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COORDINATION MEETING FOR GOVERNMENTS AND ORGANIZATIONS IMPLEMENTING OR FUNDING BIOSAFETY CAPACITY-BUILDING ACTIVITIES
Montreal, Canada
26 to 27 January 2005
Agenda item 3.2 of the provisional agenda *

A COMPILATION OF THE EXISTING BIOSAFETY CAPACITY-BUILDING INITIATIVES

Note by the Executive Secretary

1. INTRODUCTION

1. The Executive Secretary is pleased to circulate herewith, for the information of participants, a compilation of information on existing biosafety capacity-building initiatives based on the submissions made to the Executive Secretary by governments and relevant organizations prior to the present meeting and on the information registered in the capacity-building databases in the Biosafety Clearing-House.

2. Section 2 includes a compilation of the submissions that were received from the following governments and organizations: Zambian Government, German Federal Ministry for Economic Cooperation and Development (BMZ), Swedish International Development Cooperating Agency (Sida), Food and Agriculture Organization (FAO), United Nations Environment Programme (UNEP), United Nations industry and development organization (UNIDO), The World Bank, International Food Policy Research Institute (IFPRI), International Centre for Genetic Engineering and Biotechnology (ICGEB) and the Norwegian Institute of Gene Ecology (GenØk).

3. Section 3 includes summary descriptions of the on-going biosafety capacity-building projects and other initiatives that were registered in the projects database in the Biosafety Clearing-House as of 31 December 2004.

4. The note also provides, in Annex 1, a table showing all the ongoing biosafety capacity-building projects registered in the Biosafety Clearing-House and the elements of the capacity-building Action Plan to which they are contributing.

* UNEP/CBD/BS/CM-CB/1/1

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5. Finally, the note provides in Annex 2 a summary of the objectives, main activities and the scope (in terms of funding levels, timeframe and geographic coverage) of the major ongoing biosafety capacity-building initiatives.

2. COMPILATION OF THE SUBMISSIONS RECEIVED FROM GOVERNMENTS AND RELEVANT ORGANANISATIONS

SUBMISSIONS FROM GOVERNMENTS/*

ZAMBIA

[3 January 2005]
[SUBMISSION: ENGLISH]

Project: Norwegian Assistance to Build Capacity for the Implementation of the National Biotechnology and Biosafety Policy and the Cartagena Protocol on Biosafety in Zambia

1.0 Introduction

The Zambian Government has adopted the National Biotechnology and Biosafety Policy and has ratified the Cartagena Protocol on Biosafety. To this effect an appropriate legislation to establish a national biosafety regulatory mechanism be enacted in the coarse of the year.

The Royal Norwegian Government is assisting the Zambia with a project "Assistance to Build Capacity for the Implementation of the National Biotechnology and Biosafety Policy and the Cartagena Protocol on Biosafety". The Department of Science and Technology of the Ministry of Science, Technology and Vocational Training as well as the National Institute for Scientific and Industrial Research are implementing the project. It is a two year project.

2.0 Goal

The goal of the project is operationalised the National Biotechnology and Biosafety Policy and to implement the Cartagena Protocol on Biosafety.

3.0 Purpose

Component 1

The Biosafety bill has been passed by the Parliament and subsequently signed by the President

Component 2

The National Institute for Scientific and Industrial Research (NISIR) is in a position to perform its function as National Biosafety Focal Point in accordance with provisions of the Cartagena Protocol on Biosafety.

Outputs – Component 1

The three main outputs under this component are:

Output 1: The Bill on Biotechnology and Bio-safety has been developed and submitted to the Ministry of Legal Affairs

Output 2: The general public has been consulted on the regulatory framework; and

*/ All the submissions except those from Paraguay and Switzerland were originally made for the purpose of the third meeting of the Intergovernmental Committee for the Cartagena Protocol on Biosafety.

Output 3: A National Biosafety Authority has been formed and operationalised.

Outputs – Component 2

The seven main Outputs under this component are:

Output 1: The NISIR is in a position to carry out its responsibilities as Project Manager;
Output 2: Public knowledge on biotechnology and biosafety has been enhanced;
Output 3: Required facilities and infrastructure have been established;
Output4: Adequate and appropriate human resources in biotechnology and biosafety have been established and are in operation;
Output 5: NISIR has the capacity and facilities to detect GMOs
Output 6: A national Bio-technology and Biosafety information system (National Biosafety Clearing House) has been developed and is operational)
Output 7: Regional cooperation within the SADC region has been established

Regional Collaboration

The there is need for regional collaboration in the following areas:

- Training of scientists and technicians in biotechnology and biosafety;
- Harmonizing the management of biosafety information;
- Harmonizing procedures for monitoring Genetically Modified Organisms and
- Developing common procedures for assessing socio-economic factors in risk assessment.

GERMANY [28 December 2004]
[SUBMISSION: ENGLISH]

German Biosafety Capacity Building Initiative

Following the adoption of the Cartagena Protocol on Biosafety in 2000, BMZ and GTZ designed an initiative on "Capacity-Building for the Implementation of the Protocol on Biosafety". This initiative aims at providing effective support to developing countries in establishing the necessary environment for implementing the CPB at the national level, thus enabling the countries to guarantee their own national biological safety and avoid negative impacts of transnational transport and use of products of modern biotechnology on man and the environment. The main elements of the initiative are policy advice; institution building; basic and further training of decision makers, experts and multipliers; and public awareness raising, education and promotion of public participation. The first projects started in 2003. Further applications are currently being studied

Until 2004, the German Biosafety Capacity Building Initiative has supported biosafety projects in the African Union, China and Algeria. Briefs about those projects are provided below:

Project: Biosafety Capacity Building Programme in the African Union

The "Biosafety Capacity Building Programme of the African Union", funded by the German Federal Ministry for Economic Cooperation and Development (BMZ) under the German Biosafety Capacity Building Initiative, aims to put into practice its own ambition of supporting the harmonization and implementation of legal frameworks in Africa and more assertive external representation of its member states. Secondly it seeks to assist its member states in setting up national regulatory systems on the safe use, handling and transmission of GMOs.

The project is an element of the initiative taken by a large group of developing countries as part of the Rio (Earth Summit) follow-up process. They view strong environmental legislation as the foundation for any sustainable economic development.

The project is supported by the "Deutsche Gesellschaft für Technische Zusammenarbeit" (GTZ) on behalf of BMZ. It is facilitating the establishment of an AU office for biosafety. Furthermore it is developing the competences of the AU to make services available on matters of biosafety, as well as its capacities to support its member states in lobbying for African interests in international policy areas, including: assistance in formulation of national biosafety laws; training in risk assessment and risk management; development of technical papers, handbooks and information kits; and establishment of an analytical pilot laboratory in Africa for GMOs and strengthening, in a second phase, of existing national institutions..

Civil Society Participation in Algeria's Biosafety Process (2003-2005)

The German Federal Ministry for Economic Cooperation and Development (BMZ) commissioned GTZ in February 2003 to implement above-named project, in cooperation with the Algerian NGO AREA-ED (Association de Réflexion, d´Echanges et tions pour l´Environnement et le Développement), is to improve the information work in the field of biosafety, and boost the influence of civil society on the development of a national biosafety system in Algeria. AREA-ED is a member of the international NGO desertification network (RIOD) and operates as the Head Office of this network for North Africa.

Within the scope of a two-year project, an internet-based documentation system comprising all relevant information is being set up, as is a national information network. National and regional seminars are being held for multipliers and decision-makers, and strategies developed to improve lobby work in the field of shaping the national framework for biosafety. AREA-ED is to participate in international conferences on biosafety in order to gain more experience and establish contacts, and to present the project and its results.

Project tasks include the following:

a) Setting up an Information Network: Various activities and media are to be used to establish a network of NGOs, and thus strengthen the position of civil society groups.

b) Information Work: Different instruments and media are to be used to disseminate the opinions of non-governmental actors and launch a dialogue with decision-makers at national and international level. With the help of the AREA-ED experts and other staff members of the AREA-ED documentation centre, information on biotechnology and biosafety are also to be made available to interested members of the general public. Information material is to be produced in Arabic, and made available to a wide group of individuals.

c) Capacity Building: AREA-ED experts and other staff members of the NGOs involved in the project will be up-graded in the field of biosafety, with special emphasis on risk analysis and management, the precautionary approach and liability issues.

Biosafety Capacity-Building Project in China: Data Management, Promoting Expertise and Awareness Raising

The objective of the project is to support the Nanjing Institute for Environmental Sciences (NIES) in its efforts to inform decision-makers on biosafety and to develop mechanisms for PR work, so that the relevant political actors can incorporate national and international expertise and interested members of the general public in decisions pertaining to the management of genetically modified organisms.

It main components include:

a) Data Gathering and Information Management: A database makes high-quality data on biotechnology and biosafety available to both political decision-makers and interested members of the general public.
b) Capacity Building: Politicians, civil servants and academics working in the field of biotechnology and biosafety are enabled to analyze and assess the risks of modern biotechnology through publications and workshops.
c) Public relations (PR) Work: A strategy is to be developed for involving the general public in biosafety-related decisions.

SWEDEN

[11 January 2005]
[SUBMISSION: ENGLISH]

Swedish International Development Cooperating Agency's support to capacity-buildings programmes/projects in the field of Biotechnology

Sweden has, through its development agency Sida (Swedish International Development Cooperating Agency), initiated a number of projects aiming at enhancing the capacity of developing countries to handle modern biotechnology, particularly in southern and eastern Africa. We believe that capacity building is more than only increasing the capacities of governments and authorities. Capacity building is also about elevating the awareness and participation of the public through education, research and information in the field of modern biotechnology, biosafety and biotechnology policy. Below follows a list of programme/ projects supported by Sida.

1. East African Regional Programme and Research Network for Biotechnology, Biosafety and biotechnology policy Development (BIO-EARN) has been in operation since 1999 and aims at building capacity in Ethiopia, Kenya, Tanzania and Uganda). The BIO-EARN Programme has three main objectives:

- Building biotechnology, biosafety and biotechnology policy capacity
- Facilitating regional collaboration
- Stimulating the dialogue between policy makers and scientists

The Biotechnology Advisory Centre (BAC), an integrated part of the Stockholm Environment Institute (SEI) is responsible for the overall management of the programme. The major goal is to develop an East African R&D platform and infrastructure that can in the long run contribute to improved livelihoods, alleviation of poverty and improved environment. Below follows a short description of major Programme outputs and its development impact

Biotechnology Capacity Building

- *The BIO-EARN programme will produce at least 18 East African PhD students*

The development of highly educated and trained researcher that are able to adapt and develop the technologies of the ge revolution to country needs and opportunities will, potentially and in the long run, have a clear development impact in t region. The BIO-EARN PhD students have been trained in an interdisciplinary thinking and will be able to great contribute to R&D work supporting sustainable developments in the region.

All the BIO-EARN research projects are focused on East African needs and problems in the field of agriculture, environment and industrial biotechnology. It is too early to consider their impact.

- *The BIO-EARN programme has improved the ability of eleven East African R&D institutions to carry out advanced biotechnology R&D*

The BIO-EARN Programme has, through human capacity building1, infrastructure support2, policy and networking support been able to greatly strengthen eleven East African R&D institutions. As a result, these institutions are now more able to carry out advanced biotechnology R&D relevant to their own national needs. They are also much more able to engage in regional and international research collaboration, which will be increasingly important to ensure sustainability, quality and impact of future research efforts in the region. All the BIO-EARN research projects are focused on East African research problems.

Biosafety Capacity Building

➢ *The BIO-EARN Programme has greatly improved ecological risk assessment capacity in the region.*
Prior to the Programme, there was virtually no East African expertise available for biosafety risk assessment. The BIO-EARN MSc courses and PhD programme, involving three PhD students, have improved the ecological risk assessment capacity in the region significantly. A platform for sharing risk assessment data has also been developed. A common risk assessment/management decision support material3 is also under development enabling scientifically sound decisions whether or not approving future GM crops.

➢ *The BIO-EARN Programme has greatly improved biosafety regulatory implementation in the region*
Six regional biosafety workshops, involving more than 150 individuals have improved the ability of biosafety regulatory officials in committees and agencies involved to implement biosafety regulations and carry out biosafety assessment. These workshops have also enabled individuals from countries (Ethiopia and Tanzania) lacking biosafety regulatory structures to effectively participate in the development of national and institutional regulatory structures. The Programme has also contributed to improving exiting regulatory structures in Kenya, through a detailed implementation study. This study, together with a forthcoming Ugandan study will also benefit Tanzania and Ethiopia in their design of biosafety frameworks. A BIO-EARN Biosafety Resource Book, developed by the biosafety regulatory officials in the region will also facilitate implementation in the region. The resource book fills an important need in the region and will greatly facilitate the capacity building process and biosafety harmonization not only in East Africa, but hopefully also in other parts of the world. In short, the BIO-EARN resource book will;

- be a catalyst in initiating national training programs;
- be a very helpful research/teaching tool in national workshops;
- increase the self-sufficiency of developing country authorities and support their internal training efforts;
- assist and guide inexperienced regulatory authorities (and the NBC's) through their first decision making processes;
- Serve as platform for future biosafety information exchange.

The resource book was printed and distributed in February 2004

➢ *The BIO-EARN Programme has facilitated regional biosafety information sharing and harmonization of biosafety regulatory frameworks*
The workshops, seminars and common projects have developed a regional platform for biosafety information sharing. For example, the BIO-EARN capacity building activities have catalyzed of drafting biosafety guidelines in Ethiopia and Tanzania is beginning and action significantly. This process has also benefited from the information exchange within the network, making it possible to share the experiences

1 Apart from PhD students a large number of faculty staff at East African institutions has been trained.

2All East African institutions have received a significant infrastructure support. Procurement of equipment has improved infrastructure significantly at the various East African BIO-EARN research institutions. Procurement for roughly 12 MSEK worth of equipment roughly KSEK600 per institution) has been made since end of 1999.

3 Regional polled dispersal files/genes files making prediction of impact of various GM crops easier

of Uganda and Kenya. The above mentioned, BIO-EARN Biosafety Resource book, will also facilitate regional information sharing.

Biotechnology Policy Development/Awareness raising

- *The BIO-EARN Programme has created awareness among policy makers and scientists on key biotechnology issues.*

The programme has helped to expose policy makers and scientists to new policy areas not covered by traditional institutions of higher learning and on which information and guidance were lacking. Some of the conclusions and recommendations from the workshops and training course on biotechnology and public policy held in 1999, have been included in the biotechnology policy framework proposals in the region. Individuals and material from the BIO-EARN Programme have been heavily used in the policy making process in all four countries.

- *The BIO-EARN programme is supporting biotechnology product development and technology diffusion in the region*

The BIO-EARN Programme is assisting East African countries and BIO-EARN network institutions to develop biotechnology products for the market. This includes an institutional ability, to interact with private sector, NGOs or other actors involved in product development. Four county background studies and a synthesis study on ongoing product development partnerships in the region have been published. These studies together with the recommendations made on regional policy BIO-EARN seminar on product development in biotechnology4 will facilitate future biotechnology product development in the region.

- *The BIO-EARN Programme is building institutional capacity in intellectual property management*

The BIO-EARN Programme is assisting Network institutions to develop structures and policies for management of Intellectual Property. This will stimulate product development partnerships and more efficient product development in the region. It will also enable Eat African institutions to collaborate with attractive partners world wide facilitating the technology transfer process in the region.

Facilitating Regional Collaboration

- *The BIO-EARN programme has stimulated regional collaboration and sharing of knowledge and experiences.*

A large number of regional workshops and seminars and collaboration in the various research projects have greatly increased regional collaboration. For example, Ugandan policy makers have been assisting Tanzania in developing the proposal for policy framework for biosafety guideline drafting. The ability to share experiences and develop future collaborative projects has therefore strengthened the basis for scientific and policy collaboration in the region.

Stimulating the Dialogue between Policy Makers and Scientists

- *The BIO-EARN programme has stimulated the dialogue between policy makers and scientists in the region*

As a consequence of BIO-EARN programme activities, East African researchers have been encouraged to communicate with high-level policy makers. A number of national awareness meetings and site visits have facilitated the dialogue between policy makers and scientists on how to best use biotechnology R&D for country development purposes.

Potential opportunities for collaboration with other initiatives

4 The title of the workshop was "Bridging the gap between ideas and the market", and was held in Entebbe, Uganda, 12-14 November 2003.

The programme has been evaluated by two external evaluators in 2004. The evaluation report highlights some of its achievements, as well as point to some aspects to be considered for the future. The report advises on continued funding of continued efforts in building capacity for biotechnology and biosafety in the region. It advises on a careful consideration of some key aspects such as ownership and need to create synergy with national, regional and international initiatives in the region in the same and related fields (stock should be taken of new and emerging initiatives and opportunities for cooperation and synergies be discussed before a proposal is drafted).

Since Sida expects to be approached for considering continued financial support to the network (2006-2009) after the current financial commitment has ended (December2005), we would like to invite other donor to be involved in our continued discussions with BIO-EARN. Sida gives high priority to harmonization and coordination in Development cooperation as seen from the strategic priorities for the coming three-year period.

2. Bilateral Research Co-operation

Sida is also through bilateral projects strengthening technological and research capacities in various developing countries such as Bolivia, India, Nicaragua, Sri Lanka and Zimbabwe. These projects have generally aimed at increasing co-operation and exchange between scientific research institutes in Sweden and these countries, as well as resulted in *inter alias* the establishment of a an Institute for molecular biology and biotechnology in Sri Lanka.

3. Support to Non-governmental organizations

As mentioned above Sweden considers increased public awareness in the field of biosafety to be of great significance. Sida is therefore supporting a number of civil society organizations, particularly such organizations operating in the developing world. Below is a non-inclusive list over NGOs getting biosafety and genetic resources related support from Sweden:
I. The Swedish Society for Nature Conservation (SSNC) – North/South Programme,
II. GRAIN (Genetic Resources Action International). The support to consist of three projects: Harnessing Diversity, The Gaia-GRAIN project: supporting, biodiversity-related activities in Africa and beyond and The ISD/Gaia Biosafety project

III. Third World Network – Biosafety and Biodiversity Programme

IV. CBDC (Community Biodiversity Development and Conservation Programme)

V. There is also a core support to the CGIAR-institutes and ACTS (African Centre for Technology Studies) which are both involved in several biotechnology and biosafety projects.

On top of that, Sida is also supporting the publication and distribution of the journal" Biotechnology and Development Monitor" published by the University Van Amsterdam, the Netherlands.

SUBMISSIONS FROM ORGANISATIONS

FOOD AND AGRICULTURE ORGANIZATION (FAO) [18 January 2005]
[SUBMISSION: ENGLISH]

Biosafety capacity-building projects

Ongoing projects:

- TCP/BOL/2902 Fortalecimiento Institucional para la Gestión de la Seguridad de la Biotecnología
- TCP/GRN/2902 Strengthening the National Capacity in Biotechnology and Biosafety
- GCP /RAS/185/JPN Capacity Building in Biosafety of GM Crops in Asia
- TCP/PAR/3001 Apoyo a la formulación de una política nacional de biotecnología
- TCP/SWA/3003 Strengthening national capacities in formulation and implementation of legal instruments on genetically modified organisms (GMOs)
- TCP/KEN/3001 Capacity building of regulatory agencies for handling genetically modified crops, products and processed foods

Completed projects:

- TCP/MAL/2901 Capacity Building on Regulation of Import, Contained Use and Release of Genetically Modified Plants and Plant Material
- TCP/PAR/0166 (A)Fortalecimiento del Sistema Nacional de Bioseguridad

Fortalecimiento Institucional para la Gestion de la Seguridad de la Biotecnologia (TCP/BOL/2902)

País: Bolivia
Contribución de la FAO: $EE.UU. 248 000
Duración: 18 meses

Resumen del proyecto:

Si bien la biotecnología tiene potencial para mejorar las condiciones de producción de la agricultura reduciendo la utilización de insumos, la introducción de los OGM en el territorio boliviano por parte de instituciones de investigación y empresas, no conlleva solamente ventajas que pueden ser beneficiosas para el país, sino conlleva también posibles riesgos para la salud humana, el medio ambiente y la diversidad biológica, lo cual requiere el desarrollo de la capacidad nacional para la gestión de la seguridad de la biotecnología.

En 1998-1999, la Dirección General de Biodiversidad del Viceministerio de Medioambiente, Recursos Naturales y Desarrollo Forestal (VMARNDF) ha iniciado actividades (con el apoyo financiero del Fondo Mundial para el Medio Ambiente y el Programa de las Naciones Unidas para el Medio Ambiente) para establecer un "Marco Nacional de Bioseguridad": implementación del marco legal/institucional; funcionamiento del Comité Nacional de Bioseguridad; apoyo a la Red Boliviana de Biotecnología y elaboración de un Diagnóstico de la Biotecnología/Seguridad de la Biotecnología y de una Estrategia Nacional de Seguridad de la Biotecnología.

El objetivo general del presente proyecto es promover el uso seguro de la biotecnología en el sector agrícola para optimizar la producción agrícola, mejorar la seguridad alimentaria, reducir la pobreza, conservar la biodiversidad y manejando de manera sustentable los recursos naturales. Los objetivos específicos son: i) consolidar la institucionalidad del marco técnico/científico y legal para la gestión de la seguridad de la biotecnología en Bolivia, reforzando la capacidad técnica del CNB, y fortaleciendo a la Red Boliviana de Biotecnología y a la autoridad nacional competente, y; ii) difundir y socializar información para establecer una base social e institucional en relación a la evaluación y gestión de riesgos de los OGM resultantes de la biotecnología moderna.

El proyecto proporcionará los servicios de dos consultores internacionales, un especialista en biotecnología y bioseguridad (tres semanas) y un especialista en aspectos legales de bioseguridad (dos semanas), de siete consultores CTPD (duración total de seis meses) especialistas en biotecnología agrícola, en aspectos ecológicos, en aspectos legales, en riesgos biológicos y en análisis de riesgo.

También se contratan los servicios de dos consultores nacionales: un especialista en biotecnología y bioseguridad (diez meses) y un especialista en aspectos legales (dos meses). El proyecto proporcionará además los servicios de supervisión y de asesoría técnica del oficial de investigación agrícola (cinco semanas en tres misiones), del Oficial Jurídico (incluyendo una misión de una semana), del oficial regional de producción vegetal (incluyendo una misión de una semana) y del oficial regional de comunicación para el desarrollo (incluyendo una misión de una semana). El proyecto proporcionará los recursos para contratos y la realización de varios eventos de capacitación. También, el proyecto cubrirá la compra de equipos y materiales necesarios para la ejecución del proyecto y los viajes internos así como los gastos generales y directos de operación.

A finales del proyecto, se contará con los siguientes resultados: mejora el proceso de aplicación de la normativa nacional sobre seguridad de la biotecnología y existencia de propuestas para la adecuación y la complementación del marco legislativo nacional en materia de bioseguridad integrando a todos los sectores de la sociedad, incluyendo a los consumidores; incremento de la capacidad nacional para la evaluación, gestión y comunicación de riesgos derivados de los OGM (capacitando a miembros del CNB, personal técnico del Laboratorio modelo, oficiales de las instituciones involucradas en el sistema nacional de bioseguridad y otros especialistas); y, información y sensibilización de los actores clave de sectores del gobierno y de la sociedad civil, incluyendo a los consumidores, en aspectos referidos a los posibles riesgos de los OGM para la biodiversidad y la salud humana y, en aspectos relacionados con las ventajas de los OGM en la investigación y el desarrollo del sector productivo del país; información y sensibilización de los sectores fundamentales de la investigación, organizados en la Red Boliviana de Biotecnología, que realizarán acciones de investigación, discusión y análisis como apoyo a la gestión de la seguridad de la biotecnología.

Strengthening the National Capacity in Biotechnology and Biosafety (TCP/GRN/2902)

Country: Grenada
FAO Contribution: US$237 000
Duration: 12 months

Project summary:

The Government of Grenada is increasingly confronted with the risk of illegal introduction of GMOs in the country and needs instruments to handle in a safe manner the applications it receives for GMOs releases. On the other hand, the Government appears to support the idea that biotechnology, if properly integrated into the existing agricultural system, can make a significant contribution in terms of increased and more diversified agricultural production and would like to promote its use. However it is also conscious that an improper introduction and use of biotechnology and particularly GMOs can have possible adverse effects on the environment and pose risks to the conservation of biodiversity. As part of an effort to handle this problem, a National Biosafety Committee was established, but Grenada currently lacks a biosafety legislation and adequately trained human resources, as well as the technical capacity for bringing unbiased information within the everybody's reach. The Government has requested FAO assistance to address the above constraints.

The objective of the project is to provide the country with the legal and technical instruments needed to promote a safe introduction of appropriate biotechnologies in order to improve agricultural production and food security .

The project will provide the services of six TCDC consultants (one expert in agricultural biotechnology for five weeks in one mission; one expert in ecological aspects of bio-safety for five weeks in one mission; one expert in legal aspects of biosafety for five weeks in one mission; one expert in risk analysis for five weeks in one mission; one expert in post-release monitoring of GMOs for five weeks in one mission and one communication expert for ten weeks in three missions) ; one national consultant/expert in environmental and/or agricultural legislation (two months) and FAO technical backstopping services

(approximately 9.5 weeks). In addition, the project will provide for official travel, contract, training and general as well as direct operating costs.

The proposed assistance is intended to formulate a biosafety bill; train officers indirectly involved in the national biosafety system on general biotechnology concepts and the basic principles of biosafety; train National Biosafety Committee and other staff, directly involved in the national biosafety system, in all the matters related to risk analysis of GMO utilization and develop an information and communication strategy to raise awareness of possible benefits and potential risks of biotechnology application.

Capacity Building in Biosafety of GM Crops in Asia (GCP /RAS/185/JPN)

Participating countries: Bangladesh, China, India, Indonesia, Malaysia, Pakistan, the Philippines, Sri Lanka, Thailand, and Vietnam

Rationale/Significance

project was formulated to assist countries in the region in safe harnessing of the benefits of biotechnology in accordance with relevant global agreements on the subject. Furthermore, it is envisaged to establish and strengthen technical cooperation among and capacity building of Asian countries to ensure safety in the introduction and use of GM crops, based on transparent and science–based approaches. This includes: development and harmonization of an appropriate regulatory framework to deal with biosafety concerns relating to GM crops; and the collection, analysis, dissemination and exchange of information on biotechnology and GM-related biosafety standards through inventories, databases and decision-support systems.

Objective

To enhance food and livelihood security in Asia through sustainable and environment-friendly increases in the yield and quality of agricultural produce, including, where appropriate, the safe and judicious harnessing of modern biotechnology.

Expected Output

- Development of human resources, research, and technology, infrastructure, regulations and policies on Biosafety.
- Trained human resources for researching, analyzing and managing biosafety risks associated with GM crops. This will facilitate transparent, science-based and objective regulatory and policy decisions and harmonized biosafety regulations regarding the development, trade and commercialization of Gm crops.
- A benchmark reference document that will list the relative strengths, weaknesses and gaps in participating countries and the region as a whole for meeting the above objective.
- Establishment of the Asian BioNet to provide a forum for sustained regulatory collaboration among Asian countries for the safe and judicious use of modern biotechnology.
- National on biosafety aspects of Gm crops in the context of agriculture and trade policies, and consistent with agreed international standards.
- Support for research and technology development for the assessment and management of biosafety risks related to GM crops

Activities

1. Regional Consultations to: i) identify strengths and weaknesses of national capacities; ii) identify strengths and weaknesses of national capacities; iii) promote harmonization of biosafety methodologies, standards and regulations.
2. Setting up of Internet-based national and regional centers for Gm crops database management and information exchange mechanisms in line with FAO's World Agricultural Information Centre (WAICENT).
3. National stakeholder workshops to streamline national capacities for linking policy, technology and biosafety issues, and strengthen research and technology development capacity on risk assessment and management.
4. Initiation of specific research and technology development to develop methods to support scientific risk assessment of GM crops.
    - Preparation of training manuals.
    - National and regional training and workshops on procedures and methodologies for biosafety risk assessment and updating of developments on Gm crop risk and management options.
    - Special group meeting to evaluate the extent of adoption of harmonized biosafety measures, methodologies and regulations.

Apoyo a la formulación de una política nacional de biotecnología (TCP/PAR/3001)

País: Paraguay
Duración: 11 meses
Contribución de la FAO: 205 000 dólares EE.UU.

Resumen del proyecto:

La utilización de la biotecnología en el sector agrícola está todavía en un estado incipiente en Paraguay, si bien existen esfuerzos por desarrollarla, los mismos son aislados, se carece de infraestructuras, recursos humanos capacitados y financieros, adecuados y además existe una falta de coordinación entre los diferentes sectores interesados. Para aprovechar las oportunidades brindadas por la biotecnología para el desarrollo rural y la seguridad alimentaria, es necesario crear un entorno programático y operativo favorable, y concretamente es preciso que sean adecuadamente desarrollados una política estratégica de aplicación de la biotecnología, un marco regulatorio adecuado, eficientes instituciones que gobiernen o desarrollen aplicaciones de la biotecnología, una correcta información y sensibilización del público sobre los beneficios y los riesgos de la aplicación de la biotecnología, recursos humanos bien capacitados y incentivados, y recursos financieros adecuados y estables.

El objetivo principal del proyecto es apoyar la aplicación segura y sostenible de la biotecnología para fomentar el desarrollo agropecuario sostenible y optimizar la producción del sector agrícola. Los objetivos específicos son: (i) diagnosticar la situación actual de aplicación de la biotecnología a nivel nacional; (ii) identificar las necesidades y establecer las prioridades para el desarrollo rural sostenible y la seguridad alimentaria; (iii) formular una estrategia nacional de desarrollo de la biotecnología en el país (Política Nacional de Biotecnología Agropecuaria y Forestal) y (iv) preparar un plan de implementación de la estrategia de desarrollo de la biotecnología (Programa Nacional de Biotecnología Agropecuaria y Forestal) con vistas al financiamiento internacional, para apoyar el esfuerzo nacional.

El Proyecto proporcionará los servicios de siete consultores nacionales (por una duración total de 12 meses) y de cinco consultores CTPD (por un mes cada uno). El proyecto proporcionará también los servicios de supervisión y asistencia técnica del Servicio de Fomento de la Investigación y la Tecnología, del Servicio de Cultivos y Pastos y del Servicio de Derecho para el Desarrollo. El proyecto proporcionará los recursos para varios eventos de capacitación y cubrirá también los viajes internos así como los gastos generales y directos de operación.

Los resultados esperados a la finalización del proyecto incluyen: una Política Nacional de Biotecnología Agropecuaria y Forestal (incluyendo un diagnóstico de la situación presente, la identificación de las necesidades de innovación tecnológica de los sectores de cultivos, silvicultura, ganadería y pesca y una estrategia nacional de biotecnología) y un Programa Nacional de Biotecnología Agropecuaria y Forestal.

Strengthening national capacities in formulation and implementation of legal instruments on genetically modified organisms (TCP/SWA/3003)

Country: Swaziland
FAO Contribution: US$174 000
Duration: 12 months

Project summary:

Swaziland enjoys a rich biodiversity owing to its great variations in landscape, geology and climate. Its ecosystem holds great significance for biodiversity conservation because it allows for ecological processes such as migration and gene flow. Its agriculture sector is in majority of a subsistence type, which occupies more than 80 percent of the population. Recent food aid in the region raised concerns regarding the uncontrolled distribution, handling and consumption of genetically modified organisms (GMOs) in the country and the associated environmental and health risks. Swaziland, which is surrounded by countries where GMOs are regularly introduced and cultivated, does not have a biosafety legislative framework nor the human capacities in risk analysis of GMOs necessary to implement any biosafety measures. This could lead to illegal imports and cultivation of GMOs, with the associated risks to the environment and local biodiversity and to the creation of a barrier to technology transfer. The Government requested FAO assistance in addressing the most urgent needs related to biosafety.

The objective of the project is therefore to facilitate the safe introduction of appropriate biotechnologies and biotechnological products, including GMOs, in Swaziland. This would be achieved by developing a biosafety regulation and building the national capacity in the application of modern biotechnologies in agriculture and risk analysis of GMOs, as well as management of biosafety information.

The project will provide the services of one international consultant for legal aspects of biosafety (four weeks) five TCDC (Technical Cooperation among Developing Countries) experts for the training in different disciplines related to biosafety (25 weeks in total), and one national expert in agricultural legislation (two months), in addition to FAO advisory technical services from three technical units (eight weeks in total). The project will also cover official travel, materials and equipment, training, and general as well as direct operating expenses.

As a result, the project will have developed a draft biosafety law, consistent with existing national legislations as well as international conventions. In addition, 40 officers from relevant ministries and authorities will have been trained in the general concepts of biotechnology and biosafety, and ten officers from relevant ministries and scientists from the Swaziland University will have been trained in risk analysis of GMOs and management of biosafety information. The assistance is expected to ensure safe access to food relief programmes and contribute in the long term to improved agricultural production and to the overall national food security.

Capacity building of regulatory agencies for handling genetically modified crops, products and processed foods (TCP/KEN/3001)

Country: Kenya
FAO Contribution: US$238 000
Duration: 12 months

Project summary:

The Government of Kenya (GoK) believes that judicious use of biotechnology can assist them in increasing food production and availability. To this effect, GoK has ratified the Convention on Biological

Diversity and the Cartagena Protocol on Biosafety. The National Council of Science and Technology was designated to oversee the implementation of biosafety regulations and guidelines, within which the National Biosafety Committee was established, comprising representatives from the Government, non-governmental organizations, and research institutions. A National Biosafety Framework was produced and a draft Biosafety Law prepared through a UNEP/GEF pilot project. The Kenya Plant Health Inspectorate Service (KEPHIS), Kenya Bureau of Standards (KBS), and the Department of Veterinary Services (DVS) are the regulatory agencies for biotechnology and biosafety issues, but they lack the capacity in effectively undertaking biosafety operations, risk assessment and monitoring of genetically modified (GM) crops, products and processed foods. GoK requested FAO assistance in building the capacities of its regulatory agencies.

The proposal aims to build the capacities of Kenya's principal regulatory bodies KEPHIS, KBS, and DVS to efficiently and effectively carry out risk assessments and monitoring of various genetically modified products of biotechnology.

The project will provide the services of two TCDC consultants specialized respectively in ecological aspects of GM crops and biosafety information (13 weeks in total), three national consultants specialized respectively in agricultural biotechnology, risk analysis, and legal and trade aspects of biotechnology (15 weeks in total) and FAO advisory and supervisory technical services (ten weeks in total). In addition, the project will cover official travel, materials, equipment, two local contracts, in-country training and a study tour, and general as well as direct operating costs.

Regulatory officers and technicians from KEPHIS, KBS, and DVS will receive practical and theoretical training in molecular biology techniques, GM detection and quantification, biosafety, biotechnology, risk analysis, as well as on legal and trade aspects. Biosafety related technical information will be made available to relevant Kenyan regulatory bodies that will assist the National Biosafety Committee. The project will strengthen the Kenyan regulatory agencies' capacities for inspection and monitoring of GM products as well enhance cooperation among regulatory agencies within the country and in the region.

Capacity Building on Regulation of Import, Contained Use and Release of Genetically Modified Plants and Plant Material (TCP/MAL/2901)

Country: Malaysia
FAO Contribution: US$ 156 000
Lead Technical Unit: SDRR
Duration: 9 months

Project summary:

The Malaysia Government is well aware of the potential benefits and of the need to assure the safety of Genetically Modified (GM) crops. Biosafety Legislation has been drafted and is currently being examined by the Parliament. Nevertheless, GM technology is relatively new to the country and efforts to strengthen the country's capacity in the safe handling and assessment of GM products is required. For example, the first generation of GM papaya (virus resistant and with extended shelf life) is now ready for field trials and its safety must be evaluated before release. In Malaysia, technical expertise in the detection of GM plants and plant materials is currently inadequate to undertake related tasks.

The general objective of the project is to strengthen the national capacity on regulation of import, contained use and release into the environment of GM plants or plant materials.

The project provided the services of two international consultants (one person/month each) and five FAO partnership programme experts (1.5 person/months each). In addition, the project provided for FAO advisory and supervisory technical services including field missions, official travel, training and general as well as direct operating expenses. Training at different levels was delivered to personnel of regulatory bodies and research institutes, including:

- a residential course (ten days) on biosafety,

- a practical course (one week) on qualitative and quantitative methods of GMO detection,
- a hands-on course (one week) on risk assessment of GMOs,
- development of technical guidelines for risk assessment of GMOs,
- a study tour for Advanced GMO Detection and Quantification Training.

As a result, the national capacity in handling of GM plants and plant materials has been strengthened and the collaboration among different governmental bodies strongly improved.

Fortalecimiento del Sistema Nacional de Bioseguridad (TCP/PAR/0166 (A))

Duración: 15 meses

Contribución de la FAO : $EE.UU. 240 000

Resumen del proyecto:

En los países limítrofes del Paraguay ya se aplican organismos genéticamente modificados (OGM). Se tiene información de que, desde el 1996, se han estado introduciendo ilegalmente materiales genéticamente modificados en Paraguay. La Comisión de Bioseguridad (CB) de Paraguay fue creada en 1997 ante la necesidad de regular la introducción, investigación, liberación al medio ambiente y control de toda actividad relacionada con organismos vivos modificados. Esta tarea resulta muy difícil debido al hecho que no se dispone de los instrumentos legales apropiados y de personal adecuadamente capacitado para asumir la responsabilidad de controlar movimientos transfronterizos. Además, el marco legal de la CB no prevé la regulación para la liberación de los OGM con fines comerciales. Esta situación puede imposibilitar al país de mantener o mejorar su situación de productor de alimentos para exportación hacia mercados que imponen restricciones a los productos transgénicos, como la Unión Europea y el Japón.

El objetivo del proyecto es apoyar al Gobierno de Paraguay a desarrollar el sistema de bioseguridad nacional a través de la formulación de la normativa específica, el fortalecimiento institucional, la adecuación de la capacidad de análisis de riesgo para la introducción y la liberación comercial de semillas modificadas genéticamente y su análisis.

El proyecto ha proporcionado los servicios de un consultor internacional, experto en el área legal (dos misiones), un consultor nacional legal (cuatro meses), cinco expertos del programa de asociación de la FAO (por un total de 31 semanas), el apoyo técnico de la FAO (cinco misiones por un total de siete semanas), recursos para un programa de capacitación, así como equipos y materiales para las actividades de proyecto.

A finales del proyecto se puede contar con una propuesta de legislación adecuada a las necesidades nacionales en materia de bioseguridad, conforme a las convenciones y normativas internacionales, actualmente en curso de examen en el congreso. Los miembros de la CB y de otro personal de interesado (unas 35 personas en total) han sido capacitados para analizar y tomar decisiones en todo lo que se refiere a la introducción, los ensayos de campo, la investigación, la liberación, el comercio y el monitoreo de los OGM y sus derivados. Técnicos del laboratorio del Ministerio de Agricultura y de Ganadería (MAG) y de la Universidad han sido capacitados en la detección y el monitoreo de OGM y sus derivados. El laboratorio del MAG está equipado y adecuado para tal fin.

UNITED NATIONS ENVIRONMENT PROGRAMME (UNEP) [14 January 2005]
[SUBMISSION: ENGLISH]

INFORMATION NOTE ON UNEP-GEF BIOSAFETY ACTIVITIES AS OF 14TH JANUARY 2005

Introduction

1. UNEP has been assisting eligible countries for the implementation of the Cartagena Protocol on Biosafety (CPB) since 1997, in its capacity as an Implementing Agency of the GEF. UNEP has assisted

the GEF Secretariat to prepare its initial strategy on biosafety that was endorsed by the GEF Council in 2000. At present, UNEP is implementing a portfolio of capacity building projects for US$ 56 million comprising of three categories of activities:

I. Assisting 120-plus countries to prepare their draft national biosafety frameworks;
II. Assisting 8-plus countries with demonstration projects for the implementation of their national biosafety frameworks;
III. Assisting all eligible countries to access and benefit from the Biosafety Clearing-House.

2. These activities are carried out by the UNEP-GEF Biosafety Unit with a central administrative unit in Geneva handling technical, financial and administrative functions for all three projects, complemented by UNEP-GEF staff in Nairobi. An Information officer in Geneva assists all projects in responding to information needs and dissemination of results, information and outputs and supports the central website at: www.unep.ch/biosafety/. This website is central to all our work on capacity building in biosafety and allows all stakeholders to download or look at the work being carried out.

3. Key capacity building materials are made available in four UN Languages and all other documents in English. In addition to the technical staff headquartered in Geneva, the African and Pacific Island countries are serviced by staff in Nairobi and Samoa. In fulfilling its tasks, the biosafety team has developed close cooperation with all the GEF partners, including the CBD Secretariat, STAP, regional organizations such as ASEAN, SPREP, CARDI, SARC, ASARECA and other international organizations such as the EU, ICGEB, ISAAA, IFPRI, UNU, IUCN, OECD, WHO, GTZ, CIDA and the USAID-PBS Programme, as well as with the key stakeholders that include donor nations, agriculture and biotechnology industries and the NGOs.

I UNEP-GEF Project for Development of National Biosafety Frameworks in 120-plus countries

4. During the negotiation of the biosafety protocol, a UNEP/GEF pilot project for US$ 2.5 million assisting 18 countries to prepare national biosafety frameworks and promoting regional and sub-regional collaboration was successfully implemented during the period 1997-1999.

5. Building on that experience, a UNEP-GEF project was developed and has been designed (43.6 MUS $), to assist 120 countries to develop their national biosafety frameworks (NBF), and this is under execution. Out of the 1300 GEF projects, this is the first project with the participation of such a number of countries. A further add-on project to cover the final 10 eligible, interested countries has been approved, in principle, by GEF November Council.

6. The development of National Biosafety Frameworks takes countries from a zero stage up to production of a draft national biosafety framework. Support and capacity building is offered to assist in areas related to 5 key components {Biosafety Policy, Regulatory regime, System to handle requests (admin., risk assessment & management, decision-making), Follow up actions (monitoring, inspections and enforcement) , Public Awareness and Participation}.

7. A National Coordinating Committee has been set up to manage the preparation of the NBF where all stakeholders are represented, while a full-time paid National Project Coordinator (NPC) runs the project under the supervision of a National Executing Agency. Surveys are carried out of the existing national resources of biotechnology, experts, regulations and administration before moving on to gap analysis, consultation with stakeholders, and this all eventually leads on to the actual drafting of the NBF. Countries are fully supported by Regional Coordinators, who have provided continuing support and help in all aspects of project implementation and are each responsible for fifteen or more countries. This relationship is the core of the project and has been seen as one of the major successes of the project.

8. At the start of the project, a series of 4 regional workshops were held with 263 participants from 124 countries to raise awareness on the obligations under the Cartagena Protocol and about the project, and to share experiences. These workshops also helped to stimulate the elements of subregional

cooperation. Subsequently, 979 country representatives from 138 countries have attended training at 12 sub-regional workshops. Material for all these workshops has been designed with full international expert review. Each workshop took place over 4 days in one of the six subregional regional groupings and allowed participants to build up and share experiences and gain knowledge in setting up systems for decision-making (including risk assessment), the fuller involvement of the public, and the design of regulatory regime and administrative systems. One-day training has also been provided for the NPCs in financial and project management in the margins of these workshops.

9. 4 Toolkits, mirroring the 4 phases of NBF development, have been prepared with international experts to assist the national teams in understanding and carrying out of project activities, and made freely available in four UN languages and placed on the website.

10. The heavy demands on countries to carry out the full functions of an NBF lead them to the need to consider sub-regional cooperation and good progress has been made in supporting this activity, working with organizations such as SPREP, ASEAN, ASARECA, SARB, CARDI and SARC.

11. As of January 1st 2005, 24 countries had already finished their NBFs (all draft frameworks are made available at http://www.unep.ch/biosafety/news.htm#nbf). By February 1st, a further 10 countries are expected to have completed their NBFs. The original duration of the projects had been set up for 18 months, but many countries have sought extensions as a result of the complexity of the national processes required. It is expected that by the end of the Project (December 1, 2005), the majority of remaining countries (75) will have finished their national projects.

II UNEP-GEF Demonstration Projects for Implementation of National Biosafety Frameworks

12. UNEP-GEF manages 8 of the 12 GEF-funded Demonstration Projects on Implementation of National Biosafety Frameworks in Bulgaria, Cameroon, China, Cuba, Kenya, Namibia, Poland and Uganda. These were originally Pilot phase countries and finished their Pilot Projects in 1999. The demonstration projects started in September 2002 and will last, on average, 3 years, with budgets ranging between 0.5M and 1.0M US$. The aim for each country is to have the national biosafety framework fully operational by the end of the 3-year project period. i.e., the participating countries will have:

- A regulatory regime for biosafety in place, which is in line with the CP and other relevant international obligations,
- Workable and transparent systems for handling of notifications or requests for approvals (including systems for administrative handling, risk assessment and decision making),
- Workable and transparent systems for public information and public participation as well as enforcement and monitoring.

13. Establishing an adequate NBF involves an iterative process of developing a draft, implementing that draft and carrying out continuous evaluation and feedback. Considering that most operational NBFs were created over a period of several years of ‘trial and error’, it is clear that the targets set under these projects are quite ambitious.

14. The role of UNEP focuses on responding to countries’ needs and providing expert assistance and guidance as well as ensuring accountability through adequate and transparent reporting. This process of working with the countries can be described as a series of actions:

(i) Review the status of the NBF and the draft legislation at the start of the project;
(ii) Carry out a start-up workshop on the 5 key components of the NBF;
(iii) Joint preparation of a detailed work plan.
(iv) Countries carry out work plan and report on results
(v) National consultations with public and involvement
(vi) Dissemination of relevant information, e.g. biosafety policies, public participation

(vii) Continuous provision of legal, scientific and technical support by UNEP-GEF
(viii) Make all reports and documentation available on website
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15. Expert support has been provided in a number of areas such as:

- Collection and analysis of biosafety policies and public information practices from countries all over the world
- Expert panels assembled to provide reviews of drafts of biosafety legislation and draft regulations
- A Guide prepared on regulatory regimes, processing of notifications and requests, risk assessment, decision making, enforcement, monitoring, public information, public participation and international information exchange
- Guidance provided on interim measures and assistance in drafting implementing regulations
- Training given in the scientific and practical aspects of risk assessment
- Support provided in drafting operational manuals and work plans for enforcement

16. A study tour was made by the National Project Coordinators to a number of countries in Europe where biosafety frameworks have been in place for many years. In addition, the first training workshop was held in Geneva from 19 - 30 January 2004 and a second will be held in Geneva from 20th to 24th March 2005.

17. The preparation of a draft NBF will allow those countries to move onto the Implementation stage, provided that they are Parties to the Cartagena Protocol. A number of these countries are currently preparing draft projects with UNEP for the Implementation stage, and are being presented to GEF for funding.

III UNEP-GEF Project to build capacity for effective participation in the Biosafety Clearing-House (BCH) for 50-plus countries

18. A US$ 5. 1 million UNEP–GEF Biosafety Clearing-House project was approved in November 2004 to help build capacity in countries that already need to use the Biosafety Clearing-House. Since the BCH contains all the information that is required of, and by, countries in order to carry out all the functions of the CPB, the project is aiming to help all Parties and potential Parties to use, access the BCH and set up national BCH access.

19. The project originated from the needs of countries to use the Biosafety Clearing-House and was developed in close collaboration with the CBD Secretariat. This project was designed to assist up to 50 countries, with eligibility restricted to countries that were Parties to the CP by COP/MOP1 in February 2004. 61 countries were actually therefore eligible under GEF rules, and 51 of these have so far endorsed. We are now working with the first 50 countries to apply for the project.

20. Subsequently, guidance to the GEF from COP/MOP1 led to a request for expansion of eligibility to include other Parties to the CPB and all Parties to the Convention on Biological Diversity that provide clear political commitment towards becoming Parties to the CPB. This will increase the potentially eligible countries to 139 countries, in total. As a consequence of the COP guidance and the support of the May 2004 GEF Council, an add-on project for up to 89 additional countries has been developed and was approved, in principle, by the GEF November 2004 Council. Final clearance is expected in Spring 2005.

21. The BCH Capacity Building Project has a training component to strengthen capacity by training key stakeholders and an equipment component to create an enabling environment by providing some computer hardware and software for data storage and exchange. A minimal support for equipment is provided to countries in this project, complementing the funds provided in the Development Project. Additional funds may be made available to countries under potential, future GEF Implementation projects.

22. UNEP-GEF Biosafety Unit is establishing a pool of peer-reviewed regional experts to provide advice and support to countries and has advertised globally for these experts in 2004. Participating countries will be able to choose trained experts to visit and support their national projects. UNEP will be responsible for training the experts in specific materials and ensuring the high quality of support and materials provided.

23. The first Training and Selection Workshop for Regional Experts in IT and CPB, involving at least 5 experts from each of the 4 regions will take place from January 2005. The selected candidates will be available from 1st March and the first national training workshops will then be likely to start from April 2005.

24. An initial consultation for the development of a training programme for the BCH project was held with international experts in Bossey in June 2004. A further regional consultation with scientists and regional experts was held in December 2004 in Geneva to review the training programme and modules prepared in order to respond to the specific needs of each country.

25. The support programme for countries has been planned to involve national workshops, consultancies from trained regional experts, who will provide advice, ongoing support and interactive training documentation that has been prepared.

26. In addition, a high level of follow up and support from these above-mentioned regional experts will be provided to countries after the initial discussions and country-level training, including one-on-one support in assisting countries to make choices for national BCH access and to set-up and use the BCH.

UNITED NATIONS INDUSTRY AND DEVELOPMENT ORGANIZATION (UNIDO) [11 January 2005] [SUBMISSION: ENGLISH]

UNIDO'S PROGRAMME ON BIOSAFETY

PAST EXPERIENCE

UNIDO's involvement in biotechnology dates back to the mid 1980s with the establishment of the International Centre of Genetic Engineering and Biotechnology. As early as this, UNIDO together with UNEP formed an interagency ad hoc working group in biosafety, which was joined by WHO and later on by FAO. The work of the group culminated in the first international Code of Conduct for the Release of Organisms into the Environment. In 1993, UNIDO established the first on-line biosafety information resource (Biosafety Information Network and Advisory Service - BINAS) and became the Task Manager for Chapter 16 of Agenda 21 "Environmentally Sustainable Applications of Biotechnology". More recently, UNIDO developed a computer-based decision support system for the assessment of environmental impacts resulting from experimental and commercial releases of biotechnology-derived products (dtree).

In view of these achievements and in line with its mandate UNIDO, in co-operation with the Government of Chile, organized in March 2004 a Global Biotechnology Forum (GBF). This conference was attended by some 1500 participants from about 80 countries, including experts from governments, intergovernmental organizations, non-governmental organizations, scientific institutions, industry and the media.

The overall objective of the GBF was to examine the potential offered by biotechnology in all its facets for the creation of wealth and the improvement of the quality of life of people in the developing countries and countries with economies in transition.

The participants, building on the work that had previously taken place in the regional consultative meetings in Africa, Asia and the Pacific Countries, Europe and Latin America and the Caribbean examined a broad range of issues related to this objective through structured dialogue on:

- Biotechnology meeting the needs of the poor
- Biotechnology, biodiversity, energy and the environment
- Trade, regulation, bio-safety and social acceptance of biotechnology
- Biotechnology and Bio-Industry
- Biotechnology and the developing world

The participants emphasized the importance of nations increasing their efforts to achieve the Millennium Development Goals (as contained in U. N. Millennium Declaration of 2000), and they also took note of the provisions of the Monterrey Consensus. They recognized that the World Food Summit (five years after), of June 2002 urged research institutions and UN organizations to advance agricultural and other areas of research into new technologies, including biotechnology, and concluded that the introduction of such new tried and tested technologies should be accomplished in a safe manner, within appropriate regulatory frameworks, and adapted to local conditions to help improve agricultural productivity in developing countries. They also noted that the World Summit on Sustainable Development in 2002 recognized the need to provide additional financial and technical resources to developing countries to promote practicable measures to capitalize on benefits arising from biotechnology.

Participants particularly noted United Nations General Assembly resolution 58/200 of 23 December 2003, which reaffirmed the vital role of new technologies in raising the productivity and competitiveness of nations and the need, *inter alia*, for capacity-building measures promoting the transfer and diffusion of technologies to developing countries and countries in transition. In addition this resolution took note of the proposal of the Secretary General for an integrated framework for biotechnology development within the UN system and the need for strengthening coordination between relevant organizations and bodies of the system in the area of biotechnology. Participants suggested that the following initiatives and proposals could be further considered and followed up by UN organizations (based on their respective mandates and approval by their governing bodies), other international development partners, the scientific community and the private sector:

1. Formation of a multi-stakeholder forum, involving UN specialized agencies and other international bodies together with representatives of government, industry and the scientific community to serve as an ongoing platform for informed dialogue on biotechnology and the way in which its benefits may be used for the enhancement of developing countries.
2. Creation of an information network and data base as to what biotechnology activities are currently in progress in the countries with economies in transition and developing countries, together with market information on a global basis to assess technology and market potentials for new initiatives, including to identify and facilitate partnerships.
3. Enhancement of efforts for the mobilization of resources for capacity building.
4. Examination of the impact of and ways to facilitate access to intellectual property to promote the exploitation and dissemination of biotechnology in developing countries.

The participants agreed that the GBF provided valuable inputs into the UN wide effort to spread the benefits of biotechnology to the developing countries, and in particular, will contribute towards the Secretary General's system-wide integrated framework for biotechnology development.

This is the background against which UNIDO's involvement in the area of biotechnology and more particularly, biosafety needs to be presented. UNIDO as the United Nations Industrial Development Organization views biotechnology as an integral part of the knowledge-based economy and thus an important means of wealth creation. It is ushering a new model of economic activity (bio-economy)

whereby new types of enterprises are created and old industries are revitalized. Its potential to spur economic growth and enhance industrial productivity is unprecedented. In the developing world, it will have a major impact on private sector development, but its adoption will largely depend on the ability to overcome a nexus of regulatory, institutional and technology-related barriers.

Biosafety capacity building

In the last 15 years, UNIDO has organized or contributed to over 30 international biosafety training courses. Experience accrued from these show their importance in meeting the needs of member countries to enhance their regulatory oversight capacity in biotechnology but at the same time point to shortcomings. These relate to the high operational costs, which result in trade offs between the trainee intake or the course duration and number of resource persons. To address these issues and improve the effectiveness of traditional biosafety training courses UNIDO has developed a training methodology, which applies multimedia and distance learning technologies, and provides a cost-effective alternative and complementary platform to conventional 1-2 week training courses.

Distance learning overcomes geographical constraints and allows students from different parts of the world to simultaneously attend the course without interrupting their ongoing professional or academic engagements. For the same reason, it permits larger numbers of international experts to join the faculty of the course or contribute to the preparation of course material made available electronically.

This approach has already been tested successfully by UNIDO through the operation of a two semester (one year) pilot Biosafety Diploma Course in cooperation with the University of Concepción (UDEC), Chile. This diploma course is the first academically accredited course in biosafety worldwide. Based on this experience, UNIDO is currently working on plans to expand the programme to Africa and Asia.

Biosafety Diploma Course

The course's programme objective is to strengthen, through training, capacities of regulatory authorities and industry to comply to the requirements of international agreements (e.g. WTO, Codex) and conventions (e.g. CBD) dealing with development, transfer and trade of biotechnology-derived products.

Its methodology is based on sophisticated distance-learning techniques and multimedia systems. It is designed to allow continuous interaction with the students and minimal disruption of their on-going professional or academic activities. It also involves optional sessions of on-campus lectures and workshops.

The course is intended for:

- Researchers, government and industry professionals involved or interested in the assessment and management of risks related to GMOs
- Individuals engaged in public policy, legal and ethical aspects or regulation of biotechnology
- Professionals interested in teaching biosafety (train the trainers)

The student is expected to acquire the following skills:

- Ability to assess current and potential developments in biotechnology
- Advanced skills to conduct risk assessment and risk management in biotechnology
- Skills to formulate applications for the environmental release of GMOs
- Ability to interpret national and international norms and regulations in biotechnology
- Risk communication skills

The course has unique features:

- Duration. 300 hours of teaching material over 10 calendar months
- It is the only one carrying academic accreditation (diploma)

- It is modular and easy to expand or streamline to suit specific needs
- It is prepared and delivered by an international faculty of eminent scientists

THE WORLD BANK [14 January 2005]
[SUBMISSION: ENGLISH]

Summary of World Bank–GEF Projects on the Implementation of National Biosafety Frameworks

The World Bank is currently working with Colombia and India on two GEF demonstration projects to build capacity for the implementation of the Cartagena Protocol. Both projects became effective in the fall of 2003 and are expected to have a three-year duration.

Colombia – Capacity Building for Implementation of the Cartagena Protocol

The biosafety capacity building project in Colombia aims to provide the country with sufficient capacity to properly assess and manage risks associated with the transboundary movement of LMOs and thus meet the basic obligations of the Cartagena Protocol. The project has five components: 1) strengthen the legislative and regulatory frameworks and operational mechanisms for biosafety management; 2) build capacity and establish an operational system for risk assessment and management and monitoring; 3) establish a biosafety database system and linkage to the Biosafety Clearing-House (BCH); 4) support centers of excellence and a network for research, risk assessment and monitoring; and, 5) develop a project coordination unit and an inter-sectoral/inter-ministerial mechanism for formulating national policies and coordinating decision-making on biosafety issues.

Accomplishments to Date

The plan for creating a high level inter-institutional mechanism to advise the Government on the adoption of policies, regulations and unified decisions on biosafety is on target. Identification and confirmation of working groups of participating ministries was completed in June 2004 but there is a need for further consolidation of various groups.

An important goal of the project is to establish a National Biosafety Council comprised of three technical committees with expertise in environment, health and agriculture which would be created by decree and consequently have an advisory role at the onset. An assessment of a proposal on the development of normative tools to adjust the law and adopt a national legislative and policy framework which regulates and harmonizes activities related to LMOs across different sectors and organizations is underway.

In terms of establishing a system for risk management and assessment, the designation and establishment of a nucleus of institutional capacity building on biosafety and training of trainers in various ministries is on track. Specifically, groups in each institution have been identified and proposals on strengthening the groups have been received. An LMO "Level I" course was offered in the fall of 2004 at the International Center for Tropical Agriculture (CIAT).

The terms of reference of the coordinator for information sharing and dissemination using a database network and web page of the BCH were developed and it has been decided that the physical location of the national BCH will be at the Alexander von Humboldt Institute (IavH).

The centers of excellence (universities, ministries and their related institutions) are an important part of the project as they will be responsible for providing research support, analysis, and training. The location of the central laboratory has been decided upon (Instituto Colombiano Agropecuario). However, the institutional network and formulation of projects are still under revision.

Finally, in terms of the project management unit, project execution was delegated by the Ministry of Environment, which is the GEF focal point in Colombia, to IAvH. The project coordinating unit was created with a coordinator and advisor contracted in April 2004 and is functioning well. The Intersectoral

Council (IC), which is comprised of several ministries, was established in April 2004 and is presided by the Ministry of Environment. The IC has already approved an operational manual and annual work plan.

Opportunities for Collaboration

Representatives from key institutions involved in the project have expressed a desire to collaborate on a regional basis with institutions from other countries to share experiences and complement existing skill-sets on biosafety issues.

Lessons Learnt

It is necessary to strengthen inter-institutional coordination (specifically, the Inter-institutional Coordination Committee) at the highest level in order to allow key components to a biosafety framework to be prioritized such as the development of standards and inter-institutional political agreements.

The frequent change in personnel at higher levels of participating institutions has had an effect on the level of compromise that can be reached between institutions.

Administrative procedures of the different participating institutions has made it difficult to move towards operationalization of the implementation plans in an expedited manner. It is necessary to speed up procedures in order to efficiently implement the associated components of the biosafety project.

India – Capacity Building for Implementation of the Cartagena Protocol

The main objective of the India biosafety capacity building project is to develop national capacity to implement the Cartagena Protocol on Biosafety. The project consists of five components 1) establishment of a project management unit; 2) increasing institutional capacity in line ministries; 3) enhancing technical capacity for risk assessment and management of LMOs; 4) supporting centers of excellence for LMO detection, research and networking; and 5) and establishment of a BCH mechanism in the country.

Accomplishments to Date

The project was launched in November 2003 and suffered initial delays due to the process of review and negotiation with participating institutions. However, implementation of all five components is underway and the project has seen some noteworthy accomplishments.

Procedures for project management and governance, financial management and procurement have been established, and in regards to the technical component of the project (i.e. supporting institutions for LMO detection), DNA-based detection of transgenic events have been developed and validated (for herbicide resistance and insect resistance) and inter-laboratory validation completed. In addition, the efficacy of commercially available dip-stick test kits against crushed seed material of herbicide tolerant soybean and insect-resistant maize were tested, and on-site testing procedures for port authorities are currently being developed.

In regards to the BCH mechanism and related information tools, the architecture of the national BCH has been completed. The plan is to have the BCH fully functional and interoperable with the central portal of the BCH by March 31, 2005. The project web-site design has been completed, and is likewise to be operational at the end of March in 2005. Finally, the architecture for and integrated database on biosafety and production and use of LMOs in India is completed.

Opportunities for Collaboration

There has been collaboration with the USAID-funded South Asia Biosafety program through a joint analytical study on environmental and socio-economic risk assessment procedures. The capacity building project is also part of a biotechnology/biosafety communication network in India. Interaction with UNEP and UNDP on their biosafety programs will be strengthened during the coming year.

Lessons Learnt

Technical human capacity exists in India. The challenge is to link this capacity with organizations and institutions affected by or overseeing the meeting of the obligations under the Cartagena Protocol.

While technical competence is there, an awareness and holistic understanding of issues and policies related to LMOs is specific to concerned personnel in line ministries and is not yet present on an institutional level.

The biotechnology/biosafety environment in India is currently in flux. Coordination between the different line ministries and between central and state level administrations needs to be strengthened to halt the present evolution of conflicting policies.

In addition, the restriction that project resources be channeled only through the Ministry of Environment and Forests reduces the opportunity for inter-ministerial synergy in order to meet India's obligations to the Cartagena Protocol. Particularly relevant ministries would be the Ministry of Agriculture and Ministry of Science and Technology.

INTERNATIONAL FOOD POLICY RESEARCH INSTITUTE (IFPRI) [14 January 2005] [SUBMISSION: ENGLISH]

The Program for Biosafety Systems (PBS)
Building Functional Biosafety Systems among Developing Countries

1. Introduction

As developing countries address biosafety-related issues they face numerous challenges at regional, national, and local levels, such as:

- Fostering a regulatory environment characterized by transparency and stability
- Providing an effective system of accountability and stakeholder participation to build public confidence in decision making
- Harmonizing biosafety regulations with existing systems for food safety, seed and phytosanitary regulation, importation, and other relevant laws or regulations
- Developing acceptable criteria to weigh risks/benefits, for setting trade-off levels between agricultural productivity, environmental, and human health concerns.

The *Program for Biosafety Systems* responds to these issues, to the Cartagena Protocol on Biosafety, and to needs at the national (e.g. food safety assessment of GM food imports, facilitating experimental field trials) and international level (e.g. CODEX, SPS, IPPC). PBS is implemented through a consortium of public, international, regional, and local organizations. Our partner-driven approach occurs through Country/Regional Advisory Groups (CRA Groups) to identify and integrate PBS activities. *Regional Program Managers* spearhead the formation of the CRA Groups, secure coordination among partner countries and regions, engage local expertise, and ensure partnership implementation. Regional officers include: Theresa Sengooba, East Africa; Walter Alhassan, West Africa; Reynaldo Ebora, Asia, and Idah Sithole Niang, Southern Africa.

The CRA Groups prioritize and integrate policy development, communication, outreach and capacity building. PBS begins work with four countries in Asia: India, Bangladesh, Philippines, and Indonesia. In Africa, regional approaches are being developed for Eastern, Western, and Southern countries. Work plans for the four components, regions, and countries listed below are under development, and can be shared.

2. PBS Mission, Goal, and Objectives

The program's **mission** is to empower partner countries for science-based biosafety decision-making while strengthening capacity to implement biosafety through innovative system design. The **goal** of the program, as stated by USAID, the funding agency, is to more effectively address biosafety within a sustainable development strategy, anchored by agriculture-led economic growth, trade and environment objectives. Activities are in four components, with individual leaders (see Section 4):

- *Policy development/new models* (Mark Rosegrant, José Falck Zepeda, Joel Cohen, Nick Linacre and Patricia Zambrano of IFPRI; Greg Jaffe of the Center for Science in the Public Interest, and Patricia Traynor and John Komen, consultants).
- Risk assessment and the *Biotechnology and Biodiversity Interface* (BBI) grants; Hector Quemada of Western Michigan University and Karen Hokanson of the University of Minnesota.
- *Facilitating regulatory approval*; Lawrence Kent and Mark Halsey of the Donald Danforth Plant Science Center, and
- *Communication, public and food safety outreach and capacity building;* Karim Maredia of MSU, Adrianne Massey and Associates, and Lucyna Kurtyka of the International Life Sciences Institute.

Our approach to biosafety targets policy development through National Biosafety Committees and national/regional polic making bodies. National/regional work includes methodologies such as the Conceptual Framework for Biosafety system analysis and country studies, costing determinations, and BBI grants. PBS **objectives**, as stated, are to: *"develop ne models for biosafety systems that address issues of feasibility and the consequences of policy choice for developi countries; develop approaches to biosafety that are mutually supportive of host-country interests and U.S.; facilitate acce to technology; and integrate biosafety regulation into related policies and international obligations."*

3. Collaboration: Countries, Sub-Regional Organizations, Providers, and ABSPII.

PBS gives extensive effort to collaboration. Letters of agreement are being drafted between both development and implementation parts of the UNEP/GEF initiative. Collaboration with BIO-EARN is ensured though John Komen and because BIO-EARN is a member. Agreements are in place with ASARECA, COMESA, and CORAF in Africa, and potentially APO and APPARI in Asia. Developing country agendas and CRA Groups are informed through existing groups (not those solely for PBS) to ensure coordination of activities; IUCN will be involved, and several of the IARCs. Links with NGOs and civil society occur through NBCs and CRA Groups.

4. Four Components of the PBS Initiative

A. Policy development (regional/national) and new models

Modeling biosafety systems for developing countries, based on the complex and resource-intensive approaches for developed countries, is inappropriate. PBS policy work promotes, but is not limited to; science-based decision-making and policy development with information that helps policy makers understand regulatory options and tradeoffs. The Program seeks to enhance existing systems, while preparing new models for sub-regional and regional consideration. Choices regarding biosafety policies and objectives will be evaluated for their implications for agricultural growth, trade, and food security. Potential tradeoffs and complementarities between these goals, costs of systems, and levels of biosafety afforded will be examined.

Activities: a) regionally focused roundtables on new models for biosafety; b) regulation and costing determinations to characterize national approaches; c) steps to implement alternative biosafety systems in partner countries.

B. Environmental Risk Assessment and Risk Management Research

Scientific knowledge on the nature, magnitude and probability of specific biodiversity/ecological risks, and strategies to manage such risks should be the foundation for biosafety decision-making. When knowledge is lacking, assessments can be subjective and methods for risk management arbitrary. Research projects will be identified and initiated through a global call for proposal, which is under development now, and expected to be released in February. The grants will provide new knowledge upon which to conduct/complete a risk assessment or devise risk management options.

Activities: a) determining priority areas for research; b) mechanism for monitoring and evaluation of BBI grants; c) sharing information obtained through BBI grants; and, d) evaluating administration and impact of BBI research on environmental decision making.

C. Assistance with Regulatory Packages

The Consortium will help fulfill requirements for regulatory packages *through consultations and capacity building*. A *roadmap* will divide data collection into four parts, and strategic approaches sought through the PBS Consortium to advise on package preparation. Specific regulatory needs will be determined through dialogue with our partners to specify regulatory data required by public sector research needs. A new capacity building effort is being designed to strategically approach the development of regulatory packages/dossiers by scientists, and their review by regulators.

Activities: a) Incorporate biosafety concerns into *product development strategies* through consultative guidance to R&D institutions; b) preparation of information for *field trial applications and/or full regulatory packages* (safety assessment dossiers) through consultative guidance to R&D institutions

D. Communication, Food Safety, Outreach and Capacity Building

Communication, food safety, outreach and capacity building are fundamental to this PBS proposal and, to ensure greater impact, are integrated in a single component. Effective and targeted communication strategies with a consistent national/regional approach will guide outreach and capacity building. The CRA Groups and Regional Program Officers will determine priorities and processes.

Activities: Communication and outreach - a) workshops to develop communication skills among key policy makers and scientific leaders; b) supporting communication and outreach activities for other biotechnology stakeholders. *Capacity building* – a) enabling authorization and safe conduct of experimental field trials; b) policy development seminars, including results from BBI research; c) consultative guidance to regulators and scientists for the development of regulatory packages; d) food safety risk assessments and risk management training, at both a general and highly technical level.

ICGEB

[14 January 2005]
[SUBMISSION: ENGLISH]

I: ICGEB Resources for Dissemination of Information on GMO Biosafety

Since 1997, the ICGEB has concentrated efforts in the field of biosafety by setting up a dedicated Biosafety Unit aimed at providing institutional services related to genetically modified organisms (GMOs) and their environmental release. The Unit is involved in three major sectors, namely: (i) information dissemination and the establishment of a biosafety clearing-house; (ii) scientific training in risk assessment for the environmental release of GMOs (capacity building and technology transfer); and (iii) international co-operation with other international agencies involved in biosafety.

By virtue of a Memorandum of Co-operation entered into with the Secretariat of the Convention on Biological Diversity, the pre-existing ICGEB biosafety bibliographic database (www.icgeb.org/biosafety/bsfdata1.htm) is now fully accessible through the Biosafety Clearing House,

the main portal for internet-based information developed by the CBD in the framework of the Biosafety Protocol. This database now contains more than 4700 scientific articles (full references and abstracts), published in international, peer-reviewed, scientific journals since 1990, selected and classified by the ICGEB according to specific topics that could raise concern over the environmental release of GMOs.

Another important informatic tool developed by the ICGEB with the support of the Italian Ministry of the Environment, the Risk Assessment Searching Mechanism (RASM) (www.icgeb.org/biosafety/rasm.html), also continues to expand. This device, which could be very useful for the decision-making process according to Article 10 of the Cartagena Protocol, provides access to an index of the existing risk assessment documents related to official governmental decisions for the release of GMOs. The RASM now contains 475 records of risk assessment documents, relating to 122 different transgenic events from 14 plant species, issued by 18 official authorities from several countries.

As of 2003, ICGEB is also involved, together with partners from France, Germany and Hungary, in a European initiative to enhance communication regarding GMO biosafety research. The project, named GMO RES COM, is funded under the 5th European Framework Programme "Quality of Life and Management of Living Resources". It aims at the creation of a web-based, public-access database of past and current projects in GMO biosafety research. This database should improve communication

II: ICGEB Training in Evaluation of an Environmental Impact Assessment

The ICGEB has long-standing experience in providing training in the area of GMO biosafety. Since 1991, some 900 scientists from over 80 different countries have attended ICGEB's biosafety workshops, which have been held once or twice each year. For instance, the ICGEB and the Italian Institute for Overseas Agronomy (IAO) have jointly organized a course in 2004 that was attended by 44 scientists from 22 countries. Until this year, the workshops have focused on general principles of GMO risk assessment, with both introductory and advanced workshops proposed. They have attracted an extremely diverse group of participants, including both members of the competent authorities involved in evaluation of proposed releases of GMOs and also scientists active in biotechnology.

Even though the workshops are generally considered to be highly successful, starting in 2005 more focused workshops will also be offered. Many countries are in the process of developing or implementing a national biosafety framework. This new type of workshop will provide experience in the examination of the scientific data that are evaluated to produce an environmental risk assessment (ERA) report. Considering the need for members of competent authorities to gain experience in evaluation of ERAs, in 2005 a workshop will specifically focus on how to do so. For several representative case studies, first the scientific background will be presented by experts in the particular field, then participants will break into smaller groups to produce a draft ERA report with assistance from experienced members of different national competent authorities. This new 2005 workshop will be organized by the ICGEB Biosafety Unit and the IAO, as in previous years, but also with the staff of the newly established ICGEB Biosafety Outstation at Ca' Tron. The ICGEB will also sponsor a similar Biosafety Course to be organized in Peru, in August 2005, and proposes to organize similar regional courses.

Although this type of workshop is intended primarily for officers or designated experts working in the area of GMOs risk assessment at an official level (governmental agencies, scientific institutions, private sectors etc.), it should also prove useful for people actively developing GMOs, since having a clear idea of how an ERA is evaluated would be of great use for scientists by helping them to recognize key areas of risk assessment to be integrated into their biotechnology projects.

III: ICGEB Seminars in GMO Biosafety Research

With the opening of the ICGEB Biosafety Outstation at Ca' Tron in 2004, the ICGEB has significantly enhanced capacity in the area of GMO biosafety research (see *ICGEB Research Training in GMO Biosafety*). The outstation is also ideally equipped to host small scientific meetings. The ICGEB proposes to use these facilities to hold a series of informal seminars that would serve as brainstorming sessions in specific research areas pertinent to GMO biosafety. These would include questions of immediate concern for GMOs already in or close to the commercial release stage.

- One such question concerns the potential effects of gene flow from *Bt* cotton in different parts of the world. In this instance, there are several geographic areas where the potential impact of gene flow merits consideration.
- Another topic that merits attention is the impact of gene flow from GM rice to wild/weedy rice. In this case, there are widespread rice relatives that are already serious weeds (e.g. "red rice"), and there is concern that certain transgenes could contribute significantly to their weediness. At a time when commercial release of GM rice is projected in the very near future, a worldwide examination of the potential impact of various types of GM rice would be of great interest.
- At a more fundamental level of research, there is apparently a methodological problem for assessing the effects of gene flow on weediness. There are relatively well established means for assessing changes in fitness that could be caused by dissemination of a transgene, but it is much less clear if this will lead to the phenomenon of ecological release; i.e., will the new trait lead to increased population size of those plants having introgressed the transgene? Changes in population size would be the clearest measure of increased weediness, so developing research strategies that would enable prediction of the likelihood of environmental release would be extremely useful.

These three areas are simply given as examples, purposely chosen from a relatively narrow area of concern. Numerous other questions of equivalent interest could easily be identified. In particular, questions in areas of more fundamental research, not as directly related to immediate questions, should also be studied. This would include questions in the areas of mechanisms that could lead to impact, and also to baseline studies of equivalent non-transgenic systems. The ICGEB proposes to serve as a centralized resource for organizing such research seminars. This would include opening periodic calls for subjects for discussion, assisting the organizers in developing the programme, and providing the infrastructure for holding the seminars.

IV: ICGEB Research Training in GMO Biosafety

The ICGEB Outstation at Ca' Tron is a fully equipped laboratory for studies on genetically modified plants. Research there will focus on one of the central aims of the ICGEB as a whole: to carry out first class fundamental research that is or will be of importance for biotechnology in the developing world. This clearly includes providing training in biosafety research. At Ca' Tron, this fundamental research will focus on biosafety questions related to GM plants and their associated pathogens. However, the sense given to this research will be provided by development projects, which will focus on creating pathogen-resistant transgenic plants expressing transgenes that will have been designed –in the light of the fundamental research- in order to minimize the potential epidemiological and environmental risks. Creating these transgenic plants will constitute the core biotechnology project at Ca' Tron. The aim is for these two activities to in effect create a world-class center for research on pathogen-resistant transgenic plants. In this sense, these projects are expected to serve as examples that will make it possible for researchers in developing countries to better integrate biosafety concerns into their own projects. It is expected that these projects, in which the Outstation will act as a partner, will constitute a network of collaborative biotechnology projects. The collaborative projects will clearly also be a key element in the

practical part of the training program at Ca' Tron, since it is expected that scientists from developing countries will wish to carry out part of their research there.

As of the beginning of 2005, research activities at the Biosafety Outstation are only now reaching full speed. The initial major focus is on virus-resistant transgenic plants. Among the biosafety questions concerning virus-resistant transgenic plants expressing viral sequences, the epidemiological impact of recombination between transgene mRNA and viral genomes has clearly presented the most difficult scientific problem to be resolved. Although sequence analyses have clearly shown that recombination has played an important role in virus evolution, remarkably little is known about how this occurs. Several experimental systems have been developed for studying the molecular mechanisms of recombination, and there have also been studies using viral genomes modified in various ways to observe recombination events that restore viral functions. These studies have provided extremely interesting results, but in all probability provide a highly biased view of recombination as it could be expected to occur in the field. This is why, in a continuation of a long-established network of collaborations, the researchers at Ca' Tron will focus on the understanding of recombination between *Cucumber mosaic virus* (CMV) and related viruses, since this is the only system for which it is presently possible to observe recombination between wild-type viral genomes, both in the laboratory and in the field (see Tepfer 2002; de Wispelaere et al. 2005). However, in order to understand the potential impact of recombination on virus epidemiology, the researchers at Ca' Tron will explore a novel approach, integrating the tools of population biology to understanding more clearly the role of the various sources of variability in viral genomes (recombination, mutation, reassortment), and how various forms of selection pressure, such as general features of host biology, or specific resistance genes, act on this variability. This will be expected to provide a clearer perspective on what is involved in changes in viral populations, and *in fine*, whether transgenic plants expressing viral sequences will contribute to such changes.

Virus-resistant transgenic plants are being created in numerous developing countries, and one of the early undertakings at the Ca' Tron outstation will be an assessment of the present status of these projects. Even before the launch of the outstation, it has become evident that collaboration with the group at Ca' Tron will be sought by numerous groups working on virus-resistant plants. As the Ca' Tron core biotechnology project is developed, it can be expected to serve as an excellent example, of particular use for integrating similar strategies into the projects of other groups. These collaborations should be quite valuable for several reasons. First, it will be the best way to provide real training in this area for scientists in developing countries. Second, working on other plant/virus systems will certainly cast additional light on the fundamental scientific questions asked, and thus contribute to our understanding of core scientific questions.

The Outstation will also house another group, which is an extension of the Bacteriology group at ICGEB-Trieste. This group will focus on the genetic basis for interactions between rice and several of its bacterial pathogens, species of *Xanthomonas* and *Burkholderia*. In the last decade, it has become apparent that in bacteria a major level of regulation exists involving cell-cell communication (5,6). This allows bacteria to monitor their population density by a mechanism known as quorum sensing (QS), which can play a key role in bacteria. virulence. The bacteriology group recently demonstrated that rice pathogenic *Xanthomonas* and *Burkholderia* have at least one QS system present in their genome (Venturi et al., unpublished data). Initial studies at the Outstation will focus on the role of QS in rice bacterial pathogens, as this could potentially be a target to control bacterial infections, since transgenic plants which interfere with this language have been shown to be more resistant to plant pathogens such as *Erwinia carotovora* (6). Future work also intends also to address questions related to the impact of rice transgenic plants on pathogenic and beneficial bacterial populations.

The research groups working at Ca' Tron are also considering organizing biosafety practical courses in their areas of expertise.

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NORWEGIAN INSTITUTE OF GENE ECOLOGY (GENØK) [12 January 2005]
[SUBMISSION: ENGLISH]

Norwegian Institute of Gene Ecology (GenØk) Biosafety Capacity Building Programme

Over the past 2 years GenØk has been developing and implementing the GE/GMO Biosafety Capacity Building Program in cooperation (and according to the MoU) with UNEP/DEC. The Program is aimed at assisting developing countries to respond to their capacity building needs in biosafety, including scientific and technical capacity for biosafety assessment and regulation. The Program, which is financed by the Norwegian Ministry of Foreign Affairs, includes the following activities:

a) Biosafety course that provides high-level policy makers, regulators, scientists, and representatives from NGOs and civil society, especially from developing countries, countries with economies in transition and small island states, with knowledge and training in crucial genetic engineering and GMO issues. The first course was launched in Tromsø in 2003 and had 49 participants from 41 countries, and the second course in 2004 had 51 participants from 42 countries. The "raison d'être" for the course is illustrated by the 2004 application data: 376 very highly qualified applicants from nearly 120 countries. (Please find the report issues by the Norwegian Government at: <http://www.genok.org/english/lesartikkel.asp?article_id=969&id2=8S0E9ohp0qrsYrzfPQzNMoAP7

b) The Biosafety Forecast Service:, a free-to-the-public database devoted to spreading information from the elite scientific and technical literature to policy and regulatory officials in government, NGOs, the interested public and specialist researchers in academia, government and industry. The Forecast Service will be accessible to those of all training and knowledge backgrounds and assist the user in finding the research relevant to their specific risk assessment and management needs.

c) Book/CD-ROM project with the working title, "Foundations of Gene Ecology and Holistic Approaches to Risk Assessment of Genetic Engineering".

d) Master of Science studies with majors in Gene Ecology and Holistic GE/GMO Risk Assessment in cooperation with GVU (Global Virtual University)/ UNU.

GenØk is engaged in research and teaching in the professional field Gene Ecology, focusing particularly on the environmental and health related consequences of the application of gene technology and gene modification. GenØk is also engaged in the broad dissemination of information and offers advisory and consulting services in its specialist field of gene ecology.

3. OVERVIEW OF OTHER MAJOR BIOSAFETY CAPACITY-BUILDING PROJECTS REGISTETED IN THE BIOSAFETY CLEARING-HOUSE

1. The *International Service for the Acquisition of Agri-biotech Applications (ISAAA) Biosafety Initiative* has also been instrumental in promoting capacity building at both research and regulatory levels in a number of countries, namely: Kenya, Indonesia, Malaysia, Philippines, Thailand and Vietnam. It has offered several training courses and fellowships in biosafety training over the past few years. It has also supported the establishment of Biotechnology Information Centers (BIC) in its participating countries to disseminate information on biotechnology and biosafety to the public. Details can be accessed at: http://www.isaaa.org/

2. *The IUCN initiative on capacity building to implement the Biosafety Protocol in Asia*: This is assisting nine countries South East Asia to implement their national and international regulations on biosafety and build institutional and human resource capacity to implement the Protocol. It has undertaken a number of activities including: assessment of the status of biosafety and biotechnology, including existing capacities and needs, in nine countries; organization in May 2002 of the Asia Regional Workshop on Risk Assessment and Risk Management, establishment of a project website and an Information Resource Centre, dissemination of information and awareness materials; development of a "resource kit" for implementing the Protocol at the national level and development of 'media packages' on biosafety issues. 5/ Details can be accessed at: http://www.rbp-iucn.lk/biosafety/MainPage.htm.

3. *REDBIO/FAO – Technical Cooperation Network on Plant Biotechnology in Latin America and the Caribbean*: REDBIO is a network comprising public and private laboratories and institutions in Latin America and the Caribbean devoted to plant biotechnology that started in December 1990. It has a membership of over 500 members in 27 countries and is implemented by REDBIO Foundations and FAO, in collaboration with other organizations. The network focuses on promoting information exchange; education; capacity building and technical assistance both at technical/scientific and regulatory level on matters related to plant biotechnology, biosafety and Intellectual Property Rights. Its main objectives are: 1) to develop opportunities for collaboration and partnerships on research and transfer of biotechnologies; 2) to promote and facilitate the exchange of information and research results among the network members and support the updating of knowledge through the organization and facilitating the participation of the Network members in international forums and symposiums; 3) to promote and support the exchange of resources and biologic materials and access to new technologies; 4) support the formulation of national and regional policies and strategies in plant biotechnology and to support regional training activities through: courses, workshops, symposia, and in-service training on advanced plant

5/ The IUCN Biosafety initiative, implemented by the IUCN Regional Biodiversity Programme for Asia (RBP), covers 9 Asian countries namely: Bangladesh, Bhutan, Cambodia, China, Indonesia, Laos, Malaysia, Philippines and Viet Nam.

biotechnology; 5) to promote the preparation and application of a Code of Conduct on Plant Biotechnology that will favour, standardize and adapt the use of concerted concepts in biosecurity, regulation, ethics and socio-economic impact of biotechnology in the countries of the Region. Further details can be accessed at: http://www.rlc.fao.org/redes/redbio/html/home.htm

4. *BIONET-Africa: Network for Capacity Building in Biotechnology and Biosafety for African Universities (2001-to date):* BiONET-Africa seeks to strengthen the capacities of national universities in Africa to undertake biotechnology/biosafety-related collaborative research and teaching. It seeks to achieve: 1) institutional capacity building through establishment of "centers of excellence" with centralized equipment for sharing and providing analytical and diagnostic services; 2) human-resources development and training through organizing an annual 3-week refresher course for young scientists, providing scholarships for MSc., PhD training and fellowships at ICIPE and Network "training centers" in Africa; 3) information exchange & data management through electronic network linking participating universities, an interactive website and on-line network publications and newsletters; and 4) scientific, technical and institutional collaboration through supporting a Scientist Exchange Programme and supporting "centres of excellence" in learning emerging techniques in biotechnology/biosafety and in use of modern equipment and data analysis. Further details can be accessed at: http://www.icipe.org/bionet/intro.htm.

5. *EU Twinning Project PL 01/EN/IB/03 – "Biological Safety System in Poland" (2002-2004)*: This project, supported by the German Federal Ministry for Health and Social Security the Austrian Federal Environment Agency; the Spanish Institut de Recerca i Tecnologia Agroalimentariès, Barcelona and the EU PHARE Programme is intended to support Poland in the task of establishing a national biosafety system comparable to EU standards concerning the use of GMO, their deliberate release and introduction to the market. Its main components are:

a) Legal review and assessment of state of approximation of the Polish legislation to the Acquis Communautaire;
b) Strengthening of decision-making functions, including risk assessment and public participation, of the competent bodies to enable Poland to perform decision-making procedures in line with EU standards;
c) Inspection component designed to enable the Polish authorities to perform inspection procedures in line with EU standards, including adequate sampling, sample analysis and development of analytical methods, for contained use, deliberate release and placing on the market of GMOs;
d) Assistance in establishing accredited laboratories to achieve a complete national laboratory network which shall be able to give analytical support to the inspecting authorities;
e) Assistance in establishing an electronic information system to ensure fast flow, processing and exchange of information, assure transparency and fulfill information requirements in order to support the decision-making and inspection authorities; and
f) Assistance in promoting public information and public participation to support initiation of public discourse on genetic engineering and the design and conduction of a "public awareness-campaign" including development of a website, brochures, and planning and conduction of a public symposium on biosafety aspects including beneficiary and risk potentials of genetic engineering.

The specific activities and results of the project include the following: 1) strengthening of the Polish legislation regarding GMOs; 2) formulation of guidelines for procedures concerning the handling of GMO issues; 3) training of staff in handling requests and notifications and in performing adequate inspection procedures; 4) establishment of accredited laboratories appropriately equipped for inspection and control of samples in various GMO-related fields and testing; 5) establishment of an electronic information system for activities concerning GMOs and 6) a public awareness campaign on issues related to biological safety.

6. *Rockefeller Foundation Support for Capacity-Building in Agricultural Biotechnology and Biosafety*: The Rockefeller Foundation is providing support for plant biotechnology research and development capacities in developing countries, including biosafety procedures, in a number of developing countries in Africa, Asia/Pacific and Latin America through national research institutions; CGIAR institutions; developed countries agencies and Private companies. Recent examples of biosafety-related capacity-building initiatives funded by the Foundation include the following:

a) Assessment of international initiatives for building capacity in the field of biosafety and biotechnology in Southeast Asia and sub-Saharan Africa, by United Nations University Tokyo, Japan ($200,000; approved September 16, 2004;

b) Enhancing the capacity of Tanzania's Tropical Pesticides Research Institute to implement biosafety regulations and to assess and manage potential risks associated with genetically modified staple crops, through the training of one of its scientists at Agriculture and Biotechnology Strategies (Canada) Inc ($17,217; approved September 13, 2004).

c) Project by the Center for Science in the Public Interest to inform the international debate around scientific and regulatory issues related to biotechnology, and to put forward a middle ground on biotechnology in that debate ($250,000 approved May 18, 2004 and $150,000 approved March 17, 2003);

d) Project by Advocates Coalition for Development and Environment (ACODE)-Uganda to increase understanding and promote dialogues among scientists, policymakers and civil society on appropriate biotechnology and biosafety policies for eastern and Central Africa ($138,000 approved December 8, 2003);

e) Project to strengthen biosafety regulations and practices in Vietnam, implemented by the Ministry of Agriculture and Rural Development with support from Cornell University ($99,550 to Cornell University and $62,200 to MARD, approved February 2003);

f) African biosafety initiative to accelerate and improve the development and implementation of biosafety systems in sub-Saharan Africa, implemented by the Forum for Agricultural Research in Africa based in Accra, Ghana ($100,000 approved December 1, 2003);

g) Establishment of the Asia-Pacific Consortium on Agricultural Biotechnology (APCoAB), to harness the benefits of agricultural biotechnology for human and animal welfare, while safeguarding the environment and sustainable agricultural development in the Asia-Pacific region, by Asia - Pacific Association of Agricultural Research Institutions (Bangkok, Thailand; $90,000 approved December 30, 2003).

The foundation seeks to: 1) enhance the capacity of developing countries to develop and implement biosafety regulatory systems and to assess and manage potential risks associated with genetically modified crops; 2) to promote debate and dialogue around scientific and regulatory issues related to biotechnology; and 3) promote harnessment of the benefits of agricultural biotechnology for human and animal welfare, while safeguarding the environment and sustainable agricultural development. For details see: http://www.rockfound.org

Annex 1: Summary of the Ongoing Capacity-Building Initiatives and Elements of the Action Plan to Which They Contribute

Name of the lead agency	Name of the capacity-building project or activity	A: Institutional building	B: HRD & training	C: Risk assessment	D: Risk management	E: Awareness, education & participation	F: Information exchange & management including use of the BCH	G: Scientific, technical, & institutional collaboration	H: Technology transfer	I: Identification of LMOs	J: Socio-economic considerations	Other
AGBIOS - Agriculture and Biotechnology Strategies	1. AGBIOS Essential Biosafety Programme	X	X			X	X					
ASARECA - Association for Strengthening Agricultural Research in Eastern and Central Africa	2. ASARECA Biotechnology and Biosafety program	X	X	X	X			X	X			
ASEAN - Association of South East Asian Nations	3. ASEAN Activities Related to Biosafety Capacity Building	X	X	X		X	X	X				
Australian Government - Quarantine and Inspection Service	4. Training support to developing countries in new technologies for plant quarantine management		X	X								
Belgium Government - Royal Belgian Institute of Natural Sciences	5. Biosafety Clearing-House: Data Search and Input Support Project						X					
BATS - Center for Biosafety and Transdisciplinary Sustainability Management	6. BATS Biosafety and Sustainability Management Training Initiative		X					X				
Caribbean Council for Science and Technology (CCST)	7. CCST Project on Capacity Building in Biosafety for the Caribbean	X	X	X	X	X	X	X				
CGIAR - Consultative Group on International Agricultural Research	8. CGIAR Biosafety Capacity-Building Activities	X	X	X			X	X				
Danish Government - DANCEE &DANCED	9. Danish Assistance to Capacity-Building in Biosafety	X	X			X		X				
European Association for Bioindustries (EuropaBio)	10. EuropaBio Capacity Building Framework						X	X				
FAO - Food and Agriculture Organization of the United Nations	11. FAO general technical support to member countries in biotechnology and biosafety	X	X				X		X			
	12. Regional Project on Capacity Building in Biosafety of GM Crops in Asia (GCP/RAS/185/JPN)	X	X	X	X	X	X	X		X		

		Institutional building	Training	Risk assessment	Risk management	Awareness/ participation	Information exchange/ BCH	Scientific/ tech. coop.	Tech. transfer	Identification	Socio-econ. Issues	Others
	13. Capacity Building Project on Regulation of Import, Contained Use and Release of Genetically Modified Plants and Plant Material in Malaysia (TCP/MAL/2901)	X	X							X		
	14. Project on Strengthening the National Capacity in Biotechnology and Biosafety in Grenada (TCP/GRN/2902	X	X			X						
	15. Fortalecimiento Institucional para la Gestion de la Seguridad de la Biotecnologia en Bolivia (TCP/BOL/2902)	X					X				X	
	16. Capacity-Building of Regulatory Agencies for Handling Genetically Modified Crops, Products and Processed Foods in Kenya (TCP/KEN/3001)	X	X				X	X				
	17. Strengthening National Capacities in Formulation and Implementation of Legal Instruments on Genetically Modified Organisms in Swaziland (TCP/SWA/3003)	X	X			X						
	18. REDBIO/FAO - Technical Cooperation Network on Plant Biotechnology in Latin America and the Caribbean	X	X			X	X	X	X			
Germany Government - Federal Ministry for Economic Cooperation & Development (BMZ) and GTZ	19. Biosafety Capacity-Building Project in China: Data Management, Promoting Expertise and Awareness Raising		X			X	X					
	20. AREA ED Project on Civil Society Participation in Algeria's Biosafety Process		X			X	X					
	21. African Union Biosafety Capacity Building Programme	X	X	X	X	X		X				
Germany Government - Federal Ministry for Health and Social Security (BMG)	22. EU Twinning Project PL 01/EN/IB/03 – "Biological Safety System in Poland"	X	X	X	X	X	X	X	X			
GIC - Global Industry Coalition	23. GIC Regional Website Initiative		X			X	X	X				
ICGEB - International Center of Genetic Engineering and Biotechnology	24. ICGEB African Resource and Training Regional Centre for Biosafety and Protection of Biodiversity		X	X		X	X	X	X			

		Institutional building	Training	Risk assessment	Risk management	Awareness/ participation	Information exchange/ BCH	Scientific/ tech. coop.	Tech. transfer	Identification	Socio-econ. Issues	Others
	25. ICGEBNet and Biosafety Unit Capacity-Building Programme		X	X		X	X					
	26. ICGEB Biosafety Outstation		X	X	X			X	X			
ICIPE - International Center of Insect Physiology and Ecology	27. BIONET-Africa: Network for Capacity Building in Biotechnology and Biosafety for African Universities	X	X				X	X				
IFPRI - International Food Policy Research Institute	28. USAID-funded Program for Biosafety Systems (PBS)	X	X	X	X	X		X	X			
	29. ISNAR Biotechnology Service (IBS)		X				X	X				
ILRI - International Livestock Research Institute and NEPAD - New Partnership for Africa's Development	30. NEPAD Biosciences Facility for Eastern and Central Africa	X	X					X	X			
ISAAA - International Service for the Acquisition of Agri-biotech Applications	31. ISAAA Biosafety Initiative	X	X					X				
ISEES - Institute for Social, Economic and Ecological Sustainability, University of Minnesota	32. ISEES Biosafety Governance Program		X	X		X	X					
IUCN – World Conservation Union – Regional Biodiversity Programme, Asia	33. Biosafety Capacity Building Initiative in Asia	X	X	X	X	X	X	X	X	X		
	34. National Biosafety Framework support to Maldives, Cambodia, Vietnam and Sri Lanka	X	X	X	X	X	X	X	X	X		
IUED – Institut Universitaire d'Études du Développement (IUED), University of Geneva	35. Environnement et Développement durable: les enjeux de la biosécurité - Réseau Interdisciplinaire Biosécurité (Biosafety Interdisciplinary Research Network)		X	X				X				

		Institutional building	Training	Risk assessment	Risk management	Awareness/ participation	Information exchange/ BCH	Scientific/ tech. coop.	Tech. transfer	Identification	Socio-econ. Issues	Others
IDS - Institute of Development Studies, University of Sussex	36. Research Programme on Agricultural Biotechnology and Policy Process in Developing Countries	X	X			X						
Iowa State University	37. Biosafety Research Program for Genetically Modified Agricultural Products (BIGMAP)	X	X	X	X	X	X			X	X	
Norwegian Institute of Gene Ecology (GenØk)	38. GenØk Biosafety Capacity-Building Programme											
OAS - Organization of American States	39. OAS Project on Biosafety Regulations in Latin America and the Caribbean within the framework of the Biosafety Protocol	X	X	X	X	X		X				
PRI - Plant Research International	40. Biosafety Files Project	X				X	X					
Rockefeller Foundation	41. Support for Capacity-Building in Agricultural Biotechnology and Biosafety	X	X	X		X						
Swedish Government (Stockholm Environment Institute, SEI)	42. East African Regional Programme and Research Network for Biotechnology, Biosafety and Biotechnology Policy Development (BIO-EARN)	X	X	X		X						
Swiss Federal Institute of Technology Zurich (ETHZ)	43. Indo-Swiss Collaboration in Biotechnology (ISCB) Programme							X	X			
	44. IOBC GMO Guidelines Project	X	X					X				
The Edmonds Institute	45. The Edmonds Institute Biosafety Capacity-Building Initiatives					X	X					
Third World Network	46. TWN Biosafety Capacity Building Programme for Developing Countries		X			X	X					
UNDP/GEF - United Nations Development Programme/ Global Environment Facility	47. Malaysia Capacity Building Project for the Implementation of National Biosafety Framework	X	X	X		X	X					
	48. Mexico Capacity Building Project for the Implementation of National Biosafety Framework	X	X			X	X					
UNEP/GEF - United Nations Environment Programme/ Global Environment Facility	49. UNEP-GEF Project on Development of National Biosafety Frameworks	X	X	X		X		X				

		Institutional building	Training	Risk assessment	Risk management	Awareness/ participation	Information exchange/ BCH	Scientific/ tech. coop.	Tech. transfer	Identification	Socio-econ. Issues	Others
	50. UNEP-GEF Project for Building Capacity for Effective Participation in the Biosafety Clearing House (BCH)		X				X					
	51. Bulgaria Capacity Building Project for the Implementation of National Biosafety Framework	X	X	X		X	X	X				
	52. Cameroon Capacity Building Project for the Implementation of National Biosafety Framework	X	X			X	X					
	53. China Capacity Building Project for the Implementation of National Biosafety Framework	X	X	X			X					
	54. Cuba Capacity Building Project for the Implementation of National Biosafety Framework	X	X	X		X	X					
	55. Kenya Capacity Building Project for the Implementation of National Biosafety Framework	X	X			X	X					
	56. Namibia Capacity Building Project for the Implementation of National Biosafety Framework	X	X			X	X					
	57. Poland Capacity Building Project for the Implementation of National Biosafety Framework	X	X			X	X					
	58. Uganda Capacity Building Project for the Implementation of National Biosafety Framework	X	X			X	X					
UNIDO - United Nations Industrial Development Organization	59. UNIDO Biosafety Information Network and Advisory Service (BINAS)		X			X	X		X			
	60. UNIDO- University of Concepción Diploma in Biosafety	X	X	X	X							
UNU – United Nations University	61. UNU/BIOLAC Biosafety Project on Developing Guidelines for Latin America and the Caribbean	X	X			X						
	62. Rockefeller-funded project on assessment of international initiatives for building capacity in the field of biosafety and biotechnology in Southeast Asia and sub-Saharan Africa											

		Institutional building	Training	Risk assessment	Risk management	Awareness/ participation	Information exchange/ BCH	Scientific/ tech. coop.	Tech. transfer	Identification	Socio-econ. Issues	Others
US Government	63. NBII Support Project to provide BCH Templates for Databases and Websites	X	X				X					
	64. USAID Agricultural Biotechnology for Sustainable Development Project (ABSD)		X									
	65. USAID Regional Biotechnology and Biosafety Program in East/Central Africa		X									
	66. US Department of State biosafety capacity-building activities		X			X	X		X			
	67. USDA - NSF – NIH biosafety capacity-building activities	X	X									
Virginia Polytechnic Institute (Virginia Tech), USA	68. Research Project on Participatory Assessment of Social and Economic Impact of Biotechnology					X					X	
World Bank/GEF	69. Colombia Capacity Building Project for the Implementation of the National Biosafety Framework	X	X	X			X					
	70. India Capacity Building Project to Implement the National Biosafety Framework	X	X			X	X					
WRI – World Resources Institute	71. Project on Implementing the Biosafety Protocol	X				X					X	

ANNEX 2: SUMMARY OF SCOPE, OBJECTIVES AND ACTIVITIES OF MAJOR BIOSAFETY CAPACITY-BUILDING INITIATIVES

Organization	Project or program title	Period	Level of funding	Region/ Countries	Objectives	Main activities
UNEP-GEF	Development of National Biosafety Frameworks	2002-2005	43.6 M	123 countries in Africa, Asia, CEE and LAC	1. Assist countries to prepare national biosafety frameworks 2. Promote regional collaboration and exchange of experience 3. Provide information, advice and support to countries	1. Regional workshops on biosafety issues and elements of NBFs 2. Sub-regional workshops on risk assessment and public participation 3. Sub-regional workshops on regulatory regimes and administrative systems 4. Development and dissemination of awareness materials (newsletter, brochures) and other information (project website) 5. Development of guidance/ training materials (e.g. toolkits on NBF development, public participation) 6. National surveys of the current status of biotechnology, existing legal instruments and capacity-building initiatives 7. National workshops to promote awareness and discuss survey results 8. National stakeholder workshops/ consultations on NBF components 9. Preparation of NBFs, including drafting of biosafety policies, legislation and guidelines and systems for handling requests and for follow-up 10. Harmonization of national regulatory instruments
UNEP/GEF, UNDP/GEF World Bank/GEF	Demonstration projects on Implementation of National Biosafety Frameworks	2002-2005	35.1 M	12 countries: Bulgaria, Cameroon, China, Cuba, Kenya, Namibia, Poland & Uganda (UNEP), Malaysia & Mexico (UNDP) and Colombia & India (World Bank)	1. Finalizing national legislative/ administrative frameworks; 2. Strengthening human and institutional capacities (systems & infrastructure); 3. Promoting public awareness and public participation.	1. National biosafety seminars for parliamentarians, journalists and the public 2. National workshops to review and refine the draft NBFs 3. Training of lawyers and technical experts on key provisions of biosafety legislations, implementing regulations & tools 4. Study tour of the national coordinators to countries in Europe with practical experience on NBF implementation 5. Drafting/ revision of national policies, legislation and implementing regulations 6. Peer review of draft legislation by panels of experts 7. Development of formats for notifications/ requests for LMO import or release 8. Establishment of administrative systems for handling of notifications and requests for import or release LMOs 9. Establishment of registries for non-confidential information about requests for permits and decisions taken 10. Development of mechanism for reviewing risk assessments 11. Development of technical norms and standards for contained use/ field

						trials 12. Review of existing approaches for LMO monitoring 13. Development of manuals and training workshops for inspections 14. Strengthening systems for information exchange, databases & BCH links 15. Development of a practical guide on regulatory regimes for biosafety, handling of requests for permits (including systems for administrative processing, risk assessment and decision making), enforcement and monitoring for environmental effects, and public information and public participation.
UNEP/GEF	Building Capacity for Effective Participation in the Biosafety Clearing-House (BCH) of the Cartagena Protocol	2003-2006	4.61 M	51 countries, initially (88 others could potentially join)	Enable countries to fully participate in, benefit from, the BCH by: 1. Strengthening national human resource capacity, through training, in data management and in the use of the BCH 2. Assisting countries to establish appropriate infrastructure (computer hardware and software) for data storage and exchange with the BCH 3. Developing computer-based BCH training materials/ toolkits	1. Training of trainers (regional experts) in the BCH 2. National training workshops on the use of the BCH to access information required for decision-making and register information 3. Support for purchase and installation of equipment for national BCHs (with Internet connectivity) – if required, according to each country's specific needs 4. National training workshops for technical personnel that will be responsible for maintaining and registering information in the national BCH (as required) 5. Establishment of a roster of regional experts to assist in the design and development of the national participation in the BCH
IFPRI & USAID (in collaboration with: Donald Danforth Plant Science Center, Michigan State University (MSU); Western Michigan University (WMU), University of Minnesota, & International Life Sciences Institute, ILSI)	Program for Biosafety Systems (PBS)	2003-2008	14.8 M	14 countries in Asia (Bangladesh, India, Indonesia & Philippines), Eastern Africa (Kenya, Uganda, Tanzania & Ethiopia), Southern Africa (Malawi, Mozambique & Zambia) and West Africa (Ghana, Mali & Nigeria	1. Analysing the implications of different national/ regional biosafety regulatory approaches and developing new models to assist regulatory agencies 2. Facilitating regulatory approvals of specific technologies by helping R&D institutions to develop stronger applications and assisting regulatory agencies to conduct more effective reviews 3. Building scientific & technical capability to conduct environmental, food and feed safety assessments of biotechnology products and to	*Policy development and implementation* 1. Review of alternative approaches to environmental and health risk assessment and development of new approaches 2. Assessment of costs of compliance with biosafety regulations in PBS countries and the overall costs of the regulatory evaluation process itself 3. Case studies of existing regulatory systems to draw lessons that would assist in developing new models for regulatory systems and decision-making 4. Comparative legal analysis of the national regulatory systems as related to the Cartagena Protocol, Africa Model law, WTO & standard-setting bodies

					create communications capacity for policy makers and scientists 4. Supporting biosafety research, through competitive grants, to build capacity in risk assessment and management and to generate data that would help to better understand the interaction between GM crops, agriculture, and the environment	5. Regional policy roundtables to review findings from PBS studies, discuss common concerns and consider options for harmonization of approaches. *Regulatory approval strategies* 6. Technical advice to regulatory agencies in reviewing/ evaluating field trial applications and in developing regulatory systems for confined field trials 7. Training workshops for regulatory agencies on how to review confined field trial applications and for inspectors of field trials 8. Study tours for Biosafety Committee members to the Danforth Centre 9. Advice & training of potential applicants from R&D institutions in developing packages for field trial applications that address biosafety requirements *Capacity-building and communication* 10. One-week international food safety courses by Michigan State University (MSU), with emphasis on GM-foods 11. International short courses by MSU in environmental aspects of GMOs 12. Biosafety internships (3-4 months) at MSU 13. Regional workshops on safety and risk assessment of GM-derived foods 14. Training workshops in communication for spokespersons in PBS countries 15. Development of regional communication strategies to raise the profile of biotechnology and biosafety. *Biotechnology-biodiversity interface (BBI) grants*

						16. Funding of biosafety research projects, through competitive grants
Stockholm Environment Institute (SEI) in collaboration with regional/ national scientific and regulatory institutions in East Africa	East African Regional Programme and Research Network for Biotechnology, Biosafety and Biotechnology Policy Development (BIOEARN)	1999-2008	5.4 M	4 countries in Eastern Africa (Ethiopia, Kenya, Tanzania and Uganda)	Overall objective is to build national and regional capacity in biotechnology, biosafety and biotechnology policy development. The specific objectives are: 1. Enable countries to develop policies on biotechnology and biosafety, including training & dialogue in policy formulation, analysis and implementation 2. Promote collaboration in biotechnology, biosafety and biotechnology policy development 3. Foster communication between scientists, policy makers, biosafety regulatory officials and private sector 4. Promote biosafety research and contribute to building national capacity in biosafety implementation	1. Regional biosafety awareness workshops for policy-makers and the public 2. Training workshops (8) for regulatory scientists and policy makers in biosafety implementation, including biosafety assessment & management and field evaluation of GM crops for members of National Biosafety Committees 3. Country studies on biosafety implementation - analysis of regulatory systems of Kenya & Uganda to generate ideas for their improvement 4. International training programs and regional workshops on biosafety regulations, risk assessment and management 5. M.Sc. training in Ecology (6 students) at Lund University, Sweden. 6. Ph.D. training and research projects (4) in ecological risk assessment of GM crops 7. Biosafety research - ecological impact assessment research on exotic organisms and GM crops in East Africa 8. Compilation of basic biological information (botanical files and gene files) on key crops and their wild relatives (e.g. sexual or vegetative reproduction, growth rate, weediness, etc) to support local biosafety assessment 9. Development of a Biosafety Manual (resource book) for actors involved in the implementation of biosafety regulations (policy makers, scientists, regulators, applicants, NGOs and other interested stakeholders).
African Union	Africa-wide Capacity Building Programme in Biosafety	2004-2007	4.2 M	All African Union Member States	To strengthen the capacity of the African Union Member States to deal with biosafety issues	1. Assistance in formulation of national biosafety laws 2. Development of technical papers, handbooks and information kits on biosafety 3. Training in risk assessment and risk management. 4. Establishment of pilot analytical laboratories for GMOs 5. Strengthening national institutions dealing with biosafety
FAO	Capacity Building Project in Biosafety of GM Crops in Asia	2002-2005	1.2 M	10 countries: Bangladesh, China, India, Indonesia, Malaysia, Pakistan,	Overall goal: Assisting countries in safe harnessing of the benefits of biotechnology in accordance with relevant global agreements. The	1. National and regional consultations to identify existing strengths and weaknesses of national capacities 2. National stakeholder workshops to streamline national capacities for linking policy, technology and biosafety issues

				Philippines, Sri Lanka, Thailand & Viet Nam	specific objectives are: 1) Strengthen national capacity to scientifically assess and manage GMO risks 2) Establish/ strengthen technical cooperation among countries to ensure safe introduction and use of GM crops, based on transparent, science–based approaches (including harmonization of regulatory frameworks and establishment of a regional forum to facilitate regulatory collaboration and exchange of information and expertise on GM crops)	3. National and regional training workshops on procedures and methodologies for biosafety risk assessment and updates on developments in GM risk management options. 4. Regional consultations to promote harmonization of biosafety frameworks – methodologies, guidelines, standards & regulations – to deal with concerns relating to the development, trade and commercialization of GM crops 5. Meeting to evaluate the extent of adoption of harmonized biosafety measures, methodologies and regulations 6. Establishment of an Asian Biotechnology Network (Asia Bio-Net) to facilitate information exchange and data management and to provide a forum for sustained regulatory collaboration among Asian countries. 7. Setting up of Internet-based national and regional centers for GM crops database management and information exchange mechanisms, 8. Collection, analysis and exchange of GM-related information through inventories, databases and decision-support systems 9. Training manuals on technical aspects of biotechnology in relation to biosafety and risk assessment procedures fro biosafety risk of GM crops 10. Regional training workshop on GMO detection/ testing 11. National training workshops to strengthen research and technology development capacity for the assessment and management of environmental risks related to GM crops 12. Initiate specific research and technology development activities to develop methods to support scientific risk assessment of GM crops