RISK ASSESSMENT AND RISK MANAGEMENT TRAINING

ON GENETICALLY MODIFIED ORGANISMS (GMOs) FOR THE EASTERN AND SOUTHERN AFRICAN COUNTRIES

9-14 AUGUST, 2010
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<td>Advanced Informed Agreement</td>
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<td>AML</td>
<td>African Model Law on Biosafety</td>
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<td>AUC</td>
<td>African Union Commission</td>
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<td>BAT</td>
<td>Biosafety Assessment Tool</td>
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<td>BCH</td>
<td>Biosafety Cleaning house</td>
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<td>BIRC</td>
<td>Biosafety Information Resource centre</td>
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<td>Br</td>
<td>Bacillus thuringiensis</td>
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<td>CBD</td>
<td>Convention on Biological Diversity</td>
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<td>COP-MOP</td>
<td>Conference of the Parties serving as the Meeting of the Parties to the Cartagena Protocol on Biosafety</td>
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<td>CPB</td>
<td>Cartagena Protocol on Biosafety</td>
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<td>DEA</td>
<td>Department of Environmental Affairs</td>
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<td>DNA</td>
<td>Deoxyribonucleic Acid</td>
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<td>EC</td>
<td>European Commission</td>
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<td>EFSA</td>
<td>European Food Safety Authority</td>
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<td>EIA</td>
<td>Environmental Impact Assessment</td>
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<td>EU</td>
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<td>FAO</td>
<td>Food and Agricultural Organization</td>
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<td>FFPs</td>
<td>Food, Feed and Procedures</td>
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<td>GEF</td>
<td>Global Environmental Facility</td>
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<td>GM</td>
<td>Genetic Modification</td>
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<td>GMO(s)</td>
<td>Genetically Modified Organism(s)</td>
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<td>GTZ</td>
<td>Deutsche Gesellschaft fuer Technische Zusammenarbeit</td>
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<td>HRST</td>
<td>Human Resources, Science &amp; Technology</td>
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<td>IgE</td>
<td>Allergen-specific Immunoglobulin E</td>
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<td>LMO(s)</td>
<td>Living Modified Organism(s)</td>
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<td>MOP</td>
<td>Meetings of Parties</td>
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<td>mRNA</td>
<td>Messenger Ribonucleic Acid</td>
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<td>NBC</td>
<td>National Biosafety committee</td>
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<td>NBF</td>
<td>National Biosafety Framework</td>
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<td>NEMA</td>
<td>National Environmental Management Act</td>
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<td>NEMBA</td>
<td>National Environmental Management: Biodiversity Act</td>
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<td>NGO(s)</td>
<td>Non-Governmental Organization(s)</td>
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<td>OECD</td>
<td>Organization for Economic Cooperation and Development</td>
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<td>PFOA</td>
<td>Problem Formulation and Option Assessment</td>
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<td>r-DNA</td>
<td>recombinant Deoxyribonucleic Acid</td>
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<td>RA</td>
<td>Risk Assessment</td>
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<td>RAEIN-Africa</td>
<td>Regional Agricultural and Environmental Initiative Network-Africa</td>
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<td>RECs</td>
<td>Regional Economic Communities</td>
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<td>RM</td>
<td>Risk Management</td>
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<td>RNA</td>
<td>Ribonucleic Acid</td>
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<td>SADC</td>
<td>Southern Africa Development Community</td>
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<td>SOPs</td>
<td>Standard Operating Procedures</td>
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<td>Sanitary and Phytosanitary measures</td>
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EXECUTIVE SUMMARY

A training workshop on Biosafety Risk Assessment (RA) and Risk Management (RM) was held in Birchwood Hotel and OR Tambo Conference Centre, Johannesburg, South Africa from 9th -14th August 2010. The workshop was co-organised by African Union Commission (AUC) and Regional Agricultural and Environmental Initiative Network-Africa (RAEIN-Africa).

The training workshop was a follow up on the recommendations of the AUC and the Secretariat of the Convention on Biological Diversity (CBD Secretariat) African Regional Workshop on RA and RM of Genetically Modified Organisms (GMOs) which was held in Addis Ababa August 2007 and the CBD Secretariat’s Second International Meeting of Academic Institutions and Organizations involved in biosafety education and training held in Kuala Lumpur in April 2007 that called for regional training on RA and RM. This workshop is also within the framework of the biosafety activities of RAEIN-Africa.

The main objective of the training workshop was to enhance technical knowledge and skills of officials from Southern and eastern Africa to effectively implement articles 15 and 16 of the Cartagena Protocol on Biosafety (CPB) and share experiences. The focus of the Workshop was also to provide hands-on exercises with case studies that will give the participants opportunity to assess the safety of Genetic Modification (GM) products. The case studies which were used are MON 15985 Cotton for environmental safety assessment and MON 89034 –maize for food safety assessment. Apart from risk assessment and management training, the workshop participants also discussed activities geared at strengthening national biosafety regulatory systems and regional collaboration.

The event brought together 60 participants from Eastern Africa (Ethiopia, Kenya, Rwanda and Sudan) and Southern Africa (Botswana, Democratic Republic of Congo, Lesotho, Madagascar, Malawi, Mozambique, Namibia, South Africa, Swaziland, Tanzania, Zambia and Zimbabwe), among them biosafety officers, researchers, lecturers, environmentalists, environmental lawyers, agriculturists (plant and Livestock), biotechnologists, socio scientist, regulators. The workshop was participatory and interactive in nature, employing multiple methods including short paper presentations, plenary discussions, practical exercises, brainstorming, demonstration and case studies. Reflecting on the training workshop, participants expressed the need to the RAEIN Africa to organise a follow up workshop on risk assessment and to also include socioeconomic impact assessment in the training module.

On the whole the workshop was deemed a great success as it had fully achieved its goal to enhance technical knowledge and RA and RM skills of officials from Southern and eastern Africa to effectively implement articles 15 and 16 of the CPB and share experiences. The workshop was also able initiate a regional network of experts to foster ongoing mutual learning and knowledge-sharing.

Evaluation of the workshop by the participants was positive and progress over the next few months will indicate the impact on this workshop to the implementation of national biosafety programs and the Cartagena Protocol on Biosafety.
1. BACKGROUND

Most African countries are party to the Cartagena Protocol on Biosafety (CPB) and are at different levels of domesticating the Protocol. The CPB was developed to ensure precautionary approach in adoption, use and transboundary movement of the GMO products and technologies with special focus on Living Modified Organisms (LMO). One of the constraints recognized in the process of development and implementation of National Biosafety Frameworks is that of capacity building.

Among the pillars of the African Union (AU) Strategy on Biosafety is the element on “Capacity Building requesting the AU to put in place capacity building initiatives/projects to help Member States generate the required institutional and human capacities for African countries to regulate the application of modern biotechnology to reap the maximum benefits from the science while avoiding potential risks. RAEIN-Africa also in consultation with its partners identified the need to increase specialised experts in emerging technologies such as biotechnology and contribute to building capacity in key issue that inform decision-making for policy development and implementation, namely socio-economic impacts of on the environment and on health, risk assessment and risk management of modern biotechnologies.

The AUC partnership with RAEIN-Africa and its partners planned “the Biosafety Risk Assessment and Risk Management training workshop for Southern and Eastern Africa in Johannesburg, South Africa. The training workshop was a follow up on the recommendations of the AUC and the CBD Secretariat African Regional Workshop on Capacity Building and Exchange of Experience on Risk Assessment and Risk Management (RA and RM) of GMOs which was held in Addis Ababa August 2007 and the CBD Secretariat's Second International Meeting of Academic Institutions and Organizations involved in Biosafety Education and Training held in Kuala Lumpur in April 2007 that called for regional training on RA and RM. In addition it was a follow up to the first Training Workshop for National Biosafety Committees aimed at enhancing the understanding of provisions of the Cartagena Protocol on Biosafety among National Biosafety Committees members held in Johannesburg, South Africa in October, 2006.

The main objective of the training workshop was to enhance technical knowledge and skills of officials from Southern and eastern Africa to effectively implement articles 15 and 16 of the CPB and share experiences. The focus of the Workshop was also to provide hands-on exercises with case studies that will give the participants opportunity to assess the safety of GM products. The case studies which were used are MON 15985 Cotton for environmental safety assessment and MON 89034 –maize for food safety assessment.

Apart from risk assessment/management training, the workshop participants also discussed activities geared at strengthening national biosafety regulatory systems and regional collaboration.

1.1. Workshop Approach and Strategy

The workshop was participatory and interactive in nature, employing multiple methods including short paper presentations, plenary discussions and intervention by participants, practical exercises in groups, brainstorming, demonstration and case studies. Participants were given the opportunity to provide their personal and/or national lessons and experiences on the specific issues being addressed. This enabled all participants to contribute as much as possible during case studies and practical exercises as well as in other sessions.

The training workshop was organized in the following five sessions (Annex 1):

1. Opening: This session provided for statement from the African Union Biosafety Unit, Southern African Development Community (SADC) Secretariat, and an overview of RAEIN-Africa biosafety programme and workshop objectives.
II Background Presentations to the Training: This covered an introduction to Biotechnology and biosafety; legal, institutional and administrative arrangements; and sharing of experiences in NBF implementations.

III Risk assessment guiding Principles: This part covered presentations on introduction to risk assessment, environmental, food safety risk assessment, socio-economic impact assessment and assessment tools.

IV Risk Assessment Practice: Step wise assessment of two dossiers one on environmental release (MON 15985 Cotton) and food and feed (MON 89034 –maize).

V Closing: workshop evaluation, recommendation and closing remarks.

1.2. Workshop participants

The event brought together 60 participants (Annex 5) from Eastern Africa (Ethiopia, Kenya, Rwanda and Sudan) and Southern Africa (Botswana, Democratic Republic of Congo, Lesotho, Madagascar, Malawi, Mozambique, Namibia, South Africa, Swaziland, Tanzania, Zambia and Zimbabwe), among them biosafety officers, researchers, lecturers, environmentalists, environmental lawyers, agriculturists (plant and livestock), biotechnologists, socio scientist, regulators.

2. SESSION ONE: OPENING OF THE WORKSHOP

2.1 Welcome and Introductions

The conference facilitator, Mr. Abisai Mafa welcomed the participants to the joint AU-RAEIN-Africa-SADC workshop on Risk Assessment and Risk Management workshop held from the 9th to the 13th August at Birchwood Hotel, Johannesburg, South Africa. He then led the introduction section where participants were asked to state their names; organization to which they are attached to and their area of interest as far as Biosafety is concern. The workshop brought together key stakeholders and knowledgeable experts in a variety of fields relating to biotechnology and biosafety including biosafety officers, researchers, lecturers, nutritionists, environmentalists, environmental lawyers, agriculturists, biotechnologists, and veterinarians (Annex 5).

2.2 Opening Remarks

The official opening session was addressed by Mr. Bather Kone Head, Biosafety Unit Department of Human Resources, Science & Technology (HRST); Dr Keoagile Molapong Senior Program Manager SADC Secretariat; and Ms Doreen Mnyulwa-Shumba the Regional Director of RAEIN-Africa.

Opening remarks by Mr. Bather Kone

Mr. Bather Kone, Head of the Biosafety Unit at the AUC, indicated that the workshop forms part of an initiative framework of the AU-GTZ (Deutsche Gesellschaft für Internationale Zusammenarbeit) Biosafety project “support to the African Union in the matters of Biosafety”. The project aims to provide support to member states in implementing the Cartagena Protocol on Biosafety and African Model Law on Biosafety, and to eventually establish a regional approach on Biosafety issues.

Mr. Bather Kone emphasized that the workshop, organized jointly with RAEIN-Africa, provided a perfect platform for the AU-Biosafety Unit to share the African Model Law on Biosafety with its Southern and Eastern Africa partners; as requested by the African Ministerial Conference on Science and Technology held in Mombasa in November 2007.

Mr. Kone concluded by urging the African Union Commission to seriously consider the integration of biosafety issues in its priority programmes and policies as the GTZ support comes to end in December.
Opening statement by Dr. Keoagile Molapong

In his opening statements, Dr. Molapong the Senior Program Manager from the SADC Secretariat commended the joint initiative by the African Union and RAEIN-Africa that brought together participants from 19 countries in Eastern and Southern Africa to a workshop aimed at enhancing the technical knowledge and skills of officials from Africa to effectively implement the Articles 15 and 16 of the Cartagena Protocol on Biosafety and ultimately help the National Competent Authorities in decision making on risk assessment and management.

Dr. Molapong stressed the importance of capacitating countries in GMO detection, risk assessment, monitoring and evaluation and other relevant skills in order to effectively implement National Biosafety Frameworks. Dr. Molapong added that the enhancing capacities for RA and RM will give Africa leverage to exploit opportunities presented by emerging technologies including modern biotechnology whilst minimising adverse impacts on human health and biodiversity and environment.

Dr. Molapong highlighted the effort the SADC Secretariat is putting into the creation of an enabling environment for enhanced innovation in food, agriculture and environment. In addition to that, the SADC Secretariat continues to monitor the status of development of Biosafety Frame works in this region, although the slow rate of progress by the SADC countries is of concern, especially now that the countries are not only trading at a regional level but internationally as well, including countries that have commercialised GMOs.

Welcome remarks by Ms Doreen Shumba - Mnyulwa

In her welcome remarks, Ms Shumba-Mnyulwa, RAEIN-Africa Regional Director, welcomed all participants to the workshop co-organized by RAEIN-Africa and African Union Biosafety Unit. The Director emphasized that RAEIN-Africa values partnership approach to projects as they ensure sharing of lessons learnt and experiences and efficient use of resources meant for capacity building. She also highlighted the fact that RAEIN-Africa’s main goal to facilitate the creation of an enabling environment for innovations addressing the resource constrained communities’ needs through interfacing technology and society. The Network sees great potentially for emerging technologies in addressing the needs of the developing countries hence contributes to capacitating countries to regulate the application of modern biotechnology to reap the maximum benefits from the science while avoiding potential risks.

Ms Shumba-Mnyulwa mentioned that counties in Africa are at different stages of development and implementation of biosafety issues. She added that the trade of GMOs has increased globally in the past five years, but most countries in the region lack the capacities (both human and infrastructural) to test for presence and absence of GM and carry out risk assessment and to manage risks.
2.3 Conference objectives

The workshop facilitator, Mr. Mafa, gave an overview of the workshop objectives as outlined below:

Objectives of the training workshop

a) To enhance the technical knowledge and skills of officials from Africa to effectively implement the Articles 15 and 16 of the Cartagena Protocol on Biosafety through lectures, case study presentations and hands-on practical sessions, this is ultimately intended to help the National Competent Authority in decision making on risk assessment and management.

b) To facilitate the sharing of national and regional experiences and lessons learned regarding the implementation of risk assessment and risk management under the Protocol and initiate a regional network of experts to foster ongoing mutual learning and knowledge-sharing.

c) To build capacity for RA and RM of GMOs in Southern and Eastern African countries.

d) To establish a network of biosafety institutions and experts in Southern and Eastern African countries so as to promote networking and resource sharing.

e) To create a platform in which the Southern and Eastern African countries can articulate and proactively safeguard its own interests in the international discourse on GMOs.

2.4 Expectations of the participants

Participants were invited to express their expectations in connection with the outcome of the Workshop. At the closing session participants were again invited to assess whether the expectations had been met. The resulting comments and assessment are summarized in Annex 2.

3. SESSION TWO: BACKGROUND PRESENTATIONS

In order to prepare the participants for the risk assessment and the hands on practical sessions, the resource persons gave a series of introductory lectures for one and half days. The topics covered in the background lectures included an introduction to Biotechnology and biosafety; legal, institutional and administrative arrangements; and sharing of experiences in National Biosafety Framework (NBF) implementations. This section provides a summary of the background papers presented by the following resource persons: Professor Ossama Mohammad El-Tayeb (Egypt), Dr. Hans Bergmans (Netherlands), Mahlet Teshome-Kebede (Ehiopia) Alex Owusu-Biney (INEP, Kenya), Ms Wadzanayi Mandivenyi (South Africa), Ms Gillian Christians (South Africa), Ms Renusha Chanda (South Africa) and Mr. Abisai Mafa (Zimbabwe).

3.1 BIODIVERSITY, BIOTECHNOLOGY AND BIOSAFETY: THE CONNECTION

A “jargon-free” introduction to regulators and decision makers

Ossama Mohammad El-Tayeb,
Egyptian Environmental Affairs Agency

Professor Ossama Mohammad El-Tayeb, presented a paper on the introduction to biodiversity biotechnology and biosafety. This paper provided an overview of the current state of the technology involved in genetic modification of plants and microorganisms and the risks and potential benefits of the biotechnology.
Professor Ossama thought that it was important to first start by defining and giving a brief explanation of important terms such as gene, heredity, deoxyribonucleic acid (DNA), gene regulation, protein synthesis, GMO and Biotechnology. He noted that since risk assessment and management is based on the basic principles of biology and genetics it would necessary for regulators and other risk assessors to have some basic knowledge on DNA structures and function, gene expression and genetic transformation. Presented in this paper is an overview of basic molecular biology principles and a description of methods employed in producing genetically modified organisms.

He informed participants that the DNA structure and its function were discovery in the 1950s. Prior to this discovery, it was believed that proteins were the ones carrying genetic material. Another discovery in the early 20th century, described DNA as the major hereditary substance. DNA is a “double helix” of 2 strands where each strand “complements and predicts” the other strand (Figure 1).

![Figure 3.1.1: DNA double Helix](image)

Unlimited numbers of unique molecules, each forming a unique sequence of different functional molecules (genes) and each could duplicate itself precisely. Genes are arranged as a continuous, highly twisted and compacted string, or a chromosome, which carries its functions only on demand by the cell (Figure 2). The flow of genetic material from a DNA via messenger ribonucleic acid (mRNA) to a protein is illustrated in Figure 3.
Figure 3.1.2: Transcription and translation

Figure 3.1.3: Protein synthesis

The Birth of genetic engineering

Naturally, species even when sharing a common environment could not exchange DNA. In other words, there exist a genetic barrier between species that keeps species distinct.

In 1971, scientists discovered methods for the exchange of DNA between species in the laboratory against the genetic barrier. This gave birth to genetic engineering, technically known as Recombinant DNA technology. The figure below shows an overview of DNA cloning.
Using biotechnology, scientists can now develop products with desirable characteristics more quickly and less expensively by identifying the desired gene in another plant (or animal or microorganism) and integrating this desired gene into the recipient plant genome, thus creating a genetically modified organism. The contributions of genetic engineering and biotechnology to human welfare are many ranging from uses in (a) healthcare such as medicines, vaccine, diagnostics, monoclonal systems, drug delivery systems and the human genome, (b) Agriculture such as Bacillus thuringiensis (Bt) and herbicide tolerance, virus resistance, abiotic stress tolerance, (c) Industry such as enzymes from extremophiles, Bio-polymers, Novel products, Optimization of economic production and Synthetic biology; and in Environmental management for Environmental bioremediation, Long term conservation and Resurrection of fossilized genetic resources. The paper also discussed very briefly the food, human, environmental and socioeconomic concerns of GMOs.

### 3.2 INTRODUCTION TO BIOSAFETY

*Dr. Hans Bergmans*

*National Institute for Public Health and the Environment, Netherlands*

Concerns arising from the application of Gene Technology

Gene technologies have the aim to change the genetic material (DNA or RNA) of an organism (a plant, animal, or a micro-organism, including viruses) in order to adapt the properties of the organism (its phenotype) to perform a desired and useful new function. The changes in the genetic material usually result from transfer of genes and regulatory sequences from one organism (the donor) to another (the recipient). The donor and recipient may be very distantly related, e.g. when genes are transferred from a bacterium to a crop plant.

The application of gene technologies may result in a genetically modified organism (GMO). The African Model Law defines a GMO as “organism that possesses any novel combination or expression as a trait of genetic material obtained through the use of modern biotechnology”.

The main feature why use of GMOs gives rise to concerns is that they (may) possess new traits that have not been associated with the recipient organism before. Also when released into the environment, their new traits may cause environmental problems, may compromise food/feed safety, or may pose socio-economic threats.
a) Environmental concerns of GMOs
When a GMO is released into the environment, it will, as any organism that is released, have an impact on the environment. Environmental risk assessment (ERA) is performed to identify, characterize and evaluate risks that the GMO may pose to the environment. It is important to state the ‘assessment endpoints’ of an ERA, an explicit expression of the environmental value (species, ecological resource, or habitat type) that is to be protected.

Risk assessment endpoints for an ERA may be, for instance: weedingness of the GMO, potential for displacing other species in the receiving environment, effects on target organisms (in the example: development of resistance against Bt toxin in the pest insect), effects on non-target organisms (e.g. damage to populations of other, beneficial, insects), effects on human or animal health in the environment, effects on biogeochemical processes (e.g. bacterial processes in soil), or changes in agronomic practice (e.g. changes in the use of pesticides).

Environmental concerns are restricted to adverse effects of the GMO. One may also perceive benefits of the GMO; and these may be taken into account in the decision making stage of the GMO risk assessment process.

b) Food/feed safety concerns of a GMO
Food or feed safety concerns arise when the GMO, or parts of it, is used as or in food or feed. Use as or in food or feed results in chronic exposure of a consumer to the GMO, contrary to the exposure that may occur in environmental use of the GMO. Food/feed safety of a GMO implies that the GMO should not contain any new toxic or allergenic substance, at least not in quantities that will cause undesired effects.

Also, the process of the genetic modification should not have resulted in (unintended) changes of the compositional or nutritional characteristics (key nutrients and anti-nutrients, toxicants and allergens already present in the recipient) of the recipient that could cause adverse health effects in the consumer. This last aspect requires codified knowledge of naturally occurring key components in the recipient and the range of concentrations observed. As the GMO used as in food or feed may substitute other food or feed stuffs, their use may lead to changes in dietary intake of key nutrients; also this may lead to adverse effects.

c) Socio-economic and ethical aspects
The use and exploitation of GMOs may also raise socio-economic and ethical issues. The African Model Law on Biosafety mentions inter alia:
- Anticipated changes in the existing social and economic patterns resulting from the introduction of a (product of) GMO;
- Possible threats to biological diversity, traditional crops, farmers’ varieties and sustainable agriculture; economic costs due to these threats;
- Impacts likely to be posed by substituting traditional crops, products and indigenous technologies;
- Possible effects, which are contrary to the social, cultural, ethical and religious values of communities.

These concerns may be taken into consideration and evaluated in a separate (part of the) risk assessment.

**Decision making**

Decision making on an application for approval of a GMO takes into account a summary of the concerns identified above. The African Model Law on Biosafety specifies, for instance, that no approval shall be given unless it is “considered and duly determined” that the use of the GMO will:

- benefit the country without causing any significant risk to the environment, biological diversity or human health;
- contribute to sustainable development;
- not have adverse socio-economic impacts; and
- accord with the ethical values and concerns of communities and does not undermine local community or indigenous knowledge and technologies.

It should be noted that this scheme of decision making also allows taking into account potential benefits of the use of a GMO.

**Breakup session**

During this presentation, participants were asked to a breakup into groups to identify issue that they consider as risks. Annex 4 shows the concerns that were identified by the participants.

**Suggested References:**


**3.3 INTERNATIONAL MECHANISMS TO ADDRESS BIOSAFETY CONCERNS**

*Dr. Hans Bergmans
National Institute for Public Health and the Environment, Netherlands*

Biosafety concerns arising from the environmental release, use as or in food or feed, and in general trade of GMOs have profound international and regional aspects. GMOs, once released into the environment, will not be stopped by state borders, and international trade will carry GMOs across natural borders, sometimes over long distances. International and regional cooperation is therefore needed to address these biosafety concerns, and various international mechanisms have been developed for this purpose.

The presentation will describe a few of the most important international mechanisms: the Cartagena Protocol on Biosafety, addressing environmental concerns and the Codex Alimentarius Commission, addressing food safety concerns. We also discuss the role of the World Trade Organization.

**International approach to environmental concerns**

The development of GMOs intended for release into the environment, in particular GM crops, was originally concentrated in the industrialized part of the world. Soon it became clear, however, that GM crops would also reach other parts of the world, in the first place by international trade. After lengthy discussions, it was decided that a legally binding protocol would be developed to set the rules for ‘transboundary movement’ of GMOs. This
protocol, the Cartagena Protocol on Biosafety (CPB, http://bch.cbd.int/resources/downloads/cartagena-protocol-en.pdf) has the objective to “contribute to ensuring an adequate level of protection in the field of 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”. The CPB is a protocol to the Convention on Biological Diversity (http://www.cbd.int/convention/). The main instrument of the CPB is the Advance Informed Agreement (AIA) procedure for ensuring that countries are provided with the information necessary to make informed decisions before agreeing to the import of such organisms into their territory. The CPB also provides a methodology for the environmental risk assessment (ERA) of GMOs that has to be performed as part of the AIA procedure.

Recently further guidance for the performance of an ERA has been prepared. This “Roadmap for risk assessment of living modified organisms” will be presented to Conference of the Parties serving as the Meeting of the Parties to the Cartagena Protocol on Biosafety (COP/MOP) 5 in October 2010. The Roadmap is available in Annex III of a meeting document available at http://www.cbd.int/doc/meetings/bs/mop-05/official/mop-05-12-en.doc.

One important feature of the Roadmap is that it provides links (see http://bch.cbd.int/onlineconferences/roadmapref_ahteg_ra.shtml#top) to relevant background documentation, that available at the Biosafety Information Resource Centre in the Biosafety Clearing House (BCH, see http://bch.cbd.int/protocol/) of the CPB.

International approach to food safety concerns

A main issue of GMO biosafety is food safety. General food safety standards are developed by the Codex Alimentarius Commission was created in 1963 under the Joint Food And Agriculture Organization (FAO)/ World Health Organization (WHO) Food Standards Programme. The main purposes of this Programme are “protecting health of the consumers and ensuring fair trade practices in the food trade, and promoting coordination of all food standards work undertaken by international governmental and non-governmental organizations” (see http://www.codexalimentarius.net/web/index_en.jsp and ftp://ftp.fao.org/codex/Publications/understanding/Understanding_EN.pdf, “Understanding the Codex Alimentarius”).

An Intergovernmental Task Force on Foods Derived from Biotechnology under the Codex develops “standards, guidelines or recommendations, as appropriate, for foods derived from biotechnology or traits introduced into foods by biotechnology, on the bases of scientific evidence, risk analysis and having regard, where appropriate, to other legitimate factors relevant to health of consumers and protection of fair trade practice.” More information can be found in the following links: http://www.fao.org/ag/agn/agns/biotechnology_en.asp and further links mentioned there.

In the area of foods derived from biotechnology, the Codex provides guidance on human health risk analysis in its “Principles for the Risk Analysis of Foods Derived from Modern Biotechnology” (http://www.codexalimentarius.net/download/standards/10007/CXG_044e.pdf) and in its “Working Principles for Risk Analysis for Food Safety for Application by Governments” (www.codexalimentarius.net/download/standards/10751/CXG_062e.pdf).

The Codex Alimentarius Commission is one of the ‘Three Sister’ organizations that are widely recognized as ‘standard setting organizations. The other two organizations are the International Plant Protection Convention (https://www.ippc.int/) and the World Organization for Animal Health (OIE; http://www.oie.int/eng/en_index.htm)

The role of the World Trade Organization (WTO)

The WTO is, in its own words (http://www.wto.org/english/thewto_e/whatis_e/whatis_e.htm, see also http://www.wto.org/english/res_e/dolocd_e/inbr_c.pdf) “the only global international organization dealing with the rules of trade between nations”. 
The WTO is based on agreements between members, and only members are bound by these agreements. If a country is a member of a WTO agreement, this means that it has decided, probably in its policy making for trade that it is advantageous to collaborate under the specific WTO agreement. This should be kept in mind whenever there are (or seem to be) conflicting situations between the WTO agreements and the GMO policy of a country or region.

The following WTO agreements are of particular interest in relation to GMO policies:

The sanitary and phytosanitary measures (SPS) agreement:
http://www.wto.org/english/tratop_e/sps_e/spsagr_e.htm

The WTO agreement on sanitary and phytosanitary measures is of major concern for biosafety in the trade of (products from) plants and animals. “The SPS Agreement allows countries to set their own food safety and animal and plant health standards. At the same time, however, the SPS Agreement requires that such regulations be based on science, that they be applied only to the extent necessary to protect health, and that they not arbitrarily or unjustifiably discriminate between countries where identical or similar conditions prevail.”
(http://www.wto.org/english/tratop_e/sps_e/sps_agreement_cbt_e/c1s1p1_e.htm)

Clearly, this definition leaves open that there may be differences of opinion on what ‘based on science’ means, and also the terms ‘to the extent necessary’, ‘arbitrarily’ and ‘unjustifiably’ leave room for discussion.

How these terms should be handled under the SPS agreement, especially in relation to GMO issues, is not completely clear (http://www.wto.org/english/tratop_e/sps_e/sps_agreement_cbt_e/c8s1p1_e.htm).

The Technical Barrier to Trade agreement, on technical barriers to trade, (http://www.wto.org/english/tratop_e/sps_e/sps_agreement_cbt_e/c9s3p1_e.htm), may apply to trade issues around GMOs.

The TBT agreement aims “to ensure that product requirements, and procedures that are used to assess compliance with those requirements, do not create unnecessary obstacles to trade”. Again, it is the issue of what constitute an ‘unnecessary’ obstacle to trade that is not directly clear.

The discussions in the Organization for Economic Cooperation and Development Working Group on the Harmonization of Regulatory Oversight in Biotechnology, although not linked specifically to WTO disputes, are interesting in this respect. This working group produces ‘consensus documents’ on issues that are important for the GMO debate. These documents reflect the scientific principles that underpin the GMO environmental safety discussion, on which there is consensus among the OECD members. (see http://www.oecd.org/findDocumen t/0,3354,en_2649_34387_1_119829_1_1_1,00.html). The application of these principles would not be seen as raising ‘unscientific’ obstacles.

**The agreement, on Trade-related Aspects of Intellectual Property Rights (TRIPS)** (http://www.wto.org/english/tratop_e/sps_e/sps_agreement_cbt_e/c9s1p1_e.htm), lays down the minimum requirements for the protection of intellectual property rights that a member of the agreement has to enforce.

The training module quoted above states that “with respect to GMOs, countries may exclude from patentability plants and animals as well as essentially biological processes for the production of plants and animals. However, they must provide protection for microorganisms and non-biological and microbiological processes. The TRIPs Agreement also allows temporary exclusion from patentability when necessary to protect human, animal or plant life or health or to avoid prejudice to the environment. The TRIPs Agreement would normally not be invoked in a conflict regarding market access for GMOs, but it might be invoked in a dispute on intellectual property protection related to GMOs.”
It is to be recalled that the development of the African Model Law came about to serve as a model legal instrument when the United Nations Convention on Biological Diversity's Cartagena Protocol on Biosafety was delayed. The Protocol as seen by Africans did not address the priority needs of Africa and hence there was a need for a regional Model law to help in the development of national legal systems.

In the course of time, various factors such as the developments at the international level (progress in the negotiations), the developments at the AU level (decisions of ministers and the executive council), sub-regional initiatives in Africa and national research and development and legislative and policy developments called for the revision of the African Model Law. In so doing the African Union Commission's (AUC) Department of Human Resources Science and Technology (HRST) undertook the necessary procedures in the revision process through the drafting of a concept note underlying the justifications behind the need to revise the Model Law and took various steps to engage diverse stakeholders in the discussions of the revised draft Model law. Among these are Member States, Conference of Ministers of Science and Technology and conference of Ministers of Environment, regional economic communities, regional civil service organization and other regional biosafety and biotechnology initiatives.

The key new elements in the Revised Model Law are additions of the preamble, the inclusion of an article on the objective of the Model Law, and additions on the scope to include all transactions of GMOs and their products. Moreover, the addition of a more articulate provision on institutional arrangement and an article on conflict of interest and public participation are critical aspects of the Revised Model Law. The need for periodic reporting on the outcomes of monitoring and evaluation of risks of approved GMOs is also address under a risk management provision under the Revised Model Law.

A requirement of setting of thresholds for the adventitious presence of GMOs is provided. The need for capacity building as recognized in the preamble is also reflected in a whole new article under the revised text of the Model Law. Finally the time limit is set to bring a suit on liability and redress for the damage from GMOs and products at a maximum period of 10 years under the new Model Law. A provision that was widely called for especially by the civil society organizations is added regarding the recognition of community rights for GM free zones. It is believed that the revision of the Model Law provides the forum for the incorporation of the various current issues and interests of all stakeholders in the development of the technology and ensuring its safety.

3.4 THE AFRICAN MODEL LAW ON BIOSAFETY

Mahlet Teshome-Kebede
African Union Commission, Ethiopia
The Cartagena Protocol on Biosafety is a Protocol to the Convention of the Biological Diversity, which was adopted in January 2000 and came into force in September 2003. As at July 2010, there are 160 parties to the Protocol. The Protocol is rooted in the precautionary approach as contained in Principle 15 of the Rio Declaration on Environment and Development. The objective of the Protocol is “to contribute to ensuring the safe transfer, handling and use of living modified organisms (LMOs) resulting from modern biotechnology that may have adverse effects on the biological diversity, taking also into account risks to human health”. The Protocol provides for parties to:

- take legal, administrative and other measures to implement the Protocol (which is the basis for the National Biosafety Framework)
- take actions more protective of biodiversity; consistent with the Protocol objective and provisions
- have a right to subject all LMOs to risk assessment prior to taking a decision on import

The implementation of the Cartagena Protocol is also guided by the “no reservation clause” in article 38.

The National Biosafety Frameworks are procedural measures on policy/regulatory, technical and administrative frameworks to meet the obligations to the Cartagena Protocol on Biosafety in line with article 2.1. Based on this requirement, the presentation will present an overview of the National Biosafety Frameworks, the role of the NBFs in shaping national biosafety systems both as a regulatory response and a treaty obligation. The key elements of an NBF, the reasoning behind the NBF approach and the status of the NBF in line with the Global Environmental Facility (GEF) Strategy for financing biosafety will be presented.

The status of UNEP-GEF biosafety support to date is as follows:

1. Pilot Biosafety Enabling Project [1997 – 2000] - used to assess the status of biosafety and development of an inventory for 18 countries including Cameroon, Namibia, Uganda, Mauritania, Mauritius, Tunisia, Egypt, Zambia, Malawi and Kenya from Africa
2. Global Project on “Development of National Biosafety Frameworks” for 123 countries starting from 2001. The NBFs focuses on stocktaking and inventory, national consultations and drafting of policy. Technical and regulatory instruments to address biosafety. Presently 38 out of the 39 countries have developed their final draft NBFs published on the UNEP biosafety website addressing the components of the NBF
3. Biosafety Clearning House Project – This was an “add on” enabling project to assist countries to meet their BCH obligation. It started in 2004 and has assisted 139 countries. Several toolkits and training materials were developed for continuous use of the parties.
4. Implementation Projects – This intervention assist countries to operationalise their NBFs. It was started with the 12 Demonstration Projects of which 8 were handled by UNEP [Cuba, China, Namibia, Kenya, Uganda, Cameroon, Bulgaria, Poland], 2 handled by UNDP and 2 by the World Bank. Currently there are ongoing 11 GEF 3 Projects of which four are in Africa [Egypt, Mauritius, Tanzania and Tunisia]. The Implementation Projects started in 2002.

Conclusion
The interventions so far indicate the

i. Need for a functional and responsive policy/regulatory, administrative and public engagement frameworks to the operational guidance and developments in modern biotechnology and biosafety
ii. Potential for Harmonisation for technical procedures
iii. Another look at national Implementation versus Regional
iv. Specific or thematic interventions which would strengthen Decision making processes
v. Establishment of roles and responsibilities for monitoring and enforcement
Subregional Issues: Bilateral and multilateral agreements (art.14), Harmonization of regulatory mechanisms, Agreement on Simplified procedures (art.13), Agreements on the illegal transboundary movement (art. 25), Information exchange and mechanisms (art. 20), Risk Assessment & Risk management (art.20 & art.16), Cooperation in Biotech research and detection (art. 15) should be revisited in line with the proposed new strategy for Biosafety.

It is therefore important that Parties move from Generality to Specificities as per obligations with a refocused emphasis on ownership of the Protocol process in moving forward their national biosafety systems. This would mean emphasizing and building interventions to address the:

- Low capacity for scientifically sound risk assessments with the development of appropriate risk management strategies,
- Need for development and implementation of comprehensive national capacity-building strategies and action plans by each Party guided by the periodic update of the national priorities under the BCH,
- Addressing measures for integration of biosafety into the other relevant sectors, in particular agriculture, environment/biological diversity, health and science and technology sectors at the national level,
- Lack enforcement requirements related to handling, transport, packaging and identification of living modified organisms,
- Lack of trained personnel and equipment for sampling, detection and identification of LMOs,
- Political support and will.

In that vein, future and urgent areas for potential GEF support include:

- Mechanisms, rules and procedures on liability and redress for damage resulting from transboundary movements of LMOs – based on the outcome of COP/MOP5,
- Enhanced capacity to facilitate handling of LMOs including Risk Assessment and Risk Management, LMO Detection, Handling, Packaging, Transport and Identification, Monitoring and Enforcement including inspection procedures
- Socio economic consideration guidance,
3.6 NBF IMPLEMENTATION – EXPERIENCE SHARING

3.6.1 SOUTH AFRICA REGULATORY FRAMEWORK FOR GENETICALLY MODIFIED ORGANISMS

Ms Wadzanayi Mandivenyi  
Department of Environmental Affairs, South Africa

Ms Gillian Christians  
Department of Agriculture Forestry and Fisheries, South Africa

Ms Rensha Chanda  
Department of Health, South Africa

In recognition of the potential role of biotechnology in addressing the sustainable development imperatives of South Africa, a National Biotechnology Strategy was adopted in 2001. South Africa had a long history of engagement of traditional biotechnology and as a result the progression into third generation biotechnology entailing genetically modified organisms was a natural progression. In order to support these developments, South Africa has a stringent biosafety regulatory system that ensures that the technology is utilized in a manner that causes minimum disruption to the environment while at the same time addressing the country’s sustainable development goals and imperatives.

South Africa is also signatory to the Cartagena Protocol on Biosafety, and therefore has an obligation to implement an effective system to monitor and regulate Genetically Modified Organisms (GMOs). South Africa believes that in the future, applications of biotechnology may contribute to the mitigation of the environmental impacts of agriculture and therefore continues to invest in capacity building initiatives to this end. However, concerns have been raised about the possible negative impacts of widespread planting of GMO crops on South Africa’s rich and unique biodiversity, highlighting the need to strengthen legislation, decision-making, monitoring and enforcement (Pretty, 2001).

These concerns also underscore the need to take a precautionary approach to the release of GMOs into the environment, especially in biodiversity priority areas. In the case of agricultural crops consideration has to be given as to whether the crop is indigenous or exotic – this distinction is important in terms of environmental and biodiversity impacts. Any restrictions deemed applicable to GM crops in “biodiversity priority areas” should be based on concerns that are generally applicable to agricultural activity at large. This means that the same restrictions that would already apply to conventional agriculture in those areas will apply to GM crops in these same areas. Conventional agriculture is considered to be the baseline. It is important that policy and legislation between sectors is aligned, that adequate and relevant information on GMOs is made available to interested and affected parties and decisions regarding release of GMOs into the environment are transparent.

**National Regulatory Framework**

*The Genetically Modified Organisms Act*

The regulation of GMOs is principally governed by the Genetically Modified Organisms Act (GMO Act) and its subsequent amendments and their applicable regulations. Specifically the two relevant acts are:

- Genetically Modified Organisms Act 1997 (Act No. 15, 1997)
- Genetically Modified Organisms Amendment (Act No. 23 of 2006)

The act was put in place to regulate the prudent and responsible use of GMOs in South Africa. This encompasses the entire pipeline of GMO development including research and development (contained use and field trial activities), production (general release activities), import and export, transport, use and application of GMOs.
Accordingly, the act aim to ensure that any activity with a GMO in South Africa is conducted so as to limit potential risks to the environment and to human and animal health and take socio-economic considerations into account. The GMO Act and its amendment and the relevant regulations monitor all activities with GMOs according to permits issued in terms of this act. A number of types of permits can be applied for relating to the particular GMO activity, including permits for import, commodity clearance, general release, field trials and contained use.

The GMO Act is implemented by the Directorate Biosafety of the Department of Agriculture, Forestry and Fisheries. The Registrar of the GMO Act administers the act. Two regulatory bodies namely the Executive Council and the Advisory Committee evaluate and decide on applications. The Advisory Committee is composed of independent scientists with various scientific backgrounds. This body then advises the Executive Council as to the level of risk associated with the activity and whether the permit for that particular activity can be issued. This may include risk management strategies that may need to be implemented should the permit application be approved. The Executive Council is the decision making body made up of representatives from a number of government departments. If the Executive Council is satisfied with the findings of the Advisory Committee and if other issues that may be brought up by the Executive Council are resolved, including for example trade issues or consideration of public comments, a permit for that particular activity may be issued by the Registrar. Inspectors ensure compliance to permits approved under the GMO Act.

National Environmental Management Act 107 of 1998

The legislative framework provided by the National Environmental Management Act, 1998 (NEMA) (Act 107 of 1998) introduced a new era of management of the environment. NEMA defines “environment” as the surroundings within which humans exist, which is made up of:

(i) the land, water and atmosphere of the earth;
(ii) micro-organisms, organism and animal life;
(iii) any part or combination of (i) and (ii) and the interrelationships among and between them; and
(iv) the physical, chemical, aesthetic and cultural properties and conditions of these that influence human health and well-being.

Chapter 1 of NEMA sets out the National Environmental Management principles. Key among these is that environmental management must place people and their needs at the forefront of its concern, and development must be socially, environmentally and economically sustainable. Specific reference to biodiversity considerations is as follows:

• that the disturbance of ecosystems and loss of biological diversity are avoided, or, where they cannot be altogether avoided, are minimized and remedied;
• that the development, use and exploitation of renewable resources and the ecosystems of which they are part do not exceed the level beyond which their integrity is jeopardized; and
• sensitive, vulnerable, highly dynamic or stressed ecosystems, such as coastal shores, estuaries, wetlands and similar systems require specific attention in management and planning procedures, especially where they are subject to significant human resource usage and development pressure.

NEMA has several provisions that are of relevance to GMOs. NEMA stipulates a ‘risk-averse and cautious approach’ to avoid, minimize or remedy the disturbance of eco-systems and loss of biological diversity. Environmental management decisions should take into account the impact of the decisions affecting all people, as well as promote participation of interested and affected parties, take place openly and transparently, and be appropriate in relation to the assessment of social, economic and environmental costs and benefits. Inter-governmental co-ordination and harmonization of policies, legislation and actions relating to the environment is required.

NEMA contains provisions, which set out the requirements for integrated environmental management. Under NEMA, an activity which will significantly affect the environment will only be authorized after considering, investigating and assessing the impact of such activity on the environment, socio-economic conditions and cultural
heritage. This applies even to cases where authorization is governed by alternative legislation, such as the GMO Act. However, NEMA further lists certain activities, which may not be commenced without prior authorization (such authorization requiring an EIA). Details of these activities will be conveyed to the applicant after a review of the baseline information for the GMO under assessment.

National Environmental Management: Biodiversity Act 10 of 2004 (NEMBA)

The Biodiversity Act provides for:

(i) the management and conservation of biological diversity within the Republic and of the components of such biological diversity;

(ii) the use of indigenous biological resources in a sustainable manner; and

(iii) the fair and equitable sharing among stakeholders of benefits arising from bio prospecting involving indigenous biological resources.

Chapter 5 Of NEMBA: Species and organisms posing potential threats to Biodiversity in Part 3 of Section 78 specifically deal with Genetically Modified Organisms. The purpose of Chapter 5 of NEMBA is “to ensure that environmental assessments for purposes of permits in terms of the Genetically Modified Organisms Act, 1997 (Act No. 15 of 1997), are conducted in appropriate cases in accordance with Chapter 5 of the National Environmental Management Act. This therefore means that NEMBA is intended to augment rather than to duplicate the provisions of the GMO Act 15 of 1997. The relevant provisions are intended to ensure that in appropriate cases, EIAs compliant with the requirements stipulated by NEMA are carried out for the purposes of issuing permits under the GMO Act.

The provisions will take effect in cases where ‘the Minister has reason to believe’ that a trial release or general release of a GMO into the environment under a permit applied for under the GMO Act ‘may pose a threat to any indigenous species or the environment’. In such cases, the release must be treated as if it were a listed activity under NEMA and the requirements for an EIA in accordance with the NEMA provisions must be followed before a permit may be issued. The onus rests on the Minister to communicate his/her belief about the potential threat of the GMO release concerned to the Registrar of GMOs as soon as possible after the application has been received by Department of Environmental Affairs.

The Department of Environmental Affairs has provided general guidance with regards to the objectives of EIAs for GMOs, the criteria that may trigger an EIA and the administrative procedure to follow should the trigger requirements be met (this can be found in the document “Environmental Risk Assessment Framework for Genetically Modified Organisms: A Guidance Document” available from the Department of Environmental Affairs). To date an EIA for a GMO has not been required under NEMBA and consequently an EIA under NEMA has not been conducted for a GMO. If an EIA of a GMO is conducted under NEMA and the outcome of the EIA is that the particular activity is deemed acceptable the EC of the GMO Act nonetheless retains the authority to make a final decision on the granting of the permit. However, if the EIA concluded that the particular activity with a GMO poses an unacceptable level of risk then the EC may not instruct the Registrar to issue the permit (section 78 of NEMBA).

Foodstuffs, Cosmetics and Disinfectants Act (Act 54 of 1972)

Regulations governing the labelling of foodstuffs (under the Foodstuffs, Cosmetics and Disinfectants Act (Act 54 of 1972)) obtained through certain techniques of genetic modification.
3.6.2 REGULATING GENETICALLY MODIFIED ORGANISMS: ZIMBABWE’S EXPERIENCES

Abisai Mafa
National Biotechnology Authority, Zimbabwe

Zimbabwe has a population of around 12 million and the main occupation of most of the people is farming. Agriculture provides over 40% of export receipts, 60% of the raw materials for industry, livelihood support to rural communities (70% of the population) and accounts for 53% of formal employment. Agricultural industry is underpinned by agricultural research which started in 1909. The country benefited significantly from the Green Revolution technologies and second only to the United States to have come up with a successful single cross maize hybrid (SR52) during this period.

Policy and Legal Provisions

Following the Rio Earth Summit on sustainable development, there was heightened interest in responsible application of biotechnology. In 1998, the country amended its Research Act so as to provide for the management of potentially harmful technologies and undertakings, through Safety Boards (Research Amendment Act, 1998). In 2000, regulations were gazetted establishing the Biosafety Board of Zimbabwe as the sole agency responsible for advising Government on GMOs, and ensuring the safe import, export, research, development, application
and use of GMOs (Research, Biosafety Regulations, 2000). Following the country’s ratification of the Cartagena Protocol on Biosafety in 2003, a process was set in motion to review the country’s policy and legal provisions, with the support from UNEP/GEF. A comprehensive National Policy on Biotechnology was developed in 2005, and a standalone legal framework (National Biotechnology Authority Act) was enacted in 2006, repealing the Research (Biosafety) Regulations.

**Institutional and Administrative Arrangements**

In 2000, following the gazetting of the Research (Biosafety) Regulations, the Biosafety Board of Zimbabwe was established as an agency to provide oversight on GMOs. The Biosafety Board comprised of an independent Decision Making Board appointed by and reporting to the Vice President, and an Agency headed by the Registrar of Biosafety. The Board was empowered to set up committees to provide technical and administrative support.

In 2007 the Biosafety Board of Zimbabwe was transformed into the National Biotechnology Authority of Zimbabwe following the enactment of the National Biotechnology Authority Act. The setup comprises of an independent Decision Making Board appointed by the Minister Responsible for Science and Technology Development, and an Agency headed by a Chief Executive Officer who is also Registrar of Biosafety. The Board is empowered to set up committees to provide technical and administrative support.

**Decision Making Procedure**

- Applicant submits application to Registrar
- Registrar checks for completeness before tabling the application before the Board
- Board appoints a team of experts to review dossier and recommend
- Board makes a decision based on RA experts opinion and other socio-economic considerations
- Any person aggrieved by the decision of the Board may appeal to the Minister within 30 days

**Guidelines and Standard Operating Procedures**

The following guidelines and standard operating procedures (SOPs) are in place:

i) Contained Use (laboratory, greenhouse and field trials)
   - Guidelines and SOPs for registration and auditing of laboratories, greenhouses and field trials were first developed in 2000
   - These are periodically reviewed

ii) Import of LMOs for Food, Feed and Processing
   - Guidelines and SOPs for LMO FFPs first developed in 2001
   - These are periodically reviewed

The drafting of a labelling framework commenced in 2006 is work in progress.

**Risk Assessment and Risk Management Experiences (Pioneering)**

Applications received to date include the following:

- May 2000, first application for field trials with GM crops: Bt maize MON810, Cry 1A(b)
- June 2000, second application for field trials with GM crops: Bt cotton MON531, Cry 1Ac
- July 2003, Bt 11 maize
- July 2003, Bt COT102 cotton
- April 2004, first application for commodity clearance (LMO FFPs)

Other notable experience include; GM mosquito, GM micro-organisms and GM vaccines.
Capacity building in Risk Assessment and Risk Management

Three RA and RM courses have been conducted since 2003. The trained experts are entered into national database of RA experts and consulted as need arises.

Challenges

- Insufficient Financial Resources
- Limited Human Resources
- Inadequate Laboratory infrastructure
- Ignorance and polarization
- Issues related to Labelling

Conclusion and Recommendations

The application of GM technology is on the increase but there is limited capacity to ensure its safe use. There is need for capacity building in risk assessment and risk management. Also GM testing is critical. Furthermore regional harmonisation on these issues is important and public awareness, education and participation by honest knowledge brokers.

Mr. Abisai Mafa

Participants of the Training Workshop
3.7 THE EUROPEAN UNION BIOSAFETY FRAMEWORK

Dr. Hans Bergmans, s
National Institute for Public Health and the Environment, Netherlands

A discussion of the European Union (EU) Biosafety Framework may be of interest to this workshop, because it shows the evolution of this biosafety framework over a period of about 20 years. It is the result of many differences of opinion and many discussions.

The EU biosafety framework is based on the following EU Directives and Regulations:

Environmental Risk Assessment of contained use and field experiments with GMOs


This directive provides the procedures for risk assessment of contained use of GM micro-organisms. The risk assessment takes into account that the physical containment provided by the permanent structure (laboratory building, etc.) in which the activities are performed will limit the contact of the GMO with the environment.


This directive lays down the methodology of environmental risk assessment (ERA) of field experiments with GMOs (Part B of this directive; the placing on the market of GMOs, covered in Part C of this directive, is covered in the next section).

Both the approval of GMO experiments under contained use as the approval of field experiments (Part B of 2001/18/EC) are the responsibility of the individual EU member states. For that purpose, each member state has to implement the provisions of these directives into its own legislation.

Placing on the market of GMOs

Before a GMO can be approved for placing on the market within the EU, a risk assessment has to be done, that takes into account the environmental safety aspects of the GMO, as well as the food/feed safety aspects, if applicable. The procedures for placing on the market are the responsibility of the European Commission, in collaboration with the EU member states and advised by the European Food Safety Authority (EFSA).

Directive 2001/18/EC, Part C, lays down the provisions for an ERA of GMOs that are to be placed on the market. These procedures can be followed for the approval of import or cultivation of GMOs that are not intended for use as or in food or feed. Examples are cut flowers, or cotton seed for cultivation, if the cotton products are only used for the production of fiber. If any of the cotton products are used as food or feed, this procedure would not be sufficient. Also, if discussion about the risk assessment remains between the member states, the procedure under EU/1829/2003 described in the next paragraph is followed.

The Regulation (EU) No. 1829/2003, on genetically modified food and feed lays down the procedures for food and feed safety testing for GMOs that are to be used as or in food or feed. (http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:268:0001:0023:EN:PDF). It is a Regulation, which implies that it is directly legally binding for the EU member states and does not require to be implemented in national legislation (except for some legal aspects such as punitive action).

EFSA (http://www.efsa.europa.eu/en/faqs/faqgmo.htm) has been appointed as the agency that performs the risk assessment under EC/1829/2003, as well as the environmental risk assessment that is necessary for release
of the GMO. These may be concerns around spillage of GMOs that have been imported for use as or in food or feed, or, concerns around the cultivation of GMOs. EFSA performs both the food/feed safety assessment as the ERA at the same time (see http://www.efsa.europa.eu/en/sedocs/doc/99.pdf). An ERA for cultivation of a GMO is performed in close cooperation with the member states, similar to the ERA procedure according to 2001/18/EC.

The EFSA risk assessment procedure results in an opinion of the agency on the use of the GMO. This opinion, that is publicly available, is sent to the European Commission, and is the basis for a proposal of the Commission for approval or rejection of the GMO application.

This proposal is discussed by the EU member states, in a standing committee that reports to the Commission. If the vote in this committee does not result in a qualified majority for either rejection or approval, the proposal is sent on to the Council of Ministers (the Environment or the Agriculture Council). Here also a qualified majority is needed for either approval or rejection. If no qualified majority is reached (which is not an unusual situation) the European Commission takes a final decision, which will be according to its original proposal. Market approvals are valid for a period of 10 years.

After the placing on the market of a GMO is approved, member states may still claim a safeguard close, on the basis of new information on the environmental safety of the use of the GMO. The approval of a safeguard close also requires a Commission procedure, including a vote, but if granted the member state may reject the market release and use for food or feed purposes of the GMO on its territory.

Very recently new EU legislation has been promulgated that grants individual member states more possibilities to reject the use of a GMO on their territory. Once a GMO has been approved for placing on the market, the EU Regulation 1830/2003 applies. This regulation provides a framework for the traceability of products consisting of or containing GMOs) as well as food and feed produced from GMOs. (http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32003R1830:EN:HTML)
4. SESSION THREE: BACKGROUND PRESENTATIONS ON RISK ASSESSMENT GUIDELINES

4.1 INTRODUCTION TO RISK ASSESSMENT
What is risk assessment, general principles, key elements of a risk assessment framework

Dr. Flora Ismail, Lecturer
University of Dar es Salaam, Tanzania

In this session an introduction to the concept of risk assessment as part of risk analysis were outlined. Remotely management and communication were touched upon to allow ease of connection to the next session.

Definitions

‘Risk’ from GMOs relates to the chance (likelihood/ probability) that a transgene product or GMO causes a specified adverse effect. Thus Risk Assessment is the application of a formal framework or analytical process that determines this probability by assessing the source or initiator and the adverse effects for purposes of guiding decision-making.

General Principles

Risk analysis is a blend of art and science, and comprises risk identification, risk assessment, risk management and risk communication (figure 1).

![Image of Risk Assessment, Management, and Communication](image)

**Figure 4.1.1. Components of risk assessment**

Risk analysis should be comprehensive, but it must remain feasible given the available time and resources. It must be directed towards assisting those responsible for making decisions to do so in a way, which is consistent with scientific principles, legal requirements and public values. How far one goes in carrying out a risk analysis is determined by what is needed to provide the decision-maker with as much assistance as possible, in the time and with the resources available. Risk analysis requires skilful judgment as well as scientific rigour.

Challenges of incorrect use of concepts related to risk such as ‘Hazard’ (the inherent properties of a substance, object or activity with a potential for adverse, or harmful, effects to occur) and ‘Exposure’ (a quantitative measurement of the extent to which a given hazard is present) can cause unnecessary alarm.
Key elements of Risk Assessment

When looking at commonalities of the different frameworks for Risk Assessments, the understanding of the concept ‘risk’ by one framework should be clearly understood if not accepted by another is important. It is recommended that all risk assessments should be interactive and that the inter-relationship between risk assessment and risk management should not be undermined (see figure below).

![Risk Assessment model](image)

**Figure 4.1.2. Risk Assessment model**

Planning the assessment with the risk manager and communicating the risks to decision-makers and the general public are important parts of the Risk Assessments process.

Risk Assessment follows 3 basic steps as illustrated in figure below;

1) Problem formulation: this step involves clear identification of the problem at hand addressing the question ‘what could go wrong’?
2) Analysis: following problem identification characterisation of the potential or existing exposure to source/initiator and their effects is done. This is the core element of risk assessment.
3) Risk characterization: this is the final step integrating and evaluating exposure and effects information into application of risk management strategies and/or identification of strategies to address identified risks.
In this session, participants were introduced to environmental risk assessment and its guiding principles.

In general, the term environment covers the physical surroundings that are common to everybody including air, water, land, plants and wildlife. Thus, environmental risk assessment covers the risk to all ecosystems, including humans, exposed via, or impacted via, these media.

Identification, characterisation and handling of risk(s) should follow a structured approach, which is called risk analysis (risk governance), and which consists of three basic elements: risk assessment, risk management and risk communication (see figure).

Risk assessment can be described as "a process of evaluation including the identification of the attendant uncertainties, of the likelihood and severity of an adverse effect(s)/event(s) occurring to man or the environment following exposure under defined conditions to a risk source(s)". A risk assessment comprises four steps: hazard identification, hazard characterisation, exposure assessment and the integrative risk characterization. The risk assessment is a scientific exercise.
Risk management is the process of weighing policy alternatives in the light of the result of a risk assessment(s) and of other relevant evaluations, and, if required, of selecting and implementing appropriate control options (including, where appropriate, monitoring/surveillance activities).

Risk communication is the interactive exchange of information and opinions throughout the risk analysis process concerning risk. It should involve not only risk assessors and risk managers, but also consumers and a wide range of other actual or potential stakeholders.

Guiding principles

i. Science-based – Risk should be assessed using information obtained through application of science and the scientific method.

ii. Open, transparent and documented – All aspects of the process of risk analysis should be documented fully in a transparent manner.

iii. Case-by-case – Risk should be assessed on a case-by-case basis.

iv. Comparative – Risks should be compared to background.


vi. Iterative – Risks should be evaluated and reviewed as appropriate in the light of newly generated scientific data. Conclusions and assumptions should be examined relative to new information.

vii. Inclusive – The process of risk analysis should be all-encompassing. The three components of risk analysis should be applied within an overarching framework for management of food-related risks to human health and the environment.

Cartagena Protocol provisions (Article 15, annex III, Road map), key issues: non-target, invasiveness/weediness, and gene flow.

The Cartagena protocol on Biosafety was adopted in Montreal in January 2000, and came into force on 11 September 2003. It is a legally binding international agreement under the United Nations’ Convention on Biological Diversity (CBD).

The protocol recognizes that GMOs may have biodiversity, human health and socio-economic aspects that should be taken into account when making decisions about GMOs. Precaution is the basis for the protocol, and is operationalized in decision making and risk assessment.

4.3 FOOD SAFETY RISK ASSESSMENT

Samuel Kiboi
University of Nairobi, Kenya

In this session participants were introduced to the principles of risk analysis of foods derived from modern biotechnology.

Principles of risk analysis

Rationale
Foods are generally considered safe provided that care is taken during development, primary production, processing, storage, handling and preparation.
The hazards associated with foods are subjected to the risk analysis process of Codex Alimentarius Commission, and, if necessary, develop approaches to manage these risks.

**General Principles**

The following are used internationally in safety assessment of recombinant – DNA (r-DNA) foods:

- Conventional foods are generally considered to be safe, provided they are prepared and handled according to laid down standards.
- Novel foods, including r-DNA foods, are required to undergo mandatory pre-market safety assessment in some jurisdictions (e.g. Japan, Canada, Australia, New Zealand, United Kingdom, and EU).
- An explicitly cautious approach is applied to foods, such as r-DNA foods, with no history of safe use

**General considerations** (recombinant, host, donor, genetic modification, toxicity, allergenicity, compositional analysis, evaluation of metabolites, unintended effects, marker genes)

Safety assessments of r-DNA foods are undertaken according to key principles:

- Safety assessments use scientific, risk-based methods.
- Safety assessments are conducted on a case-by-case basis.
- Both intended and unintended effects of genetic modification are considered.
- Where appropriate, comparisons are made with conventionally produced foods.

Decisions with respect to safety are based on the totality of the evidence.

Risk assessment is the process of determining as accurately as possible the actual likelihood and consequences of the risks presented by exposure to identified hazards. The objective is to identify the potential for adverse effects that r-DNA foods may pose for human and animal health. Use a modified hazard identification scheme referred to as a safety assessment to identify whether a hazard is present in the whole food.

**Case by Case assessment:**

Applied to a food commodity, for the food and food products derived from that modified commodity e.g. corn (kernels, corn flour, corn syrup, oil); canola (oil); cotton (oil and linters). Foods derived from a commodity (e.g. soybeans) that have been modified with different traits are assessed separately and any subsequent use of modern biotechnology product requires a separate safety assessment.

In consideration of intended and unintended effects, safety considerations apply to all aspects of the r-DNA food and are conducted in the two phases:

1. Identification of similarities and differences
   - traditional vs. novel sources of donor DNA/genes,
   - molecular characterization – new genes, proteins, genetic stability, compositional analysis.

2. Identified differences are subjected to further scrutiny
   - toxicity/allergenicity of any new protein,
   - safety of any transferred antibiotic resistance genes,
   - safety, nutritional impact and pattern of any compositional changes.
Substantial Equivalence

CODEX Guideline paragraph 13 states that:

“The concept of substantial equivalence is a key step in the safety assessment process. However, it is not a safety assessment in itself; rather it represents the starting point which is used to structure the safety assessment of a new food relative to its conventional counterpart. This concept is used to identify similarities and differences between the new food and its conventional counterpart. It aids in the identification of potential safety and nutritional issues and is considered the most appropriate strategy to date for safety assessment of foods derived from recombinant-DNA plants. The safety assessment carried out in this way does not imply absolute safety of the new product; rather, it focuses on assessing the safety of any identified differences so that the safety of the new product can be considered relative to its conventional counterpart”.

The goal of this assessment is to identify similarities and any differences between the GM crop and conventional plant variety.

Criteria for identifying whether a novel food is at least as safe as the equivalent existing food are:

- Molecular characterization,
- Phenotypic equivalence,
- Compositional equivalence,
- Toxins,
- Allergens.

Molecular Characterisation

The safety assessment process for a transgenic food begins with the description of the host and donor organisms and the characterization of the genetic modification.

Phenotypic Equivalence:

This assessment is essential to demonstrate that there are no unexpected biological effects of the introduced trait. The following two key components are evaluated; morphological and agronomic characteristics.

Compositional Equivalence:

The goal is to establish whether components of the new food or feed fall within the generally accepted ranges of traditional varieties. The analysis looks at both beneficial and harmful components in the diet.

Toxicity

Codex Guideline paragraphs 34–40

Key considerations:

- protein expression product(s) of the inserted gene(s)
- effects resulting from disruption of gene expression due to insertion of donor DNA into the host genome

Intention to determine safety: as safe as the conventional counterpart

- e.g. conventional soybean has the potential to affect endocrine functions – GM soybean with an equivalent composition would have the same potential
Introduction of DNA can lead to the synthesis of new substances in plants. Therefore the chemical nature and function, and concentration in the edible parts and mean values must be determined. In the case of proteins, potential toxicity should focus on the amino acid sequence between the protein and known protein toxins and anti-nutrients (protease inhibitors). In addition the stability to heat or processing and degradation in appropriate gastric and intestinal model system. Toxicity studies need to be carried out in cases where the protein present in food is not similar to that have previously consumed.

Acute oral toxicity studies are normally performed in mice, to assess the possibility of adverse effects following a single exposure to the introduced protein. Animal studies have to be conducted with appropriate control treatments.

**Allergenicity (proteins) - Codex Guideline paragraphs 41-43**

True food allergies may involve several types of immunological responses. Most common types are allergen-specific immunoglobulin E (IgE) antibodies. Codex has adopted a list of the most common allergenic foods associated with IgE-mediated reactions. GM food crops can introduce potential allergenicity into the human diet. Therefore, Codex recommends that an integrated, stepwise, case-by-case approach be used in the assessment of possible allergenicity of GM food.

The following are important parameters in allergenicity assessment:

- **Source of Protein**
  - reports of allergenicity of the donor organism be described
- **Amino Acid Sequence Homology**
  - to assess the extent of a newly expressed protein is similar in structure to a known allergen
- **Pepsin Resistance**
  - to determine resistance of protein to pepsin in order to correlate to allergenic potential
- **Specific Serum Screening**
  - Sera from individuals with a clinical validated allergy to the source of the protein can be used to the specific binding to IgE class antibodies of the protein in vitro assays

**Limitations of Substantial Equivalence**

The following are the limitations of substantial equivalence concept:

- Requires sufficient analytical data to be available in the literature, or be generated through analysis,
- Its dependence on a comparator and on the information that is available, or can be generated for the comparator,
- The choice of comparator is crucial for effective application of the concept, and
- An appropriate comparator
### 4.4 SOCIO-ECONOMIC IMPACT ASSESSMENT

**RAEIN-Africa multi-disciplinary biosafety socio-economic consideration research team**

Apart from Scientific Risk Assessment and Risk Management the CPB also provides for socio-economic considerations in biosafety decision making. Mrs Patricia Masanganise presenting on behalf of the RAEIN-Africa multi-disciplinary biosafety socio-economic consideration research team looking at unpacking the socio-economic consideration shared on the experiences of the team in the process of developing a socio-economic impact assessment guideline.

In her presentation Mrs Masanganise highlighted the short coming of the CPB provisions on socio-economic considerations which included:

- Countries may consider socio-economic considerations in their decision making
- The provision limits to “the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities”
- National legislation may expand scope
- Countries may consider socio-economic assessment depending on the costs and benefits of such policy alternative.

Mrs Masanganise stressed the importance of understanding livelihoods in African setting and the importance of agriculture in rural livelihoods. The figure below highlights context of livelihood, the desired livelihood outcomes and shows that introduced technologies can influence livelihood activities.

![Diagram](image)

**Figure 4.4.1. Understanding Livelihoods**

Some of the socio-economic impact assessment approaches include:

- Cost benefit analysis
- Gross margin Analysis
- Socio impact assessment
- Sustainable livelihoods analysis.
In conclusion Mrs Masanganise highlighted the following challenges with integrating biosafety socio-economic considerations in decision making processes:

(1) Process related challenges:
- Divergence of views regarding socio-economic benefits or risks of GMOs;
- Achieving consensus on possible parameters of socio-economic assessment (harmonized approach) among Parties to the Biosafety Protocol may prove difficult;
- Absence of an internationally agreed framework/guideline.

(2) Conflicting interests:
- The need to grow more food vs. conservation and sustainable use of biodiversity;
- Challenges of using GM technologies for adapting to climate change vs. biosafety;
- Declining investment in public research and development vs. limited interest by industry to work on traits of interest to smallholder farmers.

(3) Legal challenges
- Adverse socio-economic impacts may be difficult to prove;
- Legal certainty in providing for socio-economic considerations;
- Trade disputes, in particular by non-Parties against Parties to the Protocol;
- Conflict with other international treaties – WTO and its sub-agreements.

(4) Lack of capacity
- Lack of expertise in socio-economic evaluation of the introduction of GMOs;
- Little experience in integrating socio-economic considerations into biosafety decision-making;
- Absence of baseline data.

In plenary a lot of views were expressed in relation to how to carry out Socio-economic assessment, how to come up with information to support decision making and lack of standards for assessment. In general participants acknowledged the need for a guideline on socio-economic impact assessment that will allow for generation of information for decision making by the regulatory authorities.

4.5 PROBLEM FORMULATION AND OPTION ASSESSMENT

_Hartmut Meyer_
_Gesellschaft fuer Technische Zusammenarbeit (GTZ), Germany_

The Problem Formulation and Option Assessment (PFOA) Tool has been developed by the "GMO Guidelines Project" – now "GMO Environmental Risk Assessment Project" – which is an international initiative of public sector scientists in the Global Working Group on "Transgenic Organisms in IPM and BioControl" under the patronage of the International Organisation for Biological Control. The project has published a PFOA Handbook which is freely available in the internet and three country case studies, which are freely available for scientists in developing countries. The publication of the peer-reviewed books has been supported by the Scientific and Technical Advisory Panel of the GEF.

The PFOA Tool is an instrument for technology assessment. PFOA can facilitate early, informed and transparent decisions on the suitability of certain technological options to solve unmet needs. Its major steps are:
- deliberative formulations of problems
- comparative assessments of future alternatives
  - relative to the biosafety evaluation of GMOs
  - including options that currently exist, will exist or may exist
In the context of established assessment methodologies it is important to keep in mind that PFOA cannot replace the application of instruments as Socio-Economic Assessments or Environmental Risk Assessments. PFOA can supplement or frame these more specific assessments. PFOA should also not be used as:

- merely back grounding or context setting to risk assessment
- a tool to understand how to sell the idea of GMOs to the public

The overarching approach of the PFOA is to put all people affected by a proposed GMO use and the centre of the assessment. Thus, a PFOA is characterized by the

- Participation of all stakeholders at different scales,
- Combination of public participation, scientific analysis, and political decision making,
- Improvement of transparency and legitimacy,
- Suitability as core component in country-driven, case-specific GMO assessment.

The typical process of PFOA as set up by the GMO Guidelines / GMO ERA Project and tested and improved by three country case studies in Kenya, Brazil and Vietnam consists of nine elements:

Step 1: Problem Formulation
Step 2: Prioritization and Scale of Problem
Step 3: Problem Statement
Step 4: Authority decision -- analyze options
Step 5: Options identification
Step 6: Attributes established through for Solving Problem
Step 7: Changes Required and Anticipated for a Solution Option
Step 8: Impact to the System
Step 9: Authority decision -- select an option

Through this format the PFOA is closely linked to the decision making procedures of the respective biosafety system in the country. Steps 4 and 9 require decision making by the authorities and thus ensure that a PFOA is not merely academic or alibi exercise.

As stated above, the PFOA can also serve to better perform the in most countries legally binding Environmental Risk Assessment (ERA) of GMOs. Through the additional information that are gathered especially in Step 7 and 8, the ERA can specifically take into account problematic areas that are of concern for the farmers and consumers as final users of the GMO. The existing models of ERA deliberately exclude public participation and keep the normative and scientific steps of ERA in closed circles of experts. PFOA therefore is suited to:

- Improve the science of ERA
- Provide for responsive relationship between citizens and the ERA process
- Strength the legitimacy of the ERA and GMO governance
- Link ERA with the biosafety system
- Help society evaluate technologies in the light of alternative futures

PFOA has been developed after the Cartagena Protocol has been negotiated and also after the UNEP GEF biosafety capacity building projects have been formulated. Thus, PFOA is neither element of the legally binding CPB nor was it taken up as element in the UNEP GEF capacity building projects. The concept has been introduced to the international biosafety community in 2004 at MOP-1 and since then promoted through various events and projects. As far as it is known, there is no introduction of a GMO – or an alternative option - that has been guided by a PFOA so far. Apart from the lack of linkages between PFOA and the existing formal biosafety system it is also the reservations of the technology developers against the approach that hinders its broader application. Since the concept became popular in 2004, technology developers have been eager to adopt the wording ‘problem formulation” but to restrict its application on Step 1 of the ERA, the Hazard Identification. In this context, “problem” is not understood as the problem to be solved by the application of a specific technology option but the problem to be avoided that might result from the application of GMOs. Currently, the problem
formulation usually is performed by the technology developer and is presented to the stakeholders afterwards. In addition, it is of no greater interest of a technology developer to discuss alternative options to its new technology and to risk the redirection of a development pathway using other products or methods. To the contrary, the attitude to declare the own technology as “silver bullet“ approach is common. With regard to available alternatives, a widely spread statement is that there are no alternative available – any longer – and that stakeholders have no choice but to accept the use of GMOs.

The lecture at this workshop will illustrate the theoretical concept of PFOA with the outcome of a PFOA of Bt maize in Kenya. The aim of the lecture is that the participants should:

- Inform themselves about the PFOA approach and case studies
- Develop PFOA processes in their own context
- Promote transparent and open discurses on the use of GE crops
- Do not support discurses with predetermined end-points
- Improve their national biosafety systems.

4.6 THE BIOSAFETY ASSESSMENT TOOL

Hartmut Meyer,
Gesellschaft für Technische Zusammenarbeit (GTZ), Germany

The Biosafety Assessment Tool (BAT) is a free-to-the-public and online resource to assist citizens and regulators who are reviewing the scientific data provided by developers of GMOs in support of their evaluation of safety. It is an element of the Biosafety Forecast Service being developed in the Biosafety Capacity Building Project of Norwegian Institute of Gene Ecology and its collaborators Third World Network and the Centre for Integrated Research in Biosafety (INBI). The work is funded by the Norwegian Agency for Development Cooperation. The work on the BAT started in 2004, it was presented to the public in 2009.

The aims of this Forecast Service are:

- to look ahead to emerging biotechnology developments that will create risk;
- to encourage research on those risks before significant commercial investment.

In practical terms, the Forecast Service should

- facilitate understanding of the NBF regardless of prior experience;
- help users to identify and interpret the science in GMO applications;
- help users to evaluate the quality of the applicant’s dossiers.

The text and figures of the BAT are free for public use.

Why use the Biosafety Assessment Tool?

The BAT can be used to assist you evaluating the scientific documents that should accompany an application for development or release of any GMO / LMO as required under the Cartagena Protocol on Biosafety and under you country’s NBF or biosafety legislation. Comprehensive science-based evaluations are required when GMOs should be used in food, feed, agriculture or in the environment.

Who the BAT is for?

The BAT has been developed for a broad range of users that are interested in assessing the safety data on GMOs, reporting on the safety of GMOs, or have official policy or decision maker roles in approving GMOs for use in food, feed or the environment.
It is intended to be accessible to specialists and non-specialists alike, and to assist users to identify relevant risk issues, evaluate technical information and develop responses to applications for formal governmental approval of GMOs.

The BAT was developed to simplify and accelerate the review of often highly technical information provided by developers seeking approvals and the large body of research in the specialist literature that is relevant to sound scientific decision-making. Citizens, scientists, media professionals and regulators are under considerable time stress to return opinions. The BAT was designed to help our audience make the best use of their time.

**BAT Standalone Version**

The BAT has been compiled into an HyperText Markup Language standalone version. It lacks the advance user interface functionalities of the online version <https://bat.genok.org/bat/>, but has identical content. It is ideal for people who do not always have internet access to download. <https://bat.genok.org/bat/resources/downloads/standalone/bat_standalone.zip>

**BAT Reference Data**

References used in the BAT can be downloaded below. The files are organised by chapter and were created using Endnote's XML export functionality.

**How to use the BAT?**

The BAT is arranged into three primary sections:
- Practical Assessment: when you are ready to compose a submission or review of a GMO application
- Topic Guides: when you need some background information
- Checklist: when you think you are done with your risk evaluation

**Practical Assessment**

This section is for users who are reviewing the information on a GMO. The material in the Practical Assessment is organized in a similar fashion to that of a typical application (or dossier) submitted by a GMO developer or importer seeking regulatory approval. The objective of the Practical Assessment is to assist users to critically evaluate the technical information in an application, and identify information gaps in the dossier. It provides an explanation of the significance of the main parts of an application sensitizes users to different risk perspectives and highlights areas where the science is uncertain.

**Topic Guides**

The Guides are intended to provide users with an in-depth discussion of the issues involved in hazard identification and characterization. The information presented in here is especially pertinent to first time users, non-specialists, or those just beginning to evaluate GMOs. Guides are intended to be used with Practical Assessment.

**Checklist**

The Checklists take the form of an electronic ‘reminder’. The information presented in the BAT is organized in this section according to questions that may need to be considered by decision-makers. It will point to information that may help the decision-maker to address questions specific to a country or region. This section is recommended for users that have finished their risk evaluation/assessment.

**Practical application of BAT**

The participants were introduced into the online-tool through a demonstration of selected items.

In this session further details with examples on the risk assessment elements of risk analysis and characterisation were given.

**Hazard Identification**: ‘Hazard’ is the inherent properties of a substance, object or activity with a potential for adverse, or harmful, effects to occur. The actual hazards likely to be encountered will vary depending upon the parental organism, the genetic construct, the lifecycle stages, the environment in which the organism is to be released, etc.

**Exposure assessment**: ‘Exposure’ is a quantitative measurement of the extent to which a given hazard is present. In order for a person/ environment/ organism to be exposed, the hazard must be present in a particular dimension. Exposure can be qualitative (how the recipient environment is exposed to the transgenic organism) and/ or quantitative (data needs and methodologies to establish adverse impacts).

Risk is the probability that an adverse effect will occur to someone. Risk is therefore also quantitative, and can be expressed as a probabilistic number, such as a percentage.

\[ \text{Risk} = \text{Hazard} \times \text{Exposure} \]

**Evaluation of consequences**: How are the adverse effects or consequences of exposure to transgenic elements evaluated? Both quantitative and qualitative adverse assessment will be presented, using examples the various data needs, methodologies and possible source of costs highlighted.

**Overall risk estimation**: Expressing duration, intensity, magnitude, and reach of the potential consequences of a risk in quantifiable terms. Description of the probability that an organism exposed to a specific dose of substance will develop an adverse effect.

**Recommendation for decision and management measures**: Risk communication and management:

**Risk Communication**: The interactive exchange of information and opinions throughout the risk analysis process concerning risk, risk-related factors and risk perceptions, including the explanation of risk assessment findings and the basis of risk management decisions

**Management and monitoring**:
- Physical (Physical – Exclusion zones, Barriers, Separation distances, Volunteer control, Production chain separation, Protected areas, Restrict planting times).
- Biological (Genetic Use Restriction Technologies, Chloroplast transformation, Promoter induced expression)
- Verification of the risk assessment
- Verify if gene flow occurs
- Quantify gene flow
- Compliance to risk management measures
- Early warning of adverse effects
Presenters of this session:

Dr. Flora Ismail

Dr. Samuel Kiboi

Dr. Hartmut Meyer
5. **SESSION FOUR: RISK ASSESSMENT PRACTICE**

Preceding the practical exercise on risk assessment participants were taken through the risk assessment process: hazard identification, exposure assessment, evaluation of consequences, and overall risk estimation.

For the hands-on training on the safety and risk assessment of Genetically Modified Organisms (GMOs), breakout sessions were held using the two case studies MON 15985 Cotton for environmental risk assessment and MON 89034 maize for food safety evaluation. Working groups, each comprising about 20 participants were formed. Each group was assisted by a workshop facilitator to discuss and assess the data in the case study.

The breakout sessions were divided into two parts:
- AGBIOS pre-market environmental risk assessment of transgenic plants: a case-study approach utilizing MON 15985 Cotton
- Application for authorization of MON 89034 maize in the European Union, according to Regulation (EC) No 1829/2003 on genetically modified food and feed

At the end of the sessions, the working groups met to present their findings.
6. SESSION FIVE: RECOMMENDATIONS AND CLOSING

6.1 Recommendations from Participants

Reflecting on the training workshop, participants made the following recommendations on future training workshops:

- Separation of Risk Assessment and Risk Management training courses to allow for in depth coverage of each
- More practical sessions
- Include socio-economic impact analysis in training exercises

6.2 Closing of Training Workshop

The training workshop was officially closed by Mr. Fundisile Mketeni, Deputy Director General Biodiversity and Conservation, Department of Environment affairs. The closing was preceded by statements from RAEIN-Africa, African Union Commission, and GTZ.

Mrs Patricia Masaganise on behalf of the RAEIN-Africa Secretariat emphasised the value and unit in Partnerships and that is why RAEIN-Africa partnered with the African Union Commission. She stressed that during the training workshop we all shared ideas and experiences and that the CDs of workshop materials being provided should not be allowed to gather dust but make maximum use of what they had gained.

Mr. Bather Kone, Head of the Biosafety Unit, African Union Commission in his statement pointed out that during the five days of training participants had committed themselves to learn about risk assessment and risk management of GMOs, one of the key elements of the CPB and on which Africa needed more capacity building. The training workshop was one step in the right direction. On behalf of the Director of the Department of the Human Resources Science and Technology of AU, Mr. Kone thanked trainers and trainees for fruitful deliberations and the sponsoring partners, the Netherlands and Germany governments for the financial and technical support to the initiative. Dr. Kone acknowledged RAEIN-Africa Secretariat for preparations for the training workshop.

In his closing statement, Dr. Molapong from SADC Secretariat emphasised the importance of building capacity in risk assessment and risk managements; as concerns over food safety, environmental safety and socio-economic impacts of GMOs have prevented African countries to take advantage of opportunities presented by modern biotechnology. Dr. Molapong commended RAEIN-Africa's initiative to work with AU and SADC in building capacity on biosafety issues. He informed participants that the SADC Secretariat supports this partnership and is looking forward to establishing a formal relationship with RAEIN-Africa.
Dr. Molapong took this opportunity to reveal that SADC in partnership with RAEIN-Africa will be hosting a High Level Dialogue for policy makers in agriculture, science and technology and the environment to allow deliberations on these issues and come up with a framework on the safe handling and trans-boundary movement of GMOs in the region.

Dr. Hans Bergmans from the Netherlands thanked RAEIN-Africa and the African Union for organising the training workshop and hoped that the training will be sustainable by transferring knowledge gained to others in the home countries. He hoped that his presence at the training workshop had given the participants some encouragement.

Dr. Hartmut on behalf of GTZ in his statement he stated that GTZ participation in AU Biosafety project was routed in a broader context of institutional strengthening (2005 – 2009). One of the purposes was to strengthen the capacity and support AU to engage African countries on issues of Biosafety. He acknowledged and was glad of the AU and RAEIN-Africa partnership. He informed participants that the workshop was on one side and real life was on the other side and therefore it was important for them to make use of what they had learnt.

Mr. Fundisile Mketeni, Deputy Director General, Biodiversity and Conservation, Department of Environmental Affairs, South Africa in his closing speech was honoured to share his views and shared on the South Africa regulatory system on GMOs. He stressed that as a continent we needed to improve food security and conserve biodiversity. Mr. Mketeni advised that risk assessment in one thing and risk management is another. He added that the challenges faced by countries in the region are similar therefore we can use our opportunities to face our challenges. When we deal with challenges of food security development etc. we need partners. Development comes with a risk. Mr. Fundisile Mketeni pointed out that often at meetings he has attended there was always a call for “Capacity Building” and hoped the training had given participants the required capacity. He further stressed that the need to share experiences cannot be over emphasised. He noted the mixture of young and old among the participants that it was important to get this balance. The region needed its own networks and therefore called for creation of dialogue.

Mr. Mketeni informed meeting that the South Africa government viewed the CPB as a key instrument for ensuring the responsible use of biotechnology as part of the sustainable agenda. He welcomed the convening of the regional training workshop by the AU and RAEIN-Africa. South Africa was committed to support the region process on risk assessment and risk management for genetically modified organisms. Mr. Mketeni shared that South Africa like many developing countries faced the common challenge of reconciling innovation with sustainable growth and high level health and environmental protection. As such in the country National Sustainable Development Framework, identified the use of biotechnology as a strategy for economic development and brings important benefits: economic growth, better quality of life, job opportunities and more consumer choice. However South Africa was not blind to the risks or potential risks associated with the adoption of new technologies such as biotechnology and therefore have taken an approach that considers that sustainability of current technological trends depends in turn on our ability to ensure good governance concerning the potential risks associated with new technology. In this regard risk assessment and risk management systems become key building blocks and the workshop such as this one, proved ongoing opportunity and enhance our understanding of environmental risks and appropriate management actors.

In conclusion, Mr. Mketeni committed South Africa to playing a key role in regional biotechnology and biosafety processes and was happy to share experiences in the regulation of GMOs and to provide assistance to other regulatory authorities in the region as required. On preparations for COP-MOP5 meeting in Nagoya Japan, Mr. Mketeni informed the meeting that South Africa will consider mechanisms of ensuring the effective implementation of the CPB. He pointed out that South Africa will together with the African group place great emphasis on those agenda items that assist developing countries to implement their obligations under the protocol. South Africa will advance discussions on risk assessment and risk management, capacity building and the roster of Biosafety experts together with public awareness and participation. In terms of the contentious agenda items Mr. Mketeni hoped that together with the African group will reach consensus on matters that are of mutual interest, particularly the supplementary Protocol on Liability and Redress standards for identification, handling, packaging and transport of GMOs.
RESOURCE PERSON AND TRAINERS INDEX

Professor Ossama M. El-Tayeb is Professor Emeritus of Microbiology and Immunology and Director of the Microbial Biotechnology Centre at the Faculty of Pharmacy, Cairo University. He holds a B.Sc. from Cairo University, an M.S. from Columbia University and a Ph.D. from the University of Wisconsin. He has taught at universities in Nigeria, Libya and Hungary, besides his home base in Egypt. He served as Senior Program Officer for Genetic Resources and Biotechnology at the United Nations Environment Program, 1977-1983.

He is the author of several monographs and articles on science policy and socio-economic dimensions of science and technology and has published 120 original research articles. He served as Principal Investigator on several major research projects in Egypt in collaboration with universities in the USA and Sweden. Professor Ossama has supervised many post-graduate students at several universities. He serves on the Editorial Board of several scientific journals and on the Boards of several scientific societies. He has been heavily involved with industrial consultations in Egypt.

He has served as Chairman/member of the Permanent Committee for evaluation of applicants for professorship of microbiology and immunology (since 1982); the Vice-Chairman of the Committee for the Biotechnology Sector (since 1997); the Supreme Council of Universities. He is a member of the Executive Committee for the National Strategy for Biotechnology of the Academy of Scientific Research and Technology; Head of the Ministerial Committee for Drafting a National Biosafety Legislation of the Ministry of State for Environmental Affairs and served as the Chief Negotiator for Egypt for the Cartagena Protocol on Biosafety, 1996-2000. Professor Ossama is also a member of many committees at the ministries of: health, higher education, scientific research, foreign trade, industry, agriculture and environment and of the National Specialized Councils of the Presidency.

Dr. Hans Bergmans is a Senior Scientist National Institute of Public Health and the Environment (RIVM), the Netherlands. He has 21 years’ experience as a Senior Scientist at the GMO Office, RIVM (1990 – to present). Dr Bergmans is a member of the Gene therapy Net association.

Mrs Mahlet Teshome is a Biosafety Expert and an Environmental Lawyer at the Department of Human Resources Science and Technology of the African Union Commission (AU). She has her first degree (LLB) in law and a Master’s Degree in Environment and Development Studies. At the AU she is in charge of legal issues on biosafety and assists Member States in the implementation of their national obligations on biosafety and the development of their national biosafety laws. She has given various lectures on the AU perspectives on biosafety and biotechnology, the international legal instruments relevant to biosafety and outstanding legal issues being negotiated.

Mr. Alex Owusu-Biney is the Regional Coordinator for Africa on Biosafety with UNEP’s Division of Global Environment Facility Coordination (DGEF). He supports countries in the African region through capacity building activities funded by GEF to meet obligations under the Cartagena Protocol on Biosafety. His main areas of focus are on the Development and Implementation of National Biosafety Frameworks and providing advisory support on the Biosafety Clearing House Project.

His areas of expertise include research, development and management in biotechnology and biosafety, science and technology policy and regulatory issues and information management. Alex has graduate training in Biochemistry and molecular biology with specializing in virus mediated transfer of genetic material. His work life include teaching Biochemistry at the University, food and drugs inspector and a research scientist in biotechnology/biosafety with several publications in biotechnology, biosafety and radiation biochemistry.

Prior to joining UNEP, Mr Owusu-Biney was the National Biosafety Coordinator for Ghana and was the key facilitator/technical advisor on the development of a draft biosafety framework for Ghana and several African countries especially in the West African sub region. He also reviewed several National Biosafety Frameworks including the Gambia, Ethiopia, Nigeria, Seychelles, Rwanda and Mozambique to mention a few. He was also involved in the development of the CORAF led-biotechnology and biosafety programme for the West and
Central Africa Region, AATF, USAID/PBS and the NEPAD Biosciences programme for West Africa.

Mr Owusu-Biney has also been involved in biotechnology and biosafety development issues, including the negotiations of the Cartagena Protocol for Biosafety as the representative of the Government of Ghana since 1999.

Ms Wadzanayi Mandivenyi is the Director Biosafety at the Department of Environmental Affairs in South Africa. She provides specialist and technical support on matters related to Biotechnology, GMOs and Biosafety through the relevant legislative frameworks, scientific evaluation of applications for GMO activities through the GMO Act processes and participate in the environmental risk assessment process and provide advice through written comments on the GMO applications requiring DEAT’s input in the GMO Executive Council. Ms Mandivenyi attends the GMO Executive Council meetings as technical resource for DEAT. She has developed an appropriate mechanism or system for ensuring that the relevant Biosafety legislation i.e. the GMO Act (Act No 15 of 1997), section 78 of Biodiversity Act, section 24 of the National Environmental Management Act, 107 of 1998, the draft Environmental Impact Assessment Regulations published in terms of Notice 764 Government Gazette 26503 of 25 June 2004 and Environment Conservation Act (Act No 73 of 1989) are complied with. She has developed guidelines and a framework for environmental risk assessment system.

Ms Gillian Christians is the Registrar of the GMO Act under the Department of Agriculture forestry and Fisheries in South Africa.

Ms Renusha Chanda is an Assistant Director at the Department of Health in the Directorate: Food Control. The Directorate provides an optimal non-personal preventative primary health care service in respect of the safety of food. Functions include drafting of legislation related to food safety and food labelling, providing information on food safety risks and evaluating foods produced by biotechnology, amongst other functions. The Director is the representative of the Department of Health at the Executive Council of the Genetically Modified Organisms Act, 1997 (Act 15 of 1997). Ms Chanda therefore works with the Director on all aspects related to GMOs and biotechnology in relation to human health and safety. She is also responsible for the amending and publishing of the Regulations No. R. 25 of 2004 relating to the labelling of GM foods under the Foodstuffs, Cosmetics and Disinfectants Act, 1972. She is also the national coordinator for the Codex Task Force on Food Derived from Biotechnology, which when active, develops standards for the risk assessment of GM foods.

Mr. Abisai Mafa is a sustainable agricultural, environmental and rural development practitioner with a special interest in science, technology and innovation. With a career spanning over 20 years, Mafa has worked as an educationist, research scientist, biodiversity conservation expert and agricultural technology manager. He has also worked on a number of sustainable livelihoods assignments at national, regional and international levels. Currently he heads the National Biotechnology Authority of Zimbabwe, an apex and strategic national biosciences institution with a mandate to promote the safe and responsible deployment of life sciences and biotechnology including Genetically Modified Organisms (GMOs) in all fields of human development. Mafa has worked at both field and policy level using participatory stakeholder inclusionary processes in agriculture, food security, environmental management and science and technology. Mr Mafa holds an MSc degree in applied and conservation genetics from the University of Birmingham in the UK, a BSc Honours degree in agriculture and several diplomas and certificates in other pertinent fields. He has played and continues to play a pivotal role in shaping agricultural, environmental and science, technology and innovation policies at national, regional and international levels. He is currently heavily involved in risk assessment and risk management of GMOs, food safety analysis and control, unravelling the socio-economic impacts of GMOs and promoting public awareness and participation in biosafety.

Dr. Flora AbdulRahman Ismail is a lecturer in the Botany Department at the University of Dar es Salaam, Tanzania - teaching plant physiology, tissue culture and environmental legislation and supervises undergraduate projects and MSc programmes in biosafety of gene flow and abiotic stress. Her research interests include desiccation tolerance of crops and biosafety- environmental risk assessment and transformation of cassava. She holds a BSc in Biology and Chemistry and an MSc from the University of Dar es Salaam and a PhD from
Rabourn University, the Netherlands. Dr Ismail is the Head of Botany Department, serves as coordinator of the Biosafetrain project and member of the UDSM Biosafety Committee.

**Dr. Samuel Kuria Kiboi** is a lecturer in the School of Biological Sciences at the University of Nairobi, Kenya. He teaches Plant ecology, Evolutionary Biology, population Biology, and Biosafety. He holds BSc in Biological sciences from Moi University, Kenya, MSc in theoretical ecology and a PhD in Plant Ecology and Systematics from Lund University, Sweden. Dr Kiboi has undertaken a number of biosafety related course in Genetically Modified crop plants in practice, risk evaluation of GMOs.

**Mrs. Patricia Masanganise** is a Senior Associate at Khanya-African Institute for Community Driven Development. She is a Development Specialist with over 20 years extensive experience in programme/projects design, planning and implementation of agricultural, food security and livelihoods development. Patricia has a BSc Agriculture (Honours) (Agricultural Economics), Masters in Agricultural Economics with Distinction and currently deepening her understanding of livelihoods issues through her PhD studies focusing on livelihoods opportunities in land reform settlements. Patricia is actively engaged in action research processes related to enhancing and sustaining food security and livelihoods of poor households and communities in African countries.

**Dr. Hartmut Meyer** is Biosafety Consultant at the Gesellschaft für technische Zusammenarbeit (GTZ), Germany. He is a holder of a PhD in Biology, specialised in plant biochemistry and molecular biology (1993) and a Post-doctorate in the Research Centre for Forest Ecosystems and Forest Decline, focusing on soil biochemistry and microbiology (1996). Since 1986, Dr Meyer has been doing voluntary work in Germany on various issues of genetic engineering in food and agriculture. He has been an observer at the negotiations of the Cartagena Protocol on Biosafety and other CBD meetings since 1970. Since 1997 he has been working as an independent expert on biosafety and modern biotechnology for various German institutions and NGOs.

As consultant worked on GTZ support to the African Union Commission; developed and implemented the Africa-wide Biosafety Project. He served as Chairperson of the Steering Committee of the Coordination Mechanism for Capacity Building of the Cartagena Protocol and annual Coordination Meetings. Dr Meyer is also working in the fields of intellectual property rights and access to genetic resources and benefit sharing for GTZ, and the German Protestant Church.
ANNEXES

ANNEX 1: WORKSHOP PROGRAMME

Biosafety Risk Assessment and Risk Management Training Workshop
Birchwood Hotel and OR Tambo Conference Centre, Johannesburg, South Africa
9th -14th August 2010

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
<th>Presenter/moderator</th>
</tr>
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<tbody>
<tr>
<td><strong>DAY ONE</strong></td>
<td></td>
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</tr>
<tr>
<td>0800 – 0830</td>
<td>Registration</td>
<td>RAEIN-Africa</td>
</tr>
<tr>
<td>0830 – 0845</td>
<td>Introduction of Participants</td>
<td>Facilitator (Abisai Mafa)</td>
</tr>
<tr>
<td>08.45 - 0900</td>
<td>Welcome Remarks and brief on AU Biosafety Programme</td>
<td>Mr. Bather Kone</td>
</tr>
<tr>
<td>0900 - 0915</td>
<td>SADC Statement</td>
<td>Dr. Keoagile Molapong</td>
</tr>
<tr>
<td>0915 - 0930</td>
<td>Remarks from RAEIN-Africa &amp; Brief on RAEIN-Africa Biosafety Programme</td>
<td>Mrs Doreen Shumba-Mnyulwa</td>
</tr>
<tr>
<td>0930 - 0945</td>
<td>Workshop Objectives</td>
<td>Abisai Mafa</td>
</tr>
<tr>
<td>0945 - 1000</td>
<td><strong>GROUP PHOTO and COFFEE/TEA BREAK</strong></td>
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</tr>
<tr>
<td><strong>FIRST SESSION: INTRODUCTION TO BIOTECHNOLOGY</strong></td>
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<tr>
<td>1000 – 1100</td>
<td>An Overview of Biotechnology</td>
<td>Prof. Ossama El Tayeb</td>
</tr>
<tr>
<td>1100 – 1200</td>
<td>Biodiversity, Ecosystems, the Convention on Biological Diversity (CDB),</td>
<td>Prof. Ossama El Tayeb</td>
</tr>
<tr>
<td></td>
<td>Biotechnology and the Cartagena Protocol on Biosafety</td>
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<tr>
<td>1200 – 1245</td>
<td>Plenary Discussion</td>
<td>Facilitator</td>
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<tr>
<td>1245 – 1400</td>
<td>LUNCH BREAK</td>
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<tr>
<td><strong>SECOND SESSION: INTRODUCTION TO BIOSAFETY</strong></td>
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<tr>
<td>1400 – 1500</td>
<td>An Overview of Concerns Arising from the Application of Gene Technologies</td>
<td>Dr. Hans Bergmans</td>
</tr>
<tr>
<td>1500 – 1600</td>
<td>International Mechanisms to Address Biosafety Concerns</td>
<td>Dr. Hans Bergmans</td>
</tr>
<tr>
<td><strong>1600 – 1615</strong></td>
<td><strong>COFFEE/TEA BREAK</strong></td>
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<tr>
<td>1615 – 1700</td>
<td>Plenary Discussion</td>
<td>Facilitator</td>
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<tr>
<td><strong>DAY TWO</strong></td>
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<tr>
<td>0830 – 0845</td>
<td>Recap of Day1</td>
<td>Facilitating Team</td>
</tr>
<tr>
<td>0845 – 0915</td>
<td>The African Model Law on Biosafety</td>
<td>Mrs. Mahlet Teshome</td>
</tr>
<tr>
<td>0915 – 0945</td>
<td>Overview of National Biosafety Frameworks</td>
<td>Mr. Alex Owusu-Biney</td>
</tr>
<tr>
<td>0945 -10.15</td>
<td>Plenary Discussion</td>
<td>Facilitator</td>
</tr>
<tr>
<td><strong>1015 – 1030</strong></td>
<td><strong>COFFEE/TEA BREAK</strong></td>
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<tr>
<td><strong>FOURTH SESSION: NBF IMPLEMENTATION – EXPERIENCE SHARING</strong></td>
<td></td>
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<tr>
<td>1030 – 1130</td>
<td>South African Regulatory Framework for Genetically Modified Organisms</td>
<td>Ms Wadzanayi Mandivenyi,</td>
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<tr>
<td></td>
<td></td>
<td>Ms Gillian Christians,</td>
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<td></td>
<td></td>
<td>Ms Renusha Chanda</td>
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<tr>
<td>1130 – 1200</td>
<td>Key Provisions of the Zimbabwean NBF</td>
<td>Mr. Abisai Mafa</td>
</tr>
<tr>
<td>1200 – 1230</td>
<td>The European Union Biosafety Framework</td>
<td>Dr. Hans Bergmans</td>
</tr>
<tr>
<td>1230- 1300</td>
<td>Plenary Discussion</td>
<td>Facilitator</td>
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<tr>
<td>1300 – 1400</td>
<td>LUNCH BREAK</td>
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<tr>
<td>Time</td>
<td>Activity</td>
<td>Speaker/Venue</td>
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<tr>
<td>1400 - 1500</td>
<td>Introduction to Risk Assessment</td>
<td>Dr. Flora Ismail</td>
</tr>
<tr>
<td>1500 - 1600</td>
<td>Environmental Risk Assessment</td>
<td>Dr. Samuel Kiboi</td>
</tr>
<tr>
<td>16.00 - 1615</td>
<td>COFFEE/TEA BREAK</td>
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<tr>
<td>1615 - 1700</td>
<td>Plenary Discussion Facilitator</td>
<td>Facilitator</td>
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<tr>
<td></td>
<td><strong>DAY THREE - Wednesday 11 August</strong></td>
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<tr>
<td>0830 - 0900</td>
<td>Recap Day 2</td>
<td>Facilitating Team</td>
</tr>
<tr>
<td>0900 - 1045</td>
<td>Food Safety Risk Assessment</td>
<td>Dr. Samuel Kiboi</td>
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<tr>
<td>1000 - 1045</td>
<td>Discussion</td>
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<tr>
<td>10.45-11.00</td>
<td>COFFEE/TEA BREAK</td>
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<tr>
<td>1100 - 1200</td>
<td>Socio-economic Impact Assessment</td>
<td>Ms. Patricia Masanganise</td>
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<tr>
<td>1200 - 1300</td>
<td>Discussion</td>
<td>Facilitator</td>
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<tr>
<td>1300 - 1400</td>
<td>LUNCH BREAK</td>
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<tr>
<td>1400 - 1500</td>
<td>Problem Formulation &amp; Option assessment (PFOA)</td>
<td>Dr. Hartmut Meyer</td>
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<tr>
<td>1500 - 1600</td>
<td>The Biosafety Assessment Tool (BAT)</td>
<td>Dr. Hartmut Meyer</td>
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<tr>
<td>1600 - 1615</td>
<td>COFFEE/TEA BREAK</td>
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<tr>
<td>1615 - 1645</td>
<td>Plenary Discussion Facilitator</td>
<td>Facilitator</td>
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<tr>
<td></td>
<td><strong>DAY FOUR - Thursday 12 August</strong></td>
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<tr>
<td>0800 - 0830</td>
<td>Recap of Day 3</td>
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<tr>
<td>0830 - 0915</td>
<td>Risk Assessment Process: Hazard identification, exposure assessment,</td>
<td>Dr. Flora Ismail</td>
</tr>
<tr>
<td></td>
<td>evaluation of consequences, overall risk estimation, recommendation of</td>
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<tr>
<td></td>
<td>decision and management measures</td>
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<tr>
<td>0930 - 1015</td>
<td>Discussions</td>
<td>Facilitator</td>
</tr>
<tr>
<td>1015 - 1030</td>
<td>COFFEE/TEA BREAK</td>
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<tr>
<td>1030 - 1230</td>
<td>Practical: Groups Review of Dossier for proposed environmental release of</td>
<td>Training Team</td>
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<td>Bt cotton</td>
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<tr>
<td>1300 - 1400</td>
<td>LUNCH</td>
<td></td>
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<tr>
<td>1400 - 1515</td>
<td>Group Work Continued</td>
<td>Training Team</td>
</tr>
<tr>
<td>1515 - 1530</td>
<td>COFFEE/TEA BREAK</td>
<td></td>
</tr>
<tr>
<td>1530 - 1700</td>
<td>Group Report Back and Discussions</td>
<td>Participants</td>
</tr>
<tr>
<td></td>
<td><strong>DAY FIVE - Friday 13 August</strong></td>
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</tr>
<tr>
<td>0800 - 0830</td>
<td>Recap of Day 4</td>
<td>Facilitating Team</td>
</tr>
<tr>
<td>0830 - 1015</td>
<td>Practical: Groups Review of Dossier for the proposed authority to place</td>
<td>Training Team</td>
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<tr>
<td></td>
<td>on the market (food, feed and processing) of BtxHT maize stack</td>
<td>Training Team</td>
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<tr>
<td>1015 - 1030</td>
<td>COFFEE/TEA BREAK</td>
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<tr>
<td>1030 - 1300</td>
<td>Group Work Continued</td>
<td>Training Team</td>
</tr>
<tr>
<td>1300 - 1400</td>
<td>LUNCH</td>
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<tr>
<td>1400 - 1600</td>
<td>Group Report Back and Discussions</td>
<td>Participants</td>
</tr>
<tr>
<td>1600 - 16.15</td>
<td>COFFEE/TEA BREAK</td>
<td>Workshop Organisers</td>
</tr>
<tr>
<td>1645</td>
<td>A Brief on Training Workshop</td>
<td>Workshop Organisers</td>
</tr>
<tr>
<td></td>
<td>Official Closing</td>
<td>Mr. Fundisile Mketeni, Deputy Director General, Biodiversity and Conservation DEA</td>
</tr>
<tr>
<td>1900</td>
<td>Dinner</td>
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<tr>
<td></td>
<td><strong>DAY SIX - Saturday 14 August – DEPARTURE</strong></td>
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</tbody>
</table>
## Annex 2: PARTICIPANTS EXPECTATIONS

<table>
<thead>
<tr>
<th>Expectation</th>
<th>Participants assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Better understanding of the principles of RA and RM</td>
<td>Participants understanding of RA and RM was enhance as the two were well presented</td>
</tr>
<tr>
<td>Increased skills and confidence of biosafety risk</td>
<td>Participants reported increased confidence in safety assessment of GM dossiers</td>
</tr>
<tr>
<td>assessment of GM applications</td>
<td></td>
</tr>
<tr>
<td>Clarity on biotechnology and biosafety issues</td>
<td>Participants</td>
</tr>
<tr>
<td>Acquire hands-on experience Risk assessment</td>
<td>Highly satisfied with the practical exercise</td>
</tr>
<tr>
<td>Enhance knowledge on regulations of GMOs</td>
<td>Achieved</td>
</tr>
<tr>
<td>Enhanced confidence for conducting risk assessment</td>
<td>Highly satisfied</td>
</tr>
<tr>
<td>Share/exchange experiences with each other</td>
<td>Many exchange of lessons and experiences, both during meeting and through private consultations</td>
</tr>
<tr>
<td>Establish new contacts for cooperation</td>
<td>Contacts between participants and b</td>
</tr>
</tbody>
</table>
Annex 3: HEALTH, AGRICULTURAL, ENVIRONMENTAL and SOCIO-ECONOMIC CONCERNS of GMOs (as identified by participants during a group exercise).

<table>
<thead>
<tr>
<th>Category</th>
<th>Concerns</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health Concerns</td>
<td>1. Toxicity</td>
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<td>2. Unexpected Effects</td>
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<td></td>
<td>3. Nutrition</td>
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<td></td>
<td>4. Ability to manage</td>
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<td>5. Digestibility/intolerance</td>
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<tr>
<td></td>
<td>6. Allergenicity</td>
</tr>
<tr>
<td>Agricultural Concerns</td>
<td>1. Weedness, effects on non target species, resistance development</td>
</tr>
<tr>
<td></td>
<td>2. Terminator technology leads to equity concerns (dependency issues)</td>
</tr>
<tr>
<td></td>
<td>3. Loss of indigenous knowledge (traditional agricultural methods) to commercial practices,</td>
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<td></td>
<td>4. Fear of Phasing out indigenous germplasm once only GMOs are introduced</td>
</tr>
<tr>
<td></td>
<td>5. Technology fees of GMOs is higher compared to conventional crops</td>
</tr>
<tr>
<td></td>
<td>6. Market trends and demands</td>
</tr>
<tr>
<td></td>
<td>7. Farmer capacity to effectively implement the technology</td>
</tr>
<tr>
<td>Environmental Concerns</td>
<td>1. Ability of society to seek redress from damages as a result of ill effect of GM</td>
</tr>
<tr>
<td></td>
<td>2. Product price being increased two products seed and technology</td>
</tr>
<tr>
<td></td>
<td>3. Religious and cultural “playing God”, changing the natural crossing barrier of life</td>
</tr>
<tr>
<td></td>
<td>4. Restriction on re-planting GM seeds</td>
</tr>
<tr>
<td></td>
<td>5. Loss of indigenous knowledge (e.g. seed sharing between resource poor farmers) social fabric disruptions</td>
</tr>
<tr>
<td></td>
<td>6. Limited variety of crop cultivars/use of other products</td>
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<tr>
<td></td>
<td>Loss of diversity affects sustainable livelihoods (few products on large areas)</td>
</tr>
<tr>
<td></td>
<td>7. Benefit sharing of resources poor farmers in the event of GM production</td>
</tr>
<tr>
<td>Socio-economic Concerns</td>
<td>1. Gene flow GM to non GM</td>
</tr>
<tr>
<td></td>
<td>2. Invasiveness of GM species – Biodiversity</td>
</tr>
<tr>
<td></td>
<td>3. Disruption of ecosystems – food chain</td>
</tr>
<tr>
<td></td>
<td>4. Wildlife – toxicity by the GM</td>
</tr>
<tr>
<td></td>
<td>5. Resistant forms appearance e.g pests causing diseases</td>
</tr>
<tr>
<td></td>
<td>6. Cannot recall GMOs once released in Environment</td>
</tr>
<tr>
<td></td>
<td>7. Weediness of existing plant species</td>
</tr>
<tr>
<td></td>
<td>8. All agricultural concerns</td>
</tr>
</tbody>
</table>
Annex 4: LIST OF PARTICIPANTS

Dr. Elias Peloewetse
Senior Lecturer
Department of Biological Sciences
University of Botswana
Bag 00704, Gaborone
BOTSWANA
Tel: 267 355 2604
E-mail: peloewee@mopipi.ub.bw

Ms. Balibi M Makoba
Deputy Director
Department of Agriculture
Private Bag 0033, Gaborone
BOTSWANA
Tel: +267 366 8174
Fax: +267 392 8965
Email: bmakoba@gov.bw

Mrs Tshenolo Moyo
Senior State Counsel
Attorney General
Chambers
International & Commercial Division
P/Bag 009, Gaborone
BOTSWANA
Tel: +267 361 3792
Fax: +267 395 7089
Email: trelemogeng@gov.bw

Daniel Dibue Munkamba
Researcher
Institute of National Research Agronomy
13 Av. Des Cliniques, Kinshasa
DEMOCRATIC REPUBLIC OF CONGO
Tel: +243 999 998 149
Email: Dibwe_munkamba@yahoo.fr

Mr. Belete Geda Torbi
Biosafety Programme Coordinator
Environmental Protection Authority of Ethiopia
P.O.Box: 12760, Addis Ababa
ETHIOPIA
Tel: +251 16464886 (Tel)
E-mail: gbelete@yahoo.com

Esther Nyambura Kimani
Research Officer
Kenya Agricultural Research Institute
PO Box Private Bag Njoro -20107
Nakuru
KENYA
Tel: +254 2 351 0865
E-Mail: En_kimani@yahoo.co.uk
Esther.kimani@gmail.com

Phooko Alexis Mokose
Environmental Officer
National Environment Secretariat
PO. Box 10993
New Postal Office Building
Maseru 100
LESOTHO
Tel: +266 223 11767
E-mail: pmokose@yahoo.com

Dama
CNB Member
Ministry of Environment and Forests
PO 507, Antanarivo
MADAGASCAR
Tel: +261 34 29 507 86
E-mail: damadiboka@yahoo.fr

Dr James Bokosi
Bunda College of Agriculture
PO Box 219, Lilongwe
MALAWI
Tel: +265 1 277 361
E-mail: jmbokosi@yahoo.com

Dr Francis Maideni
Department of Agricultural Research Services
PO Box 158, Lilongwe
MALAWI
Tel: +265 1 707 188
E-mail: francis.maideni@gmail.com
fmaideni@yahoo.com

Caroline Theka
Environmental Officer
Environmental Affairs Department
P/Bag 394, Lilongwe 3
MALAWI
Tel: +265 1 775 062
E-mail: caroltheka@eadmw.org
caroltheka@yahoo.com
Dr Margaret Sikwese
Lecturer
Bunda College of Agriculture
University of Malawi
P.O. Box 219, Lilongwe
MALAWI
Tel: +265 1 277 361
E-mail: mnyaganje@yahoo.com

Dacia Correia
Veterinary Faculty
Eduardo Mondlane University
Av. De Moçambique Km 1,5
C.P. 257, Maputo
MOZAMBIQUE
Tel: +258 21 475 155/83
E-mail: dacia_correia@hotmail.com

Joelma Leão
Biotechnology Centre
Eduardo Mondlane University
Av. de Moçambique, Km 1,5
C.P. 257, Maputo
MOZAMBIQUE
Tel/Fax: +258 21 477 227
E-mail: joelmaleao@yahoo.com.br

Amilia Mondlane
Ministry of Science and Technology
National Biosafety Committee
Patrice Lumumba Avenue, 770
Maputo
MOZAMBIQUE
Tel: +258 21 352 800
E-mail: amelia.mondlane@mct.gov.mz

Dr Erold Naomab
Lecturer
Bio-chemistry Department
University of Namibia
P/Bag 13301, Windhoek
NAMIBIA
Tel: +264 61 206 3384
E-mail: enaomab@unam.na
dxyerold@yahoo.com

Natasha Cheikhyoussef
Senior S&T Officer
Ministry of Education
Directorate of Research, Science and Technology
Windhoek
NAMIBIA
Tel: +264 61 270 6145
E-mail: npogori@mec.gov.na

Rosa Stella-Mbulu
Veterinary Diagnostician Specialist
Central Veterinary Lab
P/Bag 13187, Windhoek
NAMIBIA
Tel: +264 61 237 684 (Tel)
E-mail: ngendina@gmail.com
rsmbulu@cvl.com.na

Emmanuel Kabera
Rwanda Environment Management Authority
PO Box 7436, Kigali
RWANDA
Tel: +250 8 51 07 33
E-mail: kabemma@hotmail.com

Dr Tahani Yousif Elagib
Research Scientist
Agricultural Research Corporation
Biotechnology and Biosafety Research Centre
Khartoum, Shambat
SUDAN
Tel: +249 912 152 747
E-mail: tahani_3@yahoo.com

Maiyada El Bagir Abdalla
Sudanese Standard and Metrology Organization
Baladia Street, SSMO Building
Khartoum
SUDAN
E-mail: maiyada@hotmail.com

Wadzi Mandivenyi
Director of Biosafety
Department of Environmental Affairs
SOUTH AFRICA
Tel: +27 12 310 3396
E-mail: wmandivenyi@environment.gov.za
Gillian Christians  
Registrar GMO Act  
Department of Agriculture, Forestry and Fisheries  
30 Hamilton Street, Arcadia  
SOUTH AFRICA  
Tel: +27 12 319 6382  
E-mail: gillianC@daff.gov.za  
Gillianchristis@gmail.com

Renusha Chanda  
Assistant Director: Food Control  
Department of Health  
P/Bag X828, Pretoria  
SOUTH AFRICA  
Tel: +27 12 395 8797  
E-mail: chandr@health.gov.za

Nompumelelo Nhleko  
Environmental Officer  
Environmental Affairs  
P/Bag X447, Pretoria  
SOUTH AFRICA  
Tel: +27 12 310 3681  
E-mail: nnhleko@environment.gov.za

Dr Diana Earnshaw  
Lecturer  
Faculty of Agriculture  
University of Swaziland  
P.O Box 5, Kwaluseni  
SWAZILAND  
Tel: +268 527 4021 (Tel)  
E-mail: earshaw@agric.uniswa.sz

Nelson Mavuso  
Senior Agricultural Officer  
Ministry of Agriculture  
P.O Box 162, Mbabane  
SWAZILAND  
E-mail: sqcs@realnet.co.sz

Daniel Khumalo  
Biosafety Officer  
Swaziland Environment Authority  
P.O Box 2602, Mbabane  
SWAZILAND  
Tel: +268 404 7893  
E-mail: dkhumalo@sea.org.sz  
dmkhumalo@yahoo.co.uk

Dr Emmarold Mneney  
Principal Agricultural Research Officer  
Cashew Biotechnology Section  
c/o ARI-Mikocheni  
PO Box 6226, Dar es Salaam  
TANZANIA  
Tel: +255 22 277 5663  
Fax: +255 22 277 5549  
E-mail: emneney@yahoo.com

Simeon Shimbe  
Agricultural Officer  
Vice Presidents Office  
PO Box 5380, Dar es Salaam  
TANZANIA  
Tel: +255 22 211 3983  
E-mail: spshimbe@yahoo.com

Isakwisa Lameck Mwamukonda  
Legal Officer  
Division of Environment  
Vice Presidents Office  
PO Box 5380, Dar es Salaam  
TANZANIA  
Tel: +255 22 211 3983  
E-mail: isaquisa@yahoo.com

Odipio John  
National Agricultural Organization  
National Crops Research Resources Institute  
P.O.Box: 7084, Kampala  
UGANDA  
Tel: +256 772 971 868  
E-mail: jodips@gmail.com  
jodips@gmail.com

Dr Alfred J Sumani  
Acting Registrar  
National Biosafety Authority (NBA)  
c/o National Science and Technology Council  
P.O. Box: 51309, Lusaka  
ZAMBIA  
Tel: +260 211 257 596  
E-mail: chamanika@yahoo.com  
ejsumani@nstc.org.zm

Hilda Nyambe-Silavwe  
National Institute for Scientific and Industrial Research  
PO Box 49, Chilanga  
ZAMBIA  
Tel: +260 211 278 362  
E-mail:hilda_nyambe@yahoo.co.uk
Dr Jack Chipili  
Chief Agricultural Research Officer  
Zambia Agriculture Research Institute  
P/Bag 7, Chilanga  
ZAMBIA  
Tel: +260 211 278 380/130  
E-mail: jackchipili@yahoo.co.uk

Benson Gabi  
Director Operations  
Standards Association of Zimbabwe  
P.O Box 66133, Harare  
ZIMBABWE  
Tel: +263 4 753 800/1/2  
E-mail: sazlabs@mweb.co.zw  
sazlabs@zol.co.zw  
gabibenson@yahoo.com

Fredy Chinyavanhu  
Deputy Director: Food Control  
Ministry of Health  
Government Analyst Laboratory  
P.O Box CY231, Causeway  
Harare  
ZIMBABWE  
Tel: +263 4 792 026  
+263 4 708 526  
+263 4 705 261  
E-mail: fchinyavanhu@healthnet.org.zw  
fchinyavanhu@hotmail.com

Graciana Chido Motsi  
National Biotechnology Authority  
P.O Box CY2600, Harare  
ZIMBABWE  
Tel: +263 4 793 034  
Fax: +263 4 733 144  
E-mail: emotsi@nba.ac.zw;  
gcmotsi@gmail.com

Abisai Mafa  
Chief Executive Officer  
National Biotechnology Authority  
P.O Box CY2600, Harare  
ZIMBABWE  
Tel: +263 4 793 034/730012/3  
Fax: +263 4 733 144  
E-mail: mafa@nba.ac.zw  
absmaus@yahoo.com  
mafaab@gmail.com

RESOURCES PERSONS AND TRAINERS

Alex Owusu-Biney  
Regional Coordinator for Africa (Biosafety)  
Division of GEF Coordination  
United Nations Environment Programme (UNEP)  
PO Box 30552, Nairobi  
KENYA  
Tel: +254 20 762 4066  
Fax: +254 20 762 4041  
E-mail: Alex.Owusu-Biney@unep.org  
bineya@gmail.com

Professor Ossama El Tayeb  
Scientific Advisor  
Egyptian Environmental Affairs Agency  
30 Maadi Zarae Road  
Maady, Cairo  
EGYPT  
Tel:+202 333 6222  
E-mail: omtayeb@link.net

Dr Hans Bergmans  
Senior Scientist  
National Institute of Public Health and the Environment (RIVM) - GMO Office  
PO Box 1  
3720 BA Bilthoven, NETHERLANDS  
Tel: +31 302 7441 95  
E-mail: hans.bergmans@rivm.nl

Dr Hartmut Meyer  
Deutsche Gesellschaft fuer Technische Zusammenarbeit (GTZ)  
PO Box 5180  
65226  
Eschborn  
GERMANY  
Tel: +49 531 516 8746  
Fax: +49 531 516 8747  
E-mail: hmeyer@ngi.de

Patricia Masanganise  
Senior Associate  
Agriculture, Food Security and Livelihoods Development  
P. O. Box 2275, Edenvale, 1610  
Johannesburg  
SOUTH AFRICA  
Tel/Fax: +27 11 452 1665  
E-mail: trish_pcc@yahoo.co.uk  
patricia@khanya-aicdd.org
Dr. Flora Ismail  
Lecturer  
Botany Department  
University of Dar es Salaam,  
P.O. Box 35060, Dar es Salaam,  
TANZANIA  
Tel: +255 22 241 0647  
E-mail: ismailf@udsm.ac.tz

Dr. Samuel Kiboi  
School of Biological Sciences  
University of Nairobi  
P.O Box 30197 – 00100  
Nairobi  
KENYA  
Tel: +254 204 440 04 ext 2533  
E-mail: Samuel.kiboi@un.ac.ke  
Samkiboi01@yahoo.com

Dr Keoagile Molapong  
Senior Program Manager  
SADC Secretariat  
Private Bag 0095, Gaborone  
BOTSWANA  
Tel: +267 395 1863  
E-mail: kmolapong@sadc.int

Dr Dorothy Kangwa-Mulenga  
Policy and Advocacy Coordinator  
RAEIN-Africa  
P.O. Box 3243, Addis Ababa  
ETHIOPIA  
Tel: +251 11 3717700  
Fax: +251 11 3717707  
E-mail: dmulenga@unam.na  
raein@mweb.com.na

Mahlet Teshome-Kebede  
Environmental Lawyer (Biosafety)  
Department of Human Resources Science and Technology  
African Union Commission  
P.O. Box 3243, Addis Ababa  
ETHIOPIA  
Tel: +251 11 3717770  
Fax: +251 11 3717707  
E-mail: mulesh@gmail.com

Mrs Meseret Eshetu  
Administrative Assistant  
Biosafety Unit  
Department of Human Resources, Science & Technology (HRST Department)  
African Union Commission  
ETHIOPIA  
Tel: +251 11 3717700  
Fax: +251 11 3717707  
E-mail: masesetu@africa-union.org

Henry Michael Ndengejeho  
Project Officer  
RAEIN-Africa  
P.O. Box 3243, Windhoek  
NAMIBIA  
Tel: +264 61 206 3300  
Fax: +264 61 206 3350  
E-mail: hndengejeho@unam.na  
raein@mweb.com.na

Workneh Goshiye  
Finance officer  
African Union Commission  
P.O. Box 3243, Addis Ababa  
ETHIOPIA  
Tel: +251 911 645448  
E-mail: workineh@africaunion.org

Mahlet Teshome-Kebede  
Environmental Lawyer (Biosafety)  
Department of Human Resources Science and Technology  
African Union Commission  
P.O. Box 3243, Addis Ababa  
ETHIOPIA  
Tel: +251 11 3717770  
Fax: +251 11 3717707  
E-mail: mulesh@gmail.com
Shepherd Kapayapundo
Finance and Administration Manager
RAEIN-Africa
Box 23544, Windhoek
NAMIBIA
+264 61 206 3955 (Tel)
+264 61 206 3350 (Fax)
E-mail: skapayapundo@unam.na
raein@mweb.com.na

Aune David
Secretary
RAEIN-Africa
Box 23544, Windhoek
NAMIBIA
Tel: 264 61 206 3350
Fax: +264 61 206 3350
E-mail: amdavid@unam.na
raein@mweb.com.na

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RAEIN-Africa Secretariat
University of Namibia, Office G107/G108,
Box 23544, Windhoek, Namibia
E-mail: raein@mweb.com.na
Website: http://www.raein-africa.org