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Capacity-Building for the Effective Implementation of the Biosafety Protocol: Experiences and Lessons Learned From Recent Initiatives

Introductory Message

Dr. Ahmed Djoghlaf
Executive Secretary of the Convention on Biological Diversity

Back in 1992, the United Nations Conference on Environment and Development (UNCED) in its main output, Agenda 21 - the global blueprint for sustainable development- noted that the ability of a country to follow a sustainable development path is determined to a large extent by the capacity of its people and its institutions. In particular, Agenda 21 pointed out that environmentally sustainable development and application of biotechnologies, particularly in developing countries, would require a major effort to build up national and regional capacities. In this regard, it called for international and regional cooperation, including transfer of technology and know-how. Ten years later, the World Summit on Sustainable Development reiterated the need to intensify regional and international cooperation in support of national efforts, including through capacity-building, knowledge-sharing, technology transfer and mobilization of adequate and predictable financial resources. In the same vein, the Cartagena Protocol on Biosafety requires Parties to cooperate in the development and strengthening of capacities in biosafety, including biotechnology to the extent that it is required for biosafety, for the purpose of the effective implementation of the Protocol.

In the last decade, more than 130 biosafety capacity-building initiatives have been implemented in different countries with input and support from a wide range of partners. The current issue of the *Biosafety Protocol News* presents experiences, good practices and lessons learned from eight of those initiatives implemented by the Caribbean countries, India, Mexico, the Republic of Moldova, the Food and Agriculture Organization of the United Nations (FAO), the Norwgian Centre for Biosafety (GenØk), the International Centre for Genetic Engineering and Biotechnology (ICGEB) and the Program for Biosafety Systems (PBS).

A number of important lessons have been learned. One of the key lessons emerging from the articles is that informed stakeholder involvement is crucial to the success of any capacity-building initiative. Such involvement not only provides the benefit of varied insights but also helps instil a sense of shared ownership. In Moldova, for example, public hearings and stakeholder consultations were crucial in reaching consensus on different biosafety issues, national policies and actions. As highlighted in article by the PBS initiative, effective engagement of the stakeholders requires sustained and targeted awareness-building and communication through different means.

Collaboration at the regional and sub regional levels is also crucial as illustrated by the experiences from the FAO project and the projects in the Caribbean. Such collaboration offers opportunities for countries with similar situations and needs to work together at the same pace, compare notes and experiences, synchronize efforts, leverage regional opportunities and optimize the use of available resources through economies of scale.

Furthermore, as highlighted in the articles from India and Mexico, sharing

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Central African Republic and Honduras ratified the Protocol on 18 November 2008. They will become Parties to the Protocol on 16 February 2009 in accordance with Article 37(2) of the Protocol. This will bring the total number of Parties, to date to 153. The complete list of the status of ratifications is available online at: www.cbd.int/biosafety/signinglist.shtml

of information and experiences is critical to the work of scientists, regulators and decision makers and plays a central role in facilitating public awareness and informed stakeholder participation. Therefore, websites, databases, information materials and other tools are imperative.

Biosafety issues and the needs of countries are not static, but, constantly evolving. Therefore, as highlighted in the articles from ICGEB and GenØk, biosafety-building efforts must be continuously revised and adapted to new developments and the changing needs of countries. Capacity-building is an ongoing process that requires long-term commitment.

Finally, as mentioned in the article from India, biosafety should not be considered as an issue unto itself but should be addressed within the broader national development framework and agenda and mainstreamed into relevant sectoral and cross-sectoral policies and programmes. This requires strong leadership and political will.

It is clear from the articles presented in this issue of the *Biosafety Protocol News* that capacity-building is a dynamic and ongoing process that requires long-term commitment and continuous adaptation. If we are to improve capacity-building for the effective implementation of the Protocol, we must continuously learn from previous experiences and the lessons. This is a must, not an option.

I would like to pay tribute to all the authors who contributed articles to this issue. It is my hope that the experiences, good practices and the lessons shared through this issue will provide a useful resource for those implementing or planning to embark on similar initiatives.

I wish you good reading.

Prof. Leonard O'Garro-Barbados, Programme Coordinator
Biosafety in the Caribbean (UNEP-GEF)

Experiences and Lessons Learned from Capacity-Building Initiatives for Implementation of the Cartagena Protocol in the Caribbean Sub-Region

Since 2001, countries in the Caribbean subregion have been actively involved in activities to develop their national biosafety frameworks (NBFs) and strengthen their capacities to implement the Cartagena Protocol on Biosafety. Most of those activities have been supported by the Global Environment Facility (GEF) through the United Nations Environment Programme (UNEP) initially under the Global Project on Development of National Biosafety Frameworks.

For the purpose of the UNEP-GEF NBF development project, the Caribbean subregion is comprised of Suriname, Guyana, Trinidad and Tobago, Grenada, Saint Vincent and the Grenadines, Saint Lucia, Barbados, Dominica, Antigua and Barbuda, Saint Kitts and Nevis, Jamaica, Bahamas and Belize. As of December 2008, all but one of these countries completed preparing drafts of their NBFs. Project concepts to pave the way for implementation of those frameworks were approved by the GEF in November 2008. The implementation of the frameworks will be supported through a regional project covering all eligible countries. Project preparation work, which will produce the project document, began in November 2008 and is expected to be concluded in March 2009.

Countries of the Caribbean subregion decided to develop NBFs for the following reasons:

1. To be able to comply with the provisions of the Cartagena Protocol on Biosafety;
2. To set legal and policy frameworks for trade in modern biotechnology products that promote sustainable development, with an emphasis on the safe use of biotechnology through systems for minimizing its potential threats to sustainable livelihoods, human health and the environment, including biodiversity;
3. To create an enabling environment for the application of biotechnology to enhance economic development; and
4. In the case of Bahamas and Belize, to integrate biosafety relating to modern biotechnology with other areas such as food safety, health, invasive species, environment and consumer rights and protection.

The NBFs were developed through a common stepwise process recommended by UNEP-GEF Biosafety Unit. The process was administered by each Government through a designated National Executing Agency (NEA). The NEA in turn appointed an ad hoc National Coordinating Committee (NCC), which invariably comprised of representatives from relevant government agencies, inter-governmental institutions, non-governmental organizations, academic institutions and the private sector for overall management of the project on its behalf. The NEA also appointed a National Project Coordinator (NPC), who was responsible for the day-to-day administration and management of the project. The NPC also served as the secretary to the NCC and as the liaison person for the UNEP-GEF Biosafety Unit. Technical support for developing each draft NBF was provided by the NEA/NCC, consultants and the UNEP/GEF Programme Coordinator for Biosafety in the Caribbean. The process of developing a draft NBF was consultative in nature.

Prior to the development of NBFs, existing sectoral laws in all the Caribbean countries could not adequately regulate the transboundary movement of LMOs in accordance with the Cartagena Protocol. Undertaking amendments to the several relevant laws which preceded the Protocol was deemed cumbersome and legally undesirable. Consequently, with the exception of Belize, all countries in the subregion agreed to develop new biosafety laws to facilitate the implementation of the Cartagena Protocol.

The responsibilities for enforcing the sectoral laws that could be amended

to facilitate the implementation of the Cartagena Protocol fell under several different government agencies, which often function independently of each other. Some countries retained these agencies for enforcing the NBFs but recognized that effective inter-agency cooperation and coordination will be required. Others decided to create new agencies catering specifically for implementation of NBFs.

All of the above considerations determined the scope of each country's draft NBF. In all cases, however, the draft NBFs comprised of common components. These were: (i) biosafety policy; (ii) regulatory regime; (iii) systems to handle requests (including administration, risk assessment and decision-making); (iv) systems for follow-up actions (including monitoring, inspections and enforcement); and (v) systems for public awareness and participation.

In all countries, implementation of the NBFs will be overseen at the highest level by bodies designated or established by the respective biosafety laws. The names of the oversight bodies vary from country to country. Examples include: Biosafety Authority, National Biosafety Committee or Biosecurity Council. They mainly comprise of representatives of relevant government ministries but in some countries, including Saint Lucia, Dominica and Bahamas, there are explicit provisions for the inclusion of non-governmental organizations. The oversight bodies will collaborate with entities specified under the Cartagena Protocol, including the National Competent Authority, the National Focal Point of the Cartagena Protocol on Biosafety, and the Focal Point of the Biosafety Clearing-House. The functions of these bodies are often performed by a single institution in an effort to maximize the use of scarce human and material resources.

In all the Caribbean countries, with the exception of the Bahamas, the draft NBFs designated one Competent National Authority (CNA). The Bahamas designated five CNAs. In all the countries, existing government ministries and departments were designated to serve as CNAs. The CNAs are assisted by scientific advisory committees, which are responsible for conducting risk assessment. In Grenada and Bahamas, risk assessment is carried out or reviewed by the overall oversight body. In Saint Kitts and Nevis, Saint Lucia and Saint Vincent and the Grenadines, the CNAs are supported by a legislated Biosafety Unit, addition to the Scientific Advisory Committee. Staffing of the Biosafety Unit is also legally constituted and comprises the following: biosafety coordinator, information technology specialist, biosafety appraisal officer, public education specialist, administrative secretary and inspectors.

In general, the UNEP-GEF NBF Development Project was most successful in the Caribbean sub-region in terms of completion of draft NBFs and the plans for their implemention The manner in which scarce resources were optimized played a significant role in this achievement.

In the face of competing demands for the scarce human, material and financial resources, it was challenge for the Caribbean countries to make biosafety a matter of national priority. Frequently biosafety was perceived to be a low priority compared to the other areas requiring national attention and support and was often overshadowed by other emerging global challenges also requiring a government response. In this scenario, well-respected institutions and/or individuals in each of the countries, as well as the UNEP/GEF representation, had to champion biosafety to keep it on the list of priorities. The maintenance of biosafety as an area of priority in the Caribbean depends on very strong leadership.

Dr. Manoranjan Hota, Project Coordinator
GEF-World Bank Capacity Building Project
on Biosafety in India

Biosafety Capacity-Building: Experiences from India

Introduction

Environmental protection and the conservation of natural resources have been national priorities in India in the wake of various global environmental summits. India has established a stable organizational structure for environmental protection. Laws, policies and programs have been developed to address environmental management goals. The National Environment Policy, among other things, has recognized that biotechnology has immense potential to enhance livelihoods and contribute to the economic development of the country. However, it is also recognized that genetically engineered organisms (i.e., genetically modified organisms or living modified organisms, GMOs or LMOs), are inherently different and could have potential risks and hazards. As such, they need to be regulated at the national and international levels. The solution, therefore, is biosafety, which is fast emerging as a dynamic force on the socio-economic and technological front. Countries always have the sovereign right to regulate GMOs. Countries must therefore have the capacity to undertake biosafety activities so as not only to safeguard their national interests but also to comply with the international regime for environmental governance. In India, the biosafety regulatory system came into force in 1989 under the Environment Protection Act of 1986, i.e. prior to the adoption of the Cartagena Protocol on Biosafety. In order to implement the biosafety instruments for assessing and ensuring the biosafety of GMOs, India has a multi-tiered, multi-agency regulatory framework with six statutory committees, namely the: (i) Recombinant DNA Advisory Committee (RDAC) to recommend appropriate safety regulations in recombination research, use and applications; (ii) Institutional Biosafety Committee (IBSC) to prepare site-specific plans for the use of GMOs; (iii) Review Committee on Genetic Manip-

ulation (RCGM) to oversee all research and field trials on GMOs; (iv) Genetic Engineering Approval Committee (GEAC) to consider proposals relating to the release of GMOs into the environment; (v) State Biotechnology Coordination Committee (SBCC) to inspect, investigate and take punitive action in cases of violations of safety (as well as control measures in the handling of LMOs); and (vi) District Level Committee (DLC) to monitor safety regulations in installations engaged in the use of GMOs and their applications in the environment.

In the context of biosafety, capacity-building refers to the strengthening and/or development of human resources, institutions and infrastructure in order to enable countries to achieve safety in biotechnology through the effective implementation of biosafety regulations. Regulatory frameworks and related capacity-building activities need to have a reciprocal relationship and should be undertaken to promote the safe development and diffusion of biotechnology. Keeping this in mind, India implemented a medium-sized project on capacity-building in biosafety as an enabling activity of the Global Environment Facility (GEF). The main objective was to improve capacity across ministries and among key stakeholders to analyse, inform and make decisions to reduce potential risks related to LMOs. The goal was to strengthen the biosafety framework with enhanced technical and monitoring capacities and to manage information and coordination networks.

Achievements of the project

The project helped to improve capacity and coordination in decision-making on issues relating to LMOs and served as a catalyst to strengthen institutional frameworks within and across relevant ministries. This was achieved, for instance, through training of key personnel in relevant government and other specialized organizations. Capacity enhancement was also carried out for molecular diagnostics to detect LMOs so as to increase the country's ability to monitor the transboundary movements of LMOs. A study on "Environmental Risk Assessment, Socio-Economic Considerations and Decision-making support for LMOs in India" was also carried out to review the regulations, guidelines and procedures.

Furthermore, in order to facilitate the monitoring of transboundary movements of LMOs, four laboratories/institutions were strengthened with improved infrastructure and equipment. This has allowed for the evaluation and validation of the commercially available immunodiagnostic strip test methods for on-the-spot testing of imported LMOs. Development and standardization of diagnostic tools was also done for the detection of LMOs and five transgenic traits using polymerase chain reaction (PCR) as well as immunoassays. Validation of sensitive molecular methods, as well as detection of unintended introduction of LMOs into the environment, were also done. Furthermore, an integrated database on biosafety was developed for retrieval, storage and management of data on biosafety of LMOs.

In order to facilitate information-sharing and networking, a national node of the Biosafety Clearing House (BCH) was set up and is available at http://indbch.nic.in. A project website (available at http://envfor.nic.in/divisions/csurv/biosafety/default.htm) was also established. In addition, several issues of a quarterly "Biosafety Newsletter" were published. The project also produced 23 publications/documents, 1 documentary and 55 training programmes The training programmes were attended by 2,732 participants, including policymakers, members from regulatory bodies, federal and state government officials, agricultural scientists, customs officials, excise and plant quarantine officials, lawyers, media personnel, members from seed industries, civil society representatives, children and teachers.

One of the major challenges encountered was development of information materials for a wide range of stakeholders, especially those who were least exposed to biotechnology and those who had never heard of biosafety. However, this challenge was successfully met through the various publications/documents that were produced by the project and the training programmes that were systematically carried out for different stakeholders. It was a mission well accomplished. The project broadened public access to information and stakeholder participation.

Experiences and lessons learned

Capacity-building, in terms of human resources, institutional and infrastructural capacities, is an imperative for sustainable development. It is important for domestic development as well as for fulfilling international obligations under the Cartagena Protocol on Biosafety. Multiple initiatives have been taken to strengthen the existing capacities and to develop new capacities. This GEF-World Bank project was one of those initiatives. The project has laid a strong foundation for implementing the national biosafety framework. The project addressed gaps or barriers that were identified and achieved the desired objectives.

Organizations most often look for the "key to success" and the project management best practices. Some of the best practices under this project related to documentation preparation, development and implementation of training modules, meticulous monitoring and management review. Sustaining the dynamics established by the project is key to the future efforts.

One of the key lessons learned is that biosafety should not be considered in isolation but within the framework of sustainable development. Another lesson from my experience in capacity-building in India, as well as from the Asian region at large, is that it is necessary to develop an effective training and communication strategy so as to ensure that biosafety issues are addressed under domestic legislation that is in harmony with international obligations under the Cartagena Protocol on Biosafety. Also, a science-driven national biosafety policy is necessary to enhance harmonization between scientists, policymakers and other stakeholders in the implementation of the Biosafety Protocol.

Agricultural biotechnology is developing fast. Understanding its potential

and limitations continues to be a challenge both at the domestic and international levels. Capacity-building in biosafety must, therefore, be an ongoing effort. Information is the key to success and therefore it must be shared at the national, regional and international levels. There is also a need to involve all of the relevant stakeholders. Furthermore, in order to build trust among various stakeholders, a strong and efficient regulatory authority is crucial. Finally, capacity-building activities need to be targeted to the public.

Dr. Agustín López-Herrera, National Project Coordinator
Mexico (UNDP-GEF)

Best Practices and Lessons Learned from the UNDP-GEF Capacity- Building Project for the Implementation of the National Biosafety Framework of Mexico

Introduction

In 2002, Mexico was supported by the Global Environment Facility (GEF), through the United Nations Development Programme (UNDP), to implement a three-year demonstration project to strengthen its capacity in biosafety. The project support amounted to US$1.43 million. Mexico was selected to implement one of the twelve demonstration projects funded by the GEF worldwide mainly because of the following reasons: it is a very bio-diverse country, it had more than 12 years of experience in field releases of living modified organisms (LMOs), and also had a legal structure in biosafety and a system of organized ministries with a well-trained staff in both biotechnology and biosafety.

Challenges

One of the main challenges encountered during the implementation of the project was the difficulty in implementing the biosafety law for genetically modified organisms (GMOs). This was particularly with regard to the controversial area of the presence of LMOs in food products and crops. There is no federal authority with the experience to achieve the level of regulation that the law requires. In response to this challenge, experts trained under the project met to find solutions to specific problems with the biosafety law. This enabled their superiors to discuss the problems with their peers in other agencies. While this did not completely solve the present problem, it was a step forward.

Another challenge was encountered when transgenic maize was accidentally released 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. In poor areas of the country sometimes farmers plant regular grain coming from imported corn commodities instead of seed from their landrace varieties. Using some of the project finances, samples of maize were collected during a three-year period and analyzed in an internationally recognized laboratory to verify the presence of transgenes. The study established that transgenes were either not detectable or not present at all. During this three-year period, experts at the Ministry of Environment gave educational workshops to discourage farmers from using this type of grain. As a result, the landrace transgenes were eliminated.

Good practices

One of the good practices adopted under the project was the conduct of joint risk assessment by the environmental and agricultural ministries. These ministries now share information to decide whether an LMO can be approved for import.

Another good practice was the development of a database for the support of decision-makers. The database contains key information, including the genetic information, reproductive biology and molecular biology of transgenic plants, including their wild varieties. It was developed in such a way that it is possible, for example, to know in advance the hybridization rate of the improved LMO variety, and that of its wild relatives, in different environments.

Lessons learned

One of the main lessons learned is that it is useful to develop standard methodology for risk assessment which would permit the regulatory agencies to adopt a consistent approach. In Mexico, risk assessments are carried out by an interdisciplinary team of experts from different government agencies and university experts looking for common goals and using the same technical language.

Secondly, experience with the use of the database for the support of decision makers shows that it is very useful to review existing data in order to know the possible risks of an LMO. The Environmental Authority has approved this database for use in all risk assessments.

Principal achievements

The project produced a number of results. The main achievements included the following:

1) Team of experts in biosafety: The interaction of the representatives of the different competent authorities in biosafety, both during and after the project, resulted in the consolidation of a team of experts in biosafety. The federal authorities have great confidence in their abilities;
2) Methodologies for environmental risk assessment: The project developed a methodology for determining whether or not to approve the release of LMOs . It is now easier to inform the Agriculture Ministry and the Environment Ministry about decisions to allow LMO field releases. Moreover, the Environment Ministry is using a specific database for the support of decision-makers to review the possible effects caused by genetically modified crops on the non-GM crops growing alongside them;
3) Laboratories: The project financed the equipment of two LMO detection laboratories, one in the Environment Ministry and one in the Agriculture Ministry; and

4) Sustainability: Project results were recognized by the Mexican government as important and useful and, accordingly, federal authorities provided US$ 1,0 million for 2006-2008 to continue the project's capacity-building activities.

Synergies

The project personnel supported other GEF projects in the Central and South American regions. Because Mexico has vast experience in risk assessment of LMO field releases, Guatemala and Nicaragua solicited collaboration with Mexico to provide training to their respective biosafety committees and the GEF project of Colombia received a two-week training program in January 2006. In addition, an evaluation of the national biosafety framework of the GEF project of Peru was undertaken in July 2005. The Inter-American Institute of Agriculture Collaboration (IICA), in Costa Rica, also solicited advice from Mexico.

Furthermore, during the lifetime of the project, there was close interaction with the Rockefeller Foundation, the United Nations Industrial Development Organization (UNIDO), the Food and Agricultural Organization (FAO) of the United Nations, the United Nations Environment Programme (UNEP), as well as the large biotechnology companies.

Recommendations

1) It is important for countries that ratified the Cartagena Protocol on Biosafety to have a complete biosafety legal framework.
2) In addition to the legal framework, countries need to have trained personnel. They should establish the necessary administrative structures to allow the law to be fully applied.
3) Latin American countries should meet periodically to share information, develop synergies and present common positions at international meetings.

Dr. Angela Lozan, Project Manager
Biosafety Office, Moldova (UNEP/GEF)

Lessons Learned from the UNEP-GEF Projects on the Development and Implementation of the National Biosafety Framework for the Republic of Moldova

Introduction

The Republic of Moldova ratified the Cartagena Protocol on Biosafety in October 2002 and immediately initiated steps to build and strengthen its capacity to effectively implement its provisions. In terms of policy, Moldova declared biosafety as a priority for the country through the 2000 National Strategy and Action Plan in the field of Biodiversity Conservation. Action plans were developed to ensure that adequate legal and institutional capacities are in place. The current stand alone Biosafety Action Plan for the period 2009-2015 includes detailed measures and mechanisms for involvement of various stakeholders/sectoral government bodies, research and civil society.

The Moldovan Law on Biosafety was approved in 2001 and entered into force in 2003. It provides the legal framework for the regulation of various types of genetically modified organisms (GMOs) and their uses, including contained use, deliberative release into the environment, placing on the market, import-export and transboundary movements. The Ministry of Environment and Natural Resources is the National Biosafety Authority and also the National Focal Point for the Cartagena Protocol. The Ministry, working with a National Biosafety Committee (NBC), makes the decisions on GMO use in Moldova.

Moldova has also developed a national strategy for sustainable agriculture aimed at creating high-yielding plant varieties and hybrids that are resistant to unfavourable environments. It is hoped that Moldova will establish an integrated system for crops using advanced technologies. In future, it is envisaged that agriculture will combine conventional production methods with the GM technology. This arrangement calls for the setting up of a biosafety framework for effective and informed decision-making on GMOs.

To date, no permits have been given officially for any GMO imports or releases. However, recent quantitative and qualitative analyses of soybean on the market show that Moldova has some GMO products on the market. In a majority of the collected samples GMOs were detected and in half of the samples, the GM content constituted more than 5%.

Capacity-building initiatives

Moldova has been a beneficiary of the technical assistance programmes implemented by the United Nations Environment Programme-Global Environment Facility (UNEP-GEF). Three UNEP-GEF projects have been executed in Moldova. These are: (i) development of the National Biosafety Framework (NBF) for the Republic of Moldova (2002-2004); (ii) capacity-building for effective participation in the Biosafety Clearing-House (2005-2006); and (iii) support for the Implementation of the draft NBF for the Republic of Moldova (2006-2010).

The overall objective of the above assistance programmes was to strengthen and develop national capacities in biosafety in order to enable the country to meet its obligations under the Cartagena Protocol on Biosafety through the establishment of a fully operational NBF. The latter programme included the following components:

- Development of a comprehensive national biosafety policy as the basis for the development of a national regulatory regime and institutional framework;
- Strengthening of the national regulatory regime in line with Cartagena Protocol, the National Biosafety Framework, and the biosafety policy;

•Strengthening of the administrative system for handling notifications and authorization of permits;
•Establishment of a fully functional system for monitoring and enforcement; and
•Enhancement of national capacities for public awareness and participation in decision-making.

Main achievements/ successes and their contributing factors

One of the biggest achievements made, with the assistance provided by the above-mentioned projects, was the establishment of a national node for the BCH. Decision-makers and key stakeholders were also trained in the use of the BCH to search and retrieve information in order to make informed decisions regarding GMOs. The national node of the BCH has also contributed to the promotion of public awareness and to the exchange of information on biosafety (see: www.biosafety.md).

The other major achievement was the adoption of a Law on Biosafety in 2001. The law has been improved with additional amendments to enforce the risk assessment/management and monitoring requirements in accordance with the Protocol and the decisions of the Conference of the Parties serving as the meeting of the Parties to the Protocol (COP-MOP). As well, several sectoral laws in the field of agriculture, health care, environmental protection, research and innovations have been amended secondary regulations have been developed. Furthermore, procedures for handling of requests have been revised and guidelines for tracking the administrative procedures have been developed. In addition, a Biosafety Action Plan of the Republic of Moldova (2009-2015) has been developed and will be implemented through a multi-year programme.

Other achievements include the development of templates for GMO decisions, a GMO electronic register and various databases which are available through the national BCH website. A roster of national experts from research institutions has also been prepared, particularly in readiness for future risk assessment work. Furthermore, a laboratory equipped with a polymerase chain reaction (PCR) real-time system for GM detection and identification and for risk assessment analysis is now fully operational. A special guideline for post-release monitoring and risk management has also been approved.

To increase the awareness of different stakeholders about issues regarding biosafety in Moldova, a series of national public awareness workshops, targeted at specific groups, were organized. The target groups included non-governmental organizations (NGOs), scientists and the general public. Awareness materials were also produced and distributed. In addition, universities have designed special courses on biotechnology and biosafety for different target groups.

Challenges encountered and how they were addressed

The development of biosafety capacity in Moldova has encountered some challenges. These include: a lack of experienced experts to implement various activities, unavailability of the necessary data, limited access to existing databases, limited experience in risk assessment and evaluation, poor cooperation among relevant institutions, inexperience in drafting biosafety regulations and guidelines at the governmental level and the low level of awareness of biosafety issues among decision-makers and the general public.

Developing an effective coordination mechanism among the different government sectors and clearly identifying their roles and responsibilities in dealing with biosafety issues have been biggest challenges. It also took some time to develop the approval process for GMOs but finally an effective system was put in place in March 2008. This process involves stakeholder consultation before approval of any GMO. Standard methods and guidelines for risk assessment are being developed and local experts are gaining the necessary experience in their application. Validation of methods for GMO detection is also taking place at national laboratories aimed at meeting International Organization for Standardization (ISO) standards and getting the necessary the accreditation.

To overcome the above challenges, a series of seminars, training workshops and round table discussions were organized among the various stakeholders. These included decision makers from various sectors, researchers, business, consumers and civil society. At the workshops, intensive small group discussions took place among the local experts involved in the surveys and comparative analysis in the field of biosafety. Furthermore, a number of toolkits, including guidelines on surveys and a guide to national procedures and rules, were prepared in the national language to help the local consultants and available on the national biosafety website. The hosting of the Central and Eastern Europe regional workshop on capacity-building and exchange of experiences on risk assessment and risk management of LMOs, in collaboration with the Convention on Biological Diversity (CBD) Secretariat in Chisinau, from 26 to 28 November 2007, also helped to raise awareness among local scientists about the biosafety procedures adopted in other countries in the region.

Good practices and lessons learned

A number of good practices and lessons emerged during the course of implementing the three biosafety-building projects. First, the elaboration of a detailed work plan at the beginning of the project enabled us to plan and update project priorities in a timely manner. Secondly, the flexibility to rearrange the project activities as the demand arose during project implementation made the project adaptable to the emerging national needs and circumstances. The strict periodic monitoring, self-evaluation and general evaluation through quarterly and half-yearly reporting on substantive and financial matters to the UNEP Biosafety office via the Anubis electronic system, as well as the country mission visits and e-mail/phone communication also made realizing the project objectives possible.

Furthermore, the annual meeting of National Project Coordinators of the Biosafety Implementation Projects provided good opportunity to exchange of experience among the different countries. It allowed project coordinators to learn from others and take corrective measures in their own projects based on information gathered

at those meetings. The contacts and networks established during those meetings have helped us to get information easily from other project coordinators when the need arises.

From our experience, it is clear that public/stakeholder involvement at every stage of the project is crucial for the success of the project. Public hearings and consultation of relevant stakeholders during the implementation of capacity-building activities and in decision-making are very important in getting consensus on biosafety.

The Biosafety Action Plan, which ensures the involvement of all the main actors in biosafety, has created a path to enhancing sustainability in a long-term. Institutional sustainability has also been addressed through building capacity in relevant line ministries, research institutions, participating farmers, consumers, district level authorities. Furthermore, the established mechanism for cooperation between the Project Implementation Unit, Ministry of the Environment and Natural Resources, Ministry of Agriculture and Food Industry, Academy of Sciences, local authorities and farmers, including through the meetings, has fostered better understanding, communication and collaboration among the different institutions. Consequently, the main activities of the project were implemented through a consultative process thus creating a sense of ownership among all stakeholders.

A lot of work still needs to be done in Moldova to build critical capacities required for effective biosafety work. In particular, there is an urgent need to further develop capacities for risk assessment/management. This could be effectively achieved through regional cooperation and sharing of experiences, development of regional and sub-regional networks among different actors and experts, organization of regional and sub-regional workshops, organization of short-term and long-term training courses for specialists in different risk assessment and risk management fields, including LMO detection and sampling methods and publication of educational materials and guidelines.

Mr. Andrea Sonnino, Senior Agricultural Research Officer
Food and Agriculture Organization of the United Nations (FAO)

Best Practices and Lessons Learned from the FAO Regional Project on Capacity-Building in the Biosafety of GM Crops in Asia

Asia accounts for 57 percent of the global population. Agriculture is its most important source of livelihood. However, the region has only 31 percent of the world's arable land. In the last two decades there has been a steady increase in agricultural productivity stimulated by the adoption of improved technologies and appropriate government policies and programmes. Yet, about one-sixth of the population in the region is malnourished, accounting for nearly two-thirds of the world's hungry people.

In order to maintain the current level of food consumption, agricultural production in the region needs to be doubled in the next 20 years but using the ever shrinking land and water resources. In other words, Asia must produce more and more food and other agricultural products from less and less natural resources. Modern biotechnology, when safely and appropriately integrated with other agricultural production methods, has significant potential for reducing food insecurity through increased productivity. It also offers opportunities for diversification into value-added production, improved processing systems and trade in food and agriculture.

Currently, a number of genetically modified (GM) crops are in advanced stages of development, or are being commercially grown in several Asian countries. The increasing development of GM crops requires adequate legislation and controls for their testing, release, use and cross-border movements to protect human health, biodiversity and the environment. Regional harmonization of legislation, testing methodologies and risk assessments would foster better use of the limited available resources among countries. This together with improved national capacities for implementation and enforcement of the regulations would help countries in the region to appropriately use biotechnology for sustainable development.

In 2000, the 25th FAO Regional Conference for Asia and the Pacific, which as held in Yokohama, Japan, recommended that FAO should provide biosafety capacity-building support to member countries. In response to that recommendation, the Japanese Government pledged to provide funding equivalent to US$ 1.2 million for a regional biosafety capacity-building project. Subsequently, the project was initiated in May 2002 by the FAO Regional Office for Asia and the Pacific (FAO-RAP). It covered 10 countries, namely Bangladesh, China, India, Indonesia, Malaysia, Pakistan, Philippines, Sri Lanka, Thailand (the host country) and Viet Nam. Originally it was planned as a three-year project. However due to some difficulties encountered in the initial phase, the project was prolonged by seven months and was thus finalized in December 2005.

The overall goal of the project was to enhance food and livelihood security in Asia through sustainable and environment-friendly increases in the yield and quality of agricultural produce, including, where appropriate, the safe and judicious harnessing of modern biotechnology. The specific objectives of the project were:

1. To strengthen biosafety capacities of the participating countries as per their assessed needs and prospects;
2. To establish an effective Asian

BioNet to harmonize biosafety assessment and management standards, guidelines, measures and methodologies, and to promote exchange and sharing of information; and
3. To support and promote research and technology development for assessment and management of risks associated with GM crops.

During the initial phase of the project, a "**Benchmark Document**" on the needs and present status of capacity-building in biosafety of GM crops in Asia was commissioned. The document made a critical comparison of the strengths, weaknesses and gaps in the participating countries in terms of human resources, research and technology development infrastructure as well as, regulations and policies for assessing and managing biosafety risks of GM crops. The study indicated that the participating countries varied greatly in their biosafety capacities. It showed that most of the countries required considerable support to build their capacity for regulating genetically modified organisms (GMOs). Some countries had made important progress in building their capacities and could assist other participating countries. The main capacity-building needs identified were: 1) human resource enhancement; 2) infrastructure upgrading; 3) regulatory mechanisms establishment; 4) policy and programme development; 5) adequate and sustained funding; and 6) regional collaboration.

A number of project activities were successfully implemented. For example, **national stakeholder workshops** were conducted in Bangladesh, China, Indonesia, Pakistan, Philippines, Sri Lanka, Thailand, Malaysia and Viet Nam. The workshops focused on identifying national training needs and were attended by a total of 431 trainees from regulatory bodies, scientists, NGOs, and the private sector. Two **regional consultations** were also organized regarding the establishment of the Asian BioNet, which intended to provide a forum for sustained regulatory collaboration among Asian countries. The consultations were attended by major stakeholders, international organizations, NGOs, civil society, private research and development institutions. As well four annual meetings of the Steering Committee and Technical Expert Group were held. These activities enhanced the solidarity and friendship between participating countries, promoted equitable sharing of experiences, and produced positive atmosphere for promoting regional harmonization of biosafety measures.

In November 2003, **the Asian BioNet website** was established. It contained information regarding the status of biosafety implementation in participating countries, updates on the project activities, proceedings of meetings and workshops, resource documents, a photo gallery and useful links. The website did not only serve as information centre for participating countries but also mainstreamed the importance of regional collaboration.

Support for research and technology development was offered through the organization of **three regional training workshops** on GMO detection (in Thailand), public awareness and participation (in Philippines), and on risk assessment and management (in Japan). These workshops contributed to creating a common understanding of GMO management in the region.

The project also produced **training manuals** on "GMO detection" and "Public awareness and participation concerning GM crops with emphasis on risk communication". As well, proceedings of the workshop on "risk assessment and risk management of GM crops" were published in collaboration with national universities and research institutions. The project also supported the publication of the national training manual on GMO detection in Pakistan.

The major lesson learned from the project is that there is a need to synchronize the national and regional dimensions of biosafety capacity-building. The responsibility for formulating national biosafety policies and legislation rests with the national governments. It is therefore mandatory that each country develops a well-conceived regulatory framework, a solid institutional base, and well-established capacities to enforce the regulation. Regional collaboration and harmonization in biosafety can offer important opportunities of mutual benefits. The variations in the status of development of national biosafety systems in the participating countries represented both a challenge and an opportunity. While the disparities hindered equitable participation in regional activities, on the other hand, it also provided opportunities for collaboration and enabled countries with least developed biosafety systems to learn from those with more advanced biosafety systems.

In conclusion, regional collaboration in biosafety should be further promoted and extended through regional projects and well coordinated with national biosafety capacity-building efforts.

Mr. Jan Husby, Senior Adviser
The Norwegian Institute of Gene Ecology (GenØk)

Experiences and Lessons Learned from GenØk - Biosafety Capacity-Building Programme

GenØk is the National Centre for Biosafety in Norway. It works closely with the Norwegian authorities on all types of issues related to biosafety. Norway is one of the 153 countries that have ratified the Cartagena Protocol on Biosafety and is thereby bound by its obligations regarding the safe transfer, handling and use of living modified organisms (LMOs). A major issue for the Protocol is need for appropriate capacity-building and technology transfer to enable developing countries to fulfill their obligations under the Protocol. This is a challenge that requires cooperation at national, regional and international levels, including a high standard of

teaching, training and methodology transfer from countries with institutions experienced in dealing with safety of modern biotechnology.

Against this background, GenØk found it appropriate to design a Biosafety Capacity Building Programme, based on a holistic approach to genetic engineering and genetically modified organisms (GMOs), in accordance with GenØk's commitments to research in the field of biosafety and gene ecology. The Norwegian Ministry of Foreign Affairs made the implementation of the programme possible with an initial grant in 2003, which was later followed by grants from the Norwegian Agency for Development Cooperation (Norad).

During the period 2003-2008, GenØk has successfully carried out the projects under the Biosafety Capacity-Building Programme in cooperation with the University of Tromsø in Norway, the Centre for Integrated Research on Biosafety (INBI) at the University of Canterbury in New Zealand and the Third World Network. We are also extremely fortunate to have an international faculty of biosafety experts who are very committed to capacity-building and contribute to the running our activities every year.

Since the establishment of the programme in 2003, a number of notable achievements have been made:

•We have, during the last five years, trained more than 300 people in biosafety issues through our annual international biosafety courses in Tromsø. At least 100 countries have been represented at the courses;
•We have organised regional biosafety courses in Indonesia and Peru, as well as workshops in Africa, the Solomon Islands and Nicaragua;
•We have built a web-based mentoring tool (known as the Biosafety Assessment Tool) to facilitate the risk assessment process. The tool will be launched on the Internet in February 2009;
•We have published a comprehensive book on biosafety issues called Biosafety First (Ed. Terje Traavik & Lim Li Ching, 2007); and
•We have designed an online course in biosafety at the Masters' level, which had the first students in the spring of 2008.

By and large, our international biosafety course has been a great success. The high number of applicants (more than 350 per year) illustrates the demand for this type of holistic biosafety course.

Now that many countries have completed preparing their national biosafety frameworks, the need for more specialized training in advanced biosafety issues has become apparent. In order to respond to this need, GenØk will in future offer two kinds of courses. The first is the current holistic core course, which will continue to give an overview of biosafety for those new to the different issues under the Cartagena Protocol. The second is a new course, which will focus on more specialized training on different issues. The idea is to give the participants in-depth knowledge and skills in a specific area. Participants will first be introduced to the subject through a five-day course and will then attend a three-day open conference on the same topic involving top invited speakers. The first specialist course, entitled "Hazard Identification and Risk Assessment of (Trans) Gene Flow", is now being developed. Both types of courses will be organized biannually (alternating years).

In order to build capacity at the regional level with a regional focus, we will continue to organize the annual regional courses in official development assistance (ODA) countries. A biosafety research conference has also been added to our "portfolio". The first conference is planned to take place in 2010. The topic, venue and dates will be announced on the Biosafety Clearing-House).

GenØk is also offering courses with formal qualifications in biosafety. One of them is the web-based course offered in cooperation with the University of Tromsø. The course gives 10 credits under the European Credit Transfer and Accumulation System (ECTS). The first group of 20 students completed the course in the spring of 2008. The course will be offered again in 2010. We are also working towards establishing a full Master of Science and a PhD programme in biosafety at the University of Tromsø in collaboration with other universities in the South.

In collaboration with our partners at INBI in New Zealand, we are also developing a Biosafety Assessment Tool (BAT). The BAT will be a free to the public web-based service on biosafety. When launched (in February 2009) the tool couldbe used by policy and regulatory officials in government, nongovernmental organizations (NGOs), researchers and the public to customize biosafety information from the scientific and technical literature and apply it to their own risk assessments, or in evaluations of assessments carried out by others. The BAT could also assist in the identification of relevant risk issues, including used as a basis for the evaluation of technical information provided in any GMO import or release applications. A user can construct a comprehensive and context-specific assessment of technical information, as well as identify what additional issues, or biosafety relevant uncertainties, that should be addressed by either authorities or the applicant.The BAT has already been used in the course workshops where the participants prepare reports on GMO applications under the mentorship of instructors, and has become an integrated part of the annual biosafety courses in

Tromsø.

GenØk's portfolio of capacity-building projects has grown over the past few years. Our long-term contract with Norad (2008-2012) gives us the opportunity to plan ahead for more than one year. Also by having course evaluations and surveys among former participants we try to make sure that we design capacity-building activities that are demand-driven and useful for our target groups.

For further information see: www.genok.org

Mr. Decio Ripandelli, Director of Administration & External Relations and Head of the Biosafety Unit (ICGEB)
Dr. Wendy Craig
Biosafety Unit (ICGEB)

Best Practices and Lessons Learned from the ICGEB Capacity-Building Initiatives in Biosafety

The International Centre for Genetic Engineering and Biotechnology (ICGEB) is an intergovernmental organization providing centres of excellence, principally in Trieste, New Delhi and Cape Town, for advanced scientific research and training with special attention to the needs of developing countries.

The involvement of the ICGEB in biosafety capacity-building is long-standing and predates the advent of the Cartagena Protocol on Biosafety by more than a decade. During this time we have accumulated a wealth of experience and know-how in a range of biosafety activities that underpin our endeavours focusing on strengthening human and infrastructural capacity in our member states.

Our main biosafety activities include improving the level of awareness, knowledge, and expertise of scientists, government officials and other primary stakeholders through the implementation of short- and long-term training programmes (in the form of workshops and fellowships); dissemination of scientific and technical information through our biosafety webpages (http://www.icgeb.org/biosafety/); provision of tailored services commissioned by competent authorities in our member states (for example, to establish or improve specific national biosafety procedures or frameworks); and undertaking actual biosafety research fundamental to the understanding of the possible risks arising from the cultivation of genetically modified plants (GMPs) and to generating scientific data to facilitate the risk assessment and risk management of virus-resistant GMPs.

A key factor in all of the above activities has been our ability to respond to the evolving needs of our member states. For example, the first offerings of ICGEB's annual biosafety workshops in the early 1990s, when the Protocol was still in a nebulous state, were based in Italy and were both generic and introductory in nature. However, as the interest in biosafety increased at the global level, concomitant with the formulation of the CPB, the ICGEB began offering biannual workshops with the introduction of an advanced courses based on case studies. At the turn of the new century, the format of the workshops developed further and began to incorporate a more regional focus, reflecting the asymmetric needs of our member states and their desire to have instruction tailored to those specific biosafety issues of immediate impact to them. Shortly afterwards the format of the advanced workshop changed to become more practical, concentrating on providing guided experience in the evaluation of data submitted in applications for the commercial release of GM crops. This was due to the demand from our member states, the majority of whom are now Parties to the Cartagena Protocol, for experience in implementing critical aspects of their national biosafety frameworks. The portfolio of ICGEB biosafety workshops reached a peak in 2007 with the offer of four workshops a year - two regional (Khartoum, Sudan, and Belo Horizonte, Brazil) and two in Italy (the generic introductory format complemented with the revised advanced format).

Overall, during all this training, what became obvious was that not only was the number of people requiring training in biosafety increasing exponentially, but that their actual needs were changing over time such that the number and content of the workshops had to increase and to adapt to meet those needs. What is still unknown, however, is the extent to which critical masses of personnel have been sufficiently trained in order to effectively support the implementation of the national regulatory frameworks that have, or are being, drawn up.

This process of continually re-evaluating our capacity-building activities extends also to our online informatics tools used to disseminate scientific information. These have recently been overhauled, the latest of which, the Bi[blio]safety database (our long-running Biosafety

Bibliographic Database; http://www.icgeb.org/biosafety/biobiblio.html), has been redesigned so that it can also be used as a teaching tool. The revamped database will be re-launched early next year.

To meet the requirement that our activities remain topical and forward-looking, we also found it essential to select our resource personnel and advisors from those people involved in international round-table discussions and brain-storming sessions where specific complex issues, for example, the evolution of the risk-assessment paradigm with regard to stress-tolerant GM plants, acceptable strategies towards streamlining regulation, etc., are being debated or under formulation. This is intended to ensure that this crucial information is relayed directly to the primary stakeholders in our Member States. If so desired, this then allows the member states to "leap-frog" stages in the development of their regulatory regimes, for example, to make them as current and up-to-date as possible. In addition, by using renowned scientific experts as resource personnel, we ensure that our training programmes incorporate the latest scientific knowledge and skills.

Of high importance is our commitment to implementing capacity-building activities over the long-term. In our opinion, to consider, for example, a stakeholder consultation, a one-off training event or the publication of a report as a job well done does not constitute capacity-building. In fact, we believe that "fly-by-night" offerings can make local situations worse.

Furthermore, from our experience, providing training to different stakeholders, e.g. academia-based GMO developers, industrial applicants, government regulators and inspectors, together in the one room allows for greater and broader understanding and appreciation of the issues at hand, and a willingness to work together to clarify and make more efficient the decision-making process.

Of paramount importance to us has been to uphold our reputation as an "honest broker" of credible scientific and technical information and know-how. A major goal of our activities is to present available information in a fair light and to expel previous misrepresentations and misgivings on the ground. Maintaining our integrity in what at times can be a highly politically-charged arena continues to be a challenge. However, it is something that is essential to assisting our member states with their diverging political positions. Our long experience and non partisan approach have been acknowledged recently by a major donor through the provision of substantial funding for our capacity-building initiative focusing on sub-Saharan Africa. The initiative will bring all of our experience to bear, in the promotion of practical approaches to help resolve key difficulties in expediting their regulatory frameworks.

Mr. John Komen, Program Manager (PBS)
Ms. Catarina Cronquist, Program Analyst (PBS)

The Program for Biosafety Systems: Best Practices and Lessons Learned

Biosafety is a critical component in sustainable agricultural development

In 2007, Uganda's National Agricultural Research Organisation (NARO) planted the country's first confined field trial of a genetically modified (GM) crop, a banana variety expressing resistance genes to Black Sigatoka, a disease caused by the fungus Mycosphaerella fijiensis. This may prove to be a particularly important step forward for Uganda, as starch bananas are the country's main staple crop, but are increasingly affected by Black Sigatoka. Currently, the only way to fight this disease is by applying massive doses of fungicides - a practice becoming more and more ineffective as the fungus gains resistance.

The Program for Biosafety Systems (PBS) worked with a range of Ugandan and international partners to make this confined, experimental field trial happen. Collaborative activities included:

•Defining capacity needs in terms of infrastructure development and human capacity for managing confined field trials;
•Designing a contained greenhouse facility, for testing and nursing plants prior to planting in the field;
•Working with NARO scientists to complete applications for confined field testing and for importing transgenic materials resistant to Black Sigatoka;
•Training regulators on the evaluation of, and decision making on, applications for confined field trials;
•Developing detailed guidelines and standard operating procedures to be used by regulators and scientists when

reviewing and implementing field trials;
•Providing practical training to trial managers and other staff on how to implement confined field trials;
•Training crop inspectors to properly monitor trials of transgenic crops; and
•Sensitizing policy makers and relevant government officials to the purpose and importance of conducting experimental field trials.

These activities exemplify the comprehensive approach PBS uses to establish biosafety regulatory frameworks in partner countries, and illustrate the type of progressive outputs and impact the program has had so far. The program, funded by the US Agency for International Development (USAID) and implemented by the International Food Policy Research Institute (IFPRI), started in May 2003. It supports partner countries in Africa and Asia in the responsible development and safe use of agricultural biotechnology.

Particularly in Africa, the pipeline of GM products is evolving rapidly. In 2008, the government of Egypt authorized the commercial planting of GM insect-resistant maize, while Burkina Faso endorsed the commercial release of GM insect-resistant cotton, joining South Africa as African countries where commercial planting of GM crops is allowed. Several other countries have conducted confined field trials, such as Kenya and Uganda, while others will do so shortly. The development of GM subsistence crops, specifically suitable to developing countries, is moving forward with a number of field trials planned in the coming years.

PBS approach: Working towards functional biosafety regulatory frameworks

National biosafety systems serve as mechanisms to ensure the safe use of biotechnology products that do not impose unacceptable risk to human health or the environment. Each country's ability to conduct appropriate regulatory reviews, without imposing unintended constraints to technology transfer, is therefore key to determining whether or not potential benefits of new GM products will reach end users. As few developing countries have fully functioning biosafety frameworks, PBS works with technology developers, regulators and policy makers, to ensure that necessary frameworks are in place to facilitate science-based reviews and decision making on GM products. PBS's services can be summarized as follows:

•Provision of technical (regulatory, legal and policy) expertise in the development and implementation of regulations, legal instruments and policies
•Scientific knowledge and advisory services to facilitate the progress of GM products through the regulatory process
•Policy analysis and research on issues related to biosafety implementation in partner countries (for instance regarding trade, liability and redress, and socioeconomic considerations)
•Capacity building, including skills development, training and outreach centered around planned releases of GM products and the development of regulations and guidelines

Across its partner countries, PBS has made great strides in building national biosafety frameworks (including guiding policies, legal instruments, regulations and guidelines) and in establishing best practices to assess and implement confined field trials. Progress has been strongest in countries where PBS could build upon existing foundations and support mechanisms created through previous capacity building initiatives, such as the UNEP-GEF backed national biosafety framework projects.

Lessons learned and emerging best practices

It is clear that significant progress is being made towards establishing robust and fully functional biosafety regulatory systems. But none of PBS's achievements have been easy or straightforward to accomplish. Generally, because policy makers may lack familiarity with topics related to LMOs and biosafety, or because GM products may be subject of controversial public debate, political will to make clear and timely policy decisions has at times been very limited. An essential element in the system, the active involvement of knowledgeable people with skills in biosafety risk assessment and management, is being continually addressed in a hands-on, practical manner by PBS. The main lessons learned (all of equal significance) are presented below, and are taken into consideration as PBS moves into its next 5-year phase (2008 – 2013).

The main lessons are as follows:

1. Underpinning all capacity-building efforts are close collaborations between PBS and national partners. Implementation of work plans is spearheaded by country team leaders supported by local advisors as necessary, in close consultation with key national regulatory and policy making bodies.

2. Essential to providing guiding principles for the subsequent development, implementation and financing of a biosafety regulatory framework is a national biosafety policy or strategy. Critical elements of a national policy include a clear definition of a country's goals and priorities for biosafety and associated capacity development, as well as a division of responsibilities across government agencies. The development process of policies, just as for laws and regulations, is as significant as the resulting policy or legal document. Consultative multi-stakeholder approaches are indispensable, even while they may be time-consuming. Having a national policy in place also serves to build long-term government support, consistent decision making, and inclusion

of biosafety capacity development into national budgets.

3. Similar to the policy development process, the road from drafting a law to its adoption generally may be long and winding. Devising a strategy to get a policy or legal document through the system, while also investing in awareness-raising among policy makers, may reduce the time required from draft to adoption. Detailed implementing regulations are an equally essential element of a biosafety framework, as they clarify matters over which agency (-ies) regulate what, and how.

4. Vital to driving the regulatory framework forward, is to focus on a specific product in the pipeline. Once a specific product was under consideration in Malawi, Ghana and Uganda, the development of regulations and guidelines accelerated in each country.

5. In connection to the point above, confined field trials are a key component for GMO evaluations, providing crucial data necessary for progress through the product development pipeline, for regulatory submissions, and for possible commercial approvals. Further, conducting these trials in a regulatory compliant manner builds familiarity and confidence within the regulatory community, with policy makers and the public at large.

6. Collaboration across countries should be encouraged in sub-Saharan Africa as a regular feature of any biosafety capacity development activity. For example, now that confined field trials for Bt cotton are imminent in Uganda, PBS will support site visits by regulatory officials and scientists from Malawi, who may be involved in cotton field trials in the near future. This is only one area among many where cross-country collaboration may be useful.

7. To best reach out to different stakeholder groups, establishing a national program or strategy for public awareness-building should be considered a priority. A focused and sustained communication and outreach program targeting policy makers and parliamentarians is also critical to catalyze and accelerate decision making on regulatory instruments such as the Biosafety Bill and biotechnology/ biosafety policies. Building public awareness and confidence in modern biotechnology and regulatory decision making must therefore be a continuous and steady process. Local outreach groups and initiatives, supported by national scientists and policy makers (rather than outside organizations), play a vital role in awareness raising and communication activities. The recently launched BioAware program in Kenya is an excellent example of a joint venture between various government Ministries and local outreach organizations in providing balanced information to stakeholders and the general public. Similar programs or strategies are evolving in other PBS partner countries as well.

8. Using or building on existing legislation is a more realistic approach to move forward research and field trials of modern biotech products, while general, unconfined releases and commercialization may have to wait for specific national biosafety laws. With this approach, countries such as Kenya and Uganda were able to safely test and build familiarity with GM crop varieties and their regulation, before more comprehensive biosafety laws were adopted.

"The Protocol was a major step forward in international efforts towards sustainable development, and will continue to have an important role to play in our efforts to implement Agenda 21, the global programme of action on sustainable development adopted by the 1992 Earth Summit in Rio de Janeiro."

-UN Secretary-General Ban Ki-Moon

"The Protocol in short is designed to maximize the benefits from modern biotechnology while at the same time protecting biodiversity and human health from potential risks posed by LMOs. A central role for UNEP in this regard is the critical area of capacity building that will allow developing countries to establish regulatory frameworks and make informed choices on whether an LMO is a risk or an opportunity for its economy in the widest sense of these words."

-UNEP Executive Director Achim Steiner

SNAPSHOTS

4th Meeting of the BCH-IAC

McGill University visiting SCBD

5th Meeting of the Compliance Commitee

UPCOMING EVENTS:

2009
23 - 27 February 2009
Mexico City, Mexico
1st meeting of the Group of the Friends of the Co-Chairs Concerning Liability and Redress in the Context of the Cartagena Protocol on Biosafety

9 - 11 March 2009
San José, Costa Rica
Fifth Coordination Meeting for Governments and Organizations Implementing or Funding Biosafety Capacity-building Activities

2010
11 - 15 October 2010
Nagoya, Aichi Prefecture, Japan
Fifth meeting of the Conference of the Parties serving as the Meeting of the Parties to the Cartagena Protocol on Biosafety (COP-MOP 5)

For further information: http://www.cbd.int/biosafety/meetings-link.shtml

OTHER BIOSAFETY EVENTS:

2009
10 - 12 May 2009
Tehran, Iran (Islamic Republic of)
Training Course on "The Analysis of Agricultural Products for the Presence of Genetically Modified Organisms". Organized by: Naitonal Institute of Genetic Engineering and Biotechnology, Iran

14 - 16 May 2009
Rostock, Germany
Ecological Impact of Genetically Modified Organisms (ElGMO). Organized by: International Organization for Biological and Integrated Control of Noxious Animals and Plants (IOBC)

August 2009
Lima, Peru
First Latin American Biosafety Congres (ASDMAS) Organized by: ASDMAS - Desarollo Medio Ambiental Sustentable

For futher information: http://www.cbd.int/events/

PAST EVENTS:

BIOSAFETY PROTOCOL:

11th September 2008
5th Anniversary of the Cartagena Protocol on Biosafety

6-17 Oct 2008
Online conference on national experiences with, and capacity-building needs for, environmental risk assessment and post-release LMO monitoring and evaluation

3-28 November 2008
Online Forum on Capacity-Building in environmental risk assessment and post-release monitoring of LMOs

17 - 18 November 2008
Montreal, Canada
Fourth meeting of the Informal Advisory Committee on the Biosafety Clearing-House (BCH-IAC)

10-30 November 2008
First round of Discussion Groups within the Open-ended Online Expert Forum on Risk Assessment and Risk Management

19 - 21 November 2008
Kuala Lumpur, Malaysia
5th meeting of the Compliance Committee under the Protocol

1-19 December 2008
Second round of Discussion Groups within the Open-ended Online Expert Forum on Risk Assessment and Risk Management

NEW RSS ON PROTOCOL ON BIOSAFETY: http://www.cbd.int/rss/

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We would like to hear from you:

We are encouraging governments, particularly those that are Parties to the Protocol and relevant stakeholders to send articles and digital photos on their implementation, awareness and outreach activities. Please send your contributions to secretariat@cbd.int or bch@cbd.int

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