARDI), the International Development Research Centre (IDRC) in Canada, and Commonwealth Secretariat. Through the strong support of its partners, the organisers were able to extend the participation and thus benefits of the workshop to seven Caribbean countries. Beneficiary countries were Antigua and Barbuda, the Bahamas, Barbados, Guyana, St. Lucia, St. Vincent & the Grenadines, and Trinidad and Tobago. The diversity of the fifty (50) participants and presenters, of whom 13 were from other islands in the region, indicated strong support from both private and state sectors for biosafety.

The Honourable Senator Satish Ramroop, Minister of State in the Ministry of Science Technology and Tertiary Education, gave the feature address at the opening ceremony. His address highlighted the potential benefits of modern biotechnology to the region, and in particular the agricultural sector. However, the Minister stressed on the need to institute a proper framework at the national and regional level to exploit this technology in order to safeguard human health and the environment from any deleterious effects.

The workshop proceeded through oral presentations, group work, and panel discussions led by regional and international experts to address the various aspects of biosafety. Participants were most fortunate to have the services of two leaders in the field, namely, Dr. Patricia Traynor of New AgriTech Strategies, and Dr Hector Quemada of Crop Technology Consulting. Caribbean presenters and facilitators included Dr. P. Umaharan of the UWI, St. Augustine, Prof. J. Duncan of the UWI St Augustine, Dr. Cyril Roberts of CARDI Barbados, Ms. Yasmin Comeau of the National Herbrarium, Dr. Bibi Ali of CABI, Trinidad, Mr. Victor Jordan of the Ministry of Trade and Mr. Anthony Smallwood of the EU Delegation.

The range of issues covered during the 10-day workshop included:

- The Cartagena Protocol on Biosafety and other relevant international agreements,
- biosafety systems in selected developed and developing countries,
- scientific risk assessment and risk management focussing on transgenic plants,
- food safety assessments and relevant international protocols,
- decisions and decision making,
- biosafety communication,

- regional approaches to biosafety, and
- biosafety resources and support.

Additionally the status of and regulatory context for biotechnology and biosafety, existing capacities and capacity needs, as well as available support for biosafety capacity-building was identified through the presentation of reports from participating Caribbean countries.

Through small group work and a synthesis in plenary sessions model guidelines for the safe transfer, handling, use and identification of biotechnology products, especially GMOs were drafted by participants, many of whom are involved in regulatory bodies and/or national biosafety committees in their countries.

Risk assessment case studies on transgenic cotton, maize and bananas, and plenary exercises enriched the learning process and underscored the range of expertise and the rigor required to conduct a proper assessments of risks and benefits of a genetically engineered product. The cases also highlighted the importance of a congruent national biosafety framework, proper laws and regulations.

This workshop provided a rich forum for discussion of biosafety issues including potential implications for trade with the USA, Canada and the EU, and the movement of transgenic material through open intra-Caribbean borders. It is envisaged that regional networking capabilities and co-ordination in biosafety would be improved through the workshop. Thirty-seven (37) participants received certificates of participation based on the achievement of 80% attendance at the workshop.

Report

On

Capacity Building Workshop on Biosafety for the Caribbean

January 19-30, 2004

Port Of Spain, Trinidad

Acronyms

ACP - African, Caribbean & Pacific
CARDI - Caribbean Agricultural Research and Development Institute
CA - Codex Alimentarius
CCST - Caribbean Council for Science and Technology
CBD - Convention on Biological Diversity
COTED – Council for Trade and Economic Development
CPB - Cartagena Protocol on Biosafety
CTA - Technical Centre for Agricultural and Rural Co-operation ACP-EU
EMA - Environment Management Agency
EPA - Environment Protection Agency
EU - European Union
FTAA – Free Trade Area of the Americas
GE - genetically engineered
GM - genetically modified
GMO - genetically modified organism
IBC - institutional biosafety committee
IDRC - International Development Research Centre
IPM - integrated pest management
IPPC - International Plant Protection Convention
IPRs – Intellectual Property Rights
ISNAR - International System for National Agricultural Research
LMO - living modified organism
MNC – multi-national company
NIHERST - National Institute for Higher Education (Research, Science & Technology)
NBF- national biosafety framework
NBAC - National Biosafety Advisory Council
PGTF - Perez-Guerrero Trust Fund
PI - Principal Investigator
PIP - Plant Incorporated Protectant
PNT - plants with novel traits
R&D - Research & Development
SIDS- Small Island Developing States
SPS - Sanitation & Phytosanitation
UWI - University of the West Indies
WTO - World Trade Organisation

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Report on
Capacity Building Workshop on Biosafety for the Caribbean
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1.0. Introduction:

"CAPACITY BUILDING IN BIOSAFETY FOR THE CARIBBEAN" started as a regional project implemented by the Caribbean Council for Science and Technology (CCST) with the sponsorship of the Perez-Guerrero Trust Fund (PGTF) for Economic and Technical Co-operation Among Developing Countries and the Commonwealth Science Council (CSC). Initially the project's beneficiary countries were Barbados, Jamaica, Trinidad and Tobago, Antigua and Barbuda, Guyana and St. Lucia. With the support of the Technical Centre for Agricultural and Rural Co-operation ACP-EU (CTA) administered through the Caribbean Agricultural Research and Development Institute (CARDI), and the International Development Research Centre (IDRC) in Canada, the benefits of the project were extended to CARDI professionals in the region and other Caribbean countries, namely the Bahamas, Dominica, and St. Vincent and the Grenadines. The total support from all partners for the project amounted to US$59,450.

Article 15 of the Cartagena Protocol on Biosafety (CPB) to the Convention on Biological Diversity (CBD) requires Parties to undertake risk assessment and risk management procedures in line with other provisions of the Protocol. This requires capacities in both general risk assessment as well as scientific and socio-economic capacities. Compliance therefore requires multi-disciplinary expertise and ability to deal with scientific uncertainty in ways that allow technological development to take place without compromising human and environmental health.

There is a lack of critical mass of trained professionals both regionally and internationally to deal effectively with the complexity of issues related to the assessment and management of biological risks. The project therefore aimed to equip the Caribbean countries with some of the required technical expertise needed to satisfy their international obligations in Biosafety, as well as to help protect their public's health and well being. This was to be effected through the staging of a 10-day training workshop for technologists, scientists, national biosafety committee members and potential regulators in approaches to the development of biosafety systems and scientific risk assessment and management. Such training would assist beneficiary countries to put into effect institutional and operational mechanisms for biosafety management.

A team from NIHERST developed the objectives of the training workshop and the workshop outline assisted by Prof. E. Julian Duncan and Dr. P. Umaharan from the University of the West Indies. The workshop had four objectives as follows:

i. To train a cadre of Caribbean professionals in the environmental release of GMOs and their products including the methods, techniques, standards, indicators and guidelines for assessing, monitoring and controlling the risks

posed by the transfer, handling and use of genetically modified organisms (GMOs) and their products.

ii. To train Caribbean scientists and technical experts in the techniques to deal with the safe transfer, handling, use and identification of GMOs that may have adverse effects on biological diversity, the environment and human health.

iii. To formulate model guidelines for use at the national and regional levels for the safe transfer, handling, use and identification of biotechnology products, especially GMOs.

iv. To contribute to the development and harmonisation of initiatives and collaborations in the Caribbean region on biosafety.

The workshop was designed to be comprehensive covering the requirements of the Cartagena Protocol on Biosafety as well as broader social, economic and other non-science factors. Case studies were included for participants to assess real applications dealing with the release and transfer of GMOs into the environment. In addition, participants were to gain exposure to different experiences and approaches to the development of national biosafety systems in selected developed and developing countries and were to be made aware of the status of biosafety in participating Caribbean countries.

Potential international facilitators for the workshop were identified through recommendations from contacts in Latin America, web searches and a review of published works in the field. Availability and assistance from the US Fullbright Senior Specialist Program resulted in the selection of Dr. Patricia Traynor of New AgriTech Strategies, and Dr. Hector Quemada of Crop Technology Consulting. The Fullbright support was valued at US$3,000. In addition, a number of Caribbean presenters and facilitators were also identified and invited to make presentations.

Several agencies in Trinidad collaborated with the CCST and NIHERST to stage the workshop, which was conducted from January 19th to 30th at the Environmental Management Authority (EMA). They included the EMA, Ministry of Public Utilities and the Environment, the Ministry of Legal and Consumer Affairs, the Ministry of Agriculture, and the St Augustine Campus of the University of the West Indies. CCST focal points assisted in identifying regional participants.

2.0. Day 1- Monday 19th January

2.1. Opening Ceremony

Close to 70 persons attended the Opening Ceremony, which was covered by the local media. In her welcome address, Mrs. Maureen Manchouck, President of NIHERST and Secretary of the CCST, noted the keen interest shown in the workshop from the high level of participation. This she stated attested to the seriousness which the region perceived the biosafety challenge and the imperative of developing capacity at both the national and regional levels in biosafety. This capacity was needed for the region to effectively respond to international obligations such as the Cartagena Protocol for Biosafety, as well as to make critical decisions on scientific issues that have a direct bearing on the environment and public health. The workshop presented an excellent opportunity to strengthen regional collaboration in biosafety

and in biotechnology itself in light of the different situations, capabilities and needs of each country.

NIHERST's involvement and collaboration with the University of the West Indies (UWI) in biotechnology spanned nearly a decade. The vision then was to use this technology to revitalise the national and regional agricultural sector through the improvement of planting materials and the development of new food and horticultural products for export. The focus on biosafety would create the conditions for countries to re-energise the biotechnology sector so that its full potential can be realised, while simultaneously addressing safety and environmental concerns.

Mrs. Manchouck advised participants to be cognisant of the wider regional and global contexts in which the biosafety imperative was inextricably linked with issues of trade and in particular the free movement of goods. Failure to demonstrate a sense of urgency in putting systems in place would impede not only our ability to honour international commitments and to safeguard our population and environment, but could also have serious and far-reaching implications for trade and technology transfer. A regional response to biosafety was advocated given the region's current limitations with respect to capacity in the biosafety area and the high cost of compliance with the relevant international protocols, which tend to favour multinational companies over local innovation.

The above thinking informed the conceptualisation and planning for the workshop and the larger project, to which credit was given to Dr. P. Umaharan and Prof. J. Duncan for the instrumental roles which they played in the project's development.

Senator The Honourable Satish Ramroop, Minister of State in the Ministry of Science, Technology and Tertiary Education in his feature address highlighted the potential of biotechnology in alleviating food scarcity, hunger and malnutrition in the world over the coming decades. The technology was of importance to small islands that faced natural disasters that annually militated against successful crop production and food security, and which faced the depletion of virgin lands for agricultural production as housing and industrial needs increased.

However, there was controversy over the application of biotechnology and the debate on agricultural biotechnology and GM foods had become polarised. There were serious concerns that the risks might be greater in developing countries, as the application and monitoring of biosafety regulations would be less rigorous than in developed countries. For Caribbean countries with biologically rich but small eco-systems, biosafety was a serious concern.

Local and international developments created an urgent need for Trinidad and Tobago among other developing countries to develop and maintain an adequate capability in biotechnology. Trinidad and Tobago had not yet applied the technology in large-scale field trials and in the production of food as work at the UWI Department of Life Sciences, the only institution in the country that did Genetic Engineering, concentrated on increasing the novel features of ornamental plants. However, the use of biotechnology in food production was a reality in Latin America, and to a lesser

degree in CARICOM countries like Jamaica. These developments provided an impetus to institute biosafety mechanisms at the national and regional levels.

Recognising the need to exploit biotechnology in a responsible manner, the Government of Trinidad and Tobago appointed a Cabinet Committee in 2000 to develop a National Policy and Regulations on Biosafety. This Committee started work on a draft national Biosafety policy document and was chaired by the Deputy Permanent Secretary in the Ministry of Legal Affairs. Cabinet also recently agreed for Trinidad and Tobago to become a member of the International Centre for Genetic Engineering and Biotechnology (ICGEB), a body dedicated to the advancement of research and training in molecular and biotechnology with special regard to the needs of developing countries.

Minister Ramroop thanked all the agencies involved in hosting this important workshop, particularly NIHERST, and iterated that the Government of Trinidad and Tobago was acutely aware of the value of the advances in science and technology for the modernisation of that country. Indeed, the vision of the government was to achieve developed country status by the year 2020 and this required the employment of science, technology and innovation as critical factors in all areas.

Mrs. Phillipa Forde, Deputy Permanent Secretary in the Ministry of Legal and Consumer Affairs and Chairperson of the National Biosafety Committee, delivered the vote of thanks. She also underscored the importance of North-South co-operation and inter-agency co-operation in realising the workshop.

2.2. Session 1- Introduction and Background

This session was chaired by Ms. Robyn Cross who invited Dr. Traynor to say some remarks about the workshop. She expanded on the workshop's objectives, content, format, and the critical aspect of the development of model guidelines. There was group work on developing guidelines for the safe handling, transfer and use of genetically modified (GM) plants moving from the laboratory phase to limited field trials then extensive trials. Participants were introduced to the USAID technical training workbook on biosafety that was used in other training courses around the world, and to a number of sources of information and references on biotechnology and biosafety research. The workbook was not a text on genetic engineering (GE) but it covered the process of decision-making on GMOs focussing on the environmental and health safety aspects. Its limitation was that it did not cover non-safety issues such as ethical, trade and socio-economic issues.

The first presentation was by Prof. E. Julian Duncan, Emeritus Professor, UWI, St. Augustine. After a brief introduction, Prof. Duncan gave an overview of Biotechnology and what it involved. He gave a definition of the term and explained the difference between biotechnology and GE. Using the broad definition of the term biotechnology, he traced the evolution of the technology over time and explained the advances made in this field since 1950s. He focussed on some critical applications to agriculture globally. See Appendix 5 for details.

Continuing the presentation was Prof. P. Umaharan, UWI Department of Life Sciences, St. Augustine, who gave an introduction to GE. He explained that the

blueprint of life was coded in DNA molecules, which functioned as the control points in cells. Genetic modification was the alteration of the genetic makeup of an organism. This could be accomplished by plant breeding or expedited and made more precise by GE. The differences in two approaches were explained and the processes contrasted. A step by step synopsis was given of the techniques used in GE. The difference in the terms GMO and MO was given.

Participants were sensitised to the broad range of applications of biotechnology in food, manufacturing, and environmental protection. The crop biotechnology revolution was explained as a response to the doubling of population growth and decreasing land reserves. GE held the promise to doubling the achievements of the Green Revolution. Trends in GM crops were highlighted. They included bio-pesticidal plants, pharmaceutical plants, neutraceuticals and plants with biotic stress resistant properties. Research and development was also proceeding on plants that could be used as bioreactors.

Dr. Umaharan outlined the potential benefits and risks that biotechnology and GMOs posed to the Caribbean. The relevant areas of R&D for the region included technologies to protect biodiversity, develop neutraceuticals and local medicines, build new agricultural niches, develop ornamental plants with novel features, and develop biotic stress resistant plants. Building on areas of strength, he advocated work on tropical ornamentals, indigenous varieties of pineapples, hot peppers, medicinal plants, papayas and pumpkins. See Appendix 5 for full presentation.

In the question and answer period that following this joint presentation, issues relating to the relevance of R&D in the region, critical mass and the commercialisation of biotechnology and legal framework for protection of GM products arose. The following points were made:

a. Exploitation of the technology could be problematic as regards trade in GM products outside the North American market. To penetrate the American market the processes would have to be right as well as rigorous.
b. R&D at the UWI St. Augustine on ornamentals did not pose a risk to the environment since gene transfer to other species was not possible.
c. R&D in the region at present did not address problems with staple root crops and thus food security. Countries had to rely on GM planting material from South Africa. This problem was attributed by Prof. Duncan to point d. below.
d. The region did not have a successful experience with the commercialisation of biotechnology. In the early 1990s, countries failed to support Agri- Tech Ltd., CARICOM's first biotechnology company, which was created to meet the regional needs for improved planting materials for root crops, plantains, bananas among other crops. Agri-Tech was eventually wound up. It was owned by the UWI St. Augustine, NIHERST and some state companies. The UWI St. Augustine laboratory currently supplied materials to farmers but the volume of demand was not steady or large enough to generate a profit. The University was nonetheless considering developing a semi-commercial facility.
e. Greater co-operation and collaboration was needed among laboratories in the region to reap the potential for biotechnology. This was necessary to overcome the problem of a critical mass of resources and to avoid unnecessary duplication of effort. A framework for co-operation that included an agreement on areas of

specialisation in biotechnology research, development and production was proposed.

f. It was also proposed that more institutions and countries should co-operate with CCST in developing SIMBIOSIS as the forum for information and knowledge sharing on biotechnology in the region.
g. Inadequate systems for the protection of the products arising from biotechnology R&D, posed a constraint to commercialisation. In this regard, only Trinidad and Tobago had developed its national system. Barbados, Jamaica and St. Lucia were making strides. However, the issue required a regional approach whereby the smaller countries could rely on the national system in a larger country for assistance.

Prof. Duncan chaired the proceedings of this post-luncheon session and introduced Mr. V. Jordan, Trade Specialist in the Ministry of Trade & Industry, Trinidad & Tobago. He gave a synopsis of the Cartagena Protocol on Biosafety agreement and its relation to other international agreements. The Protocol was a response to the failure of the WTO Ministerial Conference held in Seattle in December 1999 to establish a working group on biotechnology that would give the WTO the mandate to regulate the transboundary movement of living modified organisms (LMOs). This failure led developing countries to push for the negotiation of a biosafety agreement outside the purview of the WTO through Article 3 of the Convention on Biological Diversity.

Mr. Jordan explained how the Protocol on Biosafety was advantageous to developing countries as regards LMOs intended for release into the environment and for food and processing. The protections included the clauses on accompanying documentation of the LMO, prior notification, the placement of the burden on the exporting country to show that a LMO was safe for the importing country, and the precautionary principle, which allowed a country to deny a LMO import as a precautionary measure. The Protocol required assessments to be conducted on scientifically sound principles and allowed for socio-economic considerations arising from the impact of LMOs. There was also the clearinghouse Mechanism that was a source of information and technical expertise for enabling the importing country to make informed decision concerning the importation of LMOs into the environment. The Protocol thus offered protection in a variety of ways to countries that lacked the institutional capacity to monitor and test LMOs for their safety.

While the framers of the Protocol on Biosafety were careful to ensure that the Protocol would not be subservient to other international agreement (i.e. the SPS agreement of the WTO), the Protocol did not say which agreement should prevail in case of a conflict between the two agreements. The focus of the SPS Agreement was with protecting “human, animal or plant life or health” and preventing the use of SPS standards as an obstacle to trade. It recognised only a scientific basis for restricting the importation of LMOs. Therefore insufficient scientific evidence could not be used to avoid taking a decision and socio-economic considerations could not be used in conducting the assessment of risks.

Mr. Jordan stated that since more countries were members of the WTO than the Protocol, the WTO would be the most likely forum to resolve conflicts between the two agreements, especially if the conflict involved a Party and a non-Party to the Protocol. The European Union and most of the African, Caribbean and Pacific (ACP)

countries had signed the Protocol and it would thus govern the trade in LMOs between the two groups of countries. EU and ACP countries that were also members of the WTO would have access to both the forums of the Protocol and the WTO in the event of a dispute. The EU had exercised its right under the SPS Agreement to adopt measures that would result with a higher level of sanitary and phytosanitary protection than would be achieved by relevant international standards. Thus the EU regulations governing the importation of LMOs were more stringent than the Protocol or the SPS Agreement.

With the exception of the United States, most of the 34 countries that make up the FTAA had signed the Convention on Biological Diversity (CBD) and the Protocol on Biosafety. So, in the absence of any domestic legislation in the individual country, the Protocol would govern the trade in LMOs between the members of the Protocol. For a FTAA member lacking domestic LMO legislation, the SPS Agreement would then govern its relations with the United Slates on trade in LMOs. Since the United States did not sign the Protocol, the U.S. would not be obligated to honour it and since it was more restrictive than the SPS Agreement, the United States would seek to use the WTO forum as a means to minimise compliance with the Protocol.

It was recommended that Caribbean countries under Article 3(3) of the SPS Agreement that set standards for the importation of LMOs, proceed to adopt the Protocol into their domestic laws, and also put in place the necessary infrastructure to monitor compliance with the Protocol. Once the Protocol was adopted, the export of LMOs from countries, including the U.S., a non-Party to the Protocol, would have to meet the Protocol standards as a condition of the laws of the Caribbean region before their LMO/GMO products would be allowed to be imported into the region. See Appendix 6 for full presentation.

2.3. Session 2- National Biosafety Systems

Dr. Traynor started her presentation on the ISNAR study on biotechnology and biosafety in developing countries, which aimed to assess the efficacy of policies and procedures and to develop recommendations for improving operations and to lessen potential obstacles to technology transfer. Its key findings showed the lack of coherence in the implementation steps being taken; the lack of inter-agency co-ordination; unclear lines of authority and responsibility; an hoc approach towards public consultation; and a clear need for technical training and public communications as priority areas for capacity-building.

Following the study, ISNAR organised in 2001 an international consultation on a conceptual framework for the development and implementation of biosafety system to assist developing countries. The published framework, Briefing Paper 47 entitled " *A Conceptual Framework for the Implementation of Biosafety: Linking Policy, Capacity & Regulation*", identified the critical decision points, choices among policy options, and the scientific and social implications of these options. It also considered regulatory implementation and capacity building. It complemented the UNEP/GEF Global Project on the Development of National Biosafety Frameworks by providing guidance to countries on the design and implementation of regulatory frameworks and related capacity building initiatives. It provided a good frame of reference for

countries but was not a road map for all to follow and each country had to tailor it to meet their needs.

Key issues and steps in developing a national biosafety system included:

a. undertaking a national inventory and evaluation of existing regulatory structures, legislation for trade in agriculture commodities, environmental protection, animal and human health safety; mechanisms for the development of public policy, legislation and regulations; agricultural priorities; human, financial, and scientific capabilities; status of biotechnology R&D; mechanisms for regional co-operation and regulatory harmonisation; and capacity building programmes;
b. determining the status of and potential for national development including among other things import and export markets, geopolitical environment, societal philosophy with respect to science, technology and the environment; environmental resources, particularly with respect to the richness of biological diversity; the potential impact of GMOs on ecosystems; the role of civil society in processes for policy and regulatory development; and administrative and enforcement capacity;
c. articulating a national policy on biotechnology and biosafety that sets the goals and objectives of the regulatory framework; is consistent with policy objectives for food, agriculture, innovation, environment, health, trade, international agreements and obligations; can provide a mechanism for effecting public dialogue and addressing issues related to the ethical, legal and social implications of biotechnology; and includes a biosafety research agenda for projects designed to support regulatory decision;
d. determining an appropriate regulatory regulatory structure required consideration *inter alia* of the objectives, regulatory triggers or subjects of the regulations, the decision-makers in the system, the process for decision-making, the stakeholders and the means of their engagement in the decision-making process, legal means for implementation, and approach to risk assessment and non-safety factors;
e. regulatory implementation should consider centralised or decentralised authority, compliance and enforcement measures, post-release monitoring and surveillance, and risk assessment research, transparency of the risk assessment process and decisions, mechanisms for public involvement, and harmonisation at the sub-regional and international levels.

Important crosscutting issues were why and how products are regulated, how and what levels decisions are made, public participation, transparency and communication, and capacity - human, financial and infrastructural. The conclusion was that a comprehensive integrated approach was needed to developing a national biotechnology policy and national biosafety system. There was no one best approach to do the job. See Appendix 8 for full presentation.

In the ensuing vigorous discussions, participants debated whether it was better to first develop a policy on biotechnology before formulating a policy on biosafety or to treat them together in one policy. There was consensus that in order to achieve coherence and to avoid a long delay, a single policy was preferable. Developing a policy could take a year and a whole system could take three years from conceptualisation to the start of implementation. Dr. Malachy Dottin from Grenada added that biotechnology and biosafety were inextricably linked. Biosafety proceeded from biotechnology and

hence countries needed first to take a stance on biotechnology. He concurred that separate policies might not be appropriate at this stage. However, the integrated policy should identify research priorities in biotechnology and biosafety. He informed participants that Grenada had adopted codes of conduct for biotechnology and they were guiding that country in developing its biosafety laws.

Participants noted that in the Caribbean there was little or no debate on GM products. Compared to the US, there was much public debate on and opposition to GM products. The question was asked if Americans were more knowledgeable than Europeans on GM products and whether this was due to public education. Dr. Traynor explained that Americans were not more informed than Europeans on the subject and that the US did not undertake a big awareness campaign. The difference in the attitude of the America public was due to the high public confidence enjoyed by the regulatory agencies, and the nature of American farming which was took place on large mechanised that were open to innovation. European farming took place on small family farms that were less mechanised. Their regulatory agencies had eroded public confidence by their treatment and mismanagement of key health risks in recent years and in the past. One participant questioned the safety of GM products on the grounds that it was still too early to tell their full impacts. Dr. Traynor responded that there were no guarantees for GM or conventional foods but scientists could say that to the best of their knowledge they were as safe as conventional foods. This led another participant to observe that it was meaningless to prepare biosafety regulations without the requisite national competence and expertise to develop or implement.

Dr. Hector Quemada made the point that communication was necessary and important from the early stages in the development of the biosafety system. Scientific expertise was also a high priority. There appeared to be a high level of expertise in the region but a different and broader set of expertise was needed to develop and implement the guidelines. A regional approach was best since countries shared more or less the same ecological systems, crops, pests and diseases and similar local constituents.

In his short address before the day's end, Dr. Quemada explained in more depth the model guidelines group project. The first part involved an analysis of the strengths and weaknesses of different national systems (Brazil, Vietnam and Canada). In part two, participants would then try to develop guidelines for laboratory and greenhouse trials. The third part involved formulating guidelines for conducting limited field trials. Part four involved extensive field trials. At each stage, participants must identify the appropriate questions.

3.0. Day 2- Tuesday 20th January

3.1. Session 2 - National Biosafety Systems cont.

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Dr. Umaharan chaired this session. Dr. Dave Persaud from the Ministry of Public Utilities & the Environment delivered a presentation on the UNEP-GEF Project in Trinidad and Tobago. Dr. Persaud gave an introduction to the UNEP/GEF Project, which approved support to 100 countries to prepare their national biosafety framework (NBF) in preparation for the entry into force of the Cartagena Protocol on Biosafety. He outlined the components of a NBF, which included a policy on biosafety, a regulatory regime, a system to handle notifications and requests, follow-up systems including enforcement and monitoring, and mechanism for public information and participation. The duration, phases of the project and their outputs were summarised. Trinidad and Tobago had just begun to embark on its national project. The EMA was the national executing agency for the project and the national co-ordinating committee was the Cabinet appointed Committee for developing a national policy and regulations on biosafety. A project co-ordinator had yet to be appointed. A sub-regional SIDS workshop on the development of a regulatory regime and administrative systems for NBFs was scheduled to be held in Port of Spain from May 11-14, 2004. See Appendix 9.

In her presentation on Biotechnology and Small Farmers, Dr. Bibi Ali of CABI Trinidad, defined the term small farmer and outlined some of the concerns that this group had expressed about agricultural biotechnology at the 2002 World Summit on Sustainable Development. The group presented to the forum a declaration affirming farming and fishing as a way of life and a culture, which provided food, employment, healing, spiritual inspirations, social education and skills development for generations. Small holder farmers, though in a majority, had been largely unheard and un-noticed globally. Noting that land, water, genetic resources, and minerals had been communally owned for generations, the group argued that these resources should never be transferred to private ownership for selfish and profit-driven gain. They advocated that the rich knowledge, best practices and technologies developed over time by small farmers should never be alienated from them, and they called for research that built on this knowledge and practice. Their systems for seed production and exchange were the key to food sovereignty at the household and country levels. Accordingly, the group denounced GM crops.

More sustainable agricultural technologies were needed in the developing world including the Caribbean to combat problems of prolonged drought, insects attack, expensive and harmful pesticides usage, weeds, and the depletion of nutrients from the soil. Explaining how agricultural modernisation made on large scale, technology and chemical intensive mono-cultural systems of production, was unsustainable, Dr. Ali went on to present the differences in production systems in the Caribbean using Antigua & Barbuda, Belize, Grenada, and Haiti as examples. There was growing recognition globally that in order to advance the sector there must be greater attention to the promotion of more sustainable small farming systems. Integrated crop management, IPM, a participatory approach were some elements in the steps forward. Attention should be paid to efforts to build the capacity of small farmers to make their own crop management decisions based on a better understanding of the agro-ecology

of their own fields and according to their own unique set of circumstances and priorities.

Dr. Ali stated that agricultural biotechnology was one tool in the basket of options that could assist the small farmer to produce effectively provided it delivered what the small farmer desired. What did the small farmer desire? They desired advances that protected indigenous seeds from GM contamination; respected traditional seed farming; avoided the debt cycle and the technological treadmill; did not compete with traditional crops; were ecologically sustainable; and were based on socially just technologies. See Appendix 10 for details.

Dr. Malachy Dottin of Grenada led the country presentations on the status of biotechnology and biosafety in the Caribbean. He elaborated on the considerable work undertaken by Grenada on the development of its national biosafety framework (NBF). Several surveys were successfully completed. They included a survey of the existing use of biotechnology and the arrangements for the safe use of biotechnology; and existing co-operative programmes for capacity building. CABI was also contracted to review the application of biotechnology in the country. A review was also undertaken of NBFs in selected countries in the region; existing mechanisms for the harmonisation of risk assessment, risk management, the sharing of data and data validation; and the extent and impact of the release of LMOs and commercial products.

The legal review and assessment was extensive and covered the following laws: the Agricultural Small Tenancies Act; Animals (control of experiments) Act; Banana (protection and quality control) Act; Fisheries Act; Food and Drugs Act; Noxious Weeds Act; Pesticides Control Act; Plant Protection Act; Public Health Act; Science and Technology Council Act; Standards Act; and the Draft Bio-safety Act. An examination was also conducted of international agreements including the Agreement on the Application of Sanitary and Phytosanitary Measures, Agreement on Pre-shipment Inspection, Agreement on Technical Barriers to Trade, Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, and the Convention on Biological Diversity.

There was in place a National Biosafety Advisory Council (NBAC) to undertake administrative functions for issues related to the Protocol on Biosafety. However, the lack of sufficient competence personnel and the lack of clarity and co-ordination in agency responsibility were major obstacles to creating an effective and consistent regulatory system for biosafety. Several recommendations were made to develop and strengthen the NBF. Among the proposals was that the NBAC should determine the context for the use and development of LMOs in terms of the country's overall development objectives, public health and safety, and sound environmental management. The Biosafety Act should establish categories of risks, and determine the critical questions that must be addressed to identify the main risks. The Council should establish clear goals and objectives for the environmental monitoring system for LMOs based on stakeholder participation and consensus, and the results of risk assessments. It should also act to develop the knowledge, capabilities, and infrastructure needed to effectively address the issue of the release of LMOs.

There was an urgent need to develop a communication strategy to keep stakeholders and other member of the public informed of the results of environmental compliance and the monitoring of environmental effects. Guidelines also needed to be developed to ensure public access to non-confidential environmental monitoring data and information, and to protect confidential data and information. It was recommended that stakeholders had an input into the design of the environmental monitoring programmes in order ensure that their concerns would be addressed.

Existing national, bilateral and multi-lateral programmes of support for capacity building included FAO support for strengthening capacity in biotechnology, biosafety and biodiversity for extension officers and teachers among others; the sub-regional Biotechnology Laboratory Programme which trained personnel in the different disciplinary areas; and the OECS training course on plant biotechnology.

The survey on the knowledge, use and position held by farmers on LMOs covered 10% of the small farmers in the country using the FAO definition of small farmer. Some 160 banana, vegetable, livestock and horticultural producers were surveyed. The survey also covered supermarkets (29), pharmacies and chemical shops (20). The findings were that a high percentage of study subjects expressed little and no knowledge of LMOs. Farmers in particular had very little knowledge about LMOs. Though most agricultural inputs were imported, farmers generally did not know whether these imports contained LMOs. Very few farmers had an understanding of the term LMO. The few who understood the concept were able to identify benefits and/or risks related to the use of LMOs. The few farmers who had used LMOs, expressed negative attitude toward their use. A small number of farmers expressed willingness to import LMO but a larger number was undecided about future import intent. The findings pointed to the important need for public education and awareness. See Appendix 11.a. for details.

Prof. Duncan presented on the current status of biotechnology R&D and biosafety in Trinidad and Tobago. The country was relatively rich in biodiversity for its size with 2656 species of vascular plants in 186 families and 670 species of vertebrate fauna in 137 families. Several agencies had responsibility for safety issues *viz*. the Foods and Drugs Division of the Ministry of Health, the Environment Management Authority, the Ministry of Public Utilities and the Environment, the Plant and Quarantine Services of the Ministry of Agriculture, Land and Marine Resources, and the Customs and Excise Division of the Ministry of Finance. The legislative framework for ensuring safety was generally old and none addressed LMOs or GMOs. The Plant Protection Regulations of 1997 provided for planting materials to be subjected to inspection and treatment as a condition for entry into the country. The Food and Drugs Act, Chapter 30:01, made it an offence for *'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 erroneous impression regarding character, value, quantity, consumption merit or safety'.* In developing a proper legal framework for biosafety, there was consensus that the approach to regulating LMOs/GMOs should be precautionary rather than prohibitive.

The findings of a national survey on the application of biotechnology and use of LMOs, underscored that R&D in this area was limited to the St. Augustine campus of

the UWI. The researchers were self-regulated in the absence of laws or regulatory bodies to oversee and monitor their work. No LMOs had to date been released into the environment and the R&D focus was not on food plants. Local chemical shops had reported that they were not importing GM materials.

The country's training needs in biosafety were considerable. There were very few nationals who were trained in biosafety relating to LMOs and GMOs. Only the university had a capability in the area but it was small. Institutional training needs included *inter alia* training on procedures for certifying labels if they were mandatory, training for regulators in risk assessment, training for assessors of applications in risk-benefit assessment, and training for impact assessments using new biological models and theoretical perspectives. The point was made that the country did not the capability to do quantitative testing on GM products and that a national laboratory, preferably the Food and Drugs Laboratory, should be developed. See Appendix 11.b.

The presentation by Mrs. Gillian Bernard on highlighted that there was strong political support for biotechnology and biosafety in Jamaica. In 1990, the National Science and Technology Policy identified Biotechnology as vital to Jamaica's development and stated that the country would move to exploit Biotechnology whilst protecting the national environment and human health. R&D in biotechnology was being undertaken at the Mona Campus of the UWI, where work was on-going on Transgenic Papaya varieties, 'Gemini' virus resistance in tomatoes, and hot peppers to yellow leaf curl. At the Northern Caribbean University work was in progress on the anti-cancer properties of sorrel (*Hibiscus sabdariffa*), while the Scientific Research Council was engaged in Tissue Culture Propagation.

In 1996, the National Biosafety Committee was established under the purview of the National Commission on Science and Technology. The Committee was mandated to develop clear guidelines for identifying and monitoring GMOs with undefined risks; prepare appropriate guidelines and codes of conduct for users of GMOs; keep abreast of relevant international developments; and conduct public education. In 2001, Jamaica signed the Cartagena Protocol on Biosafety and proceeded under its UNEP/ GEF project to undertake a Biosafety Baseline Survey and plan a Biosafety Public Education Programme. Work began in 2002 on the development of a National Biosafety Framework. A Biosafety Impact Survey was initiated. It showed a low level of knowledge on LMOs and this impacted on the amount of work needed to educate the public, and persons in the ministries of their roles as regulators. Capacity building was a critical need and there was funding for this area from UNEP/GEF, regional and regional partnerships, and The Nature Conservancy (TNC).

There was consensus that the legal framework should allow the growth of biotechnology. It should be flexible and proactive, not reactive, since the area was a dynamic one. The relevant existing laws for safety included the Plant Quarantine Act, 1993; the Plant (Importation) Control Regulation, 1997; the Natural Resources Conservation Authority Act, 1991; the Natural Resources Conservation (Permits & Licenses) Regulations, 1996; the Pesticides Act, 1975; and the Food and Drug Act.
See Appendix 11.c.

Dr. Kenneth Richardson in his presentation on the situation in the Bahamas indicated that there was very little interest in the commercial production of GM crops. At

present, there were no regulations governing the planting of GM crops, no R&D was conducted in the country on GM crops, there was no capacity for risk assessment and management of the hazards associated with GMOs, and practically no media attention was paid to issues on GMOs. The Bahamas had just embarked on developing a system of regulatory oversight through its UNEP/GEF Biosafety Project. Biosafety first came into national significance in 1994 where the First Meeting of the COP took place in Nassau. It was agreed at this meeting that discussions should begin on the need for and mechanisms of a protocol on biosafety. This resulted in the Cartagena Protocol on Biosafety, which the Bahamas signed in May 2000 and was in the process of considering its ratification.

Several pieces of legislation addressed safety and regulatory issues. They included the Agriculture and Fisheries Act (Ch. 242), Bahamas Agricultural and Industrial Corporation Act (Ch. 358), Environmental Health Services Act (Ch. 232) – Environmental and Public Health, Export Control Regulations Act (Ch. 299), Food Act (Ch. 236), Import Control Regulations Act (Ch. 298), Pharmacy Act (Ch. 227), Plants Protection Act (Ch 250), Quarantine Act (Ch. 237), Copyright Act (Ch. 323), and Industrial Property Act (Ch. 324).

The NBF project was funded jointly by Government and UNEP/GEF. The Bahamas Environment Science and Technology (BEST) Commission was the National Executing Agency and the Biodiversity Committee was the National Co-ordinating Committee. Following the receipt of funding in October 2002, the National Project Co-ordinator was appointed and the first national workshop was held in July 2003 with CAB International serving as consultants. Consultations, workshops and surveys were conducted and the country had started phase three of the NBF project.

Extensive public consultations were held with government ministries, NGOs, the private sector and other groups. The Health sector expressed the concerns that pharmaceuticals were not properly labelled or screened; GMOs were potential environment hazards; medical labs were unequipped to assess the risks of GMOs; product labelling did not reflect GMO content; and laws and legislation did not address biosafety and GMOs. NGOs were concerned that there was inadequate information, awareness and education on GMOs; insufficient local research; possible food scarcity in the event of a ban on GMOs; and a fear of cancer and allergies from GMOs.

Several recommendations arose from the consultations including new legislation for managing GMOs, better labelling of feeds and foods for GMO content, growing more food locally, a policy on GMOs for agricultural sector, developing capacity for managing GMOs, developing local expertise and research capabilities in biotechnology and biosafety. Other suggestions were to create specialist led multi-sectoral teams for risk assessment, develop a database on imported foods and feeds, strengthen capacity for surveillance and diagnostics, undertake contingency planning for harmful GMO releases into environment, promote public awareness of GMOs and their impact, and conduct training in biosafety and biotechnology.

It was important in putting together a NBF to consider the impacts of trade vs. precaution, the cost of regulation including labelling and documentation, foreign relations, national capacity, and alternative sources for food, feed, seeds and

medicines. The Bahamas looked forward to implementing the components of the NBF, increasing capacity through training and education, and developing a national website to link to Biosafety Clearing House**.** The country was going forward with strong regulatory oversight, building trust in the regulatory system, educating on Biosafety issues, and communicating with the public on benefits and safety. See Appendix 11.d.

Dr. Hector Quemada gave participants an insight to approaches to biosafety regulatory systems in developed countries focusing on the similarities and differences in the approaches of the EU, the USA, Canada and South Africa. The regulatory systems in these countries all contained rules for the contained use of GMOs in the laboratory and greenhouse settings; rules for field trials (i.e. confined release); rules for commercial release based on an assessment of environmental and food safety; and provisions for communicating decisions. The scientific principles used in their assessment of risks were the same. The key differences concerned the legal framework, the decision-making process and implementation.

In Europe, transgenic pants were regulated by national authorities and the European Commission. Specific rules governed transgenic plants grown in a contained environment, contained field trials, imports, and commercial release. For commercial releases, the rules were not limited to GE crops but applied to all novel foods. A novel food was defined as any food that was not for sale before May 15, 1997. The Novel Food Regulations, labelling regulations and traceability regulations governed such foods. Substantial documentation was needed to support an application. This included among other things a summary report of all studies conducted, evidence of substantial equivalence, the environmental risk assessment, the food safety assessment and a proposal for labelling in keeping with the labelling regulations. The food safety data was rigorous and very detailed. The process for an application was outlined. There were timelines at each stage. A significant feature was that in the event of objections to a product, the case could be decided by majority vote by the Scientific Committee for Food or the Council itself.

The USA had a co-ordinated framework with clear lines of authority and responsibility for the US Department of Agriculture (USDA), Environment Protection Agency (EPA) and Food and Drug Agency (FDA). The USDA oversaw the issuing of permits and notifications for greenhouse trials, field testing, and decisions of a non-regulatory nature for bringing GM crops to market, all of which were governed by the Plant Protection Act. Regulated products included plant pests, plants and veterinary biologics. The EPA regulated large-scale trials (10 acres and above) of plant incorporated protectants, tolerance exemption levels (i.e. the maximum amount of protectant to release into the environment), and the registration of herbicidal plants. The products it regulated included microbial and plant pesticides, new uses of existing pesticides and novel micro-organisms. The FDA regulated foods, feeds, food additives, drugs and medical devices. The responsibility for regulation was shared and each agency had a clear responsibility for certain products. In its review, the USDA looked at whether the new GM organism was safe to grow; the EPA looked at whether it was safe for the environment; and the FDA on whether it was safe to eat. An example was given of how an application for non-regulated status was processed and what kinds of data had to be submitted in support of the application.

The regulations for plants with novel traits (PNTs) were well defined in Canada. For experimentation in a contained environment, the Laboratory Biosafety Guidelines had to be followed. Confined field trials were directed by Regulatory Directive 2000-2007 under the Seeds Regulations, Part V. A PNT import was controlled by Regulatory Directive D-96-13 under the Plant Protection Act. Unconfined release was subjected to Regulatory Directive 94-08 and unregulated pesticide use required consultation with the Pest Management Regulatory Agency. The accompanying biology documents to Regulatory Directive 94-08 were available for several plants including canola, corn, flax, wheat and soyabean. The decision documents relating to an authorised unconfined release of a PNT were published. To register a new variety, the Variety Regulations under the Seeds Regulations, Part 111 applied. If livestock feed use was intended, Regulatory Directive 95-03 under the Feeds Act and Regulations applied. Human food use was controlled by Health Canada's Novel Food Regulations under the Food and Drug Act.

The South African regulatory system was briefly outlined and the data requirements to support an application. The latter included a brief description of the GM plant, data on the field performance of the GM plant, including the efficacy of the introduced trait, pollen spread, foreign genes and gene products, resistance, safety to human and animal health, environmental impact and protection measures, and socio-economic impacts. South Africa was unique in requiring an assessment of socio-economic impacts. The time limit for field testing was 90 days and for commercial release 180 days.

In summary, all regulatory systems had common elements. Regulatory systems could be centralised or involve the co-ordination of several agencies. The European system provided an example of an operational regional system. Transparency in decision-making (both to the applicant and to the public) was important to any system. See Appendix 12 for full presentation.

A stimulating question and answer period followed Dr. Quemada's presentation. The salient points made in these discussions were as follows:

a. All systems had timelines for treating with an application.
b. The EU system was pre-cautionary in approach with more weight being given in the assessment to the potential harm of the unknown but the scientific principles of the risk assessment were the same as in the US and Canada;
c. The South African system catered for the concerns of small farmers and the protection of land races. The US system built in a consideration of the consequences of crossing to native species. Where the US was a centre of bio-diversity, other laws on endangered species entered into the consideration.
d. In the US system an applicant had a legal obligation to disclose any available negative data/information on a product. This among other things made for a strong system.
e. Although the US system worked well for the most part, transgenic fish brought to light the deficiencies in the system. The fish were classified as an animal drug and fell under the purview of the FDA, however their effects were all environmental. In the case of the Singapore glow fish, which is classified as an ornamental species, none of the regulatory bodies had the authority to regulate it.

Dr. Traynor compared the regulatory systems in Egypt, Argentina and Kenya based on an ISNAR study (See Appendix13 for details). Egypt and Argentina had guidelines in place and well trained personnel. Their systems for safety relied on scientific data and had feedback mechanisms. They were also de-centralised relying on the ministry of agriculture for environment safety review and the ministry of health for the food safety review. The ministry of the environment played a minor role. They both depended on review by an advisory committee that focused on risk assessment, and approval of an application came from the minister. Committee members were unpaid volunteers. The systems worked in a timely fashion and where there were delays these were due to outside events in the main. In both systems, technical expertise was available for ad hoc consultations. The experts were drawn from research centres but this created the problem of a potential conflict of interest and redundancy on committees.

Egypt had guidelines for laboratory and greenhouse trials, and field tests. The NBC had three different sub-committees to handle these issues. All research centres had institutional biosafety committees (IBCs) and systems. Applications were reviewed by a single Principal Investigator (PI) who reported to the NBC. The PI could use ad hoc advisors as needed. The ISNAR study made several recommendations to improve Egypt's NBF. They included among other things establishing a NBC secretariat, preparing terms for membership on the NBC, devolving authority for laboratory and greenhouse trials to the IBCs, clearer guidelines in respect of stated goals, objectives, basis of decision-making and post-release measures, improved procedures for review and decision-making, and a communication plan.

In the case of Argentina, there were four sets of guidelines covering the laboratory, greenhouse and commercial stages, and also food safety. The NBC had membership from the public and private sectors, and NGOs. The review focussed on the technical aspects of safety but Argentina also had a market review, which emphasised the importance given to trade. The process followed by an applicant was very simple. The NBF was adversely affected by political change that resulted in the lack of continuity, delays at the higher level, external events, a shortage of qualified reviewers, and the potential for conflict of interest. Recommendations for improvement included greater clarification of institutional roles and responsibilities and the engagement of the ministries of health and the environment, strengthening the scientific basis of risk assessment and monitoring, and a public awareness programme.

Kenya had high level support for biotechnology and biosafety and forward-looking administrators. There was consensus on the need for a policy on biotechnology and biosafety before laws could be made. Until the Biotechnology Management and Co-ordination Act was developed in 2002, Kenya relied on its Science and Technology Act to regulate biotechnology and biosafety. Under this act, the National Council for Science and Technology acted as the umbrella body for a widely constituted NBC that included regulatory agencies, government ministries, agricultural organisations, NGOs, research centres and consumer groups. Scientific evaluations were conducted by the NBC, which had some expertise and recourse to ad hoc expert advisors. The risk assessment kept science in focus, but was narrow and cautious in approach. Under the new regulations socio-economic and non-safety factors were likely to be considered. Final authority for decisions rested with the Council and it notified the respective agencies.

The development of regulations started with a request to import a recombinant vaccine. This led to the production in 1998 of some guidelines, which had since undergone revision to include agriculture, industry and the environment. The guidelines did not include commercial release and R&D in the country had not reached the commercialisation stage. The system at present allowed for some degree of public representation on the NBC and limited involvement in the formulation of the policy and regulations through the NGOs in the NBC. Recommendations for improvement included developing more expertise in biosafety, better documentation and record-keeping of findings and decision-making, the institutionalisation of the NBC, and more formal mechanisms for public participation in decision-making.
Dr. Quemada led participants through Case Study #1. He explained the risk assessment review process using the example of the greenhouse experiment on fungus resistant sunflower covered in the workshop training manual (pgs. 79-87). The decision-making at this point was usually at the IBC level, depending on the country. The case proved useful in demonstrating to participants what were the key questions at this stage, how much information and details were needed, and what issues were safety and non-safety issues. A key issue was the safety measures needed for non-transgenic materials, and the level of detail and the confidentiality of information about the GM organism needed by the committee to make an informed decision.

While the disclosure of unintended or secondary effects were not appropriate at this stage, participants felt that disclosure could stop good research while on the other it could avoid the wastage of resources on bad research. Such information was considered useful for the committee to have but that body needed to adopt a balance approach. To discourage false reporting, penalties were recommended. Another question that arose was the safety of laboratories and greenhouses, and it was recommended that the committee should ensure that they were safely built and had safety systems in place. The point was made that before going to the greenhouse stage, the laboratory trials should demonstrate enough stability of the GM organism. In this regard, some participant considered that the information supplied by the applicant did not give sufficient details on the conditions associated with the stability of the organism and the frequency of reversions. It was noted that this information was needed at the lab stage before going to greenhouse trials and that the problem lay with the forms, which were the same for these stages. Different forms for each stage were recommended. At participants' request, Dr. Quemada provided the full write up of the Environmental Assessment and Finding of No Significant Impact that was prepared by the Animal and Plant Health Inspection Service of the USDA on the fungus resistant sunflower application. See Appendix 14.

Drs. Traynor and Quemada took participants through the *Part 1 of the Model Guidelines Project*, which involved an analysis of some existing national guidelines and regulations. In developing guidelines for the safe handling, transfer and use of biotechnology products from the laboratory all the way to commercial release, participants were asked to consider what materials and activities must be covered, who must do what, when and how, and who made the decisions. They had also to consider what the applicant must do, the sequence of the events, the time lines, the treatment of confidential information, record keeping, the role of stakeholders, provisions for compliance and enforcement, and the infrastructure needed to implement the guidelines, their costs and feasibility.

Participants were divided into four groups and each group had to review the national guidelines of selected countries based on a list of set questions (see Appendix 15 for template). Group A looked at the Canada, Group B at Vietnam, Group C at Brazil and Group D Australia/New Zealand. Each group had to select a recorder/secretary to complete the answers to the list of questions. The groups worked for a little less than two hours on their assignments and reported in plenary session the next day.

4.0. Day 3 Wednesday 21st January

4.1. Working Groups Reports

Prof. Duncan was this session, which started with the working group reports. Each group had 10 minutes to report. Ms. Cynthra Persad from Trinidad and Tobago reported for Group A, which conducted a review of Canada's *Draft Revision of Regulatory Directive 9408: Assessment Criteria for Determining Environmental Safety of Plants with Novel Traits.* The group noted that the directives had their legal bases in several acts and regulations. PNTs in confined research field trials and unconfined release were governed by the seeds act and the seeds regulations, the importation of plant materials, including PNTs were subject to the plant protection act and the plant protection regulations, and the Canadian Food Inspection Agency Fees Notice allowed for fee collection. The stated objectives of the guidelines were to provide guidance on what constituted a PNT, to define the criteria and information requirements for the environmental safety assessments of PNTs, and to describe the regulatory process for potential unconfined release authorisation. The group found the directive was not clear on scope of activities; the membership, duties and operating procedures of the NBC were not clearly defined; and the application process required a voluminous amount of supporting information. The review process relied on substantial equivalence. The access of the NBC to technical expertise was not stated. The role of the applicant in the review process was clearly stated but the operating procedures for the NBC were not clear on timelines, potential conflict of interest, the flow of the application and the relationship among the relevant authorities. The directive made provision for the treatment of confidential information and the onus was on the applicant to inform the NBC on what information was to be protected. The group also considered that the directives did not make mention of the mechanism for stakeholder involvement and the mechanism for oversight was sufficiently clear.

Mr. David Shim from Trinidad and Tobago reported for Group B, which reviewed the *Biosafety Regulations for GMOs and their Products in Vietnam (Draft).* The group found no legal basis for these regulations. However, the objectives and scope as regards the materials and activities covered, were clearly states. A shortcoming was identified in the membership of the NBC, its duties and operating procedures, which were not defined. The duties were assigned to certain ministries and provincial committees. The application process did not state clearly the entry point but there was a list of requirements in an appendix. The principles guiding the review process and outcomes were clearly defined. The role of the applicant and the operating procedures were also clearly stated but not the sequence of events. There was provision for access

to technical expertise, the protection of confidential information but not for conflict of interest. The regulations were silent on record keeping, public involvement, and infrastructure. The rules for compliance and enforcement were clearly stated but there was no mention of costs.

Mr. Julius Ross from Antigua and Barbuda presented for Group C, which reviewed the Brazilian regulations. These were clear on the composition, duties and operating procedures of the overall national commission and its constituent biosafety committees. The legal basis for the regulations, their objectives, and scope were also well defined. The process of an application in terms of entry point and procedures were clear. The principles guiding the review process and outcomes were also clear and time lines were set. There were, however, shortcomings in respect to public consultation and participation and no feedback mechanisms were stated. There were mechanisms in the regulations for compliance and issuing penalties. Significant capabilities were required of the agencies to implement the regulations and the group wondered if they had these capabilities.

Dr. Dottin reported for Group D, which examined *the Risk Analysis Framework for License Applications before the Office of the Gene Technology Regulator*. The framework had its legal basis in the Gene Technology Act of 2000 and the Gene Technology Regulations, 2001. The framework was clear in nearly every respect: objectives, scope, membership of the biosafety committee, the application process, and review process. What was not clear were the operating procedures of the committee, the treatment of confidential information and conflict of interest, compliance and penalties and where cost were incurred.

Participants found the exercise useful in identifying the strengths and weaknesses of the different systems. The gap analysis was particularly useful. They were however advised by Dr. Quemada that systems were not easily transferable. He also commented that most systems were focused on identifying and quantifying risks, but a body of work was being developed on benefits and this would facilitate a risk/benefit analysis being undertaken. In response to the question as to which systems worked well, the answer was given that the Canadian and Australian regulations did. Brazil's regulations were good on paper but officially their committee had not approved any application. Vietnam was only in the formative stage and its system was untried. It was explained that Australia and New Zealand like America and Canada had harmonised guidelines. One participant made the point that if the penalties were too detailed they would act as a disincentive to biotechnology products and this should be avoided.

4.2. Session 3- Risk Assessment & Management

Having completed the above exercise, Dr. Traynor explained to participants the whole biosafety review process in terms of what it was; why it was done; who did it; how it worked; who was affected by it; and ended her effective presentation on the goals of biosafety review. See Appendix 16 for details. This and her next presentation on risk management in the laboratory and greenhouse, set the context and equipped participants for Case Study #2, which dealt with the field trial of *Bt cotton.*

The question was asked at what point consideration should be given to alternative approaches to GE as the solution to a particular problem. Dr. Traynor replied that it was not the role of the NBC to decide this. Another view expressed by participants was that countries rich in biodiversity or with fragile ecological systems like SIDs should incorporate such considerations into the development of their guidelines. However, care was needed to ensure that the guidelines were not too restrictive. Another approach offered by Dr. Traynor was to identify what were the real risks to which crops that needed to be protected from GE instead of using biodiversity to restrict biotechnology across the board.

Dr. Traynor in her presentation on risk management in the laboratory and greenhouse went through the *NIH Guidelines, Good Laboratory Practices.* She traced their development and outlined the health and potential environmental risks from laboratory research on GMOs. She spoke on standard good risk management practices, the objectives of greenhouse biosafety guidelines, and typical structural features for containment. An important part of the presentation was the issue of the assignment of biosafety level (risk level) and an outline was given of the elements of the greenhouse biosafety levels 1-4.

The risk level was dependent on several factors: the source and nature of the introduced DNA (i.e. its pathogenicity and whether a complete coding sequence or fragment was involved), the recipient organism (i.e. was it a noxious weed, did it interbreed with the same, and the potential for out-crossing and negative impact on the ecosystem), the nature of expressed protein(s), the local environment, and the experimental procedures. Risk management could be achieved through the GMO design. For plant GMOs intended for release, risk management began with choices made in the laboratory regarding the recipient organism and its traits, the transformation method, the marker gene(s) and regulatory sequences used.

The presentation usefully summarised the standard practices for achieving containment using physical methods for the containment of pollen, seed and plant materials; biological methods for managing plant reproduction; and structural features for securing greenhouse (i.e. glazing, screening, sealing of cracks, negative air pressure, cages and isolation from other fields). These measures needed to be complemented by good greenhouse management practices that included a trained staff, restricted access to facility, posted signs with contact information, a maintained logbook of experiments, and posted contingency plans. See Appendix 17 (a) for presentation in more detail and Appendix 17(b) for *The NIH Guidelines for Research Involving Recombinant DNA Molecules: Overview and Summary of Biosafety Levels.*

In the discussions that ensued, participants inquired about the availability of guidelines for tropical greenhouses and were advised that they would have to translate what they had learnt in the workshop since no such guidelines were readily available.

Participants went into their groups to work on *Part #2 of the Model Guideline Project.* They worked for about two hours developing safety guidelines for the laboratory and greenhouse following an item list developed by Dr. Traynor (see Appendix 18 for template). The outcomes of this work were presented the following day and at the end of the workshop, the group work was synthesised by Dr. Umaharan.

Dr. Quemada then led participants through the procedures and steps for conducting environmental risk assessment of transgenic plants for both field trials and commercial release (see Appendix 19 for details). Risk was defined as hazard x exposure where a hazard was defined as the actual harm x magnitude. Potential risk was defined as a hazard and an exposure that were not well defined qualitatively and quantitatively. In field trials, consideration must be given to compatible relatives in the accessible environment, which would trigger the need for appropriate confinement measures. The primary objective of containment was to ensure no significant impacts on the environment. Here consideration must be given to out-crossing distance, the known proximity of wild populations and agricultural populations, and the management of volunteers. If these containment conditions were met, then the field trials could proceed.

For commercial release, environmental considerations were paramount. The key questions were would the GE plant present a harm to agriculture; would it become a weed or cause weediness in relatives; would it compatible relatives (transmission of genes to these relatives by itself was not a harm); and would its cultivation practices result in harm to agriculture. For transgenic plants with pesticide properties (Plant Incorporated Protectant—PIP)[1]. The pertinent questions were as follows: would the PIP cause toxicity and allergenicity to non-target organisms and humans; and would organisms develop resistance develop to the PIP.

The approach required characteristics of the non-transgenic plant, the donor organism and the transgenic plant in relationship to the non-transgenic plant, or in comparison with current agricultural practices. The approach was detailed using the USDA example of the Petition for Non-regulated status and the example of *YieldGard Rootworm™ Corn.* A detailed description of the Environmental Characterisation Data (Appendix II of the US-Canada Bilateral) was accessible from *www.inspection.gc.ca/english/plaveg/pbo/int/appenannex2e.shtml.* The test protocols for proteins were the same for the US and EU. In conclusion, environmental risk assessment required a methodical, disciplined, case by case approach and the key considerations were harm to agriculture and chemical toxicity. Requirements could be added or removed depending on the case. Lack of information in an application need not impede a decision since the regulator could review the available literature and consult with other experts.

Participants made the point that a limited field trial in the US, which was defined as 10mx 10m upwards to 1 hectare, would constitute a large area in the Caribbean context and the scale for limited trials in a SIDS context would be very different. Participants inquired if the US EPA monitored transgenic plants in Puerto Rico for their impacts so that Caribbean countries would have some baseline information to study. The workshop facilitators however did not know for sure if the EPA did. Concern was raised about antibiotic gene expressions in plants but participants were informed that the US FDA considered this technology safe; on the other hand the EU avoided antibiotic resistance markers in general, while some developing countries were using it extensively. Participants noted that the use of herbicide resistance markers had become almost commonplace where plant crops were concerned and the

[1] Bt is the only PIP for which resistance management has become a major issue.

trial conditions were easy to define. There was a wealth of information on their use in agricultural crops. There ensued some discussion on the use of IPM strategies in preference to the use of herbicide resistance markers in crops.

Participants were divided into new groups and proceeded to the Risk Assessment Case Study # 2 involving an examination of an application for the field testing of *Bt cotton* (workbook pgs. 97-105). The exercise required participants to determine the objectives of the safety field trial, pertinent biosafety issues, the primary and secondary effects the transgenic crop on the local environment, safety measures for handling pollen, seed and cotton bolls, and clean up measures at the end of the trials among other things. See Appendix 20 for template of questions.

5.0 Day 4- Thursday 22nd January

5.1. Session 3 – Risk Assessment & Risk Management cont.

Dr. Traynor and Dr. Wendy Hollingsworth chaired the day's sessions. Using the multi-media projector, Group A presented its work whilst the other groups brought up different points that they had considered and so the reporting was expedited. The case was most relevant to participants since cotton was a crop of importance to some Caribbean SIDS. It brought into perspective the expertise of the plant agronomist, entomologist and plant breeder in conducting the whole exercise. Plant breeders were identified as a valuable source of expertise and information that regulators should not overlook. The case showed that secondary effects raised more concerns than primary effects and this led participants to inquire about the scope of powers of NBCs to request an applicant to do further experiments in order to acquire information on secondary effects. It was noted that such information would be an important consideration for commercial release. Dr. Traynor indicated that the NBCs in India and South Africa had the scope of power to ask for such tests and data. At this point, participants inquired about the design of the application form and what information to request of the applicant. They were advised that the form should at least ask for the history and origin of the species, how it reproduced, what expression was done, what new genes were inserted, and the promoter-regulator sequence with diagrams of plasmid maps.

Continuing the risk assessment case studies, Dr. Quemada took participants through the example of the application for the commercial release of *Bt potatoes* in South Africa. See Appendix 21 for details. Trials had been conducted in Egypt but due to the opposition in the EU to GM foods, the *Bt potato* was not deployed to farmers. South Africa had a major problem with the tuber moth that plagued small farmer holdings and the storage of the crop after harvesting. The *Bt potato* was introduced after *Bt cotton* and *Bt maize* were introduced into the country. Industry was consulted on the introduction of the transgenic potato plant and a license was negotiated for local seed producers. The application went through a license regulatory system that involved scrutiny of the mechanism for marketing and technology delivery, public communication, and documentation ex ante of the socio-economic benefits for the subsistence and small farmer (less than 1 acre). The regulatory package included documentation on the country's regulations, Codex Alimentarius (CA), OECD standards where local standards were not instituted, and precedents for the Monsanto New Leaf Potato.

The documentation for an application for release included a description of the GM plant, general release or commodity clearance, a description of any product derived from the plant, a summary of field trials, known characteristics on pollen spread, seed dispersal, vegetative spread and waste disposal. Other data requirements included the characteristics of foreign genes and gene products, health assessment for human and animals, environmental impacts and protection, resistance, and socio-economic impacts. The health assessment had to meet the CA assessment guidelines, which were summarised as follows: description of rDNA plant, description of host plant and its uses as food, description of genetic modification, expressed substance, compositional analysis, evaluation of metabolites, nutritional variation, and food processing. If a closely related substance were already part of the food chain, then CA studies were not needed. The OECD guidelines stressed the compositional considerations of the new varieties focussing on the intended effects of the new protein including toxicology and allergenicity. Allergenicity was determined by *in vitro* digestive studies and bio-informatics analysis, which compared the sequence with known allergies. South Africa followed the OECD guidelines for toxicology studies. The OECD guidelines also took into consideration processing characteristics and chemical composition. For each crop the relevant constituent elements must be examined e.g. dry matter, sugar, protein, and vitamin content. The assessment of environmental effects was rigorous and included consideration of the effects on non-target pests, which in the case of the *Bt potato* involved laboratory studies on surrogate insects, native species and studies of insects in transgenic and non-transgenic fields. Data had to be presented on longevity in the soil, weediness, outcrossing to genetically compatible relatives and gene flow between cultivars, and whether a resistance management strategy was necessary. The regulatory requirement impacted on costs and the above tests were not cheap.

As it interested participants, the breakdown in the cost in US Dollars of the various analyses was given as follows: nutritional compositional analysis - $8 200; toxicity/allergenicity - $549, 304; and transgenic characterisation - $110, 000. The total cost for work done at an academic laboratory in the US was $667,506 compared to $834, 383 if they were done in a good private laboratory. The same tests done in South Africa cost $417, 506 for the food safety tests and $81, 000 for the environmental assessments, which gave a total of $498, 506.

Work then resumed on the Model Guidelines Project, Part 111, which dealt with Limited Field Trials. See Appendix 22 for template of questions. Participants worked in their groups for about two hours defining objectives, roles and responsibilities, administrative procedures for handling applications, record-keeping, reporting, site security, transport to/from the field, reproductive isolation guidelines, termination and clean-up, storage, compliance, post-trial monitoring, contingency planning and enforcement. Ms. Adjua Bernard-Barry from Guyana reported for Group A, Mr. Sherod James from Antigua and Barbuda presented for Group B, Mrs. Kamla Rampersad-Bissessar from Trinidad for Group C and Ms. Shawn Carter from Barbados for Group D. The work from two of the groups was fairly detailed and Group C completed a flow chart of the entire process.

The national presentations followed. Mr. Sherrod James of the Chemistry & Food Technology Division, Ministry of Agriculture, Land & Fisheries, reported on the

situation in Antigua and Barbuda. The regulatory authority spanned four government ministries: agriculture, the environment, health and trade. There was no legislation for the specific enforcement of the provisions of the Cartagena Protocol. In terms of the existing legal framework, there were eleven pieces of legislation that were relevant to biotechnology and biosafety. The key ones were the Animals (International Movement and Disease) Act, the Plant Protection Act, the Environment Bill, the Public Health Act, the External Trade Act, and the Import Protection Act. The country's capacity in biotechnology and biosafety was limited. Agriculture had more capability relative to the other agencies. Twenty-nine technicians in agriculture had skills in some relevant areas. There were also four foreign trained nationals who were engaged in genetic fingerprinting work on breadfruit cotton, fungi and bacteria. The country however needed to strengthen the capacity of the Plant Protection Unit and the existing licensing and certification processes among other things. There was also the need to enhance the Environment Division's biosafety and technical capabilities, to develop the Public Health department's capabilities in risk assessment and field monitoring among other things, and to improve capacity in trade policy, systems for licensing imports, and the development and enforcement of standards. There were major knowledge gaps on fresh water biodiversity, marine biodiversity, fungi (mushrooms) and lichens, microbial biodiversity, and the collection of varieties (i.e. fruits & vegetables, garden plants, and livestock). Key crops of importance to Antigua & Barbuda were *Capsicum chinense* (West Indian Red Pepper), *C. frutescens* (Bird Pepper), *Zea mays* (Corn), Yam, *Gossypium barbadense* (Sea Island Cotton), and Pineapple. External support for biotechnology and biosafety was forthcoming from several external agencies. CARDI was assisting with a hot pepper selection and seed programme, a cucurbit study, and work on forage legumes, forage grasses, and corn. IICA had developed model emergency action plans for both plant and animal health, undertaken a diagnosis of the plant protection system and developed a strategic plan for plant health. PAHO was assisting in establishing mechanisms and procedures to ensure an adequate level of protection in the field for the safe transfer, handling and use of LMOs. UNEP/GEF funded the development of the country's NBF document. FAO gave advice on biotechnology policies and regulatory issues, and promoted information exchange. See Appendix 23 (a) for details.

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In her status report on Barbados, Ms. Shaun Carter stated that her country recognised both opportunities and potential threats of biotechnology. As a SIDS, Barbados had a fragile ecosystem that was vulnerable to disasters and external threats by invasive biological agents. It was also heavily dependent on food imports and agricultural inputs including seeds and microbial control agents, which all had become targets for the application of biotechnology. Biosafety measures were thus critical to afford protection. Biotechnology applications in the country involved the tissue culturing of orchids, aloe, anthuriums, pineapple, ferns, bananas, and plantains at facilities of the Ministry of Agriculture and CARDI. Private sector interests were focused on tourism sector and exotic flowers while the Cave Hill campus of the UWI was engaged in work on the DNA fingerprinting of hot peppers, yams, and the black belly sheep. See Appendix 23 (b) for further details.

In response to the CPB, Cabinet created the National Biosafety/Biotechnology Committee (NBC) in 2000. Its mandate was to review the CPB with a view to its signing, identify priority actions to give effect to the Protocol and prepare an implementation plan, direct the preparation of legislation and regulations for LMOs,

and develop a public awareness programme on biosafety/biotechnology. Thus far, the Committee had made recommendations to Cabinet on the signing and ratification of the Protocol and was addressing the development of a NBF with the support of UNEP/GEF. Phase I of the NBF project commenced in September 2003 and involved data gathering on the status of Biotechnology and Biosafety in Barbados. This work was due to be completed by December 2004.

Ms. Adjua Bernard-Barry reported that there was limited application of the biotechnology in Guyana. The most significant actor in this area was the National Agricultural Research Institute (NARI), which did work on plant tissue culture with emphasis on rough lemon, pineapple, and bell yam. NARI also maintained a small *in vitro* gene bank. The Environmental Protection Act (1996) marked the first attempt to broadly address environmental issues in Guyana. Other attempts included the 1997 National Strategy for the Conservation and Sustainable Use of Biodiversity, and the National Biodiversity Action Plan. In 1999 work started on Programme Area 4 of the Plan, which involved the consolidation of the policy, legal and administrative framework for biodiversity protection and Project 17, which addressed the strengthening of the National Quarantine and Biosafety Processes. A National Biodiversity Advisory Committee was also set up. Guyana was now embarking on the Biosafety Framework Project. See Appendix 23 (c).

Mr. Terrence Gilliard reported that St. Lucia, which had an area of just 534 sq. Km and 160,000 people, was rich in flora and fauna. Agriculture, tourism and fishery were the mainstay of the economy. Biotechnology applications were limited to plant tissue culture for the mass plant propagation of ornamentals and food crop species for the local agricultural sector. This work was undertaken by the Tissue Culture Unit of the Ministry of Agriculture. St Lucia had no regulatory framework specifically for biotechnology products. However, some key issues were addressed by current regulations that included the Plant Quarantine Act (1998,no. 22) which regulated plant pests, the Pesticides and Toxic Chemicals Act that controlled pesticides and pesticidal micro-organisms, and the Dangerous Goods Act that addressed the transportation of dangerous goods, which could include LMOs. The Animals Ordinance controlled the movement of animals including fish and birds while the Wildlife Protection Act made provision for the protection, conservation and management of wildlife in St Lucia. The country needed to develop capacity in a number of areas including other biotechnology applications, LMO identification, risk assessment and management to facilitate scientific-based decision-making, and information technology and data management. The institutional capacity for the NBF had to be developed and did public participation and public awareness. See Appendix 23 (d).

Government supported human resource development in the field of biotechnology and was funding the construction of a new tissue culture laboratory. An important external source of support for capacity building and the development of the NBF was the UNEP/GEF project and the National Co-ordinating Committee was in the process of being established. Support for capacity building also came from a few regional and international agencies including UNIDO that offered distance learning programmes in the field of biosafety. St Lucia was a member of the CARICOM Working Group on GMOs.

In the discussions that ensued, it was learnt that St. Lucian producers were interested in GM bananas since pests plagued the industry and had destroyed the crop. Their application had been turned down due to concerns about their risks and also possible rejection by the EU. Glow fish also posed an environmental threat and there were concerns that the fish had entered the country in the absence of a proper regulatory framework for biosafety. Recognising that legislation could take time, it was suggested that St. Lucia and other countries could adopt a flexible approach and amend the existing laws in critical areas and defer the less pressing issues. New forms and guidelines for the approval of applications for the importation of GM products and R&D could also be instituted immediately to help regulate the situation. Many participants felt however, that for reasons of trade with the EU, countries in the region should proceed with caution on the introduction of GM crops.

6.0. Day 5- Friday 23rd January

6.1. Session 4- Food Safety

Dr. Cyril Roberts of CARDI, Barbados chaired the day's proceedings, which started with a presentation by Dr. Wendy Hollingsworth on the food safety assessments and Codex Alimentarius Standards for GM Foods. Participants learnt that the assessments of GM foods involved a range of diverse tests for detecting unintended effects to human health. These tests involved an examination of all expressed substances, the compositional analysis of key components, metabolic evaluations, food processing parameters, and determination of nutritional modifications. The purpose of the tests was to identify and measure toxicity, allergenicity, and nutritional modifications. The presentation outlined what each of these tests covered and the methodologies used. ELISA (enzyme linked immunosorbent assay), RAST (radio-allergo-sorbent tests) and PCR testing were explained.

Codex Alimentarius was a collection of harmonised internationally adopted food standards to ensure that consumer products met internationally accepted minimum standards of quality; were safe for consumption; and did not present a health hazard to humans. Standards were set for individual foods and food groups. Codex elaborated the principles for undertaking the risk analysis of foods derived from biotechnology, and provided guidelines for food safety assessments of foods derived from both rDNA plants and rDNA micro-organisms. The ISO also provided standards in its "*Draft Standards "Foodstuff – Methods of Analysis for the Detection of Genetically Modified Organisms and Derived Products"*. It detailed experimental protocols including preparations for sampling and extraction, reagents and materials, procedures, interpretation of expression of results, test reporting, screening methods and construct specific methods. Another standard was the European draft standards (prEN ISO 21572), which detailed the protein based methods for the detection of genetically modified organisms and derived products. See Appendix 24 for fuller details.

Dr. Quemada then gave an insightful presentation that put the risks of GM foods in perspective. Participants were exposed to work by the Harvard Centre for Risk Analysis, in particular the work by Ropeik and Gray (2002) that provided a practical guide for measuring risks and deciding what was safe and what was dangerous. Risks could be classed as low, medium and high depending on the likelihood of exposure to a hazardous dose and its consequences. Nothing in life was free of risk or was

absolutely safe. A thing was safe if its risks were judged to be acceptable. There were degrees of risk, and consequently degrees of safety. No decision was free of error but regulators must avoid making Type 1 errors (i.e. approving something that's not safe) and to minimise Type 2 errors (i.e. rejecting or delaying approval of something that's safe). Based on existing knowledge, the likelihood of exposure to GM foods was very high but the chance of being exposed to anything hazardous was very low. Even if GM food exposure involved a hazard, the worst case was the possibility of food allergies. Most risks from GM foods were low and this should give regulators confidence to make decisions.

Reinforcing the point that GM foods were not more hazardous than traditional foods were studies of allergenicity, which showed that 90% of the cases were caused by traditional proteins in common foods such as milk (5 proteins), soy (2 proteins), peanuts (2 proteins), tree nuts (3 proteins), crustaceae (1 protein), fish (2 proteins), and eggs (4 proteins. The length countries would go to in regulating the risks of GM foods varied due to the costs involved. A **"**simple" biotech trait from the initial access fee all the way to regulatory costs could reach $1.0 M to $4.5 M per crop per trait. "Complicated" traits could cost from $5.0 M to $15.0 M.

Dr. Quemada compared the US and EU regulatory approach to labelling and traceability. The US required bio-engineered foods to be labelled when there was a significant change in terms of nutrition, composition, conditions of use or when an allergenic component was introduced in a food, which could be harmful to human health. Labelling had to be truthful and not misleading. A GM product was essentially de-regulated, requiring no labelling, if it was safe for humans. As regards traceability, the US used market driven segregation/identity preservation.

The EU had instituted labelling regulations for novel foods and for Monsanto RR soy and Ciba Bt maize. The regulations provided for a "negative list", but it was never actually developed. The EU also extended labelling to additives and flavourings and foods sold to mass caterers. The threshold for adventitious presence was 1%. Traceability in the EU would into full force in 2004. The regulations did not apply to foods containing < 0.9 percent of GM ingredients, if the presence of such ingredients cannot be avoided. The regulations covered foods and feeds and required operators to retain and forward information at each marketing stage for up to 5 years. Industry had to maintain a system to determine by whom and for whom the GM products were supplied.

Whereas labelling covered composition, nutritional value and health implications, traceability labels had to list the ingredients or additives produced from GMOs or state that the processed food contained GMO ingredients or additives. In deciding on regulations for labelling and traceability, Caribbean countries had to consider the scope (Dna/protein/both), threshold level (1% /5% etc.), which good (raw/finished goods, restaurants), what the point along the manufacturing chain, the label information, the infrastructure (for testing, inspection and enforcement), and the capacity of producers to comply. See Appendix 25 for full details.

In discussions following these presentations, the need for a practical approach in the region was emphasised. Dr. Umaharan made the point that labelling could increase product cost by 10% - 20% based on an adventitious presence of 5%. The cost of

testing for a 1% presence would be much higher. Once labelling was mandatory, all products had to be tested along the lines stated above. In this regard, some participants suggested that the Caribbean adopt the approach of regular product testing instead of instituting restrictive rules for labelling and traceability. Additionally, a restrictive approach was not wise since 90% of the region's trade was with the US and the US did not require product labelling for GMO unless there was a health risk. Prof. Duncan stated that co-operation with Latin American laboratories was necessary for implementing any testing regime since the laboratories in the Caribbean lacked the capacity to perform the range of required tests. Indeed it had been proposed that each of the leading laboratories in LAC should acquire expertise in a particular test so that all together countries in the region could have access to the full range of required expertise. It had further been proposed that Trinidad and Tobago should develop the capability to do the testing for the sub-region.

The issue of labelling was explored in some detail. The point was made that the public needed to know if their foods contained GM products so that they would make a proper choice and therefore labelling for GM content was necessary. However, the countervailing point was made that saying that a product contained GM material did not say anything useful and without public education on GM products, the information on the GM content of products would be meaningless to the public. The layperson would not be able to comprehend what this information meant. Labelling per se did not solve the problem of helping the consumers to make more information choices and certainly was not a means to educate the public on GM products. One participant stated that developers of GM products had a responsibility to educate the public about their products as they entered the market and as such public education was not the sole responsibility of the state.

Dr. Traynor advised that in deciding on labelling, countries should also consider what would be the tone and the information content to be provided on the labels. A label should not come across as a warning. A positive approach to labelling was recommended and examples were given of positive[2] and negative labelling. Again it was emphasised that some foods that had been consumed for decades were more harmful to human health than GM foods and yet there was no negative labelling of these foods. Dr. Alston Stoddard made the points that it was the responsibility of the NBC to decide the approach to labelling. However, it would be the prerogative of technical agencies such as the bureau of standard and/or food and drugs departments to advise and monitor what went on labels and to ensure that the labelling was honest and not misleading.

Another participant made the important observation that some groups in society had religious objections to GM products and this should be respected by requiring labelling of companies. Dr. Quemada indicated that the industry was aware of these sensibilities and were being self-regulating on this issue. The Cartagena Clearing-House mechanism would help to clear the myths and untruths being spread that the industry had breached certain boundaries. The story of the strawberry with fish genes was a case in point. Dr. Traynor stated that there was global public consensus on the

[2] For example, " According to the national food safety authority this biotechnology product was tested and found to be as safe as product X produced by conventional means." Or in the case of tomato juice made transgenic tomatoes, the label could state, "This product was made from genetically engineered products that are more friendly to the environment".

acceptability of gene transfer from plant to plant, mixed views on gene transfer from animal to plant, and opposition of gene transfer from humans to plants. There was a gap in perception between the scientist and the public because to a scientist, a gene was a gene and the transfer of one gene out of hundreds was not a big deal.

The question of the terms of reference and operations of the NBC arose. Dr. Traynor advised that the national regulations needed to clearly prescribe the NBC's function, role, responsibility, scope of activities, membership (what balance of technical experts and other interests), criteria for selecting members. The source of authority for the appointment of members, their term of office, and provisions for continuity in membership should also be addressed. It was also important to document the committee procedures (frequency and convening of meetings etc.), the outputs of the committee's work, and to put in place a record management system. The regulations should also speak to the risk assessments, who were to conduct them, how, and who should take the decision on their results. The language used in the regulations (i.e. prohibitive/facilitative of biotechnology products) would reflect the developers and it was therefore important to have a balance of interests on the membership of the NBC. Terms of reference were instrumental in setting up a functioning and effective biosafety committee, and they serve to co-ordinate its operations within the larger national regulatory framework. The examples from other countries were diverse. An important consideration was the legal source of authority of the committee.

Participants inquired if it were the business of NBCs to critique the research design of an experiment. The answer was given that it was not the committee's job to re-design experiments but to comment on safety issues. It was also not the job of the committee to look at non-safety issues. Another group should have this responsibility. The issue was raised as to how to treat with confidential information and the example of Argentina was given. In that country one or two persons on the NBC read the full information in an application. Other members received sanitised copies. The two members made presentations of the information and their assessment to the other members. An applicant could, where deemed necessary, be asked to remove the confidential restriction to facilitate the committee in making a decision. It was pointed out that the regulations and guidelines should contain provisions for conflicts of interest and the use of external advisors.

6.2. Panel Discussion: Trade with the US, Canada & EU

This panel discussion was led by trade specialist in the Ministry of Trade & Industry, Trinidad & Tobago, Mr. Victor Jordan; Dr. Wendy Hollingsworth from Farm-A-Sys Agri-Services in Barbados, Dr. P. Umaharan of the St. Augustine Campus of the UWI; and Mr. Anthony Smallwood, Head of the EU Delegation in Port of Spain.

Mr. Jordan started the session by recapping the pertinent provisions of the CPB dealing with trade in LMOs, and the SPS agreements on trade in LMOs and GMOs. The Caribbean region had as their major trading partners the US, Canada and the EU. There was no conflict between EU and the Caribbean on the CPB and the EU had gone further in adopting standards for trade in LMOs that were stricter than the SPS. Most countries in the FTAA, except the US had adopted the CPB but the FTAA itself had not adopted a position on which standard would govern trade in LMOs and GMOs in the bloc. The US adhered to the SPS agreements and as a non-party to the

CPB, countries trading with it would have to be governed by the SPS agreements unless their domestic had incorporated the provisions of the CPB. At the present time, Caribbean countries had little or no trade in LMOs, whether as imports or exports. The importation of GM foods was not quantifiable though it was suspected that a large quantity of imported foods and animals feeds contained GM products. If countries intended to export GM products they would have to meet the particular standards of the importing country.

Dr. Umaharan and Dr. Hollingsworth reiterated respectively the key elements of the CPB and Codex Alimentarius. Dr. Hollingsworth also acquainted participants with the provisions of the IPPC[3], which looks at the risks of LMOs on plants. Both experts emphasised that risk assessment was scientific-based in all cases but country decision-making was not necessarily based on scientific information and included other considerations, which were concerned non-safety issues and socio-economic considerations in particular. As regards trade, the Caribbean traded with countries that were parties and non-parties to the CPB. The US, our major trading partner did not make a distinction between GM and non-GM products and the most its labels would said that a product may contain GM materials. Caribbean countries had a decision to make, which was whether they would accept US testing and standards. If we did not accept the US approach, then countries would have to conduct their own tests for safety. If countries accepted no labelling, then countries would have de-regulated GMOs. If they wanted labelling, then they had to bear substantial increases in the cost of foods because every food consignment would have to be tested. They also had to decide the information content; was it as basic as saying that the product contained GM materials or did it have to state nutrients and possible allergic effects. The stricter the requirements the more taxing their enforcement and monitoring would be and this could over stretch national regulatory systems in the Caribbean context of limited institutional and human capacity.

Dr. Hollingsworth building on Dr. Umaharan's presentation stated that Caribbean countries had to take a position on standards, namely the minimum internationally accepted standards or higher standards, and these had to be in keeping with their trade agreements. Standards had to apply for both imports and exports, and not one or the other. Then a choice had to be made on whether the standards would apply to products, processes or both. On the whole the standards in developed countries were hard for the exports of developing countries to meet.

Mr. Smallwood stated that the EU had been accused of using its sanitation and phytosanitary standards as a non- tariff barrier but the real the truth was that food safety and the precautionary principles were dear to the community because the European public. However, the data from developed and developing countries (Mexico and West Africa) on GM planting materials showed that if producers had the opportunity to plant GM crops they would. Indeed there was 60,000 acres of GM maize planted in Europe notwithstanding consumer attitudes and perceptions. He pointed out that some new studies in the US had led the NRC to urge greater caution in legislation thus reversing its earlier more liberal approach. The EU system allowed the community to have a common approach but individual member countries could pass bilateral legislation regarding sanitation and phytosanitary standards to prevent

[3] IPPC - International Plant Protection Convention.

an import from another member state. Any member state growing GM crops had also to inform the whole community. In the EU, afflatoxins in products, Roundrop ready crops, and GM maize from Egypt had been banned. Using the example of the EU treatment of Caribbean bananas, some participants expressed to Mr. Smallwood that the EU had double standards for imports and exports and concurred that the EU standards were being used as a barrier to trade with developing countries in the Caribbean. Mr. Smallwood responded that there was a distinction to be made between sanitation and phytosanitary standards and aesthetics, and the EU was rigorous on the former.

Discussion ensued on the different safety standards and monitoring regime for foods on the local and export market. The participant from the Trinidad and Tobago Food and Drugs Department informed the group that her country had signed Codex Alimentarius and thus all imported products had to meet these international standards. Exported products had to meet whatever standards the importing country had imposed. This was how international trade operated and if the importing country did not institute proper standards, its public could be exposed to inferior products. Mr. Jordan advised that countries should have the same minimum internationally accepted standards for good on the local and export market. Representatives from the Ministry of Agriculture felt that there should be more concern about the safety of local foods, which contained heavily levels of chemical and pesticide residues, and which were sold in places such as highways that added to their chemical contamination. As the situation stood, the local regulatory bodies had little capacity to monitor the sale of these foods on the local market, including do the necessary laboratory tests, much less to police GM foods.

One participant considered that the Caribbean was torn between two lovers: the US and the EU. The US public had been consuming GM foods for years and was not overly concerned for their health once the products had been approved by the FDA. On the other hand the European public had since the outbreak of certain food scares, not all related to GM foods, was very protective on biosafety issues and appeared to be over compensating consumers by their restrictions. Mr. Smallwood responded that it was still too early to tell from the data on the risks posed to human health by GM foods. There was more data on their impacts on the environment and that was not a sufficient condition to de-regulate these products. Furthermore small countries that were rich in biodiversity and had vulnerable ecosystems should take a more cautious approach.

Mr. Smallwood explained that the outbreak of BSE and foot and mouth disease in Britain was not due to regulatory failure but to deficiencies in policy in stemming the illegal importation of unsafe meat into the country by travellers and contaminated meat getting into animal feeds. Questioned on the production of GM maize in Spain, Mr. Smallwood stated that growing of GM crops were not banned in Europe but the environment was not very attractive for growers and producers. Labelling and traceability were major disincentives.

Asked to what extent the position of the EU on GM products was directed at certain vested interests, Mr. Smallwood responded that the Commission was concerned with the whole food industry and not only GM foods. A few actors dominated the industry globally and now also controlled the biotechnology industry. This monopolistic

position and the practices of the firms caused the Europeans great concern. Though Europe had a strong scientific capability, it did not lead the world in the production of GM foods because its people and governments had concerns about bio-ethics, bio-pharmaceutical and their testing, in addition to which there was a strong sentiment in favour of preserving heritage foods.

One participant remarked that the European guidelines for culling to curb the outbreak of the above-mentioned animal diseases were unrealistic in a SIDS setting as were the EU guidelines on buffer zones for GM crops. The stipulated distances would extend in the Caribbean SID context to the sea or another island. Another participant reasoned that the EU position on GM food was influenced by the community's ability to feed itself without recourse to biotechnology. Mr. Smallwood disagreed emphasising that Europe was not convinced that plant genetic engineering was not the only and the best way to improve crop yields. The EU was not against GM foods but uncritical acceptance of this technology as the panacea to global food security.

The discussion on the EU position ended by participants considering the position inconsistent in that the EU public had accepted biotechnology advances in medicine including stem cell research and European governments themselves had heavy investments in biotechnology research facilities.

Explaining that all was not lost for the Caribbean region on biotechnology, Dr. Umaharan stated that not all GM plants that relatives in the Caribbean that they could threaten, and not all GM plants had the characteristic of weediness. Each GM plant had to be assessed on a case by case basis on costs and benefits. Countries would have to assess their markets and decide where to export their products. A choose between the US and EU would have to be made where GM products are concerned.

Following the panel discussion, Dr. Grace Sirju-Charran delivered some thoughts on gender and biosafety. Picking up a thread from the panel discussion, she started by asking why were people more concerned about the GM foods than the safety of regular foods, many of which were toxic and harmful to their health. The answer rested in large part on the belief that technology had overtaken science, and all the complex interactions between the new gene and the old ones were not known and therefore warranted a pre-cautionary approach to the biotechnology.

Explaining the concept of gender, Dr. Sirju-Charran stated that not much was written about gender and biotechnology. She therefore sketched a framework for countries to gather and examine the gender aspects of biotechnology and biosafety. Key elements would include data gathering on who served on the NBC, who got trained, who was at risk (men, women, children), what impact working with the technology in the laboratory, greenhouse or field trials had on women's reproduction function, and who lost/benefited from biotechnology. The presentation touched on IPRs and knowledge systems since according to the literature, women in most countries were the keepers of indigenous knowledge.

During the question and answer period, several participants questioned the relevance of a gender perspective. Biosafety impacted on the health and well-being of men and women and did not respect gender. Given that the assessment of risk was based on science, representation on the NBC should be on the basis of expertise. Gender should

not be a consideration for membership of the committee. Mrs. Gillian Bernard shared with participants the experiences of her NBC, which comprised mainly women. She felt that with the growing number of women pursuing science, concerns about the women and their safety would be increase. Certain molecular tools were impacted more on men and others on women so the technology did give rise to gender issues.

7.0. Day 6- Monday 26th January

7.1. Session 5- Decisions and Decision-Making

Dr. Cyril Roberts of CARDI, Barbados chaired this session, which commenced with a presentation by Dr. Traynor. Regulatory decision-making on biotechnology products went beyond science and involved many non-scientific considerations because biotechnology raised whole range of concerns that traditional agriculture did not give rise as regards health, safety, the environment, ethics and morality, social and economic impacts, and trade issues. The health, safety and environmental issues could be addressed scientifically but the other effects required open dialogue. Without public input and acceptance biotechnology can not go forward. The outcome that governments and regulatory bodies desired was to have maximum safety/minimal risk using the technology.

Biotechnology aroused public concern and the public wanted their concerns met. They also wanted to have clear and simple answers, to be involved in the decision-making and to have trustworthy authorities. The public should be educated however that there were no zero risks with this technology or with traditional agriculture for that matter. Each society had to decide what was an acceptable risk for its members. The public's perceptions of biotechnology could be cautious or favourable towards them. More knowledgeable publics had the latter disposition. Dr. Traynor demonstrated the differences in the outlook of the two groups in relation to health and food safety, environmental safety, economic issues and effects on society. She also touched on some of moral concerns that had been raised by publics around the world.
Labelling often arose as a means of consumer protection. However, Dr. Traynor advised participants to consider what the label should say, was there consensus on label contents, would other foods require labelling also, and how helpful would labels be in societies with high levels of illiteracy and little public understanding of biotechnology.

The NBC had the responsibility to sort out the scientific facts. This involved recognising unsupported claims, looking at all the data, using available information, drawing on the accumulated local knowledge (breeders, farmers etc.), and applying common sense. The deep-seated, non-scientific issues that impacted on decision-making should be uncovered and openly addressed. There were different ways to treat with these issues and some countries opted to have a separate socio-economic committee to deal with these matters (Argentina which emphasised trade considerations in their analysis), mixed scientific and socio-economic committees (Philippines), or a specially constituted decision-making committee (South Africa). See Appendix 26 for details.

In the discussion period that followed, participants brought up the issue of the recall of food products made from GM corn that was meant for animal consumption and

asked about the health risks to the public and the systems that could have prevented this occurrence. Dr. Traynor explained that there were no proven health risk but the incident showed the weaknesses of the segregation system in the US and as a result the EPA changed its policy to require GM products to be safe for both human and animal consumption. This change happened in the space of months, which led participants to remark that the Caribbean environment did not facilitate such a quick response. One participant inquired if countries should first have a policy on biotechnology and biosafety before trying to establish a NBF and to pass biosafety laws. Dr. Traynor replied that many countries had the NBF and worked on the policy and laws afterwards. It was sensible to develop some mechanism for oversight and authority compliance while longer-term issues were being addressed. The formulation of laws required much input from regulators. Recognising that a few multi-national companies (MNCs) controlled key applications and there was the need to protect societies from their dominance, participants sought advise on how Caribbean SIDS should go about developing regulatory systems without putting a stop to local biotechnology. Dr. Traynor advised that countries should assess the importance of agriculture, their trade portfolio of food imports and exports, the status of local R&D in biotechnology and whether researchers were developing GM crops of importance to their needs, and whether it was beneficial to make investments in this area.

The question was asked where do we go from here. Practical steps distilled from Dr. Traynor and the group was as follows:

a. countries should initiate GEF projects or seek other sources of funding to make a start;
b. put in place a simple regulatory framework;
c. identify key stakeholders and to have diversity in this group (regulatory agencies, scientists, farmers, NGOs, research institutes etc);
d. identify priorities and rank their importance; and
e. decide whether more importance should be given to the environment or to food safety.

Participants were divided on whether laws should come first or whether it made more sense to put in place guidelines and arrangements to effect them. Drafting laws without a proper understanding of the issues could result in bad legislation and most legal draftsmen were not familiar with the issues. Dr. Roberts made the point that all Caribbean countries with the exception of Grenada were working on developing guidelines through their NBCs. Grenada started out revising its laws and was preparing a National Biosafety Act.

At the end of this vibrant discussion period, participants worked in groups on Case Study #3 – Field Test of Bananas with the *Hepatitis B* vaccine (workbook pgs. 89-96). See Appendix 28 for template of questions. The exercise challenged participants to identify and address the safety and non-safety issues relating to an application for the field trial of a familiar plant that had been engineered with a vaccine. Participants shared the results of their work in plenary session with the different groups indicating how their responses differed from their peers. One group found the measures proposed by the applicant to prevent gene flow to be costly and unnecessary and this generated discussion on the power of the NBC to recommend changes. It was pointed out that the operating guidelines of the NBC would determine if it were proper to do so. On the other hand, it was undesirable for the NBC to function in an adversarial

manner towards applicants and the committee could therefore suggest beneficial changes in the trials.

There was healthy discussion on the measures needed to protect a field trial site as this one from pilfering and to prevent the mixing of the genetically modified fruit from convention fruit. Suggestions ranged from the serious to the humorous. The question was raised as to who would become liable if someone was harmed as a result of eating trial products. It was pointed that the issue was for the legal experts to decide and not the NBC. The case brought home to participants the challenges of instituting adequate site protection measures in their environment given public behaviours and attitudes. Participants also had the benefit of thinking through the system for growing (registered/licensed farmers) and distributing the GM bananas (health centres) and the approval process for their use as a vaccine (testing and approval by food and drugs). Basically, participants proposed the methods similar to those used for drugs. Where GM products were concerned, some participants were not hopeful that Caribbean countries had the capability to deal with an emergency in the event a trial went wrong.

There followed a presentation by Dr. Traynor on decision documents as a means for attaining regulatory transparency. See Appendix 29 for details. Most countries did not pay attention to the importance of these documents as records of their decisions and the supporting information. Three criteria were given for sound decision-making:

- Credibility - who conducts the assessment, how, and its adequacy
- Accountability – who makes the final decision and on what basis
- Transparency – the process and the decision are both public information

A decision document should contain the following critical pieces of information:

- summary of the request (i.e. the nature of the request, applicant information, a description of the organism and activity),
- rationale for developing the GMO (i.e. existing constraint and alternative approaches),
- environmental assessment (ie.e identified risks, their consequences and implications, and proposed management measures including their appropriateness and adequacy),
- safety concerns raised (i.e. a brief description, the nature of their consequences and likelihood),
- mitigating measures (i.e. a description of measures to address safety concerns, their appropriateness and adequacy),
- non-safety issues (i.e. a description of the issues and an evaluation of their impact(s), and
- decision taken and justification (i.e. was application approved/not approved/approved with condition, basis for decisions, and conditions, if applicable).

Following this brief presentation, participants went into groups to prepare a decision documents for *Bt Cotton* using the outline given above. Each group then shared its write up. The exercise showed good grasp and understanding by participants of the case material.

8.0. Day 7- Tuesday 27th January

8.1. Session 6- Biosafety Communication

Ms. Gillian Bernard, GEF National Project Co-ordinator in Jamaica, chaired the morning session, which began with the insightful video *"Harvest of Fear"*. There was a record turnout by local ministry and media personnel for this session. After a brief recap by Dr. Traynor of the safety and non-safety issues in biotechnology, Ms. Arlene Stevens of the Consumer Affairs Division in Trinidad and Tobago, gave a presentation on public awareness and attitudes in her country. See Appendix 30 for details.

Ms. Stevens reported that her division's involvement in biosafety started in 2000 with the promotion of the Biosafety Protocol to the United Nations Convention on Biodiversity. In observance of World Consumer Rights Day that year, the division hosted its 5th annual symposium on the title "Genetically Modified Organisms (GMOs) - Implications for Sustainability". This event highlighted a number of issues and concerns to the public. They included the potential for antibiotic resistance, gene pollution and genetic erosion, corporate threat to food security in developing nations, the labelling of GM foods, the need for testing and research, potential impacts on agriculture and trade arrangements, and the implications of GM regulations as barriers to trade. A number of recommendations and strategies were put forward for addressing these concerns and for utilising the technology to enhance our economic sustainability and growth. Some of these recommendations emphasised the need for the establishment of a transparent and consistent regulatory mechanism, policy and legislation, outreach and education, comprehensive compulsory labelling, research and risk assessment, management and communication.

A committee was set up to formulate a national policy for the use and development of GMOs in Trinidad and Tobago. This committee was also given the responsibility to monitor the development of a clearinghouse facility to accommodate the flow of information and to establish technical teams to liase with the various organisations dealing with GMOs. It was also given the responsibility to develop a mechanism whereby the Environmental Management Authority could be designated the enforcement agency for policies on GMOs and the agency for monitoring the work of all organisations that are engaged in the production of GMOs in the country. Another task of the committee was to ensure that there was a sufficient level of public awareness on the issue of GMOs.

Following this background information, Ms. Stevens shared with participants the findings of recent surveys conducted by the division on what the Trinidad public knew and felt about GMOs. Two hundred (200) persons were randomly interviewed on the streets in different parts of the country including Port of Spain and Rio Claro. The survey showed that 70% of the respondents had never heard of GMOs. Of the 30% who had heard of GMOs, 17% got this information from newspapers, 4% from the radio, 49% from the television and 8% from magazines and 23% from other sources including school. Respondents' understanding of GMOs was limited in that some respondents confused the term with cross breeding, chemical usage in the growing process, and grafting. A record 97% of the respondents thought that GM products should be labelled for reasons of consumer choice (17.4%), public

knowledge/information (64.5%), and because one was not sure of their side effects (18.1%). 61% of the respondents said they would purchase or consume a genetically modified product. However, 39% said they would not citing reasons of the technology not being a step in the right direction, unknown side effects, and the results of product tests to be published. Nearly all respondents (95%) wanted to have more information on GMOs. Ms. Stevens concluded that the position of her division was that the consumer must be given the choice to buy/not buy GM products, the technology and its resulting products must not be stifled and must be given fair play, while the interests of the consumer is protected.

Participants asked questions on the methodology and sampling method in particular used in the surveys. Ms. Steven explained the purpose and conditions under which these preliminary surveys were undertaken. More rigorous surveys were to be forthcoming in the future. Mrs. Bernard indicated that the views of the Jamaican public were similar to Trinidad's and that their data also showed the great need for public education and awareness. In response to questions from participants, Ms. Stevens informed that there would be a public consultation on proposed national policy on biosafety before it was taken to Cabinet. She also indicated that the division would be preparing a public education campaign on biosafety in conjunction with the Information Division, Ministry of the Environment, UWI, IMA and others. Prof. Duncan advised that the public awareness programme should precede the public consultation. Dr. Hollingsworth advised that a fuller survey be undertaken to tweak the issues and questions. Mrs. Bernard recommended that country collaboration on public education given economies of scale and limited resources.

Dr. Traynor in her next presentation took participants through the steps in developing and executing a strategic approach to communication on biotechnology and biosafety. (See Appendix 31 for details.). The steps included knowing one's audiences (i.e. identifying the different sub-groups, their information needs and who they trust); preparing clear, concise and consistent messages to the target audience; identifying good spokespersons (re. credibility, style, skills and attitude); and creating information resources to address information needs and rumours (experts, speakers, library materials, information nodes).

One participant commented on the miscarriage of information by journalists and concluded that this group had to be educated in order for them to understand and report correctly on the issues. Dr. Traynor concurred and emphasised that it was necessary for the NBC to constantly engage and work with this group. Dr. Malachy indicated that the Grenada national survey had identified teachers as another strategic group to educate so they could shape the right attitudes and pass on more accurate information to students. The public also recommended that leaflets be distributed in public places such as supermarkets, shops etc. He also indicated that IICA had funding for media training. A local organiser of the workshop commented that the media did not make use of the invitation issued to attend this workshop. The suggestion was made that they needed a short separate workshop.

Mrs. Bernard stated that in Jamaica, a baseline survey was first conducted to determine what and how much the public knew about biotechnology and how they felt about its products. This was the first step towards the development of a public education programme. Some consultations were held and a subsequent survey showed

that the public had gained more knowledge of the issues as a result of the consultations. The consultations were also useful in getting the different groups to put their emotions on the table. NBCs should be aware that there would be times that they would have to hold stakeholders' hand in arriving at a consensus on policy. One NGO representative considered

One NGO representative made the point that an effective communications strategy depended on what information was given out, how, and by whom. From civil society's standpoint what was needed was more than a public relations or awareness strategy. A proper information strategy must also be in place whereby information becomes availability and accessibility to the public for individuals and NGOs to do their own research, arrive at their own position on issues and be empowered.

Commenting on the response to labelling in the Trinidad survey, Dr. Traynor pointed out that the information content on a label would not make for better choice or satisfy the need for more consumer education and knowledge on issues, if the information was not intelligible to the layman. For consumer choice all that a label needed to state was that a product was GM free or that it contained a GMO, which had no proven harmful effects to public health or the environment. The educational and information needs of the public should be addressed by other measures.

Commenting on the results of the Trinidad survey whereby 97% of the respondents gave a positive response to labelling and cited reasons of consumer choice and the need for more information, Dr. Traynor pointed out that the information content on a label would not make for better choice or satisfy the need for more education and knowledge on issues, if the information was not intelligible to the layman. Essentially for consumer choice all that a label needed to state was that a product was GM free or it contained a GMO, which had no proven harmful effects to public health or the environment.

A presentation from Dr. Traynor on communicating risk followed next (See Appendix 32 for details). The objectives of risk communication were varied: to educate the public about what biotechnology is/and is not, how safety concerns are addressed through a biosafety system, potential risks and how these are managed; to improve understanding of public values and concerns; to increase mutual trust and credibility; to provide a mechanism for the public to voice concerns; to reduce conflicts or controversies; and to respond to inaccurate perceptions. The keys to effective risk communication were to view the public as a legitimate partner; encourage stakeholder involvement from the start; and create meaningful opportunities for participation in discussions. Mechanisms must be available for public input into policy and regulation making and for keeping the public informed on issues. It was also important to recognise that the debate was not about science alone. Information must be provided through credible sources and communicators must be honest, frank and open. They should admit what they do not know, distinguish clearly between fact and opinion, and recognize their own biases. They should provide clear and accurate information and tailor information to suit their audience. Their message should be balanced and statements should be supported with data. Communicators should cultivate cooperative relationships with the media and be accessible, clear and to-the-point. (See Appendix 33 for dealing with the media). In any country, the successful long-

term use of GMOs depended on public confidence in their safety, and evidence that any risk was outweighed by benefits to the public.

Local journalist, Mr. Tony Fraser spoke on working with the media. Participants were informed that the media like any other enterprise pursued profits in order to stay in business. What sells determined what made the news. The media was not a homogenous body but there were different sub-groups: directors, editors, journalists etc. One element focussed on profits and another upheld the status quo in which the enterprise thrived. The professional journalists like everyone else had bills to pay and upheld the status quo, while young journalists tended to be fired by a desire to make a contribution to society. It was important to know the different elements and interests within the media and to cultivate the contacts accordingly.

Advertisements brought the profits, ratings captured the advertisements, and saleable news (frequently sensational news) impacted on ratings. What sold newspapers were people stories. Biosafety was important but it had to be made intelligible to the public so they could see its importance to their lives. Editors had to make a choice among hundreds of stories received for public dissemination. Unless the editors could see the relevance to the public these stories would not be printed. Participants were advised to develop a structure for communicating with the media, to cultivate a relationship with reporters, to educate a cadre of them on the issues or else their stories would continue not to be printed.

In the ensuing discussion period, Mr. Fraser emphasised to participants that they must be strategic in their approach. Issues like biosafety required a core group of journalists educated in this area or the media would not take up the issues. It was not enough to just send press releases to the media but one should call and follow-up with one's media contacts. Participants were given tips on press releases: make them interesting, keep them brief and simple, and include graphics. News conferences and telephone interviews were other strategies to employ. Some participants felt the media should play a role in educating the public and that there should be a science page. Mr. Fraser indicated the media was making progress by including a health page among others but the science page would need regular contributors. Most reporters had no science backgrounds. The interests in science had to push for more science reporting. Their messages should be pitched to the level of understanding of the layman. Mrs. Bernard reported that they had succeeded in getting the Jamaican Gleaner to print a science page but it eventually got dumped for more advertisements.

9.0. Day 8- Wednesday 28th January

9.1. Session 7- Risk Assessment & Risk Management cont.

Mr. Julius Ross from CARDI in Antigua and Barbuda chaired this session, which commenced with a presentation by Mrs. Yasmin Baskh Comeau, Curator of the National Herbarium, on the impact of biotechnology on the biodiversity in Caribbean SIDS. Biodiversity was defined, according to the CBD, as 'the variability among living organisms from all sources including, *inter alia*, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are a part; this includes diversity within species, between species and of ecosystems'. There was biodiversity at the level of the eco-system, species and genetic diversity. The

Caribbean had a total land area of 240,000 km. The area of ocean encompassing the islands was 5 million km² giving a sea/land ratio of 20:1. The population was 35 million. The natural vegetation included lowland and montane tropical forest, evergreen thicket, savanna, cactus/thorn scrub, mangrove and riverine communities. In terms of flora, the region was home to 13,000 vascular plant species, of which 6550 were single islands endemics, 2500 species were genera and 205 species were endemic genera. The number of vascular plant families excluding ferns numbered 186. The floristic diversity on each island was influenced by topography, climate and edaphic features. The vegetation types were described for the following four natural communities: coastal communities; mangrove, lagoon and riverine formations; forest and woodlands; and savannas.

From a bio-geographic perspective, the islands flora and fauna could be described as indigenous, naturally occurring, introduced or endemic. Naturally occurring flora included shadon beni and fit weed. The introduced species came by accidental (e.g. worm bush), while others were deliberate (e.g. all major crops). The introduced species became either naturalised or established as part of the indigenous flora (e.g. feral cotton) or formed an alien invasive species that threatened local species (e.g. mongoose and water grass). There were three levels of dispesal at which endemism applied: Continental (taxa extending to Florida, Central America or northern South America), Antillean (taxa not extending beyond the Caribbean islands), and Greater or Lesser Antillean groups, separately and exclusively. These divisions reflected the main events and trends of the flora history of the Neotropics.

Mrs. Baskh Comeau made a comparison between the published flora of Trinidad and Tobago in 1982 and 2002/2004, which showed a loss of diversity in key areas. Endemism drop from 9.4% to 4.9% over that period. Using the island of Chacachacare, she showed how the island had in the space of 50-60 years regained its diversity after disruption caused during the war years. The fact that the island was used as a lepersaurium and then was left uninhabited contributed to its recovery.

The main threats to biodiversity to Caribbean SIDS came from deforestation, over exploitation of natural resources, the introduction of exotic species and even eco-tourism. Logging, squatting, slash and burn among other poor agricultural practices, land development, and quarrying all contributed to de-afforestation as did mono-culture plantations of teak and pine, which were planted for re-afforestation measures. Outdated legislation reduced the effectiveness of law enforcement. The problem was made more acute by the fact that local biodiversity was seldom documented and monitored by researchers. Over fishing, illegal hunting and over harvesting of timber contributed to the loss of biodiversity. In more recent times, the introduction of exotic species including pests such as the pink mealy bug constitute new threats. Eco-tourism posed the risk of increased human impact on sensitive eco-systems and species and biopiracy. Since GM crops were not grown commercially in the Caribbean, there was little cause for concern on its impact on Caribbean biodiversity. See Appendix 34 for full presentation.

In the discussed period, participants shared the view that better legislation and enforcement were important to stem the loss of biodiversity. Participants also shared that dasheen and tannia were old world crops that were brought into the Caribbean, and yams came from Africa. Dr. Umaharan informed that endemism referred to the

uniqueness of a species in a particular region or country. Genetic diversity was also important to consider as some features of a species could be unique to the Caribbean as a result of the process of evolution in island systems. Cocoa was not indigenous but *Cacao trintario* was unique to Trinidad. Peppers were introduced into the islands from Central America by the Amerindians but the germplasm of the types found here was unique. Also wild corn in the Caribbean was different to other populations in the world. The grapefruit also evolved on the islands. These facts were given to highlight the point that the introduced species had evolved over time and genetic mapping was needed to determine the range of genetic diversity.

Prof. Duncan also made the point that mono-culture tended to erode biodiversity and with its continuation the region would loose some of its land races. Conservation of these land races had become important. Also teak plantations contributed to soil erosion in the wet season but they could be made more sustainable by inter-planting with other species. One participant pointed out that wild species were difficult to propagate and thus conserve and this needed to be investigated. Biotechnology was put forward as one of the tools that could advance the cause of biodiversity preservation.

Participants were taken to Part 1V of the Model Guidelines Project by Dr. Traynor. This involved the development of guidelines for the commercial release of GM materials. At this stage the issues were different. Questions of security, management and regulatory oversight were not relevant here. Studying the results of the environmental safety and food safety assessments, examining enforcement, monitoring and inspection measures, and contingency planning had more significance at the commercial stage. Public input into decision-making was also necessary. A sound basis must be given and a record made of the decision taken. Non-safety issues came into prominence in decision-making at this stage.

Participants worked in groups developing model guidelines for the commercial release of GM materials. See Appendix 35 for template. Their work was presented on the last day of the workshop in order to give some time to the consolidation of the richness of the group work. With the assistance of Dr. Umaharan, the results of the group work were compiled into one document and printed separately to this report.

At the request of participants, the final session for the day was modified from a case study of the importation of GM maize to a review of an actual case from Australian regarding the release of *Bt cotton* and which provided a contrast to the case in the workbook in terms of the amount of information presented on the case. Prof. Julian Duncan of the UWI St. Augustine chaired the proceedings. Participants studied the case and then in plenary had a general discussion on it. Participants helped each other in understanding the rationale for this GM plant, the likelihood of gene transfer, and of resistance being built up in local insect populations. The case was very instructive. Participants were impressed by the high quality of work undertaken by the Australian professionals, the breadth of expertise used to review this case, the cautious and precise language they used, the transparency in the system, and the documentation of the decisions taken. Participants were also impressed by the robustness of their regulatory regime. Features included a gene technology law, regulations, a gene technology regulatory office, and an advisory committee of experts. Participants noted that the *Bt cotton* required a proper insect resistant management strategy which the

applicant had put forward. The assessment of the environmental risks was very detailed and thorough, and was laid out for each stage of plant development. A clear and proper management plan was outlined for each stage. The assessors made recommendations for a contingency plan and set certain license conditions to be met for the crop's release. These conditions addressed the safety concerns but did not stop the plant's commercial release. The decisions taken and basis for same were all stated in the decision documents.

There was some discussion on whether third parties were bound by the license conditions. It was agreed that for the conditions to hold the applicant would have to enter into a contract with the sub-contractors binding them to the conditions of the license. The question of product liability was raised and it was stated that under US Product Liability Laws, a company had to ensure that its products were safe to use. It would be the company to sue if the product failed and the same would apply to a GM product. The company could also sue a contract farmer for not growing the crop according to the specified safety standards or a farmer for producing it without a license.

Participants inquired whether public opinion provided a basis to reject an application and were informed that according to the WTO rules it had to be backed by scientific data. The way to get around the WTO rules was to adopt the CPB as national law. It was deemed advisable for local laws to facilitate the need for public consultation and to say how it was to be done. Dr. Traynor reminded participants that biosafety decision-making was not about consensus and that the regulatory bodies did not operate n this basis. The safety issues were science based but the non-safety issues were values based. Dr. Dottin indicated that under the proposed biosafety law for Grenada, the minister would make the decision on an application not the NBC.

10.0. Day 9- Thursday 29th January

10.1. Session 8- Regional Approaches to Biosafety

Dr. Wendy Hollingsworth of Farm-A-Sys Agri-Services, chaired the day's proceedings. The day started with remarks by Dr. Cyril Roberts, who thanked the organisers and sponsors for staging a very useful and productive workshop. He then gave an overview of CARDI's research in biotechnology in Barbados. Primarily it focussed on the black belly sheep that was developed in Barbados and exported to other countries. In the absence of a patent, others had now claimed the sheep as theirs. CARDI's work involved identifying the genetic traits of the Barbadian black belly sheep using molecular technology. CARDI was also involved in plant micro-propagation and a citronella scented geranium to ward off mosquitoes. Apart from this involvement in biotechnology, CARDI was a member of a CARICOM working group on GMOs, which was formed two years ago by COTED. CARDI was charged with the responsibility of co-ordinating the group.

The immediate objectives of the group were to mobilise technical opinion on GMOs; assist in the formulation of policies and strategies for the development, importation, and use of GMOs; and to contribute to the acceptance and implementation of policies and strategies. The members of the group comprised member states representatives, professionals/scientists, the press, consumer, public and private sector interests. The

group planned to go about its work interviewing stakeholders, reviewing the legislation in countries and relevant conventions, build on the GEF project, prepare specific reports and hold group meetings.

Dr. Roberts proceeded to describe the biotechnology research in progress at the UWI Mona and St. Augustine. He also summarised the status of GEF funded projects in CARICOM countries. Six countries did not sign the protocol. They were Belize, Dominica, Dominican Republic, Guyana, St. Lucia and Suriname. Belize, Guyana, St. Kitts, St. Lucia and St. Vincent were added to the GEF project. Four countries were ahead of all others in implementing the GEF project and had completed Reports 1-4. These countries were Antigua & Barbuda, the Bahamas, Grenada and Jamaica. Cuba was the only country in the implementation phase. Caribbean SIDS faced many challenges to NBF development. A primary concern was capacity in terms of the lack of human resources, ineffective use of available regional and local expertise, the lack of capacity in some technical areas (e.g. RA&RM), the small pool of persons involved in many different issues, the overloading of NBC members, consultation /workshop fatigue and the lack of a scientific co-ordinating body. Communication presented another critical challenge. There was an urgent need for public awareness and education and at the same time institutions were unwillingness to share information. Political "challenges" included the lack of priority being given to the issue, outdated and fragmented laws and regulations. Managerial constraints included the lack of familiarity with UNEP and bureaucratic delays in approving matters. Efforts at harmonisation at the regional level were hampered by the lack of regional authorities in Biotechnology, the lack of regional fora for preparation for ICCP, and COP-MOP among other meetings, and insufficient agency collaboration. See Appendix 36 for details.

In the ensuing discussion period, it was learnt that the CARICOM Working Group was hampered by the lack of funding yet the group was constrained to report soon to COTED ministers. It would have been ideal to start on a regional policy first but the committee was overtaken by events. Jamaica was forced to institute guidelines for local research on transgenic papayas and Grenada had started on a national biosafety law. While mandated outputs of the group were a regional policy and strategy on biosafety, some participants held the view that the harmonisation was critical in the treatment and processing of applications. A common approach, information sharing and capacity-building were needed. Other participants considered CARICOM a weak mechanism to bring about the proposed harmonisation in light of its performance in other areas.

Participants proceeded into working groups to answer a series of questions related to the harmonisation of national biosafety systems. They had to consider the objectives of the approach, areas for harmonisation, and implementation issues. See Appendix 37 for template f questions. Drs. Roberts, Hollingsworth and Umaharan facilitated the working groups. The groups reported in plenary session and there was much commonality of views among the groups. The main highlights were as follows. The objectives of the biosafety system should be the same for all Caribbean SIDS. However, the national priorities would differ as socio-economic and other conditions varied among the islands. Participants felt national systems should be harmonised in respect of public education, definitions, application forms and minimum information on forms, information sharing particularly of results of assessments, science based

risk assessment, capacity-building, and acceptance of US and Canadian results. Participants favoured the creation of a regional advisory body and a regional clearinghouse mechanism tapping into national clearinghouses. Research on crops relevant to the region should be co-ordinated and harmonised. Finally co-operation with Latin America to build capacity, to access expertise, and to accredit laboratories was recommended. The consolidated report was finalised by Dr. Hollingsworth and is printed separately.

Dr. Umaharan presented on the research in progress at the UWI on transgenic anthuriums, a species that was endemic to the Caribbean. The colour range in anthurium was derived from interspecific hybridisation between *A. andraeanum* and species from section Calomystrium. The Caribbean pinks were believed to be the first generation interspecific hybrid of *A. andraeanum* x *A. nymphaeifolium* or *A. andraeanum* x A. *lindenianum.* The region had a comparative advantage in this crops: adaptation to the region; high productivity per acre; proximity to a potentially large North American market serviced by direct flights to several destinations; production systems suited to small holdings; and low energy costs to facilitate automation. However, the problems of cultivation included susceptibility to bacterial blight and bacterial leaf spot, capital intensive operations (100,000 -150,000 US/ ac), the high cost of planting material, and the fickle selling price of blooms which depended on novelty (0.35 - 0.80 US). Anthurium breeding at the UWI focused on resistance to diseases, horticultural attributes, and productivity. Bio-engineering was being applied to anthurium for novel bloom colours and patterns. A semi-commercial micro-propagation supported the industry's propagule needs. Anthurium breeding concentrated on the identification of promising parents. 100 varieties were evaluated for resistance and horticultural characteristics. Hybridization of promising parents was conducted and over 60,000 offspring plants were generated from 140 crosses. These were evaluated and 40 - 50 were selected and micro-propagated. The varieties were undergoing evaluation of varieties for productivity.

The breeding worked involved Kairi Blooms Ltd. and was funded by the EU while the bio-engineering work involved a collaboration with new Zealand and was funded by the IADB. Some confined field trials were conducted at the University Field Station with the objective of testing the colour expression levels under different seasons. The potential for gene flow was low since the plant was pollinated by ants, there was limited pollen movement under cultivated conditions, in addition to which the seeds did not normally form. Also, indigenous species of anthurium could not hybridise with *A. andraeanum.* There were no real non-target effects since the introduced protein was part of the flavonoid pathway of all flowering plants. No toxicity was indicated to animals**.** The plant and its parts were not consumed as food so food safety considerations were irrelevant. There were no obvious negative agricultural impacts since the markets for anthurium were normally in North America and hence no marketing difficulties were likely. See Appendix 39.

Dr. Paula Tennant of UWI Mona presented on transgenic papayas. Biotechnology tools were used as conventional methods of controlling papaya ringspot had failed and the crop was devastated in some parishes. Testing showed that all plants in the country were infected with the disease. The transgenic plants developed by Cornell University did cover the strain of the disease in Jamaica and the plant variety was also different. Researchers had to develop a new transgenic variety. A portionof the virus

was inserted into some plant cells. They were tested for four years under the purview of the NBC and the new plants showed completed resistance to the disease. Field trials on growers' orchards had been delayed by the failure to pass the regulatory guidelines for release after more than two years of preparation by the NBC. 80% of the growers were anxious to try the plant while 20% were afraid of losing their EU markets or were afraid the fruit was not safe or would carry the virus or the resistance would be temporary and not lasting. The fruit was currently undergoing testing on nutritional composition and safety. Animal studies to date showed no adverse effects. See Appendix 40.

11.0. Day 10- Friday 30th January

11.1. Session 8- Regional Approaches to Biosafety cont.

Dr. Traynor chaired this session. Each group presented their work on Part IV of the model guidelines and this was followed by a synthesis by Dr. Umaharan. Dr. Traynor reported that the groups had internalised the different issues and done good work on the case studies and the guidelines. Participants had focussed on the right issues and some group were fairly details in their recommendations on administrative procedures for handling, record-keeping, public consultations, contingency planning and environmental stewardship. There were many points of consensus among the groups.

Closing Ceremony

Ms. Joycelyn Lee Young, Registrar of NIHERST officiated at the closing ceremony. She distributed certificates, which were presented by Dr. Traynor. The number of participants reached a high of 53 but only 37 achieved an attendance rate of 80% of the sessions, which was the set requirement for the receipt of a certificate of participation. CD-ROMs of all the presentations and the case studies were presented to participants. The workshop ended on warm notes of thanks and expressions of gratitude from the participants for being given this training opportunity. Mr. Julius Ross delivered the vote of thanks on behalf of the group. Dr. Traynor also expressed her thanks to the organisers, sponsors, her fellow facilitators, and all participants, who made her visit and work most rewarding and enjoyable.

12.0. Evaluation

In their evaluation of the workshop, 79% of the respondents (38 in total) rated the facilitators as either effective or very effective (45%, 34% respectively). 87% rated the quality of the presentation as good to very good (58%, 29% respectively). Some 63% of the respondent found the workshop relevant or very relevant to their work with 42% indicating a high degree of relevance particularly to NBC members. Comments on the workshop included that it covered new areas outside participants' field of expertise, which brought a new perspective on biosafety. The wide range of interests and disciplines highlighted in the workshop contributed to its effectiveness. The materials were also comprehensive and comprehensible. 21% felt the programme was too packed but 79% disagreed. A suggestion was made for more actual case studies and regional cases, where applicable. Suggestions for additional topics

included quantitative risk assessment, assessment of ethical and socio-economic factors, IPRs and biosafety, occupational and health safety issues, and cases on fish, animal feeds and animal products.

Participants expressed a number of concerns including about the city location of the workshop, which did not work well for participants from farther areas. More NGO and farmer participation was needed at the workshop. An additional facilitator was recommended. The UWI Mona and St. Augustine research could have been used as actual case studies. There was an obvious need for more sharing of information in the region on biosafety issues. More practical exercises on cases of relevance to the region could have been adopted. A few persons felt the workshop duration was too long. Follow-up training was recommended.

Appendix 1

LIST OF PARTICIPANTS

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Appendix 2- Revised Agenda

Caribbean Biosafety Training Course
Agenda: 12 January 2004

Monday, January 19

SESSION 1. INTRODUCTION AND BACKGROUND

8:30 a.m. **Opening Ceremony**
Host Organisation

10: 00 a.m. **Coffee / Tea Break**

10:15 a.m. **Logistics**
Host Organisation

10:20 a.m. **Introduction to the Course**
Dr. Patricia Traynor, New AgriTech Strategies, USA

10: 45 a.m. **Introduction to Biotechnology and Genetic Engineering**
Prof. J. Duncan, Professor Emeritus, University of the West Indies, Trinidad & Tobago

11: 30 a.m. **Biotechnology Applications for the Caribbean**
Dr. P. Umaharan, University of the West Indies, Trinidad & Tobago

12:15 p.m. **Lunch**

1:15 p.m. **The Cartagena Protocol on Biosafety**
Mr. Victor Jordan, Ministry of Trade and Industry

SESSION 2. NATIONAL BIOSAFETY SYSTEMS

2: 15 p.m. **Conceptual Framework for Biosafety Implementation & Management Patricia Traynor,** New AgriTech Strategies, USA

3:15 p.m. **Coffee / Tea Break**

3: 30 p.m. **Introduction to Model Guidelines Project**
Dr. Hector Quemada, Crop Technology Consulting, USA

4:00 p.m. **End of Day 1**

Tuesday, January 20

8: 30 a.m. **Environmental Safety Concerns in the Caribbean**
Dr. Bibi Ali, CABI

9:15 a.m. **The UNEP-GEF Biosafety Program in Trinidad and Tobago**
Dr. Dave Persaud, Ministry of Public Utilities & Environment, Trinidad & Tobago

10: 00 a.m. **Coffee / Tea Break**

10: 15 a.m. **Biotechnology and Biosafety in the Caribbean Region**
a. Grenada

b. Trinidad and Tobago:
c. Jamaica:
d. Bahamas:

11: 00 a.m. **Approaches to Biosafety in Developed Countries**
Dr. Hector Quemada, Crop Technology Consulting, USA

11:45 a.m. **Insights from National Biosafety System Studies**
Dr. Patricia Traynor, New AgriTech Strategies, USA

12:30 p.m. **Lunch**

1: 30 p.m. **Risk Assessment Case Study #1**
Greenhouse Experiment: fungus resistant sunflowers
Hector Quemada, Crop Technology Consulting, USA

2:45 p.m. **Model Guidelines for Handling, Transferring and Using Biotech Products from the Lab to the Greenhouse to Limited Field and Extensive Field Trials**
Part 1: Analysis of Existing Guidelines and Regulations

3:15 p.m. **Coffee / Tea (during exercise)**

5: 00 p.m. **End of Day 2**

Wednesday, January 21

SESSION 3. RISK ASSESSMENT AND RISK MANAGEMENT

8: 30 a.m. **The Biosafety Review Process**
Dr. Patricia Traynor, New AgriTech Strategies, USA

9:00 a.m. **Environmental Risk Assessment**
Dr. Hector Quemada, Crop Technology Consulting, USA

9: 45 a.m. **Model Guidelines Project**
Part 2: Procedures in the Lab and Greenhouse

10: 15 a.m. **Coffee / Tea Break**

10: 30 a.m. **Part 2 (continued)**

12: 30 p.m. **Lunch**

1: 30 p.m. **Risk Management in the Lab, Greenhouse and Field**
Dr. Patricia Traynor, New AgriTech Strategies, USA

2: 15 p.m. **Risk Assessment Case Study #2 Field Test: Bt cotton**
Dr. Hector Quemada, Crop Technology Consulting, USA

3:15 p.m. Coffee / Tea Without Formal Break

4: 30 p.m. **End of Day 3**

Thursday, January 22

8: 30 a.m. **Risk Assessment Case Study #2 Field Test: Bt cotton**
Dr. Patricia Traynor, New AgriTech Strategies, USA

9: 30 p.m. **Regulatory Realities: Commercial Release of Bt Potatoes in South Africa**
Dr. Hector Quemada, Crop Technology Consulting, USA

10:00 a.m. Coffee Break

10: 15 a.m. **Model Guidelines Project**
Part 3: Conducting Limited Field Trials

12: 30 p.m. Lunch

1: 30 p.m. **Part 3 (continued)**

3: 00 p.m. **Coffee / Tea Break**

3: 15 p.m. **Biotechnology and Biosafety in the Caribbean Region**
a. Antigua & Barbuda
b. Barbados
c. Guyana
d. St Lucia

4: 15 p.m. **End of Day 4**

Friday, January 23

SESSION 4. **FOOD SAFETY**

8: 30 a.m. **GMOs – Testing for Safety and Presence in Foods**
Dr. W. Hollingsworth,

9: 15 a.m. **Putting Risks of Genetically Engineered Foods in Perspective**
Dr. Hector Quemada, Crop Technology Consulting, USA

10: 00 a.m. **Coffee / Tea Break**

11:00 a.m. **Practical Considerations for Traceability and Food Labelling**
Dr. Hector Quemada, Crop Technology Consulting, USA

12: noon **Lunch**

1: 00 p.m. **International Trade Agreements and Obligations**
Mr. Victor Jordan, Ministry of Trade and Industry

1: 45 p.m. **Panel Discussion: Trade with Canada and the USA**
Chair: Mr. Victor Jordan, Ministry of Trade and Industry

3:00 p.m. **Coffee / Tea Break**

3: 15 p.m. **Biosafety & Gender**
Dr. Grace Sirju-Charran, University of the West Indies, Trinidad & Tobago

4: 00 p.m. **End of Day 5**

Monday, January 26

SESSION 5. DECISIONS AND DECISION MAKING

8: 30 a.m. **Regulatory Decision Making**
Dr. Patricia Traynor, New AgriTech Strategies, USA

9:15 a.m. **Risk Assessment Case Study #3**
Field Test: Bananas containing a vaccine

10: 15 a.m. **Coffee / Tea Break**

11: 30 a.m. **Plenary on Field Test: Bananas containing a vaccine**

12: 30 p.m. **Lunch**

1: 15 p.m. **Plenary Exercise 1: Regulatory Decision Making**
Dr. Patricia Traynor, New AgriTech Strategies, USA

3:00 p.m. **Coffee / Tea Break**

3: 15 p.m. **Plenary Exercise 2: Decision Documents for Bt Cotton**

5: 00 p.m. **End of Day 6**

Tuesday, January 27

SESSION 6. BIOSAFETY COMMUNICATION

8: 30 a.m. **Video Presentation: *'Harvest of Fear'***

10: 00 a.m. **Coffee / Tea Break**

11: 00 a.m. **Safety and Non-Safety Issues in Biotechnology**
Dr. Patricia Traynor, New AgriTech Strategies, USA

11: 45 a.m. **Public Awareness and Attitudes in Trinidad and Tobago**
Ms. Stevens and Ms Ravelo, Consumer Affairs Division, Trinidad & Tobago

12: 30 p.m. **Lunch**

1: 30 p.m. **Communicating about Risk and Biosafety**
Dr. Patricia Traynor, New AgriTech Strategies, USA

2: 15 p.m. **Working with the Media**
Mr. Tony Fraser, Freelance Journalist

2: 45 p.m. **Coffee / Tea Break**

3:00 p.m. **Group Activity: Meet the Press**

4:00 p.m. **End of Day 7**

Wednesday, January 28

8: 30 p.m.	**Biodiversity in the Caribbean** Yasmine Comeau, National Herbarium, Trinidad and Tobago
10:00 am	**Coffee / Tea Break**
10:15 am	**Model Guidelines Project: Part 4: Commercial Release**
12: 30 p.m.	**Lunch**
1:30 p.m.	**Australian Risk Assessment Case Study: Bt Cotton**
3:00 p.m.	**Coffee / Tea Break**
3:15 p.m.	**Australian Case, continued**
5: 00 p.m.	**End of Day 8**

Thursday, January 28

Session 7. Regional Harmonisation

8:30 a.m.	**Harmonisation of Biosafety Systems** Dr. Cyril Roberts, Caribbean Agricultural Research Institute, Barbados
9:00 a.m.	**Working Group Exercise: Harmonisation of Biosafety Systems** **Priority Areas for Harmonisation**
10: 00 a.m.	**Coffee / Tea Break**
10:15 a.m.	**Harmonisation Exercise: Priority Areas, continued**
11:00 a.m.	**Reporting to Plenary**
12: 00 p.m.	**Harmonisation of Biosafety Systems: Implementation**
12:30 p.m.	**Lunch**
1:30 p.m.	**Harmonisation Exercise: Implementation continued**
2:30 p.m.	**Reporting to Plenary**
3:00 p.m.	**Coffee / Tea Break**
3:15 p.m.	**Case Study: Transgenic Anthurium** Dr. P. Umaharan, University of the West Indies, St. Augustine
3:30 p.m.	**Case Study: Transgenic Papaya** Dr. Paula. Tennant, University of the West Indies, Mona
4:00 p.m.	**Open Discussion**
5:00 p.m.	**End of Day 9**

Friday, January 28

8:30 a.m.	**Model Guidelines Project: Part 5: Synthesis and Review**
10: 00 a.m.	**Coffee / Tea Break**
10: 15 a.m.	**Model Guidelines Synthesis and Review, continued**
12: 00 p.m.	**Lunch**
1:00 p.m.	**Course Evaluation**
1: 30 p.m.	**Closing Ceremony**
2:00 p.m.	**End**

Appendix 3

FEATURE ADDRESS BY SENATOR THE HONOURABLE SATISH RAMROOP, MINISTER OF STATE IN THE MINISTRY OF SCIENCE, TECHNOLOGY AND TERTIARY EDUCATION

Mrs. Maureen Manchouck, President of NIHERST
Ms. Philippa Forde, Deputy Permanent Secretary, Ministry of Legal Affairs and Consumer Affairs
Dr Charmaine Gomes, Programme Specialist, United Nations Development Programme
Dr Wendel Parham, Executive Director of CARDI and former Permanent Secretary of the Ministry of Agriculture in Belize.
Members of the National Biosafety Committee
Other Distinguished Representatives of National, Regional and International Organisations
Other Distinguished Guests
Members of the Media
Ladies and Gentlemen

On behalf of the Government of Trinidad and Tobago, I want to welcome participants to this most important workshop entitled "Capacity Building in Biosafety for the Caribbean". To our foreign participants I also want to extend a special warm welcome.

This workshop is being hosted because it has been recognised that the Caribbean Region does not possess the required human resource and institutional capacity, to effectively deal with the complexity of issues related to the assessment and management of biological risks. Ladies and Gentlemen this challenge exists not only in this region but also internationally.

This is not surprising, as the pattern follows the increasing phenomenon of emerging technologies overtaking human resource capabilities. Training in the use of new applications is mandatory, if we are to maximise the benefits of today's technologies.

There is widespread recognition of the usefulness of biotechnology applications in averting food scarcity and malnutrition over the coming decades.
Today, we are faced with the problem of a rapidly growing global population. The global population size has passed the six billion mark and is increasing by roughly 80 million annually. Most of the rapid population growth is taking place in developing countries. As of the year 2000, statistics indicated that the number of inhabitants in the developing and developed world was estimated at 4.75 and 1.31 billion respectively. In 20 years time it is predicted to be 6.15 and 1.36 billion, respectively.
It is estimated that of the estimated six billion, there are over 800 million people who do not have sufficient access to food to meet their needs. As a result, there is a growing increase in malnutrition and associated diseases. There are thousands of children suffering from malnutrition who will not live to see the end of this day.

Ladies and gentlemen natural disasters that annually threaten small states militate against successful crop production and food security. The depletion of virgin lands for

agricultural production continues to take place as housing and industrial needs increase.

The question about the ability of nations to grow sufficient food for present and future generations therefore arises.

It is increasingly recognised that to increase food production to feed the growing population, the world must successfully produce more food per acre. The answer ladies and gentlemen may lie in the use of biotechnology. Biotechnology, I am sure many of you distinguished personnel from our regional scientific fraternity are aware, mainly covers technological applications involving reproductive biology. Biotechnology is also the manipulation, or use, of the genetic material of living organisms for specific uses.

This definition covers a wide range of diverse technologies including, for example, the use of molecular DNA markers, gene manipulation and gene transfer.

This technology which emerged in 1919 and has its roots 6000 years ago, may very well play a crucial role in addressing food shortage challenges of the future and halting the malnutrition epidemic that cannot be solved through traditional means, in spite of the best efforts of the relevant international organisations.

The application of biotechnology though, includes the use of tools that are sometimes considered controversial. The debate on the value and consequences of agricultural biotechnology has become polarised, particularly where genetically modified foods are involved.

There are many arguments for and against the use of genetic transformation technology in foods. One local newspaper recently quoted Professor Christopher Leaver, Head of the Department of Plant Sciences at Oxford University, as telling a local audience that genetically modified foods are probably safer than conventional crops. The newspaper quoted him as stating, “there is no evidence that there is any health hazard from genetically modified foods”.

However there is also the concern that the use of the technology favours farmers in developed countries where the economies can support its use.

On the other hand ladies and gentlemen, there is the very real concern that the release of genetically modified fish or animals, or the growing of genetically modified crops or forest trees, might have a negative impact on the environment.

Concerns also surround the potential risks that may be greater in developing countries, as the application and monitoring of biosafety regulations concerning GMOs would be less rigorous than in developed countries.

For Caribbean countries which have biologically rich but small eco-systems, biosafety is a serious concern.

Ladies and gentlemen, there is no escaping the fact that in many parts of the world the technology is being used. The United States of America, which is the international leader in agriculture biotechnology, is also one of the world's largest exporters of food, particularly to developing countries such as ours in the Caribbean.

We are aware that last Tuesday leaders from 34 countries in the Western Hemisphere, ended the Summit of the Americas in Mexico, with a final declaration that included reaffirming next January's deadline for creating a free trade agreement. This accord would create the world's largest free trade zone, stretching from Alaska to Argentina, with a market of some 800 million people. This would mean an influx of goods into Trinidad and Tobago and other signatories to the agreement in the Caribbean area.

Local and international developments continue to create an urgent need for Trinidad and Tobago among other developing countries to develop and maintain an adequate capability in biotechnology. Thus, biotechnology has grown in relevance and application in Trinidad and Tobago over the past decade.

Biotechnology is used currently in this country for criminal investigations (DNA Testing), disease research, analytical services, cleaning of oil spills, medical diagnosis, the rapid propagation of plants and the development of disease resistant and better quality planting material.

But we have not yet come to the place of applying the technology in large-scale field trials and the production of food. As far as the ministry is aware, the Department of Life Sciences of the University of the West Indies, is the only institution in the country that is currently involved in Genetic Engineering. Its work concentrates on improving disease resistance in plants on economic importance, the DNA fingerprinting of local peppers and increasing the novel features of ornamental plants such as the Anthurium. There is no ongoing research on the genetic modification of food crops.

The use of biotechnology in food production is a reality in Latin America particularly in the Southern Cone countries and in Cuba. It may already be a reality in CARICOM countries like Jamaica, but it most certainly will become unavoidable in spite of the many concerns. What then should our response be? We need to set in place biosafety mechanisms at the national and regional levels.

Ladies and Gentlemen Trinidad and Tobago is a signatory to the Convention on Biological Diversity and the Cartagena Protocol on Biosafety. The objective of this Protocol is to contribute to ensuring adequate levels of protection in the field of safe transfer, handling and use of Living Modified Organisms (LMOs) resulting from biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements.

Being a signatory to this Protocol brings certain demands and requirements. We are required to undertake risk assessment and risk management procedures that are in line with the other provisions of the Protocol. This is so for all the other signatories including other countries in the region such as Antigua and Barbuda, Barbados, the Bahamas, Jamaica and Grenada.

This is the principal reason for hosting this workshop. We are all aware that among the main objectives of this workshop are:

(1) To train a cadre of Caribbean professionals in the environmental release of GMOs and their products including the methods, techniques, standards, indicators and guidelines for assessing, monitoring and controlling the risks posed by the transfer, handling and use of GMOs and their products.
(2) The workshop will also address the issue of training Caribbean scientists and technical experts in the techniques to deal with the safe transfer, handling, use and identification of GMOs that may have adverse effects on biological diversity, the environment and human health.

I am aware that the workshop will not only seek to address issues related to the Protocol on Biosafety but has been broadened to encompass social, economic, and other non-science factors which will be critical for holistic approaches to biotechnology usage.

The areas include:

- Identification of international agreements of relevance to the Protocol
- Trade with the United States of America and Canada
- Strategies for public awareness, the monitoring and communication of risks
- Model guidelines and recommendations for the Caribbean Region and other Small Island Developing Countries

At the end of this workshop we anticipate among other things

1. A cadre of 50 regional scientists/technologists trained in bio-safety
2. Production of model guidelines for the safe transfer, handling, use and identity of biotechnology products/GMOs in the Caribbean
3. Knowledge dissemination on the implementation of the Biosafety Protocol and national bio-safety regulations and guidelines.
4. Recommendations to CARICOM on the building of a regional biosafety framework.

Ladies and gentlemen Government's recognition of the need to explore various aspects of biotechnology led to the appointment of the Cabinet Committee to develop a National Policy and Regulations on Biosafety. This Committee has started work on a draft national Biosafety policy document. This document is to be finalised this year.

This committee was established in 2000 and is chaired by the Deputy Permanent Secretary in the Ministry of Legal Affairs. Its terms of reference include the following:

- to monitor the development of a clearing house facility to accommodate the flow of information in and out of Trinidad and Tobago on GMOs;

- to establish technical teams to liaise with the various organisations dealing with the issue of GMOs;

- to evaluate, monitor and develop mechanisms to regulate research on GMOs;
- to develop a national policy on Biosafety, with recommendations for relevant legislation; and
- to collaborate with the University of the West Indies and other research institutions on a working paper on GMOs.

Additionally, ladies and gentlemen, very recently Cabinet agreed for Trinidad and Tobago to ratify the statutes of the International Centre for Genetic Engineering and Biotechnology (ICGEB). The ICGEB, which was conceived by the United Nations in 1983, is dedicated to the advancement of research and training in molecular and biotechnology with special regard to the needs of developing countries. Trinidad and Tobago's membership automatically entitles this country's scientific community access to the different programmes implemented. Plant genetic engineering and biosafety are two important areas to Trinidad and Tobago.

The US $5,000 annual membership fee is paid by the Ministry of Science, Technology and Tertiary Education. The local promotion of the activities of the centre is undertaken by NIHERST.

The Ministry of Science, Technology and Tertiary Education is well aware of the involvement of NIHERST, which is an agency of the ministry, in the organisation of this workshop. I am aware that the workshop was organised by NIHERST in collaboration with the following:

- The Caribbean Council for Science and Technology with the sponsorship of the Ministry of Public Utilities and the Environment
- The Perez-Guerrero Trust Fund for Economic and Technical Cupertino among Developing Countries
- The Commonwealth Secretariat
- The International Development Research Council in Canada
- CARDI
- The Technical Centre for Agricultural and Rural Co-operation of the African Caribbean and Pacific-European Union

I want to take this opportunity to publicly thank these organisations and in particular NIHERST for holding this most important workshop. I want to assure you that the Government of Trinidad and Tobago is acutely aware of the value of the advances in science and technology for the modernisation of Trinidad and Tobago.

This country is operating within an increasingly competitive global economy. The vision of the government is to achieve developed country status by the year 2020. To do so, we must see science, technology and innovation as critical factors in our day-to-day activities and also as the primary vehicles for rapid business and industrial growth and competitiveness.

At this point ladies and gentlemen, I want to wish all participants all the best in their deliberations. I hope that at the end of this workshop you would have achieved all that you set out to do.

I thank you.

Appendix 4

WELCOME BY MAUREEN MANCHOUCK, PRESIDENT OF NIHERST

Senator The Honourable Satish Ramroop, Minister in the Ministry of Science, Technology and Tertiary Education; Mrs Phillipa Forde, Deputy Permanent Secretary, Ministry of Legal Affairs; Dr. Wendel Parham, Ag. Executive Director, CARDI; Dr. Charmaine Gomes, Programme Specialist, UNDP; Main Presenters – Dr. Patricia Traynor and Mr Crosby Houston, and Dr. Hector Quemada; regional presenters; Prof. Julian Duncan, Advisor to NIHERST; members of the National Biosafety Committee; participants - national and regional; invited guests; members of the media; ladies and gentlemen.

On behalf of the Caribbean Council for Science and Technology (CCST) and NIHERST which is the secretariat for the Council, I am extremely pleased to welcome you all, participants and presenters to this most significant workshop on Biosafety. The workshop focuses on the particular circumstances of our region and is part of a larger project on "Capacity Building in Biosafety for the Caribbean" in which the CCST through the NIHERST Secretariat has played a key role in securing sponsorship and in effecting implementation as a regional project.

The main beneficiary countries of the project are Antigua, Barbados, Guyana, Jamaica, St. Lucia, Trinidad and Tobago, and the presence of participants from all these countries attests to the seriousness, which our region brings to the biosafety challenge. The region frequently criticises itself for its weak resolve in addressing obligations that have major impacts on our lives. In this instance I am happy to say that the representation I see among the participants here today augurs well for the development of capacity at both the national and regional levels which is one of the goals of the workshop. Such capacity will enable us as a region to effectively respond to the requirements of our international obligations such as the Cartagena Protocol for Biosafety and in the process develop the multidisciplinary capacity to make critical decisions on scientific issues that have a direct bearing on our environment and on the health and wellbeing of our people.

In conceptualising this workshop, NIHERST recognised the need for policy in the field to provide greater focus and coherence to our efforts. We, however, drew considerably from our role in S&T in the local and regional contexts and more specifically from our involvement in biotechnology initiatives in this country. This experience like the current focus on biotechnology safety requires for effective implementation the strengthening of the underlying scientific capacity of this country and that of others in the region. This workshop, therefore, presents us with an excellent opportunity to strengthen regional collaboration in biosafety and in biotechnology itself in light of the different situations, capabilities and needs of each country.

Prior to this country's involvement with the Cartagena Biosafety Protocol, Barbados, Jamaica and Trinidad and Tobago had begun to make significant investments in the development of a research capability in biotechnology and more recently Barbados, I understand. NIHERST and the University of the West Indies (UWI) have collaborated in the biotechnology area for at least

ten years on projects which were therefore to have a major impact on the revitalisation of the national and regional agricultural sector through the improvement of planting materials and the development of new food and horticultural products for export.

The focus on biosafety creates the conditions for us to utilise the biosafety thrust to re-energise the biotechnology sector so that its full potential can be fully realised in the country's economic development thrust, while simultaneously addressing the biosafety imperative.

Small developing countries such as those in the region intent on making their economies knowledge-based need to be very judicious in the determination of their research and development priorities. In this context, there appears to the growing recognition that biotechnology is an area, which if systematically developed in this country and the wider region can contribute significantly to our region's economic development.

Over the past seven (7) years, UWI St. Augustine has worked hard at establishing a world class biotechnology laboratory, the best in the region, I should add, and according to international experts, equal to those in the industrialised world.

It is important, however, that we be cognisant of the wider regional and global contexts in which the biosafety imperative is inextricably linked with issues of trade and in particular the free movement of goods. If we fail to demonstrate a sense of urgency in putting our house in order, we will not only be unable to honour our international commitments but more importantly we will not be able to effectively protect our environment and seriously address the far-reaching implications for trade and technology transfer, inherent in the Cartagena and other relevant Protocols.

Given the region's current limitations with respect to capacity in the biosafety area and the high cost of compliance with the relevant international protocols which tend to favour multinational companies over local innovation, it should be evident that on both the environmental and trade fronts a regional response is required. This is the thinking that has informed this workshop and the larger project.

The workshop programme is a very comprehensive one which provides considerable scope for addressing the most critical issues before us and for laying the groundwork for the establishment of a biosafety framework, the major components of which are a national policy, a regulatory system as well as systems for monitoring and inspection.

These are areas in which government has a key role to play and NIHERST looks forward to working closely with the Ministry of Science, Technology and Tertiary Education in the development of this framework and its constituent elements.

In closing, I want to wish you all a most productive workshop and to thank you all for their sponsorship and support in this endeavour.

Appendix 7

THE CARTAGENA PROTOCOL ON BIOSAFETY, AND ITS RELATION TO OTHER INTERNATIONAL TRADE AGREEMENTS by Victor Jordan, Trade Specialist, Ministry of Trade and Industry, TRINIDAD & TOBAGO

INTRODUCTION

Although the Convention on Biological Diversity (CBD) made a provision for the Protocol on Biosafety, it was the failure in December 1999 of the United States and its supporters, at the WTO Ministerial Conference in Seattle, to establish a working group on biotechnology that would give the WTO the mandate to regulate the transboundary movement of living modified organisms (LMOs), which spurred countries to negotiate the Protocol. Many developing countries were hoping that the Seattle Conference would take up the issue and negotiate an agreement that would protect them from transboundary movement of living modified organisms (LMOs), a more specific kind of genetically modified organisms (GMOs), resulting from modern biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity, and presenting a risk to human health.

Developing countries have expressed a fear of becoming dumping grounds for untested Western technologies in the field of agricultural biotechnology, and are also concerned about the impact of LMOs crops on social and economic structures in agriculture. Developing countries are especially vulnerable to the dangers of LMOs because, on the whole, they lack the institutional capacity to regulate and monitor the importation of such products.

The failure of the Seattle Ministerial Conference meant that developing countries had to push for the negotiation of a biosafety agreement outside the purview of the WTO. The most convenient avenue available was Article 3 of the CBD, which made provisions for the negotiation of a Protocol on Biosafety.

THE PROTOCOL ON BIOSAFETY

The Protocol on Biosafety is of great advantage to developing countries because, in contrast to Article 4 of the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) of the WTO, which gives the importing country the right to inspect the products, it places the burden on the exporting country to show that the LMO products are not harmful to the biological diversity of the importing country and taking into account risks to human health. In theory, the Protocol can protect the environment in developing countries although the developing country lacks the institutional capacity. The Protocol is designed to be self-executing.

An exporter wishing to export a LMOs for intentional introduction into the importing country's environment, such as seeds (Article 5 excludes pharmaceuticals) must first notify (advance informed agreement procedure) the importing country and await "written consent" before the export can take place. The importing country may and

the exporting country should be prepared to provide a risk assessment, which must be carried out in a "scientifically sound manner," before a decision on import, which hopefully will show that the product is safe. The importing country may conduct the risk assessment or request that the exporting country conduct the risk assessment at its own expense.

According to the Protocol, the importing country is under no specific time limit to respond to the exporting country, unless the exporting country requires a review or a prior decision. The Protocol also requires that the accompanying documentation clearly identify the products as LMOs. Article 10(6) of the Protocol states:

> Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of an LMO on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risk to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of the LMO in question . . .

This means that although there is no scientific evidence available to indicate that the LMO is unsafe, the importing country can deny permission to the export as a precaution, hence the precautionary principle. This approach is contrary to the Article 5(7) of the SPS Agreement of the WTO that reads:

> In case where relevant scientific evidence is insufficient, a Member may provisionally adopt Sanitary and Phytosanitary measures on the basis of available pertinent information, including that from relevant international organisations as well as from sanitary and Phytosanitary measures applied by other members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the Sanitary and Phytosanitary measure accordingly within a reasonable period of time.

For other types of LMOs, not for intentional introduction into the environment, but for LMOs intended for direct use as food, or for processing, importers are required to inform the Biosafety Clearing-House who will in turn pass on the information to the importing country, unless the importing country prefers to get the information directly. Again, the importing country may request a risk assessment. However, the standard applied to the importation of this type of LMO is not as restrictive as that required for the first type of LMOs. A non-response from the importing country does not necessarily mean that the product cannot be exported to the importing country. However, Article 11(8) like Article 10(6), under the precautionary principle, gives the importing country the right to deny the second type of LMO as a precaution if there are any misgivings.

Article 18(2)(a) also has a special labelling requirement for this second type of LMO:

> Each Party shall take measures to require that documentation accompanying:
> LMOs that are intended for direct use as food or feed, or for processing, clearly identifies that they "may contain" LMOs and are not intended for

> intentional introduction into the environment, as well as a contact point for further information . . .

The Protocol is very friendly to developing countries that do not have the resources that would be necessary to put the institutional apparatus in place to monitor and test LMOs for their safety. It allows the ClearingHouse to be a source of information and technical expertise that will enable the importing country to make informed decision concerning the importation of LMOs into the environment.

THE PROTOCOL AND THE SPS AGREEMENT OF THE WTO

The framers of the Protocol on Biosafety were careful to ensure that the Protocol would not be subservient to the SPS agreement of the WTO, when it was declared in the Preamble to the Protocol "that the above recital is not intended to subordinate this Protocol to other international agreement." The wording of the Protocol puts the agreement on the same level as the WTO. However, the Protocol does not say which agreement should prevail in case of a conflict between the two agreements.

The SPS Agreement is primarily concerned with protecting "human, animal or plant life or health" and preventing the use of SPS standards as an obstacle to trade. Therefore, it emphasises the importance of having a scientific basis for the application of such standards. The Protocol on the other hand is mainly concerned with ensuring the conservation and sustainable use of biological diversity. It seems reasonable to expect that a country with a complaint that the LMO standards are being used in a protectionist manner will choose the WTO forum to get redress instead of the forum offered by the Protocol, which on the surface is more sympathetic to environmental safety issues. There is nothing in the text of the Protocol that would preclude recourse to the WTO.

Another area of potential conflict with the WTO is Article 26 of the Protocol that allows the importing country to take into account socio-economic considerations in deciding whether or not to give consent for the importation of LMOs. Section 1 of this article reads:

The Parties, in reaching a decision to import under this Protocol or under domestic measures implementing the Protocol, may take into account, consistent with their international obligations, socio-economic considerations arising from the impact of LMOs on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities.

On the surface, this article conflicts with the SPS Agreement, which only recognises a scientific basis for restricting the importation of LMOs. This Article, without any prescribe limits, could become a tool for trade protectionism. Interestingly, however, the Article does require that exclusions based on socio-economic considerations be consistent with "international obligations." This phrase could be interpreted to mean that a country could not use socio-economic considerations unless it is consistent with WTO rules (SPS Agreement).

Since more countries are members of the WTO than are members of the Protocol, it is fair to say that the WTO will be the most likely forum to resolve conflicts between the

two agreements, especially when the conflict is between a Party and a non-Party to the Protocol. For instance since the United States did not sign the Protocol, they cannot be brought before the Protocol's dispute resolution bodies in the event of a failure to comply with the Protocol. Rather the United States would be able to bring the Party to the Protocol before the WTO, charging them with a breach of the SPS Agreement. If this happens, then it seems reasonable to expect that in the forum of the WTO issues of biological diversity would be made subservient to issues of involving the removal of barriers to trade.

THE PROTOCOL WITHIN THE CONTEXT OF THE FTAA AND THE ACP-EU TRADE AGREEMENT

The European Union (EU), its members and most of the African, Caribbean and Pacific (ACP) countries signed the CBD and the Protocol on Biosafety. This means that the Protocol would govern the trade in LMOs between the two groups of countries. Both the EU and the ACP countries are also members of the WTO, therefore, both group of countries would have access to both forums in the event of a dispute. In addition, the EU has exercised its right under the Article 3(3) of the SPS Agreement adopt measures that would "result with a higher level of sanitary phytosanitary protection than would be achieved by measures based on relevant international standards" (Protocol on Biosafety). Currently the EU has regulations that govern the importation of LMOs, which are more stringent than the Protocol or the SPS Agreement.

The Free Trade Area of the Americas (FTAA) has not been signed yet, so one cannot make a definitive statement about which document will given the trade in LMOs within the FTAA. However, with the exception of the United States most of the 34 countries that make up the FTAA have signed the Convention on Biological Diversity and the Protocol on Biosafety. So, in the absence of any domestic legislation in the individual country, the Protocol will govern the trade in LMOs between the signers of the Protocol, unless one member chooses to exercise its right under the SPS Agreement even though both parties are party to the Protocol. If a member of the FTAA does not have domestic LMO legislation in place, then in its trade relations with the United Slates, the WTO (SPS Agreement) will govern the trade in LMOs. Since the United States did not sign the Protocol, the U.S. would not be obligated to honour it and since it is more restrictive than the SPS Agreement, it seems reasonable that the United States would seek to use the forum provided by the WTO as a means to minimise compliance with the Protocol.

Of course, at a later date the members of the FTAA could decide to adopt the SPS Agreement of the WTO agreement, by reference since they are all already members of the WTO, as a means to govern the trade in LMOs within the FTAA. Because more countries are members of the WTO than the Protocol, there is a possibility that the forum provided by the WTO may in effect eclipse the entire Protocol on Biosafety. The third possibility is for the FTAA to adopt an entirely new agreement to govern the trade in LMOs. Perhaps the best option is for the FTAA to adopt the status quo — that is to use both the Protocol and the SPS agreement of the WTO because getting all its members to sign the CBD and the Protocol may not be possible.

THE CARIBBEAN'S BEST OPTION

Since for the most part, the Caribbean's major export partner, the United States of America, did not sign the CBD or the Protocol, there is no obligation on the part of the United States to honour the Protocol. Indeed, Article 24(2) of the Protocol says that non-parties to the agreement, which the United States is, can only be encouraged to adhere to the Protocol and to contribute appropriate information to the Biosafety Clearing-House. A non-party to the agreement is under no legal obligation to honour the agreement.

The Caribbean's best option and that of other countries that wish to have all exporting states adhere to the Protocol, therefore, is to adopt the Protocol, under Article 3(3) of the SPS Agreement, as part of their domestic laws to regulate the importation of LMOs. Most developed countries have already adopted laws under Article 3(3) of the SPS Agreement that set standards for the importation of LMOs. By adopting the Protocol into their domestic laws the Caribbean would join this group of countries and also put in place the necessary infrastructure to monitor compliance with the Protocol. Once the Protocol is adopted, exports of products containing LMOs from countries, including the U.S., a non-Party to the Protocol, would have to meet the standards outlined in the Protocol as a condition of the laws of the Caribbean region before their LMO/GMO products would be allowed to be imported into the region.

Comparison of Cartagena Protocol on Biosafety & WTO Sanitary and Phytosanitary Agreement

CPB	SPS
Imports i. Based on Science and Socio-economic considerations consistent with "international obligations". (Article 26(1)). a. To ensure the conservation and sustainable use of biological diversity. b. To guard against risk to human health ii. Advance Informed consent procedure a. LMOs for intentional release into environment must - Request permission to export - Provide or pay for risk assessment if requested - LMO must be clearly identified in the risk assessment - Wait for written consent - Precautionary principle has no time limit (Article 10 (6)). b. Other LMOs for use as food or for processing must - request permission through Biosafety Clearinghouse unless importing country require otherwise. - Importing country may request risk assessment. - Non-response does not mean that import can not take place. - Must clearly label import as containing LMO for release into the environment and give contact for further information. (Article 18(2)(a). Exports of LMOs i. Must follow procedures as outlined by importing member country. Ii. Must follow standards of importing country if different from Protocol. Some countries' standards are stricter than the Protocol's.	Imports i. Must be scientifically based to protect: a. human, animal or plant life or health b. preventing the use of SPS standards as an obstacle to trade. c. No mention of biodiversity. ii. Can apply precautionary principle but must make a scientific determination within a reasonable period of time (Article 5(7)). iii. May use SPS standards that give greater protection than international standards but these must be: a. Notified to the WTO b. Justified with risk assessment v. Importing country may request to inspect goods to ensure compliance with SPS standards (Article 4) Exports i. International standards, or, ii. SPS standards of importing country because they may have SPS standards giving more protection than SPS Agreement (Article 3(3)) Some countries have SPS standards are higher than international standards. Many countries have separate regulations/standards governing the importation of LMOs/GMOs.

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Appendix 17(b)

The NIH Guidelines for Research Involving Recombinant DNA Molecules: Overview and Summary of Biosafety Levels.

I. Introduction

The National Institutes of Health Guidelines address the safe conduct of research that involves construction and handling of recombinant DNA (rDNA) molecules and organisms containing them. In 1974, a Recombinant DNA Advisory Committee (RAC) was established to determine appropriate biological and physical containment practices and procedures for experiments that potentially posed risks to human health and the environment. The initial version of the NIH Guidelines was published in 1976 and amended many times since. Major changes were made in 1982, when NIH purview over recombinant DNA research was extended beyond environmental issues to human gene therapy, and in 1991, when NIH oversight of environmental release of genetically modified organisms was relinquished to the U.S. Department of Agriculture and the Environmental Protection Agency. This latter change was motivated in part by the recognition that NIH did not have the statutory authority to function as a regulatory agency. The current version of the Guidelines was published in July, 1994 and has since been amended four times.

II. Organization

Section I indicates that the Guidelines are applicable to all rDNA research which is conducted at, or sponsored by, an institution that receives any support for rDNA research from NIH. Noncompliance with the Guidelines for any particular project may result in the suspension, limitation, or termination of financial assistance for the project and of NIH funds for other rDNA work at the institution. In June, 1983, Federal agencies which support or conduct laboratory rDNA research agreed to abide by the Guidelines. Because of this agreement, as a condition for Federal funding of rDNA laboratory research, **institutions must ensure that all rDNA research conducted at or sponsored by the institution, regardless of the source of the funding, complies with the Guidelines.**

Section II of the Guidelines generally discusses risk assessment and containment of biological experiments.

Section III sets forth the review procedures for particular types of experiments, which are divided into five classes (previously four) based on requirements for notification or approval of an Institutional Biosafety Committee (IBC) or the NIH RAC. Those generally judged least risky are exempt from the Guidelines. Some require notification to an IBC, which must be established by the experimenting institution. Some require IBC approval. In general, the most potentially risky laboratory experiments require both IBC and NIH approval.

Section III-A experiments require IBC approval, RAC review, and NIH approval before initiation; the PI must submit relevant information to the NIH Office of

Recombinant DNA Activities (ORDA) and the proposal is published in the Federal Register for public comment.

These experiments include:

1. deliberate transfer of a drug resistance trait to microorganisms (qualified)
2. deliberate transfer of rDNA into humans.

Note: In July of 1997, NIH discontinued the RAC and relinquished to the U.S. Food and Drug Administration responsibility for approval of human gene therapy experiments.

Section III-B experiments require NIH/ORDA and IBC approval before initiation. These experiments include cloning of toxin molecules with LD_{50} < 100 ng/kg body weight.

Section III-C experiments require IBC approval before initiation; the PI must submit a document describing the source and nature of inserted DNA, the hosts and vectors used, whether a foreign gene will be expressed (and what it is), and the containment conditions required. These experiments include:

1. use of human or animal pathogens as host-vector systems; Biosafety Level in accordance with Risk Group of agent (lists of organisms in Appendix B-II)
2. cloning of DNA from human or animal pathogens into nonpathogenic prokaryotic or lower eukaryotic host-vector systems
3. use of infectious animal or plant viruses, or defective viruses in the presence of helper virus in tissue culture
4. transfer of DNA into the germline of whole animals, or testing of viable rDNA-modified microorganisms on whole animals
5. rDNA modified whole plants to be used for other experimental purposes or for propagation, or plants to be used together with microorganisms or insects containing rDNA
6. more than 10 liters of culture

Section III-D experiments require IBC notification at the time of initiation; these experiments include those not covered in Sections III-A, III-B, III-C, III-E, and that involve:

1. formation of rDNA molecules containing no more that two-thirds of the genome of any eukaryotic virus
2. whole plants

Section III-E experiments are exempt from the NIH Guidelines and do not require registration with the IBC. These experiments include those that:

1. are not in organisms or viruses
2. consist entirely of DNA segments from a single non-chromosomal or viral source
3. consist entirely of DNA segments from a prokaryotic host, when propagated in that host or transferred to another host by well-established physiological means
4. consist entirely of DNA segments from an eukaryotic host, when propagated in that host

5. consist entirely of DNA segments from different species that exchange DNA by known physiological processes (see Appendices A-I through A-IV)
6. do not present a significant risk to health or the environment (also see Appendix C)

Section III also describes containment conditions for broad categories of experiments. The specifics of containment conditions are found in the Appendices to the Guidelines (described below).

Section IV specifies the responsibilities of those conducting research. These include the Institution, the IBC, the Biological Safety Officer, and the Principal Investigator (PI). The Guidelines freely acknowledge that all conceivable experiments cannot be foreseen and that it is the responsibility of the experimenting institution to adhere to the intent of the Guidelines, as well as their specifics. The Guidelines state, "Motivation and good judgement are the key essentials to protection of health and the environment." Of particular relevance to these rules is the requirement that the PI make the initial determination of the required levels of physical and biological containment in accordance with the Guidelines. Section IV also specifies the responsibilities of the NIH Director, the RAC, and the ORDA. Section IV encourages voluntary compliance with the Guidelines among those institutions, particularly private sector organisations that are not otherwise required to comply.

Section V contains footnotes and references to sections I-IV.

Appendices A through F classify different microorganisms on the basis of hazard.

Appendix G describes in detail four containment levels, known as Biosafety Levels, ranging from Biosafety Level 1 (suitable for work involving agents of minimal potential hazard) through Biosafety Level 4 (for those microorganisms that are among the most hazardous).

Appendix H describes shipping requirements.

Appendix I describes biological containment.

Appendix K describes three levels of physical containment for large-scale uses of microorganisms.

Appendix M provides information regarding human gene therapy protocols.

Appendix P specifies physical and biological containment conditions and practices for experiments involving rDNA containing plants and plant-associated microorganisms.

Appendix Q outlines containment procedures for research involving animals.

III. Biosafety Levels

The NIH Guidelines specify a Biosafety Level appropriate for experiments that use various types of rDNA organisms. Biosafety Levels are different levels of physical containment achieved by a combination of laboratory practices, containment equipment, and lab design. Different combinations of these elements can be used to achieve a given Biosafety Level. In addition, the level of biological containment afforded by the host-vector system used in the experiment should be considered. The following section presents a brief listing of the practices, equipment and facilities appropriate for each level. More complete information is contained in Appendix G of the Guidelines.

Biosafety Level 1

Standard Practices

1. access is limited (at discretion of director) when experiments are in progress
2. work surfaces are decontaminated daily and after spills
3. contaminated liquid and solid wastes are decontaminated before disposal
4. only mechanical pipeting devices are used
5. no eating, drinking, smoking, cosmetic application, or food storage in the lab
6. personnel wash hands after handling rDNA materials and before leaving the lab
7. procedures are performed to minimize aerosol formation
8. lab coats are recommended

Special Practices

1. materials to be decontaminated elsewhere should be sealed in a leakproof container
2. an insect and rodent control program is in effect

Containment Equipment

(not generally required for BL1)

Lab Facilities

1. lab should be easily cleaned
2. bench tops are chemical resistant and waterproof
3. lab furniture is sturdy; spaces are accessible for cleaning
4. a hand washing sink is available
5. open windows have fly screens

Biosafety Level 2

Standard Practices

(same as for BL1 #1-8)

Special Practices

(same as for BL1) plus

1. lab director sets policies for admittance into lab
2. biohazard warning signs and information are posted, if indicated
3. lab coats are worn in lab, and removed before leaving lab
4. animals not involved in the work are not permitted in lab
5. gloves should be worn
6. all wastes from labs and animal rooms are decontaminated before disposal
7. use of needles and syringes is described
8. spills resulting in overt exposure to rDNA organisms are reported to lab director
9. baseline serum samples taken, when appropriate
10. a biosafety manual is prepared or adopted, read, and followed

Containment Equipment

1. biological safety cabinets (Class I or II) or other personal protective or containment devices are used during large-scale procedures or if likely to create aerosols

Lab Facilities
(same as for BL1 #1-5) plus
1. an autoclave is available

Biosafety Level 3

Standard Practices
(same as for BL1 #2-8) plus
1. no one under age 16 may enter the lab

Special Practices
(same as for BL1 and BL2 #1 and 2) plus
1. lab doors are kept closed during experiments
2. all activities involving rDNA organisms are conducted in biosafety cabinets or other containment devices; no work in open vessels on the open bench
3. work surfaces in safety cabinets or containment devices are decontaminated when work is finished
4. lab clothing (scrub suits, coveralls, wraparounds) is worn in the lab, is not worn outside the lab, and is decontaminated before laundering
5. gloves are to be worn
6. animals and plants not related to the work are not permitted in the lab
7. in animal rooms, surgical masks or respirators are to be worn; housing is specified
8. all wastes from labs and animal rooms are decontaminated before disposal
9. vacuum lines have filters and traps
10. use of needles and syringes is described
11. spills are reported
12. baseline serum samples are taken
13. a biosafety manual is prepared or adopted, read, and followed

Containment Equipment
1. biological safety cabinets (Class I, II, or III) or other personal protective or containment devices are used for all activities with rDNA organisms that may create aerosols

Lab Facilities
1. lab is separated from open areas by a double door
2. interior surfaces are water resistant and sealable
3. bench tops are chemical resistant and waterproof
4. lab furniture is sturdy and can be cleaned around
5. hand washing sink is foot, elbow, or automatically operated
6. windows are closed and sealed
7. access doors are self-closing
8. an autoclave is available, preferably within the lab
9. airflow is controlled by ventilation system
10. discharge of biological safety cabinet exhaust is described

Biosafety Level 4

Standard Practices
(same as for BL1 #2, 4, 5, and 7)

Special Practices
(same as for BL1 #2, BL2 #2) plus

1. viable or intact materials removed from a Class III cabinet or a maximum containment lab are double packaged and passed through disinfectant dunk tank, fumigation chamber, or airlock; all other materials are autoclaved or decontaminated before leaving the facility
2. only required personnel are allowed in the facility; doors are locked; a logbook of entry and exit is maintained
3. entry and exit is through clothing change and shower rooms; personnel shower every time they leave
4. complete lab clothing is worn; used clothing is stored in the inner change room
5. all supplies are brought in through a double-door autoclave, fumigation chamber, or airlock
6. nonessential materials are not permitted in the facility
7. use of needles and syringes is described
8. written records are kept of accidents, exposures, and absenteeism; a quarantine and medical care facility is available
9. animal cages are kept in Class III cabinets, or if other specified units are used, personnel must wear one-piece positive pressure suits

Containment Equipment

1. all procedures are conducted in Class III cabinets, or in Class I or II cabinets in conjunction with one-piece positive pressure suits equipped with life-support system

Lab Facilities

1. the facility is a separate building or clearly demarcated, isolated zone within a building; outer and inner change rooms are separated by a shower; a double-door autoclave, etc. is available
2. walls, ceiling and floor form a sealed shell that is insect and animal proof; surfaces are sealed; drains have traps; ventilation is filtered
3. fixtures are arranged to minimize horizontal surfaces; bench tops are seamless
4. a foot, elbow or automatically operated hand washing sink is near the door of each lab
5. the vacuum system is self-contained and filtered
6. doors are self-closing and lockable; windows are breakage resistant
7. all liquid effluents (sinks, cabinets, floor drains, autoclave) are decontaminated by heat before release; liquid waste from showers and toilets may be chemically decontaminated
8. ventilation is separate, maintained at negative pressure, and monitored with alarms.

Appendix 15

Model Guidelines Project: Analysis of the Biosafety Guidelines

Group _____

Title				
Legal Basis				
Objectives				
Scope	Materials		Activities	
National Biosafety Committee	Membership		Duties / Responsibilities	
	Operating procedures			
Application Process	Entry point		Data requirements	
Review Process	Guiding Principles		Access to technical expertise	
	Role of Applicant		Operating Procedures	
	Sequence of Events Apply – review -		Confidential information	
	Conflict of interest Not mentioned	Time points Not mentioned	Output	
Record-keeping	Who Nothing	What		
Mechanisms for Stakeholder Involvement				
Mechanisms for Public Information, Input				
Compliance, Enforcement and Penalties	Nothing mentioned `			
Other Significant Features	▪ Three stages defined but not clear at what information is required at these stages ▪ Much of the information requested does not directly apply to safety			

What infrastructure is needed?

Where will costs be incurred?

Appendix 20

Risk Assessment Case Study #2:
Application to Field Test Bt Cotton

What are the objectives for assuring a safe field trial?
What biosafety issues are raised in this application?
What role does the scale of the release have on biosafety questions and objectives?
What primary effects might these plants have on the local environment? What secondary effects?
Is pollen spread outside the test plot a potential risk? Explain. If so, how can the risk be reduced to an acceptable level?
Will the seed from these plants be GM? How will it be handled?
Should the release plan include an area designated as a refuge? Explain.
Will the GM cotton bolls require special handling?
What clean-up procedures should be used at the end of the trial?
Are these measures appropriate to the level of identified risk? How or how not?
Should the site be monitored in the next growing season? For what? For how long?
Is the Bt toxin expressed in these plants active against other local pest species? Is this a biosafety issue at this test scale?
Other
Other
Other
Other

Appendix 22

Model Guidelines Project: Limited Field Trials

Group _____

Objectives and scope of Guidelines	
Roles and Responsibilities	
Administrative Procedures for Handling Applications	
Record- keeping	
Reporting	
Site Security	
Access	
Transport to and from Field	
Marking and Identification	
Guidance for Reproductive Isolation	
Termination and Clean-up	
Storage	
Inspection for Compliance	
Post-Trial Monitoring	
Contingency Planning	
Enforcement Measures	
Time lines	Response to Application within 6mts of receipt to the NBC Field trial
Staff training	This will be the responsibility of the principal investigator

Appendix 28

Risk Assessment Case Study #3

Application to Field Test Bananas with a Vaccine

Safety issues

- Would it be better to do this trial in a greenhouse? Why or why not?
- How will the site be protected from casual pilfering of bananas for human consumption? Are these measures adequate? Explain.
- Is pollination a potential problem? If so, is it satisfactorily minimized?
- What will happen to the plants and the site after the trial? Are these measures adequate? Explain.
- What, if any, monitoring of impact on soil organisms should be conducted during the trial?
- At what point can the project leader sample one of the bananas for taste?
- Looking ahead, what measures could be taken to ensure that the GM bananas are not mixed with or mistaken for conventional bananas?

Non-safety issues

- What is the existing drug approval process? How applicable are the regulations to pharmaceuticals produced in plants?
- How will the distribution of vaccine-containing bananas be accomplished?
- Will farmers get a premium price for growing such high-value fruit?
- Who bears responsibility if a child eats six of these bananas?

Appendix 33

EFB Task Group on Public Perceptions of Biotechnology

Dealings With the Media

The media world, in which journalists work, is very different from the world of scientific research and even from that of scientific communication through journals and conferences. So while scientists and biotechnologists can collaborate effectively with journalists, such collaboration needs to be based on mutual understanding. Unrealistic attitudes on either side can be a recipe for dissatisfaction, or worse.

The purpose of this briefing paper is to explain, particularly for scientists working in biotechnology, how the media operate. It shows how specialists and journalists can work together in ways that are constructive and may be mutually beneficial. This briefing paper therefore differs from most others in the series, which aim to review in a balanced way the various areas of biotechnology together with their related issues and implications.

What do the media want?

Newspapers and magazines, radio and television companies, receive a vast quantity of material every day of the year. It comes in many different forms. These include announcements from companies, government departments, research institutes and other bodies; material from national and international news agencies (Reuters, for example); and releases from public relations firms representing their clients' interests. The lay media also gain ideas from specialised publications such as Nature and other major journals of science. Sheer pressure on space and broadcasting time means that journalists can use only a tiny proportion of the information they receive through these various channels. How, then, do they choose what to cover?

Journalists and their gate-keepers (see below) are receptive to novelty. Significant developments in science and technology for example, major advances in the treatment of a particular disease provide many examples of such novelty. As well as developments with concrete applications now or in the future, the media report discoveries that are simply inherently interesting. So while much "normal research" goes unreported, developments with practical implications for, say, medicine or agriculture will attract journalistic attention. The same is true of discoveries that are counter-intuitive or have an element of the unexpected.

The general media also feed off each other to a surprising degree, and they work to unwritten menus of topics that appeal to them at any one time. Stories about environmental pollution, for example, may be keenly sought this year but may be less popular with journalists and their editors next year. In engaging the interest of the media, it is helpful to be aware of what subjects are currently favoured on their agenda. Some of the most skillful initiatives in "placing" stories in the media are taken by people who see opportunities for providing new angles on stories that are already running strongly.

There is fierce competition within the media. Newspapers, for example, compete for readers and for advertising revenue. Nevertheless, their science correspondents often work closely together, attending many of the same conferences and discussing what they are planning to report. Many journalists also have an appetite for occasional "exclusive" stories which, if they are considered to be sufficiently important, their competitors will then have to follow up.

Journalists and their gate-keepers

Journalists dealing with fields such as biotechnology do not work in isolation. Like their peers in other areas, they work to agendas that are determined by "gate-keepers" in newspaper, magazine and broadcasting offices. News Editors in newspapers, for example, largely determine the topics which they believe we all, as readers and listeners, wish to know about. The space allotted to any one topic can also change, even between one edition of a newspaper and the next, as other news breaks and is given higher priority.

The majority of major newspapers in Europe employ a Science Editor. Many of these have a first degree in science, and some a PhD, while others have specialised after being general reporters. Like local newspaper journalists, general reporters (who also cover science and technology) can be expected to have little or no background knowledge on the topics they cover. However, both science editors and general reporters need to "sell" their ideas for news stories to a News Editor, who in addition will ask them to cover stories that have been initiated through other channels.

Features Editors are responsible for the longer "feature" articles in newspapers and magazines. Many of them welcome timely suggestions from outside contributors for example, a proposal for a review of hay fever and its treatment from a specialist in this area. Such proposals should be made well in advance not only for the idea to be considered and the article commissioned and written, but also for it to appear in sufficient time for readers to make use of information it contains. There are numerous opportunities for scientists and their organisations to be pro-active in this way though many are unaware of such openings, or believe (wrongly) that the media will not be interested in such proposals.

Radio and television

Broadcasting channels are like newspapers in having news-rooms to monitor the news. Science specialists, based in those news departments, provide appropriate coverage for news bulletins. They also work for current affairs programmes, responding to requests from their Editors.

Although precise titles vary in different parts of the broadcasting world and in different countries, the Editor is usually the person in overall charge of weekly and other regular science programmes, with one or more producers responsible for individual programmes in the series.

The Editor principally sets the agenda, though particular producers may be especially interested in specific topics within the general field covered by the programme. In radio, presenters often work closely with their producers in making editorial decisions. Local radio programmes, like local newspapers, are always keenly interested in stories with a local angle.

In most countries, independent production companies are now responsible for a substantial proportion of "dedicated" science programmes.

As with the print media, editors and presenters of programmes dealing regularly with science, medicine and applied disciplines invariably welcome suggestions about topics they may care to cover. Again, they are keenly interested in "pegs" on which to hang a story, so as to give an idea topicality. Examples of pegs are the publication of a paper in a major journal, the appearance of a report with public interest and the anniversary of an event such as a great

discovery or the birth or death of a famous scientist. To be of use, contacts regarding topics and pegs of this sort need to be made weeks and preferably months in advance.

Dealing with journalists

Journalists, and certainly those dealing with news, are invariably in a hurry. For those working in newspapers and broadcasting, this haste is entirely genuine. They may well be pursuing several stories in a single day, against the clock. But rapidity is also built into the media culture, so that anything (an interview, a photograph...) tends to be wanted instantly.

There are also more practical considerations if your story or message is to appear in the media when you want it too and if at all. Newspapers usually have two internal news conferences to determine what will be in the paper the next day. If a press release misses the early evening conference, your story is unlikely to make it to print the next day unless it really is important. The best time of the day to contact a news desk is early to mid morning, yet this may not be suitable for an evening paper or a lunchtime radio or television news bulletin. The shelf life of a story is also painfully short: a long term research project releases its result on a Friday afternoon; by the time of the next possible major news outlet on Monday, it will be considered old news and unlikely to get a place in the schedule. Afternoon press conferences are not a good way of getting communications into the media, and especially not on a Friday.

In reality, while journalists greatly appreciate an immediate response, it is perfectly reasonable that anyone approached by a reporter should ask for time to consider the request and how to respond.

If a journalist approaches you, in person or by telephone, make sure from the outset that you really understand what they want, what publication or programme they represent and how they propose to use any comments you make. In the case of radio and television, you should find out whether a proposed interview will be live or recorded, what is the format of the programme and who else will be taking part.

Even if you are satisfied on these points, you may want to collect your thoughts. Ask the caller to ring back in 20-30 minutes. Alternatively, say that **you** will return the call but be absolutely sure that you do so. During the interim, you can also consult colleagues. Press officers in companies, universities and elsewhere can also be invaluable in providing guidance about particular journalists, publications and programmes and their past track-record.

In the long-term, some scientists find it mutually rewarding to become acquainted with individual journalists who deal with scientific issues, whether nationally or locally. While this should certainly not provide automatic channels through which to gain media publicity, such relationships can be of value to both parties and increase mutual confidence.

Being interviewed

There are several scenarios in which you may find yourself dealing with the media. These range from a scientific conference at which you are delivering a paper, to a telephone call from a journalist asking about your own work or seeking guidance about some development in your field. If there is a choice, it is more satisfactory and reassuring to meet a journalist face-to-face than to respond to a voice on the telephone. Paradoxically, some of us are more easily tempted on the telephone into saying more than we would have wished.

A scientist may, on very rare occasions, be best advised not to speak to a journalist at all for example, one who has a long record of serious misrepresentation. There are obvious dangers

in declining an interview, however. Bear in mind too that it is entirely reasonable that a journalist should wish to talk to you. Be very cautious about total refusal.

If you are tempted to decline an interview simply because you are busy and can scarcely spare the time, remember that the journalist will go elsewhere. He or she may turn to someone who is less qualified to speak with real authority on the subject. Either way, you may wish to seek guidance from a press officer in your institute, company or university.

Even when you are speaking to specialist reporters who cover areas such as science and medicine regularly, remember that terms and ideas which are very familiar to you may be new to them and thus require careful explanation. A general reporter will know very little science at all. So do not assume much knowledge on the part of the interviewer, and do not worry about "talking down" to a journalist. It is far better to do this than to use technical jargon without any explanation. Choose commonplace words wherever possible. If technical terms are unavoidable, explain them perhaps using metaphors or analogies to get over difficult concepts.

Keys to a Successful Interview or Statement:

- Be well briefed
- Plan the points you wish to make and your responses to standard questions and arguments
- If you are in doubt, be prepared to say "I don't know"
- Be as open as possible and never lie
- Do not say "No comment", there is always something more useful which can be said
- Show concern if there is a genuine problem
- Show your organisation is addressing the situation or issue
- Be as positive as possible without sounding callous and uncaring
- Beware of admitting liability
- Have a list with contact details of trained spokes-people available to make statements on specific questions

Remember that a journalist is unlikely to stick solely to technical matters. He or she may also pose questions about the funding of your research, the repercussions of biotechnology for consumers or its implications for exports or imports. In preparing for the interview, think about the questions a reader or listener would expect to be raised and to have answered.

The most satisfactory basis for an interview from the standpoint of both parties is "on the record". This means that the journalist can use and quote anything that you say. But there may be occasions when you prefer to conduct an entire interview, or part of it, "off the record" or "non-attributably". It is important to reach an unambiguous agreement **in advance** about the conditions of the interview. 99 journalists out of 100 **will** respect any form of confidence you agree. Never use the expression "No comment". There is always something less evasive that you can say.

If you are working in collaboration with a company or institute other than your own, as part of a joint research project, you must discuss journalistic enquiries and requests for interviews with your partner organisation and agree on what you will say.

Appearing on radio or television

Some scientists, even those with initial anxieties, prove to be natural performers on radio and television. Others fare less well. Television is a particularly demanding medium, especially in the unfamiliar environment of the studio. There are some dependable pieces of advice that are usually helpful. Be prepared be absolutely clear about what you want to say and what is the purpose of your appearance. Always try to be positive. Never be angry or dismissive towards

an interviewer, however difficult this may be, because there is a danger that this will alienate viewers or listeners.

While these guidelines are useful, practical experience is much more so. For those whose work and/or position in biotechnology mean that they are likely to be approached at any time for a broadcast interview, practical training is invaluable, especially for television. When embarking on media training, make sure that you are in the hands of people who currently work, or have very recently worked, in the medium. Some courses of this sort are run by trainers who themselves have had little or no practical experience in television or radio. They are scarcely likely to be in a good position to advise you.

A key question about a radio or television appearance is whether it is recorded or live. Each has its advantages and disadvantages. While some people are more nervous about a live interview, others appreciate the opportunity to say exactly what they wish to say, without any possibility that their words will be edited before transmission. Remember that, **in a news or current affairs programme**, the interviewer may wish you to crystallise your viewpoint/comments in a "sound bite" of at most 30 seconds. Remember too that, as with public speaking, a little nervousness actually helps.

Can I check the copy?

If you help a journalist who is writing a **news** story, it is not usually realistic to expect to see and approve the final text. There is usually insufficient time, and the copy may well be edited much later in the day when it is beyond the writer's control, let alone your influence. However, journalists are usually willing, in the interests of accuracy, to phone you back to check any quotes they wish to use. This can be part of your agreement with them beforehand. Remember that, while such quotes should be accurate, they cannot carry all of the fine distinctions which are appropriate to statements made in a paper in a learned journal.

It is much more realistic to expect to see a text, or a rough-cut of a programme, if you are dealing with a journalist who is working on a longer time-scale. Examples include a writer preparing a feature article for a magazine or newspaper and a radio or television journalist making a documentary. Again, ensure that you agree on this beforehand. Writers and producers will always be grateful to you for correcting blatant inaccuracies. They do not wish to be seen to be making mistakes.

Will I be paid?

Newspapers and magazines do not usually pay for interviews, whereas radio and television programmes may offer a fee or respond positively if asked for one especially if they wish to take up a substantial amount of your time. However, there are no universal rules. On the one hand, you can reasonably expect to receive a modest fee if you are asked to go into a radio studio for a live or recorded interview. On the other hand, a television news crew may want to come to your laboratory and, despite the inevitable disruption, film you with no payment whatever. You will then have to weigh the time and inconvenience against the attendant benefits in publicity. There is often some flexibility for you to receive a fee even when it is not normally offered. Ask at the outset, not afterwards.

Television "researchers" pose particular problems. A researcher is not the producer or editor of a programme but a more junior member of staff who is employed to contact many different experts and develop a programme idea. Helping researchers can be beneficial to an organisation not least on those occasions when a scientist manages to influence a programme, plans for which were moving in some unsatisfactory direction. But dealing with researchers can also turn out to be unproductive. Much will depend upon your personal inclination and

the policy of your institution. Again, press officers can help in resolving a decision about whether to help researchers.

Press conferences and releases

At a formal press conference during a scientific meeting, for example journalists are invited to hear about new developments in research. Such occasions must be accompanied by a "hot-line", open for at least 24 hours, so that journalists unable to attend can phone for information. Before a press conference, a press officer may ask for your help in preparing a "hand-out" a sheet giving key points and the background to the announcement. Written notes of this sort are invaluable, as they are also on other occasions when you are interviewed by an individual journalist. As well as your name and position, a briefing sheet can contain information such as names of organisms and a summary of experimental results. This will be particularly useful for the general reporter who knows virtually nothing about the subject for example, a local newspaper or radio journalist (who may even welcome a short list of key questions that he or she should ask you).

Press releases should also contain information about how to contact the key individual(s) involved who **must** be available to be contacted through telephone or e-mail at the time as indicated. They are usually embargoed, with a date and time before which the contents of the release must not be used. Journals such as Nature issue press releases every week, highlighting key papers in their next issue. Publication of an institute's annual report is another occasion when press releases are used to draw attention to work described in the report.

The importance of effective press releases can hardly be exaggerated. Releases which describe developments of timely interest to journalists, which are clearly written and which contain all of the formal ingredients outlined above, are used far more widely than those which are deficient in these respects. Moreover, a company or institute that issues only well-prepared releases, carrying genuine news, encourages journalists to pay immediate attention to future releases from the same place. Press releases are not usually published verbatim, but they should be written in a style such that they could be when time is extremely short, for example.

Causes of dissatisfaction

There are, inevitably, occasions when scientists feel unhappy about the outcome of their dealings with a journalist in a newspaper article or television programme, or indeed the non-appearance of an article or broadcast item. If this happens to you, first pause and consider exactly why you are concerned. Is it because you gave your time to help with an article or programme that has been aborted? If so, while common courtesy may mean that you had a right to have been informed, there is invariably nothing else to be done. Many articles and radio and TV recordings are never used for logistical reasons quite unconnected with quality.

Again, if you believe that you have been misrepresented in an article or programme, consider carefully **why** you believe this to be so. Do you have a genuine grievance? Or are you really bothered because, for example, too much prominence has been given (in your opinion) to the ideas or achievements of another research group? In the latter case, discuss the matter with a colleague not involved in the work, wait until the next day and if you still feel as strongly, write a letter to the journalist setting out your point of view. This **will** be taken seriously.

In a particularly serious case, and again after talking to colleagues and/or your press officer, it may be appropriate to complain to the editor and/or to send a letter for publication. Even when not published, such letters **are** considered carefully and may well be taken on board when that subject is covered in future. Finally, there are options of reporting the journalist and

publication to the official body in your country that deals with complaints about the press, or to take legal action if you believe that you have been defamed.

Be realistic

Some journalists are sometimes mischievous as are some people in other walks of life. Journalists also make mistakes as do some biotechnologists. Some of them sensationalise new developments as do some biotechnology companies. Yet the vast majority of journalists do not set out to be mischievous, to make mistakes or to sensationalise their material. They work to the best of their ability and especially given the pressures on their time their output is of a high standard. Moreover, writers who specialise in areas such as science, medicine and technology have done so because they are keenly interested in those topics. They need your help, just as you may need theirs.

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The Task Group gratefully acknowledges the continuing support and funding of the European Commission for this and other briefing papers

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Caribbean Biosafety Training Course
Draft Agenda: 12 January 2004

Monday, January 19

SESSION 1. INTRODUCTION AND BACKGROUND

8:30 a.m. Opening Ceremony
Host Organization

10: 00 a.m. **Coffee / Tea Break**

10:15 a.m. **Logistics**
Host Organization

10:20 a.m. **Introduction to the Course**
Dr. Patricia Traynor, New AgriTech Strategies, USA

10: 45 a.m. **Introduction to Biotechnology and Genetic Engineering**
Prof. J. Duncan, Professor Emeritus, University of the West Indies, Trinidad & Tobago

11: 30 a.m. **Biotechnology Applications for the Caribbean**
Dr. P. Umaharan, University of the West Indies, Trinidad & Tobago

12:15 p.m. **Lunch**

1:15 p.m. **The Cartagena Protocol on Biosafety**
Mr. Victor Jordan, Ministry of Trade and Industry

SESSION 2. NATIONAL BIOSAFETY SYSTEMS

2: 15 p.m. **Conceptual Framework for Biosafety Implementation & Management**
Patricia Traynor, New AgriTech Strategies, USA

3:15 p.m. **Coffee / Tea Break**

3: 30 p.m. **Introduction to Model Guidelines Project**
Dr. Hector Quemada, Crop Technology Consulting, USA

4:00 p.m. **End of Day 1**

Tuesday, January 20

8: 30 a.m. **Environmental Safety Concerns in the Caribbean**

Dr. Bibi Ali, CABI

9:15 a.m. **The UNEP-GEF Biosafety Program in Trinidad and Tobago**
Dr. Dave Persad, Ministry of Public Utilities & Environment, Trinidad & Tobago

10: 00 a.m. **Coffee / Tea Break**

10: 15 a.m. **Biotechnology and Biosafety in the Caribbean Region**
a. Trinidad and Tobago:
b. Jamaica:
c. Bahamas:
d. @@:

11: 00 a.m. **Approaches to Biosafety in Developed Countries**
Dr. Hector Quemada, Crop Technology Consulting, USA

11:45 a.m. **Insights from National Biosafety System Studies**
Dr. Patricia Traynor, New AgriTech Strategies, USA

12:30 p.m. **Lunch**

1: 30 p.m. **Risk Assessment Case Study #1**
Greenhouse Experiment: fungus resistant sunflowers
Hector Quemada, Crop Technology Consulting, USA

2:45 p.m. **Model Guidelines for Handling, Transferring and Using Biotech Products from the Lab to the Greenhouse to Limited Field and Extensive Field Trials**
Part 1: Analysis of Existing Guidelines and Regulations

3:15 p.m. **Coffee / Tea (during exercise)**

5: 00 p.m. **End of Day 2**

Wednesday, January 21

SESSION 3. RISK ASSESSMENT AND RISK MANAGEMENT

8: 30 a.m. **The Biosafety Review Process**
Dr. Patricia Traynor, New AgriTech Strategies, USA

9:00 a.m. **Environmental Risk Assessment**
Dr. Hector Quemada, Crop Technology Consulting, USA

9: 45 a.m. **Model Guidelines Project**

Part 2: Procedures in the Lab and Greenhouse

10: 15 a.m. **Coffee / Tea Break**

10: 30 a.m. **Part 2 (continued)**

12: 30 p.m. **Lunch**

1: 30 p.m. **Risk Management in the Lab, Greenhouse and Field**
Dr. Patricia Traynor, New AgriTech Strategies, USA

2: 15 p.m. **Risk Assessment Case Study #2 Field Test: Bt cotton**
Dr. Hector Quemada, Crop Technology Consulting, USA

3:15 p.m. **Coffee / Tea Without Formal Break**

4: 30 p.m. **End of Day 3**

Thursday, January 22

8: 30 a.m. **Risk Assessment Case Study #2 Field Test: Bt cotton**
Dr. Patricia Traynor, New AgriTech Strategies, USA

9: 30 p.m. **Regulatory Realities: Commercial Release of Bt Potatoes in South Africa**
Dr. Hector Quemada, Crop Technology Consulting, USA

10:00 a.m. Coffee Break

10: 15 a.m. **Model Guidelines Project**
Part 3: Conducting Limited Field Trials

12: 30 p.m. Lunch

1: 30 p.m. **Part 3 (continued)**

3: 00 p.m. **Coffee / Tea Break**

3: 15 p.m. **Biotechnology and Biosafety in the Caribbean Region**

a. Barbados:
b. Dominica:
c. St Kitts & Nevis:
d. St Lucia:

4: 15 p.m. **End of Day 4**

Friday, January 23

SESSION 4. FOOD SAFETY

8: 30 a.m. **The CA standards for GM Food**
Dr. W. Hollingsworth,

9: 15 a.m. **Putting Risks of Genetically Engineered Foods in Perspective**
Dr. Hector Quemada, Crop Technology Consulting, USA

10: 00 a.m. **Coffee / Tea Break**

11:00 a.m. **Practical Considerations for Traceability and Food Labeling**
Dr. Hector Quemada, Crop Technology Consulting, USA

12: noon **Lunch**

1: 00 p.m. **International Trade Agreements and Obligations**
Mr. Victor Jordan, Ministry of Trade and Industry

1: 45 p.m. **Panel Discussion: Trade with Canada and the USA**
Chair: Mr. Victor Jordan, Ministry of Trade and Industry

3:00 p.m. **Coffee / Tea Break**

3: 15 p.m. **Biosafety & Gender**
Dr. Grace Sirju-Charran, University of the West Indies, Trinidad & Tobago

4: 00 p.m. **End of Day 5**

Monday, January 26

SESSION 5. DECISIONS AND DECISION MAKING

8: 30 a.m. **Regulatory Decision Making**
Dr. Patricia Traynor, New AgriTech Strategies, USA

9:15 a.m. **Risk Assessment Case Study #3**
Field Test: Bananas containing a vaccine

10: 15 a.m. **Coffee / Tea Break**

11: 30 a.m. **Plenary on Field Test: Bananas containing a vaccine**

12: 30 p.m. **Lunch**

1: 15 p.m. **Plenary Exercise 1: Regulatory Decision Making**
Dr. Patricia Traynor, New AgriTech Strategies, USA

3:00 p.m. **Coffee / Tea Break**

3: 15 p.m. **Plenary Exercise 2: Decision Documents for Bt Cotton**

5: 00 p.m. **End of Day 6**

Tuesday, January 27

SESSION 6. BIOSAFETY COMMUNICATION

8: 30 a.m. **Video Presentation: *'Harvest of Fear'***

10: 00 a.m. **Coffee / Tea Break**

11: 00 a.m. **Safety and Non-Safety Issues in Biotechnology**
Dr. Patricia Traynor, New AgriTech Strategies, USA

11: 45 a.m. **Public Awareness and Attitudes in Trinidad and Tobago**
Ms. Stevens and Ms Ravelo, Consumer Affairs Division, Trinidad & Tobago

12: 30 p.m. **Lunch**

1: 30 p.m. **Communicating about Risk and Biosafety**
Dr. Patricia Traynor, New AgriTech Strategies, USA

2: 15 p.m. **Working with the Media**
Mr. Tony Fraser, Freelance Journalist

2: 45 p.m. **Coffee / Tea Break**

3:00 p.m. **Group Activity: Meet the Press**

4:00 p.m. **End of Day 7**

Wednesday, January 28

8: 30 pm **Biodiversity in the Caribbean**
Yasmine Comeau, National Herbarium, Trinidad and Tobago

10:00 am **Coffee / Tea Break**

10:15 am **Model Guidelines Project: Part 4: Commercial Release**

12: 30 pm **Lunch**

1:30 pm	**Australian Risk Assessment Case Study: Bt Cotton**
3:00 pm	**Coffee / Tea Break**
3:15 pm	**Australian Case, continued**
5: 00 pm	**End of Day 8**

Thursday, January 28

SESSION 7. REGIONAL HARMONIZATION

8:30 am	**Harmonization of Biosafety Systems** Dr. Cyril Roberts, Caribbean Agricultural Research Institute, Barbados
9:00 am	**Working Group Exercise: Harmonisation of Biosafety Systems Priority Areas for Harmonization**
10: 00 am	**Coffee / Tea Break**
10:15 am	**Harmonization Exercise: Priority Areas, continued**
11:00 am	**Reporting to Pleanry**
12: 00 pm	**Harmonisation of Biosafety Systems: Implementation**
12:30 pm	**Lunch**
1:30 pm	**Harmonization Exercise: Implementation continued**
2:30 pm	**Reporting to Plenary**
3:00 pm	**Coffee / Tea Break**
3:15 pm	**Case Study: Transgenic Anthurium** Dr. Path Umaharan, University of the West Indies
4:00 pm	**Open Discussion**
5:00 pm	**End of Day 9**

Friday, January 28

8:30 am	**Model Guidelines Project: Part 5: Synthesis and Review**
10: 00 am	**Coffee / Tea Break**
10: 15 am	**Model Guidelines Synthesis and Review, continued**
12: 00 pm	**Lunch**
1:00 pm	**Course Evaluation**
1: 30 pm	**Closing Ceremony**
2:00 pm	**Departure**

Survey & Scoping Issues Analytical Report:

Key Research Areas in the Caribbean

January – March 2004

This work was carried out with the aid of grant from the International Development Research Centre, Ottawa, Canada

Scoping Issues: Key Research Areas in the Caribbean

This survey was an adaptation of a questionnaire, which was developed by the International Development Research Centre (IDRC) in order to identify and characterise the most relevant opinions to develop a research agenda on biotechnology applied to genetically modified organisms (GMO) production in agriculture in Latin America societies. The objective of this survey was to gather information on the same issues as are pertinent to the Caribbean.

The questionnaire was administered at the **Capacity Building Workshop on Biosafety for the Caribbean, Trinidad, on the 19-30 January 2004**. The workshop was organised by the National Institute of Higher Education, Research, Science and technology (NIHERST) with funding from the International Development Research Centre (IDRC), the Caribbean Council for Science & Technology (CCST), the United Nations Development Programme through its Perrez Guerrero Trust Fund, the Technical Centre for Agricultural and Rural Co-operation ACP-EU (CTA), the Caribbean Agricultural Research and Development Institute (CARDI) and Commonwealth Secretariat. It was also requested that participants assist in contacting and disseminating the questionnaire to a wider number of experts/specialists in the region.

Thirty-two (32) survey questionnaires were returned from the original list of fifty-two (52) participants, indicating a high level of interest among workshop participants. Through participant assistance five (5) additional questionnaires were further received from specialists in the Caribbean. In order to encompass a variety of perceptions, emphasis was placed on having surveyed participants represent different institutional scenarios and Caribbean countries.

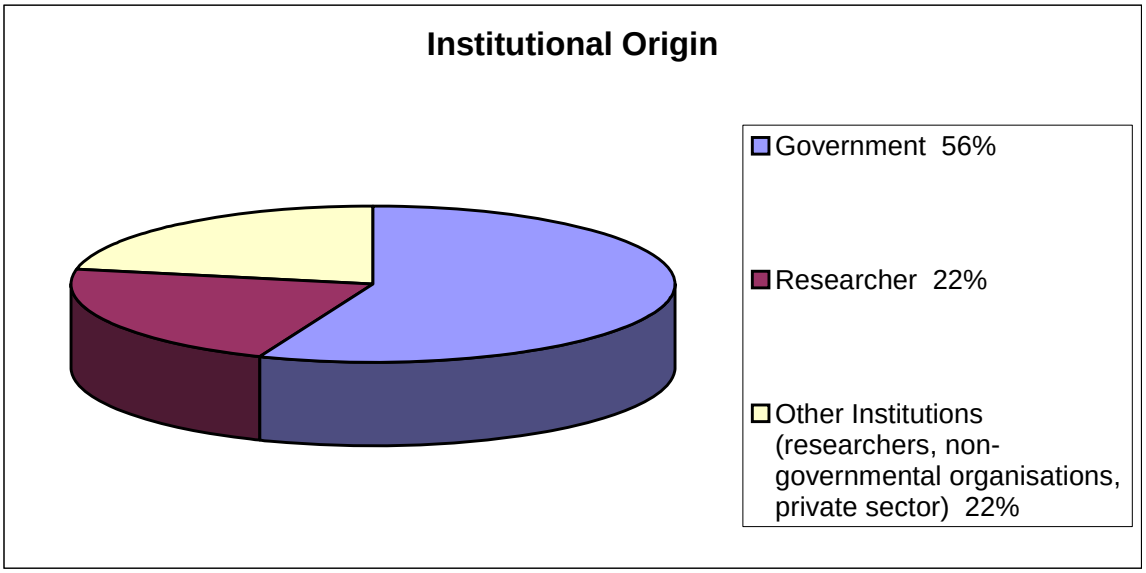
Participants came from different countries through out the Caribbean region. The majority of the returned surveys were from Trinidadians (51%) while the remaining 49% were from nationals of Jamaica, Grenada, Barbados, Saint Vincent, Antigua, Bahamas, Guyana and Saint Lucia. Workshop participants were also from different institutional scenarios. Governmental organisations made up 56% of informants, both researchers and other institutions (researchers, non-governmental organisations, private sector) accounted for 22% each of the informants.

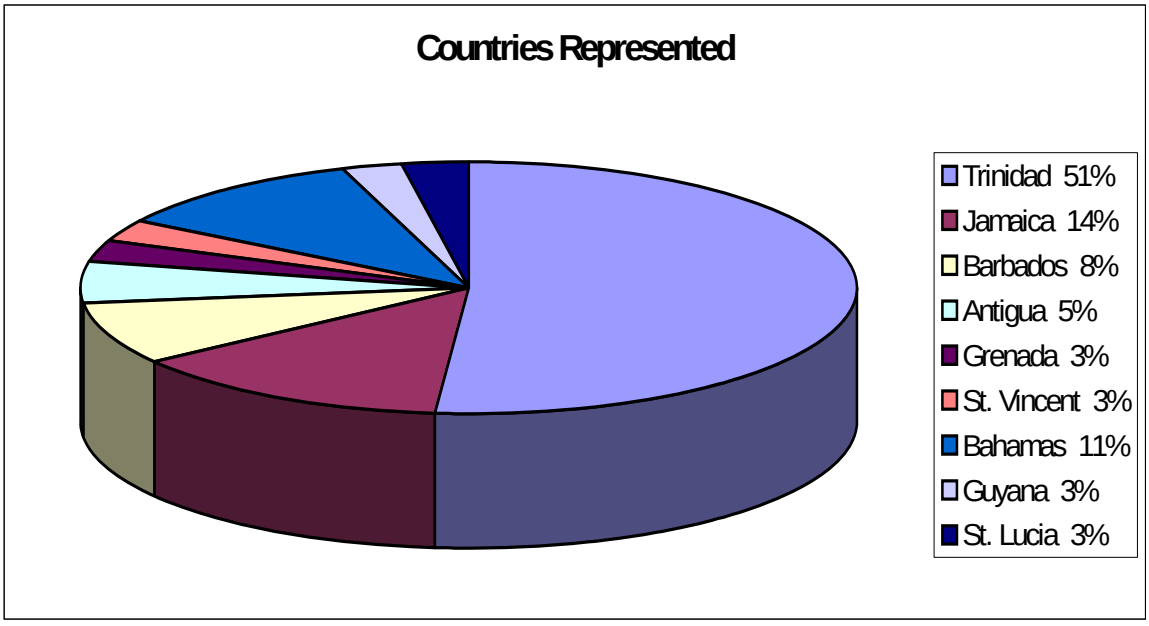
An attempt was made at separating informants according to their institutional origins that divides them into three groupings: Government institutions on one hand, academic researchers on other hand, and other institutions on another.

The purpose of this survey was to identify and characterise the most relevant opinions to develop a research agenda in biotechnology applied to the production of genetically modified organisms (GMOs) in agriculture in the countries of the Caribbean. This survey allowed research issues to be ranked and to identify the perceptions on the effects that applied biotechnology may have on Caribbean societies.

Analysis of quantitative results

Informants' Profile





General Results

The analysis of general results is based on the thirty-seven (37) surveys returned by the Caribbean regional specialists and non-specialists on the subject. The items evaluated on each line of the questionnaire have been ranked on a scale of 1-5, which represents:

1-Very Low 2-Low
3-Medium 4-High
5-Very high

The information presented on all tables is in the shape of percentage distribution of frequency of answers and presentation scales mean.

TABLE #1

Q1. How would you rate your level of experience on the following aspects related to biotechnology applied to the production of GMOs in agriculture in the region?
(Scale 1 to 5: 1 = very low and 5 = very high)

	1	2	3	4	5	No data	Total	Mean
Institutional aspects (actors, human resources, S&T systems, research, etc.)	22	27	24	24	3	0	100	2.59
Economic aspects	35	30	27	8	0	0	100	2.08
Biotechnology applied to agriculture in the Caribbean	19	27	22	24	8	0	100	2.75
Biotechnology applied to agriculture in Latin America	38	24	22	8	8	0	100	2.24
Political and legal aspects	30	32	22	11	0	2	100	2.04
Social aspects (public perception, social organisations and movements, mass media, etc.)	11	22	51	11	3	1	100	2.67
Environmental and sanitary aspects	14	19	43	19	5	0	100	2.82
Ethic aspects	27	22	35	14	3	0	100	2.47

There are no topics on which all informants have either absolute unfamiliarity or a vast comprehension as is demonstrated in Table #1. The region has a small pool of individuals with knowledge in all subject areas. The majority were acquainted with specific knowledge in their field of work. The level of experience is low particularly in regards to political, legal and economic aspects. The informants felt they had a little more experience in environmental and sanitary aspects, followed by biotechnology applied to agriculture in the Caribbean.

Table #2

Q2. Please indicate the importance you give to the following areas in developing a research agenda on biotechnology applied to the production of GMOs in agriculture in the region.
(Scale 1 to 5: where 1 = not important, 2 = a little important, 3 = relatively important, 4 = fairly important and 5 = very important)

	1	2	3	4	5	No data	Total	Mean
The relationship among actors involved (academia, governments, NGOs, companies, consumers, etc.)	0	0	3	16	81	0	100	4.78
Training of human resources	0	0	0	16	84	0	100	4.84
The role of science, technology and innovation systems	0	0	5	14	81	0	100	4.76
Biotechnology and natural resources	0	0	0	14	87	0	100	4.91
Biotechnology and biodiversity	0	0	0	11	87	1	100	4.79
Biotechnology and human health	0	0	0	22	78	0	100	4.78
Biotechnology and bio-safety	0	0	0	16	84	0	100	4.84
Public opinion and biotechnology	0	0	11	22	68	0	100	4.61
Research and development funding	0	0	22	19	59	0	100	4.37
Consumers and biotechnology	0	0	8	41	51	0	100	4.43
Funding the introduction of new biotechnologies	0	5	22	27	35	0	100	3.59
Mass media and biotechnology	0	0	11	35	54	0	100	4.43
Threats and opportunities of biotechnology in relation to the environment	0	0	0	19	78	1	100	4.66
Relation between national legal systems and biotechnology development	0	0	3	38	57	1	100	4.46
Small and medium-sized producers and biotechnology	0	5	27	16	49	1	100	4
Ways to apply biotechnological breakthroughs in food production processes	0	0	19	27	51	1	100	4.2
Ethical implications of biotechnology	0	3	14	35	46	1	100	4.18
Relations between biotechnology and macro-economic aspects in countries (competitiveness, GDP, etc.)	0	0	16	38	43	1	100	4.15
International companies and industries and biotechnology	0	8	30	27	32	1	100	3.74
Relations between political systems and the development of biotechnology	0	14	27	27	32	0	100	3.77
The impact of biotechnology on the less privileged groups (women, indigenous populations, small producers, etc)	3	0	19	22	57	0	100	4.33
Relationship between biotechnology and regional integration	0	8	16	38	38	0	100	4.06
Social movements in favour and social movements that reject it	3	5	32	38	22	0	100	3.71
Biotechnology and climate changes	5	11	22	27	35	0	100	3.76
Biotechnology and population growth	3	11	24	19	43	0	100	3.88

On average informants evaluated all topic areas as relatively important to very important. Biotechnology and natural resources (4.91), biotechnology and biosafety (4.84) and training of human resources (4.84) were the subjects participants considered most important. However not all institutional and technological subjects reflect such high importance. Funding the introduction of new biotechnologies (3.59) appeared as least important, while International compaines and industries and biotechnology (3.74), Social movements in favour and social movements that reject it (3.71) and biotechnology and climate change (3.76) also appeared as less important in comparative terms but worthy of consideration in absolute terms.

Table 2.1

	Thematic Family	**Mean**
The relationship among actors involved (academia, governments, NGOs, companies, consumers, etc.)	Institutional	4.78
Training of human resources	Institutional	4.81
The role of science, technology and innovation systems	Institutional	4.72
Biotechnology and natural resources	Technological	4.92
Biotechnology and biodiversity	Technological	4.72
Biotechnology and human health	Technological	4.75
Biotechnology and bio-safety	Technological	4.84
Public opinion and biotechnology	Socio-economic	4.57
Research and development funding	Institutional	4.28
Consumers and biotechnology	Socio-economic	4.38
Funding the introduction of new biotechnologies	Institutional	3.39
Mass media and biotechnology	Socio-economic	4.41
Threats and opportunities of biotechnology in relation to the environment	Technological	4.63
Relation between national legal systems and biotechnology development	Socio-economic	4.38
Small and medium-sized producers and biotechnology	Socio-economic	3.92
Ways to apply biotechnological breakthroughs in food production processes	Technological	4.19
Ethical implications of biotechnology	Socio-economic	4.11
Relations between biotechnology and macro-economic aspects in countries (competitiveness, GDP, etc.)	Socio-economic	4.14
International companies and industries and biotechnology	Socio-economic	3.54
Relations between political systems and the development of biotechnology	Socio-economic	3.79
The impact of biotechnology on the less privileged groups (women, indigenous populations, small producers, etc)	Socio-economic	4.22
Relationship between biotechnology and regional integration	Socio-economic	4
Social movements in favour and social movements	Socio-economic	3.63

that reject it		
Biotechnology and climate changes	Technological	3.65
Biotechnology and population growth	Technological	3.88

No distinct trend was expressed with regards to importance of thematic "families"- institutional, socio-economic and technological. Informants of the Caribbean region seemed to view topics of various "families" as connected and impacting on one another. Therefore, two topics within thematic "families" can be considered with different levels of importance.

Table #3

Q3. To what extent do you think the aspects listed below represent or could represent elements that block, facilitate or are neutral in terms of biotechnology applied to the production of GMOs in agriculture in the Caribbean?
(1 = obstacle, 2 = neutral and 3 = facilitator)

	1	2	3	No data	Total	Mean
The strengthening of democratic political systems	3	59	38	0	100	2.35
The growth of the services sector in the production system	0	43	57	0	100	2.57
The implementation of intellectual property rights	14	11	73	1	100	2.55
Regional integration and economic blocs integrated by regional countries exclusively	8	30	62	0	100	2.54
Regional integration and economic blocs integrated by regional countries and others	8	27	65	0	100	2.57
The expansion of multinational companies	27	14	59	0	100	2.32

The majority of cases presented in Table # 3 are considered as positively inclined toward the development of biotechnology. Regional integration and economic blocs integrated by regional countries and others (2.57) and the growth of the services sector in the production system (2.57) were considered as being the most facilitative. The implementation of intellectual property rights seemed to be viewed as a facilitator to 73% of the informants. The strengthening of democratic political systems seemed neutral to 59% of informants in terms of biotechnology applied to the production of GMOs. However, 27% indicated that the expansion of multinational companies would block biotechnology applied to the production of GMOs in agriculture in the Caribbean

Table #4

Q4. How would you rate the level of formal education and general knowledge on biotechnology applied to the production of GMOs in agriculture possessed by regional actors? (Scale from 1 to 5: where 1= very low and 5 = very high)

	1	2	3	4	5	No data	Total	Mean
➢ By large companies	14	35	30	19	0	0	100	2.5
➢ By academic and scientific communities	0	11	27	38	24	0	100	3.75
➢ By Universities	0	5	22	32	38	1	100	3.94
➢ By civil servants involved in the issue	19	27	38	8	5	1	100	2.44
➢ By small and medium-sized producers	35	38	16	8	3	0	100	2.06
➢ By politicians	59	27	11	0	3	2	100	1.61
➢ By consumers	68	22	5	0	3	1	100	1.42

According to Table #4, in the Caribbean region academic and scientific communities (3.75) and Universities (3.94) know the most about biotechnology applied to the production of GMOs in agriculture. Their knowledge is high in average terms. The level of knowledge of consumers (1.42) and politicians (1.61) are the lowest on the subject of biotechnology.

Table #5

Q5. In terms of the resources applied to the development of biotechnology as it relates to the production of GMOs in agriculture, in the countries of the region, if you were to decide, would you allocate less, more or the same amount of resources – compared to what is currently being allocated – to each one of the aspects listed below? (1 = less resources, 2 = the same resources and 3 = more resources)

	1	2	3	No data	Total	Mean
Resources for applied research	5	8	78	1	100	2.55
Resources to train human resources	0	8	92	0	100	2.92
Resources to update legal regulations	0	19	81	0	100	2.81
Resources to apply technological innovations in the production system	5	16	73	1	100	2.56
Resources to identify key questions for the consumers' acceptance	0	27	70	1	100	2.64
Resources to reach national and international political consensus	14	41	43	1	100	2.25
Resources for basic research	5	14	81	0	100	2.76

Table #5 conveys a general viewpoint that favours the allocation of more resources to biotechnology. The majority of informants acknowledged that more resources should be used to train human resources (2.92), to update legal regulations (2.81), and for basic research (2.76). 14% of the informants thought that fewer resources should be allocated to reach national and international political consensus.

Table #6

Q6. How would you rate the current contribution of biotechnology applied to the production of GMOs in agriculture to the following aspects of development in the regional countries. (Scale from 1 to 5 where: 1 = very negative, 2 = negative, 3 = neutral, 4 = positive, 5 = very positive)

	1	2	3	4	5	No data	Total	Mean
Contribution to the economic growth of countries	19	11	51	11	8	0	100	2.78
Contribution to the increased competitiveness of countries	19	16	43	14	5	1	100	2.61
Contribution to trade in the region	22	19	49	5	3	1	100	2.42
Contribution to the health of population	16	8	62	11	3	0	100	2.77
Contribution to the availability of natural resources	16	14	51	16	3	0	100	2.76
Contribution to the preservation of ecological systems	19	22	46	8	3	1	100	2.48
Contribution to reduction of unemployment	16	14	54	14	3	1	100	2.77
Contribution to redistribution of income and reduction of inequalities among social groups	19	14	65	0	3	1	100	2.57

According to Table #6, informants generally considered that the development of biotechnology would have neutral impact to most aspects of societies. It must be noted that in the opinion of those polled 22% stated that biotechnology would have a very negative impact on regional trade. 19% stated that biotechnology would have a very negative effect respectively on economic growth, competitiveness, ecological systems and income redistribution and reduction of inequalities among social groups.

Table #7

Q7. Please indicate your degree of agreement with the following statements. (Scale from 1 to 5 where: 1 = very much in disagreement, 2 = disagree, 3 = neither one nor the other, 4 = agree, 5 = fully agree)

	1	2	3	4	5	No data	Total	Mean
Biotechnology applied to GMO production in agriculture should be strongly encouraged by regional governments.	5	11	35	24	24	0	100	3.48
There will probably be a larger expansion of alternative agricultural systems based on agri-ecological management, given the fear of genetically modified products.	5	24	24	30	14	1	100	3.15
The application of GMOs in agriculture provide great possibilities to alleviate hunger in the region.	8	24	27	30	11	0	100	3.12
Biotechnology applied to GMO production in agriculture should be strongly accepted by social groups in the region.	8	16	49	22	5	0	100	3
The development of biotechnology applied to GMO production in agriculture basically responds to the interests of powerful economic groups	3	16	14	57	11	0	100	3.6
The development of biotechnology applied to GMO production in agriculture basically responds to the interests of some First World countries	3	19	11	41	24	1	100	3.58

Biotechnology applied to GMO production in agriculture should be considered as important as education of the population in the regional agenda	0	19	27	19	35	0	100	3.7
Biotechnology applied to GMO production in agriculture entails serious risks for the regional environment	3	16	27	30	22	1	100	3.46
Biotechnology applied to GMO production in agriculture entails serious risks for human health in the region	3	30	43	11	8	2	100	2.76

Informants were practically in agreement that biotechnology (a) should be considered as important as education; (b) it should be strongly encouraged by governments in the region; (c) it basically responds to the interest of powerful economic groups and some First World countries; and (d) it entails serious risks for the regional environment. It was not clearly perceived that the application of GMOs in agriculture provides great possibilities to alleviate hunger. In addition, there was no clear position with regard to probable expansion of alternative agricultural systems because of a fear of GMOs or that biotechnology entails serious risk for the environment or that biotechnology should be accepted socially.

Results by Institutional Sector

The results of the survey according to the institutional origin of the informants are presented below.

The groups of informants were divided based on their institutional origin, on one side the governmental organisations and the other side researchers, private sector, non-governmental organisations.

The mean for all answers is provided for groups as well as the relative difference and the absolute difference.

Table #8

Q1. How would you rate your level of experience on the following aspects related to biotechnology applied to the production of GMOs in agriculture in the region?
(Scale 1 to 5: 1 = very low and 5 = very high)

	Government	Other	Diff.	Absolute Diff.
Institutional aspects (actors, human resources, S&T systems, research, etc.)	2.4	3.21	-0.81	0.81
Economic aspects	1.9	2.46	-0.56	0.56
Biotechnology applied to agriculture in the Caribbean	2.4	3.58	-1.18	1.18
Biotechnology applied to agriculture in Latin America	1.8	2.93	-1.13	1.13
Political and legal aspects	1.7	2.35	-0.65	0.65

Social aspects (public perception, social organisations and movements, mass media, etc.)	2.6	2.81	-0.21	0.21
Environmental and sanitary aspects	2.6	3.29	-0.69	0.69
Ethic aspects	2.3	2.71	-0.41	0.41

Table #9

Q2. Please indicate the importance you give to the following areas in developing a **research agenda on biotechnology applied to the production of GMOs in agriculture in the region.**
(Scale 1 to 5: where 1 = not important, 2 = a little important, 3 = relatively important, 4 = fairly important and 5 = very important)

	Government	Other	Diff.	Absolute Diff.
The relationship among actors involved (academia, governments, NGOs, companies, consumers, etc.)	4.65	5	-0.35	0.35
Training of human resources	4.78	4.86	-0.08	0.08
The role of science, technology and innovation systems	4.76	4.72	0.04	0.04
Biotechnology and natural resources	4.83	4.93	-0.10	0.10
Biotechnology and biodiversity	4.59	4.86	-0.27	0.27
Biotechnology and human health	4.72	4.79	-0.07	0.07
Biotechnology and bio-safety	4.83	4.86	-0.03	0.03
Public opinion and biotechnology	4.54	4.57	-0.03	0.03
Research and development funding	4.21	4.43	-0.22	0.22
Consumers and biotechnology	4.39	4.36	0.03	0.03
Funding the introduction of new biotechnologies	3.94	4.17	-0.23	0.23
Mass media and biotechnology	4.33	4.43	-0.10	0.10
Threats and opportunities of biotechnology in relation to the environment	4.59	4.64	-0.05	0.05
Relation between national legal systems and biotechnology development	4.3	4.5	-0.20	0.20
Small and medium-sized producers and biotechnology	3.9	3.96	-0.06	0.06
Ways to apply biotechnological breakthroughs in food production processes	4.2	4.36	-0.16	0.16
Ethic implications of biotechnology	4.03	4.06	-0.03	0.03
Relations between biotechnology and macro-economic aspects in countries (competitiveness, GDP, etc.)	4.33	3.79	0.54	0.54
International companies and industries and biotechnology	3.49	3.88	0.39	0.39
Relations between political systems and the development of biotechnology	3.82	3.64	0.18	0.18
The impact of biotechnology on the less privileged groups (women, indigenous	4.2	4.29	-0.09	0.09

populations, small producers, etc)				
Relationship between biotechnology and regional integration	3.85	4.13	-0.28	0.28
Social movements in favour and social movements that reject it	3.78	3.52	-0.27	0.27
Biotechnology and climate changes	4	3.23	0.78	0.78
Biotechnology and population growth	3.96	3.67	-0.30	0.30

There is a significant difference on biotechnology and climate change

Table #10

Q3. To what extent do you think the aspects listed below represent or could represent elements that block, facilitate or are neutral in terms of biotechnology applied to the production of GMOs in agriculture in the Caribbean?
(1 = obstacle, 2 = neutral and 3 = facilitator)

	Government	Other	Diff.	Absolute Diff.
The strengthening of democratic political systems	2.35	2.22	0.14	0.14
The growth of the services sector in the production system	2.44	2.65	-0.21	0.21
The implementation of intellectual property rights	2.45	2.50	-0.05	0.05
Regional integration and economic blocs integrated by regional countries exclusively	2.67	2.43	0.25	0.25
Regional integration and economic blocs integrated by regional countries and others	2.56	2.65	-0.09	0.09
The expansion of multinational companies	2.56	2.07	0.49	0.49

Table #11

Q4. How would you rate the level of formal education and general knowledge on biotechnology applied to the production of GMOs in agriculture possessed by regional actors? (Scale from 1 to 5: where 1= very low and 5 = very high)

	Government	Other	Diff.	Absolute Diff.
➢ By large companies	2.61	2.44	0.17	0.17
➢ By academic and scientific communities	3.74	3.82	-0.08	0.08
➢ By Universities	4.22	3.58	0.64	0.64
➢ By civil servants involved in the issue	2.48	2.27	0.21	0.21
➢ By small and medium-sized producers	2.25	1.57	0.68	0.68
➢ By politicians	1.56	1.36	0.20	0.20
➢ By consumers	1.29	1.22	0.08	0.08

significant differences are noted on universities and small and medium producers

Table #12

Q5. In terms of the resources applied to the development of biotechnology as it relates to the production of GMOs in agriculture, in the countries of the region, if you were to decide, would you allocate less, more or the same amount of resources – compared to what is currently being allocated – to each one of the aspects listed below? (1 = less resources, 2 = the same resources and 3 = more resources)

	Government	Other	Diff.	Absolute Diff.
Resources for applied research	2.67	2.71	-0.04	0.04
Resources to train human resources	2.89	3	-0.11	0.11
Resources to update legal regulations	2.78	2.86	-0.08	0.08
Resources to apply technological innovations in the production system	2.61	2.56	0.05	0.05
Resources to identify key questions for the consumers' acceptance	2.6	2.64	-0.04	0.04
Resources to reach national and international political consensus	2.22	2.22	0	0
Resources for basic research	2.61	2.86	-0.25	0.25

Table #13

Q6. How would you rate the current contribution of biotechnology applied to the production of GMOs in agriculture to the following aspects of development in the regional countries? (Scale from 1 to 5 where: 1 = very negative, 2 = negative, 3 = neutral, 4 = positive, 5 = very positive)

	Government	Other	Diff.	Absolute Diff.
Contribution to the economic growth of countries	2.84	2.42	0.42	0.42
Contribution to the increased competitiveness of countries	2.58	2.35	0.23	0.23
Contribution to trade in the region	2.29	2.22	0.07	0.07
Contribution to the health of population	2.39	2.93	-0.57	0.57
Contribution to the availability of natural resources	2.51	2.71	-0.20	0.20
Contribution to the preservation of ecological systems	2.22	2.57	-0.35	0.35
Contribution to reduction of unemployment	2.51	2.78	-0.27	0.27
Contribution to redistribution of income and reduction of inequalities among social groups	2.16	2.71	-0.55	0.55

Table #14

Q7. Please indicate your degree of agreement with the following statements.
(Scale from 1 to 5 where: 1 = very much in disagreement, 2 = disagree, 3 = neither one nor the other, 4 = agree, 5 = fully agree)

	Government	Other	Diff.	Absolute Diff.
Biotechnology applied to GMO production in agriculture should be strongly encouraged by regional governments.	3.48	3.75	-0.27	0.27
There will probably be a larger expansion of alternative agricultural systems based on agri-ecological management, given the fear of genetically modified products.	3.36	2.85	0.51	0.51
The application of GMOs in agriculture provide great possibilities to alleviate hunger in the region.	3.16	2.94	0.23	0.23
Biotechnology applied to GMO production in agriculture should be strongly accepted by social groups in the region.	2.89	3.13	-0.24	0.24
The development of biotechnology applied to GMO production in agriculture basically responds to the interests of powerful economic groups	3.7	3.42	-0.29	0.29
The development of biotechnology applied to GMO production in agriculture basically responds to the interests of some First World countries	3.65	3.35	0.31	0.31
Biotechnology applied to GMO production in /agriculture should be considered as important as education of the population in the regional agenda	3.63	3.67	-0.04	0.04
Biotechnology applied to GMO production in agriculture entails serious risks for the regional environment	3.91	2.63	1.28	1.28
Biotechnology applied to GMO production in agriculture entails serious risks for human health in the region	3.06	2.22	0.84	0.84

Summary of open questions

Q8. What specific lines in terms of scientific and technological policy you think are more relevant vis-à-vis biotechnology applied to GMO production in agriculture in the countries of the Caribbean?

Most informants held the view that the fast pace of biotechnology development makes imperative capacity building, information access and the training of human resources, and the strengthening of infrastructure for testing, risk analysis, and the certification of research/ testing facilities.

Policy guidelines must promote the development of biotechnology, but also must ensure environmental safety, the protection of biodiversity and human health. Public awareness and education should also accompany these policy frameworks that allow safe exploitation of the technology.

It was also felt that policies should ensure that systems are put in place that allows the region to benefit from the technology, while minimising the risks. These policies should ensure national control and monitoring of GMOs and not the uncontrolled introduction and promulgation by multinational companies or local private sector companies or groups.

Another view was that the adoption and promotion of the technology should be allowed only if potential benefits were greater than potential risks.

Issues of updating and collating legislation as it applies to all aspects of GMO production were also raised. The development of an appropriate intellectual property rights system was also considered necessary to ensure that economic benefits fully accrued to the region.

Q9. What type of legal regulations do you think are more of a priority in terms of biotechnology applied to GMO production in agriculture in the Caribbean?

There is generally a lack of legislation throughout the region. However, some Caribbean countries such as Antigua and Barbuda, the Bahamas, Grenada and Jamaica are ahead in building their biosafety legislative framework.

The most frequent answers conveyed the need for legislation and regulations related to the importation of genetically modified foods and feeds, the transboundary movement of GMOs, biodiversity, human health and guidelines for research and all testing and release. It is vital that the national genetic heritage is not threatened through contamination (cross breeding). Since it is likely that GMOs will be patented and belong to specific non governmental agencies, some mechanism must be in place to secure the future of indigenous flora and fauna.

Labelling legislation and intellectual property rights were also issues raised along with the creation of the legal apparatus to meet the requirements of the Cartagena Protocol.

Also mentioned was:

- Regulations should provide for the evaluation and monitoring of GM products based on cultural practices.
- Regulations and licensing of specific cultivars to provide for review and evaluation before the introduction of any live GMOs and registration of growers and sites or production.
- Field-testing should follow strict guidelines.
- Regulations should include penalties and fines for non-compliance.
- The biosafety legislation was an imperative and should be comprehensive encompassing safety issues in the handling and use of GMOs in food and feeds.
- Contingency planning, insurance, and renumeration are aspects that should be incorporated into legal regulations.

Q10. In your opinion which area of biotechnology applied to GMO production in agriculture might be more relevant in the Caribbean in the coming years?

The majority of answers referred to:

- Novel ornamental production.
- Plant incorporated protectants, storage improvement, improved product quality, taste and nutritional high yielding varieties.
- Production of crop tolerant to stresses through genetic engineering.
- Applications of biotechnology in medicine.
- Application of GM technology to ethnic/ locally produced varieties to improve production.
- Improvement and expansion of Caribbean primary crop production for export. Risk assessment.
- Molecular techniques in plant & human disease diagnosis.
- Gene mapping for biodiversity conservation.

Production of variants that require less synthetic fertilisers, pesticides and water would be useful in conserving the resources of the countries involved. At the same time however it is vital to develop an archive of national genetic material and to protect it so that the indigenous materials are legally seen as belonging to the specific nation or region.

Q11. What are the main opportunities that different groups of food producers in the Caribbean have or could have in view of biotechnological development? (With reference to the following groups: Small and medium-sized growers, Large companies and Subsistence producers.)

Small and medium sized growers:

The responses were as follows:

- Opportunities perceived to produce improved disease free crops and to improve quality and quantity of food.
- The growth of biotechnology in the 1st world countries provides a unique opportunity for smaller, less developed nations to take advantage of the niche market for NON GMO foods, which could be sold as specialty items at a premium rate.
- Reduction of pesticide, insecticide and herbicide use, resulting in improved pest management practices.
- Lower the cost of production due to reduced inputs.
- Development of new improved more adapted regional varieties with high market potential.
- Development of novel crops for export and agro processing capacity.
- Opportunities for growth and expansion of operations and thus improve competitiveness in the national and international markets.
- Having greater access to markets.
- Reduction of chemical control costs and increased productivity and therefore income.
- Improved technology

Large companies:

The opportunities for large companies were perceived through collaborative research with GMO developers, increase profits and market share.

Subsistence producers:

The majority of informants did not see any opportunities for subsistence farmers. However, some held the view that biotechnology will provide higher yields due to reductions in the loss of crops from pest and disease and less inputs.

Q12. What are the main threats that different groups of food producers in the Caribbean have or could have exposure to in view of biotechnological development? (With reference to the following groups: Small and medium-sized growers, Large companies and Subsistence producers.)

It was felt that limited access to technology and capital would affect competitive ability. Some informant indicated that biotechnology was an expensive technology and would only benefit those who had high capital and could afford to pay. There was the risk of developing dependence on a few agro-industrial players for planting material.

Producers could also face the loss of certain markets e.g. European Union and support of sceptical consumers, and therefore lose income. There was also the potential for the technology gap between subsistence and medium to large growers/producers to widen. Loss of ability to save and incorporate improved seed varieties in production systems due to patenting of GM seeds was also viewed as a major threat. All groups could face loss of crops from disease or pest epidemics as a result of climate change and limited genetic bases. There may also be the threat from a failure to check market demand (i.e. over production of a "fancy" commodity), and the threat of damage to native biodiversity and agro-biodiversity due to gene flow.

There was also the fear of indigenous crops and other useful landraces being threatened by genetic contamination, while non-target species, weeds, insects could develop greater resistance.

Informants also expressed a concern about the lack of participation in decision making and of having new technologies forced upon them as a result. The decreased choice and development of monopolies in propagative materials and agri-materials, and dependence on external sources for food security and safety were also some threats viewed by informants. Depending on patent holder/vendor policies, nations could find themselves at the mercy of seed provides. Once they rearranged their agribusiness to focus on GMOs…. They would have to use the terms and conditions dictated by vendors.

Q13. In your opinion, what are the main impacts of GMOs/biotechnology on Small Island developing states?

Environment

The loss of biodiversity and the need for its conservation were the main concern among informants, followed by the loss of indigenous material due to close proximity of various environmental systems. A large majority of informants stressed that:

- Development efforts should be cognised of countries' fragile ecosystem.
- Recognition of the partnership between biodiversity, traditional knowledge and biotechnology is important to the sustainable use of the technology.
- Biotechnology is very important for development given the limited land resources and unsustainable use of a fragile ecosystem.

Health

Biotechnology can improved quality and quantity of food and reduced pesticide use.

Socio-economic:

The majority of opinions were of an socio-economic nature. Some potential impacts were:

- Increases in food prices if labelling became mandatory.
- Many countries were forced into acceptance of GM products.
- Trade issues, ability to meet obligations under the FTAA.

- Negative economic impacts arising from the enforcement of intellectual property rights of those who control the technology.
- Reduction in competitiveness regional and internationally due to the inability to meet required standards for some markets.
- Left behind due to lack of resources.

While many realised the potential for increased productivity using biotechnology, informants stressed the need for more efforts to improve regulations and controls, along with greater public education and awareness. Potential impacts need to be carefully reviewed, based on EIAs, and observing the precautionary principle. Monitoring is essential, with the possibility of revocation of the licenses.

Informants were concerned that Small Island Developing States were slow to adopt and use the technology because it was not widely accepted and properly understood by the public, lawmakers and policy makers.

Some perceived that the agricultural sector could be enhanced through biotechnology and thus contribute to the growth and development of the economy. There was also the potential for food security resulting in decreased dependence on some imported goods to feed increasing population.

Summary

The majority of informants' thought that their level of experience related to biotechnology was the high in regard to environmental and sanitary aspects. The perception was that universities, academics and the scientific community possess the highest level of general knowledge on biotechnology applied to the production of GMOs in agriculture. The region has a small pool of individuals with knowledge in all subject areas. The majority was acquainted with specific knowledge in their field of work.

Among those polled biotechnology and natural resources, followed closely by biosafety was given prime importance in developing a research agenda on biotechnology in the region. Regarding the research agenda, all subjects evaluated were considered as relatively important. 65% of the informants proposed that regional integration and economic blocs integrated by regional countries, along with the implementation of intellectual property rights which 73% thought will facilitate biotechnology in the Caribbean region.

Emphasis was placed on allocating more resources to train human resources and to update legal regulations. However, in general informants thought that more resources needed to be allocated throughout the various aspects of biotechnology. There was the perception that the development of biotechnology currently in the Caribbean region has a neutral impact to most aspects of societies.

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Links From ISB Website

Information Systems for Biotechnology

Generated January 29, 2004

Ag BioTech InfoNet

Covers all aspects of the application of biotechnology and genetic engineering in agricultural production and food processing and marketing; focuses on scientific reports and findings and technical analysis; covers emerging issues of widespread interest, developments in the policy arena, and major media coverage; "Sources and Links" highlights the key sites on the Internet for information on agricultural biotechnology and its implications. http://biotech-info.net/

AgBios

Look for link to Essential Biosafety, one of the richest biosafety resources on liune and available on CD. http://www.agbios.com

Ag-West Biotech

Aims to initiate, promote and support the growth of Saskatchewan's agricultural biotechnology industries and the commercialization of related food and non-food technologies, by working with industry and external stakeholders. Includes links to SABIC (Saskatchewan Agricultural Biotechnology Information Centre), and SARAS (Saskatchewan Agbiotech Regulatory Affairs Service). http://www.agwest.sk.ca/

AgBioForum Magazine

Publishes articles which enhance the on-going dialogue on the economics and management of agricultural biotechnology; provides unbiased, timely information and new ideas leading to socially responsible and economically efficient decisions in science, public policy and private strategies pertaining to agricultural biotechnology. http://www.agbioforum.org

AgBiosafety
A source of scientific, regulatory, and educational materials relevant to crop biotechnology and the current debate on the genetic modification of food; offers a comprehensive, up to date source of information on the current issues in biotechnology and food safety; provides consumers, educators, and policy makers with an easily accessible source of data and facts related to crop biotechnology, topical articles on current issues in biotechnology and food safety, and educational resources and curricula on crop biotechnology for both consumers and educators.
http://www.agbiosafety.unl.edu/

AgBiotechNet
A service provided by CAB International and supported by the Agricultural Biotechnology Support Project; publishes current information about biotechnology and biosafety for researchers and policy makers world-wide; provides access to research developments in genetic engineering and updates on economic and social issues; contains, in the *news* section, information on company news, intellectual property rights, technology transfer, biosafety, research briefs and bioinformatics. http://www.agbiotechnet.com

AgBioWorld
Devoted to bringing information about technological advances in agriculture to the developing world; provides information to teachers, scientists, journalists, and the general public on the relevance of agricultural biotechnology to sustainable development; maintains the declaration of "Scientists In Support Of Agricultural Biotechnology," and offers a discussion listserve.
http://www.agbioworld.org

AgCare
Represents Ontario's growers of field and horticultural crops on agricultural pesticide use, crops biotechnology developments, and other related environmental issues; provides Ontario crop producers' unified voice on these important matters. http://www.agcare.org

Agricultural Biotechnology Support Project (U.S.)
The Project aims to assist developing countries in the development and management of the tools and products of agricultural biotechnology; builds linkages between developing country public and private sectors, the U.S. public sector, and the U.S. private sector where much of the technology lies; focuses on specific product-oriented research activities in the context of an integrated management scheme which emphasizes human resource development, in policy as well as technical areas, and access to research and policy information for developing country scientists through a global approach to networking. http://www.iia.msu.edu/absp

Agriculture and Environment Biotechnology Commission (AEBC)
Works alongside the Human Genetics Commission (HGC) which advises on how new developments in human genetics will impact on people and health care, and the Food Standards Agency (FSA) which is the body responsible for food safety, including GM food.
http://www.aebc.gov.uk/

Agriculture Network Information Center (AgNIC)
A guide to quality agricultural information on the Internet as selected by the National Agricultural Library, Land-Grant Universities, and other institutions. AgNIC focuses on providing agricultural information in electronic format over the World Wide Web via the Internet. http://www.agnic.org/

Belgian Biosafety Server
Is the Web server of the Service of Biosafety and Biotechnology (SBB) and hosted by the federal Scientific Institute of Public Health under aegis of the Belgian Ministry for Consumer Protection, Public Health and Environment. Contains regulatory information for Belgium, Europe, and other

countries; risk assessment data; biosafety related meetings, conferences, and courses. http://biosafety.ihe.be

BIO-SCOPE.ORG
BIO-SCOPE.ORG provides access to scientific information at all levels; includes a database which can be accessed by people with varying degrees of education in biotechnology and agriculture, material for science writers and teachers, abstracts of many scientific articles and relevant press cuttings, a forum for experts and others to exchange views and plan concerted actions, meetings on biotechnology, and daily updated information on important publications from newspapers to scientific journals. Within BIO-SCOPE is a link to the "Berne Debates", which is a website on the biotech-debate, including clippings, edited op-eds, debate contributions from Bern, texts embedded into a knowledge database, and a separate database for getting the appropriate experts to answer additional questions. http://www.bio-scope.org/

BioAbility
BioAbility provides high-quality strategic business information to hundreds of clients in the biotechnology, pharmaceutical and life science communities. Our strategic planning, due diligence reports, informational studies, regional development planning, Virtual Information Service studies and many others. http://www.bioability.com

BIOBIN
A Co-operative Resource on Safety in Biotechnology, developed between OECD's BioTrack Online and UNIDO's BINAS. A resource for Regulations, Field Trials, Biotech Product Database, Biotechnology Libraries, and Tools related to biosafety. http://www.oecd.org/ehs/biobin/

Bioethics & Bioregulation
A collection of websites, electronic journals and newspapers on bioethics and bioregulation. By Cess Verhagen, Library Wageningen-UR and Gijs Kleter, Rikilt-DLO. http://www.agralin.nl/bioethics/

Biosafety Information Network and Advisory Service
A service of the United Nations Industrial Development Organization (UNIDO). Global developments in regulatory issues in biotechnology; full text of regulations and guideines from many countries; library of publications dealing with regulatory policy and issues pertaining to biological risk assessment http://binas.unido.org/binas/

Biotechnology and Development Monitor
Provides a forum for discussion on the positive and/or negative impact of biotechnological innovations and international regulations on issues such as economic growth, agricultural production, food security, shifts in national and global markets, access to technology, employment, social differentiation, and human rights. http://www.biotech-monitor.nl/

Biotechnology in Food and Agriculture
Provided by the Food and Agriculture Organization of the United Nations (FAO), this site contains a range of features that may be of value to anyone interested in the role and impact of biotechnology in food and agriculture, including: FAO Statement on Biotechnology; an overview of FAO's activities in this area, which include providing advice and assistance to Member Countries, disseminating information and monitoring new developments; an overview of biotechnology in the agro-industry, crop, fisheries, forestry and livestock sectors; and the FAO Electronic Forum on Biotechnology in Food and Agriculture, which operates a series of moderated e-mail conferences. http://www.fao.org/biotech/index.asp?lang=en

Biotechnology Industry Organization
The largest trade organization to serve and represent the emerging biotechnology industry in the United States and around the globe. Media guide to biotechnology; biotech food products list; citizen's guide to biotechnology; laws and policies; bioethics. http://www.bio.org

Biotechnology Information Directory Section
The World Wide Web Virtual Library
This directory contains well over 1000 URLs of companies, research institutes, universities, sources of information and other directories specific to biotechnology, pharmaceutical development and related fields. It places emphasis on product development and the delivery of products and services. http://www.cato.com/biotech/

Biotechnology Resource Series
A service of the Seed Biotechnology Center, Univ. California, Davis, this site maintains extensive resources on: Crop Species Biotechnology; Biotechnology Methods; Genes/Traits/Plant Characteristics; Food, Feed & Pharmaceutical Products; Organizations; and Reference Materials. http://sbc.ucdavis.edu/Outreach/resource/resource_series.htm

Biotechnology Risk Assessment Data: Facts and Conclusions
Sponsored by the USDA and the University of Florida, this web site is designed to help provide necessary background information to understand the process of gene engineering and the available data relating to the safety of GMOs and risk assessment questions. The site has several levels, with each level containing increasing detail on particular topics. You will find summaries of general areas of risk/safety assessment written by experts in the fields, followed by links to comprehensive expert reviews, together with citations of primary literature. http://www.riskassess.org/index.cfm

Biotechnology Strategies and Coordination Office (Canada)
The Biotechnology Strategies and Coordination Office (BSCO) was formally established in 1993 (although it has been in operation since 1988) to provide a one-window approach for information on biotechnology in Agriculture and Agri-Food Canada (AAFC) for departmental senior management, interdepartmental colleagues, members of the agricultural community (companies, processors, researchers, etc.), members of the public, interest groups and the media. http://www.inspection.gc.ca/english/toce.shtml

BioTrack Online
The Web site of OECD's Programme on the Harmonization of Regulatory Oversight in Biotechnology; focuses on information related to the regulatory oversight of products of biotechnology used by governments, industry and other stakeholders; contains Consensus Documents, Regulatory Developments in Member Countries, Database of Field Trials, Biotech Product Database, and a link to OECD's Internal Co-ordination Group for Biotechnology. http://www.oecd.org/biotrack

CAST: Council for Science Agriculture and Technology
Biotechnology Communications
CAST assembles, interprets, and communicates science-based information regionally, nationally, and internationally on food, fiber, agricultural, natural resource, and related societal and environmental issues to legislators, regulators, policy makers, the media, the private sector, and the public. Contains reports, publications and a list of events on agbiotechnology. http://www.cast-science.org/cast-science.lh/index.html

Center for Science in the Public Interest
The CSPI Biotechnology Project addresses scientific concerns, policies, and corporate practices

concerning plants, animals, and other organisms released into the environment or that may end up in our foods. http://www.cspinet.org/biotech/index.html

CGIAR Research Centers
The Consultative Group on International Agricultural Research promotes sustainable agricultural development based on the environmentally sound management of natural resources. Links to the 16 International Agriculture Research Centers include the Asian Rice Biotechnology Network (IRRI), the Asian Maize Biotechnology Network (CIMMYT), and ISNAR's Biotechnology Service. http://www.cgiar.org/research/index.html

CIPR (CAMBIA Intellectual Property Resource)
Developed by a team with expertise in biotechnology, intellectual property, business strategy, and informatics, CIPR facilitates a productive and strategic approach to identifying and addressing intellectual property (IP) issues relevant to biotechnology in international agriculture; and enhances the ability of public sector and small-to-medium enterprises to develop biotechnology for crop improvement worldwide. http://www.cambiaIP.org/cambiaIP/Home/welcome.htm

Commission on Genetic Resources for Food and Agriculture
A permanent forum for governments to discuss and negotiate matters relevant to genetic resources for food and agriculture; aims to ensure the conservation and sustainable utilization of genetic resources for food and agriculture, as well the fair and equitable sharing of benefits derived from their use, for present and future generations; attempts to reach international consensus on areas of global interest, through negotiations. http://www.fao.org/ag/cgrfa/

Convention on Biological Diversity
The Convention establishes three main goals: the conservation of biological diversity, the sustainable use of its components, and the fair and equitable sharing of the benefits from the use of genetic resources. Provides reports from Biosafety meetings; maintains Biosafety Clearing-House; and the database of Conventions of the Parties (COP) decisions. http://www.biodiv.org/

Council for Biotechnology Information
Called **Whybiotech**, "The council was launched in April of 2000 by seven leading biotechnology companies and two trade associations with a clear vision: to create a groundbreaking new communications initiative built on a mix of research, advertising, media relations and constituency relations." Their "vision and mission is to improve understanding and acceptance of biotechnology by collecting balanced, credible and science-based information, then communicating this information through a variety of channels." Apparently does not support Netscape. http://www.whybiotech.com/

CropBiotech Net
An information network for gaining and sharing the latest updates in crop biotechnology; responds to the needs of developing countries on all aspects of crop biotechnology; helps national programs facilitate the development of a policy environment conducive to the application of biotechnologies; and promotes public understanding of scientific advances in crop biotechnology. http://www.isaaa.org/kc/

CropGen
A consumer and media information initiative; maintained by a panel of scientists and others who advocate for GM crops by helping to achieve realism and balance in the UK public debate about crop biotechnology; highlights both potential benefits and risks. http://www.cropgen.org

Edmonds Institute
A non-profit, public interest organization dedicated to education about environment, technology,

and intellectual property rights; biosafety and international regulation of modern biotechnologies; biodiversity policies; ethical implications of new technologies; publishes reports and papers on biosafety, including a peer-reviewed "Manual for Assessing Ecological and Human Health Effects of Genetically Engineered Organisms." http://www.edmonds-institute.org/

Electronic Forum on Biotechnology in Food and Agriculture
Provides an open forum that will allow a wide range of parties, including governmental and non-governmental organizations, policy makers, and the general public, to discuss and exchange views and experiences about specific issues concerning biotechnology in food and agriculture for developing countries. http://www.fao.org/biotech/forum.htm

Electronic Journal of Biotechnology
An international scientific electronic journal which publishes papers from all areas related to Biotechnology; covers from molecular biology and the chemistry of biological process to aquatic and earth environmental aspects, as well as computational applications and policy issues directly related to Biotechnology. http://www.ejbiotechnology.info/

Environmental Biosafety Research
An interdisciplinary Journal for Research on GMOs and the Environment containing peer-reviewed research and review articles relevant to the science-based safety evaluation of all types of genetically modified organisms (GMOS) that are intended for release into the environment; offers international expertise, rapid publication, electronic distribution for research articles, reviews, and a debate forum. http://www.edpsciences.org/journal/index.cfm?edpsname=ebr

European Commission: GMOs in Food and Environment
Contains an overview of all notifications of deliberate field trials circulated so far among Member States of the European Union. The database is subdivided by Country, Plants, and Organisms other than plants. http://biotech.jrc.it/

European Federation of Biotechnology
The European Federation of Biotechnology is the non-profit association of all national and cross-national Learned Societies, Universities, Institutes, Companies and Individuals interested in the promotion of Biotechnology throughout Europe and beyond. The objective of EFB is to promote safe and ethically acceptable biotechnology for the better use of Nature's resources. EFB also wishes to expand collaborations between academic and industrial researchers throughout Europe to increase competencies, strengthen education, promote innovation and increase the benefits of biotechnological research to society at large.

The "Section on Biodiversity" is the most recently established EFB Section. Priority topics of the Section are: Benefits and threats from GMO's; How can Biodiversity help in research?; Enhancing knowledge about soil microbiology; Biodiversity and Population Genetics; and Active participation in the development and outlining of research programmes on a European level. http://www.efbweb.org/

Florida Education Initiative
A working group of scientists committed to objectively educating the public on agricultural biotechnology and genetically modified foods; provides an unbiased and balanced viewpoint on biotechnology and genetically modified foods or organisms in a manner that can be understood by the average consumer. http://www.geocities.com/ufbiotech/

Food and Drug Administration Center for Food Safety and Applied Nutrition, Biotechnology
Proposed, pending and final rules and policies regarding food biotechnology. http://www.cfsan.fda.gov/~lrd/biotechm.html

Food Biotech Info
Food Biotech Info.com is part of an effort to help deliver science-based information on various issues concerning the benefits and safety of genetically modified foods. In addition to providing information, this site also offers a schedule of lectures and seminars on food biotechnology as well as downloadable PowerPoint presentations. http://www.foodbiotechinfo.com/index.html

Food Future: GM Crops and the Environment
Aims to provide consumers with facts and figures about GM crops so that they can make informed purchases about what they buy; Good sections on the benefits, risks, and regulation of GM crops in the UK. http://www.foodfuture.org.uk/gmcrops/index.htm

Genetically Engineered Organisms-Public Issues Education Project
The GEO-PIE Project was developed at Cornell University to create objective educational materials exploring the complex scientific and social issues associated with genetic engineering, to help readers consider those issues for themselves. http://www.comm.cornell.edu/gmo/gmo.html

gmIssues
Collates documents, reports, and informed comment relating to the scientific research application, regulation, socioeconomic, and environmental implications of genetically modified crops. Includes: an introduction to the science and issues of genetic modification; a discussion of organic farming and gene transfer from genetically modified crops; a section on the views of a wide range of people and organizations on genetic modification; a GMO FAQ; and related links. http://www.gmissues.org

Harvard Center for International Development
Aims to undertake research, conduct training, provide policy advice and disseminate information on the role of science, technology and innovation in economic growth in developing countries; specific activities under the program include biotechnology and globalization, agricultural productivity in the tropics, environmentally-sound and small-scale technologies, public perception of new technologies, technical education, and science and technology advice. http://www.cid.harvard.edu/cidbiotech

Health Canada - Novel Foods
Recognizing that food is fundamental to health, the mission of the food program is to protect and improve the health of the people of Canada through science-based policies and programs related to safe and nutritious food. http://www.hc-sc.gc.ca/food-aliment/english/subjects/novel_foods_and_ingredient/novel_foods_and_ingredient.html

Information Systems for Biotechnology
Information Systems for Biotechnology (ISB) provides information on agricultural and environmental biotechnology research, product development, regulatory issues, and biosafety. The site offers a free monthly news report, searchable databases of US field tests of GM organisms and deregulated organisms, links to international field trial sources, publications, and much more. ISB is an independent project supported by a grant from the USDA/CSREES National Biological Impact Assessment Program (NBIAP) to Virginia Tech. http://www.isb.vt.edu

Institute of Food Technologists: Biotechnology and Foods
Contains background information, news, and reports intended to contribute to a meaningful dialogue on scientific issues and consumer concerns about rDNA biotechnology; Contains a comprehensive review of the scientific evidence related to biotechnology and foods. http://www.ift.org/

International Center For Genetic Engineering & Biotechnology - ICGEB
An international organization established to promote the safe use of biotechnology world-wide with special regard to the needs of the developing world; coordinates a network of national laboratories in Member Countries. ICGEB's Scientific and Institutional Services contains Bioinformatics and Computer Resources, Database Functions, Technical Support, Advisory Services, Institutional Activities, and Biotechnology Development. http://www.icgeb.trieste.it

International Rice Research Institute
IRRI is a non-profit agricultural research and training center established to improve the well-being of present and future generations of rice farmers and consumers, particularly those with low incomes. It is dedicated to helping farmers in developing countries produce more food on limited land using less water, less labor and less chemical inputs, and without harming the environment. http://www.irri.org

International Service for National Agricultural Research
The products and services provided through ISNAR's activities in biotechnology are based on the systematic analysis of policy, management and organizational requirements of countries considering their plans for biotechnology. Look for the Tool Kit for biosafety implementation. This work is unique among CGIAR centers and other international agricultural biotechnology programs. http://www.isnar.cgiar.org/

International Service for the Acquisition of Agri-biotech Applications (ISAAA)
A not-for-profit international organization co-sponsored by public and private sector institutions with the aim of facilitating the aquisition and transfer of agricultural biotechnology applications from the industrial countries, particularly proprietary technology from the private sector, to developing countries for their benefit. http://www.isaaa.org

Introduction to Agricultural Biotechnology
A self-study course completely online, offered by Purdue, with lessons that cover the issues, science and mechanics of biotechnology.
http://persephone.agcom.purdue.edu/AgCom/news/backgrd/biotech_edu.htm

Life Sciences Knowledge Center (Monsanto)
Maintains an evolving collection of news items, technical reports, and other documents representing many points of view on agricultural biotechnology; sections on biotech basics, glossary, topic library, and a discussion board. http://www.biotechknowledge.com

National Agricultural Biotechnology Council (US)
Providing people with differing viewpoints a neutral forum where they can come together and freely exchange ideas on the critical issues facing agricultural biotechnology, the National Agricultural Biotechnology Council (NABC), founded in 1988, counts among its membership the leading agricultural research and educational institutions from throughout the United States and Canada. http://www.cals.cornell.edu/extension/nabc

National Center for Biotechnology Education: gm food information
Extensive UK site linking to GM food regulations; GMOs in food production; concerns and benefits; media coverage; reports and publications; Pusztai data; further reading; and links.
http://www.ncbe.reading.ac.uk/NCBE/GMFOOD/menu.html

National Farmers Union: NFU Biotechnology Working Group
Aims to develop an understanding of the issues surrounding biotechnology, their implications to agriculture and horticulture, and to make recommendations to the Council of the NFU on biotechnology policy. http://www.nfu.co.uk/intradoc-

cgi/idc_cgi_isapi.dll?IdcService=GET_DOC_PAGE&Action=GetTemplatePage&Page=NFU_HOME_PAGE

National Institutes of Health Office of Recombinant DNA Activities
Responsible for the "NIH Guidelines For Research Involving Recombinant DNA Molecules". http://www4.od.nih.gov/oba

NRC Biotechnology Program
The National Research Council is the premiere biotechnology research agency of the Canadian federal government. The NRC Biotechnology Program was established in 1983 under the guiding principles of the National Biotechnology Strategy. http://www.nrc-cnrc.gc.ca/randd/areas/biotechnology_e.html

Office of the Gene Technology Regulator (Australia)
The Office of the Gene Technology Regulator The OGTR is a Commonwealth regulatory agency located within the Health and Aged Care portfolio. The OGTR was established by the Gene Technology Act 2000 to be responsible for a national scheme to regulate genetically modified organisms (GMOs). http://www.health.gov.au/ogtr/index.htm

Pew Initiative on Food and Biotechnology
Established to be an independent and objective source of credible information on agricultural biotechnology for the public, media and policymakers; supports informed public dialogue on ways that the regulatory system may need to evolve to address the issues posed by the anticipated development of this new technology and the growing body of scientific knowledge. http://pewagbiotech.org/about/

PlantStress
The site presents concise and updated discussions of the main stresses: drought, heat, cold, salinity, soil mineral deficiency and soil mineral toxicity. It includes a bulletin board, links list, reference database, list of files and presentations, table of quantitative trait loci and major genes for abiotic stress tolerance in plants, and a table on performance of transgenic plants carrying abiotic stress resistance genes. http://www.plantstress.com

Regulation of Biotechnology in Canada
Office of Biotechnology of the Canadian Food Inspection Agency is responsible for the regulation of products derived through biotechnology including plants, animal feeds and animal feed ingredients, fertilizers and veterinary biologics; provides links to the Plant Biosafety Office, the Policy, Planning and Coordination Directorate, and Consumer and Technical Information http://www.inspection.gc.ca/english/ppc/biotech/bioteche.shtml

SCOPE: Genetically Modified Food
The risks and benefits of genetically modified food are debated on a Web-based forum that will provide the public and policy makers with the tools to understand the debate over genetically modified foods (GMF). The information available on-line will come from top scientists in the field who study the techniques of genetic engineering and their impact on human health and the environment. The project is the project is the work of editors at Science magazine, and scientists at the University of California-Berkeley and the University of Washington. http://scope.educ.washington.edu/gmfood/index.php

Seed Biotechnology Center
Mobilizes the research, educational, and outreach resources of UC Davis in partnership with the seed industry to facilitate commercialization of new technologies for agricultural and consumer benefits; provides an extensive depth and breadth of seed biotechnology resource information and

updates, including technical information on seed production, information on reproductive biology of seed crops, and links to seed-related industry and government organizations. Contains an extensive linked list of Plant Biotechnology Tutorials available online and a comprehensive database of published literature on GM Food Safety Assessment. http://sbc.ucdavis.edu/

Southwest Biotechnology and Informatics Center (SWBIC)
SWBIC, formerly the National Biotechnology Information Facility (NBIF), provides a single-point access to a vast store of widely distributed biotechnology data; encourages information sharing between researchers; provides training in biotechnology; active in developing new sources and types of biotechnology databases. http://www.swbic.org

Special Issues on Plant GM Technology
The Plant Journal (Blackwell Science Ltd) has established this specific website for plant GM technology. Their aim is to provide a forum for the publication of in-depth review articles and case studies on all aspects of plant GM technology and its applications and to provide science-based resources to inform the GM debate impartially and in a constructive manner. There will also be links to both websites and articles prepared by such organisations as the Royal Society, United Nations, Rockefeller Foundation, and so on. http://www.blackwell-science.com/tpj/gm

Straight Talk about Biotechnology
This site includes a short introductory course on Crop Biotechnology, News and Events, a compilation of scientific information, Policy overview, and a list of other resources. http://www.dupont.com/biotech/index.html

Transgenic Crops: An Introduction and Resource Guide
Provides the general public with balanced information and links to resources on the technology and issues surrounding transgenic crops; maintains the latest news updates; contains history, description, and "how to" pages on the engineering of transgenic plants; discusses evaluation and regulation, current and future transgenic products, and risks and concers. http://www.colostate.edu/programs/lifesciences/TransgenicCrops/

ucbiotech.org
The Web site, a part of the University of California Division of Agricultural and Natural Resources Statewide Biotechnology Workgroup, provides science-based information to the public on issues relating to the application of biotechnology to crops. For the scientific community, educational tools and an extensive database of pertinent scientific literature are available to promote participation in the dialog. Teaching aids for students and teachers are provided. http://ucbiotech.org

Union of Concerned Scientists
The common threads of global sustainability and global security weave the Union of Concerned Scientists's work on agriculture, arms control, energy, global resources, and transportation into a unified vision: achieving a secure and sustainable world today without sacrificing the environment of tomorrow. http://www.ucsusa.org/index.cfm

United Nations Environment Programme International Register on Biosafety
This Web site offers information from many sources on biosafety. It focuses on information useful in establishing a regulatory framework for the safe development, transfer, and application of biotechnology. It also provides links to other Web sites concerning biosafety, biotechnology, and biodiversity. http://www.chem.unep.ch/biodiv/

University of Washington Crown Gall Group
Has sequenced and made available the genome of *Agrobacterium*; Provides the public and the

scientific community with information about the causative agent of crown gall disease: *Agrobacterium tumefaciens*; http://depts.washington.edu/agro/

US Department of State: Global Issues in Biotechnology
Offers Policy documents of Official Texts, Fact Sheets, Key Reports, and Government Agencies; in-depth reports; list of Resources. http://www.usinfo.state.gov/topical/global/biotech/

US EPA Office Pesticide Programs: Biopesticides
Includes links to the most recent EPA documents on Biopesticides, including Bt and other plant-incorporated protectants, Resistance Management, and Regulatory Reference Documents. http://www.epa.gov/pesticides/biopesticides/

US EPA Toxic Substances Control Act Office of Pollution Prevention and Toxics
This site was created to allow more efficient public, governmental and educational access to the TSCA Biotechnology Program. At this site you will find the regulation under which the Program functions, and the supplementary documents created to support this regulation, as well as status reports on the submissions, reviews, and agreements undertaken by the Program. http://www.epa.gov/opptintr/biotech/index.html

US Germplasm Resources Information Network
A program (GRIN) within the U.S. Department of Agriculture's Agricultural Research Service that provides germplasm information about plants, animals, microbes and invertebrates. http://www.ars-grin.gov

US Regulatory Oversight in Biotechnology — Responsible Agencies Overview
The Agencies primarily responsible for regulating biotechnology in the United States are the US Department of Agriculture (USDA), the Environmental Protection Agency (EPA), and the Food and Drug Administration (FDA). Products are regulated according to their intended use, with some products being regulated under more than one agency. http://www.aphis.usda.gov/brs/usregs.html

USDA APHIS Agricultural Biotechnology
Contains detailed information on how the USDA Animal and Plant Health Inspection Service (APHIS) regulates the movement, importation, and field testing of genetically engineered plants and microorganisms through permitting and notification procedures; links to other APHIS web sites containing information on permits for other types of genetically-engineered organisms or products such as transgenic arthropods, products with applications as veterinary biologics, as well as non-genetically engineered articles such as plant pests, plants and plant products, and animal and animal products. http://www.aphis.usda.gov/brs/

USDA Biotechnology Information Center
National Agricultural Library (NAL)
Provides access to a variety of information services and publications covering many aspects of agricultural biotechnology. Specific topics include theory and techniques of genetic engineering, plant and animal genetics, monoclonal antibodies, single cell proteins, food processing, biomass applications and risk assessment and bioethics. http://www.nalusda.gov/bic

USDA Biotechnology Risk Assessment Research Grants
Provides scientific information derived from the risk assessment research that it funds in order to assist Federal regulatory agencies in making science-based decisions about the safety of introducing into the environment genetically modified organisms, including plants, microorganisms, fungi, bacteria, viruses, arthropods, fish, birds, mammals, and other animals. http://www.reeusda.gov/crgam/biotechrisk/biotech.htm

USDA Initiative for Future Agriculture and Food Systems

The Initiative for future Agriculture and Food Systems IFAFS), legislated by Congress, authorized the secretary of Agriculture to establish a research, extension and education competitive grants program to address a number of critical emerging agricultural issues. These issues related to future food production, food safety, environmental quality, natural resource management, and farm income. http://www.reeusda.gov/ifafs/

Virtual Center of Biotechnology for the Americas

This site provides fast and convenient means for receiving and exchanging biotechnology-related information with particular emphasis on issues affecting Latin America. http://www.ibt.unam.mx/virtual.cgi

A Biosafety Regulatory Framework for the Caribbean: Regulatory authorities, -systems and -guidelines

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PREFACE

The biosafety guidelines presented in this report is a culmination of two weeks of deliberation by CARICOM participants in a Regional Capacity Building Workshop on Biosafety for the Caribbean conducted during the period 19-30 January, 2004. The workshop was organized by National Institute of Higher Education, Research, Science and Technology (NIHERST) with funding from IDRC/CRDI, Centre Technique de Cooperration Agricole et Rurale ACP-UE (CTA) and Caribbean Council for Science and Technology (CCST). The workshop was facilitated by Dr. Patricia L. Traynor (New Agritech Strategies, USA), Dr. Hector Quemada (Crop Technology Consulting, USA) and a number of Caribbean Biotechnology Experts.

Although the document speaks of a National Biosafety System for Trinidad and Tobago because of the familiarity of the author to the systems in Trinidad and Tobago, it can easily be extended to the countries in the rest of the CARICOM. To provide a hierarchical structure to the system, the document begins with a regional biosafety system which aims at harmonization between the national biosafety systems. Although, the document mainly deals with regulatory guidelines for laboratory, greenhouse, limited field research and commercial release of GMOs/ PNTs, I have taken the liberty to place this into a regulatory framework based on discussions at the workshop. This provides a holistic view of a regulatory framework that will allow the guidelines to be implemented. I have also hinted on how the regulatory system dealing with importation of GM foods can dove tail into the proposed system for implementation of the guidelines. This should be further developed involving regulatory agencies already involved in food safety.

I hope this document will be helpful as a nuts and bolts document in the development of a harmonious regional biosafety system that is based on common guidelines and common testing standards. The document was prepared after reviewing the US, Canadian, European and Australian guidelines and hence borrows features from many of these. I will like to acknowledge the support of IDRC/CRDI for facilitating the process of getting the documents together.

P. Umaharan, April, 2004.

A Biosafety Regulatory Framework for the Caribbean: Regulatory authorities, -systems and -guidelines

P. Umaharan, Department of Life Sciences, The University of the West Indies, St. Augustine, Republic of Trinidad and Tobago.

1.0 Introduction

The biotechnology revolution is influencing every sphere of human activity, including agriculture, human and animal health, biodiversity conservation, environmental remediation and waste recycling, industrial applications and forensics, and has unprecedented ramifications for mankind. When appropriately integrated with other technologies, biotechnology can play a significant role in meeting the needs of an expanding global population. Exploiting its potential will allow the achievement of competitiveness in every sphere of human endeavor in a sustainable manner.

The small island Caribbean states are characterized by fragile island ecosystems, with generally declining agricultural economies. The situation has worsened in recent times due to loss of preferential markets and declining competitiveness, in an increasingly globalized world. Biotechnology can provide the impetus necessary to these economies in developing niche products and services that are competitive, in a sustainable manner.

Fostering research and development in biotechnology requires a stable, enabling environment. A clearly articulated biotechnology policy within a lucidly spelt out science and technology policy is fundamental for biotechnology development. This will provide the vision and framework for human capacity development, development of technology transfer strategies and a funding structure to support research and development. In addition, a transparent and non-restrictive biosafety environment and a well developed intellectual property environment are important in fostering biotechnology development.

Genetically modified organisms/ food, cloning and stem cell culture are some biotechniques that have raised ethical, moral and safety issues. Such controversies have fueled lively and sometimes very passionate debates around the world. It is hence important to provide a transparent and safe environment for biotechnology development, so that it is not hampered by controversies, safety problems or public outcries.

The objective of a biosafety system, therefore, is to provide a transparent and safe environment for biotechnology development. Products of biotechnology, such as genetically modified organisms, are subject to special rules intended to ensure that they are used in a way not to pose an unacceptable risk to human, animal or plant health or to the environment. The small island Caribbean states, have an extremely fragile ecosystem, which needs to be managed at the highest safety standards without unduly being restrictive to biotechnology development. Trinidad and Tobago and other Caribbean countries which are signatory to the Cartagena biosafety protocol under the convention of

biological diversity, also have an obligation to implement a biosafety system that is consistent with the stipulation of the protocol.

This document provides an overview of the agreed positions on the proposed national regulatory framework for Caribbean countries, principles under which harmonization can be achieved within the region and agreed positions on the regulatory guidelines.

2.0 A Caribbean Biosafety system

It is essential that the national biosafety systems of individual Caribbean nations dove-tail in a harmonious manner within a regional biosafety system under the aegis of the CARICOM, and under some common principles, testing standards, expertise sharing agreements etc. It should however be recognized that each Caribbean country is a sovereign nation and hence the regulatory authority must reside at the national level. The CARICOM should establish a regional biosafety advisory committee (RBAC) to achieve harmonization and transparency within the trading partners.

Such a harmonized biosafety system is essential

a) to facilitate trade within the Caribbean Single Market Economy (CSME) and reduce the occurrence of trade disputes.
b) to establish a pool of experts who can bring a regional perspective to decisions making at the national level. In the Caribbean the biotechnology expertise is small and distributed between various islands and such pooling of intellectual capacity will improve safety.
c) to avoid duplication and increase efficiency. Development of common food safety standards and shared testing facilities will reduce the cost of testing and also will allow sharing of information towards greater efficiency.
d) to bring about a greater level of transparency of developments within the region by document sharing.
e) to bring greater consensus in decision making by a developing shared position documents on biology of Caribbean species, safety standards etc.
f) to develop joint public education or risk communication campaigns.
g) to lobby as a group at international fora aimed at achieving harmonization at the international level, for a Caribbean oriented perspective.

The agreement on principles of harmonization within the Caribbean region was obtained by a consensus building process and is articulated on a separate document. This document also deals in detail with the role of the CARICOM regional biosafety advisory committee.

3.0 The National biosafety system

Development of a national biosafety system involves the articulation of a biosafety policy and strategies, which will guide the development of a regulatory framework. The

regulatory development entails establishing a regulatory authority and legal framework, developing systems for biosafety implementation, guidelines and procedures. It is essential to maintain transparency at all levels of decision making.

3.1 Policy and Strategies

Each Caribbean nation should articulate a policy based on its developmental objectives and the how the nation perceives a role for biotechnology. The basis of decisions, whether scientifically based, or involves an element of socio-economic input, how the 'element' of precaution would be used in decision making, whether decisions are based on risks alone or based on risks vs benefits of the technology or risks of not using the technology. In addition, it should clarify whether the biosafety policy should be overarching dealing with all biosafety issue or confined to genetically modified organisms (GMO) or organisms with novel traits (ONT).

It was generally agreed that risk assessment and management is a scientific issue and should be done by scientists based on internationally agreed methods and procedures, since all decisions should be defendable at WTO committees. However, it was agreed that a socio-economic perspective should be incorporated through a consultative process to ensure that the decisions are socio-economically sustainable. While the use of element of 'precaution' is decision making is still being debated at international fora, it could be used as a basis, since many countries in the Caribbean are signatory to the Cartagena biosafety protocol. It was agreed that although the Cartagena biosafety protocol only deals with environmental safety of living modified organisms (LMO), a biosafety policy should be overarching and should deal with biosafety issues affecting food safety as well as public, animal and plant health issues.

3.2 Regulatory framework: authorities, roles and responsibilities

The regulatory framework envisaged for the national biosafety systems were similar to those recommended by NIH, with some modifications. Fig-1 shows the biosafety regulatory system for Trinidad and Tobago as an example – the regulatory authorities and their interactions. The proposed model borrows features from the Australian, European and US models.

3.2.1 National Biosafety Committee (NBC)

The NBC should be designated as the competent authority and all legal authorities for decision making should be vested in this authority. The national biosafety committee will be appointed by the Cabinet based on the recommendation of an advisory committee and would include various interest groups including scientists.

The NBC has the responsibility

- to develop or commission the development and updating of biosafety guidelines. It will also be responsible for distributing the guidelines to IBCs and to other stakeholders and interested parties. It will also maintain

consensus documents on issues which will guide the decision making process.

- NBC will receive applications for conducting research on LMOs and for limited or commercial release of LMOs into the environment from institutional biosafety committees (IBCs) through a secretariat. It will also receive applications for importation of GM food, feed or seed material, for field testing of LMOs by private companies, production of GM food or placing in market of GMOs. The NBC will maintain all contacts with the applicant with respect to decisions. Copies of all applications will be sent to Regional biosafety advisory committee (RBAC). If an applicant wishes to file an application in all countries of the region, then the application may be sent to RBAC, which will refer it to individual countries.

- It will be responsible for developing a review procedure for applications with timelines (Appendix-A) as well as collecting application fees. It would also develop a mechanism to resolve conflicts of interests when they arise.

    - Risk assessment and management (RAM) subcommittee will be responsible for conducting a thorough scientific review of the applications on behalf of the NBC. This subcommittee will constituted in such a way that it will be able to draw on available expertise, from within Trinidad and Tobago and if necessary from the Caribbean region. The membership will be rotated. NBC will also develop a policy to withhold confidential information before allowing access to the Risk Assessment and Management subcommittee.
    - Public input on the decisions of the RAM subcommittee may be obtained if necessary through a public forum, consisting of important stakeholders.
    - The NBC is responsible for the final decision and will superimpose socio-economic factors on the scientific review decisions and public perceptions.

- The NBC will be responsible for informing the decision to applicants and maintaining decision documents at every step of the decision making process with rationales. The decision may take the form of acceptance, acceptance with conditionalties, referred back for further information or rejection. When the application is referred for further information the clock will be stopped. It will be also be responsible for placing the decisions on gassette and notifying RBAC of decisions. The NBC will also outline appeal procedures for applicants and indicate how such appeals will be handled.

- Develop a contingency plan for unexpected eventualities and encourage the development of such by the IBCs.

- Further NBC will be charged with developing and implementing a Management Information System (MIS) that will ensure timeliness and transparency in decision making. Decision documents outlining the basis of decisions made, at each level, will be maintained and can be made available to the public based on the freedom of information act. The NBC is also responsible for implementing a system that can maintain confidentiality.

- to monitor the implementation of the biosafety guidelines in a timely and transparent manner by coordinating with other regulatory agencies such as the Environment Management Authority (EMA), Food and Drugs division of the Ministry of Health and the Plant and Animal Health Inspectorate of the Ministry of Agriculture. These agencies will operate on behalf of the NBC.

- The NBC will develop a labeling policy in collaboration with the Food and Drugs Division (FDD). The NBC is also responsible for commission the development of systems for traceability of GMOs or unique identification of GMOs.

- It will also be responsible for registering IBCs, based on predetermined set of criteria. It will also have the authority to revoke the IBC membership with conditionalities, based on evidence of non-compliance.

- It will also responsible for human resource development for regulatory implementation through commissioning training programmes.

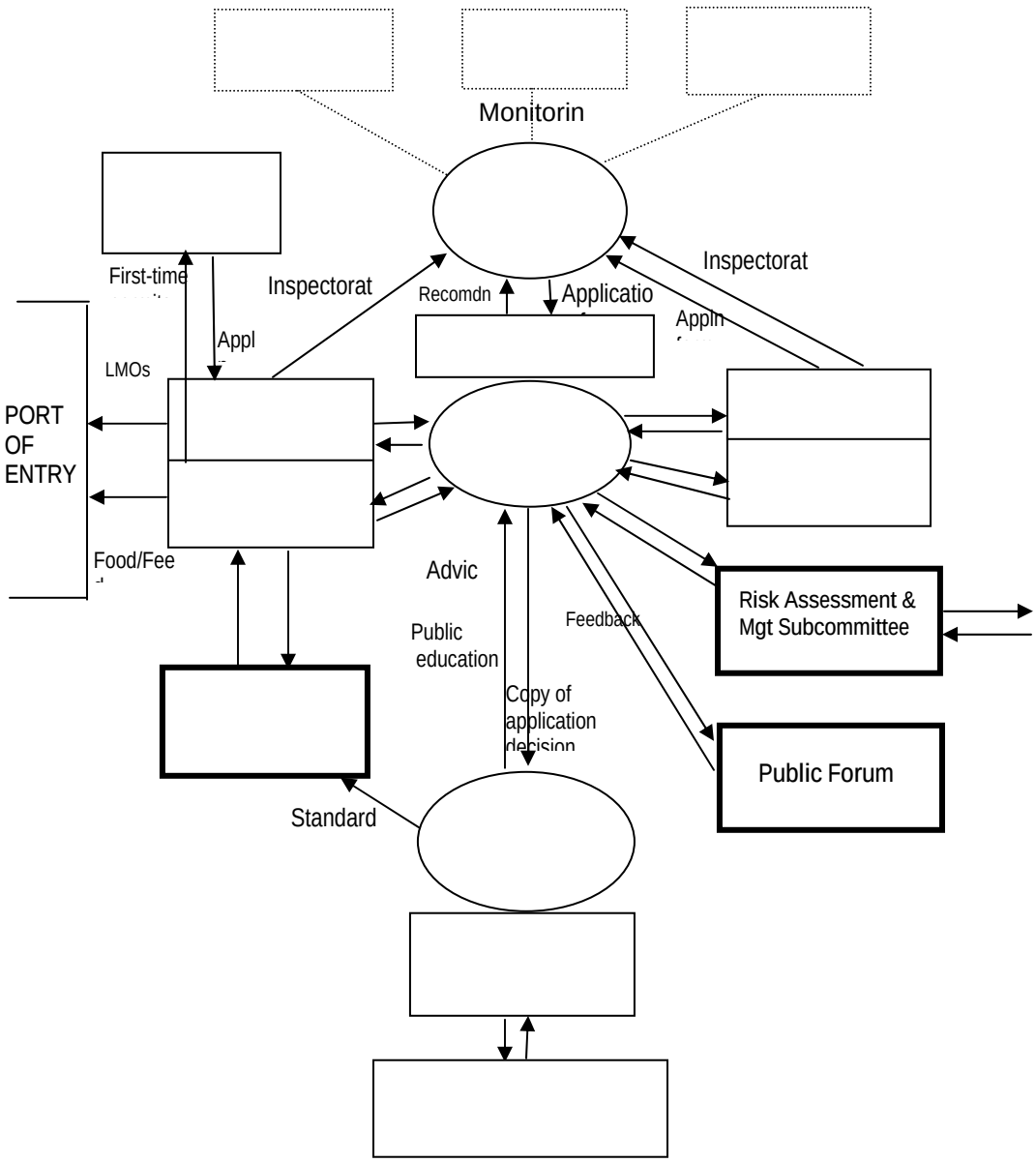
- In addition, public transparency would be maintained by a public forum, a web site and through a well structured public education campaign and risk communication programme.

- It will have the legal authority to bring recourse in the event of non-compliance by applicants, IBCs or Principal Investigators.

- It will coordinate with the regional biosafety advisory committee with respect to information exchange, dispute resolution, establishing a regional network of testing laboratories, negotiating positions at international fora, and in preparing concensus documents for decision making.

3.2.2 Other regulatory authorities –

Other regulatory agencies that will be involved in regulatory implementation would be the a) the Environment Management Authority (EMA); b) Plant and Animal Health Inspectorate of the Ministry of Agriculture and c) the Food and drugs division of the Ministry of health. All regulatory authorities will also have membership at the NBC.



NBC - National biosafety Committee
IBC - Research institution or importer of LMOs
RBAC - Reginal biosafety advisory committee
EMA - Environmental management authority
BCH - Biosafety clearing house - T&T

Fig-1- Biosafety regulatory system in Trinidad and Tobago and its relationship to the Regional Biosafety Advisory Committee (P. Umaharan, 2004)

i) Environmental Management Authority (EMA)

The EMA will have the responsibility for monitoring greenhouse as well as field trials (both restricted scale and field trials) conducted by the IBCs for adherence to environmental safety standards stipulated by the NBC, on a periodic basis, on behalf of the NBC. It also has a periodic reporting requirement to the NBC of all monitoring services performed.

j) Plant and Animal Health Inspectorate of the Ministry of Agriculture (PAHI)

PAHI is responsible for monitoring plant and animal health issues arising out of the recommendations made by the NBC. Monitoring all agricultural trials for agricultural impacts, transportation of GM planting material, suitability of site or green house will fall under the purview of PAHI on behalf of the NBC. It also has a periodic reporting requirement to the NBC of all monitoring services performed. In addition, PAHI on behalf or NBC shall be responsible for regulating the importation of genetically modified organisms (GMO's) into Trinidad and Tobago.

k) Food and Drugs division of the Ministry of Agriculture (FDD)

FDD will be responsible for receiving applications for the first time importation of genetically modified material intended for use as food or feed. The Food and Drugs will either do confirmatory tests using its facilities or through the network of affiliated food testing laboratories in the region and transmit 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) subcommittee and/ or simply obtain feedback from the public forum, prior to approval. Furthermore, FDD will develop a labeling policy consistent with recommendations from the NBC. FDD will have authority to 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

3.2.3 Regional biosafety Advisory Committee (RBAC)

This will be constituted by the CARICOM secretariat and will consist of scientists, regulators, legal personnel, trade specialists and members from the regional negotiating machinery. As the name suggests RBAC will have an advisory role.

The functions of RBAC will include

1. to develop regional positions for negotiations at international harmonization forums, by bringing the NBCs of the region together.
2. to develop food safety standards that are consistent among member countries, and assist in the establishment of a regional network of food testing laboratories.
3. to commission the development of consensus documents on crops and genetic modifications, to assist in harmonious decision making.
4. Maintain a website that summarises decisions taken by individual countries to ensure transparency. Communicate with each NBC for this. Maintain a database of human resource and biotechnology capacity within the region.

5. Mediate trade disputes arising from non-harmonious decisions taken by member countries.
6. Mount coordinated public education campaigns.

3.2.4 ***Institutional Biosafety Committee (IBC)*** –

Each institution shall establish an Institutional Biosafety Committee, whose responsibilities need not be restricted to recombinant DNA. The Institutional Biosafety Committee must be comprised of no fewer than five members, so selected that they collectively have experience and expertise in recombinant DNA technology and the capability to assess the safety of recombinant DNA research and to identify any potential risk to public health or the environment. Persons selected would have expertise in recombinant DNA technology, biological safety and physical containment as well as an expert in institutional commitments, policies, standards of professional conduct and applicable law. At least two members shall not be affiliated with the institution but may represent the interest of the community with respect to health and protection of the environment. Institutions conducting research and the BL3, BL4 levels or commercial scale research would require a designated biological safety officer, who would also be a member of the IBC. Each IBC should be registered with the NBC.

On behalf of the institution, the IBC is responsible for

- Reviewing recombinant DNA research conducted at or sponsored by the institution for compliance with the NBC Guidelines. All research projects involving recombinant DNA work require prior approval by the IBC. The applications should be prepared by the Principal Investigator describing the research work, highlighting the potential risks to plant, animal, human health and the environment and measures taken to ensure physical and biological containment. It should also indicate the competence available for management of these measures in his/ her team. This review shall include:
    - The safety level designation of the research project, BL1, BL2, BL3 or BL4 with a rationale.
    - Independent assessment of the containment levels required by the NBC Guidelines for the proposed research
    - Assessment of the facilities, procedures, practices, and training and expertise of personnel involved in research.
    - Ensuring that no research participant is enrolled in a human cloning or gene transfer experiments

- Notifying the Principal Investigator of the results of the Institutional Biosafety Committee's review and approval procedure in a timely fashion with recommendations of containment levels required. Ensuring compliance at laboratories by surveillance, data reporting, and adverse event reporting.

- Pursuing an application for GH or field trial with the NBC on behalf of the PI.

- Providing technical advice to Principal Investigators and the Institutional Biosafety

- Periodically reviewing recombinant DNA research conducted at the institution to ensure compliance with the NBC Guidelines. Appoint a biological safety officer to oversee field trials and to liase with the NBC and other regulatory authorities to conduct research under stipulated conditions (by NBC).

- Adopting emergency plans covering breech of containment, accidental spills and personnel contamination resulting from recombinant DNA research. Notifying the NBC of such incidents immediately.

- Develop a mechanism to resolve conflict of interests as well as maintain confidentiality.

- Providing advice and training on laboratory, greenhouse and field safety procedures for institute staff.

3.2.5 Principal Investigator (PI)

The Principal Investigator is responsible for full compliance with the NBC Guidelines in the conduct of recombinant DNA research. The Principal Investigator is responsible for ensuring that the reporting requirements are fulfilled and will be held accountable for any reporting lapses.

General Responsibilities

- Shall not initiate or modify recombinant DNA research which requires Institutional Biosafety Committee approval prior to initiation. Shall make an application to IBC with an initial determination of the required levels of physical and biological containment in accordance with the NBC Guidelines.
- Report any significant problems, violations of the NBC Guidelines, or any significant research-related accidents and illnesses to the IBC at the earliest possible time.
- Adhere to Institutional Biosafety Committee approved emergency plans for handling accidental spills and personnel contamination
- Comply with shipping requirements for recombinant DNA molecules
- Submit applications and get prior approval for Greenhouse or field testing from the NBC through the IBC.
- Submit information to NBC through IBC for certification of new host-vector systems
- Make available to all laboratory staff the protocols for laboratory safety and precautions to be taken.
- Instruct and train laboratory staff in the practices and techniques required to ensure safety and procedures for dealing with accidents.

- Supervise through the conduct of experiments that the stipulated safety levels are maintained.
- Maintain records in the laboratory of all biological hazard material, storage, use and disposal.

3.3 Regulatory guidelines define the structure of the biosafety framework

Regulatory guidelines describe special rules for the safe handling of transgenic materials during research and development or during their commercial exploitation. The objectives of the guidelines are to ensure that they are used in a way that does not pose unacceptable risk to human/ animal/ plant health or the environment. The guidelines are specific to each stage of GMO development, *viz* a) laboratory research, b) contained testing in greenhouses c) small and large scale field trials and d) unconfined release and d) post-release monitoring for long-term effects. An oversight mechanism is established to oversee whether the rules outlined in the guidelines are adhered to. The Plant and Animal Health Inspectorate (PAHI) and the Environment Management Authority (EMA) shall be charged with this function as described, earlier. Voluntary oversight mechanisms within each institution shall be set-up by the IBC. The rigor of the safety rules, within the guidelines depends on the biosafety level of the experiment carried out.

3.3.1 Assigning biosafety levels

The level of biosafety regulation applied to the above activities depends on the relative level of risk. The NIH guidelines 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 of GMOs.

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.

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.

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.
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.

3.4 Laboratory research guidelines

Methods for the safe handling of transgenic organisms or rDNA in laboratory settings during research and development are described in the NIH (National Institutes of Health) guidelines. There is general consensus, globally, on the laboratory guidelines used in recombinant DNA technology, and guidelines of most countries are based on the NIH guidelines. The objective of laboratory guidelines is to avoid the unintentional introduction and establishment of recombinant-DNA outside of the laboratory through a combination appropriate physical and biological containment measures.

3.4.1 Assigning biosafety levels

The level of regulatory control required for laboratory experiments depends on the assigned biosafety level for the experiment. Prior to the initiation of an experiment that is not placed on the exempt list by NBC, the PI must submit a registration document to the IBC which contains the following information: (i) the source(s) of DNA; (ii) the nature of the inserted DNA sequences; (iii) the host(s) and vector(s) to be used; (iv) if an attempt will be made to obtain expression of a foreign gene, and if so, indicate the protein that will be produced; and (v) the containment conditions that will be implemented as specified in the guidelines. The registration document shall be dated, signed by the PI, and filed with the IBC. Where necessary the IBC will apply for permission to initiate experiments to the NBC.

3.4.2 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. The following categories are recognized.

a) 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. e.g. 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), and any others that will not present any threat to the environment as determined by the NBC. NBC will also maintain a list of certified host-vector systems.

b) Experiment that require only IBC approval
The BL1 designation provides for a low level of containment for experiments involving GMOs, 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 and 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.

c) 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.

d) Experiments that require IBC approval, RAM subcommittee and public forum review and NBC approval

BL3 and 4 designation is 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.

3.4.3 Laboratory practices

For any experiment involving rDNA molecules a set of standard practices that are generally used in microbiological laboratories should be applied. Where a level of risk is assigned then additional physical and biological containment measures should be implemented.

a) Physical containment: Standard Practices and Training

The first principle of containment is strict adherence to good microbiological practices. Consequently, all personnel directly or indirectly involved in experiments using rDNA shall receive adequate instruction. At a minimum, these instructions include training in aseptic techniques and in the biology of the organisms used in the experiments so that the potential biohazards can be understood and appreciated. Any research group working with agents that are known or potential biohazards shall have an emergency plan that describes the procedures to be followed if an accident contaminates personnel or the environment. The PI shall ensure that everyone in the laboratory is familiar with both the potential hazards of the work and the emergency plan. If a research group is working with a known pathogen for which there is an effective vaccine, the vaccine should be made available to all workers. Serological monitoring, when clearly appropriate, will be provided.

b) Additional Physical Containment

The objective of physical containment is to confine organisms containing recombinant DNA molecules and to reduce the potential for exposure of the laboratory worker, persons outside of the laboratory, and the environment to organisms containing recombinant DNA molecules. Physical containment is achieved through the use of laboratory practices, containment equipment, and special laboratory design. Emphasis is placed on primary means of physical containment which are provided by laboratory practices and containment equipment. Special laboratory design provides a secondary means of protection against the accidental release of organisms outside the laboratory or to the environment. Special laboratory design is used primarily in facilities in which experiments of moderate to high potential hazard are performed. Combinations of laboratory practices, containment equipment, and special laboratory design can be made to achieve different levels of physical containment. The selection of alternative methods of primary containment is dependent, however, on the level of biological containment provided by the host-vector

c) Biological containment

In consideration of biological containment, the vector (plasmid, organelle, or virus) for the recombinant DNA and the host (bacterial, plant, or animal cell) in which the vector is propagated in the laboratory will be considered together. Any combination of vector and host which is to provide biological containment shall be chosen or constructed so that the following types of "escape" are minimized:

- survival of the vector in its host outside the laboratory, and
- transmission of the vector from the propagation host to other non-laboratory hosts.

The following levels of biological containment (host-vector systems) for prokaryotes are established.

i) *Host-Vector 1 Systems*

Host-Vector 1 systems provide a moderate level of containment. Escherichia coli K-12 Host-vector 1 Systems (EK1) - The host is always Escherichia coli K-12 or a derivative thereof, and the vectors include non-conjugative plasmids (e.g., pSC101, Co1E1, or derivatives thereof and variants of bacteriophage. The Escherichia coli K-12 hosts shall

not contain conjugation-proficient plasmids, whether autonomous or integrated, or generalized transducing phages.

ii) *Host-Vector 2 Systems (EK2)*
Host-Vector 2 Systems provide a high level of biological containment as demonstrated by data from suitable tests performed in the laboratory. Escape of the recombinant DNA either via survival of the organisms or via transmission of recombinant DNA to other organisms should be < 1/108 under specified conditions. Specific Host-Vector 2 systems are for Escherichia coli K-12 Host-Vector 2 systems (EK2) in which the vector is a plasmid, no more than 1/108 host cells shall perpetuate a cloned DNA fragment under the specified non-permissive laboratory conditions designed to represent the natural environment, either by survival of the original host or as a consequence of transmission of the cloned DNA fragment. For Escherichia coli K-12 Host-Vector 2 systems (EK2) in which the vector is a phage, no more than 1/108 phage particles shall perpetuate a cloned DNA fragment under the specified non-permissive laboratory conditions designed to represent the natural environment, either as a prophage (in the inserted or plasmid form) in the laboratory host used for phage propagation, or survival in natural environments and transferring a cloned DNA fragment to other hosts (or their resident prophages).

The laboratory safety guidelines recommended for each biosafety level is provided as Appendix-2 (adopted from the NIH guidelines).

3.5 Guidelines for greenhouse research

3.5.1 Scope and objectives

The guidelines cover research carried out on genetically modified plants or plant associated organisms in greenhouses. The term plant includes, but is not limited to, mosses, liverworts, macroscopic algae, and vascular plants. The plant associated organisms may include viruses, bacteria, fungi, protozoa, mycoplasma, nematodes, insects, mites etc. The guidelines recommend greenhouse facility specifications and containment measures for various biological experiments according to four biosafety levels (See section 3.3.1) and a fifth class encompassing experiments that are exempt.

The objective is to provide a set of special rules to ensure that the work carried out in greenhouses does not pose an unacceptable risk to human health or the environment. The guidelines are intended as a simple and convenient reference to appropriate biosafety and containment levels for GMO research conducted in greenhouses.

3.5.2 Regulatory approvals

The regulatory approvals required before commencement of experiment depends on the assigned biosafety level of the experiment. Experiments may be exempt from any approval, may require only IBC approval (BL1), may require IBC approval, RAM review and NBC approval (BL2) or require IBC approval, RAM and Public forum

review and NBC approval. Details of this process have been described in Section 3.4.2. All regulatory approval mechanisms should be supported by legislative measures.

3.5.3 Roles and responsibilities

The institutional biosafety committees serve as the local authority and are responsible for oversight to ensure that work within the institution is carried out according to the specified rules pertaining to containment conditions within greenhouses. The IBC will include at least one scientist with experience in plants and plant pathogens. A biosafety officer may be assigned by the IBC to ensure that work is carried out according to guidelines. 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.

Ultimately, the safe handling of GMOs lies with the Principal Investigator. The Principal Investigator in coordination with the greenhouse manager, other researchers and technicians should develop a containment plan and a contingency plan for each experiment according to the assigned biosafety level, which will submitted to the IBC or approval. Further approvals if required will be pursued by the IBC. This will include specific plans for the movement of gmos, access to greenhouses during the experimental period, signage, recording keeping, destruction of plant material and propagules at the end of experiment, contingencies etc. A policy and procedures manual should be prepared and shared with everyone involved in the research. The PI is also responsible for training of all researchers and technicians on biosafety procedures, where necessary, who will in turn oversee safety standards with regard to day-to-day research operations at the green house. The PI along with researchers and technicians will be responsible that an appropriate labeling system is implemented where each experimental unit can be uniquely identified, as well as an activity log maintained for each experiment and termination procedures used in destroying material.

The greenhouse manager assumes full responsibility for implementation of the biosafety procedures developed on a day-to-day basis. He/she will put in place procedures for restricting and recording access (PI determines who has 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 greenhouse facility to the required safety level, implement a routine rodent control programme, ensure that the facility is secure from possible intruders, maintain all equipment, including autoclave, in good working condition and manage the contingency plan in case of emergencies. The greenhouse manager will also take responsibility for training all greenhouse safety procedures.

The ability to take responsibilities and ability to conduct their duties in a composed, methodical manner paying attention to details and commitment to biosafety are some characteristics that should be sought in recruitment of staff. The PIs and Greenhouse managers should be trained on biosafety procedures and containment principles, who in turn will train all those working under their supervision.

3.5.4 Reporting requirements

The PI is responsible for the safety of the research activities; however, responsibility for all procedural matters at the greenhouse level lies within the purview of the greenhouse manager. The greenhouse manager shall write reports under prescribed headings, (facility integrity, security issues, access issues, signage, labeling issues, rodent control and other greenhouse management issues etc) to the PI on a monthly basis. When breaches of containment occur the greenhouse manager shall report this to the PI and IBC immediately. The PI is responsible for preparing a comprehensive report to the IBC including in addition, transportation, harvest and seed control, pollen control, termination procedures, labeling issues and technical issues relating to the experiment to the IBC with the aid of other researchers and technicians. Where high biosafety level experiments are carried out the IBC shall report monthly to the NBC on the progress of the experiment and the progress may be monitored by the biosafety officer on behalf of the IBC and PAHI on behalf of NBC. 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.

3.5.5 Containment systems

The objective of containment is to accomplish the following through a combination of physical containment, biological containment, good greenhouse management and general safety and hygiene.

- Avoid unintentional transmission of rDNA containing plant genomes or release of rDNA-derived organisms associated with plants.
- Minimize the possibility of unanticipated deleterious effects on organisms and ecosystems outside of the experimental facility
- Avoid the inadvertent spread of a serious pathogen from a greenhouse to a local agricultural crop
- Avoid the unintentional introduction and establishment of an organism in a new ecosystem.

Physical containment shall be achieved through a combination of greenhouse design, physical barriers (mesh, growth chambers), greenhouse management systems such as security, restricted access, records, reporting systems, labeling and signage, transfer procedures, decontamination and termination procedures, secure seed storage (locked cabinets) rodent control and if necessary protective clothing and general hygiene.

Biological containment can be achieved by the following. Effective dissemination of plants by pollen or seed can be prevented by one or more of the following procedures: (i) cover the reproductive structures to prevent pollen dissemination at flowering and

seed dissemination at maturity; (ii) remove reproductive structures by employing male sterile strains, or harvest the plant material prior to the reproductive stage; (iii) ensure that experimental plants flower at a time of year when cross-fertile plants are not flowering within the normal pollen dispersal range of the experimental plant; or (iv) ensure that cross-fertile plants are not growing within the known pollen dispersal range of the experimental plant. Additional biological containment strategies are required if microorganisms or macro organisms are involved in the experiment (See Appendix-3).

Containment requirements are more stringent if plant pathogens or insects are included in the experiment. Research involving transgenic plants at the BL1-P or BL2-P containment levels requires little more than the basic facilities, equipment and protocols common to most research greenhouses. However, greenhouses that offer higher level BL3-P or BL4-P containment require special design and are more expensive to build. In such instances use of growth room or growth chambers may be more economically acceptable. Appendix-3 describes the containment measures required for experiments at various biosafety levels.

3.5.6 Security and Access

These are important part of containment and should be more stringent for higher level of biosafety. The requirements for the various biosafety levels are provided in Appendix-3.

3.5.7 Labelling and identification

Each GMO experimental unit shall be individually identified and double labeled. Colour coded labels may prevent mistakes. This will allow recording of harvesting, termination procedures simple. Label should include at least an identification number, treatment, and gene construct used.

3.5.8 Transfer procedures / seed storage

A clear procedure for transfer to GM material from laboratory to greenhouse should be described. The material should be transferred in covered vehicles, properly identified. For experiments BL2-P or higher, seeds shall be transported in closed, sealed, labeled, unbreakable containers. For BL3-P and BL4-P, the container should be placed in a secondary container and the exterior surface decontaminated. The quantity in containers should be clearly specified in the label. Seeds should be clearly labeled and locked in a cabinet. A record shall be kept of person and usage of seeds from the container.

3.5.9 Termination procedures

All material from the experiment should be rendered biologically inactive before disposal. They can be inactivated by steam or chemical sterilization, autoclaving or incineration. For larger volumes, composting is acceptable for experimental plant and soil material. Prior to composting plant material can be devitalized by dehydration, or chopping and mincing. For disposing plants with fine seeds special

attention should be paid. Fine mesh bags placed around the flower heads or a sheet of dampened white paper placed under the plant can help to recover all seeds.

3.5.10 Contingencies

Contingencies can be breach due to hurricane, flooding, earthquake, fire or other natural disasters, or it can be caused by industrial action, eco-terrorists/domestic, vandalism, terrorism etc. A contingency plan should be developed identifying the most likely breach of containment that can occur. There should be a clearly articulated policy on how these can be managed by choice of greenhouse site, public education campaigns etc. Back up systems should be developed especially when higher biosafety level experiments are carried out. Signage should clearly indicate who to contact and what should be done immediately, in cases of loss of containment.

3.5.11 Inspection / oversight

Inspection systems that aim to evaluate the effectiveness of containment system should use a check list comprising at least the following.

- Who is the responsible party? Is their contact information posted on the door
- What is the nature of GMO and how is it identified?
- What is the prescribed level of containment? Do the physical facilities meet this level?
- What specific physical and biological measures are being used to achieve that level of containment?
- Are prescribed practices being followed? Can these be substantiated by records?
- Is there any areas of deficiencies with regard to containment?
- How is the area secured? What security is required?
- Is there a written plan to respond to loss of containment? What is the most likely containment breach?
- Is there a training and procedural manual available to all staff?

3.5.12 Other references:

Adair, D, Irwin, R and Traynor, P.L. (2001). A Practical Guide to Containment: greenhouse research with Transgenic plants and microbes. Information Systems for Biotechnology, USA, 59 pp.

National Institutes of Health (2002). Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines). Department of Health and Human Services, USA, 132 pp.

3.6 Guidelines for limited scale field trials.

3.6.1 Scope and objectives

The guidelines cover research carried out on genetically modified crops or plants with novel traits (PNT) in limited scale field trials. This is basically a research step and precedes unconfined commercial release into the environment.

The term plant includes, but is not limited to, mosses, liverworts, macroscopic algae, and vascular plants. GM crops refer to crops that have been modified using genes from outside the usual crossability barriers, using the recombinant-DNA technology. These are sometimes also referred to as transgenic crops. PNTs are plants containing traits not present in plants of the same species already existing as stable populations (wild or cultivated) in Trinidad and Tobago or are expressed outside the normal statistical range of similar existing traits in the plant species. As a result, plants developed through mutagenesis, somaclonal variation, widecross, protoplast fusion or other such techniques as well as plants developed through rDNA technology may be considered PNTs. Hence, PNTs are broader in definition than GM crops.

The guidelines recommend confinement measures for field experiments conducted for research purposes at any of the four biosafety levels (See Section 3.3.1) through assessments on a case-by-case basis. The objective is to provide a set of special rules to ensure that the work carried out in field does not pose an unacceptable risk to human health or the environment. The guidelines are intended as a simple and convenient reference to appropriate biosafety confinement levels for GMO research conducted in fields.

3.6.2 Regulatory approvals and Adminstrative process

The National Biosafety Committee is responsible for regulating the intentional introduction of GMOs or PNTs into the environment based on (provide legal basis). The regulations require that all such introductions should be subjected to an environmental safety assessment process, which shall be carried out by the RAM subcommittee or any of the other regulatory agencies (3.2.2). The assessment criteria are designed to be used in conjunction with species-specific biology documents that describe the biology of species to which the GMO/PNT belongs, including details of other life forms with which it interacts. The regulatory approval is required before commencement of any experiment.

New applications should be submitted if previously approved PNTs are now to be tested in a new environment or if it has been further modified genetically by gene stacking or re-mutation, re-transformation or any other way. All regulatory approval procedures should be supported by legislative measures.

a) Application process

Applications are invited from IBCs registered with the NBC, on prescribed forms available at the NBC secretariat and at the Biosafety Clearing House website. Information regarding the application process can be also obtained from these two points. Where it is a commercial outfit that is seeking regulatory approval, such applications should be directed through a registered IBC, with a clear description between the relationship and responsibilities of the IBC. The applicants are strongly encouraged to apply well in advance of the anticipated time of conducting field tests. If an initial application is rejected, the applicant is eligible to apply again with new information.

Application forms require complete contact information of the applicant, description of the plant with respect to its taxonomy, pedigree of variety used, biology of the plant, habit, life cycle, related species in the environment, interactions of PNT in the environment- out crossing frequency, volunteers effects; description of the modification for the PNT, including genes, constructs, transformation vectors and methods used, characterization of inserted DNA, protein and RNA characterization and expression profiles, description of the novel trait, description of the inheritance and stability of introduced traits that are functional in the plant, description of the parental genome, number of generations removed from the original as well as the objective of modification; Description of the experiment to be carried out and purpose; Description of the area cultivated, including a line map, description of cultivation practices, residual effects and toxicity; Risks identified and management strategies to be employed, with respect to gene flow, harvesting, seed storage and termination procedures, post-trial monitoring of the field site for volunteers/ weediness and site security. Applicant would also be asked whether any part of the application is to remain confidential business information. (CBI). Applicant is responsible for providing information completely and truthfully.

The NBC secretariat (contact information) shall receive FOUR copies of the applications for trial release of PNTs along with the application fee. The application can also be sent electronically. The NBC shall assess the eligibility of the applicant and the completeness of the application form and if unsuitable return it to the applicant within 10 working days indicating the reason for rejection. The applicant has the right resubmit with additional information, without an additional fee. If application is accepted then an acknowledgement 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.

(b) Review process and recommendations

The NBC shall commission a scientific review by the RAM subcommittee and in specific cases a public consultation through the public opinion subcommittee. 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 NBC will deliberate based on recommendations received and make recommendations within 90 days of acceptance of application. The clock may be stopped if the applicant needs to submit further information, at some evaluation step.

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 applicant will be given 30 days to respond.

c) Public information. and transparency

The decision will be gazetted and public informed thorough newspaper-advertisements prior to initiation of experiment. The NBC will publish a yearly review of applications approved. The decision documents containing the rationale behind the decision making process, should be made available to the public under the freedom of information act. The NBC should have regular public awareness and risk communication campaigns.

d) Inspection and oversight

The recommendation is sent to the regulatory authorities (PAHI/ EMA), who will be responsible for monitoring of trials carried to ensure that the risk management strategies suggested are duly implemented. The regulatory institutions will therefore liase with the applicant and conduct inspections at critical times or periodically. The regulatory authorities will send both periodic reports and adhoc reports, in cases of breach of confinement, to the NBC. The NBC usually notifies the IBC to correct the procedures within stipulated time periods. In cases of continuous breach the NBC reserves the right to terminate all procedures and revoke the approved status of the IBC.

e) Roles and responsibilities

Roles and responsibilities of RBAC, NBC, RAM, IBC, and PI are clearly described in Section 3.2. In addition, for field experiments, the IBC shall appoint a Site Manager to oversee and be responsible for operations and to observe adherence to NBC stipulated guidelines for conducting the field trial. 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.

f) Reporting

All personnel involved in operations at the site shall be accountable to the site manager. Site manager may develop a management plan for the management of the trial along with the PI, so that the research process is not hampered and there are no conflicts. The site manager along with the PI, shall send reports, periodically (specified by the NBC), to the NBC through the IBC. The reports will address the progress of the experiment with respect to technical aspects of the trial as well as safety and security aspects. The report shall flag any potential risk factors that may have not been foreseen. Any contingencies shall be reported to the NBC through the IBC, immediately, but not later than 1 week. PAHI and EMA send periodic reports to the NBC at stipulated intervals.

g) Enforcement

NBC will be authorized by law to apply penalties according the seriousness of the infraction and can range from warnings, fines, activities delayed, permits withdrawn, seizure and destruction or criminal proceedings.

3.6.3 Confinement principles and practices

The objective of confinement measures employed is to accomplish the following through a combination of physical confinement and biological confinement measures

- Avoid unintentional introduction and establishment of GMOs or PNTs into the environment through gene flow
- Minimize the possibility dispersal of seeds through natural mechanisms or theft
- Avoid the inadvertent spread of organisms through volunteer plants.
- Avoid the unintentional health influences caused by allergenicity of pollen. This is however true for specific GM plants that may express proteins that may be allergenic.

Physical confinement shall be achieved through a combination of careful site selection (where feral populations or cultivated crops of the species do not exist within stipulated isolation distances for the crop or they are carefully removed); through site security, restricting access to personnel and by posting proper signage; by implementing a system of labeling and recording system (where any changes in plant number can be discerned); and by implementing a system to carefully collect seeds (bagging the inflorescence) during harvesting and monitoring for volunteers through post-trial monitoring procedures.

Biological confinement can be achieved through male sterility or by harvesting plants prior to flowering, flower removal or bagging of flowers or by ensuring that experimental plants flower at a time of year when cross-fertile plants are not flowering within the normal pollen dispersal range of the experimental plant. Depending on the species buffer zones, insect traps, chemical sprays, and border rows (pollen traps) can be used to restrict gene flow. Restricting growing the crop two years before and two years after the trial.

The confinement measures that are appropriate for a particular field trial depend on the assigned biosafety level for the experiment. This will be part of the regulatory approval process (See Section 3.3.1).

3.6.4 Security and Access

The site should be surrounded by a high security fence and gate with locks, to prevent larceny especially for higher biosafety level experiments. The site should also have proper signage indicating the nature of the trial as well as biohazard signs, along the perimeters. Contact information of persons to be contacted in cases of breach of confinement should also be specified. These should be restricted and managed especially if the risk associated with gene flow is large as assessed through scientific risk assessment.

3,6,5 Labeling and identification

Each GMO experimental unit shall be individually identified and double labeled. This will allow recording of harvesting, and termination procedures simple, especially if plants are stagger planted. Label should include at least an identification number, treatment, and gene construct used. Colour coded labels may prevent mistakes. Labeling should be backed up by a field plan identifying each plant uniquely on a map.

3.6.6 Transfer procedures / seed storage

A clear procedure for transfer to GM material from greenhouse to the field should be developed and implemented. The material should be properly labeled and transferred in covered vehicles. For experiments BL2-P or higher, seeds shall be transported in closed, sealed, labeled, unbreakable containers. For BL3-P and BL4-P, the container should be placed in a secondary container and the exterior surface decontaminated. The quantity in containers should be clearly specified in the label. Chain of custody forms may be used to ensure that the seeds are not removed from site. Seeds should be clearly labeled and locked in a cabinet. A record shall be kept of person and usage of seeds from the container.

3.6.7 Termination procedures

All plant material from the experiment should be rendered biologically inactive before disposal. They can be inactivated by steam or chemical sterilization, autoclaving or incineration. For larger volumes, use of herbicides, desiccation/ burning or composting is acceptable for experimental plant and soil material. Prior to composting plant material can be devitalized by dehydration, or chopping and mincing. For disposing plants with fine seeds special attention should be paid. Fine mesh bags placed around the flower heads or a sheet of dampened white paper placed under the plant can help to recover all seeds. Some seeds do not burn or incinerate well, these require autoclaving.

3.6.8 Contingencies

Contingencies can result in breach of confinement due to hurricane, flooding, or earthquakes, fire etc or it can be caused by industrial action, eco-terrorists/domestic,

vandalism, terrorism etc. The IBC and NBC should be immediately informed in case of breach of confinement. A contingency plan should be developed identifying the most likely breaches of confinement that can occur. This should be supplied as part of the application process. There should be a clearly articulated policy on how these can be managed by choice of site, public education campaigns etc. Back up systems should be developed especially when higher biosafety level experiments are carried out. Signage should clearly indicate who to contact and what should be done immediately, in cases of loss of confinement. In cases of breach, fruits and flowers should be removed and destroyed.

3.6.9 Post-trial monitoring

All sites should be left fallow (or planted with an alternative crop) for a stipulated time depending on the crop and monitored for volunteers. Such volunteers should be removed and destroyed. The IBC is responsible for this process and reporting to the NBC will continue for the stipulated post-trial monitoring period. The site manager shall be charged with this responsibility. Oversight would be provided by the EMA.

3.6.10 Staff training, public awareness

The IBC is responsible for training all staff members involved in the field trial on biosafety issues relevant to limited field trials and risk management options. This could be done in collaboration with tertiary level institutions. The IBC should also prepare procedural manual for all staff involved.

3.7 Guidelines for the Commercial release of GMOs

3.7.1 Scope and objectives

The guidelines cover procedures and issues related to unconfined commercial release of genetically modified crops or plants with novel traits (PNT). This is the last regulatory step prior to issuing the transgenic crop unregulated status. The objective of this regulatory step is to provide a set of special rules to ensure that the commercial release does not pose an unacceptable risk to human health or the environment. At this stage, in addition to scientific risk assessment, the regulatory objectives include assessment of socio-economic impact of introduction, public opinion assessment and a cost-benefit analysis. The definitions for plants, GMO and PNT are provided in Section 3.5.1.

3.7.2 Agricultural, environmental and food safety issues.

The scientific risk assessment guidelines should address the following biosafety concerns/ questions in a satisfactory manner before regulatory approval for commercial release can be granted. The objective of the guidelines is to provide a systematic means of assessing whether commercial release of the GMO or PNT would pose an unacceptable risk to human, animal or plant health and to the environment.

- Will the transgenic crop become a weed? Will it be possess greater vigor and fitness, will it be early maturing or stress tolerant than the non-transgenic counterpart that it may prove to give the plant a competitive advantage.
- What is the likelihood for gene flow to occur to sexually compatible feral populations? And if gene flow does occur, does it pose an unacceptable level of risk to the feral populations? Will it cause its wild relatives to become difficult to control weeds? What effects will it have on the distribution and abundance of the population? What effects will it have on genetic resources? Can this be managed?
- Will the new cultivation practices associated with transgenic crops cause harm to agriculture? What is it effect on crop genetic diversity?
- If a GM pest resistant crop is developed, what is the likelihood of resistance breakdown? Can this be managed?
- Will there be long-term effects on the ecological balance, soil organisms or soil nutritional status? Will the transgenic plant modify the characteristics or abundance of other species?
- What is the likelihood of new pathogens evolving by recombination or transcomplementation? or is there an unintended pest risk through changes in the ecology?
- Would the transgene product affect non-target organisms, if so, what would be the effect on non-target organisms?
- Can the seeds escape and become established into the wild as volunteer plants? What would be the risk associated with this event?
- Will the pollen be toxic or cause allergenicity? Has ecotoxicology studies been carried out?
- Will the new gene product or changes associated with the GMO result in allergenicity or toxicity?
- What other unintended changes in nutritional quality, carbohydrate and protein profiles are seen in the GMO? What is the influence of the marker gene protein?
- What will be the effect of antibiotic resistant marker genes used on the environment?
- Has a complete molecular characterization carried out, with respect to the number of insertion events, sequence junction sites between gene and genomic DNA, structure and stability of inserted element, characterization of the expressed protein, post-transcriptional modifications, expression profile etc

3.7.3 Regulatory approvals and Adminstrative process

The National Biosafety Committee is responsible for regulating the intentional introduction of GMOs or PNTs into the environment based on (provide legal basis). The regulations require that all commercial releases of GMOs/PNTs should be subjected to an agricultural, environmental and food safety assessment process, which shall be carried out by the RAM subcommittee or any of the other regulatory agencies (3.2.2). The assessment criteria are designed to be used in conjunction with species-specific biology documents that describe the biology of species to which the GMO/PNT belongs, including details of other life forms with which it interacts. The regulatory approval is required before commencement of any experiment. In

addition, public opinion shall be obtained through a public forum and a complete socio-economic assessment including a cost-benefit analysis shall be carried out by the NBC.

New All regulatory approval procedures should be supported by legislative measures.

a) Application process

Applications are invited from IBCs registered with the NBC, on prescribed forms available at the NBC secretariat and at the Biosafety Clearing House website. Information regarding the application process can be also obtained from these two points. Where it is a commercial outfit that is seeking regulatory approval, such applications should be directed through a registered IBC, with a clear description of the relationship and responsibilities of the IBC. The applicants are strongly encouraged to apply well in advance of the anticipated time of commercial release and to abide by rules and regulations of the country into which commercial release is intended. If an initial application is rejected, the applicant is eligible to apply again with new information.

Application forms require complete contact information of the applicant, information on whether the GMO in question was imported or locally developed; description of the plant with respect to its taxonomy, pedigree of variety used, biology of the plant, plant habit, life cycle traits; related species in the environment, interactions of PNT in the environment with sexually compatible species and non-target species, impact on pollinator species; novelty of GMO, novel product; selective advantage with respect to life history traits, outcrossing frequency, weediness, and stress adaptations; volunteers effects; description of the modification for the PNT, 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 novel trait; description of the inheritance and stability of introduced traits that are functional in the plant, 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 GMO, residual effects and toxicity. The application should also clearly state the risks identified and how the risk would be managed. The applicant shall also outline a monitoring arrangement to assess the long-term impacts of the introduction as well as plan if contingencies arise. The former may not be necessary in all cases. All information provided by the applicant should be backed up by scientific data and rationale. Applicant would also be asked whether any part of the application is to remain confidential business information. (CBI). Applicant is responsible for providing information completely and truthfully.

The NBC secretariat (contact information) shall receive FOUR copies of the applications for trial release of PNTs along with the application fee. The application

can also be sent electronically. See Appendix-4 for application checklist. The NBC shall assess the eligibility of the applicant and the completeness of the application form and if unsuitable return it to the applicant within 10 working days indicating the reason for rejection. The applicant has the right to resubmit with additional information, without an additional fee. If application is accepted then an acknowledgement 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 NBC should have a policy to deal with confidential information. The application forms will be sent for subcommittee reviews and RBAC after such information is removed.

(b) Review process and recommendations

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 FDD to carryout a complete food safety assessment, prior to making a decision. In such cases, the clock may be stopped. The NBC shall superimpose the scientific assessment and public opinion to a socio-economic assessment and a cost-benefit analysis that 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 applicant 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 GMOs. It will also set in motion an oversight mechanism through the EMA or PAHI or both.

c) Reporting/ Record keeping

NBC is the biosafety authority under law. Applicants (IBC) shall submit applications to and seek information from only the NBC. The NBC will maintain an internet accessible database of all applications received and what stage they are in, and which ones have received approval. All subcommittees (RAM, public opinion) and regulatory authorities (FDD, PAHI and EMA) shall report to the NBC in a timely fashion. The decision documents with respect to the subcommittees and reports with respect to the regulatory authorities should be sent to the NBC. The NBC shall

collate all documents and make them available (after carefully removing proprietary information) to the public. The NBC will develop and implement a Management Information System (MIS) and shall be responsible for all public education campaigns, risk communications, notifications and advertisements. Refer to Section 3.2 for further elaboration of the roles and responsibilities.

d) Public information and transparency

The decision to allow or disallow the commercial release of a GMO will be gazetted and public informed thorough newspaper- advertisements. The NBC will publish a yearly summary of GMOs approved for commercial release. The decision documents containing the rationale behind the decision making process, should be made available to the public under the freedom of information act. The NBC should have regular public awareness and risk communication campaigns.

e) Inspection and oversight

The recommendation is sent to the regulatory authorities (PAHI/ EMA), who will be responsible for monitoring whether the risk management strategies and long-term monitoring suggested are duly implemented. The regulatory institutions will make adhoc visits to commercial fields. The regulatory authorities will send adhoc reports, as necessary, to the NBC.

f) Enforcement

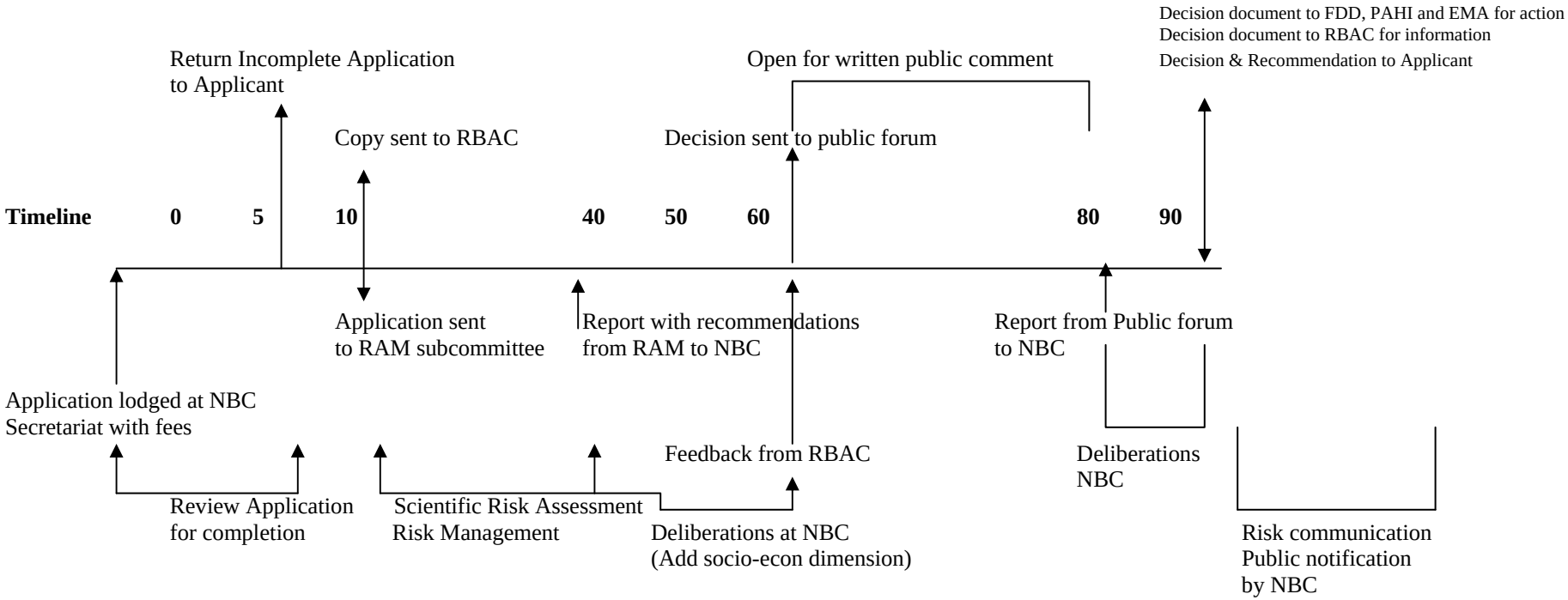
It is the duty of the applicant to ensure that all the information provided are truthful and scientifically valid. Further, the applicant is responsible for implementing the conditions applied to the approval of the application.

NBC will be authorized by law to apply fines or penalties according the seriousness of the infraction and can range from warnings, fines, activities terminated, seizure and destruction, permits withdrawn or criminal proceedings.

3.7.4 Contingencies

Contingencies can result due to adverse public opinion or unintended effects of the GMO with respect to agriculture or the environment or with respect to food safety issues. In such cases, the NBC should develop a contingency plan that could be implemented through the regulatory authorities. This may involve withdrawing food from the supermarket shelves, termination of all crops and seeds relating to that particular release, managing the public communication and mounting public information campaigns, implementing a tracking system for specific GMOs or traceability through the commodity chain etc.

APPENDIX-1 TIME LINE APPLICATION REVIEW PROCESS



APPENDIX-2: Laboratory Safety Guidelines
(Adopted from the NIH Guidelines)

Biosafety Level 1 – BL1

Standard Microbiological Practices (BL1)

- Access to the laboratory is limited or restricted at the discretion of the PI when experiments are in progress.
- Work surfaces are decontaminated once a day and after any spill of viable material.
- All contaminated liquid or solid wastes are decontaminated before disposal.
- Mechanical pipetting devices are used; mouth pipetting is prohibited.
- Eating, drinking, smoking, and applying cosmetics are not permitted in the work area.
- Food may be stored in cabinets or refrigerators designated and used for this purpose
- Persons wash their hands: (i) after they handle materials involving organisms containing recombinant DNA molecules and animals, and (ii) before exiting the laboratory.
- All procedures are performed carefully to minimize the creation of aerosols.
- In the interest of good personal hygiene, facilities (e.g., hand washing sink, shower, changing room) and protective clothing (e.g., uniforms, laboratory coats) shall be provided that are appropriate for the risk of exposure to viable organisms containing recombinant DNA molecules.

Special Practices (BL1)

- Contaminated materials that are to be decontaminated at a site away from the laboratory are placed in a durable leak-proof container which is closed before being removed from the laboratory.
- An insect and rodent control program is in effect.

Containment Equipment (BL1)

- Special containment equipment is generally not required for manipulations of agents assigned to BL1.

Laboratory Facilities (BL1)

- The laboratory is designed so that it can be easily cleaned.
- Bench tops are impervious to water and resistant to acids, alkalis, organic solvents, and moderate heat.
- Laboratory furniture is sturdy. Spaces between benches, cabinets, and equipment areaccessible for cleaning.
- Each laboratory contains a sink for hand washing.
- If the laboratory has windows that open, they are fitted with fly screens.

Biosafety Level 2 (BL2)

Standard Microbiological Practices (BL2)

- In addition to BL1 microbiological practices
- Experiments of lesser biohazard potential can be conducted concurrently in carefully demarcated areas of the same laboratory.

Special Practices (BL2)

- In addition to BL1 practices
- The Principal Investigator limits access to the laboratory. The PI has the final responsibility for assessing each circumstance and determining who may enter or work in the laboratory. The Principal Investigator establishes policies and procedures whereby only persons who have been advised of the potential hazard and meet any specific entry requirements (e.g., immunization) may enter the laboratory or animal rooms.

- When the organisms containing recombinant DNA molecules in use in the laboratory require special provisions for entry (e.g., vaccination), a hazard warning sign incorporating the universalbiosafety symbol is posted on the access door to the laboratory work area. The hazard warning sign identifiesthe agent, lists the name and telephone number of the PI or other responsible person(s), and indicates the special requirement(s) for entering the laboratory.
- Laboratory coats, gowns, smocks, or uniforms are worn while in the laboratory. Before exiting the laboratory for non-laboratory areas (e.g., cafeteria, library, administrative offices), this protective clothing is removed and left in the laboratory or covered with a clean coat not used in the laboratory.
- Animals not involved in the work being performed are not permitted in the laboratory.
- Special care is taken to avoid skin contamination with organisms containing recombinant DNA molecules; gloves should be worn when handling experimental animals and when skin contact with theagent is unavoidable.
- All wastes from laboratories and animal rooms are appropriately decontaminated before disposal.
- Hypodermic needles and syringes are used only for parenteral injection and aspiration of fluids from laboratory animals and diaphragm bottles. Only needle-locking syringes or disposable syringe-needle units (i.e., needle is integral to the syringe) are used for the injection or aspiration of fluids containing organisms that contain recombinant DNA molecules. Extreme caution should be used when handling needles and syringes to avoid autoinoculation and the generation of aerosols during use and disposal. Needles should not be bent, sheared, replaced in the needle sheath or guard, or removed from the syringe following use. The needle and syringe should be promptly placed in a puncture-resistant container and decontaminated, preferably autoclaved, before discard or reuse.
- Spills and accidents which result in overt exposures to organisms containing recombinant DNA molecules are immediately reported to the IIBC and NBC.
- When appropriate, considering the agent(s) handled, baseline serum samples for laboratory and other at-risk personnel are collected and stored. Additional serum specimens may be collected periodically depending on the agents handled or the function of the facility.
- A biosafety manual is prepared or adopted. Personnel are advised of special hazardsand are required to read and follow instructions on practices and procedures.

Containment Equipment (BL2)

Biological safety cabinets (Class I or II) or other appropriate personal protective or physical containment devices are used whenever procedures with a high potential for creating aerosols are conducted These may include centrifuging, grinding, blending, vigorous shaking or mixing, sonic disruption, opening containers of materials whose internal pressures may be different from ambient pressures, intranasal inoculation of animals, and harvesting infected tissues from animals or eggs.

Laboratory Facilities (BL2)

- The laboratory is designed so that it can be easily cleaned. Bench tops are impervious to water and resistant to acids, alkalis, organic solvents, and moderate heat. Laboratory furniture is sturdy and spaces between benches, cabinets, and equipment are accessible for cleaning. Each laboratory contains a sink for hand washing.
- If the laboratory has windows that open, they are fitted with fly screens.
- An autoclave for decontaminating laboratory wastes is available.

Biosafety Level 3 (BL3)

Standard Microbiological Practices (BL3)

- All practices mentioned for BL1
- Persons under 16 years of age shall not enter the laboratory.

- If experiments involving other organisms which require lower levels of containment are to be conducted in the same laboratory concurrently with experiments requiring BL3 level physical containment, they shall be conducted in accordance with all BL3 level laboratory practices.

Special Practices (BL3)

- In addition to BL1 and BL2 practices the following is done.
- Laboratory doors are kept closed when experiments are in progress.
- All activities involving organisms containing recombinant DNA molecules are conducted in biological safety cabinets or other physical containment devices within the containment module. No work in open vessels is conducted on the open bench.
- The work surfaces of biological safety cabinets and other containment equipment are decontaminated when work with organisms containing recombinant DNA molecules is finished. Plastic-backed paper toweling used on non-perforated work surfaces within biological safety cabinets facilitates clean-up.
- Laboratory clothing that protects street clothing (e.g., solid front or wrap-around gowns, scrub suits, coveralls) is worn in the laboratory. Laboratory clothing is not worn outside the laboratory, and it is decontaminated prior to laundering or disposal.
- Special care is taken to avoid skin contamination with contaminated materials; gloves should be worn when handling infected animals and when skin contact with infectious materials is unavoidable.
- Molded surgical masks or respirators are worn in rooms containing experimental animals.
- Animals and plants not related to the work being conducted are not permitted in the laboratory. Laboratory animals held in a BL3 area shall be housed in partial-containment caging systems, such as Horsfall units open cages placed in ventilated enclosures, solid-wall and -bottom cages covered by filter bonnets or solid-wall and –bottom cages placed on holding racks equipped with ultraviolet in radiation lamps and reflectors. **Note:** Conventional caging systems may be used provided that all personnel wear appropriate personal protective devices. These protective devices shall include at a minimum wrap-around gowns, head covers, gloves, shoe covers, and respirators. All personnel shall shower on exit from areas where these devices are required.
- Vacuum lines are protected with high efficiency particulate air/HEPA filters and liquid disinfectant traps.

Alternative Selection of Containment Equipment (BL3)

- Experimental procedures involving a host-vector system that provides a one-step higher level of biological containment than that specified may be conducted in the BL3 laboratory using containment equipment specified for the BL2 level of physical containment. Experimental procedures involving a host-vector system that provides a one-step lower level of biological containment than that specified may be conducted in the BL3 laboratory using containment equipment specified for the BL4 level of physical containment.
- Biological safety cabinets (Class I, II, or III) or other appropriate combinations of personal protective or physical containment devices (e.g., special protective clothing, masks, gloves, respirators, centrifuge safety cups, sealed centrifuge rotors, and containment caging for animals) are used for all activities with organisms containing rDNA molecules which pose a threat of aerosol exposure. These include: manipulation of cultures and of those clinical or environmental materials which may be a source of aerosols; the aerosol challenge of experimental animals; the harvesting of infected tissues or fluids from experimental animals and embryonate eggs; and the necropsy of experimental animals.

Laboratory Facilities (BL3)

- The laboratory is separated from areas which are open to unrestricted traffic flow within the building. Passage through two sets of doors is the basic requirement for entry into the laboratory from access corridors or other contiguous areas. Physical separation of the high containment laboratory from access corridors or other laboratories or activities may

be provided by a double-doored clothes change room (showers may be included), airlock, or other access facility which requires passage through two sets of doors before entering the laboratory.
- The interior surfaces of walls, floors, and ceilings are water resistant so that they can beeasily cleaned. Penetrations in these surfaces are sealed or capable of being sealed to facilitate decontaminating the area.
- Bench tops are impervious to water and resistant to acids, alkalis, organic solvents, and moderate heat.
- Laboratory furniture is sturdy and spaces between benches, cabinets, and equipment are accessible for cleaning.
- Each laboratory contains a sink for hand washing. The sink is foot, elbow, or automatically operated and is located near the laboratory exit door.
- Windows in the laboratory are closed and sealed.
- Access doors to the laboratory or containment module are self-closing.
- An autoclave for decontaminating laboratory wastes is available preferably within the laboratory.
- A ducted exhaust air ventilation system is provided. This system creates directional airflow that draws air into the laboratory through the entry area. The exhaust air is not recirculated to any other area of the building, is discharged to the outside, and is dispersed away from the occupied areas and air intakes. Personnel shall verify that the direction of the airflow (into the laboratory) is proper. The exhaust air from the laboratory room may be discharged to the outside without being filtered or otherwise treated. The high efficiency particulate air/HEPA filtered exhaust air from Class I or Class II biological safety cabinets is discharged directly to the outside or through the building exhaust system. Exhaust air from Class I or II biological safety cabinets may be recirculated within the laboratory if the cabinet is tested and certified at least every twelve months. If the HEPA-filtered exhaust air from Class I or II biological safety cabinets is to be discharged to the outside through the building exhaust air system, it is connected to this system in a manner.

Biosafety Level 4 (BL4)

Standard Microbiological Practices (BL4)
Practices as listed for BL3

Special Practices (BL4)
- In addition to BL3 practices, biological materials to be removed from the Class III cabinets or from the maximum containment laboratory in a viable or intact state are transferred to a non-breakable, sealed primary container and then enclosed in a non-breakable, sealed secondary container which is removed from the facility through a disinfectant dunk tank, fumigation chamber, or an airlock designed for this purpose.
- No materials, except for biological materials that are to remain in a viable or intact state, are removed from the maximum containment laboratory unless they have been autoclaved or decontaminated before exiting the facility. Equipment or material which might be damaged by high temperatures or steam is decontaminated by gaseous or vapor methods in an airlock or chamber designed for this purpose.
- Only persons whose presence in the facility or individual laboratory rooms is required for program or support purposes are authorized to enter. The supervisor has the final responsibility for assessing each circumstance and determining who may enter or work in the laboratory. Access to the facility is limited by means of secure, locked doors; accessibility is managed by the PI, Biological Safety Officer, or other person responsible for the physical security of the facility. Before entering, persons are advised of the potential biohazards and instructed as to appropriate safeguards for ensuring their safety. Authorized persons comply with the instructions and all other applicable entry and exit procedures. A logbook signed by all personnel indicates the date and time of each entry

and personnel enter and exit the facility only through the clothing change and shower rooms.

- Personnel shower each time they exit the facility. Personnel use the air locks to enter or exit the laboratory only in an emergency.
- Street clothing is removed in the outer clothing change room and kept there. Complete laboratory clothing (may be disposable), including undergarments, pants and shirts or jump suits, shoes, and gloves, is provided and used by all personnel entering the facility. Head covers are provided for personnel who do not wash their hair during the exit shower. When exiting the laboratory and before proceeding into the shower area, personnel remove their laboratory clothing and store it in a locker or hamper in the inner change room. Protective clothing shall be decontaminated prior to laundering or disposal.
- When materials that contain organisms containing recombinant DNA molecules or experimental animals are present in the laboratory or animal rooms, a hazard warning sign incorporating the universal biosafety symbol is posted on all access doors. The sign identifies the agent, lists the name of the PI or other responsible person(s), and indicates any special equirements for entering the area (e.g., the need for immunizations or respirators).
- Supplies and materials needed in the facility are brought in by way of the double-doored autoclave, fumigation chamber, or airlock which is appropriately decontaminated between each use. After securing the outer doors, personnel within the facility retrieve the materials by opening the interior doors or the autoclave, fumigation chamber, or airlock. These doors are secured after materials are brought into the facility.
- Hypodermic needles and syringes are used only for parenteral injection and aspiration of fluids from laboratory animals and diaphragm bottles. Only needle-locking syringes or disposable syringe-needle units (i.e., needle is integral part of unit) are used for the injection or aspiration of fluids containing organisms that contain recombinant DNA molecules. Needles should not be bent, sheared, replaced in the needle sheath or guard, or removed from the syringe following use. The needle and syringe should be placed in a puncture-resistant container and decontaminated, preferably by autoclaving before discard or reuse. Whenever possible, cannulas are used instead of sharp needles (e.g., gavage).
- A system is set up for reporting laboratory accidents, exposures, employee absenteeism, and for the medical surveillance of potential laboratory-associated illnesses. Spills and accidents which result in overt exposures to organisms containing rDNAare immediately reported to the Biological Safety Officer, Institutional Biosafety Committee, and NIH/OBA. Written records are prepared and maintained. An essential adjunct to such a reporting-surveillance system is the availability of a facility for quarantine, isolation, and medical care of personnel with potential or known laboratory associated illnesses.
- Laboratory animals involved in experiments requiring BL4 level physical containment shall be housed either in cages contained in Class III cabinets or in partial containment caging systems, such as Horsfall units, open cages placed in ventilated enclosures, or solid-wall and -bottom cages placed on holding racks equipped with ultraviolet irradiation lamps and reflectors that are located in a specially designed area in which all personnel are required to wear one-piece positive pressure suits.

Alternative Selection of Containment Equipment (BL4)

- Experimental procedures involving a host-vector system that provides a one-step higher level of biological containment than that specified may be conducted in the BL4 facility using containment equipment requirements specified for the BL3 level of physical containment.
- All procedures within the facility with agents assigned to Biosafety Level 4 are conductedin the Class III biological safety cabinet or in Class I or II biological safety cabinets used in conjunction with one-piece positive pressure personnel suits ventilated by a life-support system.

Laboratory Facilities (BL4)

- The maximum containment facility consists of either a separate building or a clearly demarcated and isolated zone within a building. Outer and inner change rooms separated by a shower are provided for personnel entering and exiting the facility. A double-doored autoclave, fumigation chamber, or ventilated airlock is provided for passage of those materials, supplies, or equipment which are not brought into the facility through the change room.
- Walls, floors, and ceilings of the facility are constructed to form a sealed internal shell which facilitates fumigation and is animal and insect proof. The internal surfaces of this shell are resistant to liquids and chemicals, thus facilitating cleaning and decontamination of the area. All penetrations in these structures and surfaces are sealed. Any drains in the floors contain traps filled with a chemical disinfectant of demonstrated efficacy against the target agent, and they are connected directly to the liquid waste decontamination system. Sewer and other ventilation lines contain high efficiency particulate air/HEPA filters.
- Internal facility appurtenances, such as light fixtures, air ducts, and utility pipes, are arranged to minimize the horizontal surface area on which dust can settle.
- Bench tops have seamless surfaces which are impervious to water and resistant to acids, alkalis, organic solvents, and moderate heat.
- Laboratory furniture is simple and of sturdy construction; and spaces between benches, cabinets, and equipment are accessible for cleaning.
- A foot, elbow, or automatically operated hand washing sink is provided near the door of each laboratory room in the facility.
- If there is a central vacuum system, it does not serve areas outside the facility. In-line high efficiency particulate air/HEPA filters are placed as near as practicable to each use point or service cock. Filters are installed to permit in-place decontamination and replacement. Other liquid and gas services to the facility are protected by devices that prevent back-flow. Appendix G-II-D-4-h. If water fountains are provided, they are foot operated and are located in the facility corridors outside the laboratory. The water service to the fountain is not connected to the back-flow protected distribution system supplying water to the laboratory areas.
- Access doors to the laboratory are self-closing and locking.
- Any windows are breakage resistant.
- A double-doored autoclave is provided for decontaminating materials passing out of the facility. The autoclave door which opens to the area external to the facility is sealed to the outer wall and automatically controlled so that the outside door can only be opened after the autoclave "sterilization" cycle has been completed.
- A pass-through dunk tank, fumigation chamber, or an equivalent decontamination method is provided so that materials and equipment
- Liquid effluent from laboratory sinks, biological safety cabinets, floors, and autoclave chambers are decontaminated by heat treatment before being released from the maximum containment facility.
- Liquid wastes from shower rooms and toilets may be decontaminated with chemical disinfectants or by heat in the liquid waste decontamination system. The procedure used for heat decontamination of liquid wastes is evaluated mechanically and biologically by using a recording thermometer and an indicator microorganism with a defined heat susceptibility pattern. If liquid wastes from the shower room are decontaminated with chemical disinfectants, the chemical used is of demonstrated efficacy against the target or indicator microorganisms.
- An individual supply and exhaust air ventilation system is provided. The system maintains pressure differentials and directional airflow as required to assure flows inward from areas outside of the facility toward areas of highest potential risk within the facility. Manometers are used to sense pressure differentials between adjacent areas maintained at different pressure levels. If a system malfunctions, the manometers sound an alarm. The supply and exhaust airflow is interlocked to assure inward (or zero) airflow at all times.

- The exhaust air from the facility is filtered through high efficiency particulate air/HEPA filters and discharged to the outside so that it is dispersed away from occupied buildings and air intakes. Within the facility, the filters are located as near the laboratories as practicable in order to reduce the length of potentially contaminated air ducts. The filter chambers are designed to allow in situ decontamination before filters are removed and to facilitate certification testing after they are replaced. Coarse filters and HEPA filters are provided to treat air supplied to the facility in order to increase the lifetime of the exhaust HEPA filters and to protect the supply air system should air pressures become unbalanced in the laboratory.
- The treated exhaust air from Class I and II biological safety cabinets may be discharged into the laboratory room environment or the outside through the facility air exhaust system. If exhaust air from Class I or II biological safety cabinets is discharged into the laboratory the cabinets are tested and certified at six-month intervals. The exhaust air from Class III biological safety cabinets is discharged, without recirculation through two sets of high efficiency particulate air/HEPA filters in series, via the facility exhaust air system. If the treated exhaust air from any of these cabinets is discharged to the outside through the facility exhaust air system, it is connected to this system in a manner (e.g., thimble unit that avoids any interference with the air balance of the cabinets or the facility exhaust air system.
- A specially designed suit area may be provided in the facility. Personnel who enter this area shall wear a one-piece positive pressure suit that is ventilated by a life-support system. The life-support system includes alarms and emergency backup breathing air tanks. Entry to this area is through an airlock fitted with airtight doors. A chemical shower is provided to decontaminate the surface of the suit before the worker exits the area. The exhaust air from the suit area is filtered by two sets of high efficiency particulate air/HEPA filters installed in series. A duplicate filtration unit, exhaust fan, and an automatically starting emergency power source are provided. The air pressure within the suit area is greater than that of any adjacent area. Emergency lighting and communication systems are provided. All penetrations into the internal shell of the suit are sealed. A double-doored autoclave is provided for decontaminating waste materials to be removed from the suit areas.

APPENDIX-3

CONTAINMENT IN GREENHOUSES
(Adapted from the NIH guidelines)

Biosafety Level 1 Containment - BL1-P

Access to the greenhouse shall be limited or restricted, at the discretion of the Greenhouse manager, when experiments are in progress. Prior to entering the greenhouse, personnel shall be required to read and follow instructions on BL1-P greenhouse practices and procedures. All procedures shall be performed in accordance with accepted greenhouse practices that are appropriate to the experimental organism. A record shall be kept of experiments currently in progress in the greenhouse facility.

Decontamination and Inactivation (BL1-P) - Experimental organisms shall be rendered biologically inactive by appropriate methods before disposal outside of the greenhouse facility.

Control of Undesired Species and Motile Macroorganisms (BL1-P) - A program shall be implemented to control undesired species (e.g., weed, rodent, or arthropod pests and pathogens), by methods appropriate to the organisms and in accordance with applicable state and Federal laws. Arthropods and other motile macro organisms shall be housed in appropriate cages. If macro organisms (e.g., flying arthropods or nematodes) are released within the greenhouse, precautions shall be taken to minimize escape from the greenhouse facility.

Concurrent Experiments Conducted in the Greenhouse (BL1-P) - Experiments involving other organisms that require containment level lower than BL1-P may be conducted in the greenhouse concurrently with experiments that require BL1-P containment, provided that all work is conducted in accordance with BL1-P greenhouse practices.

Facilities (BL1-P) - The term "greenhouse" refers to a structure with walls, a roof, and a floor designed and used principally for growing plants in a controlled and protected environment. The walls and roof are usually constructed of transparent or translucent material to allow passage of sunlight for plant growth. The term "greenhouse facility" includes the actual greenhouse rooms or compartments for growing plants, including all immediately contiguous hallways and head-house areas, and is considered part of the confinement area.

Greenhouse Design (BL1-P)

The greenhouse floor may be composed of gravel or other porous material. At a minimum, impervious (e.g., concrete) walkways are recommended. Windows and other openings in the walls and roof of the greenhouse facility may be open for ventilation as needed for proper operation and do not require any special barrier to contain or exclude pollen, microorganisms, or small flying animals (e.g., arthropods and birds); however, screens are recommended.

Biosafety Level 2 containment - BL2-P

Access to the greenhouse shall be limited or restricted, at the discretion of the Greenhouse Manager, to individuals directly involved with the experiments when they are in progress. Personnel shall be required to read and follow instructions on BL2-P practices and procedures. All procedures shall be conducted in accordance with accepted greenhouse practices that are appropriate to the experimental organisms. A record shall be kept of experimental plants, microorganisms, or small animals that are brought into or removed from the greenhouse facility. A record shall be kept of experiments currently in progress in the greenhouse facility. The Principal Investigator shall report any greenhouse accident involving the inadvertent release or spill of microorganisms to the Greenhouse Manager, Institutional Biosafety Committee,
NBC and other appropriate authorities immediately (if applicable)..

Decontamination and Inactivation (BL2-P) - Experimental organisms shall be rendered biologically inactive by appropriate methods before disposal outside of the greenhouse facility. Decontamination of run-off water is not necessarily required. If part of the greenhouse is composed of gravel or similar material, appropriate treatments should be made periodically to eliminate, or render inactive, any organisms potentially entrapped by the gravel.

Control of Undesired Species and Motile Macroorganisms (BL2-P) - A program shall be implemented to control undesired species (e.g., weed, rodent, or arthropod pests and pathogens) by methods appropriate to the organisms and in accordance with applicable state and Federal laws. Arthropods and other motile macroorganisms shall be housed in appropriate cages. If macroorganisms (e.g., flying arthropods or nematodes) are released within the greenhouse, precautions shall be taken to minimize escape from the greenhouse facility.

Concurrent Experiments Conducted in the Greenhouse (BL2-P) - Experiments involving other organisms that require a containment level lower than BL2-P may be conducted in the greenhouse concurrently with experiments that require BL2-P containment provided that all work is conducted in accordance with BL2-P greenhouse practices.

Signs (BL2-P) - A sign shall be posted indicating that a restricted experiment is in progress. The sign shall indicate the following: (i) the name of the responsible individual, (ii) the plants in use, and (iii) any special requirements for using the area. If organisms are used that have a recognized potential for causing serious detrimental impacts on managed or natural ecosystems, their presence shall be indicated on a sign posted on the greenhouse access doors. If there is a risk to human health, a sign shall be posted incorporating the universal biosafety symbol.

Transfer of Materials (BL2-P) - Materials containing experimental microorganisms, which are brought into or removed from the greenhouse facility in a viable or intact state, shall be transferred in a closed non-breakable container.

Greenhouse Practices Manual (BL2-P) - A greenhouse practices manual shall be prepared or adopted. This manual shall: (i) advice personnel of the potential consequences if such practices are not followed, and (ii) outline contingency plans to be implemented in the event of the unintentional release of organisms.

Facilities (BL2-P) - Greenhouse Design (BL2-P) - A greenhouse floor composed of an impervious material. Concrete is recommended, but gravel or other porous material under benches is acceptable unless propagules of experimental organisms are readily disseminated through soil. Soil beds are acceptable unless propagules of experimental organisms are readily disseminated through soil. Windows and other openings in the walls and roof of the greenhouse facility may be open for ventilation as needed for proper operation and do not require any special barrier to exclude pollen or microorganisms; however, screens are required to exclude small flying animals (e.g., arthropods and birds).

Autoclaves (BL2-P) - An autoclave shall be available for the treatment of contaminated greenhouse materials.

Supply and Exhaust Air Ventilation Systems (BL2-P) - If intake fans are used, measures shall be taken to minimize the ingress of arthropods. Louvers or fans shall be constructed such that they can only be opened when the fan is in operation.

BL2-P greenhouse containment requirements may be satisfied by using a growth chamber or growth room within a building provided that the external physical structure limits access and escape of microorganisms and macroorganisms in a manner that satisfies the intent of the foregoing clauses.

Biosafety Level 3 Containment - BL3-P

Greenhouse Access (BL3-P) - Authorized entry into the greenhouse shall be restricted to individuals who are required for program or support purposes. The Greenhouse Manager shall be responsible for assessing each circumstance and determining those individuals who are authorized to enter the greenhouse facility. Prior to entering the greenhouse, personnel shall be required to read and follow instructions on BL3-P practices and procedures. All procedures shall be conducted in accordance with accepted greenhouse practices that are appropriate to the experimental organisms. A record shall be kept of experimental plants, microorganisms, or small animals that are brought into or removed from the greenhouse facility. A record shall be kept of experiments currently in progress in the greenhouse facility. The Principal Investigator shall report any greenhouse accident involving the inadvertent release or spill of microorganisms to the Biological Safety Officer, Greenhouse Manager, Institutional Biosafety Committee, NBC, and other appropriate authorities immediately (if applicable). Documentation of any such accident shall be prepared and maintained.

Decontamination and Inactivation (BL3-P) - All experimental materials shall be sterilized in an autoclave or rendered biologically inactive by appropriate methods before disposal, except those that are to remain in a viable or intact state for experimental purposes; including water that comes in contact with experimental microorganisms or with material exposed to such microorganisms, and contaminated equipment and supplies.

Control of Undesired Species and Motile Macroorganisms (BL3-P) - A program shall be implemented to control undesired species (e.g., weed, rodent, or arthropod pests and pathogens) by methods appropriate to the organisms and in accordance with applicable laws. Arthropods and other motile macroorganisms shall be housed in appropriate cages. When appropriate to the organism, experiments shall be conducted within cages designed to contain the motile organisms.

Concurrent Experiments Conducted in the Greenhouse (BL3-P) - Experiments involving organisms that require a containment level lower than BL3-P ay be conducted in the greenhouse concurrently with experiments that require BL3-P containment provided that all work is conducted in accordance with BL3-P greenhouse practices.

Signs (BL3-P) - A sign shall be posted indicating that a restricted experiment is in progress. The sign shall indicate the following: (i) the name of the responsible individual, (ii) the plants in use, and (iii) any special requirements for using the area. If organisms are used that have a recognized potential for causing serious detrimental impacts on managed or natural ecosystems, their presence should be indicated on a sign posted on the greenhouse access doors. If there is a risk to human health, a sign shall be posted incorporating the universal biosafety symbol.

Transfer of Materials (BL3-P) - Experimental materials that are brought into or removed from the greenhouse facility in a viable or intact state shall be transferred to a non-breakable sealed secondary container. At the time of transfer, if the same plant species, host, or vectors are present within the effective dissemination distance of propagules of the experimental organism, the surface of the secondary container shall be decontaminated. Decontamination may be accomplished by passage through a chemical disinfectant or fumigation chamber or by an alternative procedure that has demonstrated effective inactivation of the experimental organism.

Greenhouse Practices Manual (BL3-P) - A greenhouse practices manual shall be prepared or adopted. This manual shall: (i) advise personnel of the potential consequences if such practices are not followed, and (ii) outline contingency plans to be implemented in the event of the unintentional release of organisms with recognized potential for serious detrimental impact.

Protective Clothing (BL3-P) - Disposable clothing (e.g., solid front or wrap-around gowns, scrub suits, or other appropriate clothing) shall be worn in the greenhouse if deemed necessary by the

Greenhouse Manager, because of potential dissemination of the experimental microorganisms. Protective clothing shall be removed before exiting the greenhouse and decontaminated prior to laundering or disposal.

Personnel are required to thoroughly wash their hands upon exiting the greenhouse. All procedures shall be performed carefully to minimize the creation of aerosols and excessive splashing of potting material/soil during watering, transplanting, and all experimental manipulations.

Facilities (BL3-P)
Greenhouse Design (BL3-P)
The term "greenhouse facility" includes the actual greenhouse rooms or compartments for growing plants, including all immediately contiguous hallways and head-house areas, and is considered part of the confinement area. The need to maintain negative pressure should be considered when constructing or renovating the greenhouse. The greenhouse floor shall be composed of concrete or other impervious material with provision for collection and decontamination of liquid run-off. Windows shall be closed and sealed. All glazing shall be resistant to breakage (e.g., double-pane tempered glass or equivalent). The greenhouse shall be a closed self-contained structure with a continuous covering that is separated from areas that are open to unrestricted traffic flow. The minimum requirement for greenhouse entry shall be passage through two sets of self-closing locking doors. The greenhouse facility shall be surrounded by a security fence or protected by equivalent security measures. Internal walls, ceilings, and floors shall be resistant to penetration by liquids and chemicals to facilitate cleaning and decontamination of the area. All penetrations into these structures and surfaces (e.g., plumbing and utilities) shall be sealed. Bench tops and other work surfaces should have seamless surfaces that are impervious to water and resistant to acids, alkalis, organic solvents, and moderate heat. The greenhouse contains a foot, elbow, or automatically operated sink, which is located near the exit door for hand washing.

An individual supply and exhaust air ventilation system shall be provided. The system maintains pressure differentials and directional airflow, as required, to assure inward (or zero) airflow from areas outside of the greenhouse. The exhaust air from the greenhouse facility shall be filtered through high efficiency particulate air-HEPA filters and discharged to the outside. The filter chambers shall be designed to allow *in situ* decontamination before filters are removed and to facilitate certification testing after they are replaced. Air filters shall be 80-85% average efficiency by the American Society of Heating, Refrigerating, and Air Conditioning Engineers (ASHRAE) Standard 52-68 test method using atmosphere dust. Air supply fans shall be equipped with a back-flow damper that closes when the air supply fan is off. Alternatively, a HEPA filter may be used on the air supply system instead of the filters and damper. The supply and exhaust airflow shall be interlocked to assure inward (or zero) airflow at all times.

An autoclave shall be available for decontaminating materials within the greenhouse facility. A double-door autoclave is recommended (not required) for the decontamination of materials passing out of the greenhouse facility.

BL3-P greenhouse containment requirements may be satisfied using a growth chamber or growth room within a building provided that the location, access, airflow patterns, and provisions for decontamination of experimental materials and supplies meet the intent of the foregoing clauses. Vacuum lines shall be protected with high efficiency particulate air/HEPA or equivalent filters and liquid disinfectant traps.

Biosafety Level 4 Containment - BL4-P

Greenhouse Access (BL4-P) - Authorized entry into the greenhouse shall be restricted to individuals who are required for program or support purposes. The Greenhouse Manger along with the PI shall be responsible for assessing each circumstance and determining those

individuals who are authorized to enter the greenhouse facility or work in the greenhouse during experiments. Access shall be managed by the Greenhouse Manager, Biological Safety Officer, or other individual responsible for physical security of the greenhouse facility; and access limited by means of secure, locked doors. Prior to entering, individuals shall be advised of the potential environmental hazards and instructed on appropriate safeguards for ensuring environmental safety. Individuals authorized to enter the greenhouse facility shall comply with the instructions and all other applicable entry/exit procedures. Personnel shall enter and exit the greenhouse facility only through the clothing change and shower rooms and shall shower each time they exit the greenhouse facility. Personnel shall use the airlocks to enter or exit the laboratory only in an emergency. In the event of an emergency, every reasonable effort should be made to prevent the possible transport of viable propagules from containment. Prior to entering the greenhouse, personnel shall be required to read and follow instructions on BL4-P practices and procedures.

A record shall be kept of all experimental materials brought into or removed from the greenhouse. A record shall be kept of experiments currently in progress in the greenhouse facility. A record shall be kept of all personnel entering and exiting the greenhouse facility, including the date and time of each entry. The Principal Investigator shall report any greenhouse accident involving the inadvertent release or spill of microorganisms to the Biological Safety Officer, of the IBC Greenhouse Director, IBC, NBC, and other appropriate authorities immediately (if applicable).

Decontamination and Inactivation (BL4-P) - All materials, except for those that are to remain in a viable or intact state for experimental purposes, shall be autoclaved prior to removal from the maximum containment greenhouse. Equipment or material that could be damaged by high temperatures or steam shall be decontaminated by alternative methods (e.g., gas or vapor sterilization) in an airlock or chamber designed for this purpose. Water that comes in contact with experimental microorganisms or with material exposed to such microorganisms (e.g., run-off from watering plants) shall be collected and decontaminated before disposal. Standard microbiological procedures shall be followed for decontamination of equipment and materials. Spray or liquid waste or rinse water from containers used to apply the experimental microorganisms shall be decontaminated before disposal.

Control of Undesired Species and Motile Macroorganisms (BL4-P) - A chemical control program shall be implemented to eliminate undesired pests and pathogens in accordance with applicable laws. Arthropods and other motile macroorganisms used in conjunction with experiments requiring BL4-P level physical containment shall be housed in appropriate cages. When appropriate to the organism, experiments shall be conducted within cages designed to contain the motile organisms.

Concurrent Experiments Conducted in the Greenhouse (BL4-P) - Experiments involving organisms that require a containment level lower than BL4-P may be conducted in the greenhouse concurrently with experiments that require BL4-P containment provided that all work is conducted in accordance with BL4-P greenhouse practices. When the experimental microorganisms in use require a containment level lower than BL4-P, greenhouse practices effect the level of containment required by the highest containment level microorganisms being tested.

Signs (BL4-P) - A sign shall be posted indicating that a restricted experiment is in progress. The sign shall indicate the following: (i) the name of the responsible individual, (ii) the plants in use, and (iii) any special requirements for using the area. If organisms are used that have a recognized potential for causing serious detrimental impacts on managed or natural ecosystems, their presence shall be indicated by a sign posted on the greenhouse access doors. If there is a risk to human health, a sign shall be posted incorporating the universal biosafety symbol.

Transfer of Materials (BL4-P) - (1). Experimental materials that are brought into or removed from the greenhouse in a viable or intact state shall be transferred to a non-breakable, sealed, primary container then enclosed in a nonbreakable, sealed secondary container. These

containers shall be removed from the greenhouse facility through a chemical disinfectant, fumigation chamber, or an airlock designed for this purpose. Supplies and materials shall be brought into the greenhouse facility through a doubledoor autoclave, fumigation chamber, or airlock that is appropriately decontaminated between each use. After securing the outer doors, personnel within the greenhouse facility shall retrieve the materials by opening the interior door of the autoclave, fumigation chamber, or airlock. These doors shall be secured after the materials are brought into the greenhouse facility.

Greenhouse Practices Manual (BL4-P)
A greenhouse practices manual shall be prepared or adopted. This manual shall include contingency plans to be implemented in the event of the unintentional release of experimental organisms.

Protective Clothing (BL4-P) - Street clothing shall be removed in the outer clothing change room. Complete laboratory clothing (may be disposable) including undergarments, pants, and shirts, jump suits, shoes, and hats shall be provided and worn by all personnel entering the greenhouse facility. Personnel shall remove laboratory clothing when exiting the greenhouse facility and before entering the shower area. This clothing shall be stored in a locker or hamper in the inner change room. All laboratory clothing shall be autoclaved before laundering.

Facilities (BL4-P)
Greenhouse Design (BL4-P) - The maximum containment greenhouse facility shall consist of a separate building or a clearly demarcated and isolated area within a building. The need to maintain negative pressure should be considered when constructing or renovating the greenhouse facility. Outer and inner change rooms, separated by a shower, shall be provided for personnel entering and exiting the greenhouse facility. Windows shall be closed and sealed. All glazing shall be resistant to breakage (e.g., double-pane tempered glass or equivalent). Access doors to the greenhouse shall be self-closing and locking. The greenhouse facility shall be surrounded by a security fence or protected by equivalent security measures. The walls, floors, and ceilings of the greenhouse shall be constructed to form a sealed internal shell that facilitates fumigation and is animal and arthropod-proof. These internal surfaces shall be resistant to penetration and degradation by liquids and chemicals to facilitate cleaning and decontamination of the area. All penetrations into these structures and surfaces (e.g., plumbing and utilities) shall be sealed. Bench tops and other work surfaces shall have seamless surfaces impervious to water and resistant to acids, alkalis, organic solvents, and moderate heat. A double-door autoclave, fumigation chamber, or ventilated airlock shall be provided for passage of all materials, supplies, or equipment that are not brought into the greenhouse facility through the change room.

Autoclaves (BL4-P) - A double-door autoclave shall be provided for the decontamination of materials removed from the greenhouse facility. The autoclave door, which opens to the area external to the greenhouse facility, shall be sealed to the outer wall and automatically controlled so that it can only be opened upon completion of the sterilization cycle.

Supply and Exhaust Air Ventilation Systems (BL4-P) - An individual supply and exhaust air ventilation system shall be provided. The system shall maintain pressure differentials and directional airflow as required to assure inward (or zero) airflow from areas outside of the greenhouse. Differential pressure transducers shall be used to sense pressure levels. If a system malfunctions, the transducers shall sound an alarm. A backup source of power should be considered. The supply and exhaust airflow shall be interlocked to assure inward (or zero) airflow at all times. The integrity of the greenhouse shall have an air leak rate (decay rate) not to exceed 7 percent per minute (logarithm of pressure against time) over a 20-minute period at 2 inches of water gauge pressure. Nominally, this is 0.05 inches of water gauge pressure loss in 1 minute at 2 inches water gauge pressure. Exhaust air from the greenhouse facility shall be filtered through high efficiency particulate air/HEPA filters and discharged to the outside and dispersed away from occupied buildings and air intakes. Filter chambers shall be designed to allow *in situ* decontamination before filters are removed and to facilitate certification testing after they are

replaced. HEPA filters shall be provided to treat air supplied to the greenhouse facility. HEPA filters shall be certified annually. Sewer vents and other ventilation lines contain high efficiency particulate air/HEPA filters. HEPA filters shall be certified annually. A pass-through dunk tank, fumigation chamber, or an equivalent method of decontamination shall be provided to ensure decontamination of materials and equipment that cannot be decontaminated in the autoclave. Liquid effluent from sinks, floors, and autoclave chambers shall be decontaminated by heat or chemical treatment before being released from the maximum containment greenhouse facility. Liquid wastes from shower rooms and toilets may be decontaminated by heat or chemical treatment. Autoclave and chemical decontamination of liquid wastes shall be evaluated by appropriate standard procedures for autoclaved wastes. Decontamination shall be evaluated mechanically and biologically using a recording thermometer and an indicator microorganism with a defined heat susceptibility pattern. If liquid wastes are decontaminated with chemical disinfectants, the chemicals used must have demonstrated efficacy against the target or indicator microorganisms. If there is a central vacuum system, it shall not serve areas outside of the greenhouse facility. In-line high efficiency particulate air/HEPA filters shall be placed as near as practicable to each use point or vacuum service cock. Other liquid and gas services to the greenhouse facility shall be protected by devices that prevent back-flow. HEPA filters shall be certified annually.

Biological Containment Practices

Appropriate selection of the following biological containment practices may be used to meet the containment requirements for a given organism. The present list is not exhaustive; there may be other ways of preventing effective dissemination that could possibly lead to the establishment of the organism or its genetic material in the environment resulting in deleterious consequences to managed or natural ecosystems.

Biological Containment Practices (Plants)

Effective dissemination of plants by pollen or seed can be prevented by one or more of the following procedures: (i) cover the reproductive structures to prevent pollen dissemination at flowering and seed dissemination at maturity; (ii) remove reproductive structures by employing male sterile strains, or harvest the plant material prior to the reproductive stage; (iii) ensure that experimental plants flower at a time of year when cross-fertile plants are not flowering within the normal pollen dispersal range of the experimental plant; or (iv) ensure that cross-fertile plants are not growing within the known pollen dispersal range of the experimental plant.

Biological Containment Practices (Microorganisms)

Effective dissemination of microorganisms beyond the confines of the greenhouse can be prevented by one or more of the following procedures: (i) confine all operations to injections of microorganisms or other biological procedures (including genetic manipulation) that limit replication or reproduction of viruses and microorganisms or sequences derived from microorganisms, and confine these injections to internal plant parts or adherent plant surfaces; (ii) ensure that organisms, which can serve as hosts or promote the transmission of the virus or microorganism, are not present within the farthest distance that the airborne virus or microorganism may be expected to be effectively disseminated; (iii) conduct experiments at a time of year when plants that can serve as hosts are either not growing or are not susceptible to productive infection; (iv) use viruses and other microorganisms or their genomes that have known arthropod or animal vectors, in the absence of such vectors; (v) use microorganisms that have an obligate association with the plant; or (vi) use microorganisms that are genetically disabled to minimize survival outside of the research facility and whose natural mode of transmission requires injury of the target organism, or assures that inadvertent release is unlikely to initiate productive infection of organisms outside of the experimental facility.

Biological Containment Practices (Macroorganisms)

Effective dissemination of arthropods and other small animals can be prevented by using one or more of the following procedures: (i) use non-flying, flight-impaired, or sterile arthropods; (ii) use

nonmotile or sterile strains of small animals; (iii) conduct experiments at a time of year that precludes the survival of escaping organisms; (iv) use animals that have an obligate association with a plant that is not present within the dispersal range of the organism; or (v) prevent the escape of organisms present in run-off water by chemical treatment or evaporation of run-off water.

APPENDIX-4 - Application Package Checklist

Biology document
Have you confirmed with the NBC whether a biology document has been prepared for your species? If not, have you enclosed a draft biology document for your species, following those already available.

Core characterization
Have you addressed the molecular characterization of the GMO thoroughly.

Environmental characterization
Have you addressed all the questions with respect to environmental impacts. Note that at least two seasons of trials in multiple locations in Trinidad and Tobago are normally required to address these questions.

Detection and identification
Have you provided a detection method capable of distinguishing your GMO from other commercial cultivars of the same species, along with appropriate reference material.

Food and Feed use
Have you provided all the information requested to assess food safety issues

Special crop management considerations
If your GMO carries a novel insect resistance gene, have you provided a n appropriate insect resistance management plant? If your GMO carries a novel herbicide tolerance gene, have you provided an appropriate herbicide tolerance management plan? If your GMO is intended for production of a compound for pharmaceutical or industrial use, rather than for food, feed, or fibre, you must provide standard operating procedures for production, that will ensure the plant material does not enter human food or livestock feed supply chains.

Post release monitoring plan
You must provide a general plan for post-release monitoring of environmental effects of your PNT.

Submission fee
Have you filled out the application form and enclosed your submission fee.