Report of Working Group Sessions

On

Regional Harmonisation of Biosafety Systems

Capacity Building Workshop on Biosafety for the Caribbean

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Port of Spain, Trinidad

Preface

This regional harmonisation report was prepared from information generated by Caribbean Regional participants in a Regional Capacity Building Workshop on Biosafety for the Caribbean conducted from January 19th-30th, 2004. The workshop was organised by the National Institute for Higher Education, Research, Science and Technology (NIHERST) with funding provided by IDRC/CRDI, the Centre Technique de Cooperration Agricole et Ruale ACP-UE (CTA) and the Caribbean Council for Science and Technology (CCST).

The workshop sessions were facilitated by Drs. Patricia L. Traynor (New Agritech Strategies, USA) and Hector Quemada (Crop Technology Consulting, USA) and a cadre of Caribbean Biotechnology, Trade, Legal, Environmental, Food safety and Agricultural experts.

This report is a synthesis of discussions and recommendations from the working groups in the workshop sessions on 'Regional Harmonisation of Biosafety Systems', and while not encompassing of *all* the issues related to establishing a framework to facilitate a regionally harmonised mechanism that addresses biosafety and biotechnology, provides a basis for which regional organisations such as the CARICOM Secretariat can plan their activities to address these issues.

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Wendy Hollingsworth, April 2004

Regional Harmonisation of Biosafety Systems

Objectives of Harmonisation:

Harmonisation of mechanisms, whether it is for food safety or standards, is a strategy often applied internationally to facilitate trade at all levels. A well documented example of such mechanisms is that used by several countries with respects to plant protection. Regional mechanisms for harmonisation with respects to plant protection include for example:

- The North American Plant Protection Organisation (NAPPO) which is a regional plant protection organisation of the International Plant Protection Convention (IPPC) that coordinates the efforts among Canada, the US and Mexico to protect plant resources from the entry, establishment and spread of regulated plant pests while facilitating intra/interregional trade.

- There is also the Pacific Plant Protection Organisation (PPPO) which was established in 1995 to cover phytosanitary matters in the Pacific region. There are about 22 national governments which are part of the PPPO. The PPPO has addressed issues such as development of generic regional plans for legislative and regulatory instruments and the development of guidelines, among others.

A review of any of these regional mechanisms (their mandate, establish, role and working relationship among countries), can provide the Caribbean region with a guide to establishing a regional mechanism for biosafety and biotechnology management.

The benefits to developing a regional mechanism to harmonise biosafety systems in the Caribbean include:

(a) Benefits from pooling of resources (human, physical, research activities, etc.) already in existence,
(b) Facilitation of trade regionally and internationally,
(c) Protection of human health, the environment and biodiversity,
(d) The development of common standards for food safety.

The objectives of a regionally harmonised biosafety system will need to consider the promotion of the safe use, handling, application, management, research and development of modern Biotechnology, while taking into account the transboundry movement of products derived from the activities of modern biotechnology. Additionally, any regional, or national, regulatory system must consider human health, the environment, conservation and sustainable use of biological diversity, socio-economic/cultural concerns and trade impacts.

These objectives, as identified by the various working groups (questions are provided in Appendix A), are broad and although articulated for a regional mechanism they may also reflect the national objectives of the various countries within CARICOM. One must however be cognisant that national priorities will differ from country to country and that although the general objectives of biosafety may be similar among countries, there could be some differences at the level of national legislation and the structure of national biosafety frameworks. As a consequence, a mechanism for regional harmonisation of biosafety systems should address these potential areas of divergence so as to minimise disruptions to regional and international trade and R&D.

National priorities developed to address biosafety and modern biotechnology should seek to integrate and include all relevant areas such as food safety and security, trade (import/export, protection of niche markets), sustainable development, R&D, human health and the environment and conservation and sustainable use of biodiversity. Variations in national biosafety and biotechnology priorities will impact on the development of capacity building programs and technology transfer initiatives, therefore, consideration of these differences will be crucial to securing support from regional governments for any proposed regional system.

Levels of Harmonisation Required

There are several levels from which to approach harmonisation of biosafety systems. The biosafety protocol specifically addresses the transboundary movement of living modified organisms; there is therefore a heavy focus on regulating trade in these living modified commodities. Within this context regional harmonisation can occur at the level of regional trade. There are several existing mechanisms at the level of CARICOM that facilitates trade in goods and services which can either facilitate the development of a working biosafety management system at the regional level or can guide the development of such systems. Development of regional harmonising systems in a range of economic areas, including trade, will be paramount for the effective execution of the Single Market and Economy (CSME), therefore, harmonisation of existing or new regional mechanisms will be critical to the negotiations of regional and multi-lateral trade arrangements. It is therefore desirable that both decision and policy makers advancing the implementation of the CSME and regional trade officials negotiating multi-lateral trade arrangements such as the FTAA, promote a trade environment that is conducive for developing and implementing a regionally harmonised biosafety system.

Harmonisation of biosafety systems should also be considered at the international level as such considerations will ensure that national trade obligations, both regionally and internationally, are included in the development of regional guidelines for the implementation and management of biosafety systems at the national level. These considerations will also allow for the integration of international standards in the regional biosafety system.

The success of any regional harmonisation mechanism will be dependent on pooling of regional expertise in several areas including risk analysis. Additionally, harmonisation of biosafety systems will need to consider the development of similar mechanisms, at the national level, with respects to activities related to capacity building, risk assessment, management and communication principles, public participation, standards and testing, joint lobbying and regulatory guidelines.

A regional mechanism established to harmonise biosafety systems should set some minimum level of standards or code of conduct for developing guidelines, legislation and activities related to biosafety management nationally. These minimum standards should not preclude sovereign states from adopting higher standards that are not counter to their trade obligations. Such a system is common in trade arrangements, for example, the World Trade Organisation (WTO), which sets out minimum standards (e.g. for intellectual property – TRIPs Agreement - and for sanitary and phyto-sanitary measures – the SPS Agreement) for which member states must adhere while providing for individual states to implement more stringent measures that are not trade restrictive and that promotes fair trade.

The areas of health, food safety, the environment and biodiversity can be harmonised relatively easily as national polices in these areas are similar across the region. These national policies will need to be transparent, taking into account such issues as accountability, confidentiality and case-by-case scientific assessment. Policies are generally governed by political and socio-economic concerns therefore the development of both national and regional policies will need to consider other factors in addition to science.

Biosafety and biotechnology policy can be guided by a collective decision to make use of the technologies associated with biotechnology and the desire to examine unique opportunities for the use of biotechnology (e.g. coral reefs resistant to bleaching and agricultural applications) thus creating and enabling environment for biotechnology. Alternatively, the policy may be guided by a collective decision not to utilise the technology, this view may be considered limiting and non-progressive (a 'head in the sand' approach) and any such decision may limit the region's capacity to effectively negotiate trade agreements for which trade in biotechnology products are focal.

Strategies developed to implement biosafety systems should be harmonised across the region and must take into account differing developmental objectives among countries. Some components of a harmonisation strategy may be relatively easy to accomplish, for example, public awareness and participation, research and development, information sharing, capacity/competency building, standardization of procedures and practices (forms, testing, etc.), documentation and reporting. The impetus for harmonisation of these strategies may be demand driven from within mechanisms currently driving the implementation of the CSME.

Joint capacity building projects will be essential given the size of some of the islands and their limited human resource capabilities. It will therefore be necessary to evaluate

national and regional needs, identify gaps and jointly develop programs to address these gaps. Emphasis should be placed on bringing regional countries up to some minimum level of competence in the area of biotechnology and biosafety management. The focus of capacity building should be holistic and include not only programmes to enhance human capacity (regional training) but also physical infrastructure (laboratories etc.).

Legal and Regulatory Frameworks

There are several areas within national regulatory guidelines that can be harmonised across the region. These areas may include:

- Standards and testing,
- Risk assessment, management and communication
- Documentation/data (e.g. Application forms),
- Issuing of licences
- Public awareness policy
- Legal and policy framework
- Technology transfer
- Modalities for compensation of sharing data collected in various processes should be determined
- Definitions
- Monitoring and compliance
- Enforcement

With respect to legal frameworks, any legislation implemented at the national level to facilitate a biosafety system should be regionally compatible. This compatibility will allow individual countries to protect their interests with respects to socio-cultural issues and biodiversity. Within this context, compatibility does not mean that all legal systems throughout the region will be identical. Any regional system developed should allow for slight differences in the various legal frameworks by countries and these differences should facilitate intra-regional trade.

Risk Assessment and Risk Communication

Risk assessment relevant to biotechnology and biosafety management is based on scientific testing and reviews. Such science-based approaches to risk assessment of products of modern biotechnology are widely accepted as standard with respects to trade and transboundary movement of these products. The science-based components of risk assessment and management are based on acceptable international standards such as CODEX and ISO and therefore are suited to a regional approach.

Additionally, international trade rules as established by the WTO makes reference to member states using scientific approaches for making decisions with respects to the import of traded commodities. The WTO rules make specific reference to international standards such as CODEX and the IPPC as acceptable for member states to follow. The CODEX and other international standard setting bodies such as the ISO articulates in great detail the types of tests that can be conducted to evaluate the risks of GM food products.

A regional approach to science-based assessment for biosafety and modern biotechnology will need to address the problem of limited capacity (human, financial and physical infrastructure) at the national level. It would therefore be effective to have the scientific evaluation component of risk assessment and management dealt with at the regional level where expertise and resources can be pooled to facilitate handling of applications and determining the safety of GM products.

In addition to harmonised risk assessment procedures and guidelines, there should be some degree of similarity in the risk communication mechanisms and strategies developed across the region. Such an approach can be cost effective and efficient and has the potential to reduce the degree of duplication of efforts and the amount of financial resources required to facilitate the development and implementation these strategies.

Risk communication strategies developed at the regional level will require implementation at the national level and therefore will need to take the following into consideration:

- Development of information systems that can be accessed and utilised by all countries
- Access to information generated throughout the region especially with regards to notifications, decisions and problems/lessons learnt with respect to previously approved applications etc.
- Regional Networks such as CARDI, CABI, Ministries of Agriculture, the University of the West Indies and their involvement in the communication chain
- Standardisation within the context of biosafety and biotechnology.

Preparation for Meetings:

Prior to any meeting, whether at the regional (e.g. COTED) or international level, there should be preparatory meetings of relevant persons (Regional Biosafety Expert Committee - Regulator or Chair of National Biosafety Committees), so as to coordinate a regional position and negotiation strategy if necessary. These regional meetings may however become costly and some countries may not be able to participate by sending a delegate to the meeting. This problem may be addressed by fully utilising available telecommunications technology such as tele/video-conferencing and other virtual technologies to facilitate their participation in these ‘prep’ meetings.

Regional Harmonisation: Implementation Issues

The various working groups recommended that there should be a Regional Biosafety Advisory Authority (RBAA) established and constituted with the following composition:

- One member from each National Biosafety Committee (NBC), these members would sit on the Regional Biosafety Committee (RBC). The NBC member nominated to serve on the RBAA may be the chairperson of that national committee.
- There should be representation from CARICOM and the Regional Negotiating Machinery (RNM). One member from each organisation should sit on the RBC.
- Other members for the RBC may be co-opted based on technical expertise and special interests, this membership may also include NGOs.

The regional biosafety authority will need to be autonomous and dedicated to modern biotechnology management. The RBAA should adopt a coordinating and advisory role in its relationship with the NBCs with respect to legal and regulatory issues, science, trade, international relations and regional negotiations. The RBAA's mandate should also be to facilitate regional transparency in dealing with biosafety applications.

The success of the regional authority will be enhanced by clearly defining its level of authority as well as its capacity for enforcement. Matters relevant to dispute resolution should be considered at the level of the RBAA. In addition to national governments exercising their rights with respects to enforcement within their jurisdiction, there should also be some court of higher appeal. Within this context reference was made to the Caribbean Court of Justice and the use of its mechanisms for enforcement and arbitration.

The RBAA should define the terms of reference of a pool of technical experts which should include biotechnologist, molecular biologist, economist, Attorneys, trade/environmental specialists, social scientist, and others as required. It will be necessary to establish an inventory of regional expertise, to note any deficits, and to take action to build regional capacity. The RBAA would have the mandate to deploy these experts as required by individual countries.

Funding to constitute and maintain the authority should be sourced with contributions from national governments. There should however be some mechanism developed for the RBAA to be self supporting in the long term. This may be achieved by generating financial resources from projects and assistance provided with respects to applications and other activities related to the regional biosafety system.

To assist harmonisation of regulatory procedures, countries should issue the same application forms. The design of relevant forms will need to be done with the input from all countries and as such should be within the terms of reference for the RBC. The idea is to design a general application form and countries will address those sections of relevance.

To facilitate transparency and prevent duplication of testing, test results should be shared among countries and be in a readily accessible form. The flow of information within the regional context may be as follows: the NBC will forward all relevant information (notifications, applications, test results, decisions etc.) to the RBAA to be housed in a regional clearing house (CARICOM Clearing House). Similar information would be sent to the international Biosafety Clearing House as mandated under the biosafety protocol. An assessment will be necessary to determine if information required for the regional clearing house will be different from that required for the international clearing house mechanism. Additional information required at the regional level could then be processed and made available through the Regional Clearing House Mechanism.

To avoid the need to conduct tests for which results are already available from other countries, especially developed countries, the regional mechanism may need to consider evaluating and accepting test results from countries outside the region. There is however some reservation with respects to the acceptance of all test results especially when considering environmental issues and commodity crops for which further validation may be required. Test results deemed as acceptable should be based on internationally accepted tests as defined in CODEX and ISO.

All applications received, and test results obtained, should be reviewed on a case by case basis. National decisions to accept or reject test results from other countries may be guided by advice obtained from the RBAA. Information received from other regulatory authorities may be reviewed at the regional and country level depending on a broad regional policy that takes into account food, health, environmental and trade considerations. Consideration should also be made of the fragile ecosystems of small island developing states (SIDs) such as the Caribbean. Special consideration must be made with respects to impacts on agro-ecological systems and the environment when release is sought for specific commodity crops in areas considered ‘hot spots’/centres for diversity, or where there are related species endemic to a country.

Harmonisation of risk assessment and decision making can be achieved by developing clear guidelines for managing risks associated with modern biotechnology and biosafety, so that there is no ambiguity. Harmonisation should be based on sound scientific information in accordance with international trade agreements and standards. To achieve these objectives regional guidelines will need to be clearly elucidated and documented, taking into account that decision making at the country level will be influenced by political, social and cultural factors, all of which will impact on the guidelines/regulations adopted nationally.

Public Awareness and Capacity Building

The mandate of the RBAA should include the development of generic public awareness and communication materials which can then be adapted by each country to suit its particular needs. All existing institutions (public, private, NGO's etc.) within the region with experience in public education and participation should be utilised. In addition, access to the Clearing House Mechanism (both regional and international) for data and information should be used when needed.

The following strategies will need to be considered:

- Synchronised media blitz - use audiovisual aids (internet, print, TV, radio),
- Use of innovative approaches (drama, dance)
- Adoption of regional policies with respects to a region wide network linked to country nodes
- NBC members on the Regional Biosafety Committee may advise and develop operational plans on public awareness and communication strategies. Members can then take these plans to their national committees for review and adoption.

A central Publications Agency can be established with the mandate to access, standardize and disseminate information. The regional Clearing house will need to link with other regional networks such as SIMBIOSIS and other LAC networks to facilitate the development and execution of public awareness and communication campaigns. There is also scope within the structure of the University of the West Indies to aid the region in capacity building in this area by coordinating and executing training programmes which can be developed in collaboration with strategic partners in other institutions both regionally and internationally and which may be implemented internally or externally.

Joint capacity building activities will be critical in the execution of activities and work plans of the RBAA. To accomplish these joint efforts however, first, a needs-analysis should be conducted so as to obtain an inventory of existing capacity (human and physical) with respects to development in deficient areas. The RBAA through the NBCs can link to the information provided in the UNEP/GEF national biosafety projects. Following this analysis and the identification of gaps, then a joint regional capacity building approach/strategy can be developed. Development of this strategy can be within the terms of reference of the RBAA with implementation both at the regional, sub-regional and national levels. It may be necessary to look for relevant centres of excellence and develop collaborative initiatives to facilitate national and regional training.

Existing Regional Mechanisms of Harmonisation

If labelling policies and testing standards can be harmonised in Latin America and the Caribbean then resources can be pooled and strategic alliances can be forged so as to reduce the costs of testing and labelling. Regional mechanisms will therefore need to focus on:

- Capacity building
- Testing and specialisation of laboratories
- Collaborative research
- Use of all mechanisms currently in existence
- Developing linkages and strategic partnerships
- Assess quality and capacity of laboratories in the region and bring them up to international standards
- Internationally accepted accreditation of testing laboratories within the region
- Establishing agreements with other regions
- Extra-regional and regional experts to provide training for CARICOM persons to create a critical mass of scientists to build regional capacity

Within the region there are in existence some mechanisms that can collaborate to establish a regionally harmonised system for biosafety management. These existing organisations/institutes may also be instrumental in facilitating the mandate of the proposed RBAA. Two such organisations are:

(i) The Caribbean Regional Organisation for Standards and Quality (CROSQ) whose mandate is the ….. "establishment and harmonisation of standards for the enhanced efficiency and improved quality in the production of goods and services in the Community, thereby facilitating consumer and environmental protection and improved trade within the Community and third states". CROSQ already exists and has headquarters in Barbados.

(ii) The Caribbean Agricultural Health and Food Safety Agency (CAHFSA) which is being *proposed* to replace the non-functioning Caribbean Plant Protection Commission (CPPC) but with a broader mandate. CAHFSA's mandate is proposed to strengthen the capacity of Caribbean countries to protect human, animal and plant health, with respects to production and regional and international trade. CAHFSA is still in the developmental stages and has not yet been established.

There is the need to aim for a common labelling policy and internationally accepted standards. Labelling should be positive, informative and not defamatory and should use CODEX labelling standards as a guide. The acceptable level of GM components allowed within foods may vary from country to country; however, such levels should be determined at the advisory level of the RBAA and be adopted at the national level. Harmonisation in this regard should facilitate regional and international trade.

Summary

Working group sessions on regional harmonisation of biosafety systems identified the following issues as critical to a regional mechanism established to address modern biotechnology and biosafety management:

- Harmonised national policies to facilitate intra/inter-regional trade and the processing of applications

- Consideration of socio-cultural-economic differences among countries. Regional guidelines or recommendations should make provisions for countries to express these differences in their national biosafety frameworks and supporting legislations.

- Regional standards should be compatible with international standards. There should be some minimum standards articulated with provisions for countries to set higher standards that do not have a negative impact on trade.

- An autonomous regional biosafety/biotechnology Authority, the Regional Biosafety Advisory Authority, should be established. Its mandate should be to advise regional countries with respects to guidelines, standards, legislation, and trade negotiations etc.

- There should be a pooling of resources in the region and the RBAA should be responsible for maintaining and deploying these resources as required by countries. The authority should also have responsibility for developing capacity building, public awareness and communication strategies which may be implemented at all levels.

- Collaboration between regional and hemispheric counterparts in Latin America with respects to testing, laboratory facilities, training and other capacity building initiatives.

Appendix A

Regional Harmonisation of Biosafety Systems: Working Group Questions

What areas should harmonisation be targeted in CARICOM in light of the CSME and the FTAA? Indicate where it would be most desirable to have harmonisation and instances where it is not necessary.

1. ***What are the objectives of biosafety? Are they the same for all countries? What are the national priorities? What level of harmonisation is required?***

2. ***Should national policies be harmonised across the region? Highlight specific issues.***

3. ***Should strategies to implement biosafety systems be harmonised? Detail.***

4. ***Is it important to ensure that legal frameworks established in different countries be regionally compatible to ensure smooth transboundary movement of GMOs within CARICOM?***

5. ***What elements of national regulatory guidelines should be harmonised?***

6. ***Should there be joint capacity building projects?***

7. ***What aspects of risk assessment and risk management would be amenable to a regional approach?***

8. ***Risk Communication?***

9. ***Should there be meetings prior to international fora so as to co-ordinate positions to affect joint lobby?***

Implementation issues – what mechanisms should be put in place to achieve such harmonisation?

1. ***Assuming that a regional biosafety authority was established how would you suggest that this body be constituted? How should the national biosafety committees relate to this authority?***

2. ***Should application requirements (forms) be similar (same?) across the region?***

3. ***Should data requirements and standards be similar?***

4. ***Should test results be readily accessible for sharing by all CARICOM countries?***

5. ***Should test results from US and Canadian regulatory authorities be accepted for: food safety, environmental assessments and commodity crops?***

6. ***How can risk assessment and decision making be harmonised?***

7. ***How can public awareness and communication be managed from a regional perspective to make maximum impact, given limited financial resources?***

8. ***How can joint capacity building be accomplished?***

9. ***How can we use other regional mechanisms of harmonisation e.g. laboratories and/ or results from Latin America?***

10. ***How do we address food safety systems?***