A Framework for Biosafety Implementation:
Report of a Meeting

organized by

ISNAR Biotechnology Service

July 2001, Washington, DC, USA

Edited by

M.A Mclean, R.J. Frederick, P.L. Traynor, J.I. Cohen, and J. Komen

February 2003

Citation

Mclean, M.A., R.J. Frederick, P.L. Traynor, J.I. Cohen, and J. Komen. (Eds.) 2003. A Framework for Biosafety Implementation: Report of a Meeting. The Hague, The Netherlands: International Service for National Agricultural Research.

Contents

Summary

Products arising from modern biotechnology provide new opportunities to achieve sustainable productivity gains in agriculture. At the same time, concern over possible environmental and health implications has stimulated regulatory mechanisms for food safety and environmental risk assessment. The need to build national systems for risk assessment and national biosafety frameworks is one of the priorities emerging from the Convention on Biological Diversity. The strive to apply biotechnology safely has led countries to agree on measures to ensure the safe handling and use of living modified organisms (LMOs). Measures designed to prevent adverse effects of LMOs on human health and biodiversity are laid out in a supplementary agreement to the Convention on Biological Diversity. This agreement, known as the Cartagena Protocol on Biosafety, includes articles stating that parties should cooperate in developing and strengthening human resources and institutional capacity in biosafety.

Over the past two decades, national biosafety frameworks, guidelines, and regulatory systems have often been implemented on a piecemeal basis in response to the demands or urgent needs of the moment. Ideally however a biosafety system should be developed from a comprehensive plan. Building such a system and making it operational is complex. There is no single best approach, or standard, due to national environmental, cultural, political, financial, and scientific heterogeneity.

Given these challenges and difficulties inherent in building regulatory systems and the needed operating capacities, the International Service for National Agricultural Research (ISNAR) convened an international expert consultation in July 2001 titled "A Framework for Biosafety Implementation: A Tool for Building Capacity." The purpose of the meeting was to develop a conceptual framework to address the regulatory implementation and capacity-building needs of developing countries and parties to the Cartagena Protocol. From the meeting, a framework for implementing national biosafety systems emerged. The framework covers five elements:

- setting national policies, strategies, and research agendas regarding biosafety
- conducting national inventories and evaluations
- building knowledge, skills, and capacities to design and implement a biosafety system
- developing regulations
- implementing regulations

The framework clarifies the critical decision points in the development of a national biosafety system. It examines choices among policy options and delineates some of the scientific and social dimensions of these options. The framework is meant to complement ongoing regional and global projects that are currently facilitating the development of national biosafety guidelines and frameworks.

The present report provides an overview of the main building blocks used to develop a conceptual framework for biosafety implementation.[1] It includes (1) plenary papers summarizing lessons and experiences from national, regional, and global efforts to build biosafety capacity (sections 2 through 7); (2) a "strawman" framework for implementing biosafety that was extensively reviewed and modified during the consultation (section 8); (3) the collective wisdom of participants in the consultation who contributed to the development of the conceptual framework, as summarized in the working-group synopses (section 9).

[1] A detailed description of the conceptual framework can be found in McLean, M.A., R.J. Frederick, P.L. Traynor, J.I. Cohen and J. Komen. 2002. A Conceptual Framework for Implementing Biosafety: Linking Policy, Capacity, and Regulation. ISNAR Briefing Paper No. 47. The Hague: International Service for National Agricultural Research.

1. Welcome and Introduction: Consultation Objectives

Joel I. Cohen
ISNAR, The Hague, The Netherlands

1.1 Introduction

It is a pleasure to welcome you to the expert consultation "A Framework for Biosafety Implementation: A Tool for Building Capacity." Building biosafety capacity is a topic important to all of us, especially as regards work for and with developing countries. In preparing for this meeting, we took into account the many commitments facing each of you. We hope that you will find this meeting valuable, that it adds new dimensions to other meetings you have attended. We hope to achieve this by providing a consultative process and view as to how national regulatory systems and policies are designed and implemented. The ultimate goal of the meeting is to help ISNAR define its future research and training program on biosafety capacity building.

The consultation is therefore structured to give ample opportunity to question and consider how biosafety systems are implemented, particularly taking into account four elements: relevant national policies, assessment of a country's unique conditions and capacity, the development and implementation of regulations, and building of relevant national scientific capacity.

What questions might illustrate the issues confronting us? Many questions come to mind that reflect the focus of this consultation:

- What are the key decision points in developing the essential components of a national biosafety system?
- How can we best advise and support countries with scientific and regulatory capacities as diverse as, for example, Mali and China? Some answers to this question have led to renewed efforts at regional scientific collaboration.
- How do regional collaborative efforts relate to the goals and objectives of national regulatory systems?
- Is there a clear relation between policy guidance and directives and the development and implementation of guidelines?
- What are the costing and funding implications of these systems?
- How do the independent activities of capacity-building providers relate to the policies and decisions necessary for implementing a biosafety system?
- What guidance and understanding is provided for capacity building by the Convention on Biological Diversity, the UNEP, and the Global Environment Facility (GEF)?

These questions will come up for further consideration in the working groups.

1.2 Relevance

We trust that our discussions this week will address these as well as other issues that you will bring to our attention and in so doing, the meeting will achieve a high degree of relevance. From our perspective this relevance is drawn from a number of considerations:

- Biosafety regulation is key to biotechnology product development and public perception.
- Biotechnology research is increasing in diversity and products are planted over wide areas, including in countries with currently no or weak biosafety systems.
- Many countries have committed to, or will be undertaking, efforts to build biosafety capacity, some in relation to the Cartagena Protocol on Biosafety.

- Numerous international agencies are committed to supporting capacity building, but often in fragmented efforts.
- Finally, findings from our country studies in Egypt and Argentina, while providing information on the functioning of national systems, would benefit from a comprehensive reference point to guide the implementation and improvement of national systems.

1.3 Specific Objectives

This brings us to the objectives for the three days ahead:

- build a conceptual framework for biosafety implementation
- identify key decision points, policy options, and their subsequent effects
- assess participatory processes, resource needs, and researchable topics

These objectives, as well as the title of the consultation, have evolved from those originally shared with you. We have added a more explicit focus on research, since we feel this is of critical importance to address many of the policy options and implementation decisions that will arise from the framework.

We who are involved in this work—donors, capacity-building providers, and clients—have gained insight into the diverse strategies that have been adopted to meet the biosafety challenge. We have looked at the relative merits and limitations of various approaches, the scope of planning for these efforts, and how policies at the national, ministerial, and institutional levels shape the structure and operation of national biosafety systems. This consultation aims to capitalize on that combined knowledge.

1.4 Participants, Methodology, and Format of the Consultation

To address the objectives of this consultation and build a framework for biosafety implementation, we have invited a variety of participants:

- providers of capacity-building opportunities and donor organizations supporting such programs
- national specialists and client country representatives from eight countries
- those with specialized expertise in regulation and biosafety review
- leaders of regional and international efforts in regulation and biosafety review
- agricultural economists

The format of the meeting is meant to be informal, to stimulate our best conceptual thinking. Following the kick-off presentations this morning, we will spend much of our time tomorrow in working groups building the framework. On the final day, we will evaluate and consider what we have developed from various perspectives.

1.5 A Conceptual Framework for Biosafety Implementation

To provide a meaningful starting point for our work tomorrow, this afternoon Bob Frederick will introduce a basic conceptual framework for our consideration. Why is this conceptual framework important?

- It is a first step in our systematic analysis of key decision points and policy options related to biosafety, capacity building, and requirements that arise from the Cartagena Protocol.
- It reveals key research topics that could serve as an input for making the complex decisions needed and shows some management implications of implementing biosafety systems.

- It provides a reference point for costing studies, research, and subsequent capacity-building and training opportunities.

It is our hope that the final conceptual framework that we are now setting out to formulate will clarify critical points in biosafety implementation, where a choice among policy options could have significant consequences for the ultimate performance and efficacy of a system. The framework should enable *client countries* to gain a better understanding of the issues and options they face. It should give *capacity-building providers* a tool to help them formulate and deliver assistance; and it should enable *donors* to better focus their programs for maximum impact.

I am very pleased that such a distinguished group of participants accepted our invitation to this workshop. I hope that the framework coming from our collective thinking will find broad utility, and I look forward to working with each of you on its development.

In closing, I want to express my appreciation to Pat Traynor, Bob Frederick, and John Komen for their substantial input on the structure of this consultation. I also appreciate the collaboration and discussions with Peter Hazell and other colleagues at the International Food Policy Research Institute (IFPRI).

2. Beyond Cartagena: Collaboration in Biosafety Implementation

Patricia L. Traynor
Virginia Tech, Blacksburg, VA, USA

2.1 Introduction

Implementation of the Cartagena Protocol on Biosafety (CPB) requires the collaboration of three broad groups: *client countries* tasked with formulating a realistic plan for biosafety implementation; *providers* of expertise and assistance, who apply the instruments of capacity building in biosafety implementation; and *donors* seeking to support needed and effective development programs.

2.2 Client Countries

Client countries seek to access the benefits that living modified organisms (LMOs) may confer, while confining risk to an acceptable level. Most client countries will require assistance to fulfill their responsibilities under the CPB, in particular, to develop and implement a biosafety system that meets national objectives. This can be achieved only by countries that are able to formulate a realistic plan for biosafety execution.

To implement a national biosafety system, client countries must identify the goals and objectives for the system, their impetus for taking action, and the existing national context for biotechnology and biosafety oversight. An effective system requires personnel who are adequately trained in risk assessment and who have expertise in appropriate disciplines. Its operations must be open and transparent. It must employ procedures that are clear and consistent, set appropriate data requirements, and where necessary, impose sound and reasonable procedures for managing identified risks. Regulatory decisions pertaining to LMOs must be consistent and defensible. Not least, costs for implementation and compliance cannot be prohibitively expensive.

During both the development and implementation of a national biosafety system, client countries must determine to what extent, and by what mechanisms, input from the public and private sector will be sought. Not all countries will make the same determination. Similarly, each country must decide whether to assess both risks and benefits afforded by an LMO, or risks alone. Each must decide if the economic impact(s) of technology adoption should inform a regulatory decision and if social factors, such as equity in access to technology, should be evaluated.

Other factors that may influence the operations of a national biosafety system include the normal level of public involvement in government affairs; public attitudes towards government agencies, especially the level of public trust in government institutions; and the country's prior experience with technology adoption.

National biosafety systems will need to be proactive, since LMOs with new combinations of "crop + trait + environment" are expected in the near- to mid-term. Regulatory authorities will do well to anticipate the expertise needed for upcoming biosafety reviews and the local data needed to support environmental risk assessments.

2.3 Providers

Providers seek to deliver assistance tailored to national or regional needs. They want to provide training programs of the right sort, delivered at the right time and for their programs to lead to the client country's self-sustainability/self-sufficiency.

Providers may offer policy advice based on an assessment of the extent to which existing national laws fulfill CPB requirements. The US Agency for International Development (USAID) and the

UNDP, for example, have conducted such needs identification studies. Providers may also give assistance in drafting new laws or regulations; with such programs currently being undertaken by the UNEP/Global Environment Facility (GEF) and the International Service for the Acquisition of Agri-biotech Applications (ISAAA).

Assistance programs may be directed at building the capacity of regulatory institutions. This may include strengthening the administrative capacity of the designated competent authority, the infrastructure for laboratory analyses and monitoring, the communications network and access to information, and the capacity to evaluate information. Basic and advanced training programs may be provided for decision makers, local experts, and in-country trainers to increase their competence and confidence in dealing with LMOs. Capacity-building programs have also been developed to build skills in technical risk assessment and risk management, in monitoring, and in communication skills.

Providers may further contribute by assessing public attitudes and opinions about LMOs. They may assist in planning communication programs to educate stakeholders, including the public, about how LMOs are regulated (i.e., how they are evaluated for safety). To this end, they may help identify target audiences and develop key messages, analyze media preferences, identify trusted sources of information, and train public spokespersons. Other types of assistance may help client countries explore mechanisms for public input, evaluate R&D priority setting, and provide guidance on decision making.

2.3 Donors

Many of the donor agencies active in agriculture, food security, and resource conservation support initiatives aim to reduce poverty and promote environmental protection. Ideally, donor support is driven by recipients' needs and channeled into programs that have a positive and measurable impact.

Too often, however, there is duplication of effort across different donors and programs. Better coordination among bilateral and multilateral government donor agencies and international donor organizations would help ensure maximum benefit to client countries.

2.4 Closing Remarks

The following quote, taken from a report of the first meeting of the Intergovernmental Committee for the Cartagena Protocol, seems to capture the rationale for this workshop:

> Discussions on capacity reflected how much work is needed and how little is known about the biosafety capacity needs of developing countries. Some developing country delegates noted the importance of intersessional work to assess national needs ranging from training human resources and technical development of BCH [Biosafety Clearinghouse] nodes to legislative and regulatory development and institutional means for assessing and monitoring LMO imports.
>
> (Earth Negotiations Bulletin, First Meeting of the ICCP Montpellier, France, December 2000)

Our task here is to develop a conceptual framework for building and implementing a national biosafety system. It will not be easy, since the framework must encompass the many, many steps to be taken, requirements to be met, processes to be coordinated, and stakeholders to be involved.

The hope is that through the conceptual framework we develop, client countries will gain a better understanding of the issues and options they face; providers will have a tool to help them better formulate and deliver capacity-building assistance; and donors may better focus their program funding for maximum impact.

3. UNEP/GEF Biosafety Enabling Pilot Project

Julian Kinderlerer
Sheffield Institute of Biotechnological Law & Ethics,
University of Sheffield, UK

3.1 Introduction

Article 8(g) of the Convention on Biological Diversity requires countries to

> establish or maintain means to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health.

In response to this requirement, the Global Environment Facility (GEF) Council at its meeting in November 1997 approved a pilot project to promote a comprehensive understanding of and approach to biosafety by countries in order to safeguard biological diversity under *in situ* conservation against possible adverse impacts from living modified organisms (LMOs) with novel traits resulting from biotechnology.

The project was to improve and strengthen national instruments for environmental management. The prime mechanism for its implementation was the development of national biosafety frameworks in the context of the implementation of the UNEP's International Technical Guidelines for Biosafety and any future international agreement on biosafety such as a protocol to the Convention on Biological Diversity.

The project had two related components. In the first component, 18 participating countries prepared national biosafety frameworks, including a survey of capacity both for biotechnology and for safety assessment. In the second component, a series of eight workshops were organized to explore risk analysis and management and transboundary movement of LMOs. The workshops involved many more countries than the 18 that had participated in the preparation of national biosafety frameworks.

3.2 Workshops

Regional workshops were organized in Africa, Asia/Pacific, Latin America and the Caribbean, and Central and Eastern Europe. Two back-to-back workshops were held in each of the four regional centers. Government-nominated representatives attended from a large number of countries in each region. Other participants were representatives of developed-country governments, the scientific community, United Nations organizations, the biotechnology industry, and nongovernmental organizations. Table 3.1 shows the dates, venues, and numbers of countries represented at the regional workshops.

The purpose of the workshops was to promote greater in-country awareness, understanding, and appreciation of biosafety and biotechnology issues, in particular, by developing countries and countries with economies in transition. The events served as a platform for the countries to exchange views and information on biosafety with the scientific community, relevant nongovernmental organizations, and the private sector.

The workshops focused on risk assessment and management of LMOs, looking at the potential impacts of LMOs particularly on the environment. Issues of transboundary movement of LMOs, including mechanisms for the supply and exchange of information between importing and exporting nations, constituted a major part of the workshop agenda. Organizers also attempted to clarify participants' understanding and appreciation of biosafety issues and to place the UNEP international guidelines in perspective.

Table 3.1. Regional Workshops

Region	Venue	Date	No. countries
Latin America & Caribbean	Havana, Cuba	26-30 Oct 1998	17
Central & Eastern Europe	Bled, Slovenia	11-15 Nov 1998	16
Africa	Nairobi, Kenya	23-27 Nov 1998	30
Asia-Pacific	New Delhi, India	7-11 Dec 1998	16

As mentioned, two back-to-back workshops were held in each region. The first workshop covered risk assessment and risk management, including environmental impact assessment of LMOs. The second workshop focused on the transboundary transfer of LMOs, including appropriate mechanisms and modalities for the supply and exchange of biosafety information. They also considered issues of biosafety capacity building at the national, sub-regional, regional, and global levels. Throughout, the events emphasized the importance of governments' investing, innovating, and developing resources to ensure that their economies benefit from biotechnology—not only in agriculture, but also in healthcare and industry. Potential economic impacts of the introduction of the new technology were discussed, such as the possibility of loss of markets, jobs, and changes in agricultural and cultural practices.

First workshop

At the first workshops, participants were apprised of international initiatives to ensure biosafety, including the possibility of a biosafety protocol to the Convention on Biological Diversity. Attendees were able to discuss the many concerns they shared about the new technology, especially since evidence of a backlash in Western Europe was already beginning to appear. Participants were reassured that their state of preparedness for the influx (mainly through import) of new varieties of transgenic food and crops was similar to that of other countries in their region. The background to the development of the UNEP International Technical Guidelines was explained, particularly the aim of helping countries to develop information systems and risk assessment capacity.

At each of the workshops, the participants were able to identify what was known about biotechnology within their region. There was great variation in the state of biotechnology across Africa, with Egypt, South Africa, and Zimbabwe, for example, the only countries where research using modern biotechnology techniques was known to be ongoing. In Central and Eastern Europe, research using the technology was well advanced, but little progress had been made in commercializing products of research done within the region. The introduction of novel products from other markets was said to be imminent in a number of these countries. But there was bitter debate about some of the East European countries allowing new transgenic crops to be imported and grown without any apparent review of their safety.

At each workshop, participants noted that the commercialization of transgenic crops represented the fastest introduction of a new technology in the history of agriculture. They perceived this to be due to the benefits that farmers would likely gain by using the new varieties. Participants emphasized that for trade to succeed, stakeholders need to have confidence in and understand the technologies, so they can make their own cost-benefit analyses and informed decisions—although what constituted "stakeholders" may have been improperly understood (e.g., are consumers part of this process?).

Further, the workshops concluded that strong regulatory authorities and efficient systems are needed to give users confidence in the safety of products on the market. It was evident that indigenous technologies need to be developed and protected, and the ethical issues need to be handled by strong regulatory structures that can make unbiased assessments of the safety of any introduction.

Second workshop

The second of the back-to-back workshops primarily considered issues of transboundary transfer of LMOs. It became clear that the movement of goods is partly governed by existing trade and safety agreements, which were carefully considered. Countries recognized that there would be a need for

international collaboration, at the very least at a regional level. The meetings considered unintended movements of modified organisms across national borders due, for example, to natural dispersal or breakdown in confinement systems. The delegates expressed concern at possible environmental impacts of modified organisms about which their governments may be unaware. Genetically modified organisms (GMOs) were seen to have the capacity to spread new characteristics within an ecosystem. Participants' general view was that a "precautionary principle" should be applied. LMOs were considered a special risk when released into the environment and, following risk analysis, risk management should be in place to minimize hazard to the environment.

Both labeling and the problems of complex transshipments were discussed and flagged for consideration during the process of agreeing a protocol to the Convention on Biological Diversity. Participants recognized the need to develop national capacities, including human resources and infrastructure for risk assessment, management, and monitoring. The protocol to the Convention on Biological Diversity was expected to contain provisions for capacity building in many of the participating countries. This could include training staff who are using the technologies (in cooperation with the private sector) and those involved in risk assessment and management, to ensure the safe use of the new technologies.

3.3 National Biosafety Frameworks

The 18 countries that participated in the project to develop national biosafety frameworks were chosen because of their different sizes, geography and geographical locations, and level of socioeconomic development. The countries were Bolivia, Bulgaria, Cameroon, China, Cuba, Egypt, Hungary, Kenya, Malawi, Mauritania, Mauritius, Namibia, Pakistan, Poland, The Russian Federation, Tunisia, Uganda, and Zambia. These countries were at very different stages in the development of biotechnology applications. They were expected to start in April 1998 to prepare a national biosafety framework using the UNEP International Technical Guidelines for Biosafety as a guide. Organizers hoped that this would result in a harmonized approach to risk assessment and risk management of LMOs within both the individual countries and within the regions. Pakistan was unable to start the program and eventually withdrew. Although the pilot project was expected to last 12 months, it was almost immediately recognized that this was unattainable, and it effectively was completed in 16 months.

The countries participating in the project had five objectives:

- to assess existing national capacity and roles in environmental release of LMOs and their products and to develop methods, techniques, standards, guidelines, and indicators for assessing and monitoring risks and controlling those risks posed by the transport, release, commercialization, and application of LMOs
- to facilitate national capacity building for biosafety management and formulate a package of needs, including human resource development, establishment of management mechanisms, formulation of relevant policies and regulations, and development of relevant technical guidelines and management procedures
- to promote the establishment of institutional arrangements and operational mechanisms for biosafety management and to develop human resources for biosafety management through formulating and implementing a series of training plans to upgrade expertise in this field, in particular of technical staff and managers for risk assessment/risk management of LMOs and their products
- to undertake publicity activities at the national and local levels to increase understanding and awareness of the public and decision makers of the potential benefits and risks of biotechnology applications, while increasing public awareness of biosafety and facilitating the formulation of relevant laws, regulations, and rules and supervising their enforcement
- to enhance international cooperation and communication on scientific research, legislation, information exchange, and personnel training in biosafety

In evaluating the national biosafety frameworks developed by the countries, six elements were considered:

- the regulatory system (e.g., legally binding regulations and/or non-binding guidelines)
- means of implementing the system, probably through some form of peer review involving scientific expertise drawn from those working in the field within the individual countries or, where necessary, by use of outside expertise
- the decision-making system, including impact assessment (at least risk assessment) and auditing
- the information system, both to maintain public acceptance of the biosafety system used in the region and to ensure that decisions are based on knowledge
- means of enforcement, to ensure compliance with any decisions made and to allow monitoring of what happens in the field
- means of validation, if testing is required, to identify the presence or concentration of either GMOs or LMOs

All of the countries identified the systems needed to ensure the safe use of biotechnologies within their borders, but many had not yet separated their role in promoting the technology from their role in auditing and assessing safety. Nonetheless, they recognized the need for some sort of regulatory system and indicated that even without the project, a similar process would have been needed, even if slower. All of the countries (now including Pakistan) developed guidelines or statutory instruments that enable the use of biotechnology within their borders, although only Hungary and Cuba were actually able to pass laws through their legislatures that effected a full regulatory regime.

3.4 Impacts

In sum, the project was seen as crucial for ensuring the safe use of biotechnology and ensuring that those not well versed in the technology could be confident of the safety of products imported into their countries. Participants clearly recognized the need to consider issues raised both by the development of indigenous biotechnology and by products imported from or exported to other countries.

Even where the capacity to utilize biotechnology has long been demonstrated, as in China, the project provided environmental agencies with an opportunity to map what was happening. It also encouraged development of a clear framework of regulations and guidelines. In countries where development of biotechnology is lagging relative to the industrialized countries, the project provided impetus both for establishing a regulatory framework and for kick-starting the use of biotechnology techniques. It was exciting to hear how the project shaped a new vision of this science. A project that had the assurance of safety as its primary motivation may well have furthered the more general implementation of the Convention on Biological Diversity. It also brought developing countries to a realization of both the potential benefits and risks of applying biotechnology in its many spheres of application.

4. The BIO-EARN Program: An African Regional Effort in Biotechnology and Biosafety

Charles F. Mugoya
BIO-EARN Regional Coordinator
Uganda National Council for Science and Technology, Kampala, Uganda

4.1 Overview of the BIO-EARN Program

The East African Regional Programme and Research Network for Biotechnology, Biosafety and Biotechnology Policy Development (BIO-EARN) was founded in 1998 to facilitate a concerted effort in agricultural, industrial, environmental, and food biotechnology research in the countries of Eastern Africa (Ethiopia, Kenya, Tanzania, and Uganda). In the three years since its inception, the program has worked towards meeting the challenges of modern biotechnology and biosafety under local conditions and promoting appropriate related policies. The BIO-EARN program combines several aspects of biotechnology development within one program, which has four main characteristics:

- focus on major problems and opportunities for biotechnology in East Africa in the agricultural, environmental, industrial areas
- combination of biotechnology R&D, biosafety, and biotechnology policy development
- facilitation of close collaboration between scientists, policymakers, and the private sector
- role as a catalyst in stimulating regional collaboration between research and policy institutions

BIO-EARN is wholly funded by the Swedish International Development Cooperation Agency (Sida)/Department of Research Cooperation (SAREC). Its annual budget is about US $1.5 million.

4.2 Mission and Objectives

The mission of BIO-EARN is to build capacity in biotechnology in Ethiopia, Kenya, Tanzania, and Uganda and to promote appropriate research and related policies. BIO-EARN aims to use biotechnology in a sustainable manner, to help improve livelihoods, ensure food security, and safeguard the environment. Its overall objectives are three:

- enable the countries of the region to develop biotechnologies and policies according to their own needs, abilities, and opportunities
- promote collaboration in biotechnology, biosafety, and biotechnology policy development to address key challenges and opportunities in the region
- foster communication between scientists, policymakers, biosafety regulatory officials, and the private sector nationally and regionally

4.3 Organizational Structure

BIO-EARN's organizational structure comprises its General Assembly, Steering Committee, Program Coordinators, East African National Focal Points, East African Network Partners, and the Swedish Network Partners and supporting institutions.

General Assembly

All BIO-EARN partners, including the supporting institutions, are represented at the General Assembly, which is held every second year in conjunction with BIO-EARN regional scientific meetings.

Steering Committee

The Steering Committee is a team of independent individuals who are eminent scientists in their own right. They form an advisory body providing policy guidance and direction on all activities including review and assessment of program outputs. They also ensure that decisions made at general assemblies are implemented.

Program Coordinators

BIO-EARN has two Program Coordinators. One is from the Stockholm Environment Institute (SEI) and the other is the regional East Africa coordinator responsible for overall program management, monitoring, and financial management (including support to students).

National Focal Points

East African National Focal Points are national BIO-EARN secretariats that link with partner institutions within the network countries. These are located in councils or commissions of science and technology.

East African network partners

In the four BIO-EARN member countries, network partners include both scientific institutions and policy and regulatory authorities. The policy and regulatory authorities are less involved in the active research. Rather, they facilitate biotechnology policy and biosafety capacity building.

In *Ethiopia* the national partners are the Biodiversity Conservation and Research Institute (BCRI), the Biology Department of Addis Ababa University (including the Herbarium), the Ethiopian Science and Technology Commission (ESTC), and the Environmental Protection Authority (EPA).

Partners in *Kenya* are the Department of Botany and the Department of Biochemistry at the University of Nairobi, the Kenya Agricultural Research Institute (KARI), Moi University, and the Kenya National Council for Science and Technology (KNCST).

In *Tanzania* partners are the Applied Microbiology Unit (AMU) and the Department of Botany at the University of Dar es Salaam, Mikocheni Agricultural Research Institute (MARI), and the Tanzania Commission for Science and Technology (COSTECH).

Partners in *Uganda* are Med Biotech Laboratories, the Department of Crop Science and the Department of Biochemistry at Makerere University, the Institute of Environment and Natural Resources of Makerere University, and the Uganda National Council for Science and Technology (UNCST).

The Swedish network partners

The program, through its “sandwich” model, has secured relations with relevant research institutions in Sweden and other European countries. The supporting institutes are engaged in collaborative research projects with selected institutions in East Africa and host MSc and PhD students and visiting scientists. A total of six institutions in Sweden are involved: the Department of Biotechnology of Lund University, the Department of Biotechnology and Biochemistry of the Royal Institute of Technology, the Department of Crop Science and the Department of Plant Biology at the Swedish University of Agricultural Sciences, the Department of Theoretical Ecology of Lund University, and Svalöf-Weibull AB.

Other partners in Europe are the ISNAR Biotechnology Service (IBS) based in the Netherlands; the Institute of Social Studies (ISS) in the Netherlands, and Plant Research International in the Netherlands.

4.4 BIO-EARN Activities

BIO-EARN activities are linked to three phases conceived of upon the program's inception. *Phase I* (1999-2001) is the capacity-building phase. It is best described as the initial or short-term phase in which the network and the basic capacity-building activities are established. Policy-supporting activities in this phase were coordinated mostly by the African Centre for Technology Studies (ACTS) and SEI.

Phase II (2002-2004), the current phase, concentrates on ensuring high-quality education of graduate students in the network countries. The focus is on institutional capacity building and increased networking. This is also the phase in which most of the policy-supporting activities are being coordinated by institutions in the region.

Phase III (2005-2008) will be the final phase. Here the independence of the program will be consolidated. The funding of this phase will be based on competitive grants launched at the end of phase II. East African institutions will seek support from additional donors, and efforts will be made to strengthen the economic independence of the BIO-EARN network partners from Sida/SAREC funds. Links with partners within and outside the region will be fostered, including the private sector and support to product development.

Thematic areas

Throughout the program cycle, activities are organized in three thematic areas:

- biotechnology research and capacity building
- biosafety research and capacity building
- biotechnology policy development

Projects in the *biotechnology research and capacity building* thematic area are structured as PhD projects in which East African students share their time between East African and Swedish research institutions. The agricultural biotechnology component covers two research areas. The first deals with the identification of genetic linkages to qualitative and quantitative traits, which simplifies conventional breeding efforts. This includes genotype studies on cassava, enset, and coffee and identification of resistance markers for plant viruses and fungi, in maize and sweet potato. The second relates to plant transformation, including screening and cloning of useful crop genes in order to modify starch content in cassava and sorghum and oil quality in sesame. The environmental and industrial biotechnology component includes research projects on wastewater treatment, production of biogas and production of fertilizer from organic refuse. There are also projects on the use of enzymes from extremophilic microorganisms for the utilization of renewable raw materials and degradation of pollutants.

Under the *biosafety research and capacity building* theme, ecological impact assessments of transgenic crops in an East African setting are ongoing. These are aimed at building local research capacity and developing biological background information on the behavior of exotic organisms and transgenic crops in the region. Other activities include training in biosafety assessment and field evaluation of transgenic crops. Further, to aid effective implementation, a biosafety manual is being developed for competent authorities in the region.

The *biotechnology policy development* thematic area aims to generate knowledge and train representatives from the BIO-EARN countries in biotechnology policy formulation, analysis, and implementation, as well as to raise awareness among policymakers and the public. Activities focus on intellectual property rights, access to and transfer of biotechnology, technology assessment, and public-private partnerships. Main vehicles include short training courses for policymakers and scientists, regional workshops on public policy issues, and internships for students, researchers, and policymakers at selected institutions.

4.5 BIO-EARN's Contribution to the Regional Biosafety Effort

Biosafety mechanisms aim to ensure careful design and review of organisms with novel traits, as well as proper planning and regulation of introductions of these organisms to the environment. Components of a biosafety regulatory structure are legislation, risk assessment/management systems, and control and monitoring mechanisms. Risk assessment is a key tool that offers formalized evaluation of the hazard potential of an organism and the extent of exposure to humans. Although risk might not be eliminated as a result, these procedures help keep hazards at an acceptable level. BIO-EARN is addressing biosafety regulatory challenges through biosafety research at the PhD level, biosafety capacity building, short-term regional and national training courses, national workshops, and development of a biosafety manual.

Biosafety research

During BIO-EARN's initial phase, a number of PhD students started research to compile basic biological information on the most abundant crops in the region and their wild relatives (e.g., sexual or vegetative reproduction, growth rate, weediness and weedy relatives, important pests). The aim is to create capability within the region to garner basic information relevant to environmental risk evaluation with regard to the release of GMOs. These activities are well underway and the focus is now to develop pollen dispersal files ("PDF files") for some key crops in the region. These files will be shared with the biosafety regulatory authorities in the region.

Biosafety capacity building

Capacity building in biosafety is at the heart of the BIO-EARN program. Activities undertaken so far have been geared at supporting the implementation of biosafety regulations in East Africa. Because there are also ongoing efforts by other programs in the region, BIO-EARN's focus has been to help biosafety regulatory authorities to implement biosafety regulations in an efficient and science-based manner. This is being done through regional and national training courses where regulatory scientists and policymakers are given "hands on" training in biosafety risk assessment and management.

Regional training courses

Training courses are aimed at building institutional and individual capacity in biosafety regulation, risk assessment, and management of GMOs. They are designed for scientists, policymakers, and special interest group representatives in the region. The overall goal is to assist countries in gaining enough knowledge and confidence to take regulatory decisions. The main target groups for these courses are the scientists and policymakers involved in risk assessment and risk management, to give them effective tools and training in biosafety assessment.

For example, "Tools and Methods for Biosafety Assessment" is a three-day regional training course on risk assessment and management tools. It targets present and prospective members of national biosafety committees from the four network countries. Biosafety committee members are thus exposed to practical aspects of risk assessment and risk management. A large part of the training course is devoted to group exercises in which participants assess real applications dealing with the release of GMOs into a confined environment or in the field. Apart from risk assessment/risk management training, workshop participants discuss activities to further strengthen national biosafety regulatory systems, regional collaboration, and mechanisms for public information.

"Ecological Impact Assessment of GMOs" is a one-week course aiming to build capacity in ecological impact assessment of GM crops. As such, it prepares participants for making evolutionary and ecologically sound assessments. The course is primarily oriented towards people with some previous knowledge of ecological impact assessment. Participants consist of BIO-EARN students, policymakers, and East African scientists. The course covers a wide range of ecological topics ranging from competition and herbivory, basic genetics, population ecology and evolution, to disease resistance and gene dispersal. Risk assessment is addressed using examples of real applications for releasing GMOs into a confined environment or in the field. This course is based on data developed

by the institutions involved in the collection of biological background information and the production of biological files. It thus creates a very practical link between policy implementation and local research.

"Management of Transgenic Crops" is a two-week course aiming to build capacity in biosafety management of GM crops. It is primarily oriented towards people who are involved in developing or regulating transgenic crops and assisting regulators in developing an "efficient" regulatory framework. Here, "efficient" means a science-based framework that is not overly prohibitive but which allows a step-by-step process of building confidences. The course deals with genetic engineering and its impact on plant breeding, practical aspects of risk assessment and risk management, implementation of a biosafety regulatory framework, field trial management (including large-scale monitoring), and risk communication.

National biosafety workshops

National biosafety workshops are of two types. The first type is geared towards raising awareness of potential benefits and risks related to biotechnology. These target practitioners such as plant quarantine officers, extension personnel, policymakers, stakeholders (e.g., farmer associations), the private sector, and NGOs. The second type focuses on biosafety policy development adjusted to national needs and the various stakeholders. These workshops target a narrow audience involved in policy development. They focus specifically on developing and updating national biosafety regulatory frameworks, including aspects of compliance with the biosafety protocol at the national level.[2]

Development of a regional biosafety manual

Although biosafety considerations are a critical component of modern biotechnology, the subject is not taught in universities and colleges. Consequently, many scientists in developing countries have had to be exposed to advanced training in practical risk assessment and risk management at various international and regional training courses.

To complement these efforts, BIO-EARN is developing a tool to provide guidelines on biosafety implementation to scientists and national biosafety assessors. This tool will be in the form of a biosafety manual or handbook containing relevant, comprehensive background materials. Regulatory scientists from countries that have implemented a regulatory structure and are, in their own right, leading efforts to expand the knowledge, have been invited to take active part in producing the handbook.

Due to the fast development and a continuous generation of new biosafety data the manual will not be made into a static "final" version. Rather, it will be a "living document" subjected to regular review and updating. The biosafety manual is expected to be a catalyst in initiating national training programs and a research/teaching tool for in-country trainers at national workshops. It should also assist and guide inexperienced regulatory authorities (and national biosafety committees) through their first decision-making processes and serve as a platform for future biosafety information exchange.

4.6 Lessons Learned from Phase I of BIO-EARN

BIO-EARN is a complex program that has largely achieved its set objectives in a relatively short period. Nonetheless, as the program winds up its first phase and enters its second phase, it has identified a number of lessons/needs requiring attention:

- The national focal points should be strengthened and made more proactive if they are to serve regional biosafety interests.

[2] Compliance with the biosafety protocol will be covered by a number of programs in the region, such as the UNEP-GEF program "GEF Biosafety Capacity-Building Project/Initiative: GEF Initial Strategy for Assisting Countries to Prepare for Entry into Force of the Cartagena Protocol on Biosafety" and the ACTS-NORAD "Biotechnology and Governance" training course. BIO-EARN workshops focus on aspects of biosafety regulatory development not covered by these programs (e.g., use of local biosafety data, training in risk assessment).

- Assessments of country-specific status and needs are crucial before designing regional activities.
- An appropriate mix must be found between nationally designed activities and regional activities to address common problems.
- Communication links between scientists and policymakers are crucial for creating awareness of biotechnology and biosafety at the regional level.
- Stimulating university contacts with private-sector actors by promoting research focusing on end-user needs is key in biotechnology and biosafety development.
- Development of a variety of funding mechanisms can broaden the funding base of a regional program.
- Development of mechanisms for more regional collaboration based on common research problems and on specific policy issues is a starting point in harmonizing biosafety policy at the regional level.

5. Biosafety Studies in Egypt and Argentina: Two Pathways to Implementation

Joel Cohen[1], Patricia Traynor[2], Moises Burachik[3], Magdy Madkour[4] and John Komen[5]
[1]ISNAR; [2] Virginia Tech; [3] University of Buenos Aires, Argentina; [4] AGERI, Egypt; [5] ISNAR

5.1 Introduction

Developing countries propose to use, and in some cases are using, agricultural biotechnology to address food security and development needs. They seek a positive impact from biotechnology on poor, smallholder communities as well as on important market sectors. In order to realize the benefits that biotechnology may hold, these countries must be able to assume responsibility for safety and demonstrate accountability. With limited resources, they must be capable of responding appropriately to public and commercial applications.

Biosafety capacity is of growing strategic importance. The impending adoption and implementation of the Cartagena Protocol on Biosafety (CPB) will require significantly enhanced regulatory capacity in most signatory countries. Fortunately, developing countries just beginning the process of biosafety implementation can benefit from the experiences of countries further along. Some of the approaches taken have been successful, and some have led to less satisfactory results. Analyzing the development and operations of functioning biosafety systems thus provides valuable lessons for countries seeking to build capacity in biosafety.

5.2 Biosafety Research Studies

ISNAR's Biotechnology Service (IBS) and Virginia Tech established a collaborative research project to assess the efficacy of biosafety systems in selected countries by reviewing biosafety policies and procedures associated with the introduction and commercial use of genetically modified organisms (GMOs).

The objectives of the country studies are three:

- assess the efficacy of policies and procedures for the introduction of biotechnology products
- develop recommendations for enhancing the operation of biosafety systems
- identify areas for regional and international cooperation

The studies are designed to help clarify biosafety system objectives and how these objectives relate to commercial use of GMOs. The studies examine participation, transparency, and stakeholder relations and so help build understanding of policy and managerial issues. Because the information coming from the studies can be analyzed with respect to key articles of the CPB, the country studies can provide a starting point to initiate biosafety implementation.

The research methodology includes extensive consultations with stakeholders, scientists, and national officials. Reviews of biosafety policies and procedures are structured around the four elements of national biosafety systems described by Traynor (1999):

- **Written guidelines or regulations for use and release of GMOs**. Ideally, guidelines define the framework of review by describing the objectives of the biosafety system, the scope of oversight, duties and membership of committees, and application and review procedures.
- **The people who propose releases or conduct biosafety reviews.** These include scientists seeking to test GMOs, members of institutional biosafety committees (IBCs) or technical reviewers, members of national biosafety committees (NBCs), and other stakeholders.
- **The risk assessment/risk management review process.** This is a systematic, comparative evaluation to assess the safety of a proposed activity (e.g., an experimental field trial). The

review is conducted to identify any potential risk, estimate its likeliness and the seriousness of its consequences, and determine ways to manage it.

- **Mechanisms for feedback to improve the system.** Assessing biosafety is a dynamic process driven by the continuous influx of new information. Feedback mechanisms provide a means of incorporating that new information into the review process and of increasing the competence and confidence of reviewers through accumulated experience.

The goal of a national biosafety initiative is to establish a regulatory system wherein these elements function together to produce environmentally responsible decisions, provide a mechanism for broad participation, and promote stakeholder accountability.

5.3 Biosafety Systems in Egypt and Argentina

Two studies analyzing national biosafety systems have been completed to date. The first was in Egypt (Madkour et al., 2000) and the second in Argentina (Burachik and Traynor, 2001). Both studies relied extensively on a collaborator from the concerned country and both greatly benefited from the cooperation and interest of high-level government officials.

Common features

The two countries have similar strengths: biosafety guidelines are operational, reviewers are generally confident and competent in their decision making, product reviews are largely science-based and timely, and feedback is used to improve the system. In both Egypt and Argentina, the Ministry of Agriculture is responsible for environmental safety reviews, the Ministry of Health is responsible for food safety reviews, and the Ministry of Environment has limited involvement in the regulatory process. Applications to conduct field trials or to commercially release GMOs or other biotechnology products are reviewed by advisory committees, but official approval is granted only by a minister.

Most advisory committees have a modest level of support from paid staff. However, the technical experts—those actually engaged in the risk analysis and risk management process—serve voluntarily. Both countries have a limited pool of scientists with the kinds of expertise needed for a national biosafety committee. Of these, most are engaged in applied biotechnology research programs in their home institutions. As a result, the committees must make a concerted effort to avoid conflicts of interest and to diversify their membership as much as possible.

Biosafety reviews in Egypt and Argentina take a similar step-by-step and case-by-case approach. They focus on potential environmental and human health risks, with little consideration given to either potential benefits or to the risks of continuing to use current varieties and associated growing practices (such as damaging pesticide use).

Unique features and recommendations: Egypt

Egypt is among the developing countries most advanced in the adoption and use of agricultural biotechnology. The Agricultural Genetic Engineering Research Institute (AGERI) is a center for state-of-the-art research. Activities at AGERI focus on developing pest-resistant and stress-tolerant varieties of crops such as tomato, maize, cucurbits, faba bean, cotton, and potato. In its early stages, this work, along with international collaborations that are conditional on biosafety review, and interest from international seed companies provided the impetus for establishing a biosafety system.

By ministerial decree, Egypt issued biosafety guidelines in 1994 and procedures for commercializing GM plants in 1998. At least three GM crops are now moving towards commercial release: tuber-moth-resistant potatoes, virus-resistant squash, and stemborer-resistant maize.

The review of biosafety policies and procedures in Egypt led to a number of recommendations.

1. **Revise or reissue biosafety guidelines:**
   - State principles, goals, and objectives.

- Clarify the basis for review and decision making.
- Address post-release follow up.

2. **Improve NBC and IBC operations:**

- Establish a secretariat for the NBC.
- Streamline and rotate NBC membership.
- Expand IBC authority over laboratory and greenhouse work.
- Develop a detailed application form to show data requirements.

3. **Improve procedures for product review and decision making:**

- Invest in biosafety training.
- Set timelines for decisions.
- Establish certified food safety laboratories.
- Identify data gaps and research priorities.

4. **Develop a communications plan:**

- Recognize the importance of public opinion.
- Educate media journalists.
- Train communicators.

Unique features and recommendations: Argentina

Agriculture is the most important sector of the Argentine economy, accounting for over 60% of the nation's exports. Argentina is the world's second largest exporter of GM crops. Its national biosafety system was established in 1991 in response to domestic interest and research in GM technologies and the desire by US and transnational seed companies to use Argentina as a location for off-season GM seed production and field trials. Argentina's economic dependence on commodity exports has led government regulators to impose strict data requirements on potential effects of GM crop releases on markets, in addition to the biosafety review.

A number of factors affect the operation of Argentina's national biosafety system. First, government officials change with every national election. Second, although biosafety reviews are timely, there can be delays in securing official approvals. Third, because there is a limited number of qualified reviewers, there is potential for conflicts of interest. Finally, changes in market conditions, public attitudes, or political climate can delay or stop normal operations.

The following are some of the recommendations for Argentina arising from the biosafety study.

1. **Clarify and strengthen national and institutional policies:**

- Develop and implement policies on the use of biotechnology in agriculture and the role of biosafety in technology adoption.
- Resolve issues of hierarchy and scope of authority.
- Engage the Ministry of Environment.
- Mandate additional CONABIA activities to include serving as an information resource, providing regional assistance, and advising the foreign office in international negotiations.
- Explore legal means to enforce compliance.

2. **Strengthen the scientific base:**

- Identify data needs for science-based safety assessments.
- Develop methods and mechanisms for ecological monitoring.
- Promote and support risk assessment research.

3. **Implement a public awareness program:**

- Conduct media education programs.
- Increase the visibility of the biosafety system.
- Expand opportunities to disseminate information to all interested parties.

- Provide a means for open discussion of consumer-related concerns such as labeling.

Common lessons

Some of the common features of the Egyptian and Argentine biosafety systems provide insights into lessons that may be drawn. Insights may be seen as either positive or negative, depending on the circumstances of individual countries.

1. **Review and approval processes are conducted by separate bodies; an expert advisory committee and the Minister of Agriculture:**
   - Decision-making authority remains centralized.
   - The timeline for responding to applicants is interrupted.
   - Separation of decision making provides a means to incorporate social, political, and economic issues into decision making.
   - The minister exerts control by setting either high or low priority for biotech and biosafety, as reflected in the timeliness of the official approval.
   - Separation allows biosafety evaluation to be science-based.
   - Approvals are subject to unrelated political pressures .
2. **NBCs are comprised of unpaid volunteers:**
   - Some desired experts are unable to take on added responsibilities and time commitments.
   - Members serve out of personal belief in importance of biosafety.
3. **Reviews focus only on the risks associated with GMOs; benefits are not included in the assessments:**
   - This single focus on risk simplifies the analysis, but it prevents fully informed decision making.
   - Benefits are speculative at this point (as are risks).
   - Single focus ignores risks of *not* using GM technology, allowing current practices that pose risks (i.e., pesticide applications) to continue.
4. **Components of the regulatory system are implemented as needed:**
   - As-needed implementation may make internal consistency difficult to achieve.
   - Lack of an overall plan tends to reduce coordination within, and coherency of, the total system.
   - This type of implementation allows each new component to be "fitted in" based on familiarity and experience with existing parts of the system.

The two studies also revealed some of the policy dimensions that shape national biosafety systems. Each country must define what constitutes a risk and how much risk is acceptable. These factors determine the criteria that set acceptable trade-off levels between increased productivity and possible environmental or health effects. Regulatory procedures can be designed to either raise or lower barriers to research, development, and use of GM products. The public research sector is especially vulnerable to regulatory requirements that carry a high cost of compliance. Lastly, government officials may or may not be receptive to regional approaches that could yield economies of scale.

5.4 Proposed Next Steps

Given the insights yielded by the studies in Egypt and Argentina, ISNAR and Virginia Tech propose to conduct similar national system studies in other developing countries. The newer research projects will take into account an expanded framework for biosafety implementation and include detailed costing studies related to the objectives, scope, and scale of regulatory systems. Following additional country studies, ISNAR proposes to hold an international conference "Biosafety Systems in Action."

References

Burachik, M. and P. L. Traynor. 2001. *Commercializing Agricultural Biotechnology Products in Argentina: Analysis of Biosafety Procedures.* ISNAR Discussion Paper No. 01-02. The Hague: International Service for National Agricultural Research.

Madkour, M. A., A. S. El Nawawy, and P. L. Traynor. 2000. *Analysis of a National Biosafety System: Regulatory Policies and Procedures in Egypt*. ISNAR Country Report 62. The Hague: International Service for National Agricultural Research.

Traynor, P. L. 1999. Biosafety management: Key to the environmentally responsible use of biotechnology. In: *Managing Agricultural Biotechnology: Addressing Research Program needs and Policy Implications* edited by J. I. Cohen. Wallingford, U.K.: CABI Publishing.

6. Biosafety Capacity Building: A World Bank Perspective

Eija Pehu
World Bank, Rural Development Department, USA

6.1 Introduction

The World Bank is committed to helping developing countries assess, explore, and safely use new technologies to achieve broad-based increases in agricultural productivity, to alleviate rural poverty, to enhance food security and nutrition, and to conserve the environment. There is an emerging consensus in the scientific community that biotechnology is likely to be a valuable tool in this struggle—if it is directed to production and nutritional constraints and to commodities that are important to poor producers and consumers.

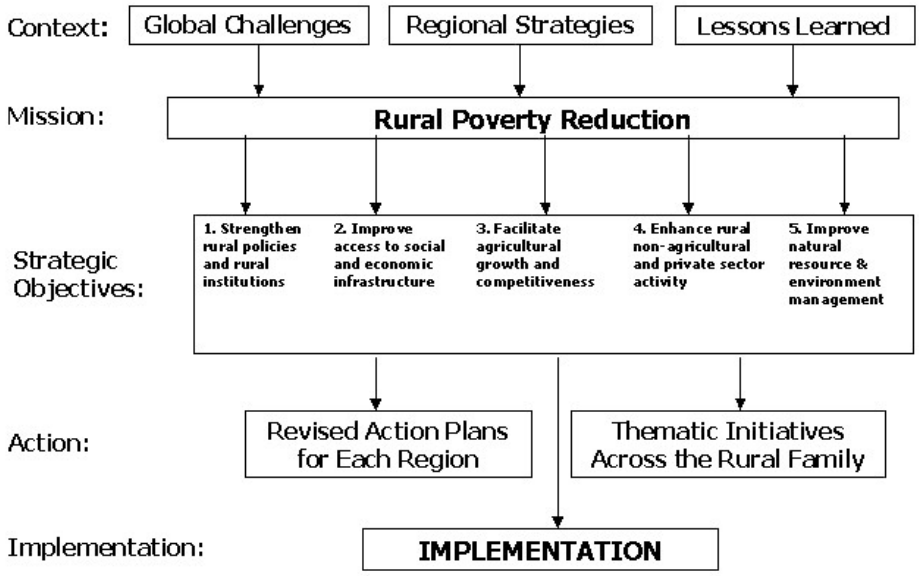
The World Bank recognizes that strategies and priorities for biotechnology will be specific to individual countries and/or regions, and that benefits and risks will be specific to each tool and to the location in which it is applied. Therefore, the central pillar of World Bank support to biotechnology is to build capacity so that policymakers, scientists, consumers, and farmers in borrower countries can make informed decisions about options for, and risks of, research and technology release.

The World Bank is prepared to support capacity building in five areas:

- evaluating the potential of biotechnology to solve high-priority problems in terms of social and private costs, benefits, and risks relative to alternatives
- promoting public-private partnerships that effectively deliver new technological options to the rural poor
- designing and implementing transparent policy, regulatory, and institutional frameworks that safeguard human health, consumer choice, and the environment while recognizing the specifics of each country and region
- informing and empowering farmers and consumers to make rational choices among options taking into account benefits, risks, and ethical considerations
- promoting regional and international cooperation for cost-effective research, acquisition of proprietary tools and products, and risk assessment

The World Bank will also participate with other partners in dialogue on key global policy issues and, in selected cases, provide leadership and leverage. This includes access to proprietary tools and technologies, management of biological assets, models of technology transfer, regional harmonization of regulatory frameworks, and development of international public goods. The World Bank will look to current international protocols for guidance on the formulation and implementation of regulations, and it will continue to contribute to discussions on international agreements related to biosafety, intellectual property rights, and genetic resources (see Figure 1).

Figure 1. Overview of the New Rural Development Strategy of the World Bank



6.2 Research Support

The World Bank has committed approximately US $2.3 billion in loans to 35 countries to support research. It places strong emphasis on building institutional capacity in all areas of agricultural research, including public- and private-sector institutions and universities. The World Bank is the largest donor to agricultural research, and lending has generally increased over time. Of this support some $50 million, less than 2.5%, has been committed to research in biotechnology, specifically tissue culture, genomics, marker technology, and transgenics.

The World Bank has increased its support to develop and implement regulatory frameworks to address issues specific to biosafety and intellectual property rights, including priority setting and strategy development, strategic alliances, and public dialogue and education. For example, it is participating in a new Global Environment Facility (GEF) initiative to coordinate biosafety capacity-building projects.

The World Bank has provided nearly US $40 million specifically to projects using the tools of modern biotechnology in India, Kenya, Brazil, Indonesia, and Peru (Table 6.1). The principles that guide this program of support are three:

- Biotechnology, including genetically modified organisms (GMOs), could potentially be a valuable tool in achieving World Bank objectives of alleviating rural poverty, enhancing food security and nutrition, and conserving the environment—if it is directed to production and nutritional constraints and to commodities that are important to poor producers and consumers.
- The applicability of new tools must be assessed on a case-by-case basis according to technology, agroecological and biodiversity conditions, the socioeconomic situation, and societal values.
- World Bank support emphasizes capacity building so that policymakers, scientists, consumers, and farmers in borrower countries can make informed decisions about options for, and risks of, research and technology release.

Table 6.1. Summary of World Bank Support to Modern Biotechnology

Country	Description of Support to Transgenics (GMOs)	Concerns/Risks
India	About $20 million allocated to support to biotech in two areas: • development of transgenics with emphasis on Bt insect resistance in rice, cotton, pigeon pea, chickpea, and horticultural crops; with some work on high-protein potatoes incorporating *Amaranthus* gene • development of tools for marker-assisted selection and support to genomics with emphasis on rice	India has made good progress in developing biosafety guidelines and implementation capacity. Bt cotton was recently approved for field testing after extensive review of potential risks. Nonetheless, a recent World Bank supervision urged that more *ex ante* evaluation be done of sustainable resistance and potential risks, as well as the incorporation of Bt resistance in a wider integrated pest management approach.
Kenya	Some support provided to develop capacity in biotech research and in biosafety evaluation. A very small amount of support provided to the development of transgenic virus-resistant sweet potatoes, which is being financed by the US Agency for International Development and other donors (including Monsanto).	Kenya recently approved biosafety guidelines and extensively evaluated the transgenic sweet potatoes prior to field testing.
Ethiopia	$3.8 million to develop capacity in biotech and an appropriate regulatory framework. No work on transgenics.	
Brazil	About $8 million in two projects for research on biotechnology and other advanced technologies. Work on molecular biology but no support to transgenics.	
Indonesia	$2.6 million to develop capacity in biotech and an appropriate regulatory framework. No work on transgenics.	
Peru	Support to build strategic capacity in biotechnology. A detailed work program is being developed.	

Key parameters for World Bank support are four:

- addressing a priority problem where transgenics are the most cost-effective way to solve a problem
- expressing novel traits that are important to poor farmers or consumers
- ensuring that biosafety regulations and capacity to assess risks and benefits are in place, or supporting countries to achieve this
- balancing support to research, accessing tools and technologies, enabling regulations, and public dialogue and education

6.3 Building Capacity in Biosafety

The World Bank recognizes the importance of biosafety capacity building that is science-based, incorporates assessment of risks and benefits, evaluates risk management options, and acknowledges the importance of achieving a balance between agricultural productivity and competitiveness and environmental concerns.

Programs directed to develop biosafety capacity in borrower countries share a number of elements. Each program:

- provides for developing and strengthening capacities for effective compliance with the Cartagena Protocol on Biosafety
- includes technical training in risk/benefit assessment and risk management
- includes training and technological support for information management

- addresses the institutional options for regulating GMOs
- provides for a regulatory framework that addresses safe handling of GMOs from laboratory to the field, large-scale experimental field trials, and commercial release of GMOs
- enables comparative assessment of national and/or regional regulatory systems and efforts at international harmonization
- includes provisions for ensuring public awareness (and education) of regulatory decisions, such as approvals for the commercial release of GMOs
- involves consultative processes that include all stakeholders, including the public

Criteria for determining support to biosafety capacity building include an evaluation of overall World Bank assistance to the agricultural sector in the client country (e.g., India), especially in the area of biotechnology; an evaluation of country-specific needs (e.g., national capacity, exports, imports) since these drive the agenda; the potential for regional initiatives; and collaboration with expert organizations (e.g., CGIAR centers).

The World Bank has several ongoing initiatives in capacity building. First is its participation in the GEF pilot project on biosafety capacity building. Second is support to transgenic crop development in India. There, the need for biosafety capacity building has been expressed by both national experts and World Bank staff. The challenge is great, as the institutional framework is quite complex. Assistance from the CGIAR centers will be sought to implement the project. Finally, in Colombia, the World Bank is formulating an agricultural sector project. The biosafety capacity-building project will complement that initiative. Implementation will be backstopped by the International Center for Tropical Agriculture (CIAT).

6.4 World Bank and Biosafety Capacity Building in the Future

The World Bank is strengthening its competence in biosafety for four reasons. First, it views the safe use of biotechnology as a positive force in international development. Second, requests from client countries for support in this area are increasing. Third, biotechnology and biosafety are increasingly seen as an important element of a competitive agricultural sector, which affects associated regulatory frameworks, for example, in food safety, phytosanitary regulations, plant variety registration, and intellectual property rights. Finally, the World Bank is involved in enhancing networking with expert organizations on biosafety (e.g., with CGIAR centers and the GEF initiative)

Other biotech-related activities in the World Bank group include continued private-sector and nongovernmental organization consultations on agro-biotech in the regions, interest of the World Bank's Board in biotechnology, and the International Finance Corporation's piloting biotech company support. In cooperation with ISNAR, the World Bank has conducted impact studies of agricultural biotechnology on the livelihoods of poor rural communities. It also convened the taskforce "Food Security for the 21st Century: The Role of Science and Technology," which includes biotechnology.

6.5 Summary

The World Bank has been active in raising the issue of biotechnology's role in reducing poverty through international fora and conferences. This has been followed up by an internal working group on agricultural biotechnology that has strived to reach consensus on key issues. One product of this effort appears in the World Bank's forthcoming "rural strategy," which contains a statement on biotechnology, supporting its safe application to enhance food security and reduce rural poverty. The World Bank envisions that biotechnology-related lending will increase. Therefore, its Rural Development Department is strengthening its capacity to assist client countries in agricultural sector development utilizing the tools of modern science.

7. Planning for the Development of Nearly 100 National Biosafety Frameworks

Christopher Briggs
UNEP/GEF Biosafety Unit, Switzerland

7.1 Introduction

In January 2000, agreement was reached on the Cartagena Protocol on Biosafety (CPB), which states its aims as follows:

> to contribute to ensuring an adequate level of protection in the safe transfer, handling, and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements.

This presentation aims to introduce the UNEP Global Environment Facility (GEF) project to develop national biosafety frameworks. This project helps countries prepare for the coming into force of the CPB by (1) establishing national biosafety frameworks, (2) sharing information and collaborating at regional and sub-regional levels, and (3) coordinating and collaborating with other organizations involved in biosafety capacity building.

7.2 The National Project

The first phase of the project was a pilot conducted in 18 countries that resulted in the preparation of national biosafety frameworks in each of the countries, draft laws in some countries, regional workshops, and enhanced sub-regional collaboration. The success of the pilot phase, and the lessons learned, led to a second phase being proposed to advance the development of national biosafety frameworks in many more countries. This phase, the UNEP/GEF Global National Project, has been approved and is now under implementation.

The aims of the UNEP/GEF Global National Project are four:[3]

- preparing countries for the CPB
- assisting a number of countries to prepare national biosafety frameworks
- promoting regional and sub-regional cooperation, inasfar as the regions and countries deem such cooperation as necessary and desirable
- providing technical support in producing national biosafety frameworks and relating with different agencies and initiatives

To join the project, a country must be a signatory to the CPB. Under current rules, countries that had not signed by the 5 June 2001 deadline will need to accede to the Protocol to qualify. Sixty eligible countries have already signed. Participant countries must further meet GEF eligibility requirements—that is, they must be a developing country or country with an economy in transition and they should either have an active UNDP program in place or be eligible for World Bank loans. Finally, the country cannot have been involved in the pilot phase and it must secure endorsement by the GEF operational focal point or political focal point. The focal point is usually a minister or deputy minister of environment, but it may also be a position held in Washington, D.C. or an entirely political post.[4]

[3] Contact information for the UNEP/GEF biosafety project, its team members, list of participating countries, and all related documents can be accessed from the website at http://www.unep.ch/biosafety/index.htm.

[4] The focal point is a post and person declared openly to GEF and these can be found on the GEF website at http://www.gefweb.org/participants/Focal_Points/focal_points.html.

7.3 National Project Expectations

Outputs

To meet the requirements of the Convention on Biological Diversity and set up a management system for living modified organisms (LMOs), it is imperative that countries inventory their national capacity including current use of modern biotechnology as defined in the CPB, existing legislation or legal instruments related to biotechnology/biosafety, and active or planned national projects for capacity building related to the safe use of biotechnology.

A report should follow containing details of existing sub-regional biosafety frameworks and mechanisms for harmonization of risk assessment/management; a roster of relevant experts within the country, identifying their experience and expertise so that adequate coverage in all areas is obtained and potential gaps identified; and a draft of legal instruments, including guidelines, as appropriate.

Any regulatory system for LMOs requires an administrative set up, for which the UNEP/GEF will provide technical support and guidance when requested. Systems for risk assessment and management, including audits, should also be developed, taking into account regional and sub-regional needs where required. The Biosafety Clearinghouse of the CPB will be a key source of biosafety information that can be instantly accessed by any country. Country needs and mechanisms for participation in the Clearinghouse need to be identified during the project, but the UNEP/GEF project does not include direct support to facilitate countries' link to the Clearinghouse.

Each country is expected to establish a mechanism for public involvement in decision making that ensures access to relevant information during both the development of the national biosafety framework and at a future time when LMOs may or may not be released into the environment. All inventories, reports, rosters, decision documents, and any other relevant documents should be available to the public and to all stakeholders. Additionally, information must flow to the Biosafety Clearinghouse once it is fully functional.

Regional and sub-regional workshops

The UNEP/GEF Global National Project will support and fund a workshop in each of the four regions: Latin America and the Caribbean, Central and Eastern Europe, Africa, and Asia and Pacific. Over three years, more than 250 government-designated experts will be able to benefit from these regional workshops, and UNEP/GEF will attempt to ensure that regional workshops continue during the life of the project and afterwards, by looking at other sources of financing. In addition, 15 sub-regional workshops will be organized to address various issues that are seen as easier to deal with at a sub-regional level, such as risk assessment and management and public involvement in decision making.

A primary goal of the workshops is to promote sub-regional and regional collaboration through formal and informal exchange of information and through the sharing of resources that may be limited in individual countries. Some resources can be pooled or made accessible through regional or sub-regional networks. Informal sub-regional advisory committees could be established to work on the development of biosafety frameworks within one region or across regions.

Expectations for the UNEP/GEF Global National Project are high given its relatively small budget over three years. Planning of regional and sub-regional activities and improved collaboration will progress as the needs and expectations of stakeholders are shared. Increased awareness of national obligations under the CPB, and in fact, of what is already required under the Convention on Biological Diversity, will promote network building and the creation of regional advisory committees and sub-regional clusters.

Improved efficiency of working practices at all levels will be achieved by a number of means:

- sharing best practices
- seeking optimal resource use
- sharing information and optimizing use of the Biosafety Clearinghouse

- coordinating with other agencies and activities
- exploring the potential for regional websites
- examining harmonization of regulatory instruments

7.4 Technical Advisory Support Team

Duties of the Global National Project technical advisory support team, based in Geneva and Nairobi, are as follows:

- providing advice to countries throughout the development of their national biosafety frameworks
- providing a website with information that complements and does not contradict the Biosafety Clearinghouse
- establishing a list serve for rapid exchange of information within regions
- publishing a quarterly newsletter
- helping to produce training materials on best practice
- helping to produce outreach materials on awareness
- liaising with countries to set up a database of resources to address public awareness issues

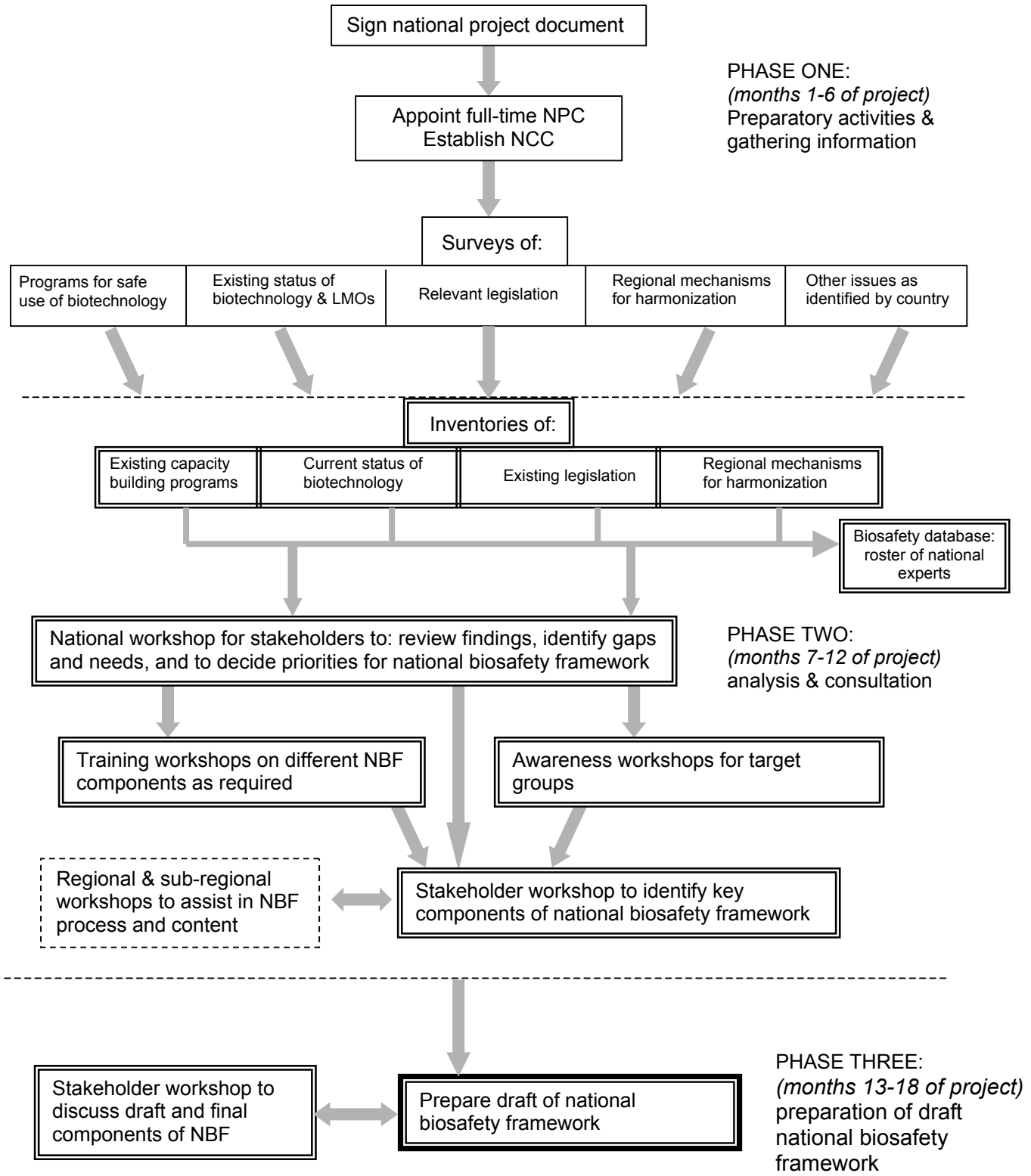
7.5 Current Status

The UNEP/GEF project to develop 100 national biosafety frameworks started in June 2001. It is designed as a three-year effort, ending in June 2004. Of the 59 eligible countries that have signed the protocol, 45 countries have joined the project. To be able to initiate collaboration with a large number of countries, the UNEP/GEF has developed a model national project document that is available to all eligible countries.[5] This acts as a memorandum of understanding that describes terms for reporting, activities, and expected outputs. It includes a simple chart (Figure 1) explaining the anticipated progression of each national effort.

Each country must initially nominate a national executing agency and appoint a national coordinator, and the collaborating countries must use a quarterly reporting system. The project model document permits the devolution of responsibility for the project to the applicant country; and the country can then ask for assistance from the UNEP/GEF biosafety team in the preparation of its national biosafety framework. UNEP/GEF will help set up workshops and facilitate access to resource personnel and materials. Participating countries report to the project authority and funding is disbursed accordingly.

[5] Available at: http://www.unep.ch/biosafety/documents.htm.

Figure 1. Suggested Flow Chart for Project to Develop National Biosafety Framework



8. Prelude to Building a Framework for Implementing Biosafety

Robert J. Frederick
US EPA Office of Research and Development, USA

8.1 Introduction

To generalize what has been happening over the last 25 years, it seems that countries have needed to go through a series of phases in order to build and implement functioning biosafety regulatory structures. The process has usually been triggered by raised awareness among policymakers and scientists of biotechnology and concepts of biosafety. Subsequently, a drafting committee is charged with the task of formulating policies and drafting biosafety guidelines/regulations (accommodating, at best, views from all sectors of society). This is followed by the formalization of guidelines/regulations and coordination of the responsibilities under the guidelines. The strengthening and development of human resources and institutional capacities in biosafety issues is next. This has included the transfer of know-how, development of appropriate facilities, training in sciences related to safety in biotechnology, and the use of biosafety risk assessment and risk management. Finally, there are attempts to harmonize guidelines and biosafety procedures regionally and worldwide.

There is, at first glance, some logic to this progression of activities in which the "completion" of one phase marks the initiation of another. However, this rarely occurs in practice. Each country finds its own starting point, usually driven by some national circumstance. The ready availability of extra-national advice and diversity of opinions on priorities have led to confusion or premature change in focus. Resource limitations (human and financial) have meant that some phases never seem to end. And because this process in many ways is plowing new ground, it has been difficult to see all the components—let alone to appreciate where complementarities are required. So, inevitably, mistakes have been made along the way.

In response to this notion, there appears to be no small value in creating some guidance on the process of implementing biosafety. There is more than sufficient experience in diverse settings and under a variety of conditions to inform a generic framework for biosafety development. This might act as a "road map" for countries just beginning the process or for those searching for the way to continue a process already begun. It might act as a prioritization aid for donor organizations deciding where their resources might be spent most effectively. It might also help guide providers (advisors, trainers, and educators) to grasp a more holistic view of what would constitute a full program.

The "strawman" framework presented here is intended as a mechanism to jump-start the process of garnering the collective knowledge and experience of consultation attendees. It is hoped that through constructive dialogue, a wealth of information will be captured and some semblance of the goals just mentioned obtained.

8.2 Strawman Framework

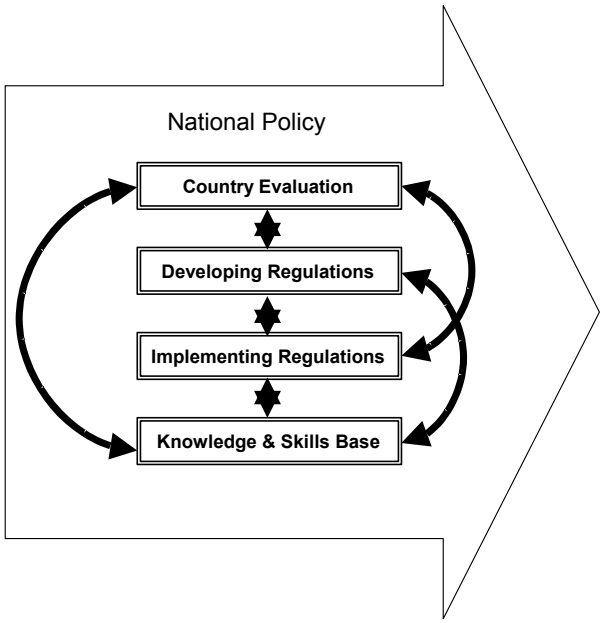
For purposes of discussion and in keeping with the intent of the consultation, components, or definable areas of focus, are proposed as necessary to build a functioning biosafety system:

- establishing national policy
- completing a country evaluation
- developing regulatory instrument(s)
- implementing the regulation(s)
- developing a supporting science base

These have been incorporated into a framework for implementing biosafety (Figure 1).

For each, some form or forms of useful measure may be applied that would be indicative of achieving "capacity," that is, reaching a level of sufficiency such that a biosafety mechanism(s) is in place and operational. There is no intention to present these as having any preferred sequential order. Ideally, they would all be achieved in concert. However, because each component is arguably linked to the others, and consequently influenced by the others, it is more reasonable to assume that they might be developed simultaneously if subcomponents were appropriately staged and coordination processes were liberally used. International agreements and cooperative efforts (whether bilateral, regional, or global) would also exert certain influence to the direction and operation of biosafety systems.

Figure 1. Preliminary Framework for Biosafety Regulation Development Illustrating the Iterative Nature of Activities



Establishing national policy

National policy is depicted as an overarching influence on biosafety implementation. The politics of trade and economic development are integral to policy development. Policy decisions both drive and direct what regulatory structures are used and how they are implemented. To the extent that these decisions reflect the interests of special groups (e.g., industry, agriculture, public interests), they may be good indicators for identifying potential stakeholders or targeting communication efforts. Knowing national priorities for health and environmental concerns provides focus for the developmental and operational stages of regulatory oversight.

Completing a country evaluation

A fundamental understanding of the influences within a country is essential for creating a smooth implementation process. Elements that might be included are an analysis of the existing regulatory infrastructure, an exploration of the socioeconomic base of the country, and a description of the geography and environmental conditions. Public reactions to technology or their environment may also be instructive.

Developing regulatory instruments

Deciding upon a regulatory structure is not necessarily straightforward. There may be no clear place to house new regulation (e.g., in the Ministry of Agriculture, the Ministry of Environment, or the Ministry of Health). All may claim the leadership position, or none may want to accept responsibility. Finding an appropriate regulatory instrument (adapting existing law, *sui generis* regulation, ministerial decree) may be time consuming and demanding, with some measure of political influence required. It must be determined whether to use advisory groups, and how they might be constituted.

Implementing regulations

In and of themselves, regulations or guidelines will not ensure safe application of biotechnologies. More important is the way particular regulations or guidelines are implemented. As diverse and disparate as regulations may be, the way they are interpreted and implemented may be even more so. Consequently, considerable thought must be given to the principles and practices of risk assessment and management for biological materials.

Developing a supporting science base

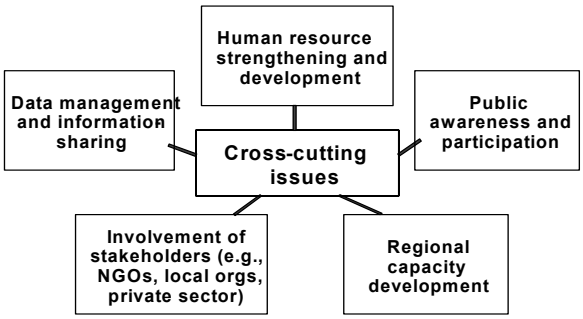
Having scientific expertise in the technology that is being regulated is crucial. Trained individuals form the pool of experts from which risk assessors can be drawn. Directed, long-term support for educational institutions may need to be given high priority. If long-term growth is needed, it must be planned for and interim solutions to expertise gaps found. It may be impossible to rely solely on the academic community for this kind of support.

These same experts may be called upon to oversee the collection and maintenance of information databases. They will conduct the research to develop technology and biosafety assessment capabilities (e.g., risk assessment research). They will be relied upon to "translate" experimental results from the language of science to something comprehensible to regulatory decision makers and the "public." The point is that even those who have basic technical expertise may need to broaden their skill base.

8.3 Cross-Cutting Issues

Many aspects, "issues" if you will, will be considered in some fashion in an implementation process (Figure 2). The few aspects listed here are only examples. Within each lies a certain complexity that invites chaos. But there is nonetheless an opportunity to tease out useful operational functions so that some order is obtained. The short discussions provided here on information exchange, stakeholder involvement and resources are meant only to illustrate the beginning of a process of organizing our thinking.

Figure 2. Cross-Cutting Issues In Implementation of a Regulatory Framework



Information exchange

Information exchange is often viewed as key to capacity building. Yet information comes in many forms and is useful only if it can be obtained and understood. Therefore, evaluation of information needs and up-front planning to fulfill those needs are prerequisites for establishing efficient mechanisms of information exchange.

Stakeholder involvement

Communication is at the core of involving interested parties in capacity-building efforts. This is more than a matter of "just getting the word out." At all stages participatory processes are increasingly recognized as imperative.

Resources

The question of resources extends to both human and financial. Bringing on board a critical mass of trained scientific personnel may be as much or more of a constraint than finding adequate budgetary allocations. Part of the building process will necessarily include estimation of the resources needed and a process for achieving the goals identified.

8.4 Conclusion

Building functional infrastructure to support the development of biotechnologies in any country may appear complex, but most will agree it is a necessary undertaking. For a country to take full advantage of the promise of this new industry, or the products derived from it, requires an adequate technology base, appropriate facilities, and regulatory mechanisms.

Creating a roadmap—a tool for determining the geography of biosafety implementation, estimating time schedules, and identifying landmarks by which progress may be measured—is an important asset for countries just beginning the process. A roadmap will also help orient those countries that have already begun their journey. With informed guidance, the caravan can be better positioned and smooth roads found. Planning can be made more intentional in both its detail and conservation of energy. The challenge will be to lay out the possibilities with clarity and prescience that describes the possible pitfalls and provides options on how to deal with them.

Note: The views expressed in this chapter are those of the author and do not necessarily reflect the views or policies of the US Environmental Protection Agency.

9. Working Group Synopses

9.1 Introduction

On the second day of the consultation, four working groups were formed to help identify the key decision points and policy options associated with the four main components of a national biosafety framework as introduced by Bob Frederick. The four groups discussed (1) country evaluation, (2) developing regulations, (3) implementing regulations, and (4) knowledge and skills base. A few broad guiding questions were suggested for the groups:

- For your group's component, please describe the scope of this component for your discussions. What are the main topics included?
- Define the key decision points in this component. Prioritize the decision points (high, medium, low) according to the importance of their consequences.
- For the high-priority decision points, what are the policy options available to address them? To start, analyze three points. Then analyze additional decision points as time permits.

The sections below summarize the working groups' discussions and recommendations.

9.2 Group 1: Country Evaluation

A country evaluation to identify and characterize factors that are important in the process of establishing and implementing a biosafety framework was considered an essential activity. Evaluation provides a means of assessing status, needs, and perspectives by answering the questions "What do we have now?" "What are we missing?" and "What do we want?" Parameters that may be considered include the following:

- knowledge base
- agricultural systems and traditions
- importance of the agricultural sector
- legal framework in terms of legislation, jurisdiction, administration, and enforcement
- political climate
- environmental conditions
- validation of capacity/capability
- status of human health, focus on food safety/security
- inventory of stakeholders (e.g., resources of information, efficiency, responsiveness)

Six key topics were initially identified and structured as in Table 9.1. The country evaluation should be considered an evolutionary process, and any list of parameters will have to be revisited.

Abstracting from Table 9.1, the decision points were formatted as follows: First, do we need a country evaluation? If the answer is yes, and it must be, who should do the evaluation? This is important, as the report must be accepted by decision makers. How and when should the evaluation be done, and what is the anticipated outcome? The report can be done at any time, even if the framework is already developed. Second, where does the biosafety framework stand? What existing policies might incorporate biosafety/biotechnology? Or will national policy related to biosafety stand alone as it may be considered a cross-cutting activity? Third, which parameters need to be considered? What determines the set of parameters to be applied?

These decision points are included, along with policy options, in Table 9.2.

Table 9.1. Key Parameters for a Country Evaluation

Topic	Sub-topic	Items
Existing domestic legal framework	Legislative	Scope Structure/hierarchy Adaptability
	Administrative	Scope Structure/hierarchy Adaptability
	Judicial	Scope Structure/hierarchy Adaptability
Infrastructure	Human	Scientists Enforcement (e.g., customs) Developers, producers, distributors Validation laboratories
	Institutional	Communications (e.g., hardware, software)
Agricultural system[1]	Economic importance	
	Structure and tradition	
	Trade status	
	Extension service	
International climate	Market	Demand Structure Influence Quality
	Standards	Packaging, labeling, traceability
	Rights and obligations	CBD, WTO, CODEX, ISO, OIE, IPPC[2] Intellectual property rights
Environment and health	Risk assessment factors	
Stakeholders	Who are they?	
	Perception Awareness Interaction	

[1] Depending on the product to be developed or regulated, this may be an economic system of which agriculture is but one part.
[2] CBD, Convention on Biodiversity; WTO, World Trade Organization; CODEX, Codex Alimentarius; ISO, International Organization for Standardization; OIE, World Organization for Animal Health; IPPC, International Plant Protection Convention.

Table 9.2. Country Evaluation Decision Points, Policy Options and Parameters

Decision point I	**Parameters to consider**
Do we do a country evaluation? 1a. Who does it? 1b. How/timeframe? 1c. What resources are needed (human, information, technical)? 1d. What is the anticipated outcome? 1e. How will we use the technology? i. develop and grow GMOs ii. import and grow (commercial, subsistence) iii. food only (bulk commodities) iv. no use of technology	1. Scope: existing conditions/constraints relevant to biosafety framework; status of these; empowerment 2. Existing legal framework: legislative/administrative/judicial; scope; structure/hierarchy; adaptability 3. Infrastructure: human resources (scientists, enforcement (customs), developers, producers, distributors) 4. Agriculture systems: importance to economic development; large-scale or subsistence production; trade status (importer/exporter); extension services, market control 5. International climate: markets; standards; politics; rights and implications (WTO, CBD, international standard-setting bodies) 6. Environmental health 7. Stakeholders: who (interested parties, reference institutions); perceptions; awareness; participation; information sharing *Biotechnology/biosafety is seen to be 'cross-cutting' within the government*
Decision point II	**Policy options available**
Should the biosafety policy be stand-alone or part of other relevant national policies?	1. Stand-alone 2. Linked to economic policy 3. Linked to food security policy 4. Linked to sustainable agriculture policy.

9.3 Group 2: Developing Regulations

The questions central to developing regulations were identified as follows:

- What will be regulated?
- How will it be regulated?
- Who will regulate?
- What is the current status of the regulatory environment?
- What is the potential cost of compliance with regulations?
- Who are the competent authorities and what should be the composition of the regulatory committees?
- How can regulations be made flexible and adaptable?
- Who has final regulatory approval authority?

Identifying the status of regulation in a country (i.e., legal instruments available, products already regulated) is a prerequisite to developing regulations that deal specifically with biosafety. So too is identifying exactly what is to be regulated—should it be the *process* used to develop new products, the *products* themselves, or *both*? The central concern with regard to biosafety was considered the movement of novel genetic material across boundaries (e.g., national borders). Ethical concerns may extend this to the movement of genetic material across plant, animal, and prokaryotic kingdoms, which is only possible with genetic engineering.

Cross-cutting issues were also identified that affect the country evaluation, the development of regulations, the implementation of regulations, and the knowledge and skills base:

- participatory processes, including access to information, training, and education; inputs into the regulatory process; identification of interested parties
- human, financial, and infrastructure resources such as scientific capability; administrative capability; funds with which to develop a biosafety framework; and buildings, laboratories, equipment, computers, and information technologies
- international treaties and agreements (e.g, the General Agreement on Tariffs and Trade, Codex Alimentarius, Convention on Biodiversity/Cartagena Protocol on Biosafety, World Trade Organization)

- legal and political environments, including societal philosophy, form of government (monarchy, republic, tribal), legal framework (constitution, courts), stability
- economic development status of markets/exports, private-sector development, financial infrastructure, agricultural systems and stability of currency
- environmental status of the country's biodiversity, especially if it is a center of origin of plants or animals used to develop living modified organisms (LMOs)

The key decision points and policy options identified are presented in Table 9.3.

Table 9.3. Developing Regulations: Decision Points and Policy Options

Decision point I What is to be regulated? When to regulate by process/product?	**Parameters to consider** 1 Process: a. technique; b. cross species; c. both 2. Product: a. imports; b. exports; c. animals; d. research; e. commodities; f. seed; f. processed products 3. Both: a. seed; b. food
Decision point II What is the standard of review?	**Policy options available** 1. Impacts being captured: a. environment/biodiversity; b. health; c. agriculture; d. socioeconomic 2. Safety standard: a. average person; b. children/elderly; c. 50%/90%/99%; d. reasonable certainty; e. substantial equivalence 3. Scope of review: a. risks only; b. benefits/risks
Decision point III Do you want/need new legislation/regulation?	**Policy options available** 1. Use existing legislation 2. Amend existing legislation 3. Draft new legislation/regulations Factors to be considered: institutional structure; participatory/advisory process; scientific inputs; enforcement process; delegation of authority; liability/redress; penalties; appeal process; timeframe for decision making; fulfillment of Cartagena Protocol; flexibility; accountability; predictability; coordination; transparency; cost of compliance; definitions; consideration of socioeconomic issues

9.4 Group 3: Implementing Regulations

In order to identify decision points for implementing biosafety regulations, the scope of the exercise was narrowed by assuming the availability/presence of the following:

- well-defined rules and regulations, including a clear definition of responsibilities for relevant agencies and/or committees
- well-trained, skilled regulatory staff
- duly equipped laboratory facilities
- adequate funds for the implementation phase

The components of the implementation process were identified as the following:

- notification of import and export
- application for approval (for release, testing, etc.)
- evaluation of applicant file (bureaucratic procedures ensuring the application is complete)
- scientific evaluation (risk assessment)
- public input
- decision taken by competent authority (risk management)

- commercialization
- post-release monitoring and follow-up

Typically, numerous agencies and committees are involved in a hierarchal implementation of regulations. The federal agencies involved are usually the ministries of agriculture, health, and environment. Further, there are national advisory councils comprised of policymakers and national biosafety committees comprised of stakeholders. National advisory subcommittees usually consist of scientific experts, as do institutional biosafety committees.

Key decision points were identified for implementing regulations, followed by a wide variety of policy options. There was recognition that governments need to consider constraints related to local socioeconomic and environmental conditions before adopting a particular policy option.

The first decision point to consider is the origin of the GM product: "Was it developed domestically or abroad?" The acceptance of an applicant's data will be contingent on its applicability to the domestic environment. With regard to the scientific evaluation of the submitted data/information, the group agreed that the amount and quality of information requested by the competent authority depends on (1) whether the product is new or similar to an existing product already approved or rejected; (2) the existence of wild relatives in the recipient country; (3) the donor organism; (4) prior knowledge of hazards; (5) the purpose of the application or level of release (e.g., greenhouse, field trial, unconfined release).

Transparency of the risk assessment process was also considered a decision point. Transparency provides an opportunity to overcome limitations in a country's own risk assessment capacities by enabling third-party review and revealing any real or perceived conflicts of interest. The question "Should the public be involved in the regulatory process?" was posed simply to confirm the democratic nature of a regulatory system in which consumers are the final users of the products regulated. The group identified a number of policy options to address the scope and extent of public engagement in the implementation process. These take into account the need to maintain at least limited confidentiality of the information submitted by the applicant. The nature of public debate was considered a decision point so as to identify policy options for information dissemination and direct or indirect public participation in the decision-making process. Regarding decision making, policy options were provided for the inclusion of public opinion: "If public opinion is to be included, to what extent, under what circumstances, and by what mechanisms?"

At the level of post-commercialization, decision points were specified relating to the nature, frequency, and mechanisms of monitoring and follow-up. Suitable policy options were identified, such as the duration of monitoring being determined by the genetically modified organism (GMO) and its potential interactions with the environment. The final decision point discussed was enforcement of regulations and prevention of their infringement. Policy options to deal with these issues, such as periodic inspections, punitive measures, and even closing borders or banning a product, were presented.

Table 9.4 presents the details of the decision points and policy options.

Table 9.4. Decision Points and Policy Options for Implementing Regulations

Decision point I Applications for approval: What to do if the product is developed abroad?	**Policy options available** 1. Accept everything (data) 2. Accept nothing 3. Accept something (might accept data from similar environment)
Decision point II Scientific evaluation: How much information is required to come to a decision?	**Policy options available** 1. Basic information (published literature) 2. Intermediate 3. Very detailed (e.g., an environmental impact assessment)
Decision factors or scenarios: 1. Completely new product or similar application already approved/rejected 2. Existence of wild relatives in the recipient country 3. Transgene (e.g., gene from fish to tomato) 4. Prior knowledge of hazards 5. Purpose of application or level of release	
Decision point III Scientific evaluation: How to ensure transparency?	**Policy options available** 1. Request second opinion/external review 2. Publish results/conclusions/recommendations before decision is taken
Decision point IV Public debate: Should the public be informed? If yes, what should be the scope/extent of public debate?	**Policy options available** 1. Yes: (a) dissemination of information (a1) before decision is taken, (a2) after decision is taken. If (a1) then (b) request information/inputs from public 2. No
Decision point V Public debate: How to disseminate information?	**Policy options available** 1. Publish as a scientific report 2. Publish in newspapers, etc. 3. Publish in other media (radio, posters, workshops)
Decision point VI Public debate: How to request input?	**Policy options available** 1. Individual written inputs (voluntary, by a deadline) 2. Written inputs from specifically invited groups and/or individuals 3. Discussion forums (possibly following from 2) 4. Any combination possible
Decision point VII Decision making: Is public opinion taken into account in the final decision?	**Policy options available** 1. Yes 2. In certain cases 3. No
Decision point VIII If public opinion is taken into account, to what extent and under what circumstances?	**Policy options available** 1. If it conforms with the national policy 2. If it provides new important information
Decision point IX Post-commercialization monitoring and follow-up: What is the scope of monitoring and follow-up in terms of time?	**Policy options available** 1. No follow-up 2. Short-term follow-up (less than 5 years) 3. Long-term follow-up (more than 5 years)
Decision point X What is the scope of monitoring and follow-up in terms of type of organism?	**Policy options available** 1. No follow-up a. for all organisms, b. for certain organisms 2. Minimum follow-up for non-critical organisms 3. Strong follow-up for some critical organisms (e.g., those with wild relatives in the host country)
Decision point XI Enforcement of regulations: How to prevent infringement?	**Policy options available** 1. Do nothing 2. Periodical inspections 3. Punitive measures 4. Close borders/stop all research/destroy the fields

9.5 Group 4: Knowledge and Skills Base

When developing a national biosafety system, a country must decide whether to limit the scope of the system to meeting the requirements of the Cartagena Protocol on Biosafety or to broaden the scope of the national biosafety system to encompass social, economic, or other "non-science" factors. This decision will dictate what knowledge/expertise is required to develop and/or implement the biosafety program. Policy options include restricting the knowledge base to the scientific disciplines required for an environmental risk assessment or also considering socioeconomic, ethical, and cultural issues. If the latter are considered, then the knowledge and skills base must be sufficiently broad so that social factors can effectively inform the decision-making process, as well as the production of information guidelines, regulations, and legislation.

One of the first steps in assessing the knowledge and skills base available, is to complete a country inventory of domestic expertise. This will include the scientific capacity of laboratories. Labs are considered an important component of an inventory because some countries may choose to require an audit or verification of data submitted by the proponent of an LMO. After evaluating the capacity for biosafety risk assessment and research, a country may wish to consider using international experts to supplement domestically available expertise. An evaluation of the means available for accessing knowledge may be undertaken to indicate how a country can effectively make knowledge and information available to facilitate decision making. The composition of the national biosafety committee (NBC) and supporting experts must be determined, as the spectrum of experts around the table will significantly influence the knowledge available.

Gaps in expertise and knowledge can be addressed, at least in part, through targeted skills development. Financial support for training initiatives should come from government, but the NBC or professional science bodies must determine the methods and content of training (whether by, e.g., national workshops, courses, or inviting international experts). Countries may want to develop a system for ongoing training to prepare for turnover of members of committees such as the NBC and in anticipation of changes in the expertise required for biosafety assessment as technological advances lead to the development of more complex LMOs than those currently on the market.

For the introduction of an LMO to be meaningfully assessed, regulatory authorities must identify system baselines or comparators for assessment. These could be agricultural systems, such as conventional, subsistence, or organic agriculture; unmanaged ecosystems, which may be particularly relevant in circumstances such as a proposed release of a GM tree species; or broader systems that also incorporate defined socioeconomic impacts of an introduction. The existing knowledge base will in part determine which baseline to chose.

Countries must decide what information is essential to make a regulatory decision. Options include using only the best available science, or expanding the scope to include other kinds of information such as cost-benefit analysis. An important consideration will be the availability and amount of domestic support for scientific research, since such support is needed to underpin regulatory decision making.

During the discussion about the knowledge and skills base required for biosafety regulation, some of the same issues were identified as in the working groups on the other three components of the national biosafety regulatory framework.

- **Human and financial resources:** Assuming that basic assessments are required as a minimum for a national biosafety system so that the obligations of the CPB can be met, the resources available will dictate the extent of the assessment process at each stage (experimental field trials, large-scale field trials, commercial releases).
- **Participatory process:** The participatory process has three basic elements—public participation, transparency, and communication. These are linked. In the context of this discussion, transparency has been characterized as the degree to which information is made available to the public during the development and implementation of a national biosafety strategy. Communication is considered the opportunity for the public to contribute information to the development of the regulatory regime and to decisions regarding the

release of an LMO. Public participation is considered to be the genuine engagement of experts and competent authorities (e.g., the NBC, regulatory authorities, scientific experts) with the public, so that the public is cognizant that they are being listened to and that their views are being taken into account.

- **Cultural and environmental contexts:** Local culture and environment should be considered at each stage of assessment—within the home country, neighboring countries (e.g., Argentina and Brazil), and in countries that are trading partners.

One of the most significant challenges in the development and implementation of a national biosafety system is the need to communicate with stakeholders, particularly the public. Effective communication is influenced by many factors: education, transparency of the system, opportunities for public input and feedback, identification and involvement of stakeholders, whether regulatory meetings are open to the public, and inclusion of members of the public on NBCs. Communication is an element that must be considered in developing a national biosafety system and when implementing the system, at all stages in the decision-making process.

The concluding format is presented in Table 9.5.

Table 9.5. Knowledge and Skills Base: Decision Points and Policy Options

Decision point I Is the knowledge required restricted to Annex II/III of the CPB?	**Parameters to consider** 1. Restricted to science 2. Science and socioeconomic/cultural 3. Science and ethical 4. Science, socioeconomic/cultural, and ethical
Decision point II 1. How do we establish what information is available and access it? 2. Is an audit or verification of data required?	**Policy options available** 1. Develop a national inventory of domestic expertise/labs 2. Use 1+ include international experts 3. Evaluate methods of accessing knowledge base 4. Decide the composition of national biosafety committee and supporting experts
Decision point III How do we develop skills of those involved in safety assessment?	**Policy options available** 1. Government supplies financial support for training 2. NBC/professional body determines method/content of training (national workshop, course, inviting international experts) 3. Develop a system for ongoing training and project future expertise required
Decision point IV What is the baseline/comparator for assessment?	**Policy options available** 1. Agricultural system (e.g., conventional, subsistence, organic) 2. Unmanaged ecosystem 3. Socioeconomic impact of introduction
Decision point V Do we assess only “need to know” questions? What is the essential information required to make a decision?	**Policy options available** 1. Best available science/cost-benefit analysis 2. Domestic support for scientific research to underpin regulatory decision making
Decision point VI How do we communicate with society effectively?	**Policy options available** Education, transparency, public feedback, stakeholders, open regulatory meetings, members of the public on NBC

10. What's Next?

The final day of the consultation was aimed at reviewing and refining the findings and recommendations of the working groups (see chapter 9) and mapping a way forward. To comment on the emerging framework, panels were formed consisting of partner country representatives, providers of technical assistance, and donor representatives. All the discussants underscored the value of developing a framework for biosafety implementation. They saw the utility of the framework in the guidance it offers in identifying national and regional capacity-building needs, as well as in designing hands-on activities to address those needs. Participants noted, however, that a country's own needs and capacities will influence how it applies the conceptual framework, so the framework should not be presented in a top-down fashion. In that regard, one partner country representative commented that the projects usually pursued are those that are funded, which are not necessarily the ones responding to national priorities. Particularly in the area of biosafety, where a growing range of capacity-building initiatives exists, participants called for concerted efforts among countries, donor agencies, and providers of technical assistance.

Through the plenary presentations and discussions and the detailed reports produced by the four working groups, the consolation made a significant contribution toward the development of a conceptual framework for biosafety implementation. Specifically, it advanced our understanding of biosafety systems, from being essentially a "checklist of tasks" to a dynamic system in which the main building blocks and decision points are closely related and the implications of different policy options can be assessed. The conceptual framework should enable countries to take a coherent, strategic approach to developing national regulatory systems, and it should help clarify the complementary roles of national implementing agencies, providers of technical assistance, and funding agencies. The framework should not be considered as prescriptive, pressing a chronological implementation of biosafety systems, since each country will almost certainly take its own individual approach. Further work is needed in terms of enhancing the framework's utility as a research and evaluation tool, explaining why some countries succeed in setting up functional biosafety systems while the process is drawn out in others.

More research is also required to enhance the "explanatory power" of the conceptual framework. Participants called for systematic analysis of different country experiences, using the framework as part of the research methodology. Including a well-defined set of evaluation criteria will help explain what approach works in a given situation, why it works, and what does not work and why. In addition, future research is needed to develop elements of the framework that have not yet been fully explored. For example, a full analysis can be done of the various relevant international agreements and organizations and regulatory systems in other sectors that influence biosafety implementation at the national level. Another research project that is still needed is to assess the regulatory costs of alternative policy options. This recommendation arises from a widespread concern that stringent biosafety regulations might act as an entry barrier to local companies and research institutes.

Since the consultation, ISNAR has tackled the meeting's main findings and recommendations. This first involved completion of a written summary of the conceptual framework, which ISNAR published in its Briefing Paper series.[6] Second, ISNAR initiated collaboration with FAO and UNEP-GEF to translate the framework into a Web-based decision-support toolbox for biosafety implementation. In further follow-up, an expert workshop on "Policy Planning and Decision Support: The Case of Biosafety" was held at FAO headquarters in Rome, 14–16 May 2002. A prototype decision-support toolbox was reviewed at that workshop and was subsequently made available through the Internet.[7] The framework has also been applied in a country study to analyze biosafety policies and procedures in Kenya. That study will be published in early 2003. Finally, the conceptual

[6] McLean, M. A., R. J. Frederick, P. L. Traynor, J. I. Cohen and J. Komen. 2002. *A Conceptual Framework for Implementing Biosafety: Linking Policy, Capacity, and Regulation.* ISNAR Briefing Paper No. 47. The Hague: International Service for National Agricultural Research.

[7] http://www.isnar.cgiar.org/ibs/biosafety/index.htm

framework has proven its value in structuring outreach events, specifically in a regional policy seminar on biosafety jointly organized with ASARECA, BIO-EARN, and CTA.

The conceptual framework has assumed a central position in ISNAR's research and service work on biosafety, and will remain key as ISNAR expands its program of work on this important subject.

Annex 1. Consultation Agenda

Day 1: Tuesday, July 24

Time	
8:00	Registration
8:30	**Welcome and Introduction: Workshop Objectives** *Joel Cohen, ISNAR*
9:00	**Cartagena and Beyond: Collaboration in Biosafety Implementation** *Pat Traynor, Virginia Tech*
9:30	**UNEP/GEF Pilot Biosafety Enabling Activity Project** *Julian Kinderlerer, University of Sheffield*
10:00	**The BIO-EARN Programme: An African Regional Effort in Biotechnology and Biosafety** *Charles Mugoya, UNCST*
10:30	Coffee / Tea Break
11:00	**Biosafety Studies in Egypt and Argentina: Two Pathways to Biosafety Implementation** *Joel Cohen, ISNAR*
11:30	**Capacity Building: A World Bank Perspective** *Eija Pehu, World Bank*
12:00	**Planning for the Development of Nearly 100 National Biosafety Frameworks** *Christopher Briggs, UNEP/GEF*
12:30	
1:00	Lunch
1:30	
2:00	**Building A Framework for Implementing Biosafety** *Bob Frederick, USEPA*
2:30	**Plenary Activity: Building the Framework** Moderator: *Bob Frederick*
3:00	
3:30	Coffee / Tea Break
4:00	**Plenary Activity: Building the Framework**, Cont'd.
4:30	
5:00	**Synthesis and Adjournment** *John Komen, ISNAR*

Day 2: Wednesday, July 25

Time	
8:30	**Introduction to Working Groups** *Pat Traynor*
9:00	**Working Groups: Identify Key Decision Points and Policy Options**
9:30	Chairs*: Group A: Jorge Huete, Center for International Development, USA* *Group B: Javier Verastegui, CamBioTec, Canada* *Group C: Catherine Ives, ABSP, USA* *Group D: Doreen Mnyulwa, Netherlands-Zimbabwe Biotechnology Program*
10:00	
10:30	Coffee / Tea Break
11:00	**Working Groups Report to Plenary**
11:30	
12:00	
12:30	Lunch
1:00	**Lunch Presentation: Economic Implications of Biosafety Policies**
1:30	*Peter Hazell, IFPRI*
2:00	**Working Groups: Implications and Consequences of Policy Choices**
2:30	
3:00	
3:30	Coffee / Tea Break
4:00	**Working Groups Report to Plenary**
4:30	
5:00	**Synthesis and Adjournment** *John Komen*

Day 3: Thursday, July 26

Time	
8:30 9:00	**The Framework Revisited** *Pat Traynor*
9:30 10:00	**Reactions to the Framework: Panel of Donors and Providers** Moderator: *Phil Dale, John Innes Centre* Panelists: *Gesa Wesseler, CTA; Liz Peri, DFID; Josette Lewis, USAID; Julian Kinderlerer, UNEP/GEF; Morven McLean, AGBIOS; Javier Verastegui, CamBioTec*
10:30	Coffee / Tea Break
11:00 11:30	**Reactions to the Framework: Panel of Country Representatives** Moderator: *Gregory Jaffe, Center for Science in the Public Interest* Panelists: *Moises Burachik, CONABIA, Argentina; Maria Teresa Barriga, Seminis Vegetable Seeds, Chile; Hanayia El-Itriby, AGERI, Egypt; Muhammad Herman, RIFCB, Indonesia; Alois Kullaya, Mikocheni Agricultural Research Institute, Tanzania*
12:00	**Plenary Discussion**
12:30 1:00 1:30	Lunch
2:00	**Evaluation Criteria** *Bob Frederick*
2:30 3:00	**Plenary Activity: Biosafety Capacity Building, Examples and Identified Needs** Moderator: *Bob Frederick*
3:30	Coffee / Tea Break
4:00	**Plenary Activity: Biosafety Capacity Building,** cont'd.
4:30	**Final Remarks and Adjournment** *Joel Cohen*

Annex 2. List of Participants

Ms. Maria Teresa BARRIGA
Seminis Vegetable Seeds
Av. Los Lenones 2025
Providencia (6651653)
Santiago-Chile Fundo Santa Julia,
Viluco, Paine
CHILE
Tel: +56-2-8242900
Fax: +56-2-8242412
Email: maria.barriga@seminis.cl

Dr. Willem BRANDENBURG
Plant Research International
P.O. Box 16
6700 AA
Wageningen
THE NETHERLANDS
Tel: +31-317-476848
Fax: +31-317-418094
Email: w.a.brandenburg@plant.wag-ur.nl

Dr. Christopher BRIGGS
UNEP/GEF Biosafety Unit
International Environment House (Room A001)
15 Chemin des Anemones
1219 Geneva
SWITZERLAND
Tel: +41-22-9178411
Fax: +41-22-9178070
Email: chris.briggs@unep.ch

Dr. Moises BURACHIK
University of Buenos Aires
Ciudad Universitaria
Pabellon II (C.P. 1428)
Buenos Aires
ARGENTINA
Tel: +54-11-45763300/3309x419
Fax: +54-11-45763384/3367
Email: mbura@bg.fcen.uba.r
Contact info for CONABIA:
Tel: +54-11-4349-2198/2178
Email: mburac@sagyp.mecon.gov.ar

Dr. Joel I. COHEN
ISNAR Biotechnology Service
c/o IFPRI/EPTD, 2033 K Street NW
Washington, D.C. 20006
USA
Tel: +1-202-8628128
Fax: +1-202-4674439
Email: j.cohen@cgiar.org

Prof. Phil DALE
John Innes Centre
Colney, Norwich, NR4 7UH
UK
Tel: +44-1603-450579
Fax: +44-1603-450045
Email: phil.dale@bbsrc.ac.uk

Dr. Andre DE KATHEN
Biotechnology and Biosafety Advisor
Ministry for Higher Education, Training and
Employment Creation, Directorate of Research,
Science and Technology
P.O. Box 13391
Windhoek
NAMIBIA
Tel: +264-61-270-6152
Fax: +264-61-270-6143
Email: dekathen@unam.na

Dr. Hanaiya EL-ITRIBY
Agricultural Genetic Engineering Research
Institute
9 El Gamaa St., Giza
EGYPT
Tel: +20-2-5680970/5734424
Fax: +20-2-5689519/5731574
Email: mggm@ageri.sci.eg
Email: madkour@ageri.sci.eg

Dr. Cathleen ENRIGHT
USDA-APHIS-PPQ-PIM
Director, Biotechnology Trade Issues
4700 River Road, Unit 140
Riverdale MD 20737
USA
Tel: +1-301-7345342
Fax: +1-301-7347639
Email: cathleen.a.enright@aphis.usda.gov

Dr. Robert J. FREDERICK
US EPA-Office of Research and Development
Ariel Rios Building (8623D)
1200 Pennsylvania Avenue
Washington, D.C. 20460
USA
Tel: +1-202-5643207
Fax: +1-202-5650077
Email: Frederick.Bob@epamail.epa.gov

Dr. Peter HAZELL
IFPRI, Environment and Production Technology Division
2033 K Street, NW
Washington, D.C. 20006-1002
USA
Tel: +1-202-8628151
Fax: +1-202-4674439
Email: p.hazell@cgiar.org

Dr. Muhammad HERMAN
Research Institute for Food Crops
Biotechnology, Molecular Biology Lab.
Jalan Tentara Pelajar 3A
Bogor 16111
INDONESIA
Tel: +62-251-316897/338893
Fax: +62-251-338820/312755
Email: mherman@indo.net.id

Dr. Jorge A. HUETE-PEREZ
Kennedy School of Government
Center for International Development
Harvard University
79 JFK Street
Cambridge MA 02138
USA
Tel: +1-617-4968898
Fax: +1-617-4969682
Email: jorge_huete@ksg.harvard.edu

Dr. Cathy IVES
Agricutural Biotechnology Support Project
Michigan State University
324 Agriculture Hall
East Lansing MI 48824-1039
USA
Tel: +1-517-4321641
Fax: +1-517-3531888
Email: ivesc@pilot.msu.edu

Mr. Gregory JAFFE
Center for Science in the Public Interest
1875 Connecticut Ave NW
Suite 300
Washington, D.C. 20009
USA
Tel: +1-202-3329110 x 369
Fax: +1-202-2654954
Email: gjaffe@cspinet.org

Dr. Julian KINDERLERER
Sheffield Institute of Biotechnological Law and Ethics
Sheffield University
Western Bank
Sheffield S10 3GH
UK
Tel: +44-114 2226708
Fax: +44-114-2309482
Email: j.kinderlerer@sheffield.ac.uk

Mr. John KOMEN
ISNAR Biotechnology Service
PO Box 93375
2509 AJ The Hague
THE NETHERLANDS
Tel: +31-70-3496161
Fax: +31-70-3819677
Email: j.komen@cgiar.org

Dr. Alois KULLAYA
Agricultural Research Institute-Mikocheni
PO Box 6226
Dar-es-Salaam
TANZANIA
Tel: +255-22-2700552
Fax: +255-22-2775549
Email: arim@africaonline.co.tz

Dr. Manuel LANTIN
CGIAR Secretariat-Science Advisor
1818 H Street NW
Mail stop G6-601
Washington, D.C. 20433
USA
Tel: +1-202-4738912
Fax: +1-202-4738110
Email: m.lantin@cgiar.org

Dr. Josette LEWIS
US Agency for International Development
G/EGAD/AFS/AEMD
Washington, D.C. 20523-2110
USA
Tel: +1-202-7125592
Fax: +1-202-2163010
Email: jlewis@usaid.gov

Dr. Morven A. MCLEAN
AGBIOS
106 St. John Street, PO Box 475
Merrickville, Ontario K0G 1N0
CANADA
Tel: +1-613-2697966
Fax: +1-613-2694367
Email: mamclean@agbios.com

Ms. Doreen MNYULWA
Netherlands-Zimbabwe Biotechnology Program
Biotechnology Trust of Zimbabwe
P.O. Box BW 267
Borrowdale, Harare
ZIMBABWE
Tel: +263-4-302304/332937
Fax: +263-4-335161

Email: biotech@samara.co.zw
Email: dmnyulwa@zol.co.zw

Dr. Charles F. MUGOYA
National Council for Science & Technology
P.O. Box 6884
Kampala
UGANDA
Tel: +256-41-250499
Fax: +256-41-234579
Email: bioearn@infocom.co.ug

Dr. Christopher NGICHABE
Kenya Agricultural Research Institute
ASARECA Biotechnology Coordinator
P.O. Box 14733
Nairobi
KENYA
Tel: +254-2-440113/447983
Fax: +256-2-583344
Email: ngichabe@skyweb.co.ke

Dr. Eija PEHU
World Bank-Rural Development Dept.
Room MC5-763
1818 H Street NW
Washington, D.C. 20433
USA
Tel: +1-202-4582422
Fax: +1-202-5223308
Email: epehu@worldbank.org

Ms. Liz PERI
Dept. for International Development
Environment Policy Department
94 Victoria Street
London SW1E 5JL
UK
Tel: +44-20-79170934
Fax: +44-20-79170679
Email: l-peri@dfid.gov.uk

Dr. Mario RAMOS
Global Environment Facility
1818 H Street NW
Washington, D.C. 20433
USA
Tel: +1-202-4733297
Fax: +1-202-5223240/3245
Email: mramos@worldbank.org

Dr. Jose Luis SOLLEIRO
Instituto de Ingenieria-UNAM
Apartado Postal 22-510
14091 Mexico DF
MEXICO
Tel: +52-5-6628631x113
Fax: +52-5-5436260
Email: solleiro@servidor.unam.mx

Ms. Corrina STEWARD
Meridian Institute
1101 14th Street NW
Suite 420
Washington, D.C. 20005
USA
Tel: +1-202-3546446
Fax: +1-202-3546441
Email: csteward@merid.org

Dr. Patricia L. TRAYNOR
120 Engel Hall
Virginia Tech
Blacksburg VA 24061
USA
Tel: +1-540-2312620
Fax: +1-540-2312614
Email: traynor@vt.edu

Dr. Javier VERASTEGUI
CamBioTec-Canada
500 Laurier Ave. W., Suite 1609
Ottawa ON K1R 5E1
CANADA
Tel: +1-613-2315237
Fax: +1-613-2317704
Email: jveraste@magma.ca

Dr. Gesa WESSELER
Technical Centre for Agricultural and Rural Cooperation ACP-EU (CTA)
P.O. Box 380, 6700 AJ Wageningen
THE NETHERLANDS
Tel: +31-317-467135
Fax: +31-317-460067
Email: wesseler@cta.nl

Ms. Yuki YOSHIMURA
Global Environment Facility
1818 H Street NW
G6-056
Washington, D.C. 20433
USA
Tel: +1-202-4734123
Fax: +1-202-5223240
Email: yyoshimura@worldbank.org

Annex 3. Acronyms

ASARECA	Association for Strengthening Agricultural Research in East and Central Africa
BIO-EARN	East African Regional Programme and Research Network for Biotechnology, Biosafety and Biotechnology Policy Development
CBD	Convention on Biological Diversity
CGIAR	Consultative Group on International Agricultural Research
CPB	Cartagena Protocol on Biosafety
CTA	Technical Centre for Agricultural and Rural Cooperation ACP-EU
FAO	Food and Agriculture Organization of the United Nations
GEF	Global Environment Facility
GMO	genetically modified organism
IBC	institutional biosafety committee
IBS	ISNAR Biotechnology Service
ICCP	Intergovernmental Committee for the Cartagena Protocol on Biosafety
IFPRI	International Food Policy Research Institute
ISNAR	International Service for National Agricultural Research
LMO	living modified organism
NBC	national biosafety committee
NBF	national biosafety framework
NGO	nongovernmental organization
UNDP	United Nations Development Programme
UNEP	United Nations Environment Programme
USAID	US Agency for International Development
WTO	World Trade Organization