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EXPERT REVIEW OF THE EFFECTIVENESS OF VARIOUS APPROACHES TO BIOSAFETY CAPACITY-BUILDING: IDENTIFYING BEST PRACTICES AND LESSONS LEARNED

Note by the Executive Secretary

1. At the fourth meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol (COP-MOP) held in 2008 in Bonn, the United Nations Environment Programme (UNEP) offered to undertake, in collaboration with the Global Environment Facility (GEF), its agencies and the Executive Secretary, an expert review of the GEF-funded capacity-building activities with a view to assessing the effectiveness of various approaches to capacity-building and developing lessons learned. In paragraph 6 of decision BS-IV/3, the COP-MOP welcomed the offer and invited Parties, other Governments, donors and relevant organization to provide additional support to extend the review to non-GEF activities and submit the review to the BCH.

2. The Executive Secretary is pleased to circulate herewith, for the information of participants in the fifth meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol, a summary of the report entitled "Expert Review of the Effectiveness of Various Approaches to Biosafety Capacity-Building: Identifying Best Practices and Lessons Learned", submitted by UNEP.

3. The report is being made available in the format and language in which it was received by the Executive Secretary.

EXPERT REVIEW OF THE EFFECTIVENESS OF VARIOUS APPROACHES TO BIOSAFETY CAPACITY-BUILDING ACTIVITIES:

IDENTIFYING BEST PRACTICES AND LESSONS LEARNED

CONTENTS

EXECUTIVE SUMMARY

The United Nations Environment Programme's Division of Global Environment Facility (GEF) Coordination (UNEP-DGEF) initiated a review of biosafety capacity-building activities in May 2009 in response to Decision BS-IV/3 taken in 2008 by the fourth meeting of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety (COP-MOP). The review, with the overall objective of assessing the effectiveness of biosafety capacity building programs and projects and recommending lesson learned, covered an analysis of recent literature on the subject, focusing on documents from past COP-MOP meetings; project-related information included in the Biosafety Clearing-House (BCH); reports by UNEP and the Secretariat of the Convention on Biological Diversity (CBD); and previous reviews of biosafety capacity-development programs and activities carried out by various organizations.

A first draft report was submitted to UNEP-DGEF in June 2010 and the final draft was submitted in September 2010. The present, abridged version was submitted to the CBD Secretariat for circulation as an information document at the COP-MOP-5 meeting in October 2010, and focuses on the main findings and recommendations rather than summarizing all background materials analyzed,.

The report recommends broad strategic changes to the current capacity development approaches and provides practical suggestions for the future direction based on experiences gained so far. Among other things, the report argues that the Parties to the Protocol, GEF, other funding agencies and implementing organizations need to be much more cognizant of the specific characteristics and challenges inherent in biosafety capacity development. It also observes that injections of funding and technical support, for example, are not likely to make much impact in countries that lack the political commitment, infrastructure and basic capacity to set up and sustain complex technical and organizational systems.

The report concludes that there is a need for a fundamental re-think and adoption of more strategic, adaptable and focused approaches. In this regard, the report makes the following recommendations and practical suggestions on the possible way forward:

(a) Reformulate a common strategy on biosafety capacity development: It is recommended that a special conference involving Parties to the Protocol, current and prospective donors and relevant organizations be organized to look comprehensively at a broad range of issues relating to the future strategy for biosafety capacity development and develop a shared understanding of its implications.

(b) Focus on the issue of mainstreaming biosafety at the national policy level: One challenge biosafety capacity development faces is expanding the awareness and commitment beyond a core group of technical professionals to include a wider range of actors, e.g., budget officials, political leaders, member of the public, the media, NGOs and others. Specifically, effective implementation of biosafety frameworks will require strong political support and the agreement of senior public sector managers in ministries such as finance, public works and personnel. It will also require the sustained allegiance of key decision makers. Capacity support programs and projects must emphasize incorporating biosafety into overall environmental and economic development policies.

(c) Develop a capacity development toolkit: A new toolkit on biosafety capacity development will be useful to country participants and other stakeholders in biosafety projects, based on the wealth of existing materials. Included in that toolkit could be capacity assessment frameworks and guidelines on monitoring and evaluation.

(d) Explore regional approaches to capacity development: Collaboration among countries on biosafety can be instrumental to maximizing the use of institutional, financial, technical, and human resources within a region. For small and developing countries, the ability to capitalize on external expertise and information from neighbouring high-capacity countries may be essential for implementing a national biosafety framework. Consequently, there is a strong case for increased emphasis on, and donor support to regional approaches and South-South collaboration.

(e) Acknowledge the implementation challenges inherent in capacity development: Biosafety decision making requires new capacities and interventions at different levels (individuals, organizations and at national policy level), which must be based on advanced science from the outset. Equally important as the scientific component, public and political support is required concurrently in order to make progress and create resilient capacity. Managing the transition from science to policy, public debate and politics is a major challenge.

(f) Adopt customized and strategic approaches to biosafety training: The need for introductory, awareness-raising type of training will continue to exist in order to broaden the critical mass of trained personnel and to deal with inevitable staff turnover and attrition. However, as indicated in previous reviews, there is a strong need for longer term, in-depth technical skills development for various NBF components and much less emphasis on the one-off, general short workshops.

(g) Strengthen the capacity support of the implementing agencies: In leading implementation of the Action Plan, GEF implementing agencies and other organizations need to address the issue of their own capabilities to adequately support the work at hand. Some of the biosafety implementing agencies remain very thin on technical expertise in biosafety and are not in a position to provide adequate technical backstopping and quality control for biosafety projects.

(h) Develop M&E systems: There is a clear need to invest in developing specific M&E systems as an integral part of implementing the biosafety capacity building Action Plan. This should go beyond the current set of indicators included in the Action Plan, which so far have hardly been applied partly due to the absence of clear M&E plans and guidelines.

(i) Promote results-based management (RBM): As the GEF's own RBM system and associated impact indicators are quite generic, applicable to a wide range of environmental programs and projects, ways and means of gauging progress on biosafety capacity development are obviously needed. RBM schemes need to be relatively simple and easy to use for country participants who have only modest incentives and time to keep them going.

(j) Improve donor coordination on biosafety: There is a need to strengthen the current Coordination Mechanism, and ensure it fosters improved coordination and actual collaboration among donors and implementing organizations, particularly in countries with multiple biosafety programs, in order to achieve the objectives of the Action Plan. In the case of biosafety, while often the same fundamental objectives are pursued, the different policies and agendas of various donors can give rise to competing approaches to capacity development which can overwhelm countries with limited institutional capacities.

SECTION I. BACKGROUND AND SCOPE

1. INTRODUCTION

The United Nations Environment Programme's Division of Global Environment Facility (GEF) Coordination (UNEP-DGEF) initiated a review of biosafety capacity-building activities in May 2009 in response to Decision BS-IV/3 taken in 2008 by the fourth meeting of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety (COP-MOP). This involved at the outset a period of consultations in which the Terms of Reference (see Annex 1) were defined and candidate consultants identified. Following an international search, UNEP contracted two consultants. The review started on February 15 2010.

The review, with the overall objective of assessing the effectiveness of biosafety capacity building programs and projects and recommending lesson learned, covered an analysis of recent literature on the subject, focusing on documents from past COP-MOP meetings; project-related information included in the Biosafety Clearing-House (BCH); reports by UNEP and the Secretariat of the Convention on Biological Diversity (CBD); and previous reviews of biosafety capacity-development programs and activities carried out by various organizations.

It should be noted therefore that the scope of the review had some inherent limitations as follows:

- Due to time and budget limitations, no field work or surveys were planned or conducted under the review.

- Most of the reviews and other reports issued by the GEF, UNEP and CBD Secretariat focus on broader issues of programme / project design and implementation. Few of these documents contain an analysis of the capacity issues encountered at the field level. No common analytical framework exists to do this. This lack of written analysis combined with the absence of field work has limited the empirical data and operational insight that could be included in this report.

- As a result, the review suggests broad strategic changes to the current capacity development initiatives and approaches aimed at supporting the development and implementation of biosafety frameworks at country level. These recommendations intend to add value to current and future biosafety capacity development programs and activities. The review does not, however, come up with specific operational recommendations that could be implemented immediately at the field level in particular countries. In order to move to this next level of analysis and diagnosis, efforts will be required to gather detailed feedback on in-country experiences, coupled with field work to make sure that the general recommendations proposed in this study are tailored and customized to meet a specific set of circumstances across a range of countries.

The report focuses on the main findings and recommendations rather than summarizing the background materials analyzed. Section 2 introduces the overall rationale and goal for the review. Section 3 analyzes how biosafety capacity development has been approached under the Cartagena Protocol on Biosafety (CPB), as laid down in the Capacity Building Action Plan and decisions of the meetings of the Parties to the Protocol. Section 4 outlines some of the donor-supported biosafety capacity development programs. Section 5 distils a set of critical issues emerging from several previous reviews of donor-supported biosafety capacity development, followed by this report's views on the main issues and challenges at hand.

Finally, Section 6 points to suggested future directions for biosafety capacity development based on experiences gained so far.

2. RATIONALE AND GOAL

This review was prepared in response to the MOP-4 decision BS-IV/3 (2008), paragraph 6, which:

"Welcomes the offer of UNEP to undertake an expert review of capacity building activities under GEF funding, in collaboration with GEF, its agencies and the Executive Secretary, with a view to assessing the effectiveness of various approaches to capacity-building and developing lessons learned and invites Parties, other Governments, donors and relevant organization to provide additional support to extend the review to non-GEF activities and submit the review to the BCH."[1]

It is broadly agreed that capacity development is a prerequisite for the effective implementation of the Cartagena Protocol on Biosafety (CPB). The CPB seeks to protect biological diversity from the potential risks posed by transboundary movements of "living modified organisms" (LMOs) resulting from modern biotechnology. It establishes common procedures and guiding principles ensuring that countries are provided with the information necessary to make informed decisions on the import of such organisms into their territory. The CPB entered into force on 11 September 2003. By the time of drafting this report (September 2010), 159 countries and the European Union are Parties to the Protocol.[2]

2.1 Capacity development for biosafety – the challenge

Advancements in biotechnology over the last 25 years have transformed the scientific ability to discover genes of economic importance and to develop genetically modified organisms (GMOs) for medical, agricultural and environmental technologies and products. Agenda 21, the action plan of the United Nations Conference on Environment and Development held in Rio de Janeiro in 1992 includes a chapter on "Environmentally Sound Management of Biotechnology" that emphasizes the need to strengthen the endogenous capacities and establish enabling mechanisms for the development and environmentally-sound application of biotechnology.[3]

The application of biotechnology has expanded during the last 15-20 years. For example, genetically modified (GM) crops have been adopted, produced, consumed, and traded in an increasing number of countries. However, only a few GM crops—soybeans, cotton, maize, and canola have been commercialized and occupy the lion's share of global GM crop production area (see Figure 1 below)[4]. These products, particularly maize and soybeans are prominent in international commodity trade and in emergency food aid shipments and therefore fall within the scope of the CPB.

[1] URL: http://www.cbd.int/decision/mop/?id=11682

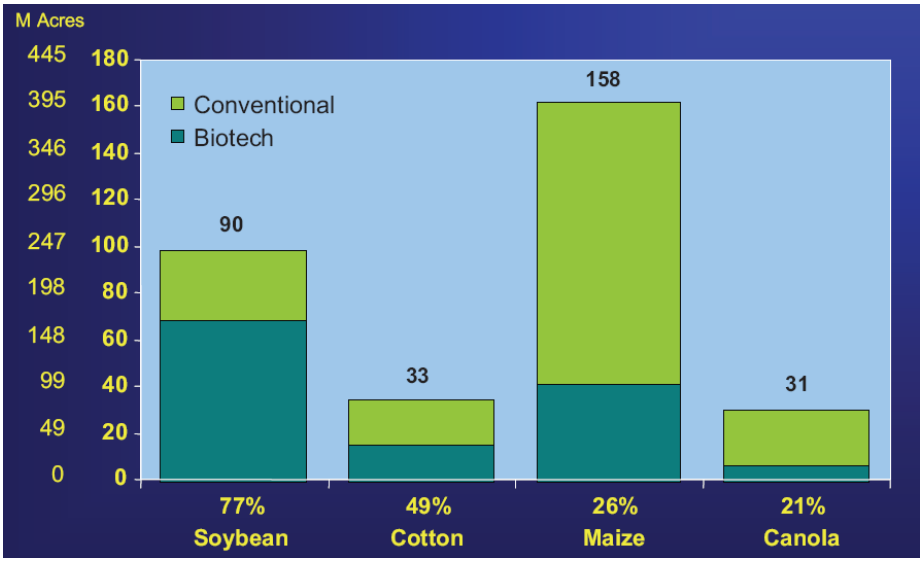
[2] For a current list of Parties to the Protocol, see URL: http://bch.cbd.int/protocol/parties/

[3] URL: http://www.un.org/esa/dsd/agenda21/res_agenda21_16.shtml

[4] For details see: James, C. 2009. Global Status of Commercialized Biotech/GM Crops: 2009. ISAAA Brief No. 41. Ithaca, NY: International Service for the Acquisition of Agri-biotech Applications. Available at URL: http://www.isaaa.org/resources/publications/briefs/41/contents/default.asp

In order to be able to implement their obligations under the CPB, Parties need appropriate institutional mechanisms and infrastructure, well-trained human resources, and political commitment, adequate funding as well as easy access to relevant information on LMOs. In the last few years the Global Environment Facility (GEF) and a range of multilateral and bilateral donor agencies have provided support to a wide array of biosafety capacity development projects.

Figure 1. Global adoption rates for principal genetically modified crops (million hectare; million acre), 2009



Source: James, C. 2010. Global Status of Commercialized Biotech/GM Crops: 2009. ISAAA Brief 41.

While progress has undoubtedly been made, especially in defining and establishing national biosafety frameworks in a number of countries, there is growing concern that many Parties still do not have the necessary capacity in place at the national level to implement the Protocol. And they appear to have no prospects for developing it in the foreseeable future. This issue has been noted in successive meetings of the Compliance Committee under the Cartagena Protocol on Biosafety. In its 5th meeting in November 2008, for example, the Committee noted that:

"*[T]here are significant gaps regarding the introduction of the necessary legal, administrative and other measure required to implement the Protocol. The Committee considered this to be a serious issue of non-compliance* […]".[5]

This situation should be a major factor to consider in the development and implementation of the Strategic Plan[6] for the Cartagena Protocol on Biosafety (2011-2020), which is currently under development and will

[5] CBD Secretariat. 2008. Review of General Issues of Compliance based on the Revised Analysis of Information Contained in the First National Reports. UNEP/CBD/BS/CC/5/3.

[6] The draft Strategic Plan and associated discussion forum can be accessed at URL: http://bch.cbd.int/onlineconferences/spforum.shtml

be tabled at the next COP-MOP[7] in October 2010. A high proportion of countries without functioning domestic frameworks could create a situation that becomes a major impediment to achieving the objectives of the Protocol in general, and to achieving the specific objectives set out in the draft Strategic Plan. Moreover, as new elements are added to the Protocol such as a proposed supplementary protocol dealing with liability and redress, the pattern of implementation issues gaps and associated capacity development constraints will become increasingly difficult to address.

The key question that this study therefore examines is why, after more than 10 years of technical assistance and donor support, a majority of countries have not developed adequate capacity to fully implement the Protocol's main provisions. To provide an answer to this question, this report distils its findings and recommendations from a review of project documents, CBD Secretariat resources (reports, online conferences), and past evaluations on a range of projects and approaches. Previous studies and reports have touched on the subject of biosafety capacity building, and will serve as information sources for this analysis.

The report argues the need to rethink and improve the general approach to biosafety capacity development. To date, the dominant approach has been narrowly conceived as a process of implementing a set of legal and technical requirements as described in various Cartagena Protocol documents. Put another way, it has been implicitly seen as a functional means of implementation to larger technical and policy ends. Such an approach to capacity development can succeed in more institutionally-advanced countries, which already have a basic institutional infrastructure in place. But it has little chance of helping low-income and fragile states to develop the institutions they need to address biosafety issues effectively.

Discussions and reviews dealing with capacity development are hampered by the fact that there is no broadly accepted definition of capacity in use at the moment.[8] Different counties, donors, and professional technical and academic disciplines see capacity issues differently. In management schools, capacity development often means organizational development. At the United Nations and the World Bank, capacity building typically refers to improving national institutions' performance, for example in governance and economic management. Many donor-supported programs equate capacity development with training and workshops, or with development of physical infrastructure. It is often assumed that developing individual capacities (e.g., through training and workshops) will automatically lead to improved organizational capacity and performance. What is needed is for stakeholders at the country level to come up with their own working definition that is customized to meet their individual circumstances.

Part of the overall approach underpinning the Cartagena Protocol is to put in place a global system that can provide a more comprehensive approach to achieving a global public good. For this objective to be achieved, many currently low-capacity countries need to be included. However, for the foreseeable future, many of them have no possibility of putting in place the complex capabilities that will be needed for them to fully participate in the global system. The time and associated resources required to do this, which would be decades rather than years, needs to be taken into account. Any global effort in biosafety must therefore impose some uniform standards while at the same time fostering a diversified response at the

[7] COP-MOP: the Conference of the Parties to the Convention on Biological Diversity serving as the meeting of the Parties to the Protocol (COP-MOP) is the governing body of the Cartagena Protocol on Biosafety.

[8] Two examples may be useful. The UNDP provides a functional definition …"the ability of individuals, organizations and societies to perform functions, solve problems and set and achieve objectives in a sustainable manner. A more systems-oriented version is "capacity is that combination of skills, attributes and relationships in a human system that enables it to create development value for others".

country level. Every biosafety capacity development effort thus faces some conflicting objectives that are not easy to recognize or manage.

Box 1. Key provisions under the Cartagena Protocol

The Cartagena Protocol's scope is the "transboundary movement, transit, handling, and use of all living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health" (Article 4). Living modified organisms (LMOs) are organisms (such as seeds, trees or fish) that contain novel genetic material introduced through in vitro techniques (e.g. recombinant DNA) or cell fusion (Article 3).

Although the Protocol covers all LMOs, it primarily addresses two particular uses of LMOs: (1) those that will be intentionally introduced into the environment; and (2) those used for food, feed or processing (FFP). For LMOs used for other purposes, such as LMOs used in the laboratory, the Protocol leaves any regulation to the discretion of the individual country.

To ensure the safe transfer, handling, and use of LMOs, the Protocol sets up two separate procedures. For the first time that LMOs will be intentionally introduced into the environment, the Protocol sets up an "Advance Informed Agreement ("AIA")" procedure (Article 7). That procedure requires that an exporter of an LMO provide a notice with detailed information about the LMO to the importing country (Article 8). The importing country then reviews the information, conducts a risk assessment, and decides, based on the risk assessment results, whether to approve or reject the LMO (Articles 10 and 15). In deciding whether to accept the LMO, the importing country can invoke risk management measures to address issues that arise from the risk assessment (Article 16). The importing country also can err on the side of precaution and not approve an LMO if there is insufficient information to adequately assess its particular potential risks (Article 10(6)).

The second procedure set up by the Protocol is for LMOs for FFP (such as maize, soybeans, wheat, or other grains that directly will be fed to humans or animals or used for processing). For those LMOs, the AIA procedure is not required (Article 11). Instead, the Protocol establishes a simpler system that reflects the decreased likelihood that those LMOs will affect a country's biodiversity. Before the LMO can be exported to another country, the only requirement is that the safety decision in the exporting country is communicated to other countries through the Biosafety Clearinghouse. A country may require the exporter to seek its prior consent, however, under its domestic regulatory framework, as long as that requirement has been posted on the Biosafety Clearinghouse (Article 11).

When a country decides to allow the import of an LMO, the Protocol also requires that LMOs approved for shipment from one country to another must be safely transported, handled and packaged. The shipments must be accompanied by documentation that clearly identifies the LMOs.

SECTION II. PROGRESS TO DATE

3. CAPACITY DEVELOPMENT UNDER THE CARTAGENA PROTOCOL ON BIOSAFETY

This section analyzes how biosafety capacity-building has been considered and defined under the Cartagena Protocol. Since its adoption, a number of decisions and initiatives were taken to support the strengthening of biosafety capacities in countries that are party to the Protocol, as discussed below. A key element involves the capacity building Action Plan (see 3.2 below), which details the required capacities for implementation of the Protocol at the country level.

3.1 Developing national biosafety frameworks

The Protocol provides considerable flexibility as to how countries may meet their various obligations. National biosafety frameworks (NBFs) are seen as instrumental in enabling governments to comply with their obligations under international agreements such as the CPB and other international agreements and standards that affect biosafety decision making including those laid down in relevant WTO agreements and the Codex Alimentarius.

An NBF is loosely defined as a combination of policy, legal, administrative and technical instruments that are put in place to address safety for the environment and human health in the application of modern biotechnology. The key components of an NBF, as defined in various UNEP-GEF project documents, are generally:

1. Overall government policies pertaining to biosafety;
2. Regulatory regime / legal framework;
3. System to handle requests (administrative, risk assessment and management, decision making);
4. Follow-up activities (enforcement, monitoring);
5. Public awareness and participation.

Developing an NBF and making it operational is complicated by the fact that there is no single best approach or standard that reflects national environmental, cultural, political, financial, and scientific heterogeneity. General principles of biosafety, and related risk assessment and risk management have been articulated in many documents, among them the Cartagena Protocol, OECD publications[9] and the UNEP International Technical Guidelines for Safety in Biotechnology.[10]

A clear process for risk assessment and management is central to any NBF. With reference to the Cartagena Protocol, as stated in Article 16, each Party has an obligation to:

"*establish and maintain appropriate mechanisms, measures and strategies to regulate manage and control risks identified in the risk assessment provisions*."

Parties have agreed to carry out such risk management functions under the CPB, but so far limited guidance was provided as to how a country fulfills this obligation. To address this need, the COP-MOP4 (2008) established an Ad Hoc Technical Expert Group (AHTEG) on Risk Assessment and Risk Management. This AHTEG has, among other things, developed detailed "Guidance on Risk Assessment

[9] Available at the OECD website at URL: http://www.oecd.org/findDocument/0,3354,en_2649_34385_1_119699_1_1_1,00.html

[10] URL: http://www.unep.org/biosafety/Documents/Techguidelines.pdf.

of Living Modified Organisms", which includes a "Roadmap for Risk Assessment of Living Modified Organisms". The AHTEG's proposals will be discussed at the upcoming COP-MOP5.

3.2 Key required capacities and indicators: The Capacity Building Action Plan

The five main NBF elements are also reflected in discussions on capacity building under the Cartagena Protocol. From the very beginning of the Protocol negotiations leading up to its signing in 2000, biosafety capacity building has been a central theme. Article 22 of the CPB affirms the importance of capacity development in biosafety, stating that:

"[…] Parties shall cooperate in the development and/or strengthening of human resources and institutional capacities in biosafety, including biotechnology to the extent that it is required for biosafety, for the purpose of the effective implementation of this Protocol […]".[11]

Work done in the period 2000-03 by the Intergovernmental Committee for the Cartagena Protocol on Biosafety (ICCP) resulted in a detailed overview[12] of "key required capacities" for implementation of the Cartagena Protocol, and broadly classified required capacities under the following headings:

(i) Institution building
- Needs assessment and biosafety framework planning
- Biosafety regime development, including legal and regulatory structures and processes to manage risk assessment and risk management
- Long-term regime building / maintenance

(ii) Risk assessment
- General risk assessment capacities
- Science and socio-economic capacities

(iii) Risk management
- General risk management capacities
- Decision-making capacities
- Implementation of decisions, including identification and handling of LMOs, monitoring of environmental impacts, enforcement and compliance

(iv) Cross-cutting capacities
- Data management and information sharing
- Human resources strengthening and development
- Public awareness and participation
- Involvement of stakeholders
- Regional capacity development

Documentation prepared by the CBD Secretariat for the ICCP emphasized that the full set of capacities would be primarily required for countries where there is an extensive or growing domestic biotechnology sector that requires appropriate biosafety controls, and that:

[11] URL: http://www.cbd.int/biosafety/articles.shtml?a=cpb-22

[12] See: ICCP. 2000. *Indicative framework for capacity-building under the Cartagena Protocol on Biosafety*. UNEP/CBD/ICCP/1/4, 10 October 2000. URL: http://www.cbd.int/doc/meetings/bs/iccp-01/official/iccp-01-04-en.pdf

"[D]eveloping a comprehensive national capacity for all countries would [...] be costly. Consequently, setting clear priorities among countries and within each country to determine needs will be required for capacity-building programmes, given finite financial and technological resources." (p.7)

The above guidance was however not fully taken into account in subsequent developments. In September 2003, when the CPB's entry into force was imminent, the CBD Executive Secretary issued a notification on "Requirements that need to be fulfilled as at the date of entry into force of the Cartagena Protocol on Biosafety"[13], conveying a detailed list of requirements following the Protocol's entry into force. In addition, at its first meeting in 2004, the COP-MOP endorsed a comprehensive "Action Plan for Building Capacities for the Effective Implementation of Protocol"[14]. The Action Plan includes a detailed and comprehensive overview of tasks to be addressed at the national level. It also stresses the need to prioritize and carefully sequence capacity building actions according to individual countries' needs and priorities. Apparently, and understandably, many signatory countries viewed the Action Plan as a set of minimum requirements rather than guidance for setting their own priorities.

The COP-MOP1 (2004) also considered a preliminary, detailed set of criteria and indicators for monitoring implementation of the Action Plan, and established a Coordination Mechanism for its implementation. Finally, the COP-MOP decided to include capacity-building as one of the standing items on its medium-term programme of work up to its fifth meeting in 2010.

At the third meeting of the Parties (COP-MOP3) in 2006, the Action Plan was updated in 2006 and countries were requested to address some of the key factors limiting the implementation and effectiveness of the Action Plan through the following actions:

i. Promoting coordination of donor assistance for biosafety initiatives at the country level;
ii. Mobilizing funding from a wide range of sources;
iii. Providing, where possible, adequate allocations for biosafety capacity-building activities in the national budgets; and
iv. Coordinating and harmonizing biosafety frameworks at the regional and sub-regional levels.

As will be noted in sections below, there is very little evidence in terms of specific steps taken to address these limiting factors.

In 2008, COP-MOP4 adopted a revised, expanded set of indicators for monitoring the implementation of the updated Action Plan[15]. Following recommendations by the CBD Secretariat's Liaison Group on Capacity Building in Biosafety, indicators were added for new elements in the capacity building action plan not yet covered by earlier versions. This includes, among others, socio-economic considerations, documentation requirements and confidential information.

The Liaison Group also noted that the set of indicators had not been widely used by governments and relevant organizations, and there was no feedback on the experiences and lessons learned in their use. Organizations such as UNEP and the World Bank have incorporated indicators drawn from the set of indicators in their stocktaking activities and in the monitoring and evaluation of their biosafety projects. For

[13] Full text notification available at URL: http://www.cbd.int/doc/notifications/2003/ntf-2003-093-cpb-en.pdf

[14] MOP 1 Decision BS-I/5. URL: http://www.cbd.int/decision/mop/?id=8287

[15] Available at URL: https://www.cbd.int/doc/meetings/bs/mop-04/official/mop-04-04-add1-en.pdf

example, indicators are specified in most of the GEF-funded biosafety projects to facilitate the monitoring and evaluation of the projects' performance and progress, often drawn from the Action Plan indicators. The Liaison Group recommended, in its meeting in 2009, that a meeting of experts in monitoring and evaluation be convened to carry out a professional revision of the indicators, as part of the process for developing the strategic plan for the Protocol. The GEF Secretariat, in light of its experience in developing, monitoring and evaluating various biosafety capacity-building projects, should be closely involved as well as donor agencies funding biosafety activities.

Despite the limited use of the indicators to date, countries that have ratified the CPB are requested to regularly submit their capacity building needs and priorities to the CBD Secretariat in line with the Action Plan and set of indicators. Upon receipt, this information is recorded in the Biosafety Clearing-House. Recent submissions have been received, at the time of writing this report, from 14 countries[16]. Even for countries with prior experience in GMO assessment and decision-making, such as Egypt, Mexico and Poland, reported capacity-building needs are many and varied even though these countries indicate that some of the needs were partially or fully addressed. Generally, countries express a strong need for continued training and education and training materials on current challenges related to, for instance, risk assessment, post-release monitoring, socio-economic analysis, LMO detection — and the need for funding support to address those needs. For other countries, the list of capacity building needs tend to be longer though not differentiated as to what constitute immediate, medium-term or longer-term priorities.

4. RESPONDING TO THE ACTION PLAN: OVERVIEW OF CURRENT BIOSAFETY CAPACITY BUILDING INITIATIVES AND APPROACHES

As called for in the Action Plan, and reflecting the international debate over potential and actual benefits and risks of modern biotechnology, a growing number of donor agencies support biosafety capacity building projects as summarized in sections below. Financing for biosafety capacity building received a boost following the adoption of the Cartagena Protocol in 2000, and the designation of the Global Environment Facility (GEF) as the financial mechanism for supporting the implementation of the Protocol.

While GEF-supported projects together form the lion's share of biosafety capacity building projects, they are complemented by a wide range of projects supported by other UN agencies and international organizations, bilateral donor agencies, and private foundations. These will not be covered exhaustively in this report; details can be found in the relevant official document for COP-MOP5 on the "Status of Capacity-Building Activities" (UNEP/CBD/BS/COP-MOP/5/4)[17] and in Annex 2 to this report.

It should be noted that this section does not present an exhaustive overview of capacity building programs or activities on biosafety, which would be beyond the scope of this review, and focuses on the ones that are either GEF supported or ongoing programs supported by other UN and donor agencies.

[16] Benin, Côte d'Ivoire, Dominican Republic, Egypt, Latvia, Lithuania, Mexico, Niger, Nigeria, Poland, Moldova, Saint Lucia, Togo, Venezuela.

[17] Available at URL: http://www.cbd.int/doc/meetings/bs/mop-05/official/mop-05-04-en.pdf

Box 2. Lessons from the UNEP-GEF NBF Development Projects

As of July 2009, 111 countries had completed the development of their National Biosafety Projects (NBFs) and their draft NBFs are available online via the UNEP website.[18] Of the total number of NBFs,

- 38 were completed by countries in Africa,
- 29 in Asia and the Pacific,
- 18 countries in Central and Eastern Europe,
- 26 in Latin America and the Caribbean.

These projects have generated a wealth of in-country experience in building capacity for biosafety. A comparative analysis commissioned by UNEP (2006) focusing on the NBF development projects highlights some key lessons that are relevant to capacity building activities in biosafety:

- The most important lesson emerging from the experiences is that biosafety is a sustainable development issue, and that it cannot be considered in isolation from a country's development priorities.
- Recognition of biosafety as a sustainable development issue means that the development of the NBF, and particularly the resultant product i.e. the national biosafety framework, must be responsive to national needs and priorities in order to promote sustainability of the NBF.
- The importance of a country-driven process in preparing the NBF - the strong emphasis on this principle throughout the project has promoted a strong sense of national ownership, illustrated by the support from government in many of the countries to, not only seek outside assistance for capacity building for implementation of their NBF, but also to commit substantial government resources to both setting up the necessary systems and to maintain them on an on-going basis through financial allocations in the national budget for recurrent costs.
- An inclusive approach is needed in order to ensure the involvement of all stakeholders; this is crucial if the NBF is to be accepted by all parties within the country. This will not only help ensure support for the implementation of the NBF, but will also help promote the sustainability of the achievements.

Source: UNEP-GEF Biosafety Unit. 2006. A Comparative Analysis of Experiences and Lessons From the UNEP-GEF Biosafety Projects. Nairobi: United Nations Environment Programme. URL: http://www.unep.org/biosafety/Documents/UNEPGEFBiosafety_comp_analysisDec2006.pdf

4.1 GEF supported projects: Developing and implementing national biosafety frameworks

Based on the early Protocol negotiations and various COP decisions, an ambitious agenda was adopted for GEF-supported projects aimed at implementing the Cartagena Protocol in signatory countries. In November 2000, the GEF Council approved an initial strategy[19] to assist countries to prepare for the entry into force of the Cartagena Protocol. The following projects were approved based on this strategy (for details, see Table 1 below):

1. A global project (2001 – 2007) on the "Development of National Biosafety Frameworks", assisting 130 countries in setting up their national frameworks (see also Box 2 above).

[18] : http://www.unep.org/biosafety/

[19] URL: http://www.unep.org/biosafety/Documents/GEF_strategy.pdf

2. A global project (2004 – 2008) on "Building Capacity for the effective participation of Parties in the Biosafety Clearing House" (BCH), assisting 139 countries to participate in the BCH.
3. Twelve demonstration projects (2001 – 2006) on "Implementation of National Biosafety Frameworks" (of which 8 projects were managed by UNEP-DGEF; see also Table 1 below).

UNEP developed a detailed toolkit[20] to guide the development of National Biosafety Frameworks (NBFs), and also issued informal guidelines regarding the implementation projects.

The initial GEF strategy was followed by a final GEF Strategy for Financing Biosafety Activities (2007 – 2010) adopted in 2006, with the overall objective to:

"[H]elp build the capacity of eligible countries to implement their national biosafety frameworks (NBFs), through activities at the national, subregional and regional levels."

Based on this strategy, under GEF-3, 11 new implementation projects were approved in late 2006 and these are currently either recently completed or about to complete (see Table 1 below for participating countries).

In addition, a total of 31 country project requests are currently in various stages of review and approval for a third round of implementation projects under GEF-4. Out of these, there are a number where project implementation has begun, such as Bhutan, Guatemala, Lao PDR and Madagascar.[21] The recent implementation projects have objectives similar to the demonstration projects, and all aim at establishing a "fully functional regulatory regime" for biotechnology.

Finally, some countries are entering into a second implementation phase for strengthening specific components of their NBF through a GEF full size project. This so far includes India where a 4-year project, approved early 2009, will emphasize capacity development in areas such as risk assessment / risk management; socio-economic assessments; handling, transport, packaging and identification; LMO detection; and, information dissemination to promote public awareness. Cameroon recently received a project preparation grant to develop a full-sized project on establishing a national monitoring and control system for LMOs and alien invasive species.

[20] Available at URL: http://www.unep.ch/biosafety/old_site/resources.htm

[21] A detailed overview of recent GEF support for biosafety can be found in document UNEP/CBD/BS/COP-MOP/5/5 (30 June 2010), "Matters Related to the Financial Mechanism and Resources". Available at URL: http://www.cbd.int/doc/meetings/bs/mop-05/official/mop-05-05-en.pdf

Table 1. GEF supported implementation projects (2001-2006): Summary of achievements in 8 countries

Project component	Summary of achievements
1. National policy	▪ 1 national policy adopted (Kenya) ▪ 3 national policies drafted (Cuba, Poland, Uganda)
2. Regulatory regime	▪ 3 biosafety acts / laws adopted (Bulgaria, Cameroon, Namibia) ▪ 4 biosafety acts / laws drafted (China, Kenya, Poland, Uganda) ▪ Implementing regulations enacted in 4 countries (Bulgaria, Cameroon, Cuba, Namibia)
3. Handling of notifications	▪ Administrative procedures established (*all countries*) ▪ Guidelines, manuals developed for risk assessment, risk management (*all countries*) ▪ BCH launched in 4 countries (Bulgaria, China, Kenya, Poland) ▪ Technical training conducted on risk assessment, risk management (*all countries*)
4. Monitoring and inspections	▪ LMO testing and detection units equipped in 6 countries (Bulgaria, Cameroon, China, Namibia, Poland, Uganda) ▪ Environmental impact studies conducted in 2 countries (Bulgaria, China) ▪ Guidelines, manuals developed for environmental monitoring and inspections (*all countries*) ▪ Technical training conducted on monitoring and inspections (*all countries*)
5. Public information and awareness	▪ Strategies for biosafety communication, awareness developed in 3 countries (Cuba, Kenya, Uganda) ▪ Awareness and outreach materials published (*all countries*) ▪ Awareness-raising workshops conducted for policy makers, journalists, farmers and other stakeholders (*all countries*)

Source: UNEP-GEF Biosafety Unit. 2008. Guidance towards implementation of National Biosafety Frameworks: Lessons learned from the UNEP demonstration projects. Nairobi: United Nations Environment Programme. URL: http://www.unep.org/biosafety/files/Final%20National%20Biosafety%20Frameworks.pdf

4.2 Multi-country projects supported by GEF

While the initial rounds of GEF support strongly focused on country-level projects aimed at NBF development and implementation, the December 2006 GEF Strategy (2007 – 2010) placed increased emphasis on multi-country projects, following advice from COP-MOP to support common approaches and synergies at regional or sub-regional levels. Such multi-country initiatives are being implemented for the following sub-regions (see Table 2 for details):

i. Latin America: Four countries collaborate in the World Bank managed project "Multi-Country Capacity-Building for Compliance with the Cartagena Protocol on Biosafety".

ii. West Africa: Another World Bank managed regional project involves 8 countries in West Africa. This project also covers 4 years (2008 – 2011) and is implemented by WAEMU, the West African Economic and Monetary Union.

iii. Caribbean subregion: A third multi-country project, involving 13 Caribbean countries and managed by UNEP, was approved by GEF Council in 2009 and awaiting implementation. The project, with a 5-year timeframe, is expected to be implemented with the Secretariat of

CARICOM, the Caribbean Community, who recently established a regional Working Group on Biotechnology encompassing biosafety.

In total, according to the GEF Projects Database,[22] approved funding for the national and multi-country biosafety activities (including BCH support) and the initial Pilot Project during the period 1998 - 2010 amounts to US$ 201 million, of which around US$ 107 million is provided by GEF and US$ 94 through country co-financing.

4.3 Other UN agencies, international organizations, and bilateral donor programmes

Apart from UNEP, UNDP, and the World Bank, who manage implementation of the above GEF supported projects, other UN agencies, international organizations and bilateral donors support biosafety capacity building. Examples are included in the overview table below (Table 2), while further details can be found in annex 2.

Table 2. Overview of biosafety capacity development programmes

Project / programme	**Implementing agency**	**Country focus**	**Funding** *(excl. country co-financing)*	**Goal / objectives**
GEF supported projects				
Development of National Biosafety Frameworks (2001-2007)[23]	UNEP	123 countries in Africa, Asia and Pacific, Latin America and Caribbean, Central and Eastern Europe	GEF: US$ 34 million	Defining NBFs; Regional, sub-regional collaboration
Building Capacity for the effective participation of Parties in the Biosafety Clearing House (2004 – 2008)	UNEP	109 countries in Africa, Asia and Pacific, Latin America and Caribbean, Central and Eastern Europe	GEF: US$ 13.5 million	Supporting countries in fulfilling their BCH obligations as well as taking advantage of its benefits, by providing advice, training, and equipment.
Implementation of National Biosafety Frameworks (2001 – 2006)	UNEP (8 countries) UNDP (2) World Bank (2)	12 countries: Bulgaria, Cameroon, China, Colombia, Cuba, India, Kenya, Malaysia, Mexico, Namibia, Poland, and Uganda	GEF: US$ 9.2 million	Establish a regulatory regime, in line with national priorities and international obligations; Establish systems for handling notifications, incl. administrative processing, risk assessment and decision making, enforcement and monitoring, public information and participation
Implementation of National Biosafety Frameworks (2006 – 2010)	UNEP	11 countries: Cambodia, Czech Republic, Egypt, Estonia, Lithuania, Mauritius, Moldova, Slovakia, Tanzania, Tunisia, and Vietnam	GEF: US$ 7.4 million	As above

[22] Accessible at URL: http://www.gefonline.org/

[23] Details on all GEF supported projects can be found on URL: www.gefonline.org

Project / programme	Implementing agency	Country focus	Funding *(excl. country co-financing)*	Goal / objectives
Implementation of National Biosafety Frameworks (2010, ongoing)	UNEP	Albania, Bhutan, Costa Rica, Ecuador, El Salvador, Guatemala, Lao PDR, and Madagascar	GEF: US$ 5.1 million	As above
"Phase II" NBF implementation (2010, ongoing)	UNEP	India	GEF: US$ 2.7 million	Strengthen the biosafety management system with special emphasis on risk assessment and management, handling, transport, packaging and identification of LMOs, socio-economic considerations and public awareness

Project / programme	Implementing agency	Country focus	Funding (excl. country co-financing)	Goal / objectives
Multi-Country Capacity-Building for Compliance with the Cartagena Protocol on Biosafety (2008 – 2011)	World Bank CIAT	Brazil, Colombia, Costa Rica and Peru	GEF: US$ 5 million	Strengthening technical capacity in risk assessment and management; strengthening biosafety decision-making capacity; and public awareness
West Africa Regional Biosafety Programme (2007 – 2010)	World Bank WEAMU	Benin, Burkina Faso, Côte d'Ivoire, Guinea Bissau, Mali, Niger, Senegal and Togo	GEF: US$ 5.4 million	Establish and implement a shared biosafety regulatory framework, to be achieved through three components: (a) regional common approaches in risk assessment of GMOs/LMOs; (b) institutional capacity for preparing regional laws and regulations on biosafety; (c) strengthening capacities of stakeholders and raising public awareness
Regional Project for Implementing National Biosafety Frameworks in the Caribbean Sub-region (*pending*)	UNEP CARICOM	Antigua & Barbuda, Bahamas, Barbados, Belize, Dominica, Grenada, Guyana, St Kitts & Nevis, St Lucia, Surinam, St Vincent & Grenadines, and Trinidad & Tobago	GEF: US$ 6.1 million	Implementing NBFs in participating countries; establishing regional cooperation in biosafety
Other UN agencies and international organizations				
FAO Building Biosafety Capacities[24]	FAO	- 15 country projects: Africa (5), Asia (3), Eastern Europe (1) and Latin America and the	FAO: US$ 7.5 million	Assist countries and regions in building strong technical, institutional and information sharing capacities to ensure the safe

[24] Further details on FAO's activities can be found at URL: http://www.fao.org/biotech/doc.asp

		Caribbean (6) - 4 sub-regional projects: Asia (10 countries), Central Europe (3), Latin America (6) and the Middle East (6) - 2 global projects: training in GMO detection and monitoring; and, GM food safety assessment		use of modern biotechnologies and enhance sustainable agriculture and food production
e-Biosafety Training Programme[25]	UNIDO	Global	Fee-based courses	Strengthen professional expertise in biosafety management
ICGEB Biosafety Unit[26]	ICGEB	- Global - Africa (through Gates Foundation grant)	- Fee-based courses - Gates Foundation: US$ 3 million	Capacity building / training; information dissemination; international collaboration

Programs supported by bilateral donors and foundations				
Project / programme	**Implementing agency**	**Country focus**	**Funding (excl. country co-financing)**	**Goal / objectives**
South Asia Biosafety Programme[27]	IFPRI ILSI Center for Environmental Risk Assessment	Bangladesh, India	USAID: US$ 2 million	Developing and applying sound science to the environmental risk assessment of agricultural biotechnologies
BioSafeTrain[28]	University of Copenhagen	Kenya, Tanzania, Uganda	DANIDA: US$ 1.4 million	Build regional capacity in biosafety and ecological risk assessment; enhance regional collaborations in biosafety; promote North – South collaboration
African Union Biosafety Project[29]	African Union GTZ, Germany	AU member states	BMZ: US$ 2.6 million	Provide the AU with the necessary capacities and instruments to support its Member States in implementing the Cartagena Protocol on Biosafety and the African Model Law on Safety in Biotechnology
Norwegian Center for Biosafety[30]	Genøk, Norway	- Global (training program) - South Africa - Zambia	NORAD: - US$ 2.9 million (training) - US$ 0.9	Provide countries with scientific and technical capacity for biosafety assessment and regulation; build capacities for countries to conduct scientific risk assessment and risk

[25] http://binas.unido.org/ebiosafety/

[26] http://www.icgeb.org/~bsafesrv/

[27] http://cera-gmc.org/index.php?action=s._asia_biosafety_program

[28] http://www.biosafetrain.dk

[29] http://www.africa-union.org/root/au/auc/departments/hrst/biosafety/AU_Biosafety.htm

[30] http://www.genok.com/

			million (S.Africa) - US$ 0.5 million (Zambia)	management, and address other technical biosafety regulation needs
African Biosafety Network of Expertise[31]	ABNE	Africa	Gates Foundation: US$ 10 million	Technical assistance, biosafety related tools and resources, training workshops for regulators
Capacity Strengthening for the Safe Management of Biotechnology in Sub-Sahara Africa[32]	FARA	Burkina Faso, Ghana, Nigeria, Kenya, Malawi, Uganda	Syngenta Foundation: US$ 1.3 million	Training in biotechnology stewardship; train stewardship leaders
Southern Africa Biosafety and Environment Programme[33]	RAEIN-Africa	SADC countries	The Netherlands: n.a.	Development and implementation of biosafety systems; build legal, technical, and socio-economic expertise; promote and foster networking and collaboration.
ASEAN Centre for Biodiversity[34]	ACB	ASEAN countries	European Union: n.a.	Strengthen biosafety management in ASEAN countries; regional biosafety guidelines
Hemispheric Biotechnology and Biosafety Program[35] – biosafety component	IICA	Latin America and the Caribbean	n.a.	Development, implementation and communication of transparent, science-based policies and regulatory frameworks and, where appropriate, facilitate regional harmonization

In addition to the programs recorded in table 2 above, a good number of one-off workshops and conferences on biosafety take place each year, as recorded in the BCH database on capacity building opportunities. Governments actively supporting such events include Austria (recent workshops supported in Croatia, Malaysia, among others) and the USA through its Foreign Agricultural Service (FAS). Finally, the CBD Secretariat itself has taken on an important role in biosafety training, with recent regional workshops organized on identification and documentation of LMOs, and on risk assessment and risk management of LMOs.

4.4 The Coordination Mechanism

In view of the diverse landscape of capacity building programs and activities, the COP-MOP at its first meeting adopted a Coordination Mechanism to promote partnerships, complementarities and synergies between various capacity-building initiatives. This would be achieved through: sharing of information on existing initiatives, opportunities and needs; exchange of resource materials and reports; facilitating interaction and dialogue and fostering ongoing collaboration and networking, including through coordination meetings. Practical steps that were taken to implement the mechanism include:

- Establishing a Liaison Group on Capacity Building in Biosafety;

[31] http://www.nepadbiosafety.net

[32] http://www.syngentafoundation.org/index.cfm?pageID=533

[33] http://www.raein-africa.org/index.html

[34] http://www.aseanbiodiversity.org/

[35] http://www.iica.int/Eng/organizacion/LTGC/Biotecnologia/Pages/default.aspx

- Annual coordination meetings of donor agencies and implementing organizations supporting biosafety capacity building;
- Regular coordination meetings of academic institutions and organizations offering biosafety education and training programs;
- Biosafety capacity building databases on the BCH.

The Coordination Mechanism on the one hand has been valuable in promoting exchange of information among funding and implementing agencies, and in generating guidelines for capacity-development programs and activities generally and for regional collaboration in biosafety capacity development. It also resulted in a comprehensive, and regularly updated "who is who" in biosafety capacity development and training (through meeting reports and the BCH), which is an essential precondition for any coordination efforts. On the other hand, there is very little evidence of actual coordination of capacity building efforts, e.g., joint work plan or strategy development in countries or sub-regions where multiple donors and implementing agencies are active.

5. ASSESSING RELEVANCE AND EFFECTIVENESS OF VARIOUS APPROACHES TO BIOSAFETY CAPACITY BUILDING

From the review of available reports and information on previous and ongoing biosafety capacity-building initiatives, a number of important issues and inherent challenges emerge. These are discussed in this section. Many of these issues and challenges were also touched upon in previous evaluations and assessments by other organizations, including those briefly presented below.

All the analysis to date have concluded that deficiencies continue to exist regarding the domestic implementation of the Cartagena Protocol and there associated gaps in national biosafety capacities. A recent draft discussion paper[36] issued by the CBD Secretariat also concludes that:

"Notwithstanding the significant activity and effort that has been devoted to the Protocol's implementation since its adoption, there remain gaps and deficiencies in implementation." (p.4)

Specifically relevant to the current review, the paper states that:

"[…] it is evident that a state that has completed the NBF process is not necessarily in a position to implement the Protocol in terms, for example, of dealing with an application for the first import of an LMO for intentional introduction into the environment. In some cases, while draft legislation may have been prepared, it has not been enacted; and in others secondary regulations that form an integral component of an operational regulatory system have not been finalised and adopted. In numerous cases, it is suggested, even though a regulatory framework has been put in place, Parties may not be in a position to process an application due to a lack of sufficient technical or other capacity." (p.3)

[36] SCBD. 2010. *Assessment and Review under Article 35 of the Cartagena Protocol on Biosafety: Discussion Paper on a Proposed Framework for the Second Assessment and Review*. UNEP/CBD/BS/COP-MOP/5/15, 22 January 2010.

5.1 Assessing relevance and effectiveness: Findings from past assessments

Although project evaluations do not appear to be a regular feature in biosafety capacity building programmes, a number of recent reviews were commissioned including:

- A mid-term evaluation of the UNEP-GEF NBF development project, commissioned to external reviewers by the UNEP Evaluation and Oversight Unit (2003)[37;]
- An evaluation of GEF support for biosafety (2006) commissioned to a team of external reviewers by GEF's Evaluation Office[38;]
- A terminal evaluation (2009) of the UNEP-GEF Biosafety Clearing-House (BCH) project, commissioned to an external reviewer by the UNEP Evaluation and Oversight Unit[39];
- UNEP Biosafety Unit's internally commissioned reviews of the NBF development projects (2006)40 and the set of 8 pilot implementation projects (2008)[41];
- FAO internal self-assessment report, providing an overview of the experience gained and lessons learned from its past and ongoing capacity-building initiatives in biosafety and biotechnology[42];
- Donor-agency commissioned reviews of special programs such as PBS and BIO-EARN;
- A study, supported by the Rockefeller Foundation, by the United Nations University – Institute of Advanced Studies (UNU-IAS) presenting a comprehensive assessment (2008) of biotechnology and biosafety capacity development activities[43].

While not addressing the particular characteristics and inherent challenges of biosafety capacity development, collectively the assessments listed above provide a rich collection of recommendations as to how biosafety capacity building projects could be improved.

The evaluations looking at GEF supported projects, including those commissioned by UNEP, identify important flaws in project design and implementation — commonly found in other capacity support projects. These flaws are primarily related to the ambitious scope of the projects, lack of a strategic approach, and limited time and funding available to complete them. While the necessary adjustments were made in the design and implementation of subsequent projects, generally the GEF-supported projects have resulted in a great number of outputs (e.g., draft policies, draft legal instruments and guidelines, proposed

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[37] Navajas, H. and J.H. Seyani. 2003. *Development of National Biosafety Frameworks: Mid-term Evaluation of a Global Initiative*. GF/6010-01-01. Nairobi: UNEP Evaluation and Oversight Unit. URL: http://www.unep.ch/biosafety/old_site/development/devdocuments/Midtermreview.pdf

[38] GEF. 2006. *Evaluation of GEF Support for Biosafety. Full Report*. Washington, DC: GEF Evaluation Office.

[39] Navajas, H. 2009. *Terminal Evaluation of project GF/6010-04-02 (4771) GFL/2328-2716-4771 – "Building Capacity for Participation in the Biosafety Clearing-House (BCH)" – Phase I*. Nairobi: UNEP Evaluation and Oversight Unit. URL: http://bch.cbd.int/database/record-v4.shtml?documentid=101049

[40] UNEP. 2006. *A Comparative Analysis of Experiences and Lessons from the UNEP-GEF Biosafety Projects*. Geneva: UNEP-GEF Biosafety Unit. URL: http://www.unep.org/biosafety/Documents/UNEPGEFBiosafety_comp_analysisDec2006.pdf

[41] UNEP. 2008. *Guidance towards Implementation of National Biosafety Frameworks: Lessons Learned from the UNEP Demonstration Projects*. Geneva: UNEP Biosafety Unit. URL: http://www.unep.org/biosafety/files/Final%20National%20Biosafety%20Frameworks.pdf

[42] FAO, 2009. *Building Biosafety Capacities: FAO'S Experience and Outlook*, An overview of the experience gained from FAO capacity-building projects in agricultural biotechnology and biosafety, FAO, Rome. URL: http://www.fao.org/docrep/012/i1033e/i1033e00.htm

[43] Johnston, S., C. Monagle, J. Green and R. Mackenzie. 2008. *Internationally Funded Training in Biotechnology and Biosafety: Is it Bridging the Biotech Divide?* Yokohama: UNU Institute of Advanced Studies. URL: http://www.ias.unu.edu/sub_page.aspx?catID=111&ddlID=673

but not fully functional competent authorities) that many countries have not been able to operationalise after the project completion. Various practical suggestions are provided in these evaluation reports that could contribute to improved project performance and effectiveness.

The BCH project evaluation (2009), for example, raises the fundamental issue of sustainability after project completion and points out that while overall the project performance was satisfactory, limited progress was made in sustaining in-country capacities to access and use the BCH. The overall momentum declined in many countries, particularly those that lacked biosafety frameworks and procedures, at the end of the project. Gaps in legislation, institutional mandates and coordination needed to be addressed before the knowledge and skills generated by the BCH project could be used and retained. The evaluation also raised questions on the timing of the project:

"*Was it prematurely implemented in countries that are at incipient stages of national biosafety framework development? Should the project have been implemented in countries where basic enabling conditions were lacking?*" (p.20).

Following the series of BCH projects implemented in 109 countries, it is quite striking to note that for example in terms of "Country Decisions and other Communications"[44] most recipient countries in the BCH project are still not contributing the required information[45]. From the African continent, for example, only South Africa has submitted data in this category while a larger set of countries have taken decisions on LMO introductions. This situation is also reflected in the low number of national clearinghouses or websites that are fully functional in recipient countries, particularly those in Africa.

Generally, sustainability and timing issues have come up in most biosafety capacity-building reviews to date. Summarizing all recommendations from completed evaluations goes beyond the scope of this report. However, the 2006 GEF evaluation and the UNU-IAS study point to a number of crucial issues in biosafety capacity development, as outlined below.

5.2 Evaluation of GEF support for biosafety (2006)

The 2006 GEF evaluation includes chapter 7 on capacity development, specifically dealing with capacity development in risk assessment and risk management. In the NBF development projects, countries were expected to focus on establishing mechanisms to conduct risk assessments rather than providing detailed technical training which was intended to be a priority during the subsequent implementation phase. The evaluation notes that in nearly all countries, the mechanism for risk assessment took the form of an expert committee, such as a national biosafety committee, sometimes with more technically oriented subcommittees for conducting product-specific reviews. The evaluation team concludes that:

"*For many countries, staffing of this committee alone will be a challenge, and, at project completion, the risk assessment and risk management structures are often just a plan on paper or are in the formative stages*." (p.56)

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[44] Such decisions include, among others, those on contained use of LMOs; LMO-FFPs; LMOs for introduction into the environment; risk assessments; other decisions. Data accessed at URL: http://bch.cbd.int/database/decisions/

[45] To illustrate this point, the most recent update on "Operation and Activities of the Biosafety Clearing-House" (UNEP/CBD/BS/COP-MOP/5/3; June 2010) reports that: *"[T]here is still only a limited number of decisions on the intentional introduction of LMOs into the environment and a significant absence of the summary reports of their risk assessments related to the decisions submitted*." Report accessed at URL: http://www.cbd.int/doc/meetings/bs/mop-05/official/mop-05-03-en.pdf

The 2006 GEF evaluation also looked into risk assessment and risk management capacity development in the NBF implementation projects. Some countries participating in these projects had significant prior experience in dealing with biosafety. Still the dominant approach to capacity building in risk assessment / risk management was through the usual approach of short-term (3 to 5 day) workshops. The evaluation report states that:

"*The utility of shorter workshops, while positive in the context of raising awareness, is minimal as a tool for establishing sustainable institutional capability and the confidence for sound regulatory decision making.*" (p.57)

Chapter 8 of the GEF evaluation report assesses the development of biosafety policy and regulations, and draws a number of important conclusions relating to the subject of this review. First, it points to the fact that for countries anticipating low levels of involvement in LMO activity (referred to as "low baseline countries"), only a limited number of legislative tasks are urgently needed as the CPB itself provides alternatives to the development of comprehensive legislation (p.62):

- As an alternative to developing a legal framework addressing the introduction of LMOs, Parties may decide to use article 10 of the Protocol, adopting it as an interim measure;
- As an alternative to developing a decision-making process addressing LMO-FFPs, Parties may decide to directly utilize provisions of article 11.6 of the Protocol.

The report noted that by then, only a few countries such as Barbados, Dominican Republic and Saint Lucia had communicated government decisions on such interim measures through the BCH. Adopting such interim measures and a step-by-step approach to steadily build up a full NBF appears as a sound option to many countries with moderate or low existing biosafety capacities. However, the evaluation further pointed out that this option is only rarely chosen, and that the production of comprehensive biosafety legislation was considered a mandatory requirement by most teams responsible for the NBF development projects.

"*Low baseline countries, in particular, appear to have adopted relatively comprehensive framework laws. These are often similar in coverage and content—necessitating relatively high levels of further administrative development (regulations, operational structures, and other legal needs) and detailed institutional and regulatory requirements for risk assessment.*" (p.64)

5.3 UNU review of internationally funded training in biotechnology and biosafety

The UNU-IAS (2008) study involved an in-depth review of biotechnology and biosafety capacity building programs, and is the only attempt so far to comprehensively look at the inherent challenges. This assessment found that a majority of developing countries, including most countries of Africa, Central Asia, Oceania and the Caribbean, were unable to manage modern biotechnology and implement their National Biosafety Frameworks. The study noted that capacity deficiencies are:

"[…] *so pervasive and broad that there is no effective international system of biosafety at the moment. In addition, the volume of resources available to address these needs in the coming years appears insufficient to provide the necessary support for countries to implement their basic obligations under the CPB.*" (p.11)

This study also analyzed specific capacity building gaps. Among others, it was observed that:

- The principal focus of projects so far has been on the development of policy and regulatory regimes. Scientific training that has taken place focused most commonly on risk assessment. There are many needs remaining in areas such as non-crop biotechnologies, risk management and socio-economic assessments.
- Current project cycles of 2 to 5 years do not provide adequate support to ensure lasting results. Longer term projects and programmatic approaches to capacity building are needed.
- For individual countries, there is a need to prioritize issues, identify their capacity building needs and invest their own resources if they wish to benefit more from international assistance.
- Timing was an issue in a number of NBF country projects. In one case, for example, 2 university labs were equipped with GMO detection technology while technical guidelines and procedures for the actual detection of GMOs did not exist.
- There is an acute need for more sophisticated analysis of capacity building needs. The relatively simple methods used to identify needs do not allow a strategic approach to the issue for donor agencies, recipients, educators and international organizations.
- Projects need to move away from the heavy reliance on workshops as the prime delivery mechanism. Innovative and targeted approaches are required for the design and delivery of training, including emphasis on learning-by-doing and iterative approaches.

5.4 Key findings from the current review

Sections below summarize the predominant capacity development strategies and approaches that been used for some years, and their main limitations. It should be emphasized that the strategies and approaches adopted so far represent an understandable response to the context and pressures shaping the implementation of the CPB, as a large number of countries was requesting assistance. This has clearly contributed to progress made in a number of countries, especially those with some existing capacities.

(1) Important achievements

The GEF, UN agencies, donor agencies and implementing organizations have responded to the requests for capacity-building support with an impressive range of projects and activities, carried out in close collaboration with national and regional partners. This support, while addressing a sometimes controversial and politically sensitive issue, has contributed to the relatively rapid ratification of the CPB, raised awareness and fostered informed debate about biosafety within the broader area of biodiversity conservation and sustainable use. Completed and draft NBFs generally provide a sensible way forward for countries to continue developing and refining their regulatory systems.

The review of various initiatives points to a number of important achievements made in the area of biosafety capacity development, as confirmed in related reviews and reports. Some of the main achievements include the following:

i. A good number of countries have developed or are in the process of developing biosafety policies, laws, and implementing regulations and guidelines largely with support of donor-funded projects and programs, though progress has been uneven across countries. However, for many countries, more work is needed to achieve fully functional national biosafety systems. In some cases, priorities for follow-up support have been identified.

ii. As reported in the above mentioned UNEP evaluations, coordination mechanisms created under some of GEF-supported country projects continue functioning beyond the life of the projects, either as National Biosafety Committees or as informal advisory bodies to government and to other biosafety technical assistance programs.

iii. Support programs have produced some valuable generic resource materials that can be readily adapted and used by many countries as they define and implement their NBFs. These include, among others: the UNEP NBF development toolkit[46]; the FAO training toolkit on GM Food Safety Assessment[47]; GMO ERA project risk assessment handbook[48]; the BIO-EARN Biosafety Resource Book[49]; and, the PBS Integrated Confinement System[50] for genetically engineered plants.

iv. The number of countries that have experience with LMOs and biosafety decision making has gradually grown and opportunities for tailored hands-on training have expanded. For example, some countries that participated in the first round of GEF-supported implementation projects, have taken decisions on confined field trials of genetically modified crop plants and have hosted hands-on training for prospective field trial managers from several other countries.

v. A number of regional political and economic integrations organizations have developed a strong interest in biosafety, partially as a result of various capacity development support projects. These include the African Union; the Common Market for East and Southern Africa (COMESA); the West African Economic and Monetary Union (WAEMU); the Caribbean Community (CARICOM); the Organization of American States (OAS); and, the Association of South East Asian Nations (ASEAN), which have active programs on biotechnology and biosafety. Such regional and sub-regional initiatives, while still evolving, could become a conduit to promoting collaboration among countries, sharing resources and biosafety information, and possibly providing financial support for continued biosafety capacity development.

(2) Current approaches and limitations to biosafety capacity development

Common challenges currently facing governments, funding organizations and implementing agencies include: building upon the achievements made so far (including those mentioned above), learning from over a decade of experience, and agreeing on new strategic directions. Based on this review, new directions will have to be taken with respect to the following approaches and limitations to biosafety capacity development:

a. A globalized and inclusive approach

Capacity development interventions have generally had three strategic objectives in mind, namely promoting:

1. Promoting international awareness and ratification of the Cartagena Protocol;

[46] Available at URL: http://www.unep.org/biosafety/Toolkit.aspx

[47] Available at URL: http://www.fao.org/docrep/012/i0110e/i0110e00.htm

[48] Available at: http://www.gmoera.umn.edu/public/publications/index.html

[49] Available at: http://www.bio-earn.org/Content/Downloads/biosafety/2004-Biosafety%20Resource%20Book.pdf

[50] http://programs.ifpri.org/pbs/pbspubs.asp#train

2. Development of technical and organizational capacity at the country level; and
3. Development of biosafety capacity as part of a comprehensive global system.

These three objectives obviously reinforce each other especially over the medium and longer term. But they also give rise to significant trade-offs particularly in the short run.

One of the key findings from this review is that trade-offs between objective 1 and 2 above have shaped the approach to biosafety capacity development in many projects supported by the GEF and other donor agencies. The strategy has been to involve as many countries as possible, and as many actors and stakeholders as possible. As well, the strategy has been to cover all or most aspects of what constitutes a functional NBF — not considering more basic, interim approaches in the initial stages. The emphasis has been on inclusion and comprehensiveness of coverage.

The general approach to biosafety capacity development, including implementation of the Action Plan, has been to reach as many countries as possible with as few costs as possible. This is in line with the objective of achieving international awareness, support and compliance with the CPB. In particular, the emphasis has been on supporting and setting up comprehensive national biosafety frameworks (NBFs) as the key objective.

Another key finding is that whereas most projects were country- and needs-driven in principle, in practice, the capacity development approach to date has been to put forward standardized packages of interventions. This can be seen, for example, in the key elements/ list of required capacities included in the Action Plan; the UNEP toolkits; and the set of indicators adopted by the COP-MOP. Taken together these would add up to a comprehensive package of biosafety capacity development tools. This comprehensive approach, which tries to cover all aspects of a biosafety system simultaneously, has in some instances resulted in serious timing issues at the level of project management. For example, there are cases where national Biosafety Clearing-House nodes or LMO detection laboratories were set up in the absence of a clear, functional regulatory framework.

b. A focus on the technical and the functional approach

The default approach to biosafety capacity building adopted to date involves a techno-functional perspective, i.e. focusing on the development of formal technical and functional capabilities especially of individuals and organizations, for instance, in environmental risk assessment and biosafety decision-making. This approach is in general planned, top-down and generic based on international best practice. It focuses on addressing gaps and constraints in country capacity and is also reliant on short-term training and transfer of knowledge and technology as the key strategies to capacity development. Other classic ways of delivering ‘hard’ support include technical assistance, financial incentives, restructuring and equipment supply. The techno-functional approach is almost always necessary in some form especially in biosafety capacity development efforts. But it is also almost always never enough to make intended capacities effective and sustainable by themselves. In particular, this approach does not address the key issue of what leads a capacity development intervention to become embedded and legitimized with a country’s legal and political system. Nor does it usually contain much analysis of the contextual or supporting factors that need to be in place to make such an approach effective.

Capacity development for biosafety is not simple or straightforward. Modest injections of funding and technical support, for example, are not likely to make much impact in countries that lack the political

commitment, infrastructure and basic capacity to set up and sustain complex technical and organizational systems.

c. A modest level of analysis of capacity issues

The key CPB documents related to capacity development, including the Capacity-Building Action Plan itself, while useful in presenting a complete list of eventually required capacities, do not contain much analysis or guidance on how such capacities can be developed. They do not, for example, explain the particular characteristics of biosafety from a capacity perspective that need to be taken into account. And it is not clear exactly which individuals or units are responsible for providing the longer-term strategic and technical support.

From the review it is clear that, with a few exceptions, the approach of many biosafety capacity-building programs has been to focus almost exclusively on developing technical and functional capabilities, often through national and regional workshops, sometimes well past the point of utility. Little analysis appears to have been made with respect to the human behavioural issues involved in capacity development for biosafety. One capacity lesson that has been learned in the last 50 years it is the need to combine the technical and the human aspects in any effort to develop capacity.

Finally, the review reveals that much of the biosafety capacity-building effort has been based on "optimal thinking", which sets out all the pieces of the capacity puzzle that would be needed to put in place a fully-functioning biosafety system, almost assuming every country would be in a position to choose the best way forward. However, there are always constraints and limitations and "no go" areas in each country. Put another way, assuming the possibility of optimal outcomes is not feasible for most countries, what are more relevant are outcomes that might be "good enough" or "satisfactory" rather than optimal.

d. Availability of minimal financial resources

Most biosafety capacity development initiatives have experienced pervasive and continual under-investment. The 2003 mid-term evaluation of the UNEP-GEF NBF development project was among the first reports to point to the implications of the limited financial resources available, and this point was confirmed in subsequent reviews. This gap, combined with the need to invest in as many countries as possible has led to inevitable outcomes. These include, among others, little technical backstopping from the implementing organizations or external experts; little support for purchase of essential equipment; and, under-remuneration of country staff and consultants. In many cases, the actual investment in individual countries has not matched the rather ambitious objective of implementing a fully functional NBF.

Previous reviews also pointed to the negative implications of GEF's Resource Allocation Framework (RAF) on funding available for biosafety capacity development. For the period 2007-2010, around US$ 1 billion was allocated under RAF for the Biodiversity Focal Area that includes biosafety as one of four strategic objectives. Country allocations were determined using select criteria to establish their potential to create global benefits for biodiversity (Global Benefits Index, or GBI-bio) and the other based on past performance in implementing GEF projects (GEF Performance Index). Without entering into a detailed discussion on the RAF[51], its implications for biosafety funding have been that:

[51] GEF's own evaluation of the RAF can be found on URL: http://www.thegef.org/gef/sites/thegef.org/files/documents/RAF_MTR-Report.pdf

i. Countries most in need of biosafety capacity support may have ended up with low overall GEF biodiversity allocations; this appears to be especially the case for a large group of African countries and Small Island Developing States. The way that the RAF allocations have been determined gives most resources to the "megadiverse" countries, especially large countries covering multiple ecoregions. The emphasis of the RAF on past performance also benefits those countries with adequate capacity already in place.

ii. Within the general allocation for biodiversity, countries were expected to identify biosafety as a priority for GEF support. However, under the tight allocations for many countries, there has been a general reluctance to use the national allocation to address issues perceived as more precautionary and strategic in nature, such as biosafety.

iii. While increased emphasis on multi-country biosafety projects was called for in previous reviews of GEF biosafety support, the emphasis on country allocations did not encourage regional project development, as participating countries had to carefully weigh the benefits of sub-regional collaboration over national projects. As a result, only a few regional GEF supported biosafety projects are currently active.

Clearly, the RAF privileged biodiversity conservation over biosafety capacity development and country projects over sub-regional initiatives, contributing to the overall situation of limited programme resources. The System for Transparent Allocation of Resources (STAR) recently introduced to replace the RAF is expected to provide improvements in resource allocation – particularly as it now favours low GDP countries. However, no allocation framework will change the situation of a rather low overall allocation of around US$ 40 million to biosafety under GEF-5, which is significantly lower compared to funding available under GEF-4 (around US$ 75 million).

e. A 'lite' approach to capacity development

Given the situation of minimal, and even decreasing financial resources, biosafety capacity development has implicitly been based on the principle of *self organizing*. In the short term emphasis has been put on what are thought to be catalytic interventions such as training or workshops with the assumption that countries, using their own resources, would then begin a spontaneous process of capacity development to produce an acceptable biosafety system. This approach — which can be referred to as "capacity development lite" — has worked in certain circumstances, particularly in countries that already have some capacity in biotechnology and biosafety. However, the suitability of such an approach in the future, especially in low-baseline countries, is questionable.

Capacity development programs have also made the assumption that policy-makers and other senior officials in participating countries would see the value of biosafety frameworks, given a widely accepted Cartagena Protocol, and that they would make the necessary resources available to put a system for biosafety in place. However, in some countries biosafety is still not universally accepted as a public policy priority, particularly at higher political levels, in part due to controversies and misinformation around LMOs and biosafety which have hampered local political support and the adoption of national policies and legal instruments by senior officials and parliaments.

f. A focus on the short term, "easy" elements

Most biosafety support projects to date have focused on short-term efforts of 2-3 years with the assumption that these would make a significant difference to capacity development. However as pointed

out earlier capacity development is a generational task that may last several decades in countries with low initial baselines, and needing continuous maintenance thereafter. What has been accomplished to date represents a valuable but only an initial step in this long-term process.

Biosafety capacity development support has also so far has focused on the relatively easier 'what' parts of the capacity development puzzle, including biosafety policy development, enactment of some legal provisions, limited establishment of formal structures, development of technical skills and some awareness raising. However, in most countries the easy part is now at least partially over. The hard part lies ahead. This includes bringing drafts to adoption, making NBFs fully functional and putting in place complex capabilities in order to arrive at balanced decisions on LMO introductions. And, the risk exists of many countries getting stuck in their efforts to get beyond this easy stage.

g. Limited attention to the issue of sustainability

Related to the previous point on country motivation and commitment, there are two additional aspects of the sustainability issue. The first has to do with the resilience of the organizational structures and capabilities developed to support biosafety decision-making in low capacity countries. The second relates to the issue of cost and continuing access to financial support. Biosafety regulation entails costs, including: the cost for creating and maintaining the institutions, procedures and tools for implementing biosafety; and the costs to applicants for compliance with biosafety regulations. The question of the cost of biosafety capacity development also has to be considered.

The approach to biosafety capacity development to date has been useful in generating better understanding of the special characteristics of biosafety, producing a rich set of practical experiences in NBF development and implementation, and identifying ways to improve project management. In particular, it has made a contribution to the increased awareness and ratification of the CPB itself. Put another way, the initial steps have made it possible to get enabling frameworks and stakeholder support in place globally. Undeniably, progress has been made on several components of the Capacity Building Action Plan, particularly in institutional development and introductory training, primarily in countries that had existing expertise in the regulation of modern biotechnology. All of this has been done with very limited resources at all levels. The comparatively small amounts of funding provided to date have been, on balance and considering the challenges, a sensible investment. The challenge now is to find a way to build on the results to date and move to a new level of capacity development outcomes.

h. Limited attention to the social, economic and political factors

For many countries, issues surrounding biotech and biosafety revive insecurities and frustration about their vulnerability and disempowerment in the international economic system. An issue with similar emotive power might be that of the privatization of water, user fees and the use of private companies to manage urban water resources in countries such as Bolivia and The Philippines.[52] Population control issues also have many of the same characteristics.[53]

[52] For an account of the battle over the water concession in Manila, see: Dumol, M. 2000. *The Manila Water Concession: A Key Government Official's Diary of the World's Largest Privatization.* Directions in Development. Washington DC: World Bank.

[53] See: Warwick, D.P. 1982. *Bitter Pills: Population Policies and their Implementation in Eight Developing Countries*. New York: Cambridge University Press.

Few topics bring on the combination of factors — technical, the socio-economic and the political — that biosafety induces. The technical part is self-evident. The social, economic and the political come from two sides. First is the connection to food and environmental challenges, to potential price increases, to family welfare and survival, to the returns to small farmers.[54] All of these issues touch the majority of people in poor countries in tangible and existential ways. The second source is the connection to the behaviour of and possible motivations of international private corporations which have been instrumental in developing and spreading biotechnology. Some groups in the agriculture sector welcome the introduction of LMOs. Others are uncertain. Still others are resolutely opposed to their introduction. Recent experiences in many countries underline the extended difficulties that face any effort to put in place regulatory frameworks and develop national capacities to support biosafety in a predictable and transparent manner.[55]

Unlike some other capacity issues in sectors such as financial management or health, biosafety issues need to be communicated carefully to various interest groups, civil society and to the general public. Biosafety capacity development must therefore include resources for communication, social marketing and other forms of participatory outreach. Most of the past and present capacity development efforts in biosafety appear to come from the "supply side" in terms of donor support, government programs, private sector marketing. But the nature of the "demand side" from potential users is less clear and appears more divergent. Some groups in the agriculture sector welcome the introduction of LMOs. Others are uncertain. Still others are resolutely opposed to their introduction. Recent experiences in many countries underline the extended difficulties that face any effort to put in place regulatory frameworks and develop national capacities to support biosafety in a predictable and transparent manner.[56]

Biosafety involves building capabilities in one of the most difficult areas for low-capacity states, covering the assessment and management of (potential) risks of LMOs coupled with enforcement of regulatory frameworks. Governments must frequently contend with groups and individuals who may have the logistical, political and financial power to evade state control. To complicate matters, the import and/or distribution of a few bags of unauthorized seeds can undermine the whole biosafety system in a country. There can be a large gap between biosafety capacity and the subsequent performance of the overall system.

[54] See: Gruere, G., P. Mehta-Bhatt, D. Sengupta. 2008. *Cotton and Farmer Suicides in India: Reviewing the Evidence.* Discussion Paper 00808. Washington DC: International Food Policy Research Institute.

[55] The Kenya case illustrates this general point. Drafting of biosafety guidelines started in the early 1990s; development of a comprehensive biosafety law in 2001 with UNEP-GEF support. Following a long period of review, revisions and polarized debates, a Biosafety Law was signed in February 2009. See: Karembu, M., D. Otunge and D. Wafula. 2010. *Developing a Biosafety Law: Lessons from Kenyan Experience.* Nairobi: ISAAA AfriCenter.

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SECTION III. SUGGESTED NEW DIRECTIONS

6. NEW DIRECTIONS FOR BIOSAFETY CAPACITY DEVELOPMENT

The approach to biosafety capacity development to date has been useful in generating better understanding of the special characteristics of biosafety, producing a range of practical experiences in NBF development and implementation, and identifying ways to improve project management. In particular, it has made a contribution to the increased awareness and ratification of the CPB itself. Put another way, the initial steps have made it possible to get enabling frameworks and stakeholder support in place globally. Undeniably, progress has been made on several components of the Capacity Building Action Plan, particularly in institutional development and introductory training, primarily in countries that had existing expertise in the regulation of modern biotechnology. All of this has been done with very limited resources at all levels. The comparatively small amounts of funding provided to date have been, on balance and considering the challenges, a sensible investment. The challenge now is to find a way to build on the results to date and move to a new level of capacity development outcomes.

The challenge facing Parties to the Protocol, the international donor community and other organizations is twofold: first, recognizing the effects of trade-offs on the progress of global biosafety capacity development to date; and, second, finding ways to transition to new ways to approach the biosafety capacity development challenges.

Countries, the GEF and other organizations supporting biosafety capacity development also face a major dilemma. One the one hand, they have few strategic choices in terms of approaches to capacity development. From the beginning, implementation of the Action Plan has had to balance conflicting priorities and interests with organizational and financial realities. On the other hand, the time has come to fundamentally rethink the current approach. There is a clear risk of the CPB ending up trapped in a position that is no longer tenable. The current approach can still be symbolically attractive and can be relevant on a few occasions for a few countries. However, it will have little chance of making a sustainable difference in many countries.

On the other hand, the time has come to fundamentally rethink the current approach. There is a clear risk of the CPB ending up trapped in a position that is no longer useful. The current approach can still be symbolically attractive and can be relevant on a few occasions for a few countries. However, it will have little chance of making a sustainable difference to a critical mass of countries.

The GEF-commissioned evaluation of 2006 and the UNU-IAS assessment report of 2008 touched on many of these same issues raised below but their recommendations appear to have had only limited impact in terms of change of direction. Without major changes to the current approach including some in the short term, the support for biosafety capacity development is likely lose traction and effectiveness. And the passage of time will make the choices and options more difficult.

As noted in Section 5, previous evaluations and assessments generated a rich set of recommendations and practical suggestions as to how the performance of biosafety capacity development projects can be improved. This report does not attempt to repeat those findings here. The key challenge for governments and organizations supporting the Action Plan implementation and biosafety capacity development in general, is to fully integrate such findings in the new ways of doing business. In addition, a number of priority actions stand out, as outlined below.

It should be emphasized that recommendations below are more strategic in nature than operational, partly because this review did not involve any field work to guide the analysis. The key overall conclusion is that the current capacity development approach needs fundamental rethinking and revision.

6.1 Considering the different perspectives and approaches

As mentioned earlier, a narrower approach to capacity development, i.e., providing technical inputs that can help country participants implement their own approach to the Protocol has succeeded in most middle-income and some low-income states. But it is not generating capacity gains in most low-income and virtually all fragile and post-conflict states. In those situations, additional perspectives are highly relevant. These could include the following:

i. A human behavioural approach which brings more focus on the influence of individual motivation, informality, power relations, leadership, followership, country ownership and commitment, individual and inter-organizational relationships, and the dynamics of complex personal and organizational change. This approach both helps to develop certain key capabilities, e.g. leadership and, more importantly, helps to create the conditions that allow the techno-functional approach to be effective. Almost none of the documents reviewed for this report paid much attention, for example, to the politics and power dynamics of biosafety capacity development despite their crucial importance.

ii. A perspective that looks at the broader societal dynamics which shape the way capacity emerges and survives. This aspect focuses on historical and cultural influences, elite behaviour, potential levels of conflict and violence, legitimacy with citizens, levels of social capital, state-society relationships, and so on. In many cases, these factors can either create the space for capacity development to go ahead; or they can constrain opportunities for capacity development. In the latter context, no amount of donor enthusiasm or technical and financial resources will make much difference.

iii. A final perspective in capacity development is that of the level of existing country resources that could in theory contribute to capacity development. Included in such a list would be pools of national skills, research capabilities at the university levels, state of country laboratories, access to donor funding and support, national traditions of scientific, environmental and social concerns. Countries that possess or can access such resources have a substantial advantage in capacity development for biosafety. Those that do not find it hard to make progress. This raises an obvious question for the work by organizations supporting biosafety capacity development: How should biosafety capacity development be addressed in states that have few, if any, country resources available to support it?

The challenge in any capacity-building intervention is to get some balance and synthesis amongst the different perspectives and approaches. Or, at least they should be taken into account when designing capacity development interventions. Some factors will be much more amenable to donor influence, e.g., those related to knowledge and skills transfer. Some may be completely beyond donor control or influence, e.g., most political factors. But what does seem important is for all the participants to be at least aware of the complex pattern of factors that will likely intermingle to induce, or not, the emergence of country capacity.

6.2 Rethink the trade-offs and refocus the approach

It seems clear that from the perspective of capacity development, the current overall approach to biosafety capacity development has outlived its usefulness. After more than 10 years of technical assistance and donor support, the majority of CPB Parties are still not in a position to implement the key provisions of the Protocol. There needs to be a fundamental re-think of the current approach, and adoption of more focused strategies towards biosafety capacity development. None of this will be easy given the continuing shortage of resources.

In any new approach, Parties themselves need to decide what types of biosafety capacities should be built and which ones should get priority. For example, the CPB is now widely regarded as a well-established international protocol including by non-members. The effort to build its global presence now needs less attention. As well, the strategic objective of putting a functioning global biosafety system in place, while an admirable and a continuing one, should be given less emphasis as it remains a long-term objective that will take decades to achieve.

The strategic objective that now matters the most in the short and medium term is helping to develop or strengthen the biosafety systems of individual countries and sub-regional systems where relevant. In the next phase, progress towards effective implementation of the Action Plan would also require addressing the under-funding and under-strategizing that have characterized the previous phases. Developing complex biosafety capacities is now up against difficult issues related to food security and agricultural development, trade and food aid, with associated media controversies and politicking. What is needed is an approach that is more tailored, customized and focused on the particular contexts and problems and opportunities at the country level.

The variation in country progress towards having functional NBFs illustrates the point. Countries have gradually stratified into different groups at different levels of capacity (although they were likely always in these implicit categories from the outset).

1. The countries that were going to make it on their own with only modest support, e.g. countries with existing capacity in biotechnology science and regulation; and, countries with additional reasons to implement an NBF such as those recently joining the European Union, or aspiring to join.

2. The low- to medium capacity, high support countries such as Kenya and Uganda, among others. The term ‘high support’, in this context refers to those countries having ready access to financial and technical assistance in biosafety from a variety of external and domestic sources.

3. Low capacity, low support with little or no prospect of major additional assistance beyond the GEF projects.

The most urgent need now lies with the low capacity, low support countries that for a range of reasons are making slow progress at best. In this category of countries, there is limited “capacity to build capacity”; little in the way of own financial resources; and, in most cases only modest country commitment at high political levels. The UNU-IAS study (2008) estimated this category to comprise about 100 countries mostly in Africa, Central Asia, Oceania, and the Caribbean, or a little under two thirds of all the signatories to the CPB.

6.3 Addressing the particular capacity development needs of countries at different levels

In Section 6.2 above, three categories of countries that have widely differing capacity needs and possibilities have been identified. A series of choices then arises: Should funding agencies continue to support countries on the basis of potential performance or evident need? Do they need to continue an approach of broadly scattered funding for political or any other reasons? Or should they intensify support to a range of underperforming countries within the budgetary and staff limits?

- One option is to continue spreading funds across a range of all three country categories much as is the case at the moment. However, the likely outcomes of this option would include the dissipation of financial and human resources with little increased impact on country capacities. In particular, such a strategy is likely to make the least impact on the third category of countries which need the most support.

- The second option is to provide less assistance to countries in the first two categories and make more resources available to those in the third, including access to substantial technical assistance. In this case, countries and organizations supporting the implementation of the Action Plan would be asked to prioritize and concentrate efforts to generate greater impact in selected countries.

In particular, governments and organizations providing biosafety capacity development support need to get a much better sense of the capacity development challenges facing the above three categories of countries, especially the low capacity countries. As mentioned earlier, the focus so far is mainly on a techno-functional approach to capacity development, a pattern that is typical of interventions that are highly technical in nature. But a continued emphasis on such an approach is not likely to be sufficient in the future. For example, it will not result in the creation or strengthening of effective, sustainable institutions at the country level.

What should be done specifically?

First of all, there is a need to develop a process that takes a detailed analysis of the situation at the field level in a number of representative countries within each category, and come up with capacity development strategies that fit their particular conditions. The main component of such process would involve a "self assessment" of results and impact from completed biosafety support projects. The purpose would be to get a clear comparative sense of the variety of the capacity challenges across a range of countries and how they might be addressed within the resources available. Without investment in some more detailed analysis, research and learning on capacity issues, biosafety support programs will remain guessing and hoping about their potential contribution.

Secondly, the overall approach to capacity building in countries at different levels (see the 3 categories above) of capacity should become more concentrated and prioritized, following broad guidance as below:

Category 1 countries: Different options can be considered in order to address the needs of countries at higher levels of biosafety capacity development[57] and with a track record in LMO decision making. Those countries have completed most, if not all stages of NBF development and implementation, and the necessary institutions and structures are funded by national budgets. Therefore, they may not need additional financial resources for further NBF development, but rather access to international regulatory or

[57] Such countries currently include Brazil, China, Cuba, India, Mexico, the Philippines and South Africa, among others.

legal expertise in order to deal with specific LMO introductions and associated regulatory challenges. Various mechanisms can be conceived to provide such expertise, including the Roster of Experts[58]. High-capacity countries should also be encouraged to assume a collaborative support role in regional and sub-regional biosafety capacity development initiatives, and become a venue for South-South cooperation and in-depth training.

Category 2: For low- to medium capacity countries, where substantial NBF development and implementation efforts are still required, but which already receive a high level of support from a variety of programs and organizations, an analysis should look at ways of rationalizing biosafety capacity assistance to these countries — on the assumption that support from existing sources would continue to be available. The emphasis for such countries would therefore be on donor coordination and harmonization, and formulation of a long-term capacity development strategy.

Category 3: For low capacity countries, in the short run and in the absence of domestic regulatory frameworks, attention should be given to possibilities of adopting interim measures, as noted in the GEF evaluation of 2006, instead of attempting to implement comprehensive NBFs right from the beginning. Interim measures could use the Protocol itself as a basis for LMO decision making, or existing legal instruments in the country related to, for example, phytosanitary measures. It would allow countries to comply with the main provisions of the Protocol while elaborating a longer-term strategic plan for developing biosafety capacity in a more comprehensive way.

There are two final points about the development of any action plan or strategy for biosafety capacity development at the country level that need to be considered. First, the current approach has been primarily top-down with the broad outlines decided centrally. It is suggested that a new strategy be gradually developed as needs and opportunities at the country level become clearer and more defined. This approach would be more suitable at the current stage of development.

Second, capacity development efforts need to bear in mind the prevailing resource-poor, low-capacity environments. The country needs may be huge but absorptive capacity and readiness may be lacking. That dilemma needs to be reflected in the design of any intervention.

6.4 Recommendations for improving the performance of current and planned biosafety capacity development initiatives

This review signals the need for the COP-MOP, GEF, other funding agencies and implementing organizations to be much more aware, strategic, and adaptable and focused in terms of their approaches to biosafety capacity development. To help in this transition, this report presents below some operational guidance and options for improving, and adopting a more strategic approach to, biosafety capacity development, based on an analysis of experiences and lessons learned in various previous programs. Specifically, the guidance proposes improvements to the current approaches to implement the Action Plan for Building Capacities for the Effective Implementation of the Cartagena Protocol, and the associated set of indicators.

In order to define a more focused overall strategy, based on the current review, the following actions would have priority:

[58] Available at URL: http://bch.cbd.int/database/experts/

(1) Reformulate a common strategy on biosafety capacity development

Few meetings have been organized to look strategically and comprehensively at a broad range of issues to do with capacity development, except to some extent the annual meetings under the Coordination Mechanism established by the COP-MOP, UNEP's national biosafety project coordinators' meetings, and the on-line conferences as organized by the CBD Secretariat. However, their impact on the overall approaches to biosafety capacity development is very limited.

It is recommended that a conference involving Parties to the Protocol, current and prospective donors and relevant organizations be organized to look comprehensively at a broad range of issues relating to the future strategy for capacity development and develop a shared understanding of its implications. Possible outcomes of such a conference would be an Updated Action Plan for Building Capacities for the Effective Implementation of the Biosafety Protocol; a toolkit for capacity assessment frameworks; and, guidelines on monitoring and evaluation as discussed in Recommendation 3 below.

A list of capacity development questions that could be discussed at such a workshop include the following:

- What are the strategic objectives, and key factors to address in any effort to develop biosafety capacity in countries at widely differing stages of development?
- What would a capacity development strategy for biosafety look like for the low capacity countries?
- What would a 'good enough' impact on biosafety in these conditions look like?
- What might a useful capacity assessment framework look like that could fit these differing conditions?
- What contribution can external financial and technical support be reasonably expected to make to capacity development in these countries?
- How should technical assistance be structured in the three categories?
- What could be done to encourage country ownership and commitment to biosafety issues?
- Who will pay for biosafety capacity development in the years ahead and how?
- How should biosafety be integrated with other existing, relevant environmental and agricultural legal / regulatory frameworks? And, what would be the options for adequate interim measures?
- How would monitoring and evaluation differ in the three categories?
- What would be the appropriate timing and sequencing for specific planned interventions?
- What international experience in biosafety capacity development might be helpful to the GEF and its implementing organizations?
- What could be done on a regional basis to help countries develop their capabilities? Twinning with more advanced countries? Special TA and training arrangements?
- Can partnerships with the private sector in various countries be used to good effect?

(2) Focus on the issue of mainstreaming biosafety at the national policy level

Capacity support programs and projects must emphasize mainstreaming — incorporating biosafety into overall environmental and economic development policies. From the reports reviewed, it appears that the early stages of biosafety capacity development are usually dominated by a core group of technical staff and biosafety experts both in countries themselves and internationally, unlike, for example, healthcare or education where a broader country coalition is usually dominant at the outset. One challenge biosafety capacity development faces is expanding the awareness and commitment beyond a core group of technical professionals to include a wider range of actors, e.g., budget officials, political leaders, member

of the public, the media, NGOs and others. Specifically, effective implementation of biosafety frameworks will require strong political support and the agreement of senior public sector managers in ministries such as finance, public works and personnel. It will also require the sustained allegiance of key decision makers, who will need to become more involved in the design stages of biosafety capacity support projects and their implementation.

For biosafety capacity support programs, this raises questions such as: Can biosafety be championed by country actors with real power inside the bureaucratic and political systems? Can it win development and recurrent budget support on a regular basis? As mentioned earlier, the implicit positive assumptions about these aspects of country commitment do not seem to have been validated in the early phases given the current pattern of lack of country financial support. Failure to make that transition to a wider circle of support can leave the issue of biosafety isolated in bureaucratic circles. Part of the transition that needs to be made, lies in the area of management, facilitation, mediation, community mobilization, political persuasion and others.[59] This mix of technology management and public outreach is difficult to get right in any country.[60]

(3) Develop a capacity development toolkit

A new toolkit on biosafety capacity development will be useful to government participants and other stakeholders involved in biosafety projects, based on the wealth of existing materials. Included in that toolkit could be capacity assessment frameworks and guidelines on monitoring and evaluation.

The following three general points on the design of capacity assessment frameworks should be considered[61]. First, many frameworks already exist but few are used or add much value. Most are too generic. They rely mainly on perspectives on capacity development and management that are commonly found in industrialized countries. They generate little ownership, allegiance or use from country participants. The real challenge is to help country participants, within broad guidelines, develop their own frameworks that respond to their particular needs and conditions in biosafety. In particular, frameworks are needed to assess absorptive capacity and feasibility as well as need.

Second, the same approach for the design of indicators is recommended. The COP-MOP has produced over the years a series of capacity indicators that also appear to have had little operational application. The exercise in coming up with a customized assessment framework could and should be used to help participants, again with broad guidelines, design their own indicators which could be used for managing, reporting, monitoring and evaluation.

Finally, the issue of time should be seriously considered. The pattern of results to date suggests that the time needed to develop the capabilities for biosafety have been consistently underestimated. As the focus of the work shifts to the implementation phases in low-capacity states, there is a need to lengthen the time required to create or enhance the organizations and institutions required to make progress.

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[59] See: Blauert, J. and S. Zadek (eds.). 1998. *Mediating Sustainability: Growing Policy from the Grassroots*. West Hartford: Kumarian Press.

[60] This is not an issue limited to low-income countries. For the same patterns, for example, in US education, see Ravitch, D. 2010. *The Death and Life of the Great American School System*. New York: Basic Books.

[61] These points are derived from Baser, H. and P. Morgan (2008). Capacity, Change and Performance. Study Report. Maastricht, The Netherlands: European Centre for Development Policy Management.

(4) Explore regional approaches to capacity development

Implicit in the Cartagena Protocol is the assumption that cooperation among Parties at sub-regional, regional and global levels, including cooperation on information sharing, capacity-building and awareness-raising, is crucial for ensuring the safe transfer, handling and use of LMOs across borders. Cooperation can occur on different fronts — at the level of decision making authority, risk assessment and associated guidelines, and administration. Each of these has inherent challenges related with the divergent national policy objectives and biosafety capacities found in any (sub-) regional organization. The complexity involved can be illustrated by the long-drawn debate and protracted decision making in the European Union, recently resulting in a decision allowing EU Member States to decide for themselves — rather than EU bodies — how they regulate (or, prohibit) the cultivation of GM crops in their territories.

Biosafety collaboration among countries can be instrumental to maximizing the use of institutional, financial, technical, and human resources within a region. For small and developing countries, the ability to capitalize on external expertise and information from neighbouring high-capacity countries may be an essential condition for implementing their national biosafety frameworks. Consequently, there is a strong case for increased emphasis on, and donor support to regional approaches.

Regional biosafety collaboration is already being considered, as described above, to a greater or lesser extent, in regional groupings including but not limited to ASEAN[62] (Southeast Asia), CARICOM[63] (Caribbean countries), COMESA[64] (East and Southern Africa), and WAEMU[65] (West Africa). Lessons from, and challenges encountered in such initiatives should be documented and used in designing future regional projects.

(5) Acknowledge the implementation challenges inherent in capacity development

In addressing the implementation of biosafety frameworks, it is important from the outset to address the implementation challenges. Capabilities in some sectors, e.g., currency rate management systems in a central bank, are relatively easy to develop. In those sectors, broad public understanding and support may not be required, and interventions are limited to the institution involved for the most part. Biosafety capacity development faces much harder challenges. For example, new capacities and interventions at different levels and institutions (individuals, organizations and at national policy level) must be based on advanced science from the outset. Equally important, public and political support is required concurrently in order to make progress and to create resilient capacity. Managing the transition from science to policy, public debate and politics is a major challenge.

Other implementation issues in biosafety capacity development seem daunting. Several of the reports analyzed as part of this review, as well as the NBF reports completed by participating countries, list a myriad of organizations which had to collaborate and coordinate to implement the biosafety support programs and resulting frameworks.[66] This involves creating new institutions and routines not just fine-

[62] Association of South East Asian Nations

[63] Caribbean Community

[64] Common Market for East and Southern Africa

[65] West African Economic and Monetary Union

[66] The case studies in the annexes of the UNU-IAS (2008) report list the type of organizations in each country that have to collaborate.

tuning old ones.[67] Collaboration at the national level has involved an unusual combination of actors such as customs, environmental ministries, universities and the like. The technical capabilities in areas such as risk assessment are difficult to put in place for any state let alone one with a low-capacity base. New laws and regulations also have to be put in place. And all of this must be done in mainly public sector organizations which gives rise to another usual set of constraints, including lack of recurrent financing, extended bureaucratic delays, lack of inter-ministerial coordination, poor salaries and staff incentives, politicization, high staff turnover, lack of equipment and other professional support, competition from other priorities.[68] The logical conclusion is that many countries have somehow gotten through the easy introductory stages only to hit the capacity wall when they had to address the challenges of implementation and sustainability.

The potential of governments to generate the necessary commitment and motivation to support biosafety has not been obvious given the competing demands especially in small and poor states. National co-financing of biosafety capacity development has been, and is always going to be an issue. A logical stance would be for governments to do the minimum to keep up international appearances but not large enough to make a real difference. A likely outcome of that effort has been the creation of "shell structures" in biosafety that only appear to function but that, in reality, can deliver little. From this review, and (lack of) information submitted to the Biosafety Clearing-House, a growing number of such structures are beginning to appear across a range of countries.

(6) Adopt customized and strategic approaches to biosafety training

At the core of biosafety management is the need for highly skilled people that many countries do not have in large numbers, particularly countries whose university systems are weak or whose private sector firms do little in biosafety. A sustained effort would have to be made to develop these technical skills, all of which would command a high price internationally.[69] Brain drain to the private sector or international organizations that offer higher wages and benefits is a major capacity development challenge in many countries. It affects the level of sustainability of training and technical assistance in biosafety. For some countries, scientists in the diaspora might be an alternative source of expertise, although this would come with its own set of issues. For many low-income countries, biosafety skills would also largely be new unlike those, for example, in animal husbandry or civil engineering.

Parties to the Protocol, donor organizations and national, regional and international implementing agencies need to continue to invest in training initiatives as a major component of capacity development. And the need for introductory, awareness-raising type of training will continue to exist in order to broaden the critical mass of trained personnel and to deal with inevitable staff turnover and attrition. However, as indicated in several reports, there is a strong need for longer term training and in-depth technical skills development for various NBF components. The GEF evaluation and the UNU-IAS report made a

[67] Another relevant case study illustrating the implementation issues, and time required to establish and maintain a national biosafety framework can be found in Manalo, A.J. and G.P. Ramon. 2008. *Considerations in Setting up a Regulatory System for Biotech Crops: the Philippine Experience*. Unpublished report. Manila: Biotechnology Coalition of the Philippines. For example, the study records 47 government issuances on biosafety, the first one dating back to 1987 establishing the National Biosafety Committee of the Philippines.

[68] See Grindle, M. (ed.). 1997. *Getting Good Government: Capacity Building in the Public Sectors of Developing Countries*. Cambridge, MA: Harvard University Press.

[69] See, for example, D. Lipincott. 1997. "Saturation Training: Bolstering Capacity in the Indonesian Ministry of Finance", in Grindle, 1997.

convincing case for a wider range of training options and much less emphasis on the one-off, general short-term workshops.

Emphasis must be seriously placed on customized and tailored solutions addressing particular needs and challenges in different countries. First of all, training plans should be directly linked with a country's strategic objectives, or government strategy for biosafety, and contribute directly to clearly defined results (for example, developing and/or applying a country's risk assessment guidelines; or, assessing a specific planned LMO introduction). Secondly, GEF and implementing agencies and the CBD Secretariat could work towards a rational division of labour with current internationally accepted providers of biosafety training at the introductory and advanced levels. These would need to be carefully selected from the "academically accredited" biosafety courses recorded in the BCH, while focusing on supporting strategic long-term, hands-on skills development of key individuals responsible for biosafety decision-making.

(7) Strengthen capacity support at the implementing agencies

Organizations implementing biosafety programs and projects are often very thin on technical expertise and are not in a position to provide much technical backstopping and quality control for biosafety projects. In facilitating implementation of the Action Plan, biosafety implementing agencies and other organizations need to address the issue of their own capabilities to adequately support the work at hand. Most agencies simply assume that the demands of capacity development work can be integrated easily into their existing structures. But most then quickly face a series of issues:

- Some basic critical mass of technical support at the field level is essential. Ways need to be found to provide this on a continuous basis particularly to low capacity countries.

- The demands of capacity development require donor agencies to rethink some of their planning, financial management and project operations. Procedures that allow little flexibility, adaptation and experimentation can stunt the space and room to manoeuvre that country participants' need to help make capacity development effective. Efforts also have to be made speed up implementation to avoid continual delays that drain energy and ownership out of situations.

- Capacity development needs a large amount of institutional learning, adaptiveness and experimentation. Efforts will need to be made to create a better match between the current decision-making and consensus-seeking system and the pace of change at the field level.

- The various GEF biosafety implementing agencies and the CBD Secretariat need ready access to independent experts that can give them specific biosafety capacity technical support. A broader critical mass should be developed, for instance as a cross-agency biosafety team working for multiple implementing agencies rather than each agency building up its own limited expertise. In addition, the necessary expertise could be more systematically tapped from other established biosafety capacity development programs, and/or through the revamped Roster of Experts on the BCH.

- Existing innovative methodologies to project design and implementation should be considered and tested. For example, the technique known as Rapid Results Approach[70] which focuses on jumpstarting organizational change projects and improving implementation capacity in a short

[70] For further details on RRA, see URL: http://www.rapidresults.org/index.php

period of time could be useful in building ownership, commitment and rapid results in biosafety projects.

(8) Develop monitoring and evaluation (M&E) systems

Currently, the system of monitoring and evaluating progress and performance of biosafety capacity-development appears underdeveloped. Beyond the UNEP- and GEF-commissioned evaluations, independent evaluations at the individual country or project level are not a common feature. There is a clear need to invest in developing M&E systems as an integral part of implementing the Action Plan. This should go beyond the current set of indicators, which so far have hardly been applied partly due to the absence of clear M&E plans and guidelines. Techniques associated with "development evaluation"[71] would fit the biosafety projects well. More effort also needs to be made to make any evaluations utilization-focused, in an effort to have the results feed into programme direction and execution.

(9) Encourage results-based management (RBM)

Results-based management (RBM) is an important common feature in most organizations that support capacity development. The GEF, implementing countries and organizations supporting biosafety capacity development need to think through the various challenges to making RBM work effectively for biosafety projects. As the GEF's own RBM system and associated impact indicators are quite generic and applicable to a wide range of environmental programs and projects, ways and means of gauging progress on biosafety capacity development are obviously needed. For example, impact pathway analysis would greatly strengthen project design and implementation. In addition, attention should be given to the following:

- Effective RBM schemes need to be based on a shared understanding of how and when and why capacity is likely to emerge in a variety of circumstances in different countries. At the moment, there is no such shared understanding.

- RBM schemes need to at least try to capture some of the intangible aspects of capacity. Reliance, for example, on the techno-functional aspects only gives the project stakeholders a narrow misleading picture.

- Many RBM schemes are not given the time to develop a pattern of outcomes by the time donor support comes to en end. More effort needs to be made to get the short versus medium versus long term balance right.

- Country participants need to have a major role in designing indicators and timelines. Without such involvement, RBM schemes turn into the costs of doing business with external donors. As part of an emerging common strategy to biosafety capacity development (see point (1) above), country representatives must take the lead in developing a revised Set of Indicators for Monitoring Implementation of the Action Plan for Building Capacities for the Effective Implementation of the Protocol.

- RBM schemes need to be relatively simple and easy to use for country participants who have only modest incentives and time to keep them going.

[71] For a comprehensive sourcebook on development evaluation, see Morra Imas, L.G. and R. Rist. 2009. The Road to Results: Designing and Conducting Effective Development Evaluations. Washington D.C.: The World Bank. See also URL: www.worldbank.org/r2r

(10) Improve donor coordination on biosafety

There is a need for a stronger Coordination Mechanism that actively fosters improved coordination and actual collaboration among donors and implementing organizations, particularly in countries with multiple biosafety programs, in order to achieve the objectives of the Action Plan. In the case of biosafety, while often the same fundamental objectives are pursued, the different policies and agendas of various donors can give rise to competing approaches to capacity development which can overwhelm countries with limited institutional capacities. Lessons could be learned from the implementation of the OECD-DAC Paris Declaration and related Accra Agenda for Action[72], which stress the need for both country ownership and donor harmonization.

7. SUMMARY

The essential message of this report is the following: There is a need for serious efforts to make the process of biosafety capacity development more effective on a country-by-country basis. The capacity development support projects to date have made a significant contribution particularly in states that are able to use such assistance effectively as a supplement to their own efforts. However, those countries starting from a low-capacity base have, not surprisingly, found it difficult to move beyond the draft NBFs and build effective capacity for implementation and service delivery in biosafety. Without durable, long-term technical and financial support in these states, the overall progress on implementing the CPB will remain slow at best.

In order to allow for the type of biosafety support required to countries most in need, considering current and future funding limitations, the current comprehensive and inclusive approach to biosafety capacity development will have to be amended. Therefore, this report has offered, as a first step, a number of recommendations for a strategic re-thinking of the current approach to biosafety capacity development. However, further work is needed especially by participating countries to fill in the operational details, based on experiences and lessons learned to date, that would allow the implementation of the agreed way forward. In particular, more effort is needed to strategically manage the process of biosafety capacity development.

[72] For further details, see URL: http://www.oecd.org/document/18/0,3343,en_2649_3236398_35401554_1_1_1_1,00.html

ANNEX 1. TERMS OF REFERENCE

EXPERT REVIEW TO ASSESS THE EFFECTIVENESS OF VARIOUS APPROACHES TO BIOSAFETY CAPACITY-BUILDING ACTIVITIES FUNDED BY THE GLOBAL ENIVIRONMENT FACILITY (GEF) AND OTHER AGENCIES AND IDENTIFY THE BEST PRACTICES AND LESSONS LEARNED

Terms of Reference

Purpose

In its decision BS-IV/3, paragraph 6, the Conference of the Parties serving as the meeting of the Parties to the Protocol (COP-MOP) welcomed the offer of the United Nations Environment Programme (UNEP) to undertake an expert review of biosafety capacity-building activities under GEF funding, in collaboration with Global Environment Facility (GEF), its implementing agencies and the Executive Secretary, with a view to assessing the effectiveness of various approaches to capacity-building and developing lessons learned and invited Parties, other Governments, donors and relevant organization to provide additional support to extend the review to non-GEF activities and submit the review to the Biosafety Clearing-House (BCH).

The purpose of the current expert review is to carry out a comparative analysis of the biosafety capacity-building projects funded by the GEF and other agencies with a view to assessing the relative effectiveness of various approaches, tools and mechanisms adopted within the context of facilitating the implementation of the Cartagena Protocol on Biosafety and document the emerging experiences, good practices and general lessons learned.

The COP-MOP in 2008 called for this study to assess the effectiveness of the different approaches adopted by various biosafety capacity-building initiatives and to compile the lessons learned. The outcomes of the study are intended to assist Parties to the Protocol as well as the GEF and other agencies providing support to developing countries to improve the planning and implementation of their initiatives.

The results of the study will also guide the discussions and decisions of the COP-MOP regarding capacity-building, including revision of the global capacity-building action plan and improve the guidance to the GEF. The study's report is intended for submission and consideration as an information document at the next COP-MOP, to be held October 11 – 15, 2010, in Nagoya, Japan.

Over the last ten years, a wide range of biosafety capacity-building projects and other initiatives have been implemented in developing countries and countries with economies in transition. These initiatives have adopted an array of approaches, tools and mechanisms. Some of the approaches adopted include: training and education (including through conferences, seminars and workshops, training of trainers programmes, short non-academic courses, long-term academic courses), learning by doing (e.g. through staff exchanges / attachments, internships and other mentoring programmes), fellowship and scholarship programmes, partnership initiatives (e.g. twinning programmes), Internet-enabled distance learning, dissemination / exchange of information, development of toolkits and other resource materials, Internet-based information databases, web-based networking and discussion forums, partnership development and other approaches and mechanisms. These approaches have had varying levels of effectiveness and impact, under different conditions.

Tasks

Specifically, the expert review will involve the following tasks, organized in three stages:

Stage 1, Desk study: February 1, 2010 – March 31, 2010

1. Carryout a desk review of relevant background documents, existing evaluation reports and case studies of biosafety projects and activities funded by the GEF and other donor agencies to identify the different approaches (and the associated tools, methodologies, mechanisms and strategies) that have been adopted.

2. Assess the relevance and effectiveness of the different capacity-building approaches adopted by donor agencies and implementing organizations, and the factors that have influenced their success or failure.

Stage 2, Analysis: April 1 – 30, 2010

3. Document the emerging experiences, good practices and general lessons learned that might help Parties and the GEF and other donor agencies to improve the design and implementation of biosafety capacity-building interventions.

4. Identify the main challenges encountered in the design and implementation of biosafety capacity-building projects and analyse how those challenges may have affected the effectiveness of different approaches to capacity-building.

Stage 3, Formulation of recommendations: May 1 – 31, 2010

5. Review and propose revisions to the current "Set of Indicators for Monitoring Implementation of the Action Plan for Building Capacities for the Effective Implementation of the Protocol", as endorsed at COP-MOP4, which aims to track and assess, over time, the effectiveness and impact of biosafety capacity-building projects and activities at the global level.

6. Propose options for improving the overall effectiveness and impact of biosafety capacity-building projects and activities funded by the GEF and other donor agencies.

7. Based on the findings of the review, identify elements that may be considered in the development of the capacity-building component of the strategic plan for the Cartagena Protocol on Biosafety and the review of the Action Plan for the Capacity-Building for the Effective Implementation of the Protocol.

Deliverables

1) February 15, 2010: An inception report setting out the framework for the study, including the methodology and approach to be used and the specific questions to be analysed.

2) April 1, 2010: A first draft report based on the desk study conducted in stage 1.

3) June 7, 2010: A comprehensive assessment report, with an executive summary, analyzing the various approaches to capacity-building for the implementation of the Cartagena Protocol on Biosafety and the experiences, good practices and lessons learned.

ANNEX 2. SELECTED EXAMPLES OF BIOSAFETY CAPACITY DEVELOPMENT PROGRAMMES

Apart from UNEP, UNDP, and the World Bank, who manage implementation of GEF supported projects as presented in section 4 of the main report, other UN agencies and bilateral donor agencies support biosafety capacity building. Examples are summarized in this Annex. The projects and programs were selected to illustrate the thematic and geographic spread of ongoing biosafety capacity development support programmes, not to provide an exhaustive overview.

1. Other UN agencies and international organizations

Apart from UNEP, UNDP, and the World Bank, who manage implementation of GEF supported projects as presented in section 4 of the main report, other UN agencies support biosafety capacity building. Examples are summarized in this Annex.

The UN Food and Agriculture Organization (FAO) recently issued a review of its projects in agricultural biotechnology and biosafety[73]. Since 2002, FAO implemented 26 projects at the country and sub-regional level, with total funding of around US$ 7.5 million. Projects were undertaken at the following levels:

1. Country level: Fifteen projects had a national focus, and include the development and implementation of regulations, training regulatory personnel, infrastructure development and public awareness. They were carried out in sub-Saharah Africa (5), Asia (3), Eastern Europe (1) and Latin America and the Caribbean (6).

2. Sub-regional: Four projects were carried out assisting multiple country in establishing biosafety networks, delivering topical training, and organizing consultations on sub-regional harmonization of rules and regulations. Sub-regional projects were completed in Asia (involving 10 countries), Central Europe (3 countries), Latin America (6 countries) and the Middle East (6 countries).

3. Global: Two global FAO projects involve training activities targeting specific technical capacities in (i) GMO detection and monitoring; and (ii) GM food safety assessment.

The UN Industrial Development Organization (UNIDO), which has a long track record in biosafety, currently focuses on offering academic, MSc degree biosafety training through a combination of distance learning and on-campus sessions. The course contents focuses on risk assessment / risk management, legal and policy aspects. The course goal is to ensure that trainees from different backgrounds such as life sciences, social sciences, law or economics acquire the skills necessary in terms of basic biotechnological knowledge, regulatory concepts and risk assessment procedures. The programme is currently given in cooperation with the following universities:

- Marche Polytechnic University, Ancona, Italy
- Pontifical Catholic University of Minas Gerais, Belo Horizonte, Brazil
- Ghent University, Ghent, Belgium

[73] Sensi, A., K. Ghosh, M.T. Takeuchi and A. Sonnino. 2009. Building Biosafety Capacities: FAO's Experience and Outlook. An overview of the experience gained from FAO capacity building projects in agricultural biotechnology and biosafety. Rome: Food and Agriculture Organization of the United Nations.

The International Center for Genetic Engineering and Biotechnology (ICGEB), an autonomous intergovernmental organization, established a Biosafety Unit in 1997, which since then runs an expanding programme for biosafety information dissemination and technical training. Specific activities include:

1. Information dissemination: ICGEB maintains an on-line, searchable Biosafety Bibliographic Database, which is linked the CBD's Biosafety Clearinghouse. The database contains almost 8,000 records (full reference and abstract) of scientific articles published in international peer-reviewed journals since 1990. Another service provided is the Risk Assessment Searching Mechanism, consisting of an online collection of risk assessment documents related to official government decisions regarding the general release of GMOs worldwide.

2. Technical training: Since the early 1990s ICGEB runs an active training programme consisting of regular annual courses in its host country (Italy) and courses in member countries with a regional focus. These courses have evolved from a general introduction to principles of biosafety to a range of specialized courses on topics such as risk assessment / risk management, LMO detection, etc.

In 2008, ICGEB received a US$ 3 million grant from the Bill & Melinda Gates Foundation supporting technical training and biosafety fellowships in sub-Sahara Africa. The grant also encourages participation in regional and international conferences. As part of this program, ICGEB currently supports 5 MSc level fellowships in GM crop risk assessment, with training provided at the University of Aberystwyth, UK.

2. Special programs supported by bilateral donor agencies and foundations[74]

A range of special, donor-agency supported programs complement the GEF and international programs introduced above. They cover a wide spectrum of objectives, services and activities, as outlined below.

The Program for Biosafety Systems (PBS), supported by the US Agency for International Development, works with partner countries in Africa (Nigeria, Kenya, Uganda, Malawi, Mozambique) and Asia (the Philippines, Indonesia, Vietnam) to develop and implement a programme of activities tailored to biosafety needs identified by local collaborators. In addition, PBS works with regional policy-making bodies such as COMESA[75] on subjects of common interest, such as LMO commodity trade and the development of regional technical guidelines. The scope of PBS activities includes the following:

- Policy and regulatory development: The PBS policy component analyzes the implications of different country and regional regulatory approaches for genetically modified organisms. Choices regarding biosafety policies and objectives are evaluated for their implications for agricultural growth, trade, and food security. Legal expert advice is provided to countries drafting legal instruments and implementing regulations.
- Grants for scientific research on environmental risk issues: The focus of the Biotechnology-Biodiversity Interface (BBI) grant program, managed by PBS, is on the need to better understand the interaction between genetically engineered crops, agriculture, and the environment. Through BBI, 11 competitive grants aimed at addressing the effects of agricultural biotechnology, particularly genetically engineered crops, on natural biodiversity as it occurs in developing countries.

[74] Information for this section largely derived from the CBD Biosafety Clearing-House, and programme updates submitted to the CBD Secretariat

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

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

Another USAID-supported program, the South Asia Biosafety Programme **(**SABP) assists the governments of Bangladesh and India in further strengthening institutional governance of biotechnology. The programme builds on existing efforts to advise governments on enhancing and streamlining government systems to realize the benefits of agricultural biotechnology within a transparent, efficient and responsive regulatory framework that ensures the safety of new foods and animal feeds, and protects the environment. SABP works with its in-country partners to:

- Identify and respond to technical training needs for food, feed and environmental safety assessment.
- Develop a sustainable network of trained, authoritative local experts to communicate both the benefits and the concerns associated with new agricultural biotechnologies to farmers and other stakeholder groups.
- Facilitate systems for permitting the safe conduct of experimental field trials of new crops developed using biotechnology so that scientists and farmers can evaluate them.
- Raise the profile of biotechnology and biosafety on the policy agenda within Bangladesh and India and to address the policy issues within the overall context of economic and agricultural development, international trade and environmental sustainability.

Activities to date have focused on regulatory development (guidelines and detailed operating procedures) and associated training in the area of field trial compliance management; food safety assessments; and, socioeconomic analysis and assessment of trade impacts.

BioSafeTrain, funded by the Danish International Development Assistance, is a collaborative initiative between the Danish Royal Veterinary and Agricultural University and the following four East African institutions: Makerere University, University of Dar es Salaam, University of Nairobi and the Kenya Agricultural Research Institute. It was launched in December 2004 and involves masters- and doctoral-level training in agricultural and environmental impacts of genetically modified (GM) plants. Some of the program's collaborative activities include:

- Joint supervision of students at the local universities and research institutes by both Danish and local professors and experts
- Upgrading of existing biotechnology and biosafety research infrastructure/facilities
- Undertaking of research on biosafety of GM crops, including the testing and revision of suggested standard procedures for GM plant biosafety.

The African Union's Biosafety Project's broad goal is to contribute to capacity building for an Africa-wide biosafety system. The project is implemented by the AU and German Technical Cooperation (GTZ), funded by the German Federal Ministry for Economic Cooperation and Development (BMZ). The target is to provide the AU Commission with the requisite competence and technical tools to assist its Member States in implementing the Cartagena Protocol and using the African Model Law on Biosafety. The project also aims to integrate the topic biosafety into the political and institutional frameworks of the AU and into its support services for the Member States. The substantive activities of the Project have started in January 2006 and are planned to end in 2010. Activities included, among others:

- Developing a regional strategy for biosafety

- Review and revision of the African Model Law on Biosafety
- Organizing subregional workshops discussing integration and harmonization around biosafety issues
- Supporting AU member countries in preparing for COP-MOP and associated meetings.

The Norwegian Center for Biosafety, Genøk, implements since 2003 a biosafety capacity building programme funded by the Norwegian Agency for Development Cooperation (NORAD). Under this program, bilateral projects are conducted with the following countries:

- Zambia: Support has been extended to the responsible Ministry for the development of a legal framework and the administrative set-up to handle GMO issues; and, to develop laboratory capacity to detect GMOs. The project was finalized in 2009.
- South Africa: An Environmental Biosafety Cooperation Project has been established between South Africa and Norway. One aspect of this involves biosafety research between the GMO Testing Facility (University of the Free State, South Africa), researchers from the University of the North West and Fort Hare, South Africa and Genøk. The aim of the biosafety project is to improve capacity to conduct research, monitoring and assessments on the environmental impacts of GMOs used in agriculture as well as improved biosafety management and research through focusing on post release monitoring research of GM maize in terms of gene flow, impacts on target and non target insects as well as the microbial soil rhizosphere.

In addition to bilateral collaboration and support, Genøk runs an active biosafety training programme that includes:

- An annual course (since 2003) "Holistic Foundations for Assessment and Regulation of Genetic Engineering and Genetically Modified Organisms"
- Regional biosafety courses: Asia in 2006 (conducted in Indonesia); Latin America in 2007 (conducted in Peru); Southern Africa 2009 (conducted in South Africa)
- An MSc level academic programme is under development.

The African Biosafety Network of Expertise (ABNE) was established in Ouagadougou, Burkina Faso, in 2009 by NEPAD's Office of Science and Technology with financial support from the Bill and Melinda Gates Foundation. As a 5-year, US$ 10 million program, ABNE aims at addressing the problem of a lack of expertise and experience, as well as limited networking among the available expertise and institutions in Africa on biosafety. ABNE focuses on providing technical assistance, biosafety related tools and resources to members of the National Biosafety Committees (NBC), the Institutional Biosafety Committees (IBC) and staff of the plant quarantine agencies (PQs) so that they are better able to make their own science-based regulatory decisions towards implementing national biosafety regulatory frameworks. Initial activities in target countries primarily involved workshops dealing with the management of field trials for GM crops, and assessing their general, commercial release in the near future.

The Forum for Agricultural Research in Africa (FARA) and the Syngenta Foundation for Sustainable Agriculture (SFSA) recently launched a programme "Strengthening capacity for safe biotechnology management in Sub-Saharan Africa" (SABIMA). This is a 3 - year project (2009 - 2011), with a total budget of around US$ 1.3 million, involving six countries in Sub - Saharan Africa: Burkina Faso, Ghana, Nigeria, Kenya, Uganda and Malawi. Training so far targeted public plant breeding institutes, where participants were exposed to the "Excellence through Stewardship" (ETS) program, which is an industry coordinated initiative to promote global adoption of stewardship programs and quality management systems for the full life cycle of GM products.