ENHANCING BIOSAFETY SCIENTIFIC EXPERTISE IN SUB-SAHARAN AFRICA

DIALOGUE SUMMARY

Grottaferrata, Italy
12 - 14 March 2002

INTRODUCTION

Increasingly, regional and national projects and initiatives in sub-Saharan Africa are focusing on building capacity for biosafety.[1] Many of these activities focus on developing legal and regulatory systems for biotechnology products. A range of projects and initiatives are also aimed at enhancing biosafety scientific capacity. While important efforts are underway, the range of stakeholders interested in biosafety issues agree that additional efforts are needed in the area of biosafety scientific expertise.

From 12 to 14 March 2002, representatives from NGOs, research organizations, governments, regional organizations in sub-Saharan Africa, international organizations, foundations, and companies met to explore opportunities for enhancing biosafety scientific expertise at the regional and national levels in sub-Saharan Africa. The dialogue was convened and facilitated by the Meridian Institute[2] and supported by the Rockefeller Foundation. For more than two years, Meridian Institute, with support from the Rockefeller Foundation, has been exploring issues and convening dialogues related to sustainable agricultural systems, biotechnology, food security, biosafety, and intellectual property rights. The primary focus has been on identifying issues critical to improving food security and agricultural research that result in public good for subsistence farmers.

This Dialogue Summary was written by Meridian Institute facilitators based on their detailed meeting notes. It does not represent a summary negotiated by the participants. Dialogue members participated in the meeting in their individual capacities, not as formal representatives of their institutions.[3]

BIOSAFETY – A PRIORITY IN SUB-SAHARAN AFRICA

At several times in the discussions, participants raised the question of whether (funding for) biosafety scientific capacity building and the development of biosafety systems in

[1] For discussion purposes, participants used the following definition of biosafety: "*policies and procedures adopted to ensure the safe application of biotechnology products*." Furthermore, participants agreed that their discussion should not be limited to issues related to transboundary movements of LMOs.
[2] Meridian Institute is a neutral, non-governmental, non-profit organization whose mission is to help diverse interests solve problems and resolve conflicts arising from the integration of environmental, economic, and social issues. Please visit www.merid.org for more information about Meridian Institute.
[3] A participant list is included as Appendix D.

general should be a priority for countries in sub-Saharan Africa, especially those countries that do not have their own biotechnology research and development programs. Several participants indicated that pressures to develop biosafety systems are coming from different directions. Even if a country is not developing biotechnology products domestically, there are already several countries that have received requests for permission to import GMOs. Once GMOs are permitted in one country, it is highly likely that they will be exported to neighboring countries through informal seed trade systems. Furthermore, several participants indicated that for those countries that are developing products using biotechnology, it is critical that they put a biosafety system in place. Many participants stated that GMOs will easily cross borders through informal means (e.g., seeds), which suggests the importance of regional approaches and regional cooperation or coordination. Many countries in Africa are already using GMOs in the form of imported commodities for food and feed.

THE ROLE OF SCIENTISTS IN THE BIOSAFETY ARENA

It is obvious that scientists play critical, but different roles in the series of processes and activities that make up the biosafety decision-making process. Scientists operate within a biosafety system that consists of: laws, regulations, and guidelines; institutional bodies and frameworks; risk assessment and risk management (including post-release monitoring) processes; and mechanisms for feedback to improve the system. Within the biosafety system, scientists participate in different aspects of the decision-making process about the safe application of biotechnology products, and their roles may include:

- Carrying out risk assessments and reviews;
- Supporting specific regulatory review processes;
- Assisting the public and decision-makers in interpreting scientific data on the risks and benefits of GMOs;
- Advising government ministries on biosafety policies;
- Undertaking biosafety research to fill regional gaps in biosafety data; or
- Training other scientists.

The Role of Scientists in Risk Assessment vs. Decision-Making

For the purpose of analyzing the role of scientists in the biosafety arena, participants discussed the distinctions between science-based activities such as risk assessments on the one hand and policy-based activities such as risk management and biosafety decision-making on the other. Scientists play an obvious role in carrying out and evaluating the predominantly scientific activities related to risk assessments, and get involved in the scientific aspects of risk management (such as reviewing risk management plans and monitoring environmental impacts). In risk management and decision-making scientists play an important role as advisors and communicators when they inform decision-makers and the public about the results of scientific risk assessments, help decision-makers (and the public) interpret these results, advocate for certain decisions, or perform an official duty, for instance as members of a decision-making body.

These different roles have obvious implications for the capacity-building needs. One participant stressed that there is power in recognizing the differences between the scientific risk assessment process and the decision-making process, and that scientists need to address both, simultaneously. In the scientific process, scientists may attempt to determine the degree of risk associated with certain technologies. In the decision-making process, society has to decide as to what level of risk is acceptable.

Scientific Expertise Needed for Biosafety Risk Assessments

Many different scientific disciplines are involved in performing biosafety risk assessments. The following overview shows the main disciplines used for 150 risk assessment reviews conducted in South Africa:

Scientific expertise needed for the first 150 risk assessment reviews in South Africa between 1989 and 1997[4]		
Molecular biology Microbiology Biochemistry	Plant Physiology Plant Pathology Plant Taxonomy	Entomology Agronomy Plant Genetics
Ecology Pollination Biology Human Health Veterinary Science	Soil Biology Food Safety Environmental Risk Assessment Weather	Transport Legal and more …

Scientific Expertise for Biosafety and Other Risk Assessments

Most participants agreed that scientific expertise needed for conducting and reviewing risk assessments for agricultural biotechnology products overlaps significantly with expertise needed for non-GM agricultural products. Thus, participants maintained a view that strategies for developing biosafety scientific expertise should consider the synergies with projects focused on capacity building in other arenas such as food safety, biocontrol and conventional agricultural. A few participants stated their view that the biological mechanisms and possible impacts of GMOs are not fundamentally different from non-GMOs and, thus, should be treated similarly.

The participant from the Food and Agricultural Organization (FAO) introduced the concept of *biosecurity, which puts biosafety in a broader framework of approaches to avoid or minimize risk to agriculture from all potentially harmful species, including invasive species and GMOs.* Some participants noted that adopting the broad scope of the biosecurity concept would stimulate countries to develop a coordinated approach to

[4] This overview was provided by Ms. Muffy Koch, Innovation Biotechnology, Kyalami, South Africa.

the requirements of a range of related international treaties, such as the Cartagena Protocol on Biosafety, the Codex Alimentarius, and the International Plant Protection Convention.

Some participants, while acknowledging the usefulness of concepts such as biosecurity, felt that countries in sub-Saharan Africa should initially focus their efforts and resources on enhancing scientific expertise regarding the safe application of biotechnology products (biosafety). They thought that biosafety systems could later be expanded and integrated with other systems to cover the broader scope of biosecurity.

The Role of Scientists in Decision-Making

As scientists study the impacts of biotechnology products and modified organisms, they have to also assist decision-makers and the public in interpreting research results. *In particular, scientists need to help people decide whether certain measured effects are dangerous or not.* For instance, if research shows that genetically modified material has spread from a GM crop to non-GM crop several miles away, researchers need to help people understand whether this finding should be cause for concern or not. Participants identified a need for more research to determine to what extent GMOs present a risk to human health and the environment.

To facilitate clear communication between scientists and decision-makers but also with the public, countries need to develop strong links between scientific risk assessments, biosafety decision-making and broader biotechnology policies. Unfortunately, these links are often weak or non-existent.

The Role of Scientists in Communicating with the Public

Participants raised several issues regarding the role of scientists in communicating with the public. Most agreed that scientists have an important role to play in educating the public about the risks and benefits of GMOs and assisting society in making informed decisions about the acceptability of GMOs. As they communicate with the public, scientists will face several challenges, such as:

- A lack of understanding of biotechnology by the general public;
- Existing negative public perceptions of risk associated with GMOs;
- Influence of public concerns in Europe on public perceptions in Africa, especially public concerns in those European countries with which they have historical ties;
- A lack of coordination between government ministries and departments that may negatively influence public trust in the decision-making system; and,
- Conditions attached to research funding that may negatively influence the public's perception of scientific independence.

APPROACHES TO RISK ASSESSEMENT AND REVIEW

Of the African countries represented at the meeting, South Africa probably has the most experience with biosafety assessments. *In relation to both domestic and international permit applications South Africa has used information provided by the applicants, without having to conduct their own tests. Applicants provide the detailed information required to review an application, so that the government's risk assessment becomes a paper exercise.* If the information provided by an applicant is unclear or incomplete in some areas, South Africa asks the applicant to perform additional research or testing. The review board carefully reviews and assesses the data provided and will work closely with applicants to try and address constraints they face in obtaining the data requested. A country using this system would not have to develop its own risk assessment infrastructure.

Participants saw merit in this approach, but many indicated that some level of national capacity to carry out tests would be required. Regarding imported crops, the political climate in many countries requires they test for GM content to satisfy public concerns.

In order to optimize resources for conducting risk assessments, some participants suggested looking into regional approaches that avoid duplication of risk assessments and might consist of developing regional centers of excellence that review or conduct risk assessments. *Participants were receptive to the idea of regional coordination and possibly developing regional centers of excellence as long as they were connected to national initiatives and activities.*

Need for a Flexible Biosafety System

In an approach where the applicant is required to provide all the information necessary for a risk assessment review, the cost may become prohibitive for domestic researchers, especially those in the public sector. Participants suggested that the review system should be flexible. For instance, countries could develop a fee structure that considers differences between applicants (e.g., public sector or private sector). The system could also set flexible standards, but that would create difficulties as to ensuring transparency and equity of the system and maintaining a level playing field for all stakeholders, and may compromise public trust in the system (public backlash could result from lower standards and the perception that this would let a developing country become a testing or a dumping ground for GMOs).

Participants agreed that the system should be a learning system that, over time, uses the lessons learned through experience to make the system effective and easy to operate, and builds confidence in its ability to deal with the complex (scientific) aspects of biosafety. Participants also raised the question how the system could balance protection (of the public) and proportionality (of the regulatory requirements set for the product compared to the risks associated with the product).

In developing biosafety systems, some participants suggested that countries study and learn from approaches used in the United States and Europe. Other participants cautioned that systems in Europe and the United States might not be appropriate for countries in sub-Saharan Africa. In particular, some participants suggested that the costs associated with getting approvals for products under these systems, if adopted by African countries could prevent technologies from reaching subsistence farmers. In response to this observation, a participant suggested that developing countries examine the regulatory approval process used for the development of virus resistant papaya by Cornell University and the University of Hawaii; the process used for this product allowed these public sector institutions to maneuver through the regulatory system without the investment ordinarily made by private sector companies.

Biosafety Committees

In relation to the discussion of biosafety systems, participants briefly talked about how you select members of a biosafety committee – should they be scientists, or political appointees? Most felt that the biosafety committee should reflect the objective and scope of the biosafety policies that are in place. Expertise on the types of issues addressed in these policies, such as technology transfer, protection of indigenous knowledge and resources, or socio-economic issues should be reflected in the committee. Different approaches can be used to make the right scientific expertise available to the biosafety committee. Scientists of different disciplines can be appointed to the committee, or the committee can be given the authority to engage any scientific expert that is appropriate to the case in its decision-making.

NEEDS AND STRATEGIES RELATIVE TO ENHANCING BIOSAFETY SCIENTIFIC EXPERTISE IN SUB-SAHARAN AFRICA

Important work has been carried out or is underway to enhance biosafety scientific expertise in sub-Saharan Africa. Information on many relevant programs was compiled by Meridian Institute prior to the meeting and included in the background materials for meeting participants. Participants also made additional materials available at the meeting. A list of references can be found in Appendix A. Furthermore, participants provided verbal information on relevant initiatives. Appendix B contains a summary of the information provided by dialogue participants.

Based on their common knowledge of baseline activities for the enhancement of biosafety scientific expertise, participants identified an extensive list of needs and possible strategies (see Appendix C) and emphasized that each is important and merits closer examination. However, due to time constraints they selected the following five categories of needs for detailed discussions:

- Training;
- Research;
- Communication;

- Coordination; and,
- Management Systems.

Participants broke up into five sub-groups, and each sub-group discussed one of these priority categories of needs. The groups met for nearly ½ a day and reported the specific needs and strategies they identified to the plenary. Each of the five topics was also discussed in plenary. Following is a summary of the sub-group reports and the plenary discussions on each topic. Participants noted regional differences in scientific capacity, for instance between West and Central Africa and Southern and Eastern Africa, but did not specify how those regional differences affect needs and strategies for enhancing biosafety scientific expertise in sub-Saharan Africa.

Training

The sub-group identified five priority objectives for training programs and an extensive range of strategies for achieving these priority objectives.

Priority Objectives
Create competence in risk assessment methodology and decision-making processes (risk-benefit). *Target group: scientists and biosafety boards*
Create familiarity with risk assessment methodology. *Target group: biosafety boards*
Create awareness of risk assessment methodology. *Target group: media, civil society, and general public*
Create national and regional core group of expertise (a core group of experts that can further train others). *Target group: scientists*
Enhance regional and national scientific capacity in risk assessment. *Target group: scientists*

Strategies
Compile training manuals.
Conduct biosafety training needs assessments.
Test biosafety regulatory mechanism (do a dry run of regulatory mechanisms to familiarize everyone involved with the system).
Create databases.
Create a learning system by monitoring and evaluating activities.
Create fellowships and internships.
Create reverse fellowships.
Develop appropriate colloquiums about national regulatory systems at local training institutions.
Conduct workshops and seminars to address short-term training needs.
Explore opportunities for distance and e-learning.
Identify content providers (experts who can assist in identifying information needed for risk assessments and decision-making).
Coordinate training programs at national and regional level.
Take advantage of worldwide expertise in areas of concern using existing bilateral and international organizations.
Develop mechanisms for developing country access to information that is available internationally (for instance by organizing international workshops and fora).
Identify sources for basic information.
Promote South-South cooperation on specific commodities.

A lively discussion followed presentation of these objectives and strategies. Participants wondered how training should be funded. Several participants indicated that many training programs exist and that several donor agencies are funding such programs. However, participants also felt that coordination among donors should be improved in

order to maximize resources. *The UNEP/GEF program has made coordination one of its tasks and it is developing a matrix of available training programs and resources. In addition, during a recent stakeholder meeting in Southern Africa, the FAO was singled out as a trusted source of information and ideally situated to take on a coordinating role.* Several participants felt that those who take on a coordinating role need to involve stakeholders in Africa in their activities to ensure that their priorities are reflected in donor programs. Others also suggested that the organization that takes on a coordinating role should employ some form of quality control for training programs and resources.

Several suggestions were made for making training programs sustainable. Participants recognized the importance of targeting training programs to specific needs and circumstances in each country, but they also indicated that core training materials can be developed that can be adapted to different situations and can be used repeatedly. Core training materials already exist that use case-studies as training material, for example: Michigan State University has developed training materials focused on Africa, and a Dutch funded project for biosafety in Central and Eastern Europe has also developed training materials (See information on the Matra project at http://www.biosafety-cee.org/frames.htm). These materials can be adapted and expanded to meet needs in sub-Saharan Africa. Another suggestion was that African experts gain the knowledge and skills to train others in their home countries (train-the-trainer concept).

Participants also discussed what training would be needed to help scientists communicate with policy-makers about the potential risks and benefits associated with specific GMOs. One suggestion was that content providers would help provide information for scientists, the general public, and policy makers that would help people with the interpretation of information about GMOs. Some participants also suggested that risk experts should play a coordinating role in steering people to the best sources of information.

Special attention was given to the idea of developing case studies and workshops on analysis of already performed risk assessments for specific commodities in different developing countries. Such case studies would provide concrete examples of how GM crops are being grown and what guidelines/best practices have been established that work well in practice. Regional review workshops could be organized to assess existing biosafety data on commodities that are approved in the United States, Europe, or elsewhere and used in Africa, and identify gaps in available data. These workshops could also develop statements on biosafety aspects of specific commodities. These concrete examples would be good training materials, but would also provide good information to communicate to the general public and help people understand how biotechnology and biosafety work in practice. The FAO and the University of Zimbabwe are exploring the possibility of carrying out such case studies.

Biosafety Research

The sub-group defined biosafety research as the collection of relevant and complementary data for risk assessment and decision-making in African release environments. The group identified the following priority areas where research is needed:

Priority Needs
Impact of GMOs on flora and fauna (biodiversity, non-targeted species, gene-flows, microorganisms, nematodes, etc).
Impact on small farmers cropping systems (there are also large commercial farms, but that is not where additional research is most pressing).
Identification of relevant baseline data.
Refinement of field trial protocols (best practices – trials undertaken vary per region, and protocols need to be refined for specific regions).
Post release monitoring systems (development of methodologies about what to do when there is impact after release).
Review food safety data (information to consumers about how safe this food is and if it meets Codex Alimentarius criteria).
Resistance management of pests (need to know level of resistance that is built in some of these products and how to manage this).

Strategies
Development of regional collaborative research (prevent duplication between countries).
Encourage linkages between applicants, NARS, universities (also discuss with private sector applicants).
Ask applicants to relate risk assessment to small farming systems.
Analyze food safety data of existing GMO products at sub-regional level (prevent duplication).

Participants in the discussion pointed out that basic data is needed on biodiversity and ecosystems, and on the effects of farming practices on ecosystems and biodiversity. A study of the effects of a specific crop (and/or livestock) in the local environment would be useful. They also indicated that resistance management is an important research topic. Participants suggested that the institutions best positioned to conduct the necessary research should be identified on a case-by-case basis, based on the specialized knowledge of the topic in question.

Participants indicated that it would be useful to assess existing research, such as the research conducted in North America, Europe and baseline data collected in East Africa under the BIO-EARN program. A participant suggested that African scientists should consider contacting the Science Council of the CG system because the science council has called for ideas about challenge problems. Some of the ideas expressed by participants in this dialogue could be submitted to the science council for a challenge problem.

Communication

The sub-group stressed that communication includes information sharing and networking among scientists, between scientists and policy-makers, and between scientists and the general public, but focused its time on needs and strategies regarding communication among scientists. The group summarized benefits of communication and identified strategies for increased communication among scientists.

Benefits of Communication
Prevents duplication of efforts.
Increases leverage for scientists.
Helps identify stakeholder needs.
Increases public participation.
Stimulates South-South collaboration.

Strategies
Develop case studies of biosafety scenarios in Africa. It would be useful to involve commodity networks and include commodity related research.
Establish information centers (with increased access to the Internet). There is a need for developing information centers in each country and some budget to establish and continue these centers.
North-South collaboration in the form of internships and distribution of information by international research centers.

Several participants stressed that communication with the public is of the highest priority. One participant stressed that effective communication with the public can be achieved by targeting information to the needs and concerns of specific stakeholder groups (such as consumers, farmers, etc.). Another suggested that scientists in Africa should carry out needs assessments to identify the key questions the public is most concerned with. Research that responds to a clear need or concern will be easier to communicate.

Communication needs to be two-way; it needs to provide information and listen to concerns and perspectives. A participant recounted his experiences working with farmers and engaging them in the decision-making process regarding GMOs. The open communication yielded information that was valuable in the decision-making process, but it also made these stakeholders aware of and informed about the issues relating to the possible release of a GM crop.

Participants discussed the connection between training and communication, and indicated that *communication and raising awareness can effectively be achieved through undergraduate programs that include biosafety training.* The Swiss Centre BATS and several groups in South Africa and Zimbabwe either have programs or are developing programs to integrate biosafety training in high school curricula.

Participants also addressed the role of the press in communicating scientific information to the public. One participant indicated that the press's primary task is to inform the public. Educating the public is a secondary task (if at all). Some participants indicated that African press has participated in funded, educational projects. The Community Technology Development Association of Zimbabwe has experience engaging the media in workshops and providing them with information, such as fact sheets. and assistance in interpreting biosafety information. Participants suggested developing a clearinghouse of experts who can communicate with the public and the press as issues arise. Others suggested that phone in radio programs can be an effective medium to work with the media and reach out to the public.

A participant pointed out that the Biosafety Association in France may be of great help to scientists communicating amongst each other and getting access to journals, case studies of African examples, and Africa specific teaching modules.

The German Development Agency GTZ is funding projects for public communication about biosafety, and may be interested in additional proposals.

Coordination

The sub-group took a four-step approach that included identifying:

1) what needs coordination;
2) at what level coordination needs to happen;
3) why coordination is beneficial; and,
4) strategies for promoting coordination.

Coordination of What?
Rules and policies.
Risk assessment and management.
Advocacy and dialogue.
Networks and scientific capacities.
Training.
Collaborative research projects.
Regional centers of excellence.
Information dissemination.
Funding.
National biosafety frameworks and regional harmonization.
Curricula development.
Technology transfer between public and private sectors at regional and national levels.

Coordination at What Levels?
National (various national institutions share responsibilities and authority).
Regional (a joint approach across the African continent).
Sub-Regional.

Why Coordinate?
To facilitate efficient utilization of resources to avoid duplication of resources both physical and human.
To facilitate timely review of applications.
To facilitate transboundary movements and collaboration in research.
To facilitate harmonization and coordination for multi-donor projects.
To facilitate communications at country and regional levels.
Facilitate harmonization of biosafety systems.

Strategies
Ensure effective advocacy, leadership in advocacy, and dialogue.
Create networks of scientists and laboratories within countries and regions.
Offer training opportunities at national and regional levels.
Develop collaborative joint research projects.
Develop regional centers of excellence to provide information on biosafety.
Seek funding for biosafety activities from donor/partner agencies (national and international).
Promote development of national biosafety frameworks and regional harmonization.
Create mechanisms for information dissemination to enhance biosafety transparency and public trust.
Develop appropriate curricula for training.
Link good breeding programs to biotechnology and biosafety programs.
Act as a broker in technology transfer between public and private sectors at regional and national levels.

Participants distinguished between networking, coordination and harmonization. They suggested that networking and voluntary coordination are relatively easy steps to take and may be a stepping-stone to more formal coordination. Formal coordination will require increased national commitments and authority vested in a coordinating body. *Examples of coordinating bodies that already exist are BIO-EARN, ASARECA and UNEP/GE. All have some level of intergovernmental authority and play coordinating roles. The SARB Programme and Biotechnology Trust of Zimbabwe (BTZ) also plays a coordinating role. The coordinating roles of these organizations are still evolving.*

Participants held divergent views on the need for harmonization (of policies and regulations). Some felt that, although coordination is essential, harmonization might not be necessary. Others felt strongly that harmonization is essential to strengthen regional efforts.

Participants briefly discussed the experience with the biosafety focal point, which was based in Harare during the 1990's, but was discontinued due to lack of funding and government commitment. This focal point had a strong coordinating function and was seen as successful in launching several biosafety initiatives in Eastern and Southern Africa. Participants felt that a lack of support from national governments in the region eventually caused this project to falter.

Management Systems

The sub-group that discussed this topic suggested that the Cartagena Protocol on Biosafety offers countries a framework for biosafety management systems, but that other issues such as trade and domestic concerns should also be taken into account when developing management systems. In this context, sovereign decision-making authority is a guiding principle, but common features across borders would be useful considering the regional aspects of biosafety. National management systems can assist in coordinating the many activities that are already going on in each country.

Regardless of what format countries choose, the management system should be well defined with clear rules, roles and responsibilities within the system. Countries should have one national system managed by a competent body with a focal point, and with parallel tracks for medical, plants, and other products (it should be one system with different sources of expertise).

Functions of a Management System
Receive ideas and applications.
Process applications.
Assess applications and formulate recommendations.
Move applications to decision-making authority.
Raise public awareness and coordination.
Set clear standards.
Receive support from the authorizing environment.

Features of a Management System
It should be realistic, affordable, relevant, lean and efficient.
Responsibilities in the system should be divided between a registrar/secretariat, and a national body (a council, board, or commission), which is made up of stakeholders. This national body should be competent and representative.
The council need not be expert, but needs access to national, regional, and international scientific and other expertise.
A management system may consist of two or three tracks within one structure; a track for national applications and tracks for foreign or commercial applications. A system consisting of different tracks would address the issue of different resources and levels of expertise between different applicants, but it would need to resolve the issue of equity. In recognizing the need to assist domestic applicants, the system could include a flexible fee structure; a council to help local entrepreneurs; and an international grant facility.
The management system would need sufficient resources, including expertise and information technology.

Strategies
Be flexible in developing a system: big countries that export will need a different system from smaller countries that are concerned with local production.
Countries also need to decide whether and how the system modifies a precautionary approach by applying the principle of proportionality.
Recognize the value in partnerships, partnerships between countries, public-private partnerships, etc.
Develop a learning system and facilitate information exchange about the system.
Address issues of intellectual property protection and confidentiality by developing a system that is transparent, and at the same time applies confidentiality policies that prevent company investments from becoming freely available to competitors in the marketplace.
Address ethical issues relating to biosafety and biotechnology.

Some participants in the plenary discussion stressed the need to develop management systems that are lean and efficient. Many of the systems currently being put in place are very laborious. Countries need to learn from these experiences and adapt their systems to result in lean and efficient structures. Others suggested that assessments of existing biosafety systems would be very valuable (e.g., ISNAR studies referenced in Annex A).

CONCLUDING REMARKS

Many building blocks for biosafety systems are being put in place in sub-Saharan Africa, and many programs and initiatives are taking place to enhance the scientific expertise necessary to implement biosafety systems. It was clear that many participants from countries in sub-Saharan Africa place great importance on developing biosafety systems to be able to respond to developments at national, regional and international levels. As countries decide on whether to develop biosafety systems, they need to develop systems that are clear, transparent and flexible and are designed to adapt to the lessons learned and experience gained over time.

It is obvious that scientists play critical, but different roles as they carry out risk assessments and reviews, and as they assist the public and decision-makers in interpreting scientific data on the risks and benefits of GMOs. There are many opportunities for enhancing the expertise available in sub-Saharan Africa's scientific community to perform their different roles in relation to biosafety. In order to capitalize on these opportunities and maximize resources, activities need to be responsive to national needs and concerns, and countries should look at programs and activities that are already in place and build on those activities so that they become institutionalized and sustainable. There is an important role for regional activities to support national level efforts by coordinating activities and possibly sharing tasks (such as risk assessments).

Participants showed considerable enthusiasm for several specific suggestions for biosafety capacity building initiatives to enhance existing expertise, programs and initiatives in sub-Saharan Africa. Some of the suggestions expressed during the meeting, include:

- Developing case studies and workshops on analysis of existing risk assessments for specific commodities;
- Developing programs to involve the press in communicating scientific information to the public;
- Analyzing and further developing the coordinating role of existing organizations;
- Analyzing existing biosafety research (from the United States, Europe, Africa, and elsewhere) to assess where gaps exist in data that is relevant to Africa;
- Continuing to strengthen relationships between scientists in Africa to facilitate information exchange, coordination and collaboration.

Several individuals at the meeting indicated their interest in following up on these suggestions and using the connections established during the meeting to collaborate on developing additional activities.

APPENDIX A

ENHANCING BIOSAFETY SCIENTIFIC EXPERTISE
REFERENCES TO INFORMATION ON PAST AND CURRENT PROGRAMS*

12-14 March 2002 – Grottaferrata, Italy

The documents referred to below were part of the background materials sent to dialogue participants ahead of the meeting, or were handed out to participants at the meeting. Copies of the documents can be obtained by contacting Shawn Walker of Meridian Institute by e-mail at shawnwalker@merid.org.

General Background on Biosafety Capacity Building

1. Joel I. Cohen (2001) "Harnessing Biotechnology for the Poor: challenges ahead for capacity, safety and public investment", Journal of Human Development, Vol. 2, No. 2

Enhancing Biosafety Scientific Expertise - Related Activities

2. Recommendations from the African Consultation of Government-Designated Experts to Review Draft International Technical Guidelines for Safety in Biotechnology and Related Capacity-Building Requirements (6 September 1995), in Report of the Global Consultations of Government Designated Experts on International Technical Guidelines for Safety in Biotechnology, United Nations Development Programme, UNEP/Global Consultations/Biosafety/Inf.1

3. BMZ (2000) "Capacity Building for the Implementation of the Cartagena Protocol on Biosafety", The German Federal Ministry for Economic Cooperation and Development, Bonn, Germany

4. Centre BATS, Description of Organization and PowerPoint Slides of New Biosafety Training Program, www.bats.ch

5. Executive Secretary of the Convention on Biological Diversity (2000) "Capacity-Building (Article 22, Article 28): Indicative framework for capacity-building under the Cartagena Protocol on Biosafety", CBD Secretariat, Montreal, Canada, document available at www.biodiv.org

* This is not an exhaustive overview of past and current activities for enhancing biosafety scientific capacity in sub-Saharan Africa, but provides sources for information on key programs and initiatives as identified by the participants in the dialogue on Enhancing Biosafety Scientific Expertise in Sub-Saharan Africa.

6. International Centre for Genetic Engineering and Biotechnology, Description of Organization, Risk Assessment Searching Mechanism, Bibliographic Biosafety Database, and Biosafety Workshop, available at www.icgeb.trieste.it.

7. Third World Academy of Sciences (2000) "Scientific Capacity Building in Africa; Participants at a meeting in Trieste explore new options for getting Africa's scientific research efforts back on track", TWAS Newsletter, Vol. 12, No. 2, Trieste, Italy.

8. Third World Academy of Sciences (2001) "Pathways of Hope; Programmes to combat river blindness provide both a success story and cautionary tale", TWAS Newsletter, Vol. 13, No. 1, Trieste, Italy.

9. ICCP (2001) "Report of the Intergovernmental Committee for the Cartagena Protocol on Biosafety on the Work of its Second Meeting", CBD Secretariat, Montreal, Canada, document available at www.biodiv.org.

10. Convention on Biological Diversity, Capacity-Building Efforts of Biotechnology Industry, project information accessed on February 27, 2002 at http://bch.biodiv.org/Pilot/

11. Convention on Biological Diversity, Biosafety Clearing-House, information accessed on February 27, 2002 at http://bch.biodiv.org/Pilot/

12. GEF Council (2000) "Initial Strategy for Assisting Countries to Prepare for the Entry Into Force of the Cartagena Protocol on Biosafety", Global Environment Facility, Geneva, Switzerland

13. UNEP-GEF Project on Development of National Biosafety Frameworks, Participating Countries in Africa, www.unep.ch/biosafety

Biosafety in sub-Saharan Africa

Documents describing scientific expertise, technical and regulatory capacity relevant to biosafety and biotechnology in sub-Saharan Africa.

14. Agricultural Biotechnology Assessment in Zimbabwe

15. ASARECA (1999) "Considering Biosafety and Biotechnology from an ASARECA Perspective: Assessing the Feasibility of a Regional Initiative on Biotechnology for Agricultural Research in Eastern and Central Africa" Association for Strengthening Agricultural Research in Eastern and Central Africa, Uganda

16. BIO-EARN Program information, www.bio-earn.org

17. J.S. Kasonta (1999) “Status of Biotechnology in Tanzania: National Activities, Priorities and Policies”, Tanzania Commission for Science and Technology, P.O. Box 4302, Dar es Salaam, Tanzania

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APPENDIX B

ENHANCING BIOSAFETY SCIENTIFIC EXPERTISE INFORMATION ON PAST AND CURRENT PROGRAMS IN SUB-SAHARAN AFRICA AS PROVIDED BY DIALOGUE PARTICIPANTS

12-14 March 2002 – Grottaferrata, Italy

During the dialogue, participants provided information on a number of relevant programs and initiatives. The following overview contains cursory information on these programs. Additional information can be found by following the links to each program's website or by directly contacting the program.

- AfricaBio (http://www.africabio.com/index.shtml) conducts a number of public awareness projects and projects relating to policy issues in biotechnology and biosafety in Southern Africa (South Africa, Zimbabwe, Zambia, Malawi, Mozambique, Namibia).

- African Biotechnology Stakeholders Forum (ABSF - www.absfafrica.org/main.htm) runs programs to raise awareness and address biotechnology policy issues in Kenya, Uganda, Tanzania, and Ethiopia.

- The Agricultural Biotechnology Support Project (ABSP - http://www.iia.msu.edu/absp/ is working with a team of biosafety experts in the development of a "Workbook on Risk Assessment and Risk Management for Agricultural Biotechnology." The workbook is designed to complement technical training for developing country scientists, Institutional Biosafety Committee members, and members of the National Biosafety Committees. The workbook is being tested in Africa.

- Biotechnology Trust of Zimbabwe is working on a Consultative Regional Biosafety Project in Eastern and Southern Africa to assess constraints, gaps, needs and priorities in biosafety and biotechnology. This regional assessment assumes that GM products will move between countries once they have been introduced in one country or another.

- The East African Regional Program and Research Network for Biotechnology, Biosafety, and Biotechnology Policy Development (BIO-EARN – www.bio-earn.org) is developing a biosafety training manual that covers risk assessment but also decision-making. The manual is being tested in Africa. BIO-EARN is also involved in developing prototypes of good practices manuals for laboratories.

- The Food and Agricultural Organization (FAO - www.fao.org) is preparing a biosafety briefing guide for decision-makers. The guide is about to go to press. The FAO has also conducted a survey of biotechnology and biosafety in Africa that will be available shortly. FAO is working to build a database of training initiatives and

manuals in the world to capitalize on available resources. FAO itself gets many requests for assistance that include training, and will consider such requests from countries in sub-Saharan Africa.

- The International Plant Genetic Resources Institute (IPGRI – www.ipgri.org) has secured funding from Portugal to conduct a biotechnology needs assessment for Portuguese speaking countries.

- ISNAR (www.cgiar.org/isnar) and Virginia Polytechnic Institute and State University (Virginia Tech) have established a collaborative research project to review the design and implementation of biosafety policies and procedures in developing countries. The joint project will develop a set of recommendations that address identified gaps in the technical, human, and information resources needed to strengthen a national biosafety regulatory system. Under this partnership, biosafety country studies have been conducted in Egypt and Argentina, and support has been provided to a range of biosafety capacity-building initiatives, primarily in sub-Sahara Africa. ISNAR and Virginia Tech are currently developing a comprehensive, long-term program to support biosafety policy development and implementation, which will have a strong focus on sub-Sahara Africa.

- Southern African Regional Biosafety (SARB) Programme seeks to build biosafety capacity in Southern Africa by running regional and national activities identified by stakeholders as important for capacity development. This program will also support regional cooperation and the harmonization of biosafety implementation in the region.

- The Rockefeller Foundation (www.rockfound.org) funds numerous activities related to food security, biotechnology, biosafety, and intellectual property rights. Some of the projects highlighted during the meeting included:

  - A project that involves several universities in sub-Saharan Africa who are collaborating on issues relating to agricultural biotechnology, such as intellectual property and plant breeding. The University of Cape Town coordinates the project.
  - The Rockefeller Foundation also supports projects focused on raising awareness and addressing policy issues relating to agricultural biotechnology that are run by AfricaBio (projects in South Africa, Zimbabwe, Zambia, Malawi, Mozambique, Namibia), and ABSF (projects in Kenya, Uganda, Tanzania, and Ethiopia).
  - The Rockefeller Foundation is working to develop, with assistance from other funders, the African Agricultural Technology Foundation, which will facilitate and manage transfer of agricultural technologies between companies and countries in sub-Saharan Africa.

- Third World Academy of Sciences (TWAS – www.twas.org) is involved in at least two programs that may be relevant to biosafety scientific expertise. TWAS and the South Centre publish a database of 450 research centers and universities in

developing countries that contribute to the indigenous plant network. A TWAS fellowship program has been in place for 20 years, which targets young scientists for South-South collaboration.

- The UNEP/GEF global project on the development of National Biosafety Frameworks (http://www.unep.ch/biosafety/index.htm), in addition to assisting countries in developing biosafety frameworks, has recently approved assistance to eight African countries to implement these countries' biosafety frameworks. Assistance will address issues regarding database development, laboratories for GMO detection, etc.

- Cote d'Ivoire and Nigeria have been working on biosafety laws and both countries are close to completing their legislation.

- Zimbabwe has a regulatory framework for biotechnology and biosafety. The country also has established the Biotechnology Association of Zimbabwe, which has membership from cross-sections of stakeholders to discuss and elucidate controversial matters regarding biotechnology and biosafety.

A brief discussion of three regional African programs follows. Those who are interested in learning more about each regional program are encouraged to visit the program websites or contact the program directly. Appendix A contains references to documents regarding each program.

- The BIO-EARN program (www.bio-earn.org) was developed after extensive consultations with the participating countries. The program's principal objective is to build national capacity and competence in biotechnology, biosafety and biotechnology policy in Ethiopia, Kenya, Tanzania, and Uganda. The program is designed to respond to needs identified by stakeholders in the region (e.g., biosafety and policy-related issues such as intellectual property and access to genetic resources have been added to the program since its inception).

  The first phase of the BIO-EARN program focused on developing research and institutional capacity. There are 17 Ph.D. projects underway; 14 relate to biotechnology, and 3 are specific to biosafety researching basic biological information on east African crops and wild relatives. Each student is provided with a budget for acquiring laboratory and other research equipment. Several students have consolidated their budget and are sharing equipment.

  BIO-EARN has developed regional biosafety training programs and national workshops, and has conducted over 15 workshops aimed at building institutional and personal capacity in biosafety risk management and risk assessment.

  Funding during the first 3 years of the program was, among others, used to acquire laboratory equipment for each Ph.D. student. Funding during the next 3 years of the program will also be applied to help build information technology capacity and

acquire other equipment. National governments in the region are providing in-kind support, such as support staff, laboratory space, Internet running costs, etc.

- The UNEP/GEF global project on the development of National Biosafety Frameworks (www.unep.ch/biosafety) uses a strategy that involves assisting countries in developing national frameworks, providing information on the legal and regulatory aspects of biosafety, and coordinating activities with other organizations. It is now working with 43 countries in Africa that are putting frameworks in place, and is creating linkages between these countries, for instance by organizing regional workshops and collaboration, and encourages information sharing to improve networking. Workshops have been organized to share information and share lessons learned from the pilot phase of the UNEP/GEF project.
  During 2002, the project is planning to conduct two regional workshops on risk assessment in Africa. The workshops will address priority issues for risk assessments, and develop a mechanism for collaboration and sharing risk assessment tasks.

- The Association for Strengthening Agricultural Research in Eastern and Central Africa (ASARECA – www.asareca.org) is developing an initiative on biotechnology and biosafety. The initiative is still in its planning phase. Planning is being conducted at the national level (in the 10 member countries) and at regional level and involves a broad range of stakeholders. It is believed that a regional approach will increase critical mass for biotechnology research and a regional approach will facilitate dissemination of national level research to other countries.

APPENDIX C

AN OVERVIEW OF NEEDS AND STRATEGIES REGARDING ENHANCEMENT OF BIOSAFETY SCIENTIFIC CAPACITY IN SUB-SAHARAN AFRICA

Needs
Risk Assessment ▪ Ability to coordinate multi-disciplinary analyses ▪ Enhancement of technological and institutional capacities for risk assessment ▪ Capacity to identify and access appropriate outside expertise ▪ Understanding of relevant biotechnology processes and applications ▪ Enhancement of related scientific, technical capacities
Communication ▪ Among scientists ▪ Between scientists and policy makers ▪ Among national level ministries and institutions ▪ Increase public understanding of biotechnology ▪ Increasing role of scientists as advocates for biotechnology and biosafety
Biosafety research ▪ Assessment of existing biosafety data to identify gaps ▪ Biosafety research to generate appropriate data for tropical and equatorial environments ▪ Country-driven as opposed to donor-driven priorities (research specifically designed to address country needs) ▪ Analyze risks to conservation and sustainable use of biodiversity ▪ Analyze risks to human health of effects on biodiversity ▪ Analyze ecosystem effects of living modified organism introduction ▪ Information regarding the effects of biotechnology products and whether these effects matter (what systems, tests, or thresholds are needed); communicate and understand not only risk, but also harm ▪ Inventory of existing and anticipated biotechnology programs and practices
Training for scientists, technicians and decision-makers ▪ Training for scientists and technicians ▪ Training for decision-makers, such as officers in ministries and other personnel involved in the biosafety system ▪ Training at every level; each country needs its own expertise ▪ Human resource training in risk assessment and various

disciplines that constitute biotechnology; upgrade laboratories ▪ Assume national biosafety frameworks are being covered by UNEP/GEF project (scientific risk assessment, risk management and monitoring, biosafety communication training) ▪ Training and information exchange; to ensure that national scientific expertise is there and keeping expertise up-to-date (information exchange) ▪ Approved training for scientists and technicians targeted to establishing and maintaining standards
Building institutional frameworks, including institutional capacities beyond individuals
Staff continuity – incentives to prevent qualified staff from switching to other jobs in the same country or abroad
Technicians to support Ph.D. level staff
National government support (financial and organizational) ▪ Capacity building needs to be country driven with national government support ▪ National leadership, ownership and support including staffing, funding, standards, and processes
Sustainable funding for both salaries and operational budgets ▪ Capacity building in a holistic manner that will ensure sustainable funding and relevant supporting mechanisms to retain capacity built ▪ Integration of existing initiatives into a coherent, realistic and sustainable system (how and by whom?) ▪ Sustainability and continuity of biotechnology and biosafety initiatives
Management systems and structures to support biosafety ▪ Capacity to assure the integrity of safety data. - Who does the tests - Standards of Practice, chain of custody, GLPs, etc. ▪ Decision recommendation capacity. Capacity to take a definitive stand on decisions of research, field-testing, and commercialization. ▪ Management systems and structures to support biosafety. A discussion/conclusion on how safety assessments are implemented in administrative procedures is key to achieve a workable system
Evaluation and learning systems ▪ Evaluation of capacity-building projects (lessons learned) ▪ Learning capacity; rules and processes that respond to increasing knowledge by deregulating, or decreasing or increasing stringency of regulation ▪ Evaluation, lesson-learned, monitoring, information sharing (networks)
Greater public trust in scientists and the regulatory system

▪ If biotech products and services are to be evaluated and approved in a product-by-product, case-by-case, nation-by-nation basis, trust between scientific community and larger society is a critical issue
Infrastructure ▪ Laboratories and equipment ▪ Quarantine facilities ▪ Technology development, detection, etc.
Coordination and harmonization of rules and policies within regions and sub-regions ▪ Coordination of the multiplicity of projects and events by multiple donors and stakeholders ▪ Sharing of data and information ▪ Coordination of harmonization of rules and policies within regions and sub-regions (food and biotechnology products will cross borders).
Risk Management Needs ▪ Define specific expertise for biosafety managers ▪ Impartial review of proposed management regime prior to decision-making ▪ Identification and handling of living modified organisms at point of import ▪ Monitoring of environmental impacts against expected impacts

Potential Strategies
Create networks of scientists within countries and regions
Create training opportunities ▪ Training for scientists and laboratory technicians ▪ Industry sponsored training ▪ Regional workshops ▪ Fellowships ▪ Focus on Ph.D. level trainees who can train others
Focus on a few countries in a comprehensive and holistic fashion to "get it right" that could serve as model
Develop collaborative research opportunities
Develop Regional Centers of Excellence. These centers could perform a range of tasks including: ▪ Providing information related to risk assessments ▪ Conducting risk assessments ▪ Conducting targeted testing for GMO content ▪ Etc.
Improve acceptability of information by obtaining information from perceived neutral sources (e.g. FAO) and organizations working on the ground (e.g. SARB, ASARECA, AfricaBio, ACTS, etc.)
Develop structures for integrating scientists in government decision-

making
Introduce biosafety in secondary school and college curricula to raise interest and awareness
Expand conventional breeding programs
Develop public-private partnerships
Increase the number of “on-budget” vs. “off-budget” projects
Use private sector data in risk assessments and relying on private sector to address questions raised by countries in risk assessments

APPENDIX D

MEETING ON ENHANCING BIOSAFETY SCIENTIFIC EXPERTISE IN SUB-SAHARAN AFRICA PARTICIPANT LIST

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