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UPDATE ON ONGOING BIOSAFETY CAPACITY-BUILDING INITIATIVES: A COMPILATION OF SUBMISSIONS MADE AT THE SECOND COORDINATION MEETING; 18-20 JANUARY, TROMSO, NORWAY

CONTENTS

SUBMISSIONS FROM PARTIES AND OTHER GOVERNMENTS	3
BAHAMAS	3
BULGARIA	4
CHINA	
CUBA	7
MALAYSIA	9
MEXICO	10
MOLDOVA (REPUBLIC OF)	13
SWEDEN	16
TOGO	17
ZAMBIA	18
SUBMISSIONS FROM ORGANIZATIONS	19
UNITED NATIONS ORGANIZATIONS AND AGENCIES	19
FAO	19
UNEP-GEF BIOSAFETY UNIT	23
UNIDO	
THE WORLD BANK	27
INTERGOVERNMENTAL ORGANIZATIONS	29
ICGEB	29

26

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UNEP/CBD/BS/COP-MOP/3/INF/11 Page 2

IPGRI (ON BEHALF OF THE CONSULTATIVE GROUP ON I	NTERNATIONAL
AGRICULTURAL RESEARCH, CGIAR)	32
PROGRAM FOR BIOSAFETY SYSTEMS, IFPRI	35
REGIONAL ORGANIZATIONS AND INITIATIVES	37
AFRICAN UNION COMMISSION	37
ORGANIZATION OF AMERICAN STATES (OAS)	38
NON GOVERNMENTAL ORGANIZATIONS	39
AREA-ED/GTZ PROJECT	39
PUBLIC RESEARCH AND REGULATION (PRRI)	42
THIRD WORLD NETWORK (TWN)	43
ACADEMIC AND RESEARCH INSTITUTIONS	46
DANISH INSTITUTE OF AGRICULTURAL SCIENCES – BIOSAFE'TRA	AIN PROJECT 46
GMO ERA PROJECT	47

SUBMISSIONS FROM PARTIES AND OTHER GOVERNMENTS

BAHAMAS	[11 JANUARY 2006]
	[SUBMISSION: ENGLISH]

UPDATE ON THE BAHAMAS NATIONAL BIOSAFETY CAPACITY-BUILDING EFFORTS

Stacey Wells-Moultrie
The Bahamas Environment Science and Technology Commission

Overall achievements

1. The Bahamas completed development of its draft National Biosafety Framework under the GEF-funded initiative in 2005. The Bahamas, through the process, was also able to develop a National Biosecurity Strategy as well as draft legislation for biosafety and biosecurity. These documents are all in draft form as they are yet to be approved by Cabinet for release as official policy and law.

Lessons learned

- 2. Completing the National Biosafety Framework (NBF) involved a great deal of coordination within country. The need for this coordination was one reason why the decision to also develop a National Biosecurity Strategy was taken. For an archipelagic small island nation, like The Bahamas, it would be impossible to replicate the administrative and management systems for biosafety for other related issues, such as invasive species, and to replicate this system for 13 islands. It was decided that to be most efficient, it was best to design systems that could cover a myriad of issues on all of the islands. This would provide most effective use of the financial, institutional and human resources available in the country.
- 3. Executing the project also proved to be very challenging as biosafety is a new issue for the Bahamian public. Engaging the public in this issue meant making this issue attractive, or as advertisers would say, "sexy". We were able to do this through the medium of television. We aired a PBS documentary on GMOs for two nights and followed the documentary on the second night with a panel discussion; panellists provided differing views on biotechnology and GMO development and use. The discussion also provided an opportunity for informing the public about policy and systems being developed to manage these organisms. These programs were aired on national television enabling those involved with the NBF project to reach not just people in the capital, but persons on all thirteen islands.

Efforts to collaborate and build synergies with others

- 4. Throughout development of its NBF and following its completion, The Bahamas has been engaged in dialogue with other Small Island Developing States (SIDS) about its framework and National Biosecurity Strategy and why the decision was taken to develop both. Workshops organized by the UNEP-GEF Biosafety Unit enabled opportunities for such dialogue which has continued via e-mail even after the project has been completed for The Bahamas. The Bahamas has been able to share with other SIDS, expertise it has been able to access and processes it used to enable it to successfully complete the NBF project.
- 5. Within The Bahamas, the Government has been able to build synergies in environmental management overall through the National Capacity Needs Self-Assessment project funded by GEF. This project enabled collaboration amongst stakeholders involved with biodiversity, biosafety, climate change

Page 4

and desertification to determine the best means of achieving implementation of various international environmental agreements associated with these issues. The project has resulted in the development of a draft National Capacity Needs Framework and a draft National Environmental Management and Action Plan; these documents prioritize capacity needs and set goals for environmental management in The Bahamas.

BULGARIA	[3 JANUARY 2006]
	[SUBMISSION: ENGLISH]

EXPERIENCES, PRACTICES AND LESSONS LEARNED IN CAPACITY-BUILDING FOR BIOSAFETY IN BULGARIA

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- 1. This report provides a self-assessment made by project personnel of Bulgarian UNEP-GEF implementing phase project to design and implement the national biosafety frameworks. Its aim is to assist policy makers in identifying tools that may help them to meet their obligations by drawing on the experience of Bulgaria, which is party to the Cartagena Protocol on Biosafety.
- 2. Our approach is to identify useful lessons that other countries can learn from us about what works, what does not works, when and why in the application of Bulgarian strategies and tools to design and implement National Biosafety Frameworks (NBF). It is not prescriptive, but aims to provide a toolkit for policy-makers faced with similar challenges that may help them.
- 3. The design and implementation of NBF is of course very country specific. It reflects the requirements and needs peculiar to each society. The report provide a good illustration of the range of factors which distinguish Bulgaria from other countries and lead to tension between the pressure to harmonize international rules on the trade in GMOs, on one hand and the need to respond to and accommodate local needs and priorities, on the other. Among those factors are considered the particular country's trading relationship with the European Union, Bulgarian country's specific strategic position or competitive capacity in relation to the biotechnology industry and essential domestic factors like political culture, legal system and socio-economic issues. Nevertheless the country specific differences, faced with similar challenges, there is much that Parties can learn from one another about the design and implementation of their NBF.

CHINA	[6 JANUARY 2006]
	[SUBMISSION: ENGLISH]

ONGOING AND PLANNED BIOSAFETY ACTIVITIES ON CAPACITY-BUILDING IN CHINA

Dayuan Xue Nanjing Institute of Environmental Sciences, China

1. During the past three years, China has conducted two projects on biosafety capacity building. One is UNEP/GEF Demonstration Project for Implementation of National Biosafety Framework in China

and another one is GTZ funded Project of Biosafety Capacity Building in China: Data Management, Expertise Enhancement and Awareness Improvement. The former is a government-oriented project conducted by SEPA (China State Environmental Protection Administration) and joined by other ministries, and the later one is executed by Nanjing Institute of Environmental Science directly under SEPA, collaborated with some NGOs and universities. In addition, a UNEP/GEF case study project of China State Biosafety Framework Preparation was conducted during 1997-1999.

1. UNEP/GEF Project of China National Biosafety Framework Preparation

2. The project was headed by SEPA and co-conducted by 8 ministries of environment, agriculture, forestry, commerce, science and technology, education, public health and science academy. Based on the precautionary principle, the Framework proposed the outlines of state policies on biotechnology development and biosafety management, the systematic structure of biosafety legislation, the frame technical guidelines for GMOs' risk assessment, risk management and environmental monitoring, national focuses on biosafety capacity building and priority projects on GMOs management for the next 10 years. The framework was finished and issued by government in 1999. It has established a foundation on biosafety capacity building in China.

2. UNEP/GEF Demonstration Project on Implementation of China's National Biosafety Framework.

3. This project is a follow-up activity for implementation of China National Biosafety Framework, with funding of USD 997400 during 2002 to 2005. The project has focused on such themes as below:

National Biosafety Policy and Legislation: The project has proposed a series of national policies on biosafety issues, such as national strategy for GMO technology development, policies for management of LMOs trans-boundary movement, and national coordination mechanism for related governmental departments. As a main outcome, the project has developed a draft of "GMOs' Biosafety Law". This draft law, as a comprehensive regime, comprises several chapters of GMOs' risk assessment, risk management, environmental monitoring, transboundary movement, labeling system, liability and redress, emergency treatment, and so on. Nevertheless law development is a long way for law development, the project has initiated the process and the further inter-ministerial negotiation and consultation will be continued in the next a few years before the law is launched.

Technical guidelines for risk assessment, risk management and environmental monitoring for GMOs. A series of detailed technical guidelines have been drafted out by the project and other national projects. Totally, there are about 40 guidelines under preparation. For example, the guidelines for GM plants include risk assessments for insect-resistant GMOs, disease-resistant GMOs, herbicides-resistant GMOs and gene flow of GMOs. Others include guidelines of risk assessment for GM animals, GM fishes, GM micro-organisms and GM foods. The guidelines of environmental monitoring for the environmentally released and commercialized GMOs comprise the impacts of Bt cotton on target insects, non-target insects, natural enemy, silkworms and soil micro-organisms.

BCH establishment: The project has directly promoted the establishment of China National Biosafety Clearing House (BCH) Mechanism and a national website special on biosafety has been established with the address of www.biosafety.gov.cn. The BCH contains a great deal of data and information, including governmental policies, regulations, information for commercialized GM crops, approved importing of GMOs and biosafety workshops. Also the BCH has a lot of linkages to governmental sectors. However, the BCH needs more construction and inter-ministerial coordination, because it does not have detailed information on agro-GMO applications, risk assessments and approvals.

Personal training: The project has involved in many scientists and officials and they have conducted a lot of researches. The several training courses have been run special for the officials and technicians who are in charge of biosafety issues. Besides of this project, China has run many courses to training local officials in agro-GMOs fields. However, personal training is still very week and needs to be enhanced.

3. GTZ Funded Project of Biosafety Capacity Building in China

4. The GTZ project is a supplement to UNEP/GEF Demonstration Project for Biosafety Framework Implementation. This project is conducted by Nanjing Institute of Environmental Science, SEPA of China, collaborated with Greenpeace China, Biosafety Branch of China Society of Agro-biotechnology, China Renmin University, etc. The project has focused on the activities as follow:

Develop database on GMOs researches, cases information for field trail and commercialization, as well as details of the institutions and experts who conduct the GMOs researches, based on institutional surveys and personal investigations.

Establish a web site, feeding in of data, accessing it to the Internet, linking it to the national Biosafety Clearing House Mechanism, making the majority of data accessible to the public. Now the web site is under construction.

Publish a bi-monthly biosafety newsletter. The newsletter has been published 24 terms totally. As an extra, a seasonally biosafety magazine to compile biosafety articles is also published for 10 volumes. The copies of the newsletter and magazine have been widely delivered to governmental officials, scientists, journalists and other readers. A biosafety network for readers has been formed.

Compile and publish EU Regulations on GMOs Management in Chinese version. Total 13 current EU regulations and documents were translated and edited in the compilation. The compilation has been published in 2005 and the copies were also delivered to related officials and experts. It is helpful for Chinese government to learn experience from EU.

Promote international expertise exchange on biosafety. The GTZ project has funded two international workshops (each 3 days) in 2004 (Beijing) and 2005 (Nanjing) respectively. Totally about 20 foreign experts from EU countries, Norway, USA, Malaysia and other countries exchanged their experience with Chinese experts and governmental officials in the two workshops. The workshops are characterized by a wide participation for all stakeholders of governmental officials, scientists and biotechnologists, media journalists, NGOs, enterprise and biotech company people. The high level officials from more than 10 ministries of environment, foreign affairs, agriculture, forestry, commerce, science and technology, public health, food and drug, quarantine and inspection, intellectual property right and science academy participated the two workshops. The workshops have produced a large impact on national biosafety policies in China.

Investigate public awareness on GMOs and food safety. A questionnaire interview survey was conducted in 12 supermarkets and 6 universities in Beijing, 2004 and 1600 consumers were investigated. The survey results revealed that 64.9% interviewees were not acquaintance to GMOs and GM products, while only 2.3% of respondents had a good understanding. With respect to GMOs labeling, 45.3% of interviewees dd not know that GMOs are enforced labeling in China, another 42.6% couldn't identify the existing GMOs labels because the labels are not clear. Other surveys are also conducted in China with a same trend. Based on the investigation, a framework on public participation in biosafety for government consideration will be formulated as a planned project activity.

4. Present Status and Capacity Building Needs

- 5. By end of 2004, Ministry of Agriculture had received 1044 cases of GMOs applications of which 707 cases were approved, including 446 cases for field trials (contained trial), 198 cases for environmental release (field trial under 1 hectare) and 55 cases for productive trials (larger than 2 hectare) and 73 cases for commercialization. Most commercialized cases are insect-resistant *Bt* transgenic cotton and only a few for late-ripened and virus resistant tomato, virus resistant sweet pepper and color-changed petunia. In 2005, the plantation of *Bt* cotton was up to 4.5 million hectares, accounting for 70% of whole cotton plantation.
- 6. In 2001, the State Council issued the Biosafety Regulation for Agro-GMOs. Based on the regulation, three detailed implementation sub-regulations were issued in 2002 for GMOs risk assessment, importing GMOs management and GMOs labeling system. The regulation requests documentation for importing GMOs and the 17 GMOs products from 5 GM crops are listed for labeling in market. To enhance GMOs detection, now 22 laboratories distributed in whole China have been selected for construction.
- 7. For enhancement of capacity building, China needs more efforts in GMOs legislation, in particular to stipulate for a GMOs Law that can enlarge GMOs' scope to GM trees, flowers and medicines, not only limited to agro-GMOs. Also the attention needs to strengthen execution of the current regulations, especially strengthen enforcement of GMOs labeling in local areas.
- 8. Biosafety research is a priority for capacity building in China. During the past years China has put 8 million US dollars for GMOs biosafety researches, which is not a big figure comparing with the investment in biotechnology development. So more financial supporting for biosafety research is necessary, a potential source should be the financial mechanism of Cartagena Protocol.
- 9. The laboratory facilities for GMOs detection and field monitoring system are also significant As China imports 20 million ton GM grains each year, well-equipment laboratories are needed for quarantine and inspection of GMOs trade, especially in port cities. China has commercialized Bt cotton for 8 years, therefore, a field monitoring system is needed for establishment, which is essential to risk management of Bt cotton and other potential environmentally released GM crops.
- 10. In addition, China needs to set up public participation mechanism. Now the public is lower awareness on GMOs and GM food and shortage for participating in governmental decision-making of GMOs' environmental release and commercialization. Capacity building is needed to establish formal channels for public to get relevant information and give their opinions, and ensure consumers' right to know what they eat and right to choice their foods.

CUBA	[23 DECEMBER 2005]
	[SUBMISSION: ENGLISH]

PRACTICAL EXPERIENCES, BEST PRACTICES AND ACHIEVEMENTS FROM THE CUBA-UNEP/GEF PROJECT: IMPLEMENTATION OF NATIONAL BIOSAFETY FRAMEWORKS

Lenia Arce National Center for Biosafety, Cuba Page 8

1. The implementation of the Cuba-UNEP-GEF project on implementation of national biosafety frameworks project has led to:

The completion of the technical base (the creation of the Committee on Standardization. CTN 94) and the legal base (Decree-Law 190 and the rest of the regulations) on Biosafety that make possible the fulfillment of the Cartagena Protocol provisions from a better position.

The strengthening of the National Center of Biological Safety at a national level (NCBS) This Center is the National Authority for Cartagena Protocol.

The elaboration of the National Biosafety Strategy.

The elaboration of the LMOs risk assessment and monitoring methodology and the rest of the documentation regarding risk assessment process on the whole, such as, check lists guidelines etc.

The upgrading of the levels of awareness on Biosafety matters (training), which means that specialists involved in Biosafety activities, either from the NCBS or from the rest of the administrative bodies, are trained and have acquired some Biosafety skills.

The development of a Master Degree about Biosafety.

The possibility of watching over the compliance with the legislation in force (System of Inspection) and the development of a manual for performing biosafety inspections.

The fact of taking control over biological agents (System of Authorizations).

Concerning Information Exchange, the servers for the communication node and computers procured for the Institution and the regional branches are running. The Intranet was designed and installed. There is an active involvement in the information sharing with the BCH.

2. All these aspects have taken into account the broad involvement of different groups of stakeholders due to the great variety of project activities, regulatory activities, capacity building. Stakeholders (Universities, NGOs and Biotech Industry mainly) have been actively engaged specifically in the process of making the biosafety legislation, national strategy and training activities.

Main challenges

3. In the process of the implementation of the UNEP/GEF Project we have had some challenges to deal with. Such challenges were and some of them still are a consequence of the particular characteristics of Cuba concerning socio economic framework and within it, the Biosafety framework. We can mention here as a main challenge, the particular economical conditions in Cuba marked by an economical blockade we have been facing for more than 40 years. This situation places Cuba in a different position related to another countries referred to, because we were compelled to looking for other initiatives to try to mitigate its effects. Some of the specific challenges include the following:

Financial constraints regarding resources procurement for the strengthening of the National Biosafety System in general, including facilities which produce LMOs.

Primacy of scientific and economic criteria over safety issues.

Unawareness on safety culture issues.

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

The current functional structure of the NCBS has hindered the normal compliance of some task of the project.

How we dealt with these challenges

- 4. Unquestionably both, the UNEP/GEF Pilot Project in 1998 and the current Project UNEP/GEF Implementation of the National Biosafety Framework, have been the main way to deal with these challenges. The achievements above mentioned show how some of them have been addressed.
- 5. However we have applied some national initiatives that have contributed to dealing with these challenges. In matter of development of the human resources in general, and particularly to make that all those who are in charge of making decisions, change their mind on Biosafety-related topics, we have outlined a training program which includes Biosafety aspects aimed at executive personnel. In addition we have had coordination meetings with those state bodies strongly involved in Biosafety activities in order to set agreements about scopes, competences etc. In this case we have the Ministry of Public Health and the Ministry of Agriculture involved. We have also a National System of Biological Safety that it was created since 1996 and it is currently developed nationwide by having one representative specialized in biosafety issues and located in each province of the country. In addition we planned to make some changes in the functional structure of the NCBS in order to achieve a better fulfillment of the project and the Cartagena Protocol provisions.

Lessons learned

6. In the course of implementing the project, we have learned the following lessons:

We have learnt that from the end of a Project to the beginning of another project, there always is a deadlock period in which achievements on capacity building can be threatened.

We have learnt also about the necessity of updating the priorities on capacity building matter, which Cuba will analyse next year. This analysis will be based on the achievements reached through this project and its result will be submitted to the BCH.

Cuba is currently able to orienting its capacity building priorities towards more technical necessities i.e. the design and operation of a laboratory for identification and detection of LMOs.

Finally we consider that the exchange of experiences at regional and sub regional levels constitutes a very important issue. It allows the common use of the capabilities developed by other countries of the region, due to the similarities in language, culture etc which enriches the experiences of all these countries.

Opportunities for collaboration

7. Cuba can offer some opportunities for collaboration mainly focused on development of human resources, which means, training on Biosafety issues. Unfortunately our training program just can be developed in Spanish language; however we are working hard in order to extend it to the English language. We are involved now in the process of developing technical material about spheres like risk assessment among others that we will be pleased to share when this work is finished.

MALAYSIA	[24 JANUARY 2006]
	[SUBMISSION: ENGLISH]

UPDATE ON MALAYSIA'S BIOSAFETY ACTIVITIES AND CAPACITY BUILDING INITIATIVES

K. Nagulendran Ministry of Natural Resources and Environment, Malaysia

- 1. Malaysia played an important role in the early days of the CBD negotiations to introduce provisions on biosafety in the text of the convention. Since ratifying the CBD in 1994, Malaysia launched the National Policy on Biological Diversity in 1998. The policy has 15 strategies and 87 action plans to give direction to the nation on biodiversity management, where there is one strategy (Strategy XI) dedicated on biosafety which among others calls for the need for a national framework on biosafety. In 1996, the Government established the Genetic Modification Advisory Committee (GMAC) which came up with administrative guideline on the release of GMOs to the Environment (1997). This guideline is voluntary by nature and is an administrative procedure which has no legal implication. Malaysia started drafting her National Biosafety legal framework since 1997 known as the Biosafety Bill (when it is approved by the Parliament it will be known as the Biosafety Act). The Bill was developed with consultation of various stakeholders and is envisaged to be tabled in the Malaysian Parliament in 2006 for approval.
- 2. In the absence of a legal framework, Biosafety measures are done administratively, where GMAC advises the Ministry of Natural Resource and Environment, Malaysia (NRE) on any application on LMOs for contained use, introduction into the environment of for FFP. With the view of having the legal biosafety framework in place soon, Malaysia has taken some steps in developing her capacity. Malaysia through the Chemistry Department has facilities for GMO testing and this facility has been accredited as ASEAN Reference Centre for GMO testing. The Malayan University (Universiti Malaya) with assistance from UNIDO has planned to offer a Post Graduate Diploma in Biosafety eLearning course beginning this year. Malaysia too sends participants for the UNEP/ GENOK Holistic Foundations for Assessment and Regulation of Genetic Engineering and Genetically Modified Organisms workshop which are carried out in an annual basis to build up capacity on biosafety.
- 3. Nevertheless Malaysia still needs to build up her capacity further in various aspects of biosafety especially in GMO testing, risk assessment & management and other technical as well as legal areas. This capacity has to be build especially once the legal framework is in place and also to meet our obligations under the Cartagena Protocol on Biosafety. In this light, Malaysia has applied for the GEF project (through UNDP) on Capacity Building for Implementation of Malaysia's National Biosafety Framework. Malaysia is still awaiting for the final approval from GEF. This project is very important to complement Malaysia's initiatives and efforts in biosafety capacity building and Malaysia hopes this project will be approved by GEF soon.
- 4. In conclusion although there are some measures in place on capacity building on Biosafety but it is very minimal at the moment and we hope it will further be enhanced especially once the GEF project on capacity building as mentioned above starts.

MEXICO	[6 JANUARY 2006]
	[SUBMISSION: ENGLISH]

MEXICO-UNDP/GEF CAPACITY BUILDING PROJECT FOR THE IMPLEMENTATION OF THE NATIONAL BIOSAFETY FRAMEWORK: BEST PRACTICES AND LESSONS LEARNED IN CAPACITY-BUILDING FOR BIOSAFETY

Agustín López-Herrera National Project Coordinator

Introduction

Mexico was supported by the GEF as a demonstrative project in 2002 to strengthen its capacity in biosafety. The support given was of US\$1.43 million with a three-year plan. The characteristics for which Mexico was selected are as follows: being a very diverse country; having 12 years of experience in field releases of the LMO; having a legal structure in biosafety; and a system of organized ministries as a focus point in biosafety with a well trained staff in both biotechnology and biosafety.

Challenges

The main challenges and limitations encountered during the implementation of the project include the following:

1) Biosafety law of genetically modified organisms

Implement the law in all its aspects in collaboration with all the relevant authorities.

<u>Limitations</u>: The law has serious complications in its implementation and it is very difficult in the controversial area of the presence of OGM in food products and in crops. There is a lack of federal authority with the experience to achieve the level of regulation that the law asks for.

<u>Solution</u>: Experts trained in the project meet to find solutions to specific problems of the biosafety law, to enable their superiors to discuss the problems with their peers at other agencies. This procedure does not completely solve the present problem, but it is a step forward.

2) Flow of transgenic genes to wild relatives in maize.

Transgenic maize was released by accident in a small community in the state of Oaxaca, where only landraces are grown. When the presence of transgenes in landraces was detected, the world accused Mexico of negligence.

<u>Limitations</u>: In poor areas of the country it is a common practice to plant grain for food instead of seed from their landrace varieties. Sometimes in hurricane-prone areas it is harder to obtain seed, and farmers decide to plant regular grain coming from importing corn commodities. Mexico imports 6 million tons of maize from the United States every year.

Solution: Using some of the project finances, samples of maize were collected during a three-year period, and were analyzed in an internationally recognized laboratory to verify the presence of transgenes after this period. The result of this study was that transgenes were either not detectable or were not there. During this three-year period, experts at the Environmental Ministry gave educational workshops to discourage farmers once more from using this type of grain. With these actions, the landrace transgenes were eliminated. Another measure taken by the Mexican government was not to distribute maize coming from the United States, where the indigenous population is high.

Good Practices

- 1) *Methodologies: Risk Assessment:* The environmental and agricultural ministries jointly evaluate risks. These agencies share information to decide whether LMO can be experimentally liberated.
- 2) *Training of teachers:* The project financed two courses that were given to technical agricultural schoolteachers throughout the country. The success of these courses helped the education authorities to incorporate the subjects of biotechnology and biosafety into the curriculum of agricultural technician courses.
- 3) Database for the support of decision makers: This was developed with all the genetic information, reproductive biology and molecular biology of plants related to transgenic plants, including the wild varieties, in such a way that it is possible to know in advance the improved variety hybridization rate, as well as that of its wild relatives, in different environments of LMO field releases.

Lessons Learned

- 1) *Methodologies: Risk Assessment:* Having a consensual methodology permitted the government to adopt this way of action as an official mechanism. This assessment originated in an interdisciplinary team from different government agencies looking for common goals and using the same technical language.
- 2) *Training of teachers:* The authority agreement to incorporate new subjects into the curriculum of technical agriculture courses was largely thanks to pressures applied by teachers who wanted to obtain more actualized information on subjects such as biosafety and biotechnology.
- 3) Database for the support of decision makers: This information shows that it is very useful to know the possible risks in the genetic flow. Competent authorities have adopted this database for use in all risk assessments.

Principal Achievements

- 1) Confirmation of a team of experts in biosafety: The interaction of the representatives of the competent authorities in biosafety in the advancement of the UNDP-GEF project, both during and after the project, resulted in the consolidation of a team of experts in biosafety which is held in great confidence by federal authorities for their abilities.
- 2) Methodologies for environmental and agricultural risk assessment: The methodology for determining whether or not to approve the LMO release was expanded, and now it is easier to obtain the approval of the biosafety committee members and prepare technical summaries to inform the public about the application to perform LMO field releases. There are now electronic documents available online containing all the information, including biosafety measures, of current applications for LMO field releases, as well as information on the results of all applications for the past 15 years. Environmental risk evaluation can now be done through a specific methodology. The objective of this methodology is to know the possible effects caused by the genetically modified crops on the crops growing alongside them.
- 3) Laboratories: The project financed the equipment of two detection laboratories, one in the environment ministry and one in the agricultural ministry.
- 4) Sustainability: Project results were recognized by the Mexican government as important and useful. As such, federal authorities committed a further US\$1.4 million for 2005-2006 to continue with the project capability creation activities.

Synergies

- 1) Project personnel have supported other GEF projects: In the Central and South American regions Mexico has vast experience in risk assessment of LMO field releases. This is why the GEF projects of countries such as Guatemala and Nicaragua have solicited collaboration with Mexico to provide training to their respective biosafety committees. An evaluation of the national biosafety framework of the GEF project of Peru was performed in July 2005. The Interamerican Institute of Agriculture Collaboration (IICA, Spanish acronym) in Costa Rica solicited several advisories to expand the proposals: "A regulatory framework model for modified organisms for agriculture and husbandry use in Central American countries" and "A hemispheric developmental plan in biotechnology." In 2006 an open Masters program developed jointly by the IICA and the College of Postgraduate Studies of Mexico, will begin for Mexican and Central American professionals. This Masters program will contain biotechnology and biosafety information as part of its curriculum. Also, personnel from the GEF project of Colombia will receive a two-week training program in January 2006.
- 2) *International organizations and companies:* During the lifetime of the project, there has been a strong interaction with the Rockefeller Foundation, UNIDO, FAO, UNEP, as well as the large biotechnology companies.

Recommendations

- 1) It is convenient for the countries that ratified the Cartagena Protocol to have a complete legal framework with laws, rules, and standards.
- 2) In addition to the legal framework, the countries must possess all the administrative requirements that allow the law to be exercised to its fullest extent.
- 3) The countries of the region must meet periodically to create synergies and present them as proposals at international meetings.

MOLDOVA (REPUBLIC OF)	[11 JANUARY 2006]
	[SUBMISSION: ENGLISH]

ONGOING BIOSAFETY CAPACITY-BUILDING INITIATIVES IN THE REPUBLIC OF MOLDOVA

Angela Lozan Ministry of Ecology and Natural Resources, Moldova

Current Status of Biosafety

- Ratified the Convention on Biological Diversity on 16.05.1995
- Ratified the Cartagena Protocol on Biosafety on 11.10.2002
- Ratified the Aarhus Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters on 07.04.99
- Adopted the Biological Diversity Conservation National Strategy and Action Plan on 27.04.2001
- Adopted the National Law on Biosafety on 21.12.2001
- Established a National Biosafety Committee on 25.09.2003
- Adopted regulation on authorisation of the activities regarding of testing, production, use or marketing of GMOs on 25.09.2003

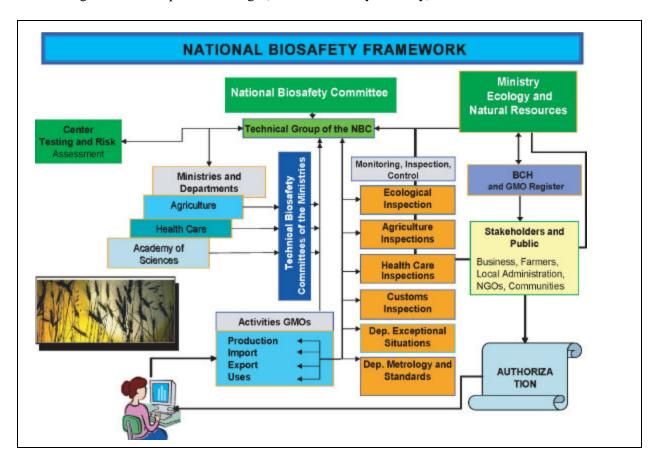
 Developed a Guide on Information and Public Consultations on Genetically Modi?ed Organisms – 10.02.2004

Biosafety in projects that contribute to the synergies and complementary initiatives

- **UNEP-GEF Project** "Development of the National Biosafety Framework (NBF) for the Republic of Moldova, 2002-2004
- **UK** "Support the Implementation of the National Biosafety Framework of the Republic of Moldova, 2003-2005
- UNEP-GEF Project "Capacity Building for Effective Participation in the BCH", 2005-2006
- **UNDP-GEF Project** "National Self-assessment of Capacity Building Needs for Global Environmental Management", 2003-2005
- **UNEP-GEF MSP Project Proposal** "Support the Implementation of the National Biosafety Framework of the Republic of Moldova", (submitted).

Good Practices performed

- National Biosafety Framework elaborated
- National laws and regulations on GMOs approved
- Awareness raising: workshops & round tables for experts, researches, decision-makers and public authorities
- Publications (books, brochures, guidelines), web-page, dissemination
- First BCH Training course and regional advising (BCH Internet Training module)
- Sub-regional workshops and trainings (Lithuania, Turkey, Norway)



Priorities Identified for Moldova

- Enforce comprehensive National Biosafety Policy as the basis for the development of the adequate national regulations and institutional framework
- Establish responsive and fully functional national regulation framework in line with CP and national needs
- Enable national system for handling request and decision-making as well as performing risk assessment and management associated to LMOs
- Encourage national system for "follow-up" activities, namely monitoring of environmental effects and legislation enforcement
- Enlarge public awareness, education and participation to ensure access to information

Lessons learnt

- The CP proven as target priority at the national level
- A number of government and NGOs present an efficient partnership
- National stakeholders were highly interested in improving knowledge and continue to promote the biosafety principles
- Limited technical and financial resources do not permit to ensure efficient operation of national biosafety framework
- Unauthorized import of GMOs food and unlabeled feed (9 samples)
- Poor synergy and complementary in Biosafety initiatives

Synergism on Biosafety initiatives and the development policies of the country

- The Aarhus Convention on Access to Information, 1999
- National Concept for Natural Farming, Production and Distribution of Environmentally Clean and non-GMO Food, 2000
- Concept of the Environmental Policy of the R. Moldova, 2001
- National Action Plan on Health and Environment, 2001
- Strategy for Economic Growth and Poverty Reduction (2004-2006), 2004
- Action Plan "Republic of Moldova European Union", 2005
- NAP on Building Capacities for the Integrated Implementation of the Rio Environmental Conventions for the period 2005-2010, 2005 (under approval)

Barriers and impediments

- Uncoordinated/Disconnect activities promoted by responsible institutions
- Insufficient financial allocations for implementing the environmental plans and strategies
- Limited access to information on Biosafety and lack of statistical data on GMOs
- Insufficient national capacity to implement appropriate Biosafety measures
- Lack of efficient inspection, custom control and emergency procedures on biosafety
- Insufficient capacities in GMOs detection
- Secondary and sectoral regulation not harmonized

Proposals to the effective implementation Cartagena Protocol

- Strengthen synergy and complementary principle in various Biosafety related initiatives/projects at national level: Environmental security; Biodiversity conservation; Health care and the environment; Agricultural biological production; Food and feed safety; Poverty reduction; and Rural development
- Consolidate efforts and synergy effects of projects implemented under UNEP, WB, UNDP, FAO, USAID, TACIS and others.

• Enlarge definition of the LMOs covered under the CP and include clones, organisms with not DNA recombinant, but genetically transformed, pharmaceuticals for humans obtained with LMOs

SWEDEN	[16 JANUARY 2006]
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UPDATE ON THE EAST AFRICAN REGIONAL PROGRAMME AND RESEARCH NETWORK FOR BIOTECHNOLOGY, BIOSAFETY AND BIOTECHNOLOGY POLICY DEVELOPMENT (BIO-EARN)

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- 1. The Swedish International Development Agency, Sida has provided support to the Eastern African programme and research network for biotechnology, biosafety and biotechnology policy, BIO-EARN, since 1999. The programme has mainly focused on building capacity in biotechnology, bio-safety and biotechnology policy development in Ethiopia, Kenya, Tanzania and Uganda. The main modalities have been research training (human resources and research infrastructure). The programme involves research cooperation between 15 research institutions in Eastern Africa (Ethiopia, Kenya, Tanzania and Uganda), Sweden and other European countries, linked in a research network.
- 2. BIO-EARN has trained 17 PhD students in agricultural, environmental and industrial biotechnology and 6 MSc students has been trained in biosafety research, out of which 3 proceeded for PhD studies. BIO-EARN also organized six regional bio-safety workshops, with >150 participants, and improved the ability of bio-safety regulatory officials to implement bio-safety regulations and carry out bio-safety assessments. The programme has also developed a common risk assessment/management decision support material. In addition a BIO-EARN bio-safety resource book has been developed in collaboration with the bio-safety regulatory officials in the region to facilitate biosafety implementation and information sharing. Individuals and material from the BIO-EARN Programme have been used as resources in policymaking process in all four countries.
- 3. The programme was evaluated in 2004. The evaluators note that BIO-EARN took a rather action-oriented approach in selecting research partners, rather than formalising its activities at the institutional levels. This approach has been instrumental to rapid programme start-up, creating a clear output in terms of trained researchers and functioning laboratories. The consequences of this somewhat informal approach are weak institutional commitment and insufficient ownership of the programme in the region.
- 4. The reviewers strongly supported the continuation of the BIO-EARN Programme and emphasised that planning should take into account the changed biotechnology environment in the region. They point to the need for stronger ownership of such a programme and clear structures for governance and management at all levels. An application that has responded to the recommendations of the evaluators, and the concerns of key relevant actors at national and regional level, has been submitted to Sida through the Uganda National Council for Science and Technology (UNCST) and is presented in this Memorandum.
- 5. In short, it is proposed that the programme be exclusively coordinated from Eastern Africa through a BIO-EARN Regional Office housed at the Inter University Council of Eastern Africa (IUCEA) in Kampala. The application concerns support for five large biotechnology R&D projects which involve

BIO-EARN PhD graduates. Research training will be an integrated part of regional research projects in collaboration with Swedish institutions. A minor fund is also proposed in order to support strategic demonstration projects, policy research and integrative research across the programme.

6. Sida has decided to continue to support BIO-EARN during the period 2006-2009 of at most MSEK 77, of which at most MSEK 16,2 during 2006, at most MSEK 19,5 during 2007, at most MSEK 20,2 during 2008 and MSEK 21,1 during 2009.

TOGO	[30 DECEMBER 2005]
	[SUBMISSION: ENGLISH]

OVERVIEW OF THE PROGRESS IN AND EFFECTIVENESS OF, THE IMPLEMENTATION OF BIOSAFETY CAPACITY BUILDING ACTION PLAN IN REPUBLIC OF TOGO

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Republic of Togo was one of the first developing countries to ratify and become Party of Cartagena Protocol on biosafety. Furthermore, in accordance with different decisions of Conferences Of Parties serving as Meetings of Parties (COP-MOP), Togo is implementing the capacity building action plan of the Cartagena Protocol. This note presents the summary of the progress in, effectiveness of and difficulties in this implementation.

I. Progress realised

Some progress was made by Togo in capacity building action plan implementation in institutional and human resources level. For example:

- Togo had adopted its National Biosafety Framework (N.B.F.)
- Law on introduction, transport and handling of GMOs and LMOs in Togo is already introduced at the national assembly for study and adoption
- National Competent Authority (NCA), National Project Coordinator (NPC) and National Biosafety clearing House coordinator were designated.
- National Biosafety Experts were submitted to the roster of experts in the BCH.

II. Difficulties encountered

The main difficulties in implementation of capacity building action plan encountered in Togo are common to developing countries in general and to sub-saharian African countries in particular. These difficulties are of a financial and technical nature.

Regarding funding management, Togo is largely dependant on donor's assistance but because of socio political problems, it cannot receive bilateral support from principal developed countries donors. Only Global Environment Facility (GEF) had provided financial support to Togo for setting up its national biosafety framework under project N° GF/2716-02-4387.

The lack of financial means did not also allow National Competent Authority (NCA) of Togo to start national BCH activities and to organize workshops for public training, awareness, participation and education on risks related to the GMOs and LMOs use and handling.

UNEP/CBD/BS/COP-MOP/3/INF/11

Page 18

With regard to infrastructure, Togo does not have laboratories enabling it on the one hand, to determine the GMOs content in imported foods and on the other hand, to evaluate the risks on human health and on the environment.

As well, the lack of institutional, technical and scientific collaboration and exchange of information between Togo and countries in the sub-region regarding biosafety policies, laws and regulations should also be mentioned.

ZAMBIA	[30 DECEMBER 2005]
	[SUBMISSION: ENGLISH]

ZAMBIA-NORWAY IN BIOSAFETY CAPACITY-BUILDING

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Introduction

The aim of the project is to assist Zambia implement the Cartagena Protocol on Biosafety and the National Biotechnology and Biosafety Policy. The project had two components. The purpose of Component I was to take steps that would lead to the enactment of legislation that govern the research, development, application and commercialisation of modern biotechnology. The purpose of Component II was to assist the National Institute for Scientific and Industrial Research (NISIR) perform its function as National Biosafety Focal Point in accordance with provisions of the Cartagena Protocol on Biosafety.

Achievements

The project facilitated the implementation of the some aspects of the Convention on Biological Diversity (CBD), Cartagena Protocol on Biosafety and the National Biotechnology and Biosafety Policy.

Through the project Zambia has taken measures to implement Article 8 (g) of the CBD that urges Parties to establish or maintain means to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health. This is through the Zambia Cabinet "Acceptance in Principle" of a "Biosafety Bill". Upon enactment the legislation will establish a national biosafety regulatory mechanism.

The project has assisted Zambia domesticate Article 22 of the Cartagena Protocol on Biosafety that requires Parties to cooperate in the development and strengthening of capacities in biosafety, including through existing organizations and through private sector involvement. This is through the purchase of equipment for the molecular biology laboratory that will specialize in GMO testing with the assistance of the Royal Norwegian Government. The Zambian Government has rehabilitated and renovated a molecular biology laboratory at NISIR that will specialize in GMO testing. Zambian scientists and technicians will be trained in Norway.

Brochures on modern biotechnology and GMOs have been developed by MSTVT and NISIR in order to implement paragraphs (a) and (b) of Article 23 of the Cartagena Protocol on Biosafety. Paragraph (a) states that "Parties shall: Promote and facilitate public awareness, education and participation concerning the safe transfer, handling and use of living modified organisms in relation to the conservation and

sustainable use of biological diversity, taking also into account risks to human health. In doing so, the Parties shall cooperate, as appropriate, with other States and international bodies". While paragraph (b) states that "Parties shall: Endeavour to ensure that public awareness and education encompass access to information on living modified organisms identified in accordance with this Protocol that may be imported".

Lessons Learnt

- There must be political will to have a biosafety policy that will should be functional.
- It is important that there is ownership of the biosafety policy by all stakeholders through their active participation in the development of the policy.
- Agencies developing the biosafety policy must be committed to it and must have a vision of how it would be implemented.
- The development of a biosafety policy must be tied to the identification of entities that will implement the policy.
- The country and the cooperating partners must share a common vision of the project and must be committed to seeing its implementation.
- Cooperating partners need to explore different ways of furthering their collaboration and should take advantage of opportunities that will further the realisation of the objectives of the project.
- Constant communication between collaborating institutions in addition to formal reporting requirement is important.
- Collaborating institutions It helps to have positive interpersonal relationship between individual involved in the implementation.
- It is important always to keep in mind the beneficiaries of the project.
- Biosafety capacity building should be implemented in a wholesome manner by encompassing both human resource development as well as infrastructural establishment and strengthening.
- Biosafety capacity building assistance should be mutually driven by recipients and providers taking into account aspirations of recipients and the interests of providers.

Recommendation

• The Secretariat should monitor biosafety capacity building assistance in order to see who is providing assistance, who is receiving assistance and who is not receiving any assistance.

SUBMISSIONS FROM ORGANIZATIONS

UNITED NATIONS ORGANIZATIONS AND AGENCIES

FAO	[27 JANUARY 2006]
	[SUBMISSION: ENGLISH]

UPDATE ON FAO ACTIVITIES IN THE FIELD OF BIOSAFETY CAPACITY-BUILDING

Food and Agriculture Organization of the United Nations (FAO)

- 1. The Food and Agriculture Organization of the United Nations (FAO) is involved in a number of activities in the field of biosafety capacity-building. These are highlighted below:
- 2. FAO has responded to several requests for assistance in building or strengthening national biosafety systems, including development and implementation of regulations, training of personnel of

regulatory bodies in risk analysis of GMOs, communication and public participation in biosafety-related decision making, and upgrading of laboratory capacities from a number of countries. Technical Cooperation Projects have been completed or are currently under implementation in several countries, including Bolivia, Grenada, Kenya, Malaysia, Paraguay and Swaziland, while others are under formulation or in the pipeline. Training in biosafety at national level has been provided in Benin, Colombia, Ivory Coast and Syria. A TCP was also implemented in Argentina to assist the country and the evaluation of the investments and costs of segregation of GMOs in the production and supply chain (compliance of Art. 18 of the Cartagena Protocol).

- 3. Assistance in biotechnology policy development has been requested by a number of countries, and related Technical Cooperation Projects (TCPs) have been completed or are being implemented in several countries, including Bangladesh, Nicaragua, Paraguay and Swaziland, while others, are at different stages of formulation. The national biotechnology policies include elements of biosafety policy.
- 4. Asian Bio-Net, a regional project financed by Japan, operational in ten countries, namely Bangladesh, China, India, Indonesia, Malaysia, Pakistan, the Philippines, Sri Lanka, Thailand and Vietnam, has been recently completed (http://asiabionet.org/). It contributed to strengthening capacities in legislation, regulations, policies and programmes for biosafety; establishing national biosafety systems and improving public awareness; and promoting research and technology development for generation and safe use of GM crops. The project's activities included the establishment of a regional biosafety network, the deliver of training opportunities at regional and national level, production of outreach materials for public awareness and the organization of consultations for harmonization of protocols and procedures. The final Focal Point meeting of the project decided to make use of some residual funds to sustain the network and the webbased activities and set the main elements of a further phase of the project, to be submitted to international agencies for consideration and funding.
- 5. In response to requests from members for assistance in technical training for GM seed testing and plant variety verification, FAO has teamed with International Seed Testing Association (ISTA) since 2003, to conduct hands-on training courses at the regional and sub—regional level on 'Electrophoretic and PCR based Methods for Varietal Verification and GMO Detection. The practical courses are conducted jointly with the national government seed testing agencies and often in partnership with the relevant regional organisation. They are designed for technical staff of the national seed testing agencies and agriculture research institutes in the public sector as well as small and medium sector private enterprises, dealing with testing and analysis of Genetically Modified Seeds. Worldwide, seven such courses have been held so far at the regional and sub-regional level. It has seen participation of 150 technical staff from 80 countries. A handbook for GM seed testing has also been distributed to the trainees. In 2006, additional sub-regional courses will be organised to meet incoming member government requests.
- 6. A sub-regional Workshop on Agricultural Biotechnology and Biosafety for Food Security and Rural Development in the Caucasus Region and Moldova, was held in Yerevan, Armenia, in 2003. The workshop provided research managers and decision makers with information on recent developments in the field of agricultural biotechnology and biosafety and allowed an exchange of updated biotechnology/biosafety information between their countries. The proceedings of the workshop have been recently published.
- 7. A CARICOM Workshop "Towards harmonization of Caribbean biotechnology", was held in Port of Spain, Trinidad in April 2005. The workshop, co-funded by the Project "Promoting CARICOM/CARIFORUM Food Security", and FAO, was attended by participants in representation of 12 countries, CARDI, CARICOM, IICA, FAO and UNEP and discussed possible coordination of several current initiatives, recommended the main elements of a Caribbean policy on GMOs and biotechnology, and identified four priority areas for the formulation of a sub-regional TCP proposal.

- 8. FAO is now in the process of launching Agricultural Biotechnology Network in Africa (ABNETA) to assist in coordinating information exchange and public relations activities among national and regional organizations for the safe use of biotechnology applications to support food security and poverty alleviation. The need for a coordinated approach for networking and information exchange has been long identified as an indispensable tool for biotechnological development in Africa and FAO has been identified as a key organisation in developing such a facility for African countries, given the success of the biotechnology networks established by FAO in Latin America-Caribbean (REDBIO) and in South Asia (ASIA- BIONET). ABNETA will have two regional hubs to directly manage and oversee activities in Southern and Eastern Africa and West and Central Africa respectively. It will be linked to the FAO-Biotech website and work closely with the partners including the National Agriculture Research Systems, Strategic Alliance for Biotechnology Research in African Development (SABRAD), the African Biotechnology Stakeholders Forum (ABSF), the Global Biodiversity Institute, National Biosafety Committees, SADC Food Security Unit, and relevant regional organisations.
- 9. The *Technical Cooperation Network on Plant Biotechnology in Latin American and the Caribbean* (REDBIO) started its activities at December 1990 with the objective of accelerating the process of adaptation, generation, transfer and application of plant biotechnology to contribute to the solution of crop production constraints and genetic resources conservation for the countries of the Region. REDBIO membership includes at present 526 members from public and private laboratories and institutions devoted to plant biotechnology in 27 countries of Latin America and the Caribbean.
- 10. FAO hosted an Expert Consultation on "Genetically Modified Organisms in Crop Production and Their Effects on the Environment: Methodologies for Monitoring and the Way Ahead" in January, 2005 in Rome, with the aim of reviewing the scientific basis for, and procedures to establish, effective post-release monitoring of genetically modified (GM) crops and develop guidelines to strengthen member countries' capacities to design and carry out monitoring programmes. The participants represented a wide range of expertise from research institutes, universities, international agencies, regulatory agencies, the private sector and civil society. The experts emphasized the critical importance of planning the process. The major outputs of the meeting were:
 - A review of scientific criteria and procedures that address the technical aspects of monitoring environmental effects of GM crops;
 - Two strategies that could be used as the basis of efficient monitoring programmes. An action plan
 designed to launch pilot monitoring projects through a series of activities which are interlinked to
 make promote a flexible, non- linear monitoring process. Full stakeholder engagement is vital for
 its success and must be fostered through formal and informal networks, alliances and initiatives. It
 must build trust and transparency which is the only way to sustain an effective link between
 monitoring and the resulting actions.
 - Recommendations for scientists managing the monitoring process, policy and decision makers, FAO and other relevant international agencies

The full report with the action plan is available at ftp://ftp.fao.org/docrep/fao/008/ae738e/ae738e00.pdf

11. A major role played by FAO is to provide its Members and their institutions with factual, comprehensive and current information on international developments relating to biotechnology applications. Information activities include:

The FAO website on biotechnology (http://www.fao.org/biotech/index.asp) in Arabic, Chinese, English, French and Spanish, the e-mail newsletter

FAO-BiotechNews, sent in English, French, Spanish and Russian to almost 4,000 subscribers,

The FAO Electronic Forum on Biotechnology in Food and Agriculture (http://www.fao.org/biotech/forum.asp) with about 3 000 members, and hosted 13 moderated e-mail conferences on topics relevant for biotechnology and biosafety capacity building.

The FAO-BioDeC database: http://www.fao.org/biotech/inventoryadmin/dep/default.asp is a searchable database providing information on crop biotechnology products/techniques in use or in the pipeline, biotechnology-related policies, regulations and activities in developing countries, backed-up by a network of national correspondents. A paper analysing the information contained in FAO-BioDeC was published in 2005.

The FAO *Glossary of Biotechnology for Food and Agriculture* in Arabic, English, French, Spanish and Vietnamese contains definitions of about 3 200 biotechnology terms and acronyms used in agricultural biotechnology. The Glossary is also available as a multilingual searchable database (http://www.fao.org/biotech/index_glossary.asp).

The Annotated bibliography on the economic and socio-economic impact of agricultural biotechnology in developing countries. The document brings together a wide range of assessments of the economic and socio-economic impact of agricultural biotechnology, including LMOs in developing countries (ftp://ftp.fao.org/sd/SDR/SDRR/bibliography1.pdf).

The State of Food and Agriculture (SOFA 2003-04), which considered the theme *Agricultural biotechnology: meeting the needs of the poor?* (http://www.fao.org/documents/show_cdr.asp?url_file=/docrep/006/Y5160E/Y5160E00.HTM). The subject was examined comprehensively in nine chapters grouped under three main headings: framing the debate; the evidence so far; and making biotechnology work for the poor.

The *Biosafety Resources website* (http://www.fao.org/sd/sdrr/biosafety/) presents a collection of training resources on different biosafety issues, classified into four groups: guidelines, manuals, reports and toolkits.

- 12. In the field of food safety issues arising from biotechnology, FAO, jointly with WHO, has held several expert consultations to consider how the safety assessment of foods derived from genetically modified organisms should be conducted (the reports of the series of expert consultations are available at http://www.fao.org/es/ESN/food/risk biotech consultations en.stm). Based on the scientific advice provided by these joint expert consultations, the Codex Alimentarius Commission, which is the executive organ of the Joint FAO/WHO Food Standards Programme, adopted overarching principles for risk analysis of foods derived from modern biotechnology (CAC/GL 44) in general. In addition, guidelines for food safety assessment of foods derived from recombinant-DNA plants (CAC/GL 45) and of foods produced using recombinant-DNA microorganisms (CAC/GL 46) were also adopted. These documents can be used by governments as basic protocols in evaluating safety of these products from the viewpoint of food safety (http://www.codexalimentarius.net/web/standard_list.do?lang=en). The Commission in July 2004, decided to re-establish the ad hoc Intergovernmental Task Force for Foods Derived from Biotechnology to pursue its work in this area and the fifth session was held in Japan, from 19 to 23 This meeting identified areas for future work, which included food safety assessment of foods derived from recombinant-DNA animals as well as food safety assessment of foods derived from recombinant-DNA plants modified for nutritional or health benefits. The re-established Task Force is expected to complete its work by 2009.
- 13. In order to improve the capability of regulatory authorities, particularly those of developing countries, to implement the internationally-agreed Codex texts, FAO and WHO are in the process of

developing a guidance document, as well as a training package on the safety assessment of foods derived from modern biotechnology. The guidance document is intended to assist national governments to assess, manage and communicate risks, including enforcement, associated with foods derived from modern biotechnology or to interpret the results of assessments undertaken by other authorities or recognized expert bodies, including access to analytical technology. FAO and WHO are also developing, in cooperation with other international agencies and donor countries, a training package and will implement a series of regional train- the trainer courses to assist developing countries in this regard.

- 14. FAO is planning to hold a technical consultation on biosafety within the *Biosecurity* framework in Rome from 28 February to 3 March 2006. The consultation aims to address actual and potential issues related to the safe use of new biotechnologies across the relevant sectors, within FAO's mandate. FAO has also recently peer reviewed a *Biosecurity* Risk Analysis Manual and *Biosecurity capacity building needs assessment tool*, which also address biosafety within a Biosecurity framework. These tools will be pilot tested, translated, and made widely available in due course.
- 15. Coordination with organizations implementing or funding biosafety capacity-building activities has been constantly pursued. Examples include the FAO participation in mid-term review of the World Bank-GEF Project *Capacity building for the implementation of the Cartagena Protocol on Biosafety in Colombia*, the active membership in the UNEP-GEF Biosafety Steering Committee, the contribution to the biosafety training course organized by ICGEB in Peru, the participation in the Coordination Mechanism adopted by the COP-MOP of the Cartagena Protocol on Biosafety, and the continuous feeding and updating of the Capacity Building Projects Database in the BCH.

UNEP-GEF BIOSAFETY UNIT	[11 JANUARY 2006]
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PROGRESS IN, AND LESSONS LEARNED FROM, THE UNEP-GEF PROJECTS ON CAPACITY-BUILDING FOR THE DEVELOPMENT AND IMPLEMENTATION OF NATIONAL BIOSAFETY FRAMEWORKS

Chris Briggs UNEP-GEF Biosafety Unit, Geneva

Introduction

The GEF Council approved the Initial Strategy for capacity building for the Cartagena Protocol on Biosafety in November 2000. The main activities in the strategy included:

- A project to assist countries to develop National Biosafety Frameworks (NBFs)
- A limited number of demonstration projects to assist in implementing the National Biosafety Frameworks:
- Support for countries to effectively participate in the Biosafety Clearing House
- Coordination with other organizations to provide biosafety-related assistance
- Enhancement of advice to GEF on biosafety issues

1) UNEP-GEF Project on Development of NBFs - assisting up to 130 countries to develop their NBFs

The status of the project as of 1st June 2005 was as follows:

• 126 countries have endorsed the project and 121 have started

UNEP/CBD/BS/COP-MOP/3/INF/11

Page 24

- 57 countries have completed draft NBFs (12 CEE, 20 Africa, 21Asia, 4 Latin America)
- 54 countries have draft NBFs and are eligible for GEF Implementation projects

Outcomes and Lessons Learned from the NBF Development Project:

- It is helpful to break down the project into manageable phases, goals and outcomes
- Keeping needs of developing countries at centre of all efforts is essential for success
- Neutrality of UNEP is key to UNEP's relationship with countries
- Adapting documents, procedures and systems to countries' needs was necessary to assist them
- The existence of 7 Regional Coordinators giving daily support to countries, managing project and relationships well and providing technical advice in very specialized field was useful
- Toolkits have been useful to countries when they are complemented by RC support. All toolkits were revised and internationally peer reviewed by stakeholders
- Use of National Coordinating Committee is key for ensuring consultation between ministries and all other stakeholders, so consensus can be reached
- Success with countries is a result of global teamwork
- Set of 16 Workshops and continuing contact with RCs led to closer linkages and South-South cooperation
- Networking and cooperation between countries has to be actively supported and platforms set up that can later lead on to more formal cooperation mechanisms
- Countries need to implement NBFs before agreements can happen and formalizing regional cooperation
- Best practices are being collected by UNEP
- Information flow is key to meeting needs of countries and for helping with transparency.

2) BCH Project - building capacity of up to 139 countries to access and use the BCH

Outcomes and Lessons Learned:

- Project developed as direct response to country needs for access and use of the BCH and developed with the SCBD;
- Expert meeting in 2004 advised UNEP to use a network of Regional Advisors, using call-down contracts, living and working in the same regions to deliver support
- Over 80 countries are now reviewing their nBCH plans and training and equipment needs with aid of the Regional Advisors

3) NBF Implementation Projects - 8 demonstration projects (out of 12) on Implementation of NBF

All 8 UNEP-GEF countries were originally in the GEF Pilot phase; they started in September 2002 each for a duration of 3 years and a budget of US\$ 500K to 1.0 million. 3 projects were completed by end of 2005.

Lessons Learned:

- Development of project in a consultative and inclusive process helps in sustainability
- Project team needs 4-6 persons to run work
- 3 to 6 yrs are needed to make an NBF operational
- Cost depends on governmental commitment, industry contribution, country size, population
- Estimated cost to set-up: 0.6-7.5 mil \$ US
- Estimated cost to maintain: US\$ 50 to 200 K per year
- Sharing experiences, documents, etc both in-country and within region is essential for success

- Language and culture are barriers to sharing, so translation of many relevant documents essential
- Appreciation for UNEP's technical support and the training in administration and other areas
- Recommend longer country visits
- Recommend more frequent meetings for all NPCs
- Follow up strategy needed after implementation
- Toolkits and documents should be there at start of project
- Provide updates on Biosafety e.g. CPB, WTO, etc
- More regular technical discussion on country reports and performance
- Organize field visits to see biotech/biosafety
- Consider increasing financial support & contingency funding for currency fluctuation

Positive achievements of the project:

- Operational NBFs at end of project (3 countries by end 2005)
- Laws are enacted in countries
- Enhanced capacities achieved in human resources and laboratory facilities
- Improved public perception & change to more positive attitude
- Project has been fully incorporated into national plans and system
- Awareness has been created through websites, publications and databases
- Cooperation achieved between relevant Ministries and stakeholders
- Networking & information sharing between countries at regional & international levels

Challenges faced

- Bureaucracy in government and conflict of interest between Ministries
- Delays in enactment of Biosafety Law
- Harmonization of domestic laws with international obligations and other countries within region
- Change of project staff, and of Ministers and Ministries responsible for Biosafety

Plans for the future

- Completion of Development Phase of NBFs
- Remaining 70 country NBFs due to be completed by end of 2006
- Last 6 countries involved in Development Project may finish after 2006
- BCH project rolls out for up to 139 countries with over 80 countries participating today
- Evaluation of all activities under "GEF Initial Strategy" completed by GEF OME with positive results on UNEP's performance
- A new GEF Strategy for Biosafety is being developed and includes more elements for regional and sub-regional cooperation
- National projects complemented by sub-regional components and sub-regional cooperation
- Enhanced sharing of information, experiences and resources at all levels
- Identification and strengthening of regional centres of expertise in Biosafety
- Cooperation with other projects, agencies, etc.
- Revised GEF Strategy to be presented to GEF Council in June 2006

Launch of full NBF Implementation Phase

- 54 countries eligible by December 2005
- 15 projects already submitted to GEF (Cambodia, Czech Republic, DPR Korea, Estonia, Egypt, Lithuania, Mauritius, Tunisia, Liberia, Tanzania, Iran, Vietnam, Moldova, Slovakia, Latvia)
- Czech Republic MSP endorsed and more expected

UNEP/CBD/BS/COP-MOP/3/INF/11

Page 26

- Up to 100 more countries likely to request projects for implementation of NBFs
- Political will for regional harmonization is emerging spontaneously (e.g. ECOWAS, Caribbean, Pacific)

Subregional NBF Implementation projects

- UNEP has submitted 5 sub-regional project concepts for 74 countries to GEF for review (CEECCA-16, ECOWAS-15, WA/NA-13, SADC-14, Caribbean-15)
- World Bank has had two multi-country concepts (Latin America-5 and West Africa-6) approved and projects will be presented to GEF by June 2006

Cooperation with others initiatives

- Cooperation with other capacity building projects and organizations very active at national and international levels
- Other agencies (e.g. UNIDO, FAO, ADB) likely to become more involved in Biosafety under new GEF strategy
- Coordination takes up more time as number of organizations involved is increasing
- Coordination mechanism complements this active dialogue between players

UNIDO	[11 JANUARY 2006]
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UPDATE ON UNIDO'S BIOSAFETY TRAINING PROGRAMME

George T. Tzotzos Biotechnology Unit, UNIDO

- 1. UNIDO's involvement in biosafety started as early as 1984 with the establishment of an *ad hoc* interagency (UNEP, WHO, FAO) working group on biosafety. In 1991, UNIDO, on behalf of the group, developed the first Voluntary Code of Conduct for the Release of Organisms into the Environment. In 1993, UNIDO established the Biosafety Information Network and Advisory Service (BINAS), which is currently recognised as one of the major repositories of on-line information in biosafety. In recognition of its work, UNIDO became Task Manager for Chapter 16 of Agenda 21 "Environmentally Sound Applications of Biotechnology". More recently, UNIDO developed a computer-based decision support system for risk assessment in biotechnology (DTREE) as well as a comprehensive biosafety training package based on distance learning technologies (*e*-Biosafety).
- 2. To assist developing countries in the implementation of the Cartagena Protocol on Biosafety UNIDO considered different interventions for capacity-building at the level of regulatory bodies. As the training of large numbers of regulators at the enterprise, institutional and national level requires significant resources in terms of finance and expertise UNIDO considered that multimedia technology, and particularly distance learning, provide cost-effective solutions and a complementary platform to conventional on-site training. Distance learning overcomes geographical constraints and allows trainees to simultaneously attend the course without disruption of their professional career. For the same reason, it makes it possible to include in the course faculty internationally recognised experts thus ensuring a high quality standard of training.

- 3. Therefore, UNIDO with its long-standing involvement in biosafety related activities and recognising the potential on new e-learning technologies has developed a comprehensive programme in biosafety training as well as the necessary infrastructure for the provision of the programme. The programme was tested for two consecutive academic years (2003 -2005) at the University of Concepción (UDEC), Chile. The course being the first of its kind in the world, in that it provided academic accreditation in biosafety at the postgraduate level, was distinctively interdisciplinary, involving students and faculty from life sciences, engineering, social sciences and law. Elearning was combined with optional on-campus sessions enhancing interaction of the trainees with the faculty. The success of the course generated is attested to by the high number of applications received from many parts of the world as well as requests of member countries to host regional training centres based on UNIDO's programme.
- 4. Following such requests, the course will be offered in the course of 2006 by the Universities of Dar El Salaam, Kuala Lumpur and Concepción covering, respectively, Africa, Asia and Latin America. The three regional training centres will be operationally interlinked and the course supervised by an international advisory board.

THE WORLD BANK	[11 JANUARY 2006]
	[SUBMISSION: ENGLISH]

A SUMMARY OF THE WORLD BANK BIOSAFETY CAPACITY-BUILDING ACTIVITIES

Mary-Ellen Foley Environment Department, The World Bank

1. The World Bank is currently working with Colombia and India on two GEF biosafety demonstration projects and is also working with counterparts in several countries in Latin America and in West Africa to develop regional projects under the GEF's interim strategy on biosafety.

Colombia Project on Capacity Building for Implementation of the Cartagena Protocol

2. The project aims to provide the country with capacity to assess and manage risks associated with the transboundary movement of LMOs and thus meet the basic obligations of the Cartagena Protocol by:

1) strengthening the regulatory framework and operational mechanisms on biosafety; 2) building capacity and establishing an operational system for risk assessment and management and monitoring; 3) establishing a database and linkage to the Biosafety Clearing-House (BCH); 4) supporting centers of excellence and a research network; and, 5) developing a project coordination unit (PCU) and an intersectoral mechanism for formulating national policies / coordinating decision-making on biosafety issues.

Accomplishments to Date

3. The project underwent a mid-term review in July 2005 and is scheduled to complete in 2006. Measures to strengthen the regulatory framework and operational mechanisms have been taken with the creation and active functioning of inter-ministerial working groups. Although efforts are underway to develop a national instrument on biosafety with the creation of an inter-ministerial coordination committee, there was some disagreement between ministries on what form a national instrument would take (such as a biosafety law). The PCU is working with the working groups and Intersectoral Council to look at different legal and institutional approaches that would work best for the country.

UNEP/CBD/BS/COP-MOP/3/INF/11

Page 28

4. The component on a system for risk management and assessment is underway with a nucleus of institutional capacity building on biosafety established and training of trainers in various ministries completed. Most of training and courses envisioned in the proposal have been delivered and the focus will turn towards civil society as well as new government personnel. The third component on the BCH is nearly completed with the development and launching of the Colombia BCH site in December 2005 (see www.bch.org.co/). The location of the central laboratory under the centers of excellence component and its related equipment has been decided upon. The tripartite agreement between the three main institutions has yet to be signed, pending the identification of resources for post-project running of the facility.

Opportunities for Collaboration

5. Representatives from key institutions involved in the project decided to collaborate on a regional basis with institutions from other countries to share experiences and complement existing skill-sets on biosafety issues. This has led to a regional project proposal (see below). In addition, Colombia has been keen on South-South collaboration and had training conducted by experts of other countries, e.g. Mexico.

Lessons Learnt to Date

- The need for strengthening inter-institutional coordination at the highest level in order to allow key components to a biosafety framework to be prioritized such as inter-institutional political agreements continues to be the major lesson learned in this project.
- Civil society should be included in the capacity building components of NBF implementation projects in
 order to enrich the debate and extend the social base of the national biosafety strategy. Moreover,
 capacity building training needs to be more targeted towards certain groups, such as for customs and
 port authorities or judges and other legal personnel.

India Project on Capacity-Building for Implementation of the Cartagena Protocol

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

Accomplishments to Date

- 7. Implementation of all five components is underway with clear progress in the implementation of Components 2-5. Procedures for project management and governance, financial management and procurement have been established, and DNA-based detection of transgenic events have been developed and validated, inter-laboratory validation completed and three commercially available diagnostic kits for LMOs FFPs tested under the technical component of the project.
- 8. The national BCH architecture is completed and population of the website initiated. An integrated database for biosafety and the production and use of LMOs in India was developed and three related databases populated. A training needs assessment was recently completed and the focus of the project in the coming months will be to implement the associated training plan under Component 1. For more information on the project, see http://www.envfor.nic.in/divisions/csurv/biosafety/default.htm.

Opportunities for collaboration

9. Collaboration included that 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.

Lessons learnt

- The challenge is to link human capacity with organizations and institutions affected by or overseeing the meeting of the obligations under the Cartagena Protocol.
- 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.
- 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.

Regional Biosafety Project Proposals

- 10. An estimated US\$10 million (US\$5 million of this would be from the GEF) multi-country project for biosafety in major centers of biodiversity is under preparation and expected to be submitted for GEF Council consideration by early 2006. The project will aim to further build technical capacity for the safe deployment of transgenic crops in Brazil, Colombia, Costa Rica, México and Peru. The approach focuses on centers of excellence in these countries and their complementary skills to accomplish project objectives as well as to sustain collaboration on biosafety and adherence to protocol obligations post-project implementation. The project will be accordingly executed by the International Center for Tropical Agriculture (CIAT).
- 11. A second project concept aims to build biosafety capacity to implement the protocol in cotton producing countries (Benin, Burkino Faso, Cote d'Ivoire, Mali, Senegal, Togo) using a sub-regional approach. The objective will be to enable these countries to manage the environmental risks of agricultural biotechnology in the sub-region by ensuring adequate levels of protection in the transfer, handling and use of transgenic crops starting with Bt cotton. The proposal will also aim to build capacity in regards to managing any socio-economic impacts of transgenic crops. The concept has entered the GEF project pipeline and GEF SEC has recommended approval of project preparation funds.

INTERGOVERNMENTAL ORGANIZATIONS

ICGEB	
	[3 JANUARY 2006]
	[SUBMISSION: ENGLISH]

CAPACITY-BUILDING ACTIVITIES IN GMO BIOSAFETY AT THE INTERNATIONAL CENTER FOR GENETIC ENGINEERING AND BIOTECHNOLOGY (ICGEB)

Decio Ripandelli Biosafety Unit, ICGEB

Introduction

1. As one of the initial actors in the provision of biosafety support, the International Centre for Genetic Engineering and Biotechnology (ICGEB) has a long-standing engagement in capacity building. Its series of biosafety training courses was launched as early as 1991, and since then the Centre has progressively extended and enriched its commitment to biosafety with other activities. A major step was made in 1997, when the ICGEB set up a dedicated Biosafety Unit, in order to enhance the Centre's ability to provide institutional services related to the biosafety of genetically modified organisms (GMOs) and their environmental release. In late 2004, with the support of the Fondazione Cassamarca, the ICGEB created a Biosafety Outstation, focused primarily on GMO biosafety research. The Unit and the Outstation work closely together 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 cooperation with other international agencies involved in biosafety.

Dissemination of information

- 2. By virtue of a Memorandum of Cooperation entered into with the Secretariat of the Convention on **Biological** Diversity (CBD), **ICGEB** biosafety bibliographic the (www.icgeb.org/biosafety/bsfdatal.htm) is 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 contains more than 5,000 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 GM0s. To assist visitor access to the full version of an article, each record contains the corresponding author's Email address and/or a DOI (Digital Object Identifier - a unique string which links directly to the article on the journal website).
- 3. Another important informatics tool, developed by the ICGEB with the support of the Italian Ministry of the Environment, is the Risk Assessment Searching Mechanism (RASM) (www.icgeb.org/biosafety/rasm.html). This device, which should prove to be very useful for the decision-making process according to Article 10 of the Cartagena Protocol, provides access to existing online risk assessment documents related to official governmental decisions for the release of GM0s. To date, it contains links to 564 records of risk assessment documents, relating to 142 different transgenic events from 19 plant species issued by 27 official authorities. RASM links to RA documents from 20 countries, with more than 75 % of records from non-CPB party authorities. Typical government sources include national/regional food standard authorities, environmental protection agencies and departments of agriculture. RASM is a searchable interlinked database, the majority of records of which provide further links to online databases when relevant, for information concerning inserted nucleotide (transgene and/or regulatory) sequences and OECD unique identifiers.
- 4. ICGEB was also involved in a European initiative named GMO RES COM (www.inra.fr/europe/cimorescom/) which resulted in the creation of a web-based, public-access database of past and current projects in GMO biosafety research. This database was developed to enhance communication regarding past and present GMO biosafety research. It provides access to information for all worldwide stakeholders, including the general public, industry, and national and international agencies. In addition, it is helping to improve communication within the scientific community, as well as between researchers and the public at large. The database is now public and biosafety research project leaders worldwide are encouraged to enter their projects directly into the database. In a future refinement, a direct link between the GMO RES COM database and the existing ICGEB bibliographic database will be created. Through these three linked databases, the-ICGEB is equipped to play a central role in providing access to information on the biosafety of GMOs.

- 5. The ICGEB is playing an increasing role in the publication of scientific articles in the area of GMO biosafety. The Italian Ministry of the Environment has provided funds for the publication of an information booklet on GMOs, as well as the Collection of Biosafety Reviews which is a compilation of scientific studies in areas of major interest for biosafety and risk assessment, prepared specifically for ICGEB by internationally recognised scientists. In addition, the ICGEB Biosafety Outstation at Ca' Tron now houses the editorial office of a multidisciplinary international journal focused on GMO biosafety research, Environmental Biosafety Research (www.edpsciences.org/ebr/), the official journal of the International Society for Biosafety Research (www.edpsciences.org/ebr/), and has appeared quarterly since 2002.
- 6. Finally, and in the framework of the Agreement entered into with the Italian Ministry for the Environment, the ICGEB has been directly involved in the elaboration of Italy's Biosafety Clearing House, an internet-based portal (http://bch.minambiente.it) divided into five main sections (General Information, Biosafety, Legislation, GMO Documents and Decisions, Biosafety Clearing House); four of these sections are relevant to Italy's obligations by virtue of its being a Party to the Cartagena Protocol, while one relates to the European Directive 2001/18/CE, regulating GMO releases, either for experimental or commercial purposes.

Training

- 7. 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. The participants have come from extremely diverse backgrounds, and have included members of competent authorities, regulators and scientists active in biotechnology. The collaboration with the Italian Institute for Overseas Agronomy (IAO) has facilitated an expansion of the workshop series to include annual and biannual events. Until 2004 the workshops focused on the general principles of GMO risk assessment, with both introductory and advanced workshops undertaken. The identification of specific biosafety needs in various countries, as well as the arrival of new personnel at the Biosafety Unit and Outstation, has led the ICGEB to expand its offering of biosafety training courses.
- 8. A broader range of course subjects has been elaborated, for example in 2005 a more focused workshop was established, providing experience in the evaluation of the scientific data that are provided in an environmental risk assessment (ERA) report. Many countries are in the process of developing or implementing a national biosafety framework and their competent authorities need to gain experience in such ERA appraisals. Also, the series of regional courses has been extended and the content tailored to directly address biosafety concerns in those counties. Previously supported workshops were conducted in Russia, Venezuela and Peru and the next regional workshop, entitled "Detection of Genetically Modified Organisms (GMO) and Genetically Modified Food (GMF)", is planned for Sri Lanka in March 2006.

Research at the ICGEB Biosafety Outstation at Ca' Tron

9. In late 2004, the Biosafety Outstation became fully operational for carrying out research in the area of GMO biosafety. The two research groups working at Ca' Tron, Plant Virology and Plant Bacteriology, focus on unique biosafety questions related to GM plants and their associated pathogens. However, the sense given to this research is provided by proposed development projects, which will focus on creating pathogen-resistant transgenic plants expressing transgenes that will have been designed in order to mimimise potential epidemiological and environmental risks. 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

Page 32

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.

- 10. Furthermore, ICGEB has started a collaborative initiative with the Academy of Sciences for the Developing World (TWAS), aimed at supporting research projects focused on plant biotechnology and resistance to abiotic stress, which should contain specific biosafety aspects. This programme, also aimed at stimulating the collaboration among different laboratories in developing countries, should represent a concrete example of South-South cooperation on issues directly related to the safe use of biotechnology
- 11. ICGEB is progressively enhancing its unique resource in the area of GMO biosafety, including both theoretical and practical training. Clearly, these efforts will only be fully successful in the context of collaboration with a range of partners worldwide, therefore the ICGEB remains open to approaches from other actors to form alliances in the furtherance of assistance offered in the biosafety arena.

IPGRI (ON BEHALF OF THE CONSULTATIVE	[27 JANUARY 2006]
GROUP ON INTERNATIONAL AGRICULTURAL	[SUBMISSION: ENGLISH]
RESEARCH, CGIAR)	

ACTIVITY REPORT ON BIOSAFETY CAPACITY DEVELOPMENT ACTIVITIES FUTURE HARVEST CENTRES OF THE CONSULTATIVE GROUP ON INTERNATIONAL AGRICULTURAL RESEARCH (CGIAR) $_{1}$

Elizabeth Goldberg Capacity Development Research and Support Unit, International Plant Genetic Resources Institute, IPGRI

Introduction

- 1. This report is provided by the Future Harvest Centres of the Consultative Group on International Agricultural Research (often collectively referred to as 'the CG Centres') in order to share information about some of the biosafety capacity strengthening activities that we have been engaged in.
- 2. There are 15 Future Harvest Centres located around the world. The FH Centres engage in agricultural science to reduce poverty, foster human well-being, and protect the environment. Our work is divided into five areas:
 - Sustainable production of crops, livestock, fisheries and forests
 - Enhancing national agricultural research systems
 - Germplasm improvement
 - Germplasm characterization and conservation, and

¹ This is a collective report submitted by IPGRI on behalf of the Future Harvest Centres of the CGIAR.

² The Future Harvest Centres include: Centro Internacional de Mejoramiento de Maiz y Trigo (CIMMYT), Centro Internacional de Agricultura Tropical (CIAT), Centro Internacional de la Papa (CIP), International Rice Research Institute (IRRI), International Food Policy Research Institute (IFPRI), WorldAgroforestry Center (ICRAF), WorldFish Center, Center for International Forestry Research (CIFOR), International Livestock Research Institute (ILRI), West African Rice Development Association (WARDA), International Water Management Institute (IWMI), International Institute of Tropical Agriculture (IITA), International Center for Agricultural Research in the Dry Areas (ICARDA), International Crops Research Institute for the Semi-Arid Tropics (ICRISAT) and International Plant Genetic Resources Institute (IPGRI).

- Research and capacity strengthening concerning policies that impact upon agriculture's potential contribution to livelihoods
- 3. Eleven of the Centres collectively hold approximately 545,000 accessions of seeds (and other forms of reproductive material). Pursuant to agreements entered into between the Centres and FAO in 1994, those materials (or germplasm) are held "in trust for the benefit of the international community." The Centres make those materials available directly to users, upon request, without restriction, for the purpose of scientific research, plant breeding, or genetic resources conservation. Recipients are not allowed to seek IPRs over those materials 'in the form received'. The Centres are planning to sign agreements with the Governing Body of the International Treaty on Plant Genetic Resources for Food and Agriculture to place their collections under the Treaty. The genebanks distribute 40,000 to 50,000 samples per year directly to users, for which 80% of recipients are national programmes in developing countries.
- 4. In the context of their work, the Future Harvest Centres are actively engaged in strengthening institutional and human capacity in the area of biosafety, through training, technical advice, public awareness, generating models for analyzing the potential flows of transgenes through populations and measuring the socioeconomic impact of the introduction and use of LMOs.
- 5. Below are a few examples of this work, which are illustrative examples and not intended to be inclusive of all the work underway:
- o In 2005, the Centres developed and adopted the "Guiding Principles to address the possibility of unintentional presence of transgenes in ex situ collections." By way of follow-up to these Guiding Principles, the Centres are starting to develop crop-specific guidelines setting best practices for the acquisition of new materials and the maintenance of collections to avoid the accidental introgression of transgenes. To complement these efforts, the Centres will maintain a database, to be posted on a publicly accessible website, on the global status, crop-by-crop, of GM research and development. These tools will be made publicly available; users outside the FH Centres may want to use them as part of their strategies to manage their own collections. The Guiding Principles and the data base were recently considered by the Working Group on Plant Genetic Resources for Food and Agriculture of the Commission on Genetic Resources for Food and Agriculture, which noted their potential utility for a much broader set of users.
- O Two Centres (IPGRI and IFPRI) and the CGIAR System-wide Genetic Resources Programme (SGRP), recently published a module to train trainers entitled *Law and Policy of Relevance to the Management of Plant Genetic Resources; Learning Module with Review of Regional Policy Instruments, Developments and Trends*. The module includes training materials addressing, among other areas, Phytosanitary and Biosafety regulation designed to assist genetic resource managers understand relevant global and regional laws to give them confidence doing their jobs. A number of CG Centres, and more recently, national partners and regional crop genetic resources networks, have used, or are planning to use, the policy training module as the basis for policy training workshops.
- o Five of the FH Centres are partners in the consortium "Program for Biosafety Systems" or PBS, a project funded by USAID, which seeks to increase countries' abilities to create systems and make biosafety decisions based on scientific evidence and to improve the understanding and safe use of biotechnology to support farmer welfare. PBS has five components: Risk assessment research; Policy development and implementation; Regulatory approval strategies; Education/training in biosafety and food safety; and Communication strategies and outreach. It will assist national governments in studying the policies and procedures necessary to evaluate and manage the potential harmful effects of modern biotechnology on the environment and human health. One of the Centres IFPRI is the host of the global consortium.

- o The Centres' biosafety capacity development is closely linked to the research carried out in the Centres on biosafety issues. This research, given previous work in crop breeding and genetics, reproductive biology, field ecology and GIS, is usually related to environmental biosafety. Centres' environmental biosafety research has generally been targeted to crop landraces and their wild relatives, using the FH Centres 'mandate crops' as model case studies. For example, at CIAT, the topics of this research include:
 - Documentation of genetically compatible species, and their range of natural distribution, including crop modern cultivars, traditional landraces and wild relatives. Includes GIS tolls and methodologies to make this information readily available to users.
 - Documentation of gene flow events from transgenic and non-transgenic plants towards landraces and wild relatives, in terms of frequency, range of distribution, spatial distance, involvement of several species and time persistence of alien alleles, mainly on rice and bean models in Colombia and Costa Rica, supported by BMZ.
 - Effect of transgenic crops on non-target associated biota including monitoring effects of Bt crops on non-target aerial insects, soil anthropods and nematodes, supported by USAID with input from Cornell University.
 - Socio-economic analyses of how transgenic crops may affect production, consumers' preferences and special niches for landraces.
 - Workshops and courses on biosafety for NARS researchers, national authorities responsible for regulation of introduction and management of transgenic crops and other government officials, and the media.
- o CIMMYT has been particularly active with respect to biosafety activities associated with deployment of Bt maize in Africa, working the Kenya Agricultural Research Institute (KARI), supporting technical and infrastructural capacity building and raising awareness about biotechnology in general and Bt maize in particular (project is funded by the Syngenta Foundation). Lessons learnt in Kenya should provide valuable insights for other maize growing countries in Africa and beyond. CIMMYT has also done a great deal of work generating baseline data on maize gene flow in Mexico (funded by the Rockefeller Foundation) to inform the development of appropriate regulatory structures related to potential deployment of genetically engineered maize. The project will lead to substantial technical and policy-based capacity building across the region.
- o ILRI is hosting Beca, Biosciences eastern and central Africa, NEPAD's center of excellence based in Nairobi which is a capacity building and research platform for Africa to enhance the application of biosciences, including biotechnology and biosafety, to address agricultural constraints in Africa. Risk assessments are currently being carried out for the establishment of this center.
- o Media workshops have been carried out in India, Bangladesh and Niger in 2005 organized by ICRISAT in order to create greater awareness and understanding in the media about technical issues concerning GM crops. Another workshop is planned for Kenya in the future.
- o FH Centres are increasing their participation in regional biosafety capacity development initiatives. Currently CIAT, together with CIP and EMBRAPA, is preparing a regional initiative to further strengthen the biosafety technical capacity of countries (Mexico, Costa Rica, Colombia, Brazil and Peru) for safe deployment of transgenic crops. This is being supported by GEF/ World Bank.
- 6. The FH Centres of the CGIAR are increasing their levels of involvement in capacity building with respect to the development of biosafety policies and regulations. Most of this work is firmly grounded in the biological and socioeconomic scientific expertise of the Centres and their experiences as international public sector research organizations dedicated to the production and distribution of public goods. The FH

Centres look forward to further strengthening our work in this field by forging connections with other organizations and situating our capacity building work within the larger global framework of activities that this body is assisting to coordinate.

PROGRAM FOR BIOSAFETY SYSTEMS, IFPRI	[6 JANUARY 2006]
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THE PROGRAM FOR BIOSAFETY SYSTEMS (PBS)

John Komen,
Program for Biosafety Systems (PBS)
URL: http://www.ifpri.org/themes/pbs/pbs.htm

- 1. This paper presents a case study on the Program for Biosafety Systems (PBS) emphasizing a number of key achievements and remaining challenges. PBS mission is to support partner countries in Africa and Asia in the responsible development and safe use of agricultural biotechnology.
- 2. The Program for Biosafety Systems (PBS) contributes to the implementation of the Cartagena Protocol by supporting partner countries as they develop the policy and legal framework, administrative procedures, technically qualified personnel and outreach mechanisms integral to their national biosafety systems. PBS work emphasizes sound science-based decision making and research, while also addressing socioeconomic considerations. PBS works with partner countries in Africa and Asia to develop and implement a program of activities tailored to biosafety needs identified by local collaborators.

Project activities

3. The scope of activities includes the following:

Policy and regulatory development through stakeholder participation: The policy component analyzes the implications of different country and regional regulatory approaches for genetically modified organisms and develops new decision models to assist regulatory agencies. Choices regarding biosafety policies and objectives are evaluated for their implications for agricultural growth, trade, and food security.

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

Strategic planning for communications and outreach: Clear and consistent communications about biotechnology and biosafety are key to the success of biosafety capacity development in partner countries. Improving the understanding of biotechnology and biosafety in a wide array of audiences is essential to achieving this goal.

Grants for scientific research on environmental risk issues: The focus of the Biotechnology-Biodiversity Interface (BBI) grant program, managed by PBS, is on the need to better understand the interaction between genetically engineered crops, agriculture, and the environment. Environmental risks and benefits, and their applicability to the agricultural realities of different ecological regions, must be assessed on a case-by-case basis. Through BBI, competitive grants fund biosafety

Page 36

research aimed at addressing the effects of agricultural biotechnology, particularly genetically engineered crops, on natural biodiversity as it occurs in developing countries.

Assistance with regulatory documentation for proposed field testing: For the benefits of agricultural biotechnology to reach farmers and consumers in developing countries, specific agricultural products must be developed, tested, and deployed. Each step along this process must be carried out following good biosafety practices and in conformity with national biosafety regulations. This component of PBS aims to help public sector R&D institutions to incorporate biosafety into their product development efforts and to comply with regulatory requirements. It also aims to help regulatory agencies to carry out their roles effectively in the review, approval, and inspection processes.

Main achievements

4. Selected PBS achievements include:

Contributing to (regional) policy making: A number of African governments are in the process of drafting, or revising overall guiding policies on biotechnology and biosafety, usually backed by laws or decrees stipulating the guiding principles for GM applications and products. PBS supports national policy development where needed; examples will be presented during the meeting. Regional policy research projects in collaboration with ECAPAPA, ACTS and FANRPAN aim to inform the policy process. Legal analysis and review has been done on drafts of legal documents and recommendations made to ensure such documents establish workable, understandable and transparent regulatory systems that are consistent with international obligations. In East Africa, recommendations and issues emerging from this work were brought to a regional meeting of legal and regulatory experts to explore opportunities for harmonizing biosafety systems.

Establishing the BBI competitive grants program: Scientific data are essential for assessing environmental risks and benefits of transgenic organisms, particularly in centers of diversity. Impacts will differ from one ecological region to another and should be evaluated on a case-by-case basis, in and by developing countries. The focus of the Biotechnology Biodiversity Interface (BBI) grants mechanism, managed by PBS since 2003, is on the need to better understand the interaction among transgenic crops and animals, agriculture, and biodiversity. To date, 8 project proposals have been awarded, with scientific leadership by developing-country research institutes. PBS regional coordinators and advisory groups are instrumental in identifying BBI priorities, launching calls for proposals and supporting potential grantees.

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

Towards an integrated approach to biosafety training: So far, PBS training and education events have been primarily organized in response to needs and challenges expressed by partners

in Asia and Africa. This has been a valid approach in order to establish a strong training component, and to develop and test training materials and methods. This approach ensures the relevance of PBS-supported activities, but does not necessarily lead to impact towards achieving PBS outcomes and milestones. Besides, a dispersion of activities was observed across PBS components and countries, calling for greater coordination and integration. PBS agreed on a set of common principles to be followed in the design, implementation and evaluation of training and education activities. They were derived from a review of past events in partner countries, drawing lessons from successful approaches. As a result, PBS will continue moving away from introductory, generic training activities to targeted interventions supporting a clearly defined goal. It will also result in more individual and small-group training and less events for a wide audience. Examples of this approach will be provided during the presentation.

Lessons Learned

5. A number of lessons learned during program implementation over the last 23 years will be presented, along with the main **challenges** encountered by PBS. These relate to:

Implementing a partner-driven approach: Efforts have been made from the very beginning to increase leadership and program management by partner countries. Regional coordinators, national coordinators (where relevant) and regional / national advisory groups were instrumental in this process. However, particularly in countries where the biosafety system is in a state of flux, this may result in long lead times before activities are agreed and implemented, while program results and impact are expected in the short run.

Moving policies from draft to adoption: Supporting the development of policies, legal instruments and implementation provisions, such as application forms and operating procedures, is vital but often only works at the drafting stages. When it comes to actual adoption by policy-making bodies, the process becomes fuzzy and unpredictable. In many countries, there are no strong incentives to champion biosafety policies and regulations, for various reasons. Obviously, such uncertainties result in delays in program implementation.

Determining impact from research and technical assistance: As PBS impacts on "soft" objectives — such as improved policies, people skills, decision making procedures — it is not always clear what results the program generates, and what its impact is in terms of measurable indicators. Coming up with an "impact roadmap" for PBS has presented a challenge in itself, and so far has been given less attention than desirable — also due to the fact that looming deadlines and immediate program management challenges tend to take priority over longer-term planning. The Coordination Meeting could be valuable in providing guidance and cooperation on this subject.

REGIONAL ORGANIZATIONS AND INITIATIVES

AFRICAN UNION COMMISSION	[11 JANUARY 2006]
	[SUBMISSION: ENGLISH]

AFRICA-WIDE CAPACITY BUILDING IN BIOSAFETY PROJECT /SUPPORT OF THE AU IN MATTERS OF BIOSAFETY

Bather Kone African Union Biosafety Unit

1- Introduction

Page 38

The Project is the outcome of cooperation between the African Union Commission and the German assistance "German Biosafety Capacity-Building Initiative for the Implementation of the Cartagena Protocol.

2- Background and Justification

Capacity building is required for Africa for the implementation of the Cartagena Protocol , but also for other activities specific to the African Countries which are not covered by the Protocol and need to be regulated at national level.

The African Model Law on Safety in Biotechnology has been initiated to feel the gaps of the Protocol.

3- Objective

The general objective of the Project is to help the African Union to possess the necessary capacity and effectiveness instruments to support its Member States creating national regulatory systems on biosafety. The results to reach are: strategies for AU in biosafety, network for continuous information and strategic options for technical and laboratory capacities

4- Ongoing activities

The Project have held at the AUC Headquarter in Addis in December 2005 a workshop to review the project activities and adopt a work plan for 2006.

The establishment of the Biosafety Unit at the AUC in the Department of Human Resources Science and Technology is in process. One expert in already in place.

Actions are taken January 2006 to inform Member States and Officials at national level in charge of the Cartagena Protocol on the project and the preparatory meeting of the COP/MOP 3

5- Planned Activities for Year 1 of the Project (2006)

The Year 1 work plan is focused on the following items:

- Set up the Biosafety Office in the AUC, and basic capacity building for the two Biosafety Experts and the Administrative Assistant;
- Support the African Delegates for the negotiations of COP/MOP 3 in Curitiba in March 2006;
- Prepare a strategy for Africa in Biosafety;
- Review and adopt the African Model Law on Safety in Biotechnology;
- Prepare the Ministerial Meeting.

ORGANIZATION OF AMERICAN STATES (OAS)	[6 JANUARY 2006]
	[SUBMISSION: ENGLISH]

CAPACITY BUILDING FOR THE SAFE AND SUSTAINABLE USE OF BIOTECHNOLOGY, WITHIN THE FRAMEWORK OF THE BIOSAFETY PROTOCOL SUPPORTED BY THE ORGANIZATION OF AMERICAN STATES

Dr Lionel Gil Coordinator General Faculty of Medicine, University of Chile

The objective is to reinforce the national and regional capacities in: the evaluation and handling of GMOs risks, the management and innovation of the agri-food biotechnology industry, public awareness about GMOs and the generation of information for national and international networks in Biosafety that include the public and private sector and universities.

The participants countries are: Argentina, Brazil, Colombia, Chile, Costa Rica, Ecuador, El Salvador, Grenada, Jamaica, Mexico, Nicaragua, Panama, Paraguay, Peru, and Trinidad & Tobago, Venezuela and Uruguay been countries not formally participating in the Project have also joined in some activities

The activities included: organization of training courses and seminars; publication of reports, papers and books on the topics covered by the project; implementation of a web page; advising to parliaments in the discussion of biotechnology and Biosafety laws.

During 2004-2005 the project has organized five Regional Courses and six International Seminars in biotechnology fields such as: risk assessment and risk management of GMO food and plants with novel traits; DNA analysis and traceability in GMOs and derived food; innovation and management in biotechnology, Public Awareness. In addition, regarding the activities of the project 5 papers in peer review journals and book has been published

In the Practical and theoretical courses and seminar activities held in Panama, Argentina, Venezuela, Brazil, Colombia and Chile, have been trained 250 professionals from 17 countries representing almost 150 institutions. To the International Seminars have attended 900 professionals

The project is a good example of practical synergies and complementary between Biosafety capacity building initiatives at the country and at the Regional level. The project has strength the north-south cooperation, in Biosafety training through the collaboration of institutions such as: CFIA and Health Canada from Canada, USDA-APHIS and ILSI USA, Institute Pasteur, France, University of Leipzig, Germany, University of British Columbia, Canada, Similarly the south-south interactions has been strength working with institutions from Argentina: SAGPyA, SENASA, INIA and CONABIA, Brazil, EMBRAPA; Colombia, ICA; Venezuela, IDEA, Chile, CONICYT, CORFO, Ministries of Health and Economy and University of Chile. In addition synergies have also implemented with UNU-BIOLAC.

Poner todos mis datos:

"Construcción de Capacidades para el uso seguro y sustentable de la Biotecnología Agro-alimentaria en América Latina y el Caribe, en el marco del Protocolo de Bioseguridad y del futuro acuerdo ALCA"

NON GOVERNMENTAL ORGANIZATIONS

AREA-ED/GTZ PROJECT	[18 JANUARY 2006]
	[SUBMISSION: ENGLISH]

AREA-ED/GTZ PROJECT ON PUBLIC PARTICIPATION ON BIOSAFETY PROCESS IN ALGERIA: RESULTS, FOLLOW UP AND IMPLICATION FOR THE NATIONAL BIOSAFETY FRAMEWORK AND THE REGIONAL STRATEGY

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Introduction

AREA-ED became involved in the biosafety process in Algeria because there was little public debate on the use of genetically modified organisms. Most NGOs working in the fields of the environment, consumer protection and agriculture in Algeria had limited understanding of the biosafety issues partly due to the low levels of expertise in science and legislation, absence of research or production of modern biotechnology products and due to the fact that the first generation commercialized GMOs were not of special interest. However, there were concerns about people becoming passive consumers and Algeria becoming a land of experimentations through importation of food and agricultural inputs and introduction of new crops such as wheat and trees with no control. This is in view of the facts that Algeria's fragile agrarian systems, which support more than 1/3 of the population, are not adapted to intensive agriculture.

Civil Society Organizations (CSOs) have a key role in informing and training all the stakeholders. AREA-ED initiative plays an important interface role between farmers, NGO's, experts and policy makers into the process of information and training and by their involvement into the institutional commissions. The association has been involved on issues related to GMOs and biosafety since 1999 when it organized its first conference. It has participated in various international conferences and also attended two experts meetings on the African Model Laws (2000 and 2001). It has also coordinated one project funded by GAIA-GRAIN on capacity-building of AREA-ED on biosafety process (2002) and the current project funded by GTZ. From the beginning, AREA-ED was assisted by two French NGOs, BEDE (Montpellier) and Inf'OGM (Paris).

The Project: Enabling Civil Society in Biosafety Process in Algeria, which is funded by GTZ, started in October 2003 for a period of 2 years. It aims at enforcing information means and increases the public participation to build a national biosafety system and offer the public an opportunity to contribute to and strengthen the national biosafety framework (NBF) project.

Activities and achievements of the project:

- 1. Information dissemination work, including the selection, translation, condensation and distribution of information throughout a newsletter and a web site. The main results included the following:
- Published 4 issues of the newsletter: "Biosécurité-dz" (in French and Arabic)
- Created a website: www.areaed.asso.dz/biosecurite in November 2004, which has provided a permanent access tool to information on GMOs and Biosafety.
- Developed an African francophone citizen watch.
- 1. Enhancing public debate, training and exchanges

Awareness:

- OGM.DZ : Scientific and cultural manifestation on GMOs, throughout 6 Algerian cities.(16-17 April 2005)
- Educational exhibition "Les OGM en question" explaining Biodiversity, Biosafety and Ethical concepts.
- Public debate and scientific conferences
- Theatre play « Le péché ogémique » explaining in simple and funny way controversies around GMOs.

Training and exchange workshops

- Participation of the large public to the biosafety: Information and traceability. (Algiers, December 2003)
- Impact of GMOs on peasant agriculture and participation of the public in the process of biosafety and protection of genetic resources. (Gharadaïa, September 2004)
- Options for implementing a regulation framework for GMOs control and protection of biological resources. (Tipaza, April 2005)
- Prevent the biotechnological risks on agriculture; participation of Maghrebian civil society in the biosafety process. (Algiers, 14-15 January 2006)
- 3. Promotion of participation in the general biosafety process

At an international level

- Presentation of the project under the GTZ side-event at MOP-COP 2 in Montreal
- Participation at several conferences at regional and international levels: WESCANA, Mediterranean and francophone African regions

At a national level

 AREA-ED is a member of the national committee of coordination of the UNEP-GEF project on development of NBF

Results and Follow-Up

After two years of workshops, meetings and discussions throughout the country with many stakeholders, a national platform for the public debate on biosafety is currently set up by civil society organizations. Recalling the state sovereignty and its responsibility to implement a precautionary policies for the preservation of national genetic patrimony and public health, two major issues of concerns will be followed-up, namely: regulatory measures, and public participation on biosafety process.

- 1. Biosafety Regulatory frameworks.
- Complete the opening conceded with the open market of WTO, by regulatory system of control of GMO and protection of genetic resources with taking into account the other international treaties (TIRPAA, African model laws) and which is based on precautionary principle, socio-economic consideration and public participation.
- Before the setting of a complete biosafety regulatory system, including labeling, traceability and liability, responsibility and reparation regulations, the moratorium should be strengthened with efficient control measures
- Harmonization of the regulatory framework in the Maghrebian countries and strengthen capacities of delegations in COP-MOP (number and expertise)
- Set up public participation mechanisms in the regulatory framework and identification of the concerned actors (farmers, consumers)
- A specific laws to protect traditional varieties and farmer rights. Creation of registers of local varieties and required 0 % contamination for seeds.

2. Public participation in biosafety process

- Agri-Research: Responsible research based on precautionary principle, innovative research on modern biotech including biosafety and alternatives of biotech agriculture
- Creation of REMDO: Réseau Maghrébin de Détection des OGM. Two laboratories (INA-Algiers and ISBM-Monastir)
- Project of training course for francophone countries in the spirit of GENOK training course
- Education : Conception of pedagogical tools in Arabic and French
- Creation of circle of teachers and perspectives of introduction on pedagogical programs (AREA-ED)
- Follow the work of translation in Arabic and French (several NGOs)
- Information Network through the Web site of AREA-ED
- Citizen watch on biosafety and biological resources protection
- Regional network for exchange of information and experiences (WESCANA, Francophone Africa and Mediterranean countries).
- Action of awareness: organization of public debate (National assembly, Chambre nationale de l'agriculture, farmer organizations).

PUBLIC RESEARCH AND REGULATION (PRRI)	[12 JANUARY 2006]
	[SUBMISSION: ENGLISH]

PRRI - BIOSAFETY CAPACITY BUILDING ACTIVITIES

Piet van der Meer Foundation Public Research and Regulations

The Public Research and Regulation Initiative (PRRI) is established to involve the public research sector in regulations and international agreements relevant to modern biotechnology, such as the Cartagena Protocol on Biosafety. To this end, the PRRI is involved a number of capacity building activities, primarily aimed at capacity building in the public research community. Examples of these activities are summarized below.

1. Informing public researchers about the Cartagena Protocol on Biosafety (CPB) and involving public researchers in the Meetings of the Parties to the CPB.

The PRRI produced a background paper and organized meetings for public researchers on the background, content and implementation of the CPB as well as about the ongoing discussions and procedures of the Meetings of the Parties. The PRRI arranged for public researchers to be involved in Meetings of the Parties to the CPB and the Aarhus Convention. The background paper and reports of the meetings as well as reports of PRRI participation in COP-MOP meetings are available on the PRRI web site, under 'International agreements'.

2. Informing public researchers about discussions on specific topics under the CPB, the Convention on Biological Diversity (CBD) and the Aarhus Convention.

As part of the meetings mentioned above, the PRRI introduced the background of a number of specific issues discussed under the CPB, the CBD and the Aarhus convention, including: notifications, risk assessment, liability and redress, public awareness and socio-economic considerations. On the basis of

consultations, PRRI statements on these topics were prepared. The reports of the seminar and preparatory meetings as well as the PRRI statements are available on the PRRI web site, under 'International agreements'.

3. Providing information about public research in modern biotechnology.

For the purpose of informing policy makers, regulators and the general public, the PRRI has produced an overview of the background and objectives of public research in the field of modern biotechnology. This overview, which will be regularly updated, is available on the PRRI web site, under "Public research".

4. Providing practical guidance for public researchers notifications and risk assessment for releases into the environment of genetically modified organisms.

Since the late 80s, many documents and case studies have been produced that explain the general approaches for notifications and risk assessment. While most of these documents are encouragingly consistent and useful, communications from public researchers from all over the world show that there is a need to work these general approaches out in practical guidance that goes step by step through the entire process. The PRRI has set out to collate the vast, collective experience from its members to produce such practical guidance for public researchers. The first module of that PRRI Guide focuses on genetically modified crop plants and includes: 1) guidance on the process of notification, 2) guidance on the general, administrative information requirements, 3) guidance on the technical information requirements, 4) guidance on risk assessment, 5) an Annex with examples of a summaries of relevant characteristics of genes that are frequently used with genetic modification, 7) n Annex with examples of risk assessment.

The Guide can be, and is being, used:

- (a) for notifications of releases that a public research institute wishes to carry out in the country where it is based as well as for releases in other countries;
- (b) for notifications required under domestic regulations as well as for notifications required under the CPB, by public researchers who are preparing notifications as well as by people involved in reviewing notifications.

Versions of this Guide are made available on the PRRI web site, under "cross cutting issues".

5. Outreach to non-English speaking public researchers.

To assist non-English speaking public researchers, the PRRI has established working groups that make the main documents available into French, Spanish and Russian, and of which contact persons are available for questions in those languages.

THIRD WORLD NETWORK (TWN)	[27 JANUARY 2006]
	[SUBMISSION: ENGLISH]

THIRD WORLD NETWORK BIOSAFETY CAPACITY BUILDING ACTIVITIES

Lin Li Lim Third World Network The Third World Network (TWN) has implemented a number of biosafety capacity-building initiatives. Examples include the following:

1. Organising and participating in meetings

TWN has been engaging in biosafety capacity building activities since the negotiations of the Biosafety Protocol through organising and co-organising seminars, workshops and conferences, and through providing resource persons to speak at and train participants at meetings organized by NGOs and civil society organisations, governments, intergovernmental bodies and international organisations. For example, before the 1st Meeting of the Parties of the Biosafety Protocol and the 7th Conference of the Parties to the Convention on Biological Diversity, TWN co-organised and facilitated a capacity building seminar on biosafety and biodiversity issues for national NGOs in Malaysia, in collaboration with the Malaysian Environmental NGOs coalition (MENGO). A one-day seminar on the latest scientific findings and socio-economic aspects of biosafety was also held, and this was open to all participants of MOP1.

TWN representatives have also been resource persons and trainers at numerous capacity-building meetings organized by NGOs and civil society organisations and networks.

At the national level, in 2005, TWN was engaged in capacity building activities in Malaysia. For example, through a DANIDA funded project, TWN was invited to provide key resource people to train Malaysian regulators, civil servants, policy makers and NGOs in Multilateral Environmental Agreements including the Biosafety Protocol. A web-based training module has been developed from this by an NGO tasked with this activity.

TWN has also collaborated with the Nanjing Institute of Environmental Science and the State Environmental Protection Authority of China in 2 national-level workshops to raise public awareness and to promote biosafety research and science.

At the regional level, capacity building activities have also taken place. For example, a preparatory meeting to build capacity on biosafety regulatory issues and for the Biosafety Protocol negotiations was co-organized for GRULAC countries before MOP 1.

In meetings organized by intergovernmental bodies and international organisations such as ASEAN, FAO and the UNEP-GEF development of national biosafety frameworks project, TWN has participated as resource persons.

- 2. **Technical information and assistance:** Upon request, TWN provides technical information and assistance to policy makers, regulators, NGOs, and civil society groups on biosafety policies, laws and regulation.
- 3. **Information sharing:** Information gathering and dissemination is an important component of the capacity building exercise. To this end, TWN:

Operates a website, Biosafety Information Centre (<u>www.biosafety-info.net</u>), where biosafety-relevant information is posted.

Operates a listserve, Biosafety Information Service, where recipients receive a few key pieces of biosafety information highlights a week.

Publishes a number of biosafety-related publications, including a Biotechnology and Biosafety Series, Biosafety Briefings and other publications which are widely distributed.

- 4. Capacity building courses: TWN has been collaborating with the Norwegian Institute of Gene Ecology, the New Zealand Institute of Gene Ecology and the University of Tromso in organizing international biosafety training courses. The first course was held in 2003, in Tromso, Norway. Subsequent courses were held in Tromso in 2004 and 2005, organized by the UN Environment Programme, the Norwegian Institute of Gene Ecology, and the University of Tromso. Around 40 participants from developing countries are selected and funded, on a competitive basis, to attend the course every year. The participants include policy makers, regulators, scientists, civil society and NGO representatives who are engaged in biosafety/GMO work. Although priority is given to developing countries, the course is also open to participants from developed countries who can obtain their own funding, as biosafety capacity is often lacking as much in developed as in developing countries. Participants from economies in transition are also included in the course. The course takes place over 2 weeks, with a combination of lectures, group work, and hands-on laboratory sessions. The course is premised on providing the participants with the basic foundations on which to assess the risks related to genetic engineering and genetically modified organisms in a holistic manner, and in accordance with the Precautionary Principle. The course is science-based (including social sciences) and also covers policy, legal, regulatory and public participation aspects. Participants of the courses are offered the opportunity to obtain 12 European Community Course Credit Transfer System (ECTS) that would contribute to a doctoral degree, on completion of the course and the successful submission of a written paper.
- 5. TWN, together with the Bogor Agricultural Institute in Indonesia and the Norwegian Institute of Gene Ecology co-organised a sub-regional course for South East Asian participants in January 2006 in Bogor, Indonesia. The theme for these courses is: Holistic Foundations for Assessment and Regulation of Genetic Engineering and Genetically Modified Organisms. Further international courses are planned for 2006 and 2007. Other sub-regional and regional courses will also be considered. To complement the biosafety capacity building courses, a book and CD-rom will be published and produced, which reflects and augments the training course. This would serve as a consolidated textbook for those who have participated in the course as well as being a useful reader for those who have not.
- 6. **Public awareness and participation:** TWN also collaborates with national NGOs, regional and international NGO networks to conduct seminars and workshops to raise public awareness on biosafety. This is in accordance with the Biosafety Protocol's support for public awareness and public participation in decision making related to biosafety and GMOs. A number of the above activities are carried out with the support of the Swedish International Biodiversity programme (SwedBio).
- 7. **Co-operation with UNEP-GEF Development of National Biosafety Frameworks project:** TWN is the NGO liaison point with the UNEP-GEF development project. This has helped to facilitate wider participation of NGOs from different regions in the regional and sub-regional meetings of the project, and in national-level meetings of the project. This has also helped to widen the spread of information to NGOs about the project, and to facilitate NGO feedback to, and communications with, the project.
- 8. **Participation in the CBD Liaison Group and the Coordination Mechanism for biosafety capacity building:** TWN is the NGO representative in the Liaison Group which advises the Executive Secretary of the Convention on Biological Diversity on biosafety capacity building issues, and is taking part in the Coordination Mechanism for the Action Plan for Building Capacities for the Effective Implementation of the Protocol through the Coordination Meetings.

ACADEMIC AND RESEARCH INSTITUTIONS

DANISH INSTITUTE OF AGRICULTURAL	[12 JANUARY 2006]
SCIENCES – BIOSAFE'TRAIN PROJECT	[SUBMISSION: ENGLISH]

"BIOSAFETRAIN: CAPACITY BUILDING FOR BIOSAFETY AND ECOLOGICAL IMPACT ASSESSMENT OF TRANSGENIC PLANTS IN EAST AFRICA"

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For further information: www.biosafetrain.dk

Introduction

The BioSafeTrain-project, funded by the programme on Enhancement of Research Capacity (ENRECA), Danida, is a collaborative project between partners Denmark and three East African countries. The project started in December 2004 and we have currently working on phase 1 (3-y) of the project.

The long-term vision of the project is in to build up capacity to cope with the challenges of introducing genetically modified crops in this region by developing a platform for capacity building on biosafety impact assessment of transgenic plants. In this period we aim to:

- Develop a training platform structure, a Biosafety Training Laboratory, where students and other relevant persons from East African countries can supplement their education with extra degrees or training on GM plant biosafety/ecological risk assessment.
- Develop a research agenda adapted to local conditions on relevant biosafety topics, and during this process also generate new knowledge in order to realize this agenda.
- Offer M.Sc. and Ph.D.-level educational training on agricultural and environmental impacts of GM plants, through joint African-Danish supervision at the local university/institute and perform relevant research projects locally.
- Offer a Diploma in Biosafety, as part of the continuing education initiatives that exists at certain universities.
- Test and revise suggested standard procedures for GM plant biosafety
- Improve existing capacity with regard to infrastructure by upgrading current biotechnology/biosafety facilities

The details for the Biosafety Training Laboratory are currently being specified. Once completed, this will consists of facilities for training at the Universities of Nairobi and Dar es Salaam, a confinement glasshouse established at KARI and a quarantine facility at Makerere University that the project group may use in collaboration. The first graduate research projects (4 PhDs and 6 MSc) have started.

Subjects for the first training courses have been decided, and they are under development. The courses will focus on biosafety/ecology, biotechnology, practical aspects in the cultivation and handling of GM crops, risk assessment and evaluation, and the broader societal aspects. We intend to offer the first course in late 2006.

Lessons learned

- 1. Provide opportunities for students as well as to participating scientists from developing countries to form their own networks.
- 2. Plan for project sustainability. First, avoid dependence on single persons (link with teams or deputies). Seek to "institutionalise" links.

Collaborations with other projects

GMO ERA Project: BST is collaborating on training activities in East Africa with the Swiss-funded GMO-ERA Project. We shall use the published risk assessment recommendations with a view to test/modify the procedures. GMO-ERA is providing their training resources and additional funding to support participants at our African training courses.

Similarly, we shall use the resources published by Bio-Earn (E African, SIDA-funded), COTRAN (Bt-cotton in China, EU-funded) and other relevant projects. We are partner in the newly formed "Konigswinter Coalition", a network of EU- biosafety capacity building initiatives. This should ensure that further collaboration and co-ordination is achieved.

GMO ERA PROJECT	[12 JANUARY 2006]
	[SUBMISSION: ENGLISH]

INTERNATIONAL PROJECT ON GMO ENVIRONMENTAL RISK ASSESSMENT METHODOLOGIES (GMO-ERA)

Gabor L. Lövei http://www.gmo-guidelines.info/

Overall achievements

The GMO ERA Project is a pioneering initiative driven by public sector scientists to develop tools to support environmental risk assessment (ERA) of genetically modified organisms (GMOs). Our goal is to give decision makers around the globe tools and training to help them decide what information and data are most important and appropriate for an ERA that is tailored to the GM crop and agricultural system in their country. Our methods enable local scientists and decision makers to reach their own decisions, based on transparent and scientific processes. The project is a consortium of partners on five continents, including the Vietnam Ministry of Agriculture and Rural Development (MARD) and Embrapa (Brazilian Agricultural Research Corporation).

The GMO ERA Project has over 700 contacts in 116 countries. It is conducted by a network of 280 public sector scientists (the 'Core Group') working on the science supporting environmental risk assessment of genetically modified organisms. Over 70% of the Core Group are scientists in developing countries. The project ran three workshops with a total of over 130 of these scientists, who then wrote the project books: Environmental Risk Assessment of GMOs Volume 1: A Case Study of Bt Maize in Kenya. Hilbeck, A & Andow, DA (eds) (2004) CABI Publishing, Wallingford, UK (57 co-authors) and Environmental Risk Assessment of GMOs Volume 2: Methodologies for Assessing Bt Cotton in Brazil. Hilbeck, A, Andow, DA & Fontes, EMG (eds) (2006) CABI Publishing, Wallingford, UK (74 co-authors).

Lessons learned

Teaching and learning approach and need for teaching tools: The project teaching approach is based on participatory and experiential learning, involving small group activities dealing with concrete, relevant scientific problems. The groups apply their own expertise to adapt the methodologies to the regional situation. This approach has been very successful, and in the next two years we will carry out similar capacity building activities to create Expert Training-Teams (ETT) to develop and validate teaching tools that use the project methodologies developed so far.

Problem Formulation and Options Assessment (PFOA): PFOA is a methodology for a multistakeholder dialogue of the risks and benefits of a new GMO technology intended to frame the scientific risk assessment. Piloted in the first project phase, it was well received. The project will produce a guided design and decision-making resource (PFOA handbook) that will allow any country to develop their own PFOA. ETT members will carry out activities to embed PFOA in a policy context in one of the project regions.

Collaborations with other projects

BioSafeTrain project: The GMO ERA Project will collaborate on training activities in East Africa with an exciting new Danida funded project. The long-term vision of the BioSafeTrain Project is to build up capacity to cope with the challenges of introducing genetically modified crops in East Africa by developing a platform for capacity building on biosafety impact assessment of transgenic plants.

Others: As has already happened in the past, the GMO ERA Project will also seek opportunities in the next year to contribute to the capacity building efforts of the RiBios project, the Centres for Gene Ecology, and the ICGEB, and will communicate closely with the CBD Secretariat, the UNEP GEF Biosafety Unit and the UNEP GEF implementation projects, the FAO, and others. Discussions are also underway to collaborate with regional capacity building projects in South America and South East Asia.
