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FIFTH COORDINATION MEETING FOR GOVERNMENTS AND ORGANIZATIONS IMPLEMENTING OR FUNDING BIOSAFETY CAPACITY-BUILDING ACTIVITIES
San José, Costa Rica, 9-11 March 2009

# CAPACITY-BUILDING PROJECTS/INITIATIVES

*Update on the Ongoing Biosafety Capacity-Building Projects and Other Initiatives: A compilation of submissions from Governments and Organizations*

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## COUNTRY SUBMISSIONS

**CAMBODIA** [10 MARCH 2009]
[SUBMISSION: ENGLISH]

### Update on Biosafety Capacity-Building Projects in Cambodia

March 10, 2009

1. Cambodia is committed to the implementation of the Convention on Biological Diversity and Cartagena Protocol on Biosafety. Since Cambodia became a Party to the Protocol on Biosafety (2003), the country has made a great progress in terms of biosafety framework development. The country has improved in overall capacity through implementing the UNEP/GEF funded project on Development of the National Biosafety Framework (2003-2005). Through the project, Cambodia produced some materials including biosafety law, which was passed by the Parliament in December 2007, training on risk assessment and risk management for relevant stakeholders; maintain BCH website, and promoting public understanding on Cartagena Protocol in Biosafety.

2. Cambodia also participated in the UNEP/GEF funded project on Building Capacity for Effective Participation in the Biosafety Clearing-House in 2006. The project provided capacity for enhancing capacity to communicate via BCH website and increased capacity of data entry persons from relevant ministries which provided information on the release of living modified organisms (LMOs) and biotechnology regulation to the Ministry of Environment.

3. In March 2006, Cambodia has been provided fund to implement the National Biosafety Framework, which is aimed building capacity of the five component set in the NBF. The project is scheduled to undertake activities from August 2006 on. The goal of the project is to assist the Royal Government of Cambodia to put in place a workable and transparent national biosafety framework, in line with national development priorities, Agenda 21, and the CBD. This goal will be achieved through the following specific objectives:
    a. To assist Royal Government of Cambodia (RGC) to establish and consolidate a fully functional and responsive regulatory regime in line with Cartagena Protocol and national needs and priorities;
    b. To assist RGC to establish and consolidate a functional national system for handling requests, carry out risk assessment decision-making and administrative tasks;
    c. To assist RGC to establish and consolidate a functional national system for "follow -up" activities such as monitoring of risk exposure and environmental effects, and strengthening of enforcement mechanisms, institutions and procedures; and
    d. To assist RGC to establish and consolidate a functional national biosafety system for public awareness, education, participation, and access to information.
4. This project would help RGC to strengthen the existing institutional and technical structures and infrastructures needed to meet the obligations of the Protocol, and have an operational National Biosafety Framework. This project will contribute to:
    - The building of capacity for implementation of the Cambodia's National Law on Biosafety and Sub-Decree on Management and Control of LMOs and relevant guidelines to ensure the safe use of modern biotechnology;
    - Putting in place specific technical guidelines for facilitating transport, handling and use of LMOs;
    - The strengthening of appropriate institutional structures for risk assessment and decision making;
    - The development and implementation of policies for biotechnology and biosafety;

- The training of decision makers, scientists, and administrative and technical staff on legal and technical matters;
- The reinforcement of the existing infrastructures (laboratories) to strengthen monitoring and identification of LMOs;
- Setting up and making operational a mechanism for monitoring and enforcement
- The strengthening of communication and information exchange relating to biosafety
- both at the national level as well as through the BCH
- Systems for strengthening public awareness, education and participation in decision making on LMOs.

5. **Achievements:** Insofar, Cambodia produced certain outputs in terms of capacity building. This includes: Risk Assessment and Risk Management Guideline (in Khmer and English), a draft sub-decree on LMOs management, application forms for LMOs release, glossary on biosafety and biotechnology in Khmer, draft action plan on biosafety and biotechnology, draft biosafety curriculum for secondary school and training manual on biotechnology. Cambodia is developing a mini-lab on LMOs testing, which will be ready in mid-2009. Moreover, Cambodia continues to train lawyers, border inspectors, custom officers, phyto-sanitary inspectors, veterinary agents and environmental agents to be familiar with system of release of LMOs into the environment. Through the project, more than 1,000 students participated in biosafety debate on a national TV. Expert discussion on biosafety has been organized via a radio station to promote public understanding on biosafety, advantages and disadvantages of LMOs application and obligation of the CPB.

6. **Lessons learned:** The UNEP/GEF funded project on implementing the NBF has arriving at certain successes and sustainability, among these are as follows:
   - **a.** The establishment of a coordination mechanism for relevant agencies to take in the implementation of the project is important to ensure the outputs of the project and this is important to draw attention to various decision-makers to support future capacity building initiatives;
   - **b.** Public understanding on biosafety should be promoted at all level and all means especially TV and radio programs to that local people can reach the message initiated at the national level;
   - **c.** It is wise to involve all relevant stakeholders when drafting the action plan on biosafety and biotechnology so that priority areas on capacity building are addressed in the policy;
   - **d.** A regional cooperation is essential to promote information sharing and experiences on implementing the projects notably capacity development on biosafety.

**REPUBLIC OF CUBA** [4 MARCH 2009]
[SUBMISSION: ENGLISH]

**Update on Ongoing and Planned Biosafety Capacity-Building Projects/Initiatives in Cuba**
**Practical experiences and achievements on capacity building activities**

1. As part of UNEP/GEF's first capacity-building initiatives, the National Center for Biological Safety (NCBS) of Cuba participated from 1998 in the Pilot Phase of the UNEP-GEF biosafety projects for the Development of National Biosafety Frameworks, which aimed to allow participating countries to design and develop a national framework for the effective implementation of the Cartagena Protocol. During 2002-2007, Cuba also formed part of the series of UNEP-GEF demonstration projects for the

implementation of these frameworks, which contributed to the consolidation of national biosafety structures. The fact that much of what was put into operation is in constant use, is undergoing updating and upgrading, is being disseminated nationwide and/or is considered durable and technically sound, is a demonstration of the usefulness and impact of the GEF projects.

2. Notwithstanding those progresses, there is a strong need for institutional coordination and capacity building around demands for technological resources, infrastructure and analytical tools primarily for LMOs identification and detection. Available capacity is therefore insufficient to stay afoot with all these tasks.

3. The tasks pending for a more effective rapport with the Cartagena Protocol, identified by the NCBS as priority needs when the Implementation UNEP-GEF project was finalized, include:

(a) Maintaining a high rate of training in accordance with local needs;

(b) Greater involvement and coordination with other entities relevant to biosafety; and

(c) Better infrastructure relating to LMO detection, in support of risk management and regulatory compliance, and for sustaining BCH participation.

**Current initiatives**

4. Taking the above into account, currently, we are involved in the preparation of a new UNEP/GEF project named *Completion and Strengthening of the Cuban National Biosafety framework for the Effective Implementation of the CP.*

5. The current project therefore seeks to address all the above issues by structuring itself around 4 main components: 1) Institutional coordination for regulatory, BCH and decision-making purposes; 2) Imports, exports and transit in relation to the Protocol, with emphasis of LMOs for food, feed and processing; 3) Human resources training; and 4) Scientific and technological capacities of National Competent Authorities. Although the project's components focus on the biosafety framework's weakest points, and do not cover the framework as a whole, they will contribute to the robustness of the complete framework.

6. Given that in Cuba, the introduction of exotic species into the environment and related human health issues (exposure and consumption) are part of a wider system of biological safety, the proposed project will aid the country in the safe use of biotechnology by further strengthening its existing mechanisms for environmental protection and human safeguards.

7. Apart from the above project, we are preparing other one to be submitted to FAO. This project will allow getting assistance for designing, developing and implementing a post – release monitoring system of LMOs.

8. Cuba’s main barrier to adequately addressing those tasks is the financial constrains it faces in strengthening its existing National Biosafety Framework and responding to continuous training needs, given the embargo situation that has prevailed for decades and the limited coordination among relevant authorities whose mandates and management decisions bear influence on biosafety. There are also technological constraints that limit Cuba’s participation in the BCH, whereby greater technological capacity for connecting to and accessing the BCH central portal, and for eventually developing a national BCH, are needed

**Main difficulties**

2. In spite of having this situation, there are others problems to deal with. Some of them are:

- Primacy of scientific and economic criteria over safety issues.
- Unawareness on safety culture issues.

- Existence of some state regulatory bodies which are strongly involved in Biosafety activities so their competences can be overlapped.

**How we deal with these difficulties - initiatives undertaken with national resources**

3. In matter of development of the human resources in general, and particularly to make that all those who are in charge of making decisions, change their mind on Biosafety-related topics, we have outlined a training program which includes Biosafety aspects aimed at executive personnel. In addition we have had coordination meetings with those state bodies strongly involved in Biosafety activities in order to set agreements about scopes, competences etc. In this case we have the Ministry of Public Health and the Ministry of Agriculture involved. We have also a National System of Biological Safety that it was created since 1996 and it is currently developed nationwide by having one representative specialized in biosafety issues and located in each province of the country.

**Lessons learned**

9. We have learnt that from the end of a Project to the beginning of another project, there always is a deadlock period in which achievements on capacity building can be threatened. Despite the efforts and the compromise of the government, the budget is not enough for the sustainability of most of the activities, mainly, the activities in which financial resources are the core component, this is the case of the technical infrastructure.

10. We have learnt also that the update of the necessities and priorities on capacity building matter and training necessities, are permanent tasks. In the case of training activities, knowledge about biotechnology in a general sense is strongly needed by the specialists of the regulatory agency, when this sphere is enhanced in our country. Cuba is currently able to orienting its capacity building priorities towards more technical necessities i.e. the design and operation of a laboratory for identification and detection of LMOs.

4. Finally we consider that the exchange of experiences at regional and sub regional levels constitutes a very important issue. It allows the common use of the capabilities developed by other countries of the region, due to the similarities in language, culture etc which enriches the experiences of all these countries. On the other hand, the exchange of information among regulatory agencies from developing countries and developed countries, by using the direct contact, would be very useful, especially for risk assessment and risk management process.

**Opportunities for collaboration**

11. Cuba can offer some opportunities for collaboration mainly focused on development of human resources, which means, training on Biosafety issues. Unfortunately our training program just can be developed in Spanish language. In illustration of this potential, Cuba has already offered collaboration to countries such as Venezuela, Paraguay, Bolivia, to name a few, with the aim of strengthening local human resources in biosafety matters.

12. In addition we have developed some initiatives with Colombia which may result in a possible bilateral cooperation agreement regarding the design and the implementation of an international training course (a possible master degree) on Biosafety, aimed with emphasis at Latin-American countries.

| **CZECH REPUBLIC** | [5 MARCH 2009]<br>[SUBMISSION: ENGLISH] |
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**Biosafety Capacity Building Activities in the Czech Republic**

1. Capacity building activities aiming at the Cartagena Protocol implementation have been developed in the Czech Republic within the following UNEP/GEF Projects:

(a) Development of the National Biosafety Framework for Czech Republic (2002 – 2004;

(b) Implementation of the Draft National Biosafety Framework for the Czech Republic (2006- 2010)

(c) Add-on Project - Building Capacity for Effective Participation in the Biosafety Clearing House (2006-2008).

2. The first mentioned Project assessed the existing national capacity and role of responsible bodies. The results are summarised in the final Report "*National Biosafety Framework for the Czech Republic"* (Ministry of the Environment, Prague, March 2004).

3. The implementation project (2006 – 2010) aims to assist in implementation of adopted measures within the biosafety framework in the country. The implementing activities focus on five components of the National Biosafety Framework: Biosafety policy, Regulatory regime, Handling requests for permits, Monitoring of environmental effects and enforcement, Public information, participation and awareness. The Ministry of the Environment serves as the National Executing Agency. National Coordinating Committee (NCC) assists in coordination of scheduled activities and consists of representatives of authorities and institutions responsible for biosafety policy, regulations and monitoring and other important stakeholders (Ministry of Agriculture, Ministry of Health, Ministry of the Environment, universities, research institutions, NGOs represented by Greenpeace). A close cooperation has been developed with the Czech Commission for the Use of Genetically Modified Organisms and Genetic Products. The Project is supported (through co-financing) by the Ministry of the Environment, Ministry of Agriculture and Ministry of Health, which are the main sectors responsible for biosafety regulation in the Czech Republic.

4. The Add-on BCH Project resulted in establishing of the National BCH System. New website has been developed and serves for communication with CBD/CPB Secretariat and information sharing in English (www.mzp.cz/biosafety), whereas Ministry of the Environment website (www.mzp.cz – Environmental Risks – GMOs) offers information in national – Czech language.

5. Capacity building represents an important part of the Projects and corresponding activities have the following main forms:

6. Meetings with policy makers, inspection personnel, experts, researcher and NGOs. These serve for information exchange, enhancement of inter-sectoral cooperation and coordination of procedures and actions.

7. Workshops and trainings are focused mainly on enhancement of biosafety knowledge, latest development in related fields and adopted measures at global, regional and national levels, instruction for applicants, training of inspection personnel etc. Participants are different stakeholders according to the theme of the given action (administration officials, researchers, teachers, environmental educators, NGOs). In some of them regional experts participated. As to international organizations, besides UNEP cooperation mainly with FAO has been developed (Ministry of Agriculture, Czech Commission for Cooperation with FAO) resulting in organization of yearly workshops on topical biosafety issues for Central and East European Countries in Prague.

8. Publications and other information material have been edited on biodiversity and biosafety issues, including workshops Proceedings, survey of Terms on Genetic Resources and Biosafety (Czech – English) as well as posters presented on the occasion of various national and international conferences and workshops. In view of the focused group they were mostly published in Czech (with English summary). The list of publications is annexed.

**Lessons learned**

9. Development of the UNEP/GEF Projects revealed some prerequisites for reaching success and sustainability of adopted measures, among them mainly:

(a) Cooperation among different sectors, as well as inside sectors (different departments, institution) and coordination of efforts, leading to better understanding of problems, integration of biosafety interest into national policy and sectoral programmes and to financial support of required procedures and actions.

(b) Involvement of various stakeholders and enhancement of awareness on the issue.

(c) Dissemination of information tailored to different stakeholders groups (publications, presentations, internet - Biosafety Clearing House).

(d) Regional cooperation enabling exchange of information and experience.

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| **MALAYSIA** | [10 MARCH 2009]<br>[SUBMISSION: ENGLISH] |
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**Update on Ongoing and Planned Biosafety Capacity-Building Projects/Initiatives in Malaysia**

The Biosafety Act was passed by Parliament in July 2007. In April 2008 the Government approved the formation of a Core Group on Biosafety tasked with the responsibility of implementing the Biosafety Act whereby some 25 posts were created. Consistent with the objective of the government to make biotechnology an area for generating new income, several enabling activities have been carried to make the Biosafety Act a more friendly piece of legislation. In this regard regulations have been drafted where detail have been spelled out. In addition a list of exemptions has also been. Several elements in relation to timeliness has also been prepared which could be included in the standard operation procedures of the Biosafety Department .

To date several awareness seminars have been carried out. In 2008 a Workshop on Risk Assessment and Risk management of Transgenic Insects was carried and on 11-13 March 2009 another Workshop on Transgenic Crop Plants has been planned. The University of Malaya also offers a master degree course on biosafety in cooperation with UNIDO. We are now in the process of finalizing our website on biosafety. The GEF project on biosafety has been very useful in this regard.

Among the challenges for the future to work with the private sector to enable resources to be optimized particularly in building capacity on biosafety.

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| **MEXICO** | [11 MARCH 2009]<br>[SUBMISSION: ENGLISH] |
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**Update on capacity building activities in Mexico since the India meeting in 2008.**
**March 2009**

A second phase national project (2006-2009) on capacity building towards aiming on the implementation of the Cartagena Protocol has almost been completed. This was a Mexican government financed project but through the UNDP agency in Mexico (given the previous good experience obtained with UNDP through the GEF project on capacity building 2002-2005).

In this second phase the Ministries of Agriculture (SAGARPA), Environment (SEMARNAT), Health (SALUD) and CONABIO have been participating with the Coordination of the Inter-secretarial Commission on Biosafety and Genetically Modified Organisms (CIBIOGEM). Health for example commissioned through a public call the study that detected and quantified the different varieties contained in samples of the 8 million Tons of maize imports in the different ports of entry of the country to the GMO detection lab of the National University (UNAM). While CONABIO has for example used these funds to validate its ecological niche prediction maps used as part of its risk assessment methodology for cotton, brassicas, cucurbitas and pine trees.

Mexico has been putting efforts into creating a network on monitoring that includes a detection labs network at the national level, although these are still at an early stage of development. There is also an initiative from the Advisory Scientific Council to Start a Research Network on GMOS.

Mexico has also been giving capacity building at an institutional level to Colombia, including socioeconomic issues as well as risk assessment and database usage. Capacity building was also included in the UNDP project commissioned to UNAM by the Ministry of Health. This effort included also the personnel from the Ministry of Agriculture (SAGARPA). In that project, DNA quantification and identification technologies, manuals, as well as hands-on work on DNA extraction, amplification and quantification were included as part of the training of government officials.

Twenty new public servants have been hired by the Ministry of Agriculture to deal with Biosafety issues those include monitoring, risk assessment to plant and animal health, and inspections for law enforcement previsions. A significant amount of resources in comparison with previous years had being directed to monitoring activities and inspection.

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| **SOUTH AFRICA** | [11 MARCH 2009]<br>[SUBMISSION: ENGLISH] |
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**Country Report On Biosafety Capacity Building: South Africa**

Prof. C.D. Viljoen

An Environmental Biosafety Cooperation Project has been established between South Africa and Norway. One aspect of this involves biosafety research between the GMO Testing Facility (University of the Free State, South Africa), researchers from the University of the North West and Fort Hare, South Africa and GENOK (Centre for Gene Ecology, Norway). The aim of the biosafety project is to improve capacity to conduct research, monitoring and assessments on the environmental impacts of GMOs used in agriculture as well as improved biosafety management and research through focusing on post release monitoring research of GM maize in terms of gene flow, impacts on target and non target insects as well as the microbial soil rhizosphere.

An additional aspect of the South Africa-Norway Cooperation Project is to hold a Biosafety workshop: "Holistic Foundations for Assessment and Regulation of Genetic Engineering and Genetically Modified Organisms", presented by the GMO Testing Facility (SA) and GENOK (Norway), and will be held in Bloemfontein, South Africa from 28 June 2009 to 03 July 2009 (english.genok.org or **www.ufs.ac.za** or www.sanbi.org**)** for approximately 65 participants. The workshop targets participants from countries in Southern Africa and is designed to provide policy makers, regulators, scientists and NGOs with holistic

training in issues of biosafety including the potential impact on the environment and human health, regulatory systems, risk assessment and risk assessment review as well as LMO detection.

In addition, SANBI (South African National Biodiversity Institute) has been mandated to oversee post release monitoring in South Africa. A workshop was held to establish a frame work for post release monitoring in South Africa from 4-7 November 2008.

Biosafety SA, was established to support biotechnology innovation by ensuring the development of safe sustainable biotechnology products. Biosafety SA aims to act as a facilitator to bring the different components required to take a biotechnology product from development through to commercialization.

**ORGANIZATION SUBMISSIONS**

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| **ASEAN CENTRE FOR BIODIVERSITY** | [11 MARCH 2009]<br>[SUBMISSION: ENGLISH] |
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## Background

The **ASEAN CENTRE FOR BIODIVERSITY** (ACB) is an intergovernmental and international regional centre of excellence of the Association of Southeast Asian Nations (ASEAN) which aims to create, promote, and develop links with the public, private sector, civil society, international development institutions, and donor community for the sustainable use of biodiversity.

ACB's raison d e'tre is to build strategic networking and partnerships so that resources could be mobilized optimally to augment effective programmes and enable knowledge management. The key outcome is to achieve socially responsible access, equitable sharing, utilization and conservation of natural ecosystems and the biodiversity they contain for the present and future generations of ASEAN Member States (AMS).

The ACB is managed by a Governing Board, which is composed of the ASEAN Senior Officials on the Environment (ASOEN) and the Secretary-General of the ASEAN.

ACB's scope of activities covers a wide range of thematic areas pertaining to the key focus areas for sustainable use of biodiversity resources. Specific to the area of capacity building for biosafety, hereunder are the modest initiatives of the Centre:

## Southeast Asian Workshop on Risk Assessment of GMOs/LMOs and Enforcement of Biosafety Regulations (4-6 December 2007, Malaysia)

The South East Asian Workshop on Risk Assessment of GMOs/LMOs and Enforcement of Biosafety Regulations was held from 4-6 December 2007 in Kuala Lumpur, Malaysia. It was organised by the Ministry of Natural Resources and Environment, Malaysia and Umweltbundesamt – Federal Environment Agency, Austria, in collaboration with the ASEAN Centre for Biodiversity, Third World Network and the NRE-UNDP-GEF Biosafety Capacity Building Project.

Many countries in the South East Asian region are in the process of developing or implementing their biosafety frameworks, policies and laws. As these systems are set in place, capacity is needed in order to undertake scientific risk assessments of GMOs/LMOs and to enforce biosafety regulations, requiring monitoring, inspection and detection capabilities.

The objectives of the workshop were to:

- build capacity in crucial areas related to biosafety implementation
- provide training in scientific risk assessment of GMOs/LMOs
- increase knowledge in issues necessary for the enforcement of biosafety regulations, such as inspection and detection
- learn from the biosafety implementation experiences of other countries in the region

Workshop sessions focused particularly on GMO/LMO scientific risk assessment, including practical examination of case study dossiers, and enforcement issues, such as inspection and detection. The

workshop also provided an opportunity for participants to share regional experiences in biosafety implementation.

## Workshop on Risk Assessment of GMOs/LMOs and Enforcement of Biosafety (22-24 June 2008, Cambodia)

Biosafety is a term coined to describe efforts to reduce the potential risks that may be caused by biotechnology and its products such as GMOs and LMOs. It was identified as a critical issue by the Convention on Biological Diversity (CBD) in 1992. Years later, the Cartagena Protocol on Biosafety was adopted in 2000 to ensure that while maximum benefits are reaped from biotechnologies, adequate safety measures are in place to guard against possible risks to humans and the environment.

Within the ASEAN region, countries initiated the same efforts to anticipate these risks through the enactment of national policies. The ASEAN Centre for Biodiversity (ACB) is at the forefront together with its partner ASEAN Member States (AMS) in the advancement of the Protocol.

In December 2007, a "Workshop on Risk Assessment of GMOs/LMOs and Enhancement of Biosafety Regulations" was held in Malaysia. This activity was jointly organized by ACB and the Ministry of Natural Resources and Environment of Malaysia in collaboration with the Federal Environment Agency of Austria, Third World Network, and the UNEP-GEF Biosafety Capacity Building Project. The successful workshop has identified the need to continue similar capacity building activities to discuss broader biosafety issues in the ASEAN context.

In fulfilment of the recommendation, ACB and the Ministry of the Environment of Cambodia have organized a follow up "Workshop on Risk Assessment of GMOs/LMOs and Enforcement of Biosafety Regulations" on 22-24 June 2008. The goal of the workshop was to enhance regional capacity, promote better understanding, and strengthen cooperation in the ASEAN region by providing a venue for sharing up-to-date scientific information on the emerging areas of biosafety and risk assessment. The workshop had four (4) sessions and was attended by over 40 participants from the AMS, ASEAN Secretariat, and ACB.

At the end of the activity, participants made recommendations mostly addressed to ACB. Some of these suggest that ACB shall: lead the process in the preparation of the Regional Guidelines on Risk Assessment; collect information on available methodologies, criteria, and procedures on risk assessment; and compile related national policies for sharing with other ASEAN countries to aid in the development of their national policies on biosafety.

## Regional Workshop on Biosafety Capacity Building Activities (19-22 November 2008, Vietnam)

Over the last two years, the ASEAN Centre for Biodiversity (ACB) has organized or cooperated to organize a series of regional workshops on biosafety in order to enhance cooperation at regional level on biosafety management. The workshops focus on regional cooperation on risk assessment and risk management of GMOs to concretize orientations for and indentify more opportunities for regional cooperation.

The Vietnam Environment Protection Agency supports ACB's activity on risk assessment and management by organizing a regional workshop in Da Lat, Vietnam. The follow-up workshop focused on:

- Biosafety management framework of ASEAN member countries.

- Risk assessment, risk management, and development of ASEAN Guidelines for managing GMOs/LMOs;
- Monitoring and enforcement of GMOs and related products.

Approximately 50 participants from all over Vietnam and across the ASEAN region participated in the workshop. Majority of participants were attendees of the past two workshops on risk assessment and management organized by ACB. In addition, Resource people from UNEP, Governments of Australia, and Austria as well as from Monsanto, CropLife International, and the US Environment Protection Agency and Department of Agriculture were present.

## ASEAN Regional Guidelines for Risk Assessment of GMOs/LMOs

Because risk assessment should be carried out on a case-by-case basis, it is vital to evaluate such assessment from a specific country perspective and bring it into the regional level. For the case of ASEAN member states (AMS), risk assessment should be undertaken with inputs from ASEAN nationals with appropriate qualification and experiences in relevant fields. With assistance from its partners, the ASEAN – through the ASEAN Centre for Biodiversity (ACB) with financial assistance from the European Union – requires an effective regional mechanism and guideline that coordinate the regional collective actions so that biosafety and risk management protocols for genetically-/living-modified organisms are mainstreamed in both the regional and national development agenda.

At present, ACB is engaged in coming up with practical guidelines to implement biosafety regulations and risk assessment protocol in the ASEAN region; validate the guidelines and pilot test the Guidelines among AMS; and undertake further capacity building activities on risk assessment for AMS.

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| **INTER AMERICAN INSTITUTE FOR COOPERATION ON AGRICULTURE** | [11 MARCH 2009]<br>[SUBMISSION: ENGLISH] |
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**Hemispheric Biotechnology and Biosafety Program**
**Plan 2008-2009**

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### IICA ORGANIZATION

Recognizing the significant regional differences that exist in the hemisphere on biotechnology and biosafety, and mindful of the challenges that the new agrobiotechnologies pose, the opportunities they offer and the need to strengthen national capabilities in this field. IICA's member countries called for the need for a hemispheric agrobiotechnology program. Such a program should lead to joint action aimed at sharing information, integrating efforts, tapping opportunities and improving access to the technologies available to find solutions to common problems and enhance national capabilities.

### PURPOSE

To facilitate mechanisms for the development, management and responsible use of agrobiotechnology in order to promote competitive and sustainable agriculture in the Americas.

**MISSION**

Identify and promote opportunities for the execution of activities between all interested parties, utilizing available resources and existing institutional (national and regional) channels.

To achieve the above, IICA through the HBBP, will coordinate joint activities among interested parties in order to promote efficient information sharing, capacity building and consulting in public policy development and decision making.

**OBJECTIVES**

1. To support the gathering, analysis and dissemination of existing information to enable national officials to design policies and take decisions based on scientific and technical evidence, and provide the public with objective information on agrobiotechnologies.

2. To support the member countries in conducting needs assessment at the national and regional levels, to determine the development and appropriate use of agrobiotechnologies.

3. To support the development, implementation and communication of transparent, science-based policies and regulatory frameworks and, where appropriate, facilitate regional harmonization.

4. To promote transparent communications on the risks and benefits of agrobiotechnology, and encourage the authorities to make the issue of public perception an important component of national agrobiotechnology policies and programs.

5. To support the development of scientific and technological capabilities in the field of agrobiotechnology by means of regional strategies and cooperation among countries and regions, considering the solution to national and local problems.

6. To promote studies, discussions and analyses of the implications of national and international norms and regulations, as well as international negotiations and agreements, on matters related to agrobiotechnology and biosafety, with special emphasis on their impact on trade.

**INTRODUCTION**

In alliance with the International Service for the Acquisition of Agrobiotech Applications (ISAAA) and with collaboration of the Global Development Learning Network (GDLN) of the World Bank, in March of 2008 a videoconference was organized with the purpose of spreading information updates on the development and adoption of the Agrobiotechnology in Latin America. The activity included several members of the international media, and reached approximately two million people throughout the Hemisphere.

The IICA's System on Scientific Information on Biotechnology and Biosafety has been strengthened during this year. This System broadcast an electronic bulletin issued by INFOAGRO/Biotechnology reaching no less than 1254 registered users, most of which are personnel from different sectors such as public, private and the academia. In the same fashion, the area has produced three documents that describe the political and economical situation of Biotechnology in Latin America.

In the Central, Southern and Andean Regions, we have advanced in our process of creating a regional strategy on Biotechnology and Biosafety; including some projects oriented to the development and appropriate use of the biotechnology. This course of action had allowed us to gather enough information to estimate the current situation of Latin American countries on this matter, and it has helped us to create

a platform for the exchange of experiences and information in the adoption of the biotechnology; emphasizing, among others topics, food security.

The Andean Region needs assessment process that IICA undertook in 2007 has taken us to the conceptualization and discussion of a project for food supply diversification, aimed at vulnerable populations of the Andean Region. This project will merge the use of biotechnological tools with traditional methods in production of local staple crops.

In Paraguay, for example, IICA has offered technical cooperation for capacity building on intellectual property rights in Biotechnology. At the same time, IICA has been supporting the construction of an academic profile for the creation of a career in Biotechnology.

The Biotechnology and Biosafety Area has been organizing Preparatory Technical Meetings around the negotiations of the Cartagena Protocol of Biosafety. The latest of which, was oriented to the COP/MOP 4, which took place in Bonn, Germany during the 12th -16th of May. The main objective of these preparatory meetings particularly, was to share information prior to the negotiations about articles 15, 16, 18, 23, 26, 27, 30, 33, 35 programmed in the agenda of this international forum.

These meetings have had financial support from several partner institutions such as AGCanada, USDA and BIO; which have made possible the participation of delegations from countries all around the Americas. Previous to these meetings, IICA prepared a working document on the discussions regarding the upcoming meeting. For instant, the latest document produced was about legal aspects of the implementation for article 27 of the PCB, which was used a foundation for the discussion at the assembly of attendees.

**ACTIVITIES OF HEMISPHERIC BIOTECHNOLOGY AND BIOSAFETY PROGRAM IN 2008**

In a similar way and with the collaboration previously mentioned, IICA continues to work on preparing its member countries for the negotiations of the Ad Hoc Group on Liability and Redress. For this purpose, IICA organized a meeting in November of 2008 in San Jose, Costa Rica. This meeting constituted a necessary preparation for the world-wide meeting summoned by the secretary of the PCB in February of 2008 in Mexico DF, Mexico. The objective of these meetings is to obtain a greater involvement from LAC countries on the process of negotiation of Articles of the PCB, keeping in mind that the LAC region has a highly active trade of GMOs.

In this same spirit, IICA has prepared a series of technical documents referring to the development of biotechnology in the hemisphere as well as its impact, policies, opportunities, risks, challenges, adoption and implications for its countries, as well as the agreements reached at international fora like Cartagena Protocol of Biosafety or *Codex Alimentarius*; always within the scope of biotechnology and biosafety.
Our program contemplates the bellow indicated activities that deal with policy and regulatory framework issues, information dissemination and sharing, impact assessment of agricultural biotechnology or needs assessment including benefits opportunities.

**Regional Strategies of Biotechnology and Biosafety**

Within the frame of the PHBB, it is mandatory for IICA to initialize processes of needs identification in the regions or countries that request it. In this way, our office has concentrated its efforts in the creation of Regional Strategies that allows Latin American as one region to level out the existing differences in development as well as in the use of Biotechnology, directed to the agricultural sector.

With the same spirit, and because there are in some regions with divergent political positions that makes it difficult to the develop strategies and regional projects. IICA has proposed to implement activities to the

benefit of the countries with the objective of leveling its competence and correcting differences in capacity building in subjects as biotechnology, biosafety and communication of science. This disadvantage, has been identified by the own regions as its mayor challenge in the development of their countries.

During the processes undertaken in Andean, Central and the Caribbean Regions IICA has detected weaknesses in diverse areas related to the proper use of the biotechnology. Among them, it has been found the absence of policies, regulatory marks, deficiencies in communication, etc. In some of these countries we have finished the diagnosis and written the strategies while is some others we are still in the initial phase. It has been programmed in 2009 to follow the activities paused in 2008.

**Food supply diversification for vulnerable populations. Use of biotechnology tools in native food crops for the Andean Region**

The objective of this project is to contribute to the food security and autonomy of vulnerable populations in the Andean countries, through diversification of food supply and consumption, using biotechnological tools in traditional crops (cui, quinoa, yuca, etc.), without losing sight of the proper use of natural resources.

The program will be structured at national level with central and local governments, research institutes and technology centers; supported by networks of social actors and institutional organizations in each country. The idea is to establish cooperative ties and share knowledge within the Andean territories.

**ACTIVITIES FOR 2009**

The Andean region consists primarily of three main regions: coastal, rainforest and high Andes. The direct beneficiaries of the program are the families of small producers in rural areas identified in these sub regions, where a vulnerable population concentrates. Also, part of the project is to work with vulnerable populations, located in the urban poverty belts of the cities of Caracas, Bogota, Quito, Guayaquil, Portoviejo, Machala, Lima and La Paz,

The main project has been divided in 5 sub projects as follows: Innovation in production, development of markets for native products, Promotion of traditional and native products for regional markets, Institutional Development of Institutions, Knowledge Management. Our office is working in collaboration with the department of Natural Resources at IICA, the Regional Direction for the Andean Region, and the regional offices of IICA in each country.

**Cartagena Protocol on Biosafety:**

COPMOP 4 in 2008 established a group of friends concerning Article #27 (Liability and Redress) in the context of Cartagena Protocol on Biosafety. This group has been entrusted with the task of negotiating the international rules and procedures in the field of liability and redress for damage resulting from transboundary movements of living modified organisms. Its first meeting will be hold in Mexico City from January 23rd to January 27th. In the eventual case that the objective of the summit is not reached, the group will meet again in Malaysia in 2010.

It is of utter interest for IICA to offer a space that provides the opportunity to discuss and to advance in the clarity on the subject, especially, for the 6 delegate countries of the Latin American Region that will have vote at the negotiations. For this reason, our team has organized a series of meetings and virtual forum, whose objective is to constitute a platform for the exchange of questions and information to prepare our member countries for the upcoming meetings of the PCB. From this process, IICA will prepare a compilation document of the development of the negotiation as well as the state of the

discussion about the topic in its member countries. This document will serve as a base to suggest a route of technical cooperation needed by the countries involved in it.

**Communication and public awareness of Biotechnology in Latin America**

The topic of public awareness in Biotechnology becomes important since it is within the society where the positive or negative reaction about technological progress becomes true. In other words, is in the basis of the society, where technology and specially Biotechnology becomes legitimized. Even more important, more social actors have been involved with the decision –making in Biotech policy, making misinformation a terrible weapon against technological progress.

In this context, the Biotechnology and Biosafety Department from IICA along with IFIC, have agreed to develop a common Project on a communication strategy in biotechnology and GMO foods, which could be later used in other regions of Latin America and the Caribbean. The objective of this program is to develop and promote a science-based communication system, to allow policy makers, consumer, communicators and the general public to have access to objective information on agricultural biotechnology, and its related products.

One of the main activities of the project will be to establish an efficient communication strategy to disseminate updated information in biotechnology in a way easily understood by key stakeholders, policy makers, communicators, consumers, etc. A key element for this purpose is the improvement of our webpage, the goal is to turn the IICA'S Biotechnology page into a highly interactive website, where its visitors will access online courses, have access to updated information, and exchange information.

**Release of information on the development and adoption of agrobiotechnology in cooperation with ISAAA**

One of the lines of action of the Inter-American Biotechnology and Biosafety Program (IBBP) deals specifically with the provision of information on biotechnology. IBBP/IICA has established strategic partnerships with reference centers and centers of excellence on biotechnology. One of the most significant actions of these partnerships is an activity held jointly with the International Service for the Acquisition of Agrobiotech Applications (ISAAA) to disseminate information on advances in agrobiotechnologies. ISAAA is a not-for-profit organization that delivers the benefits of new agricultural biotechnologies to the poor in developing countries, which has become the center of reference for evolution and adoption of agrobiotechnology in the world.

Every year ISAAA publish his Annual Report about "The global status of commercialized Biotech/GM crops" and more recently, IICA/IBBP has been organizing seminars in agreement with ISAAA for every region (Central America, Andean Region) to inform member countries about the latest advances on biotechnology adoption and their impact on the competitiveness of their agricultural sector.

**Programmed Publications**

According to the expressed idea of the delegates in the last meeting of the PCB held in IICA headquarters in 2008. There is a need from the countries to know the state of the art of the legislation about Biotechnology in Latin America, including topics such as Biosafety, event releases, Liability and Redress and Intellectual property. Given the successful experience in the Southern Region for data collection of this nature, it has been considered to extrapolate this experience to the rest of Latin America, using existing platforms like the Prociandino for the Andean Region and SICTA for the Central Region. The idea is to collect as much data as possible to publish a document that will be available for government officials and private institutions all over the region.

**Implementation of National Biosafety Framework for Costa Rica. Project PNUMA-FMAM GFL2328-2716-4A35**

The activities developed within this project contemplate strategies for the promotion and the improvement of social and public awareness, education and public participation, monitoring and assessment systems and mechanisms of the potential risks and adverse effects. For this reason the project have been divided in four components:

1) Regulatory System: It will provide a legal framework of Biosafety and the promotion of a safe policy in Biotechnology in accordance with the PCB.

2) Administrative System: It will develop a national administrative infrastructure in which the Biosafety Framework will operate.

3) Capacity Building: It will create the technical capacity for the national authorities and related institutions for a comprehensive management of Biosafety in Costa Rica.

4) Public awareness and education: It will establish links for a long term training of the national authorities, and it will incorporate Biosafety as a topic in universities and any formal education institutions.

Given the experience of our Institute in capacity building, and the project we are developing in Public awareness, the Ministry of Agriculture in Costa Rica has invited us to participate in the formulation and the implementation of the components 3 and 4 of the framework.

This project still in the planning stage, but is expected to operate in the second semester of 2009.

**Programmed Courses**

New Biotech products and sub products are being created every day, It is important for Latin America and the Caribbean to have technically trained personnel who can evaluate risks, propose strategies of management and advise the local authorities, acting within a proper and efficient regulatory framework. Specific legislation needs to be developed and whenever in place, to be improved, in order to protect human health, and biodiversity.

With this in mind, we are proposing a workshop that should provide information on the tools available for a proper assessment of the risks deriving from the use of LMO, whether as food, feed, or source of commodities. Strategies for risk management and LMOs detection will be also discussed, as well as issues in public perception and bioethics.

The course will be aimed to regulators, policy makers, and key actors in the risk assessment process. This includes, people from government, scientific institutions, and private sector involved in manipulation of LMOs. Preference will be given to applicants from Central America, and the Andean Region.

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| **INTERNATIONAL CENTRE FOR GENETIC ENGINEERING AND BIOTECHNOLOGY (ICGEB)** | [7 MARCH 2009]<br>[SUBMISSION: ENGLISH] |

**A New ICGEB Initiative: Assisting the Development of Effective Safety and Regulatory Systems for the Products of Modern Biotechnology in Sub-Saharan Africa**

**By Decio Ripandelli**

1. ICGEB has recently started the implementation of a new project, funded by the Bill and Melinda Gates Foundation, aimed at assisting governments and scientists in Sub-Saharan Africa, to support the implementation of reliable regulatory systems that follow recognized international guidelines to protect consumers and the environment. The project's goals align with recommendations in a recent report by the African Union (AU) and the New Partnership for Africa's Development (NEPAD), which highlight the need for Africa to develop scientific capacity to assess and regulate biotechnology and inform policies.

## Introduction

2. The involvement of the International Centre for Genetic Engineering and Biotechnology (ICGEB) in the arena of biosafety capacity-building is long-standing and has resulted in a wealth of experience and know-how in a range of biosafety activities that underpin its endeavours focusing on strengthening human and infrastructural capacity in ICGEB Member States. These include:

(a) Improving the level of awareness, knowledge, and expertise of scientists, government officials and other primary stakeholders through the implementation of short- and long-term training programmes (in the form of workshops and fellowships);

(b) Dissemination of relevant scientific and technical information via our biosafety web pages (http://www.icgeb.org/biosafety/) and during the training programmes;

(c) Providing tailored services commissioned by competent authorities in Member States to establish or improve specific national biosafety procedures or frameworks; and

(d) Undertaking actual biosafety research fundamental to the understanding of the possible risks arising from the cultivation of genetically modified plants. A major goal of the Centre's activities is to represent this information in a fair light and to expel previous mis-representations and misgivings on the ground.

3. ICGEB's long experience and nonpartisan approach has certainly be one of the aspects that has convinced the Bill and Melinda Gates Foundation to consider funding this three-year ambitious initiative in Sub-Saharan Africa, which will bring all of the Centre's experience to bear, in the promotion of practical approaches to help resolve key difficulties in expediting the regulatory frameworks of the Countries in the Region.

## The Project

4. The prime objective of the initiative is to strengthen the ability of countries in Sub-Saharan Africa to fully integrate into the worldwide effort to assure full and balanced consideration of biosafety issues in pursuing appropriate uses of modern biotechnology. This will be achieved by the establishment and staffing, in the newly launched ICGEB Cape Town Component, of a satellite focal point of biosafety expertise to support local and regional regulatory systems overseeing the use of GMOs, and providing advanced training to scientists and members of National Competent Authorities (NCAs). Together these will improve the generation, communication and use of essential information necessary for GMO risk/safety assessment. Initial consultations will ensure the country-orientated identification of current

knowledge gaps and capacity building needs for fully executing regulatory decision-making with regard to GMOs and their derived products in a more efficient, equitable and effective manner. Extension of the project into additional global regions will be considered.

5. As modern biotechnology progresses, and the creation of GMOs already begun in various countries in Sub-Saharan Africa, it is important to develop biosafety considerations, including research and the vast pool of current scientific knowledge, with experts of these regions. Despite the efforts of the UNEP GEF programme, still few Sub-Saharan African countries have fully functional biosafety legal frameworks whilst the remaining countries have only interim biosafety frameworks or none at all. The status of science in these national biosafety regulatory frameworks, the drafting of regulations sufficiently stringent in order to protect against genuine ascertainable risks (as determined by the application of best available science), as well as the ability of decision-makers to discern the appropriateness of data necessary to adequately conduct a risk assessment, all have considerable consequences. For example, superfluous data often confuses decision-making, diverting time and efforts from the more serious of the identified potential risks, thereby slowing down the procedure and increasing associated costs. This ICGEB project foresees a package of three complementary and interconnected objectives, tackling problems inherent in biosafety capacity building on a number of levels and aims at strengthening the role of science during the appropriate risk assessment phase of the decision-making process, especially by:

(a) providing greater access to current scientific information;

(b) training in how to make best use of this data; and

(c) filling locally-identified gaps in information required by the regulatory process but not already addressed by the scientific community.

**The Activities**

6. Working primarily out of the Cape Town Component, ICGEB is creating a regional focal point on biosafety which will be staffed, by early 2010, with 3 full time biosafety specialists. Two of these specialists are being presently trained in the Biosafety Unit in Trieste to become fully conversant in biosafety issues, particularly those currently impacting sub-Saharan Africa. They will transfer to Cape Town by July 2009 where they will carry out a stakeholder consultation in the region to ensure that the capacity-building activities being implemented within the programme directly meet the locally-identified needs on the ground.

7. These activities are to be focused on assisting stakeholders at several levels. By the completion of the project at the end of 2011, it is expected that approximately 250 scientists and regulators providing essential services to their respective NCAs will have participated in a series of workshops, equipping them with specialised training in key areas of GMO regulation. In addition, a total of ten fellows will have completed and graduated from a Masters degree course specifically designed to develop expertise in the risk assessment of GM plants and crops to be deliberately released into the environment, both experimentally and commercially. Furthermore, financial support will be provided for up to forty experts in the region to facilitate their attendance at important regional and international biosafety conferences, so that not only will they be able to keep abreast of the latest developments in biosafety issues, as well as developing and fostering links with the international scientific community, but also help direct agendas towards issues of primary relevance to Africa.

**Where are we now?**

8. Although the project was formally initiated in June 2008, concrete activities started only at the end of the year, through the recruitment process of the first two “biosafety specialists” which have started their training in Trieste in February 2009, and through the participation of 5 African experts into the 10th ISBGMO, in Wellington, New Zealand, in November 2008. The two fellows currently “on board” are

heavily involved in desktop studies and planning of project activities, and have had a proactive role in the preparatory phase of a questionnaire aimed at collecting specific information on:

(a) Current situation of biosafety regulatory systems in every Sub-Saharan Africa country;

(b) Risk assessment practices in these countries;

(c) Composition and training needs of each NCA.

9. The questionnaire has been sent at the beginning of March to over 600 contact points, policy-makers, researchers and biosafety and biotechnology stakeholders active within Sub-Saharan Africa and will be the basis upon which the focal point in Cape Town will operate to identify the needs of the interested countries. Meanwhile, ICGEB has signed a MOU with the University of Wales, Aberystwyth (UK) to offer a 1-year academic Masters course on "Risk Assessment of GM Crops" to eligible candidates from the Region, and the relevant call for applications was issued last week (five fellowships in the Academic Year 2009-2010 and another five in 2010-2011).

**What's next?**

10. A third biosafety fellow, to operate from the Cape Town Component, should be recruited by the end of 2009 (the relevant call for applications has been posted last week) and, in September 2009, the project's External Advisory Board is due to meet in Cape Town, to be updated on progress of the project and to agree further strategic implementation of project activities. By the end of September, the selected candidates for the MSc course in Aberystwyth should begin their studies, while the first regional workshop (out of nine foreseen) should be organized (several options still available).

11. The ICGEB initiative will work "hand in hand" with another major project funded by the Gates Foundation, and executed by NEPAD to establish an African Network of Biosafety Expertise (ABNE). To that effect, appropriate mechanisms are foreseen to ensure the exchange of information and data, the complementarity of individual web-sites contents and linkage, the regional complementarities (if and when necessary), and other instrumental synergies that will increase the reach of each individual project. On the other hand, the efficacy of the project will be evaluated annually to ensure that the overall programme is responsive to evolving situations in the target region. Should results prove promising, it is expected that similar initiatives could be replicated in Southern Asia and beyond: in order to formally initiate this process, a special workshop will be organized in Southern Asia, with invited personnel involved in national biosafety frameworks in the Region (Bangladesh, India, Pakistan and Sri Lanka), by the start of the third year of the programme. These key representatives of the national competent authorities and scientists taking part in the GMOs development and/or decision process will be targeted for intensive discussions in order to gather data, identify common gaps in biosafety knowledge and expertise, and to formulate a plan for a new proposal for essential biosafety capacity building efforts in Southern Asia.

[04 MARCH 2009]
[SUBMISSION: ENGLISH]

**INTERNATIONAL FOOD POLICY RESEARCH INSTITUTE**

## The Program for Biosafety Systems (PBS)

***John Komen, PBS program manager***
URL: http://www.ifpri.org/pbs/pbs.asp

The Program for Biosafety Systems (PBS) contributes to the implementation of the Cartagena Protocol by supporting partner countries as they develop the policy and legal framework, administrative procedures, technically qualified personnel and outreach mechanisms vital to their national biosafety systems. PBS

work emphasizes sound science-based decision making and research, while also addressing socioeconomic considerations. PBS works with partner countries in Africa (Ghana, Nigeria, Kenya, Uganda, Malawi, Mozambique) and Asia (the Philippines) to develop and implement a program of activities tailored to biosafety needs identified by local collaborators. In addition, PBS works with regional policy-making bodies such as COMESA[1] on subjects of common interest, such as LMO commodity trade and the development of regional technical guidelines.

**Project activities**

The scope of PBS activities includes the following:

(a) *Policy and regulatory development:* The PBS policy component analyzes the implications of different country and regional regulatory approaches for genetically modified organisms. Choices regarding biosafety policies and objectives are evaluated for their implications for agricultural growth, trade, and food security. Legal expert advice is provided to countries drafting legal instruments and implementing regulations.

(b) *Grants for scientific research on environmental risk issues:* The focus of the Biotechnology-Biodiversity Interface (BBI) grant program, managed by PBS, is on the need to better understand the interaction between genetically engineered crops, agriculture, and the environment. Through BBI, 11 competitive grants aimed at addressing the effects of agricultural biotechnology, particularly genetically engineered crops, on natural biodiversity as it occurs in developing countries.

(c) *Assistance with regulatory documentation for proposed field testing:* This component of PBS provides public sector R&D institutions with the support they need to incorporate biosafety considerations into their product development efforts and to comply with regulatory requirements. It also aims to help regulatory agencies to effectively carry out their roles in the review, approval, and inspection processes.

(d) *Technical training in environmental and food risk assessment:* PBS maintains an active program of training and outreach activities. The overall aim of such activities is to ensure that the people involved in biosafety decision-making are competent and confident to assess planned releases of GMOs and GM food products using the best available science.

**Main achievements**

Selected PBS achievements include:

(a) *Contributing to (regional) policy making:* A number of African governments are in the process of drafting, or revising overall guiding policies on biotechnology and biosafety, usually backed by laws or decrees stipulating the specific procedures for GM applications and products. PBS supports national policy development where needed, notably in countries who are in the process of defining their national biosafety systems, e.g., in Malawi, Ghana and Uganda. In Malawi, PBS supported a process of grassroots consultations in key agricultural zones, providing inputs into a draft policy on biotechnology and biosafety developed by a multi-stakeholder Biotechnology Policy Taskforce. The final policy document was submitted to Cabinet in early 2007 and eventually adopted by the Government of Malawi in April 2008. In the meantime, work started to revise the Biosafety Act (2002) to better define regulatory roles and responsibilities among relevant government agencies. The Government of Malawi gazetted the revised Law in August 2007, enabling the formal appointment of a National Biosafety Regulatory Committee.

[1] COMESA: Common Market for East and Southern Africa

(b) Regional policy research projects in collaboration with ECAPAPA2, ACTS3 and FANRPAN4 aim to inform the policy process in sub-Sahara Africa. For example, the Regional Approach to Biotechnology and Biosafety Policy in Eastern and Southern Africa (RABESA) initiative, supported by the COMESA Secretariat, in its first phase analyzed the likely trade implications of planting GM crops for selected countries in East and Southern Africa. Based on the outcomes of the study (available at: http://www.acts.or.ke/pubs/monographs/index.html), the COMESA Secretariat drafted a set of guiding principles on regional trade flows of GM commodities, which are currently elaborated by a team of regional experts in a follow-up phase of the initiative.

(c) In addition, detailed legal analysis and review is being done on (drafts of) laws and regulations, and recommendations made to ensure such documents establish workable, understandable and transparent regulatory systems that are consistent with international obligations. In Eastern Africa, this work has been review through regional policy seminars organized by the East African Community (EAC).

(d) *Establishing the BBI competitive grants program*: Scientific data are essential for assessing environmental risks and benefits of GMOs, particularly in centers of diversity. Impacts will differ from one ecological region to another and should be evaluated on a case-by-case basis, in and by developing countries. The focus of the Biotechnology-Biodiversity Interface (BBI) grants mechanism, managed by PBS since 2003, is on the need to better understand the interaction among GM crops and animals, agriculture, and biodiversity. To date, 11 project proposals (see for details: http://www.ifpri.org/pbs/pdf/bbiprojects.pdf) have been awarded, with scientific leadership by developing-country research institutes. PBS in-country team leaders and advisory groups were instrumental in identifying BBI priorities, launching calls for proposals and supporting potential grantees. Findings from the BBI projects are being reviewed through regional technical review meetings and international conferences.

(e) *Integrated Confinement System for GM plants*: Confined field trials (CFTs) play a critical role in the evaluation and development of new technologies intended to improve agricultural productivity. General guidelines for assessing and deciding on CFTs have been adopted in most partner countries. However, their implementation must be carefully managed in order to assure that the experimental material remains confined, so that no effect on the environment and human or animal health is allowed. Aware of the need for a comprehensive and encompassing approach —comprising the development of detailed guidelines, tailored training and technical assistance— in the critical area of biosafety for confined field trials, PBS and partners in developing countries have developed an "Integrated Confinement System" applicable to confined field trials as well as contained glasshouse experiments. The system has been developed through collaborative work in East Africa, and has the following elements: (a) CFT Guideline; (b) Containment Manual; (c) Confinement Manual; (d) Regulatory Procedures; (e) Trial Managers handbook; and, (f) Inspectors' handbook.

(f) In partnership with the Uganda National Council for Science and Technology, PBS developed detailed guidelines and standard operating procedures (SOPs) for confined field trials, adopted by the government of Uganda under existing legal authority. This work enabled the Uganda National Biosafety Committee to review and approve field trial applications for GM fungal-resistant banana and Bt cotton.

(g) *An integrated approach to biosafety training and education*: PBS continues to provide targeted training interventions supporting a clearly defined goal, addressing a concrete biosafety challenge. Recent training events focused on, for example, reviewing and managing actual field trial applications;

2 ECAPAPA: Eastern and Central Africa Programme for Agricultural Policy Analysis

3 ACTS: African Centre for Technology Studies

4 FANRPAN: Food, Agriculture and Natural Resources Policy Analysis Network

developing national GM food safety regulations in line with international (Codex) standards; developing training curriculum and materials by African universities. A case from the Philippines serves to illustrate this point, and how policy development went hand in hand with technical training. Over the last several years, PBS is collaborating with the Philippines Bureau of Plant Industry (BPI) in providing technical assistance and training to build insect- and weed resistance management policies for GM maize varieties that are commercially available in the country. PBS-supported activities ranged from internship programs in the US and Canada, aimed at drafting guidelines and training materials, to implementing local training programs on insect- and weed resistance management, targeting crop protection officers of the different regions in the Philippines.

[04 MARCH 2009]

**RAEIN-AFRICA** [SUBMISSION: ENGLISH]

**Regional Agricultural and Environmental Initiatives Network –Africa (RAEIN-Africa) activities under the Regulatory Innovation: Breaking Biosafety Boundaries for Innovation in Southern Africa Project (RIBBB-SA)**

**By Doreen Shumba-Mnyulwa**

1. RAEIN-Africa is a regional network working in southern African countries with the purpose of enhancing capacity of stakeholders to undertake research, influence policy formulation, and apply scientific and technological innovations that are people centred and gender sensitive through inclusive participatory processes for sustainable development.

2. Even before the advent of the CPB, there were many efforts to build regulatory and technical capacity in developing countries, for the development and enforcement of National Biosafety Frameworks (NBFs). Developing countries have attempted to use policy and development models (e.g. ISNAR, UNEP and the OAU models) on biosafety from developed countries with limited success. . In the case of Southern Africa, only 6 out of the 15 countries have managed to develop systems on biosafety. These include South Africa, Malawi, Mauritius, Namibia, Zambia and Zimbabwe.

3. Constraints faced by countries to develop biosafety systems include; inadequate capacity (human and infrastructure) be they legal, administrative or technical, lack of financial resources and the lack of skills and knowledge to mainstream biosafety issues into the national development agendas. The situation is complicated by the bureaucracy and or red tape within the policy and legal formulation processes, lack of coordination at all levels as well as compartmentalisation of mandates and activities along ministries and departments leading to institutional rivalry in government institutions. With biosafety issues aligned to many government ministries/departments, there is a challenge on who should coordinate the development and or implementation efforts of the biosafety frameworks.

4. While the presence of appropriate advanced technological developments can catalyse development of regulatory frameworks in modern biotechnology the lack of policy and legal instruments in developing countries hinder innovativeness. The lack of awareness on modern biotechnology across all levels reduces the importance that policy makers and implementers place on issues of biosafety. In civil society arena, in addition to lack of awareness, territorial protection and external influence on programming leads to their limited inputs to catalysing the process of development and implementation of NBFs.

5. Recognising the challenges and the limited progress in implementing the Cartagena Protocol, RAEIN-Africa is using its experiences in participatory approaches to apply the innovation systems

concept to raise awareness and build the relevant skills and knowledge of the actors. The goal is to uplift biosafety and allied issues in the region in national development agendas and hence accelerate development and implementation of NBFs. In using the innovation systems concept, the capacity building process will entail changing the mindsets of the actors and strengthening the social capital, resulting in trust amongst the actors and commitment to the process.

**RAEIN-Africa's strategy**

6. RAEIN-Africa's strategy in capacity building for biosafety framework implementation is based on an earlier experience in a biotechnology for resource poor farmers programme implemented in Colombia, Kenya, India and Zimbabwe. In this programme, use of participatory approaches enabled varied institutional interaction, leading to innovative creation of knowledge, capacity building and influencing of policy. In addition, the participation of resource poor farmers in making decisions about the interventions improved their livelihoods. The network recently embarked on a five year programme, of which one of the projects is 'The Regulatory Innovation: Breaking Biosafety Boundaries for innovation in Southern Africa (RIBBB-SA)'. The programme is supported by the DGIS of the Netherlands. The objectives of the project are: to generate knowledge for informed risk assessment on socio-economic considerations and environment issues in the SADC region, to develop and strengthen competencies of key actors within the innovation systems to enable interface of policy, research and society for enhancing livelihoods, to strengthen the voice of key actors to effectively participate, drive and influence development and implementation of NBFs, to develop partnership arrangements at national level for the application and use of biosafety to improve livelihoods, to strengthen national, regional and international partnerships for collaboration and experience sharing on the implementation of the Cartagena Protocol on biosafety.

7. Whilst the project will facilitate capacity building in technical skills, the network will also endeavour to promote dialogue amongst the actors, thereby strengthening the systems that interfaces policy, research and society and promoting learning and innovation. The importance of institutional development and effective governance structures in these processes will be observed and shared. Efforts will be on creating an understanding of interactions between and among the inter-twinned components of innovation systems and at the same time strengthening the development actors' capacity to implement biosafety systems. The capacity building activities will have clear link with the policy processes if biosafety is to become an integral part of science and technology innovation policy.

8. The project activities will focus on: building a strong politically and civil society constituency for science and technology innovation to influence development and implementation of biosafety frameworks (e.g. creating an understanding and improving the quality of participation), increasing the understanding of key biosafety concepts, risk assessment and risk management as it relates to socio-economic considerations, environment and regulatory aspects of biosafety, improving the interface between and among various sectors contributing to the implementation of biosafety, influencing policy and improving information generation and flow and facilitating shared learning processes.

9. It is expected that implementation of the activities will result in a number of outputs, including: a methodology or tool for guiding assessments of socio-economic risks in Southern African countries, improved capacities in using the innovation systems approach to enhance the interface of biosafety policy, research and society, increased regional understanding and application of standardised biosafety rules and regulations in the region, innovative ways of public awareness and effective participation of development actors in biosafety decision making processes, specifically influencing policy and practice.

10. As a strategy to avoid spreading the resources too thinly, the network will identify countries where specific activities based on the status of biosafety frameworks in these countries. The issue of networking and sharing of experiences will however be implemented in all the SADC countries.

11. Realising the complexity of institutions and governance in the developing countries setting where institutions and governance are more informed and influenced by political agendas rather than social and economic justice issues, the network endeavours to facilitate dialogue and stakeholder consultations in the capacity building processes. Ensuring that the innovation systems concept performs as expected under the complexities, capacity building initiatives in developing countries should invest some resources into building a shared understanding of the capacity gaps, facilitating and managing dialogues, resolving conflicts, hence contributing to changing of attitudes and building trust. Creating such an environment will increase performance of science and technology and therefore positively impact on livelihoods.

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