



## Convention on Biological Diversity

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SEVENTH COORDINATION MEETING FOR  
GOVERNMENTS AND ORGANIZATIONS  
IMPLEMENTING OR FUNDING BIOSAFETY  
CAPACITY-BUILDING ACTIVITIES  
Chisinau, Republic of Moldova, 4–6 April 2011

### 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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## SUBMISSIONS FROM PARTIES

**AUSTRIA**

[01 APRIL 2011]  
[SUBMISSION: ENGLISH]

### **Austrian Biosafety Capacity Building Activities 2010**

Malaysia: Laboratory training course,

In April 2010 Austria co-funded a workshop on GMO detection which was carried out in co-operation with the Department of Chemistry Malaysia (KIMIA) in Kuala Lumpur, Malaysia. This course was a follow-up activity of a training course held in 2009.

This advanced course, in which experts from the Environment Agency Austria acted as resource persons, focused on the topics quantitative PCR, measurement uncertainty and results interpretation.

Ukraine: Analysis of GMO legislation and risk assessment procedure

The Environment Agency Austria carries out a Twinning project (funded by the EU) on ecological audit. Part of this 18 month project, which started in September 2010, is an analysis of the current legislation and the development of guidance on risk assessment and the authorization procedure for GMOs.

The project is carried out in co-operation with the Ministry of Environment of the Ukraine.

**CAMBODIA**

[30 MARCH 2011]  
[SUBMISSION: ENGLISH]

### **What Issues Does the Implementation of the National Biosafety Framework Project for Cambodia Address? (GFL-2328-2716-4934)**

#### **Project Summary**

In 2005 the Ministry of the Environment submitted a proposal to the UNEP/GEF to get more fund to implement the National Biosafety Framework (NBF). March 2006, Cambodia has been provided fund to implement the National Biosafety Framework. 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 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.
- D. To assist RGC to establish and consolidate a functional national biosafety system for public awareness, education, participation, and access to information.

## Background

The Royal Government of Cambodia (RGC) recognizes a clear need for ensuring the sustainable use of biological resources and for environmental sustainability. Initiatives in support of these priorities have contributed to the sustainable development of the country. As a Party to the Convention on Biodiversity since 09 February 1995, Cambodia completed its NBSAP in early 2002, and the government promulgated it on 27 July 2002.

The NBSAP provides a framework for action at all levels that will enhance Cambodia's ability to ensure the productivity, diversity and integrity of natural systems and, as a result, our ability as a nation to reduce poverty and improve the quality of life of all Cambodians. It promotes the conservation of biodiversity and the sustainable use of our biological resources, and describes how we will contribute to international efforts to implement the Convention. The NBSAP outlined 17 themes and 98 priority actions, which were adopted by the government and can be grouped in three broad categories: actions promoting awareness and capacity building of government staff and local communities for biodiversity conservation and sustainable use of biological resources; actions promoting the implementation of community-based natural resource management; and actions aimed at clarifying ministerial jurisdictions, reducing responsibility overlap and promoting inter-ministerial coordination and collaboration. One of the 17 themes of the NBSAP addressed the government policy toward biosafety and biotechnology development.

The National Biosafety Framework, finalized on 30 June, 2004 with financial assistance from UNEP/GEF, is a positive step towards fulfillment of these national initiatives and the country's international obligation under the Cartagena Protocol, which Cambodia ratified on 17 September, 2003. The NBF development came through the MOE. MOE coordinated with line ministries, NGOs, academic institutions and private sector to develop its the NBF.

Cambodia was now seeking assistance from GEF for an MSP to implement its NBF until it has been approved in March 2006. This made Cambodia became the Second Country out of the countries participated in the Development of the National Biosafety Framework in undertaking the implementation of its NBF. 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 GMOs.

## Expected project outputs by component

### Specific Objectives and outcomes<sup>1</sup>:

<b>Component A</b>	To assist RGC to establish and consolidate a fully functional and responsive regulatory regime in line with Cartagena Protocol and national needs and priorities.
<b>Outcomes</b>	<i>RGC has a fully functional and responsive regulatory regime in line with CP and national needs; Regulatory regime published and made accessible to all stakeholders; Application and enforcement of the regulatory regime.</i>
<b>Component B</b>	To assist RGC to establish and consolidate a functional national system for handling request, carry out risk assessment, decision-making, and administrative tasks.
<b>Outcomes</b>	<b>RGC has a functional national system for handling request and decision-making as well as performing risk assessment and management associated to LMOs;</b> <i>A fully functional decision-making system; A fully functional administrative system; A fully functional system for handling, storing and exchanging information including the effective use of the BCH, to complement the BCH project.</i>
<b>Component C</b>	To assist RGC to establish and consolidate a functional national system for “follow-up”, namely monitoring of risk exposure and environmental effects and enforcement.
<b>Outcomes</b>	<i>Establishment of roles and responsibilities for monitoring and enforcement; Strengthen systems for enforcement; Emergency response procedures established and operational.</i>
<b>Component D</b>	To assist RGC to establish and consolidate a functional national system for public awareness, education, participation, access to information.
<b>Outcomes</b>	<i>RGC has a functional national system for public awareness, education, participation, access to information: National system established for access and sharing of information; Strengthen system for public awareness and education; Strengthened political and public support for biosafety; Strengthen system for public participation in decision-making.</i>

### Outputs:

#### 1- An operational, workable, transparent and effective regulatory regime on biosafety

- Biosafety law enacted
- Training workshops on biosafety issues and the requirements of the Cartagena Protocol for legal experts, NBSC member, policy makers and parliamentarians;
- Consultation workshops with key stakeholders to identify biosafety issues;
- Biosafety task force set up within government;
- Training manuals prepared for lawyers and relevant personnel in government;
- Training workshops and materials for staff implementing biosafety law and regulations.
- Mechanism set up for internal information sharing on biosafety;
- Cessation or revocation Prakas established for non-compliance
- Procedures established for systematic review and update of biosafety regulations.

<sup>1</sup> One more component has been split into Component A- on policy. Component D became component E. Overall coordination including technical assistance from UNEP and auditing are under component F, which was created after the project approval.

**2- Procedures for handling applications established and updated in accordance with the Cartagena Protocol**

- Institutional roles and responsibilities for handling applications, risk assessment and risk management, emergency response, dealing with accidental release, monitoring and enforcement identified and codified within the regulatory regime;
- Identification NCA(s) and relevant biosafety focal points;
- System for handling applications in place, including relevant manuals, procedures and guidelines;
- Procedures and guidelines for risk assessment and management established;
- Check-list prepared for risk assessment;
- Procedures and guidelines for emergency responses established;
- Procedures and guidelines monitoring and enforcement established
- Experts responsible for risk assessment identified within the country;
- Laboratory facilities established for RA;
- Relevant scientists and technical experts trained in RA procedures, including LMO detection;
- Training workshops for relevant personnel in emergency responses, monitoring and enforcement;
- Roles and responsibilities of decision making body established and codified;
- Mechanism and procedures for decision making established;
- Training workshops for members of decision making body;
- Guidelines developed for decision making on LMOs;
- Mechanisms for public participation in decision making established;
- Socio-economic priorities defined for Cambodia for decision making on LMOs;
- National biosafety databank set up;
- Website on biosafety developed and set up;
- Mechanisms established for external data input by stakeholders.

**3- Establishment of mechanism and procedures for monitoring of environmental effects, and enforcement**

- Roles and responsibilities of various agencies in monitoring and enforcement defined and codified;
- Infrastructure for monitoring and enforcement established
- Guidelines, manuals and procedures prepared and published for monitoring and enforcement;
- Training workshops for technical, border control and field personnel in monitoring and enforcement;
- Legal training workshops for key personnel involved in monitoring and enforcement;
- Strengthened capacity for monitoring and enforcement in relevant agencies, including border control;
- Criteria for monitoring established;
- Guidelines, manuals and procedures prepared and published for emergency responses, including remediation;
- Training workshops for relevant personnel in emergency response procedures;
- Audit procedures established for monitoring and enforcement.

**4- Increased public awareness of biosafety and involvement in decision-making on biosafety.**

- Surveys on public perception on LMOs carried out;
- Training workshops for all stakeholders on access to biosafety information;
- Training materials on biosafety information prepared and published;
- Outreach materials on accessing biosafety prepared and published;
- Library and database on biosafety established;
- Biosafety awareness and education materials prepared and published;
- Training workshops for all stakeholders on biosafety and biotechnology;

- Awareness and education activities carried out, including workshops, focus group meetings, TV shows, newspaper articles, public debates, radio talks, etc;
- Curricula developed for biosafety for use in schools;
- Training workshops for educators in biosafety;
- Entry points for public participation in decision making on LMOs identified and institutionalized.

#### **Budget**

- **From GEF** : **US\$641,280**
- **Covered period** : **August 2006-July 2010**

#### **Output produced:**

- 1) Risk Assessment and Risk Management Guideline of LMOs;
- 2) A Training Manual on Risk Assessment and Risk Management;
- 3) Sub-Decree on Mechanism and Procedures to implement the Law on Biosafety;
- 4) Action Plan on Biosafety and Modern Biotechnology (2010-2014);
- 5) Lab on Biotechnology established;
- 6) A Training Manual on Monitoring, Compliance and Enforcement of Transboundary Movement of LMOs;
- 7) A Training Manual on Inspection and Monitoring;
- 8) A Training Curriculum on Modern Biotechnology;
- 9) A Glossary on Modern Biotechnology in Khmer;
- 10) Series of trainings for at 500 participants on CPB; risk assessment; law on biosafety and monitoring;
- 11) Trained for 50 journalists on CPB and related matters.
- 12) Maintained and updated Cambodia's Biosafety Clearing-House.

#### **CZECH REPUBLIC**

[01 APRIL 2011]  
[SUBMISSION: ENGLISH]

#### **Biosafety Capacity-Building Activities – Czech Republic**

On the basis of the updated version of the Action Plan for Building Capacities for the Effective Implementation of the Cartagena Protocol on Biosafety adopted during COP/MOP 3 (Decision BS-III/3) the Czech Republic contributes to its implementation through the following activities:

Integration of biosafety issues into national broader strategies and programmes, such as Strategy for Sustainable Development, State Environmental Policy, State Programme on Nature Conservation and Landscape Protection, Strategy on Biodiversity Conservation, Food Safety Strategy (ad 7+8 of Action Plan).

Mobilizing funding (mainly Government funding) and coordination between different sectors in line with completed UNEP/GEF Project on Biosafety Implementation (within Project co-financing of activities) (ad 10a of Action Plan).

Providing allocation for biosafety capacity-building activities through responsible national bodies and corresponding programmes (ad 10c of Action Plan).

Instruction meeting with applicants on request procedure regarding the use of genetically modified organisms. (Organized once a year, on the basis of experience and problems met during the preceding year.) (Ad 11b of Action Plan.)

Training of inspection personnel on selected topical issues. (Organized once a year within the Czech Environmental Inspectorate.) (Ad 11b of Action Plan.)

Training of experts on topical biosafety issues (in line with international development). (Ad 11b of Action Plan.)

Cooperation and experience sharing with CEE countries (e.g. Croatia as an EU candidate country) and new EU member states (especially Slovakia) in the National Biosafety Framework development. Participation of the Czech Republic in the Liaison Group on Capacity-Building for Biosafety and in Coordination Meetings for Government and Organizations Implementing or Funding Biosafety Capacity-Building Activities. (Ad 11d of Action Plan).

Publicizing experience through website of the Ministry of the Environment, BCH and issue focused publications (ad 12 of Action Plan and 18 – Coordination Mechanism).

Support of bilateral and multilateral activities through regular contribution of the Czech Republic to the GEF Trust Fund (since 1994 as the first CEE country). (Related to 8 and 15 of Action Plan.)

March 14, 2011

Milena Roudná, National UNEP/GEF Project Coordinator

**Workshops organized within the UNEP/GEF Project “Support for the Implementation of the National Biosafety Framework – Czech Republic”**

**2010**

**Use of Genetically Modified Organisms in the Czech Republic and Public Awareness.**

In cooperation with the Scientific-technical Society, Prague, January 28. Workshop on the occasion of the tenth anniversary of the adoption of the Cartagena Protocol on Biosafety and beginning of the 2010 International Year of Biodiversity.

**News from Genetic Modifications Field.** In cooperation with the Institute of Chemical Technology, Prague and Biotechnological Society, Prague, May 15.

Workshop for experts on scientific use of genetically modified organisms.

**New Technology and Biodiversity Conservation**

Within the Ministry of the Environment series of workshops organized on the occasion of the 2010 IYB, May 26, Prague

**Biotechnology in Forestry II.** Prague, June 2.

Workshop for forestry experts. Information on 2010 IYB and related international commitments.

**Genetic Resources – Biosafety Principals and Risks of Genetic Erosion**

In cooperation with the Technical-scientific Society, Prague, June 10.

Workshop for experts.

**International Year of Biodiversity – Related Projects and Programmes**

In cooperation with the Technical-scientific Society, Prague, November 2.

Workshop both for experts and a wider public.

**Genetically Modified Organisms and Biosafety Measures**

In cooperation with University and Centre for Agricultural Research, Olomouc, Northern Moravia, November 3. Workshop for experts and University students.

**Nature Diversity Conservation and Role of International Organizations**

Workshop for general public, November 26, Eastern Bohemia (local level)

**Nature Diversity Conservation and 2010 International year of Biodiversity**

Workshop for general public, November 27, Northern Bohemia (local level).

**UNEP/GEF Project – Final Workshop**

In cooperation with the Technical-scientific Society, Prague, November 30.

Workshop both for experts and a wider public.

**Czech Commission on the Use of Genetically Modified Organisms and Genetic Products – Open Meeting + Instruction Meeting for Applicants on Request**

In cooperation with the Institute of Chemical Technology, Prague, December 2.

Meeting open to wider public.

**Workshop on Food Safety**

Organized by the Centre for Environmental Education and Ethics, December 1, Trutnov, Eastern Bohemia.

Workshop for public.

**Questions about Genetic Modifications.**

Workshop organized by the Centre of Environmental Education and Ethics, December 13, Trutnov, Eastern Bohemia. Workshop for public.

**Questions about Genetic Modifications.**

Workshop organized by the Centre for Environmental Education and Ethics, December 14, Hradec Králové, Eastern Bohemia. Workshop for public.

**Workshops 2011**

**Possibilities of Genetic Modifications Use and Biosafety Measures.**

In cooperation with the Technical-scientific Society, Prague.

**Outcomes and Experience of the UNEP/GEF Project on Biosafety Implementation.**

In cooperation with Nature Conservation Union, local organization Eastern Bohemia.

**Outcomes of the COP/MOP 5 and Public Engagement.**

In cooperation with the Technical-scientific Society, Prague.

**Use of New Biotechnology in Trees Conservation.**

In cooperation with the Technical-scientific Society, Prague. (On the occasion of the International Year of Forests.)

**REPUBLIC OF MOLDOVA**

[31 MARCH 2011]

[SUBMISSION: ENGLISH]

**Republic of Moldova: Short Summary on Biosafety Capacity Building activities**

Republic of Moldova has finished successfully the UNEP/GEF project “ Support for Implementation of the National Biosafety Framework for Moldova” in 2010. The main outputs of the project are referred to the following:

The multiple outputs of the Project concerning the regulation, policy, guidelines materials, trainings and workshops, published and outreach materials, testing laboratory, etc. are in the broad use by the National Biosafety Committee, national biosafety authorities – Ministry of Environment, as well as sectorial

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central authorities as Ministry of Agriculture and Food Industry, Ministry of Healthcare, Ministry of Economy, Ministry of Education, Department of Custom Control.

#### **National Biosafety Action Plan.**

A broad number of various stakeholders were involved into the preparation work of the National Biosafety Action Plan for years 2009-2015, which promoted to the improvements in their professional capacities, and awareness related to the identification of gaps, needs and future steps to be undertaken from establishing of the national biosafety framework in Moldova. This document was largely consulted with governmental divisions, farmers, NGOs, academia, etc.

#### **National Biosafety Law and branch legislation.**

The Draft amendments to the National Biosafety Law related to the confidential information, monitoring, inspection and control, emergency cases, traceability, BCH etc, was prepared, consulted and submitted for approval. As the result, the amendment related to the licensing requirements to GMO uses was approved in 2007.

Draft amendments for branch legislation in the field of environmental protection are related to the Law on Environmental Protection, Law on Natural Protected Areas Fund, Law on Vegetation, Law on Wildlife, Law on Protection of Animals used for Experimental or Research Scopes. The mentioned Draft has been submitted to the Ministry of Environment and National Biosafety Committee and in the process of approval.

Draft amendment in the field of agriculture has been prepared and submitted to the Government and Parliament for approval. In 2008 it has been approved by the Government Decision and passed through the first reading in the Parliament.

#### **GMO Testing Laboratory**

The 7300 real-time PCR-machine have been procured from ABI Intl. (Agrobiotech) Company. Additionally, laboratory reagent kits and markers for maize and soy bean necessary to detect GMOs, were purchased. The laboratory on Seed Certification within the Center of Seed Control and Certification of the Ministry of Agriculture and Food Ministry was reinforced with this equipment and materials in order to strengthen capacities for GMOs seed testing and other agricultural planting materials. To be mentioned that this laboratory passed the National Accreditation to the ISO 17025 and is in the process of upgrading the methodologies related to GMO testing.

The joint Biosafety laboratory within the State University and Academic University of Moldova is available to provide GMO testing for fruit and vegetables, at the moment for a certain number of samples. Using the capacities of this laboratory, in common with the Ecological Inspectorate and National Biosafety Committee, a number of GMO tests of vegetables were performed in 2008-2010.

Manual on Methodological Aspects in Testing of GM Plants in the national language was prepared and published in 2008 (1000 copies). It includes modern methods and techniques, testing protocols along with the theoretical chapters regarding the modern biotechnology and genetics, and Moldovan experience in research and development in molecular biology, genetics, biotechnology and laboratory testing.

Manual on Techniques and Requirements in Biological Safety involving requirements for biosecurity in laboratory, was published in 2008 (500 copies) and is available for laboratory managers and operating personnel in the laboratories for GMO detection, as well as the laboratories of the Institute of Genetics, Institute of Botany, Institute of Microbiology, Institute of Zoology, Institute of Plants Protection and Ecological Agriculture, Research Institute of Agrotechnology and many others.

### **Handling of requests**

The Technical Committees on Biosafety within the ministries and Academy of Sciences were established with the advisory functions to the National Biosafety Committee and participate in the Risk Assessment review of notifications in the specific fields of activities, such as contained use, or effects on environment, effects on the healthcare and agriculture.

The Capacities of National Biosafety Committee were strengthened with special manual prepared and described the track of procedural steps of the notifications examination, risk assessment procedures, consultation with public and final decision-making. In the same context, national BCH website has been regularly updated and also provides new templates on GMO Register, biosafety databases, Register of interested public and NGO as well as network of national laboratories and research institutions, are available and provides the advisory support to the national Biosafety Committee and National biosafety authorities.

During the project implementation, biosafety databases were created and established via BCH website. These include institutional setting-up, national authorities and decision-making bodies, Biosafety National Focal points, biosafety and branch regulations, research institutions and testing laboratories, GMO Register, Roster of RA experts, Register of interested public and NGOs, research laboratories, templates for decisions on contained use, deliberate release, food, feed and processing (article 11), transboundary movement, books and publications.

### **Risk Assessment**

The National Biosafety Committee, as well as the involved related research institutions and academia have benefited from the project activities to develop their ability to provide GMO-related risk assessment procedures. For this scope, two regulations have been elaborated, including on study realization of risk assessment on environment and monitoring plan elaboration (for experts), and guidelines on risk assessment on human health, biodiversity and environment, provoked by the GMO deliberate release in environment and placing to the market. The regulations were approved and available.

Check-list for RA has been prepared and available and provides the guidance to the members of National Biosafety Committee for requesting information on RA during examination of notifications.

A five-day Training Workshop has been organized on Risk Assessment and Risk Management with the invited external expert and broad participation of experts, authorities, teachers, students, etc. with the scope to familiarize the stakeholders with modern requirements, procedures, experience of Russia and other countries to provide RA, research data, available international links and resources on these issues. The training was organized on the base of the Ministry of Environment, Institute of Genetics, State University of Moldova and State Agricultural University.

### **Monitoring and enforcement**

Technical guidelines in monitoring, inspection and control which clarify the roles and responsibilities of branch inspection bodies drafted and submitted to the ministry of Environment and Ministry of Agriculture for approval. Technical Instruction on application of Annex Nr.52 "Monitoring Plan" to the Governmental Decision Nr.1153 approved and available. Regulation on packaging, labeling, stocking and transportation of GMOs and transit drafted. Regulation on traceability and labeling of GMOs and traceability of food and feed for animals obtained from GMOs drafted.

### **Import/export, transit and Custom Control**

The following Regulations have been drafted, consulted and submitted for approval:

Regulation on activities authorization connected with the obtaining, testing, using and commercialization of GMOs Nr. 1153 of 25.09.2003 has been amended with the provision to introduce in Custom

Declaration information whether the imported product/seeds, etc. is GMO or not (approved); Regulation concerning the procedure of control of GMOs import, export and transportation; Regulation on transboundary movement and application of customs procedures in the field of import, export, transit of GMOs at the boundary checkpoints; Regulation on transboundary transportation of GMOs and Regulation on packaging, labeling, stacking and transportation of GMOs, as well as their transit.

### **Public Awareness, Education and Participation**

To ensure public involvement in participation during the decision-making process, the National Biosafety Committee and Ministry of Environment developed their capacities in this regard.

The mechanism of public information, education and participation has been established through the regulatory documents: Regulation on information and public participation in decision-making concerning the authorization of activities related to GMOs (approved By the Decision Nr.36 of 10.09.2009). This mechanism envisages the responsibility of the Government and Biosafety Committee to provide information to the interested public during the examination of notification process; it stipulates the list of interested public groups, namely: NGOs, associations of consumers, mass-media, scientific community, academy, farmers, etc.

A number of 20 workshops and trainings have been organized with the involvement of interested public in Chisinau and other localities in Moldova and provided awareness and training on how to proceed with public consultation and information exchange with governmental officials, public, scientists, etc.

BCH website involves the register of interested public and templates for obtaining the feedback from the public, which give opportunities to National Biosafety Committee to take into consideration the public's reaction during the decision-making. The website also gives new information regarding biosafety in the country, databases related to administrative setting up, legal procedures for notification and authorization, as well as regulations in progress.

Educational institutions, university teachers and students engaged in molecular biology, genetics, agro-biology were provided with educational curricula on GMO and biosafety course, genetics and plants trans-genesis, agricultural biotechnology and biosafety. The manuals and teaching books and laboratory guidelines have been written and published with the support of the project and transmitted to the libraries, university faculties and chairs, and especially, to the State University of Moldova, State Agrarian University, Trans-Dniestrian State University. The school and lyceum teachers and students were engaged in large debates on the topic of the GMO use and biosafety, and published books and brochures have been disseminated to the participants and transmitted to school libraries. For example, such events have been organized at the Lyceum of the Academy of Sciences, "Prometeu" academic lyceum, "Mircea Eliade" lyceum et al.

Number of NGO has been involved in the process of establishing the national mechanism of public awareness and public participation in decision-making process. To be mentioned that Ecotiras, Ecospectrum, field branches of Ecological Movement of Moldova, REC-Moldova, Gutta, Terra Nostra, Ecochimie and others contributed a lot to provide public awareness and information via the seminars, workshops, round table, TV discussions, newspapers, articles, field visits and direct discussions with farmers, agricultural workers, local authorities, teachers, local NGOs, medical personnel, consumers. The National Register of NGO and interested public was elaborated and is available via BCH-website and serves for information of public and feedback with their opinion related to the GMO decision-making.

Mass-media were broadly involved in trainings and workshops. A number of TV, radio and press-conferences, round-table sessions were organized. Interviews and open discussions with specialists and project team and consultants have been held at “Publika TV”, “NIT”, “Jurnal TV”, “Moldova 1” TV channels, “Natura” magazine, “Kishinev News” weekly newspaper, etc.

### **Publications**

A number of 13 books, manuals, brochures, reporting materials, outreach materials were published and broadly disseminated. These publications serve for broad information and education of interested public as well as provide the specific information regarding the fundamental knowledge on modern biotechnology and biosafety, technical manuals on GMOs testing and identification, techniques for the laboratory biosecurity, risk assessment guidelines, regulatory and institutional framework on biosafety, public information and participation in decision-making, etc.

### **BCH Phase II project.**

Moldova is eligible to participate at the global BCH –II project starting 2011. The main activities will be focused to training of local personnel to ensure the new rules and procedures for the BCH system and transition of national information to the Central BCH Portal.

**PIF/PPG Proposal for the new Biosafety Project on Capacity building** is in the stage of preparation.

## SUBMISSIONS FROM ORGANIZATIONS

**FOOD AND AGRICULTURE ORGANIZATION OF  
THE UNITED NATIONS**

[01 APRIL 2011]  
[SUBMISSION: ENGLISH]

### **DEVELOPING BIOSAFETY CAPACITIES: EXPERIENCE OF THE FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS**

#### **FAO Corporate Strategy**

Capacity development is at the heart of the FAO's mandate, aiming at enhancing long-term food and livelihood security through sustainable and environment-friendly increases in the quantity and quality of agricultural produce. Capacity Development that has traditionally been associated with knowledge transfer and training of individuals, yet is seen as a complex, non-linear and long-term change process “whereby people, organizations and society as a whole unleash, strengthen, create, adapt and maintain capacity over time”<sup>2</sup> across the three interlinked individual, organizational, and enabling environment dimensions. These principles are embedded in the new FAO Corporate Strategy on Capacity Development, in which, in conformity with other UN agencies, FAO adopted the term ‘capacity development’, instead of ‘capacity-building’ to reflect the evolution from the original concept of an essentially externally-driven process in which there were no pre-existing capacities, to a new concept that places strong emphasis on national ownership and on endogenous change processes.

#### **FAO and Biosafety**

FAO has been addressing biosafety and related aspects since the late 1990s, before the Cartagena Protocol came into force. As the subject has evolved, many environment, trade and food related aspects of biosafety and its impact on agriculture have been considered by FAO's intergovernmental bodies, including its Committee on Agriculture (COAG), regional conferences, the Commission on Genetic Resources for Food and Agriculture (CGRFA), as well as the Secretariat of the International Treaty on Plant Genetic Resources (ITPGRFA). Through its Interdepartmental Working Group on Biosafety, FAO promotes its corporate strategy on biosafety and regularly participates in the Conference of the Parties serving as the Meeting of the Parties to the Cartagena Protocol on Biosafety and working groups on biotechnology, risk assessment, capacity development and communication.

Capacity development is the main challenge in the implementation of the related biosafety frameworks in the developing countries and in countries with transition economies. Together with other UN agencies and relevant stakeholders, and in line with Article 22 of the Cartagena Protocol on Biosafety, FAO has carried out numerous capacity development initiatives in biosafety as it relates to food and agriculture. Since 2002, FAO has launched a series of projects to assist countries and regions in developing strong technical, institutional and information sharing capacities to ensure the safe use of modern biotechnologies and enhance sustainable agriculture and food production.

#### **Biosafety capacity development projects**

To date, the total funding of biosafety capacity development projects at national, subregional and regional, inerrregional and global level amounts to approximately USD 7.5 million, covering more than 80 countries in all regions.

Eighteen projects have a **national** focus, and aim at supporting countries in meeting the obligations arising from the Cartagena Protocol on Biosafety as well as establishing effective linkages among all relevant stakeholders. Capacity development activities include elaborating and implementing regulations,

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<sup>2</sup> Source: OECD/DAC

training personnel of regulatory bodies in risk assessment and detection of GMOs, upgrading infrastructure and improving communication, public awareness and participation in biosafety decision-making. Four projects are carried out at **subregional** level, and assist countries by establishing biosafety networks, delivering issue-specific training (GMO detection and GM food safety assessment, etc.) and organizing technical meetings for subregional harmonization of rules and regulations. Furthermore, within an **interregional** project, training in various aspects of biosafety is provided to Eastern Europe and Central Asia. A series of workshops were also carried out in the Caribbean, Central and Eastern Europe, Central Asia, the Near East and Latin America on topics ranging from the establishment of a common biosafety policy to more specific technical and managerial issues, such as risk analysis and appropriate communication approaches. Two **global** projects consist of training programmes targeting the enhancement of specific technical capacities in: GMO detection and monitoring; and GM food safety assessment.

FAO has also taken the lead in expanding the knowledge base in areas such as public communication, post-release monitoring, socio-economic issues and consumer concerns arising from the use of modern biotechnology through expert workshops, consultations and technical publications. All these activities are being carried out in full partnership with national agencies, international agricultural research centres, donors, other UNUN bodies and civil society organizations.

### **FAO training programme**

All FAO biosafety capacity development projects revolve around a common axis: the training programme. Training touches on biosafety aspects of relevance to agricultural biotechnology, and is shaped to meet specific capacity development demands. Based on countries' requests for assistance, national projects may also include other components on: policy development and formulation; regulatory aspects; GMO detection and monitoring; and, communication, participation and public awareness. Each project has a training component that consists of delivery of training courses on agricultural biosafety and supporting training materials.

A typical training programme is composed of the following modules, encompassing both lectures and exercises designed to integrate competencies of the different actors involved:

□ Agricultural biotechnology, which reviews basic scientific techniques employed in producing GMOs and emphasizing on: basic concepts of biotechnology; genes: structure and function; promoters, vectors and transformation cassettes; plant transformation and selection techniques; biotechnology for the improvement of animal breeding; genetic engineering of micro-organisms of interest to agriculture; and, detection methods for GMOs. It also provides a brief description of current and emerging uses of biotechnology in crops, livestock and fisheries in order to enhance the understanding of the technologies and ways in which they complement and extend other approaches. *These concepts and principles are critical in ensuring pro-active participation to the process of reviewing dossiers and taking part in decision-making.*

□ Ecological aspects, which provide the necessary background information on ecology and evolution needed to analyse and understand the consequences of introducing GMOs into the environment, and to show that many areas in ecology can benefit from research tools based on applications of molecular genetics and biotechnology. These tools include investigations into population biology and evolution, and conservation and use of genetic resources for both human requirements and environmental protection.

□ Risk analysis, which raises awareness on biological risks, concepts, principles, and methodologies of risk assessment, risk management and risk communication. It focuses on crop biotechnology and environmental risk assessment of GM crops since these are of immediate interest to most countries.

□ GMO monitoring, which addresses use and monitoring of GMOs under containment, confinement and limited field trials, as well as post-release monitoring of GMOs. It also covers surveillance and emergency planning.

□ Legal aspects, which provide an overview of the existing legal tools and frameworks on biotechnology and biosafety, and offer a thorough description of the international regulatory instruments. It also includes considerations of legal relevance for drafting and implementing national biosafety frameworks.

FAO's training courses follow a specific policy: whenever possible, *experts from developing countries or countries with economies in transition are employed as trainers* through a special Organisation's programme. Under the direct coordination and supervision of the FAO project manager, the experts are responsible for preparing and revising lectures and training materials of each training session, in line with the specific needs of the recipient country.

In line with the broader UN development cooperation objectives, special attention has also been devoted to *ensuring gender balance* within each training workshop and in other project activities.

### **Experience gained and the way forward**

An in-depth monitoring of the FAO capacity development activities in biosafety, resulting from the first round of projects developed and implemented by FAO since 2002 on the basis of in-house review reports, studies, issues emerging from the national /regional project steering committees as well as external inputs.<sup>3</sup> Below some of the main conclusions are presented.

- FAO possess an explicit comparative advantage on technical issues in food and agriculture with relevance to biosafety and most of the products of modern biotechnology of today are in use in the agricultural sector. Moreover, the Organisation complements other agencies' work in: providing specialized scientific and technical training and assistance in many emerging areas as new biotechnologies, nanotechnologies and new applications in aquatic organisms, insects etc.; and providing appropriate information material, development of best management practices in GM and non-GM seed production, especially for use by the national seed production agencies.
- With an eye towards the future, FAO will not only make use of its technical in-house expertise to meet capacity development needs; the Organization intends to enhance its role of exchange node to activate and coordinate existing networks of technical expertise.
- FAO only provides capacity development support upon request from Member Governments. These needs depend on country specific conditions and countries are encouraged to identify their own needs, priorities and development objectives. Thus, biosafety mainstreaming into national development plans and involvement of relevant stakeholders at national level are crucial to the success of any assistance intervention. Currently, at a stage when many countries are moving from drafting to implementing their biosafety frameworks, FAO responds to an increasing number of requests for intensifying efforts and focusing on aspects related to risk analysis (risk assessment, management and communication), GMO detection and post-release monitoring, as well as communication and socio-economic considerations. Specific training tools have been fine-tuned and are in use.
- National biosafety capacity development needs are increasingly linked to the regional dimension because of shared environmental, human health, animal health and socio-economic issues, as well as political realities. FAO intends to play a leading role in clarifying, elaborating and communicating the scientific basis for regional approaches (both among and within countries) towards biosafety risk analysis.
- Despite being an active partner of the Biosafety Capacity Building Coordination Mechanism, information on FAO's biosafety activities was fragmented and insufficiently disseminated. The Organization intends to pay more attention to outreach activities and information at different operational levels. This is also necessary to highlight achievements and progress of actions, as well as enhance opportunities for synergies and collaboration among different initiatives.
- FAO is progressively strengthening its collaboration with the GEF based on its comparative advantages. FAO has mainly relied on its own financial resources to fund biosafety capacity development activities. Other funding sources will be approached, including GEF, and partnering with other agencies<sup>4</sup> further enhanced.

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<sup>3</sup> "Building biosafety capacities: FAO's experience and outlook", FAO, Rome 2009  
<http://www.fao.org/docrep/012/i1033e/i1033e00.htm>

<sup>4</sup> To date, FAO is engaging in long-term alliances for the benefit of agriculture and the environment with UNDP, the World Bank (WB), the United Nations Development Programme (UNDP), Convention on Biological Diversity (CBD), Asian Development Bank (ADB), as well as with other stakeholders, including NGOs.

- The FAO policy to contract preferably experts from developing and transition economies' countries as trainers has proved to be very effective in South-South Cooperation, expanding biosafety networks among these countries, and better serving the biosafety technical assistance needs in complex and fragile social, economic and environmental contexts. The biosafety activities will continue to follow this approach.
- The FAO Agricultural Biosafety Compendium will serve as reference material for future capacity building activities and will represent the basis for further local training, thus improving sustainability of project results. It will be made available to countries upon request and will be placed on the Web site for easy access and downloading. If possible, the training package will be translated into the official UN languages to ensure accessibility and wide divulgation.

**INTERNATIONAL FOOD POLICY RESEARCH  
INSTITUTE**

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### **The Program for Biosafety Systems (PBS)**

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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 (Nigeria, Kenya, Uganda, Malawi, Mozambique) and Asia (the Philippines, Indonesia, Vietnam) 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<sup>5</sup> 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

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<sup>5</sup>: COMESA: Common Market for East and Southern Africa



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.

### **PBS's main achievements**

Examples of recent 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 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 and adoption of detailed implementing regulations.

(b) Policy consultations at the national, regional and international level are informed by IFPRI-led PBS policy analysis and publications on emerging issues (e.g., socioeconomic assessments, labeling, liability and redress) related to biosafety implementation. This growing body of literature is available through policy briefs and discussion papers posted on the PBS website: <http://programs.ifpri.org/pbs/pbspubs.asp>. In collaboration with RAEIN-Africa and the University of Pretoria, in March 2010 PBS co-organized a training program on socioeconomic assessment of GMOs for SADC countries. This was followed by a well attended side event during COP10-MOP5 on socioeconomics, jointly organized with RAEIN-Africa.

(c) 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 and farm-level impacts of planting GM crops for selected countries in East and Southern Africa. Based on the outcomes of the study, the COMESA Secretariat drafted a set of guiding principles on regional trade flows of GM commodities, which were elaborated by a team of regional experts in a follow-up phase of the initiative. In 2009 and 2010, COMESA member countries reviewed draft regional guidelines and policies regarding GMO releases and trade, which are currently being reviewed through a series of national consultations.

(d) *National biosafety framework implementation:* 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 such as the Cartagena Protocol. In recent years, technical support was provided to the government of Kenya's review and finalization of a proposed Biosafety Bill, in partnership with the National Council for Science and Technology. Kenya's bill was initially developed with UNEP-GEF support, and eventually signed into law in early 2009. Similar support is provided to Uganda, in collaboration with the Uganda National Council for Science and Technology, where a proposed biosafety bill is under consideration by government. In Nigeria, where a draft bill has been under development

since 2006, PBS established collaboration with the National Biotechnology Development Authority and co-organized a public hearing in December 2009 regarding the proposed biosafety bill. Following adoption by the country's National Assembly, Nigeria's proposed biosafety bill is currently under review by the Senate.

(e) *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 projects (see for details: <http://www.ifpri.org/pbs/pdf/bbipprojects.pdf>) have been awarded and completed, with scientific leadership by developing-country research institutes. A growing number of outputs from BBI projects are available as peer-reviewed publications.

(f) *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. ICS materials are available in English, French and Portuguese.

(g) In collaboration 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, bacterial wilt-resistant banana, virus-resistant cassava, nutrition-enhanced banana, and Bt cotton. Using the ICS handbooks as a starting point, Malawi's NBRC recently adopted detailed SOPs for planned field trials for Bt cotton. The ICS is also adopted for sound field trial management in countries such as Nigeria (Bt cowpea, nutrition-enhanced cassava) and Vietnam (Bt maize).

(h) *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; 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. Knowledge gained in insect-resistance management (IRM) schemes is currently applied in developing IRM guidelines for the planned introduction of insect-resistant eggplant.

**INTER-AMERICAN INSTITUTE FOR  
COOPERATION ON AGRICULTURE**

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**Biotechnology and Biosafety**

**Hemispheric Program on Biotechnology and Biosafety**

**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, promote and coordinate opportunities for the execution of activities between all interested parties, in order to promote efficient information sharing, capacity building and consulting in public policy development and

**Regional Needs**

- Promotion safe trade in agricultural biotech products
- Assistance to member countries in developing policies for the development of biotechnology and biosafety
- Exchange of information technical information on Biotech
- Capacity building on technical apolitical aspects of biosafety
- Upon request, needs assessment and development of regional strategies

**Public Awareness**

**ACTIVITIES**

- Workshops on Risk communication for the Andean Region (Ecuador, Bolivia).
- Technical publications on LLP (Croplife), Coexistence (IICA) and Risk analysis on FFP (UNL).
- Broadcast of ISAAA report 2010

**OBJECTIVE**

- Provide transparent and objective information about the benefits and risks of agricultural biotechnology to support decision-making on biosafety in the region

**CapacityBuilding**

**ACTIVITIES**

- Continuing education program on biosafety (partnership with ICGEB)

- Pilot course in Bolivia and Ecuador (Risk Assessment)

#### OBJECTIVE

- Support countries in the development of scientific and technological innovation in biotechnology and Biosafety.

#### **National Policy**

#### ACTIVITIES

- Survey of Biosafety legislation in Central America (IICA, ISU)
- Support to UNEP-GEF Projects for Salvador, Costa Rica, Guatemala and the Caribbean Region.
- LLP Forum

#### OBJECTIVE

- Support the analysis and dissemination of policy formulation and regulatory frameworks in Biotechnology and Biosafety to facilitate harmonization in the region.

#### **International Policy**

#### ACTIVITIES

- Training workshop on socio-economic considerations in the field of PCB for the Group of Latin America and the Caribbean (GRULAC) (USDA)

#### OBJECTIVE

- Promote discussion of international standards and regulations on agro-biotechnology and biosafety to facilitate its implementation in member states.

#### **Cooperation Agreements**

- CROPLIFE
- BIO (Biotechnology IndustriaOrganization)
- USDA
- University of Nebraska
- Iowa State University
- CINVESTAV

#### **Strategic Partners**

- International Center for Genetic Engineering and Biotechnology (ICGEB)
- FAO

- CGIAR
- International life Science Institute (ILSI)
- Cartagena Protocol
- International Grain Trade Council (IGTC)
- US Grain Council
- USAID
- AgriCanada
- NABI
- GT5
- CARICOM
- Banco Mundial (UNEP GEF)
- Codex Committee on Methods of Analysis and Sampling (CCMAS)

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