
March 9 -12, 2004, Dar Es Salaam, United Republic of Tanzania
## INTRODUCTION

TO THE WORKSHOP ................................................................. 3

### OPENING OF THE WORKSHOP

Address by Mr. John Hendra, United Nations Development Programme Resident Representative and United Nations Resident Coordinator in the United Republic of Tanzania .......................... 5

Address by the Hon. Arcado D. Ntagazwa, Minister of State Environment of the Office of the Vice President of the United Republic of Tanzania ................................................................. 5

Official opening and address by His Excellency Dr. Ali Mohammed Shein, Vice President of the United Republic of Tanzania ................. 6

Introduction to the Workshop ................................................. 6

Ground rules of the Workshop ................................................. 7

Expectations and concerns .................................................... 7

### II. SETTING THE SCENE

Introduction to the UNEP/GEF Global Biosafety Development Project and the Implementation Projects ......................................................... 7

Overview of key components of a National Biosafety Framework ................................................................. 8

### III. TRENDS IN THE DEVELOPMENT OF NBFS IN THE SUBREGION

Sharing of regional experiences on NBF development ................................................................. 9

Country presentations ............................................................. 9

### IV. INTERNATIONAL OBLIGATIONS

Introduction to national obligations and rights under the Cartagena Protocol ......................................................... 11

Introduction to other international instruments and to national obligations and rights that may affect NBF regulatory systems ......................................................... 11

Project overview and linkage to NBF ........................................ 12

### V. REGULATORY REGIME

Introduction to choices of a regulatory regime ......................................................... 13

Studies by CISD .................................................................. 15

Country presentations ............................................................. 15

Introduction to elements of a regulatory regime and general provisions ......................................................... 16

Introduction to operational provisions of a regulatory regime ......................................................... 17

Introduction to other elements of a regulatory regime ......................................................... 18

Focus groups .................................................................. 19

### VI. ADMINISTRATIVE SYSTEMS

Introduction to general administrative tasks ......................................................... 20

Introduction to administrative tasks relevant under the AIA procedures and overview of when and where to apply the AIA or FFP procedures ......................................................... 22

Focus groups .................................................................. 22

Case study presentations on administrative tasks ......................................................... 23

Introduction to subregional grouping cooperation ......................................................... 24

### VII. CONCLUDING SESSION OF THE WORKSHOP

Participants List ................................................................. 26

Annex I: Keynote address by His Excellency Dr. Ali Mohammed Shein, Vice President of the United Republic of Tanzania ......................................................... 37

Annex II: Workplan ................................................................. 43

Annex IV: Ground Rules ................................................................. 50

Annex V: Participants Expectations and Concerns ......................................................... 51

Annex VI: Results of the Focus Group Exercise on Regulatory Regimes ......................................................... 52

Annex VII: Focus Group Exercise on Administrative Systems ......................................................... 58

Annex VIII: Exercise in geographically based group cooperation ......................................................... 68

Annex IX: Workshop Evaluation by Participants ......................................................... 72
INTRODUCTION

1. The United Nations Environment Programme (UNEP) - Global Environment Facility (GEF) Project on the Development of National Biosafety Frameworks (NBFs) is one of the main components of the GEF Initial Strategy for assisting countries to prepare for the entry into force of the Cartagena Protocol on Biosafety, approved by the 16th GEF Council in November 2000. The project, which was initiated in June 2001 for a three-year duration, is designed to (a) assist up to 100 eligible countries to prepare their NBFs; and (b) to promote regional and subregional collaboration and exchange experience on issues of relevance to the NBFs. The overall objective of the project is to prepare countries for the entry into force of the Cartagena Protocol by, inter alia, assisting in the implementation of the following activities:

(a) Assessing current technological capacity to manage biosafety issues, and the implications of this for implementation of an NBF;

(b) Strengthening national capacity to develop national regulatory biosafety frameworks;

(c) Strengthening national capacity for competent decision-making on notifications and requests relating to living modified organisms (LMOs), including the establishment of administrative systems to assist in this;

(d) Applying other measures, according to the Protocol, taking into account the work of the Intergovernmental Committee for the Cartagena Protocol on Biosafety (ICCP) and the decisions of the first meeting of the Conference of the Parties to the Convention on Biological Diversity serving as the meeting of the Parties to the Cartagena Protocol;

(e) Supporting regional and subregional collaboration, including harmonization of the implementation of national regulations;

(f) Raising public awareness and improving information flow to the public on the issues surrounding the release of LMOs, to promote informed debate and to ensure transparency with respect to the regulation of LMOs;

(g) Providing all stakeholders with an opportunity to be involved in the design and implementation of the NBF.

2. The project is coordinated by the UNEP/GEF Biosafety Project Team. A regional coordinator for each region is available within the Team, to provide advice and support to countries throughout the implementation of their national projects to develop NBFs, which are intended to last a maximum of 18 months.

3. In parallel with the work with individual countries, the Biosafety Team already held regional workshops in Africa (Kenya, 16-19 January 2002), Central and Eastern Europe (Slovakia, 5-9 February
2002), Asia-Pacific (China, 4-8 March 2002) and the Latin America and the Caribbean region (Buenos Aires, 8-10 May 2002), in order to improve countries’ understanding of the key issues of the development of NBFs. The workshops were targeted at National Project Coordinators (NPCs) of participating countries or potential NPCs from countries yet to join the project.

4. To assist progress at the subregional level, a series of 12 training workshops have been planned from November 2002, to help build capacity in: the decision-making process (risk assessment, risk management, etc.); public participation; administrative systems; and regulatory systems. It was decided that the first subset of six workshops, scheduled for November 2002 - May 2003, would deal with risk assessment and management, and public awareness and participation. The following six subregional groupings would be addressed: Francophone Africa; Anglophone Africa; Asia; Small Island Developing States (SIDS); Latin America; and Central and Eastern Europe, including Central Asia.

5. The first subset of workshops, on the subject of risk assessment and management, and public awareness and participation, was held in Anglophone Africa (Namibia, 12 to 15 November 2002); Latin America (Mexico, 10 to 13 December 2002); Asia (Malaysia, 21 to 24 January 2003); the small island developing States (SIDS) (Fiji, 18 to 21 February 2003); Francophone Africa (Senegal, 22 to 25 April 2003); and the Countries of Central and Eastern Europe, the Caucasus and Central Asia (CEECCA) (Lithuania, from 27 to 30 May 2003).

6. It was decided that the second subset of workshops, scheduled for October 2003 to May 2004, would deal with “Development of a Regulatory Regime and Administrative Systems for NBFs”. Within this subset of workshops, to date, workshops have been convened for the following: Asian countries, held in Shiraz, Islamic Republic of Iran, from 19 to 22 October 2003; Latin America, held in Santiago, Chile, from 25 to 28 November 2003; and countries of Central and Eastern Europe, the Caucasus and Central Asia (CEECCA), held in Antalya, Turkey, from 9 to 12 December 2004. The Workshops were convened by the UNEP/GEF Biosafety Project Team, in collaboration with the Governments of the host countries.

7. The Anglophone Africa Subregional Workshop on the Development of a Regulatory Regime and Administrative Systems for NBFs was held at the Golden Tulip Hotel, Dar Es Salaam, United Republic of Tanzania, from 9 to 12 March 2004. It was convened by the UNEP/GEF Biosafety Project Team, in collaboration with the Government of the United Republic of Tanzania.

8. A list of participants is attached as Annex I to the present report.
OPENING OF THE WORKSHOP

9. The plenary session of the Workshop was opened at 9 a.m on Tuesday, 9 March 2004. Ms. Mary Mushi, Permanent Secretary of the Office of the Vice-President of the United Republic of Tanzania, acted as officiator of the opening ceremony of the Workshop. She expressed thanks to UNEP/GEF for the convening of the Workshop and for the work to support the developing countries.

10. Mr. Charles Gbedemah, Regional Coordinator for Africa, UNEP-GEF Biosafety Unit, on behalf of the UNEP Biosafety Team, welcomed participants and expressed gratitude to the Government of the United Republic of Tanzania and to its Ministry of Environment for hosting the Workshop and for the assistance and support provided in the logistical and administrative arrangements.

Address by Mr. John Hendra, United Nations Development Programme Resident Representative and United Nations Resident Coordinator in the United Republic of Tanzania

11. Mr. Hendra welcomed all participants and expressed thanks to UNEP/GEF and to the Office of the Vice President of the United Republic of Tanzania for convening the current timely and important Workshop. The current meeting showed the country’s commitment to the United Nations, to the environment and to the issues to be discussed at the Workshop. Recent global challenges had emerged, whereby attempts to tackle and eradicate poverty sometimes had negative secondary effects. The Cartagena Protocol and the UNEP/GEF project aimed to tackle the issue of biosafety, and both UNDP and the United Nations were keen to see an NBF in place and the United Republic of Tanzania in order to guide the operations of the country in that field. That would also support the national efforts aimed at poverty alleviation. The role of the private sector in the NBF was important, as was the issue of trade, and public/private partnerships played a significant role in that context. He hoped that the Workshop would give participants a chance to reflect on all the issues and challenges involved and would support them in the development of robust NBFs. He wished all participants an enjoyable and productive stay in the country.

Address by the Hon. Arcado D. Ntagazwa, Minister of State Environment of the Office of the Vice President of the United Republic of Tanzania

12. Mr. Ntagazwa welcomed the more than 100 experts from more than 25 countries from the subregion and others from outside Africa, who had gathered to share experiences regarding the development of NBFs for the implementation of the Cartagena Protocol. The United Republic of Tanzania had acceded to the Protocol on 16 March 2003 and had been one of the countries involved in the UNEP/GEF Biosafety Project on the development of NBFs. With the support of UNEP/GEF, in collaboration with stakeholders country-wide, a process for developing an NBF had been launched in September 2002. The process involved
establishment of a system of legal, technical, and administrative mechanisms to address safety in the field of modern biotechnology. The development of the NBF commenced with the formation of a National Coordinating Committee (NCC), comprising members from relevant ministries and institutions from the Tanzanian mainland and Zanzibar. To date, a Country report on Biosafety and Biotechnology, draft regulations on biosafety and draft Biosafety Guidelines had been prepared. He was confident that the current subregional Workshop would further enhance the understanding of the issues in the implementation of the Biosafety Protocol and improvement of the draft documents.

Official opening and address by  His Excellency Dr. Ali Mohammed Shein, Vice President of the United Republic of Tanzania

13. Dr. Shein expressed his great pleasure at officiating at the opening ceremony of the Workshop and extended a warm welcome to all participants. The text of the keynote address by Dr. Shein was made available to participants and is contained in Annex II of the present report.

14. Following his keynote address, Dr. Shein declared the Workshop to be officially open.

Introduction to the Workshop

15. At the opening session, on 9 March 2004, Mr. Charles Gbedemah, Regional Coordinator for Africa, UNEP-GEF Biosafety Unit, gave a brief introduction to the aims and content of the Workshop, and introduced its work plan (the work plan is contained in Annex III of the present report). He explained that the main objectives lay in providing participants with a better understanding of: the elements of regulatory regimes of NBFs; how the laws, regulations and guidelines formed part of the administrative process to operationalize an NBF; how a well-coordinated NBF made it possible to meet the obligations under the Protocol; and how to promote interactions among National Project Coordinators (NPCs), with a view to enhancing regional and subregional cooperation. He stressed that case studies would be provided and examples would be given, illustrating experiences with regulatory regimes in the region and showing how activities could be coordinated within an NBF. In conclusion, he encouraged participants to promote networking amongst themselves and to provide feedback on the programme before them.
Ground rules of the Workshop

16. Participants nominated and agreed to adhere to the following set of ground rules for the Workshop, which are set out in Annex IV to the present report.

Expectations and concerns

17. Participants were invited to express their expectations and concerns in connection with the outcome of the Workshop. The resulting comments are summarized in the table contained in Annex V to the present report, as well as the comments made at the closing session of the Workshop, assessing whether the expectations had been met.

II. SETTING THE SCENE

Introduction to the UNEP/GEF Global Biosafety Development Project and the Implementation Projects

18. Mr. David Heron, Task Manager, UNEP-GEF Biosafety Unit, Implementation Project, briefly outlined the GEF Initial Strategy on Biosafety and its components and activities. Stressing that NBFs varied from country to country, he noted a number of their common components, including: Government policy on Biosafety; regulatory regime for biosafety; system to handle notifications/requests for permits; systems for follow-up, enforcement and environmental effects monitoring; and systems for public information, public awareness and public participation. He described the background, objectives status and content of the UNEP/GEF Development Project for NBFs and the Workshops held to date. He also briefly outlined the target, status and activities under the UNEP/GEF Project on Implementation of NBFs and described the role of UNEP in that context. He gave examples of the support provided under the project in the following areas: policies on biosafety; regulatory regimes; handling and notifications; enforcement; monitoring of environmental effects; public information, awareness and participation; and project management. In conclusion, he pointed to the lessons learned and the characteristics of the projects, stressing that the NBF development had to be country-driven, flexible and tailor-made, and underlining the importance of collaboration among many countries and organizations. He noted the role of UNEP in providing expert support, accountability and coordination and pointed to the project’s two-track approach, whereby it aimed to assist both in the building of a robust NBF, and in the immediate implementation of the Cartagena Protocol.
19. Turning to the Project on Capacity-building for the Biosafety Clearing-House (BCH), he described its aim to develop core human resources and establish an appropriate national infrastructure so as to enable eligible countries to fully participate in, and benefit from, the BCH. During the three-year duration of this enabling activity the focus would be on training and equipment components. Under training came development and documentation of training material, workshops and exchange of experiences and practices among participating countries. Under the equipment component came provision of appropriate hardware and software, based on the choice of a national BCH and on the sustainability strategy. He described the national-level participation, the training materials available through the project, and the national-level implementation of the project. In conclusion, he provided the coordinates of contact persons from whom to obtain further information.

Overview of key components of a National Biosafety Framework

20. Ms. Liina Eek, Assistant Regional Coordinator for Central and Eastern Europe, described the five main elements of NBFs which the Biosafety Team considered to be the key components. The first of them, biosafety policy, was usually part of a Government’s broader policy on biotechnology in general, and on agricultural production, health care and environmental protection. The second element, the regulatory regime for biosafety, was often a combination of laws, acts or decrees, complemented by implementing technical regulations and guidelines. The third element, a system to handle notifications or requests for certain activities (such as releases of LMOs) typically included administrative functions, decision-making and public participation. The fourth key element comprised systems for follow-up activities (such as enforcement and monitoring of environmental effects). And the fifth element involved approaches for public awareness, information and participation, whereby the stakeholders were informed and involved in the development and implementation of the NBF itself.

21. During the discussion, participants pointed to: the difficulty of implementing the key elements of developing an NBF in reality; the complexity of the decisions required within a specific time-frame; the problems of public involvement in countries with high levels of illiteracy; the need to ensure the sustainability of the project from the outset; the importance of having a person with political weight as the Chair of the National Coordinating Committee (NCC); and the urgent need for capacity-building.

22. A number of participants also sought further information or clarification on: what regimes were in place in developing countries to control LMO seeds; how to come up with a national vision for biosafety; how contamination of genetic material in neighbouring countries could be prevented by those that had already released LMOs; how the precautionary principle applied in decision-making; and the influence of industry in the process of peer review of the decisions and legislation on LMOs.
III. TRENDS IN THE DEVELOPMENT OF NBFS IN THE SUBREGION

Sharing of regional experiences on NBF development

23. Mr. Charles Gbedemah, Regional Coordinator for Africa, UNEP-GEF Biosafety Unit, gave an overview of the current status of NBFS in the subregion. He pointed to the rationale for an NBF and for a national vision, together with priorities and a policy. He noted that three countries were currently in phase One of the project to develop an NBF; 10 were in phase two; and five were in phase three. Four countries in the subregion were currently implementing their NBFS. He pointed to the gaps identified in the legislation surveys carried out, noting that some countries lacked principle legislation; others had legislation without enforcement mandates; and in some countries the statutes were not LMO-sensitive or complementary to the Protocol. He outlined the challenges countries faced in deciding whether to modify existing legislation, or whether to opt for totally new laws to govern LMOs. In addition, he noted the gaps in the administrative systems of the countries of the subregion.

Country presentations

24. Following the introduction, participants from three countries in the subregion gave presentations on their national efforts for the development of NBFS, setting out how they had arrived at their current stages; what choices they had made; and what lessons had been learned.

25. Ms. Muffy Koch, Golden Genomics CC, Presenter, gave a presentation on the development of the NBF in South Africa. She described the background and history of the process, noting that the interim arrangements set up in the country had lasted from 1989 to 199 and had provided invaluable experience for the development of a workable biosafety regime and framework. In 1997, the GMO Act (15) had been passed, and had been implemented in 1999. She described the composition and activities of the interim process, as well as the applications for permits that had been received in the period concerned. The interim body had faced major constraints: it was a voluntary process; it was not able to handle non-agricultural LMOs; and it lacked the expertise to tackle non-safety issues. Because of the wide variety of expertise required by different LMOs, a number of reviewers had been engaged to support the work of the interim body. In light of the amount of time that could be needed to ensure the passage of a law on biosafety, and considering the valuable experience gained, she encouraged countries to adopt an interim procedure, pending the finalization of the NBF.
26. In order to ensure the long-term effectiveness of the mechanism, she underlined the need to ensure the sustainability of the process from the outset. Major discussion points in the development of the LMO regulation had been: the scope; the concept of a new law versus existing legislation; the harmonization with existing laws; the need for science to maintain a distance in the decision-making process, particularly taking into account non-safety considerations, such as socioeconomic issues; the need for the process to be expandable, in order to carry out science-based risk assessment; the constitution of workable and credible biosafety bodies; the problem of identifying an administering ministry; socioeconomic reviews; and how to gather public input. In conclusion, she outlined the composition and work processes of the GMO Act (15).

27. Ms. Martha Kandawa-Schultz, Namibia Biotechnology Alliance, presented the history of the development of the NBF in Namibia. Noting that the drafting of a Biosafety Act had taken longer than first thought, going through more than ten drafting stages, she stressed the importance of not being over-hasty in the drafting process, in order to ensure inputs from all those affected. Within the process, stakeholder workshops and other awareness-raising initiatives had proved to be valuable. Noting that, as an interim measure, an attempt had been made to adapt current legislation to accommodate LMOs, she explained that it had not been possible due to the cross-cutting nature of biotechnology and biosafety issues. She described the lessons learned and the problems experienced, including: evaluation of existing laws; getting political attention; deciding on who was responsible for what, and why; deciding how much to put in the Bill and how much to put in regulations or guidelines; the database of experts; stakeholder interest; the scope of the Biosafety Bill; and how far to include products of LMOs in the scope. She outlined the elements of the Biosafety Bill, currently in draft form before ministers, and of the National Policy. Noting the advanced stage of preparations, she hoped that Namibia would soon be in a position to ratify the Cartagena Protocol.

28. Mr. Charles Mugoya, Ugandan National Council for Science and Technology, reported that Uganda had participated in the UNEP/GEF pilot project for the development of an NBF, and had adopted an NBF based on the assistance provided and on the tenets that had been developed after much thought and analysis. The regulatory regime for biosafety had a very broad scope, covering transit, contained use, deliberate release, placing on the market, import and export of LMOs. Some of the existing legislation had been found to cover adequately the issues raised by biotechnology, which had essentially been viewed as a tool. Administrative mechanisms had been set up under the regulations and he described the functioning of the system for handling requests/notifications for import permits, which also allowed the public 30 days to comment on the request and on the opinion of the National Biosafety Council. Internal administrative systems were under development to guide the process. Monitoring and enforcement measures made use of existing institutions, with additional training for those already in the field, although the establishment of new institutions was also envisaged. In conclusion, he described Uganda’s strategies for public information and participation, including the translation of selected publications into the main national languages.
29. During the discussion, participants raised the following main points: the problems encountered in involving ministries and inspiring overall political will on biosafety issues; how biosafety decisions taken in one country could impact on another country; the problem of already existing contamination by LMOs; how to decide whether to incorporate LMO issues into existing legislation, or whether to develop new laws; questions raised by transit of LMOs; whether customs officers could detect unidentified LMO shipments; possible entry points for applications for a permit to import LMOs; how to ensure the confidentiality of information; how to involve the public, and at what stage of the process; the need to develop capacities for risk assessment for LMOs in the subregion; how to balance the demands of those who wish to import LMOs and those who want to protect export markets; how to address illegal transboundary movements of LMOs, particularly through unscrupulous seed merchants; the possible power exercised over a Government by the scientific community; and the need to avoid excluding the public and civil society but, rather, to seek out their constructive contributions to the overall debate.

30. Participants also sought further information or clarification concerning: the composition of various bodies within the biosafety regulatory frameworks presented; the question of fees and costs for handling the dossiers; how small farmers were involved in the decision-making process; the appeal process for rejected applications for permits; and the translation of biotechnology terminology into national languages.

IV. INTERNATIONAL OBLIGATIONS

Introduction to national obligations and rights under the Cartagena Protocol

31. Mr. Worku Damena Yifru, Legal Officer, Biosafety Division of the Secretariat of the Convention on Biological Diversity, gave a presentation, introducing a country’s responsibilities and national obligations under the Cartagena Protocol. Referring to the major provisions of the Protocol, he outlined its general nature and scope and pointed to specific requirements in the administrative, procedural and legal fields, as well as in other important areas.

32. In the subsequent discussion, participants highlighted: the question of compliance; how Parties were expected to interact with countries that did not, or would not, adhere to the Protocol; the issue of ensuring confidentiality of information; issues of dispute resolution, and liability and redress.

Introduction to other international instruments and to national obligations and rights that may affect NBF regulatory systems

33. In her presentation, Ms. Tomme Young, Senior Legal Officer, IUCN, Resource Person, pointed to the multiplicity of other international agreements that were relevant to biosafety issues, including the instruments under the system of the Convention on Biological Diversity; international trade instruments;
international conservation instruments; other relevant agreements, and regional approaches and instruments. Referring to the integrated implementation of international law, she outlined the functioning of such law, and ways in which countries could integrate its provisions, harmonize them and make use of the synergies that could be created at the national level. Stressing that the Cartagena Protocol was part of a system of environmental agreements, she briefly outlined the other multilateral conservation agreements that could impact on the Protocol and vice versa. She briefly described the World Trade Organization, in particular its instruments that were relevant to trade in LMOs, especially the General Agreement on Tariffs and Trade; the Agreement on Sanitary and Phytosanitary Measures (SPS); the Agreement on Technical Barriers to Trade (TBT); the Trade Related Intellectual Property System (TRIPs). Noting that the dispute settlement procedure of WTO recognized no designated standards body for the environment, she flagged possible future problems and issues with respect to the potential conflict between the right of a nation to protect its people, and the right to free trade. In that context, the issue of labelling of LMOs and their products was also contentious. She underlined the importance of a country finding out what agreements were in force in its neighbouring countries and, after signing an agreement, investigating the possibilities of regional cooperation and/or special trade requirements or options. In conclusion, she observed that there were a great many things to take into account, many of which were not obvious at first sight, in the preparation of a regulatory regime.

34. During the discussion, participants raised the following main issues: the apparently irreconcilable opposition of the WTO to environmental agreements; what would happen if the Cartagena Protocol were seen to be in conflict with the WTO; the complexity of the trade/environment issue; polarization of views on trade in LMOs; whether labelling could constitute a barrier to trade; and whether refusal of food aid constituted a trade issue.

Project overview and linkage to NBF

35. Mr. Nizar Mohammed underlined the importance of taking stock, before proceeding to the third phase of the project and preparing a regulatory regime, in order to better assess how far has been travelled and where to go next. The stocktaking would help to determine the scope and format of what came next. A basic infrastructure and certain core structures are needed to draft an NBF. It was necessary to build gradually on what had been attained and what legislation was in place, looking at what was still needed and asking what resources would be required and whether they were available. He reiterated the importance of keeping in mind the sustainability of the system throughout the development process. The project had only an 18-month duration, but the NBF had to be durable and able to take into account a country’s future needs and priorities.
V. REGULATORY REGIME

Introduction to choices of a regulatory regime

36. Mr. David Townend, Sheffield (UK) Institute of Biotechnology Law and Ethics, presenter, said that the obligations placed on signatory countries from the Convention on Biological Diversity (Article 8.g) and the Biosafety Protocol (Article 2) offer a considerable degree of choice in their implementation. The obligations are alongside broader requirements that States may have undertaken through other Treaties, for example the WTO, or simply from the broader issues and agenda of the Convention or their own biotechnology policy objectives. The Protocol did not prescribe a particular instrument with direct effect to implement into signatories’ domestic law; neither did it prescribe a method for implantation. It gave certain requirements and choices of how to include a particular internationally agreed set of minimum standards within the legal, scientific, trade, and socio-political cultures of the signatories’ countries. To that end, Parties must develop policy, evaluate their legal and scientific environment, draft regulations, test and refine them, and then evaluate and revise them. At all times consultation was crucial. That journey of development was not linear – the process of drafting would undoubtedly reopen questions of policy. Further, one should, in the initial stages, focus on the “guts” of the Regulatory Regime and move to fully worked instruments at the later stages of the process. One should also consider how the administrative system was given authority through the regulatory regime.

37. He said that the Legal and Scientific Audit already undertaken would have shown that within national law there were many rules and instruments addressing the use of biology in one’s country (for example, Food Laws, Health and Safety Laws, Import and Export Laws, perhaps GMO laws, and Patent Laws etc.). That was a most important resource for understanding how to meet the obligations and objectives for the implementation of the Protocol. It also showed that there were many different sorts, or levels, of instruments already in use within the broader biology regulatory regime and that there were many different labels for the instruments. There were, perhaps, five different levels of instruments available to be used, perhaps in combination, to create any regulatory regime: Level 1, instruments written and approved by legislature, Parliament, House of Assembly, and then promulgated with binding effect; Level 2, binding instruments created through power delegated to an individual or group requiring formal approval by the legislature before promulgation; Level 3, binding instruments created through power delegated to an individual or group without requiring formal approval by the legislature before promulgation; Level 4a, binding decisions interpreting the instruments of Levels 1-3 by Courts or other adjudicators; Level 4b, binding decisions of Courts creating law independent of other instruments; Level 5, non-binding instruments created through delegated power to individuals or groups (in- or outside government). When one compared different jurisdictions, the labels for each of the Levels were very different or were used very differently. For
example, “Regulation” was used to label different things at different levels of instruments in the EU, UK and USA, where the same term labelled different sorts of instrument. One should look to the function of the instrument to make the comparison, rather than to the semantics.

38. Asking what were the options in considering how to use instruments from those Levels, he stated that, first, it was essential to understand the obligations and objectives that each country wished to achieve. Then one could consider: can these obligations and objectives be achieved by amending existing laws, by adding extra elements to existing laws, or by creating new laws? Alongside this, there were further legal tools running through the consideration of how to develop the legal regime. These were “obligations”, “authority”, “accountability” and “Natural Justice”. Those broad concepts were discussed in detail in the supporting introductory paper on the Law, provided in the materials given to participants. Beyond this, there was a set of variable considerations that indicated what sorts of instruments were most appropriate to develop the regulatory regime. These were “adaptability”, “acceptance and confidence”, and “workability and sustainability”. Adaptability: because biotechnology was a constantly changing area, and many requirements were technical, the length of time both to create and change or revise any particular instrument had to be considered. If the function to be covered required regular change, was it appropriate to have an instrument that required many years to change? That was a first element in the balance. Acceptance and Confidence represented the second. The impact of a particular instrument on acceptance or confidence of both the public and the business community also had to be considered. The instruments must have legitimacy, which could relate to the method of their creation and inherent importance of their Level. Finally, was the regulatory regime envisaged both workable and sustainable? Was it affordable in terms of finance, and resources? In conclusion, he asked: would the choices made implement the obligations and objectives of the policy and achieve predictability, clarity, transparency, accountability, fairness and confidence in a practical regime?

39. During the discussion, participants raised the issues of: how to get scientists and legal people to cooperate and interact in the development work; the complexity of the tasks; whether a moratorium on LMOs was a viable option; inflamed public opinion and refusal to accept a law which is seen as an invasion of rights; the need to take into account the entire cultural environment; the question of appeal and judicial review; and the fact that the regulatory regime need not be confined only to the provisions of the Cartagena Protocol, although they represented an absolute minimum – countries were free to include whatever they wanted in the framework, over and above those considerations.
Studies by CISD

40. Ms. Kathrynn Garforth, Centre for International Sustainable Development (CISD), Facilitator, introduced case studies of the NBFs in Canada and the Philippines. Following the five components identified by UNEP/GEF, she compared the Government policy; regulatory framework; permitting mechanism; monitoring and enforcement and public participation in each of the NBFs. The comparison revealed that, in some cases, the countries had elected to apply very different approaches in the development of the NBF, although many common elements were in place. This illustrated the way in which the “no one size fits all” approach had to be applied by countries in their work to prepare an NBF.

Country presentations

41. Ms. Patricia Kameri-Mbote, Parklands Faculty of Law, Kenya, gave a presentation on the lessons learned from developing an NBF in Kenya, describing the Kenyan context; the Policy on Biotechnology and Biosafety, and its objective; the Biotechnology and Biosafety Bill, its status and its objectives; the regulations and guidelines in place since 1998 and their applications; the clear linkage between policy, law and regulations and guidelines; the need for synergy; the challenges; the choice of regulatory regime; the choice of the Ministry of Science as the locus; and meetings with stakeholders. She concluded that: the regulatory regime should be facilitative for identified national goals and objectives; the regime was not set in stone, and had to be adaptable; there was a need to ensure that the regulatory agencies could adapt to changing contexts without unnecessary fetters; there was a need to build capacity to implement the regulatory regime.

42. Mr. Palamagamba John Kabudi, University of Dar Es Salaam, in his presentation on development of an NBF in the United Republic of Tanzania, described the particular situation of the country, whereby environmental matters were considered to be a non-Union matter. However, it would have been impractical to have regulatory regimes. For that reason, the Office of the Vice President of the United Republic of Tanzania had been chosen as the entity responsible for dealing with the Cartagena Protocol and related matters of biosafety and biotechnology. He described the Government policies; the status of and the approach to the NBF in the country; the steps in developing the NBF; and the proposed regulations and institutional arrangements. In conclusion, he said that his country intended to put an effective NBF in place in the near future, which would not represent an irrational impediment to the use of the products of modern biotechnology.

43. Mr. George Sarpong, University of Ghana, described the factors influencing the need for a new legal regulation in Ghana to deal with biosafety. He outlined the rationale behind the choice of a proposed
regulatory regime and the factors that influenced that choice. He also described the elements and functions of the regulatory regime. He explained why existing agencies had been chosen to implement the regime in coordination, and gave examples.

44. Mr. Abisai Mafa, Biosafety Board of Zimbabwe, described the national Policy on Biosafety and Biotechnology; the GMO regulatory framework and its scope and history; the mechanism and structures for implementing the NBF; the gaps identified in the NBF. He explained that new mechanisms were to be put in place to address those gaps and a revision of the NBF was expected.

45. Ms. Darja Stanic Racman, National Programme Coordinator of Slovenia, described the factors influencing the choice of NBF in the country, pointing to the fact that its accession to the European Union in May 2004 would mean that the EU regulations would have to be implemented from that point onward. How to tailor the EU regulations so that they would function within the country’s administrative system had been a factor, and it had also been considered that a new GMO Act would be a better option than trying to accommodate biosafety issues within existing laws. However, while having the ready-made EU regulations at its disposal had brought benefits, fitting it into an existing administrative system brought sub-optimal solutions. Moreover, putting in place such a regulation did not imply that there was the capacity to implement it. In addition, because others had formulated the rules of the game, there was a danger that stakeholders in Slovenia had not been consulted sufficiently and no real consensus had been reached.

46. During the discussion, participants raised the following points: whether the African Model Law on Biosafety had been applied by relevant countries in drafting their NBFs; how the public had been consulted and involved in the drafting work; common elements of the NBFs within the countries under review; and the importance of networking.

*Introduction to elements of a regulatory regime and general provisions*

47. Mr. Gregory Jaffe, Biotechnology Project Centre for Science in the Public Interest, Resource Person, described some of the characteristics of a regulatory regime, noting the need for adequate legal authority, transparency, consistency, clarity, adaptability, and the need for it to be workable and enforceable. He listed the operational provisions of a regulatory regime, the substance of the regime, as comprising procedures for permits and notifications; risk assessment obligations; risk management authorities; and safety standards. Other provisions, to help the system work in practice, included enforcement; public participation; monitoring; confidentiality; emergency measures; and the transition period.
48. Concentrating on the general provisions, which formed the foundation of the regulatory regime, he said that the objective gave the answer to the question of why the regulatory regime was needed, and set out the aims, goals and purpose of the regime. He listed possible objectives and gave examples from regimes already in force. Concerning the scope, which dealt with what the regime had to cover, he noted that it usually comprised two parts: what activities; and what objects. He listed examples from regimes in force. The general provision on definitions was important, and he noted possible terms, which might need to be defined, and cited examples of how that had been done in existing regimes. Concerning institutional arrangements, dealing with ‘who would do what’ with respect to the regime, he noted the possible competent authority and ministries, giving examples. He pointed to the role, composition and responsibilities of the Advisory Committee, providing examples from regimes already in force. He noted that the general obligations with respect to activities under the regime usually placed responsibilities on those using the technology. In conclusion, he pointed to the need to decide what had to be in law, as opposed to what could be in guidance; balance specificity with flexibility; be mindful of the minimum required under the Protocol; decide what else, if anything, the regime should cover; recall that the development of an NBF was an iterative process, whereby it might be necessary to revisit steps already taken in light of subsequent developments.

*Introduction to operational provisions of a regulatory regime*

49. Mr. David Heron gave a summary of the requirements under the Cartagena Protocol with respect to a regulatory regime and an administrative system and listed the following as examples of possible operational provisions of the regime: contained use; introduction into the environment; placing on the market; and import and export. For each of these operational provisions it was necessary to: carry out a risk assessment prior to the activity; apply adequate safety measures; request permit for or notify certain activities; and carry out procedures for decision-making. In addition, for contained use, it was necessary to implement safety measures, comprising two complementary components: containment measures; and work procedures. Those safety measures depended on the organisms involved; the involved genes and modifications; and the type of facility.

50. Turning to the procedural provisions or final clauses of the regime, by way of example he listed: information requirements; public information; confidentiality; appeal procedures; enforcement, compliance and liability; review mechanism; and entry into force/transition period. In conclusion he stressed the following important aspects for the provisions of a regulatory regime: clarity (objective, scope, structure); transparency (procedures); consistency; workability; enforceability; adaptability; and legality.
51. Mr. Jaffe gave a brief presentation on how to address “placing on the market” in the regulatory regime, citing the examples of food or feed, or commercial seed intended to be sold. He noted that the usual obligations applied – carry out a risk assessment prior to the activity; apply adequate safety measures (risk management); approve application – with the addition of a requirement for post-approval information on the BCH. He described the responsibilities of the applicant and listed the following guidance for the conduct of a risk assessment: may be in compliance with Annex II of the Protocol; may involve the Scientific Advisory Committee; should be specific to the receiving environment; a comparison should be made with the risks posed by non-modified organisms in a similar environment; carried out on a case-by-case basis; look to guidelines from relevant international organizations. He pointed to the application of adequate safety measures in the risk management and the need for transparency in the process. The decision-making process should be consistent with the obligations of the Protocol; apply the precautionary approach; may take socioeconomic considerations into account; and should have flexibility built into it. He summarized the content of a decision document and pointed to the information to be provided to the BCH.

52. Ms. Garforth gave an overview of exporter and importer obligations within the Protocol procedures for advanced informed agreement and LMOs for food, feed or processing and provided a number of examples of how these obligations were implemented in major producers and exporters of LMOs.

Introduction to other elements of a regulatory regime

53. Mr. David Heron gave a presentation on the operational provision of a regulatory regime concerning public information and public participation. He said that, in order to provide for informed decisions throughout the society, countries were urged to provide opportunities for public awareness, public information and public participation. Public awareness and information, educating the public so that they could make better informed decisions, involved government institutions; social and cultural institutions; interest groups; and individuals. Public participation implied efforts to involve the disparate interest groups outside the Government in an interaction with both the Government and one another. He underlined the great importance of having public information and participation throughout the entire development of the regulatory system. In that way, people would be able to “buy in” to the system, and that would help to ensure its long-term sustainability.

54. Mr. Jaffe gave a brief presentation on addressing confidentiality in the regulatory regime. He summarized the Protocol’s requirements on the subject and suggested that the issue be tackled by (a) reviewing and analysing relevant domestic laws; (b) reviewing how confidential information was protected in other regulatory contexts; and (c) reviewing any court decisions. He offered several definitions of the word confidential, noting that the Protocol itself did not define the term. Noting the need for justification of a claim of confidentiality, he offered examples of the type of proof that was needed, such as: the applicant kept
the information confidential; it would be of value to a competitor; and it was not otherwise publicly available. He listed information that might be considered not confidential, and pointed to the procedures concerning who would decide; what were the appeal rights; and how to ensure confidential information was not inadvertently released. In conclusion, he said that the issue of confidential information in a regulatory regime was a balancing of interests between the right of an applicant to safeguard information that was of commercial value, and the public right to know and to participate in the process.

55. Following the presentations, participants were invited to comment on how the public in their countries was involved in the decision-making processes of the regulatory regime and in setting policy and law-making, and how that involvement could be improved. One participant considered that, because of the connection which many people in the South had to the land, public participation on agricultural issues there was easier than in the developed countries of the North. Several other participants took a contrary view, pointing to the problems of illiteracy and distance, lack of infrastructure and mass media, all of which hampered true public involvement and participation.

Focus groups

56. For the purpose of the exercise, six focus groups were constituted, each of which was invited to consider one of the following issues: (a) monitoring, compliance and enforcement; (b) liability and redress; and (c) mechanisms for review appeal system and response to new information. The aim of the exercise was, first, to address how the system works after one or more applications had been approved; and, second, to give participants an opportunity to work through some examples, which would enable them to consider other elements in the future.

57. For the subject chosen, each group was asked to answer the following questions:

- Who/what bodies can be responsible for a regulatory regime’s application and what factors affect this choice?
- What are the priorities for these activities and how are they set?

58. The designated rapporteurs of the respective groups reported to plenary on the outcome of their group’s deliberations. The results of the exercise in the focus groups are contained in Annex VI of the present report. During the discussion of the work of the focus groups, the following points and issues were raised: how to approach the issue of redress for damage caused by a Government-approved activity; how can liability for an accidental, as opposed to an intentional, harmful occurrence be gauged and how would that affect liability; in the event of harm or damage from LMOs, who can bring a complaint; what principle could be used in assessing the burden of proof, in a case of harm or damage caused by LMOs; who pays if an LMO contaminates a neighbouring country, and how can the “polluter pays” principle be applied; the need to distinguish between individual and State responsibility on questions of liability and redress; the need to
look at how other multilateral treaties, such as the Basel Convention on Transboundary Movements of Hazardous Wastes and their Disposal, have dealt with liability and redress; the limitations that national liability and redress regimes might have in the face of harm caused by LMOs; what should be the level of liability, strict, absolute, or some other.

59. Attention was drawn to the UNEP Guidelines on compliance and enforcement of multilateral environmental agreements, which set out guidance for countries on how to approach those issues at the national level. It was also observed that the discussions in the focus groups had shown that the issues that had been considered gave rise to a great many further questions. While the exercise had proved valuable in bringing up such questions and in giving participants a broader view of the issues, it was important to see how they related to the existing situation, systems and capacities in individual countries. Participants were invited to use what had been learned in the exercise for addressing similar kinds of problems in other systems, in order to identify gaps and tackle other issues in similar contexts.

VI. ADMINISTRATIVE SYSTEMS

Introduction to general administrative tasks

60. Mr. Heron, referring to Article 2 of the Protocol, pointed to the need for countries to establish the machinery behind the scenes that would ensure the day-to-day running of the regulatory framework. Such machinery would, by its nature, be cross-cutting and would have to deal with notifications or requests for permits; enforcement and monitoring; and public information and participation. To develop such machinery, it is first necessary to survey, analyse and make a choice of what administrative systems were already in place in the country. Then, interim measure could be drafted and adopted, while the actual administrative system was being set in place. Following the actual implementation of the administrative system, there would be a need for its review and possible adaptation.

61. Enumerating the elements to be put in place, he explained that competent authorities had to be designated, given a mandate and physically established, furnished and staffed with trained personnel. The handling of requests called for administrative processing, the conduct of risk assessment, and decision-making on the application, each of which in turn could be subdivided into a number of further administrative elements, which he illustrated. The same applied to enforcement, public information and participation, and information exchange. Throughout his explanation of the different components involved, Mr. Heron also signalled those which had to be reported for inclusion on the BCH. He also drew attention to the checklist prepared by the Intergovernmental Committee for the Cartagena Protocol (ICCP) and contained in
recommendation 3/5 of its third meeting. In conclusion, he reiterated the importance of including the elements that he had described within the design of the administrative system.

62. Following Mr. Heron’s presentation of the theory, Muffy Koch presented the administrative system currently being used to support the regulatory regime in South Africa. By means of a flow-chart she outlined the components of the country’s 1997 GMO Act 15 and listed the following challenges that had arisen in its implementation: the need for the system to become operational “on the run”; understanding the specific roles of all the players; clarifying uncertainties; expanding to meet new technological demands; remaining effective, efficient and affordable; communication with all actors; and remaining neutral and defending decisions. She described each of the bodies established under the system, noting their responsibilities, staffing and capacity and pointed to the practical challenges in implementing each of them. In conclusion, she described the current implementation challenges within the whole GMO administrative system as comprising: the need to be effective and efficient in the face of a growing demand; a fast-track mechanism for familiar applications with understood risk and risk management; the need for more effective public outreach mechanisms; the need for more capacity to deal with CH obligations; and the sudden increase in the number of import/export applications. Concerning review, she pointed to the ongoing review of both the GMO legislation and the regulatory and administrative processes, which was taking into account the obligations under the Protocol, the new biodiversity regulations and the views of the public.

63. During the discussion, participants raised questions concerning: risk assessment and regulations governing transit of LMOs in South Africa; the fee structure for processing an application for a permit to import an LMO; the justification for a fast-track investigation procedure; how to ensure effectiveness in the light of the staff constraints and the expanding workload; and at what stage the public were invited to participate in the decision-making process.

64. One participant expressed the view that the public had not been sufficiently involved in the preparation of the South African GMO Act 15, that there had been a lack of transparency in the approval and release of GMOs, and inadequate risk assessment had been carried out by the country itself. She also questioned whether government officials had the appropriate expertise to take on board the impact on socioeconomic issues. Another participant asked whether South Africa had a mechanism for the public to raise issues after a permit had been issued for an LMO. In reply, it was explained that the Government carried out an extensive audit of a risk assessment prepared by the applicant, which was considered adequate. On socioeconomic issues, several independent sources of expertise were called upon by the Government. Concerning public involvement, it was expected that the ongoing review process in the country would address the issue further.
Introduction to administrative tasks relevant under the AIA procedures and overview of when and where to apply the AIA or FFP procedures

65. Mr. Yifra gave a presentation on the AIA procedure and the procedure under Article 11 of the Protocol, and set out the respective elements of the two procedures. He also provided comparative summaries of the two procedures, which listed the LMOs covered by each of them, as well as the actors and the trigger for the respective procedure. He compared the obligations under each procedure, and their requirements with regard to decisions and decision-making, and vis a vis the BCH.

66. During the discussion, participants raised the following points: the problem of potential synergy between LMO crops, and which procedure would apply in the case of an interaction between an LMO governed by the Protocol and a pharmaceutical LMO; the sovereignty of national legislation, and a country’s ability to go beyond the scope of the Cartagena Protocol in deciding what elements of biosafety it decides to cover in its legislation; and the idea that, while LMO pharmaceuticals were exempted under the Protocol, they should be the subject of legislation on purely environmental grounds.

Focus groups

67. Mr. Heron introduced a focus group exercise on administrative tasks related to an NBF. Participants were given checklists of obligations under the protocol, and were invited to complete with regard to the following:

- Designate one national authority responsible for liaison with the Secretariat and provide name/address to Secretariat;
- Designate one or more competent authorities responsible for performing administrative functions under the Protocol and provide names and addresses to the Secretariat. If more than one, indicate the types of LMOs for which each competent authority is responsible;
- Provide to the BCH (i) any relevant existing national laws, regulations or guidelines (ii) any bilateral, regional or multilateral agreements or arrangements;
- Monitor the implementation of obligations under the Protocol and submit to the Secretariat periodic reports at intervals to be determined.
68. For the purpose of the exercise, six focus groups were constituted. Three of them were invited to consider the following issue from the Protocol: “Ensure that risk assessments are carried out for decisions taken under Article 10 and that they are carried out in a scientifically sound manner”. Three of them were invited to consider a second issue: “Promote and facilitate public awareness, education and participation concerning the safe transfer, handling and use of LMOs”.

69. For the relevant issue, each group was asked to answer the following questions:

- What is the current status in your country to meet this obligation under the Cartagena Protocol?
- What still needs to be done, and how might it be done?

70. The rapporteurs of the respective focus groups reported to plenary on the outcome of the work in their group.

71. Summarizing and commenting on the outcome of the focus groups, Mr. Townend underlined the importance of embedding the right to public participation in the entire regulatory regime. Lawyers and scientists need to learn to communicate effectively with people and find out their concerns. Training and capacity-building would be needed in that context, just as for the conduct of risk assessment. It was valuable to have national experts undertaking audits, since that was not necessarily a soft science exercise and could be more demanding and complex than preparing a risk assessment ab initio. On the question of authority, it was important to have a thread of authority running through the entire administrative system and regulatory regime. In conclusion, he reiterated that training of the public and of expertise was a vital investment in the future of the country, that would bring great benefits in the long term and would help to ensure the sustainability of the system.

Case study presentations on administrative tasks

72. Mr. Jaffe, in his presentation on monitoring compliance and conducting enforcement, described some of its goals and noted the different types of monitoring that could take place within the regulatory regime. The monitoring mechanisms comprised; self-monitoring by the applicant; and government monitoring, and he outlined the administrative tasks to be carried out under each of those. Legal authority was also important, particularly as a basis for inspections, which were needed to maintain the integrity of the regulatory system. He gave examples of compliance monitoring for a field trial permit and also for a commercial release permit.
73. Concerning enforcement, he noted the chief goals, namely: addressing current violations and violators; deterring future violators; and ensure adherence to the conditions of the permit. To carry out enforcement, a country needed a host of legal authorities to carry out inspections; to collect evidence; to bring administrative or judicial action; to impose a penalty or fine; to collect expenses and/or reimbursement for harm caused; and to obtain injunctive relief. He also listed the administrative tasks incumbent upon enforcement. In conclusion, he noted the key points of monitoring and enforcement: make very clear the obligations of the applicant and of the Government; define what constitutes compliance; define who is the responsible party; consider resources and targeting; ensure transparency.

74. During the discussion, participants draw attention to the following: the problems of enforcement and appropriateness of using economic incentives to ensure compliance under a biosafety regime; how to define penalties in case of harm; the “polluter pays” principle; whether and how countries can have an influence on the decisions taken by neighbouring countries concerning permits; whether and how the details of permits can be made available to the public; the importance of subregional cooperation in compliance and enforcement; and how countries could reduce the differences between their systems and synergise their common points on the issues in question.

75. Mr. Malose Daniel Matlala, Department of Agriculture, Government of South Africa, gave a brief presentation on administrative tasks related to risk assessment and risk management in his country, to be carried out before receiving an application; on receipt of an application; towards decision-making; in decision-making; after the issue of permits; and in ad hoc administration. By way of conclusions he noted: biosafety administration grows with the number of applications; it requires considerable management of paper; it is very time-consuming and repetitive. He replied to questions raised by participants, seeking further information on the system in South Africa.

Introduction to subregional grouping cooperation

The situation in the countries of the Association of Southeast Asian Nations (ASEAN)

Mr. Mohammed gave a brief overview of developments in the ASEAN region, where the biotechnology industry was growing, and countries were elaborating biosafety guidelines in cooperation with one another. That brought the advantage that the smaller countries of the region and those with limited experience of biotechnology were able to take part in the sharing of expertise. UNEP/GEF was working with the ASEAN countries to see how they could harmonize their NBFs as they evolved. He considered that to be a valuable example of how to use an existing political/economic grouping to branch out into other areas.
Cooperation project between the African Union and the Government of Germany

Ms. Martha Kandawa-Schulz gave a brief presentation of a project on cooperation between the African Union (AU) and the Government of Germany in order to fill the gaps the African countries had identified with regard to modern biotechnology and their ability to implement the Cartagena Protocol. The following gaps had been identified: domestic development of LMOs; contained use; approval of deliberate release; approval of food made from LMOs; and traceability of food containing LMOs. Noting that the African Model Law on Safety and Biotechnology had been used as a background, she described the activity of the German Technical Cooperation Agency (GTZ) and the impact of the project on cooperation between the donor country and the AU and regional organizations.

A framework for regional cooperation – lessons learned from the seed sector

Mr. Isaac Minde, Coordinator, Eastern and Central Africa Programme for Agricultural Policy Analysis (ECAPAPA) of the Association for Strengthening Agricultural Research in Eastern and Central Africa (ASARECA), gave a presentation on an ASARECA project for rationalization and harmonization of seed policies, laws, regulations and procedures in Eastern and Central Africa. He described the background, funding, objectives and justification of the project and pointed to the main areas of rationalization and harmonization. He pointed to the methodology and process applied, and highlighted some of the achievements of the project, as well as the lessons learned in project implementation. He underlined the following conclusions: patience is needed, since it takes time to see and feel the impact; change is about people; there is a need to identify the proper tools for managing people to effect the desired change; science is important, but not sufficient for the change process; reaching agreements are the easy part; always remain guided by the long-term development goals. He answered questions seeking clarification on elements of the project.

ASARECA: Conceptual biosafety cooperation

Mr. Christopher Ngichabe, ASARECA, gave a presentation on a regional approach to biosafety: the ASARECA initiative. He gave the background to ASARECA and its strategic objective and described its biotechnology and biosafety programme. Setting out the rationale and the prerequisites for a regional approach, he addressed the different levels of harmonization (political, technical and legislative) and the harmonization of the competent authorities, administrative procedures and technical standards. He outlined the issues encountered in the harmonization of the five key elements of an NBF (policy; legal regulatory system; administrative system; monitoring; public anticipation and awareness) and concluded with the question: can ASARECA work with UNEP/GEF to begin harmonizing potential areas in the NBFs of the countries in the region?

During the discussion, participants pointed to possible collaboration with the countries of the SADCC region and with other African organizations; participants also raised the issue of environmental impact assessment in a transboundary context. One participant pointed out that the East African Legislative Assembly had asked UNEP to hold an awareness-raising seminar on LMOs.

76. For the purpose of an exercise, geographically-based groups were constituted, each of which was invited to answer the following questions:

- Why do you need cooperation?
- How do you go about it?
- What needs to be put in place?
77. The designated spokespersons for the groups reported back to plenary on the outcome of the discussions in the groups. The results of the exercise in the focus groups are contained in Annex VIII of the present report.

VII. CONCLUDING SESSION OF THE WORKSHOP

On 12 March 2004, the Workshop held its concluding plenary session.

*Expectations and Concerns – Revisited*

At the closing session of the Workshop, Mr. Mohammed invited participants to again go through the list of expectations and concerns that they had drawn up at the very opening of the Workshop four days previously, to see which of them had been met or not. The list of expectations and concerns containing the observations made at the closing stage of the Workshops is contained in Annex III to the present report.

*Evaluation Exercise and Closure of the Workshop*

Mr. Mohammed informed participants that their comments on the Workshop would provide important feedback to help the Biosafety Team further refine the process, and invited them to complete the evaluation form provided for the purpose. In conclusion, on behalf of the Biosafety Team, he thanked all participants for their hard work, he reiterated his thanks to the Government and people of the United Republic of Tanzania for hosting the Workshop and for their hospitality, and thanked all who had participated and who had worked in front of, and behind the scenes to contribute to the success of the Workshops.

*Closing address by the Hon. Arcado D. Ntagazwa, Minister of State Environment of the Office of the Vice President of the United Republic of Tanzania*

In his closing address Mr. Ntagazwa expressed thanks to all participants for their deep sense of commitment and cooperation during their deliberations on the important issues examined at the Workshop. He wished participants a pleasant remainder of their stay and expressed the hope that they would again chose to pay a visit to the United Republic of Tanzania. After the customary exchange of courtesies, the Workshop closed at 5.30 p.m. on Friday, 12 March 2004.

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Annex II: Keynote address by His Excellency Dr. Ali Mohammed Shein, Vice President of the United Republic of Tanzania

It gives me great pleasure and honour to be with you this morning to officiate the opening ceremony of this important sub-regional workshop on developing Regulatory Regime and Administration Systems for National Biosafety Frameworks for the Anglophone African Countries.

My first task is to welcome you all, and express my sincere appreciation to you for availing your valuable time to participate in this workshop, despite your other equally important commitments. I would like to extend a warm welcome to our distinguished guests from the sub-region and to those from outside the sub-region.

Your participation in this workshop is a sign of your commitment and dedication to the provision of an adequate level of safe transfer, handling and use of living modified organisms resulting from modern biotechnology.

To the UNEP-GEF, the organizers of this workshop, I would like to thank you for choosing Tanzania to host this workshop.

I need not stress the significance of biosafety which is the subject of your workshop. In the last century, conventional breeding produced a vast number of varieties and hybrids that have contributed immensely to higher grain yield, stability of harvests and farm income in developed countries. There have been significant improvements in resistance to diseases and insects, and in tolerance to a range of abiotic stresses, especially soil toxicities. It is now possible to take a single gene from a plant or animal cell and insert it into another totally different species to give that species a desired property, such as resistance to disease or pest.

Modern biotechnology is a powerful tool that offers several opportunities to humankind. Numerous opportunities exist in medicine, industry, the environment and agriculture. There are a number of fascinating developments that are in commercial applications in agriculture.
Transgenic varieties and hybrids of cotton, maize, potatoes, containing genes, which effectively control a number of serious insect pests, are in commercial application. The use of such varieties greatly reduces the need for insecticide sprays and dusts. Considerable progress has also been made in the development of transgenic plants of oilseed rape, soybeans, sugar beet and wheat with tolerance to a number of herbicides. This can lead to a reduction in the overall herbicide use through much more specific interventions and dosages. I am informed that experience is available in developing cereal varieties with greater tolerance for soil alkalinity, free aluminium and iron toxicities. These varieties help to ameliorate the soil degradation problems in many irrigation schemes. They can also allow agriculture to succeed into acid soil areas, thus adding more arable land to the production base. Greater tolerance of abiotic extremes, such as drought, heat and cold can benefit irrigated fields.

There are now on the global market, transgenic plants, such as tomatoes and strawberries that have been modified using a gene from a cold water fish to protect the plants from frost. Some varieties of potato and corn have received genes from bacterium that enables them to produce their own insecticide, thus reducing the need to spray chemical insecticides.

In medicine, many of you are aware of the use of biotechnology in insulin production. Millions of people the world over depend on this insulin for survival. I am also informed that microorganisms that degrade oil have been developed through modern biotechnology and these can play a crucial role in cleaning seas and the environment in the event of oil spills.

Genetically Modified Organisms (GMOs) are becoming part of an increasing number of products, including foods and food additives, beverages, drugs, adhesives and fuels. Agricultural and pharmaceutical LMOs have rapidly become a multi-billion-dollar global industry.

Despite these advances, biotechnology has raised concerns about potential side-effects on human health and the environment, including risks to biological diversity and socio-economic, cultural and ethical issues. The hazards of Genetically Modified Organisms (GMOs) to biological diversity and human and animal health are now widely acknowledged. Particularly serious consequences are associated with the potential for horizontal gene transfer, including the spread of anti-biotic resistance marker genes, that would render infectious diseases untreatable; the
generation of new viruses and bacterial that cause diseases; and harmful mutations which may lead to stubborn diseases such as cancer.

The world community has also expressed concern on the effect of GM crops to intensify corporate monopoly on food, driving family farmers to destitution, and preventing the essential shift to sustainable agriculture that can guarantee food security and human health. In recent years a newly patented technology for the genetic engineering of plants to produce sterile seeds has emerged. The technology, dubbed, “Terminator Technology” is designed to force farmers to buy seed from the Gene Giants, rather than using seed from previous years harvest. Genetic seed sterilization has become an industry-wide goal. The technology has been widely condemned as a threat to biodiversity, as well as to food security, because over 1.4 billion people, primarily the poor in the South, depend on farm-saved seeds.

These concerns and opportunities surrounding modern biotechnology dictate that we develop appropriate policies and regulations to direct the use of biotechnology. Most importantly, is the fact that no country can go alone. The coming together of so many of you from the sub-regional is clear testimony that you realise and recognise this fact. You, as policymakers and scientists are duty bound to develop policies that will allow the safe and environmentally sound application of biotechnology. I understand each country has been working tirelessly towards realising this goal and I congratulate you for the efforts you are undertaking.

As you know, Tanzania is a party to the Convention on Biological Diversity and to the Biosafety Protocol of that Convention. The Convention on Biological Diversity is a landmark from the perspective that it is the treaty that addresses biodiversity comprehensively, and commits the community of nations to conserve biodiversity, to use biological resources sustainably and to share fairly and equitably the benefits arising from the commercial use of genetic resources. It is the first time that biodiversity as such, is comprehensively addressed, i.e. genetic resources, species and ecosystems; and the first time that genetic diversity is specifically covered in a binding global treaty. The convention contains a series of far-reaching obligations related to the conservation of biological diversity and the sustainable use of its components. On the strategic planning side, it creates obligations to develop national strategies and plans, to integrate the conservation and sustainable use of biological diversity into relevant sectoral or cross-sectoral plans, programmes and policies, as well as into decision-making, based on good science.
Correspondingly, the Biosafety Protocol is a historic global agreement, being the first time that international law recognizes Genetic Engineering of organisms as distinct and inherently different, requiring a regulatory framework of its own. The objective of the Protocol is to minimize the adverse effects of modern biotechnology through safe transfer, handling and use of living modified organisms. The Protocol addresses the potential risks posed by cross-border trade and accidental releases of LMOs. It recognizes the right of any Contracting Party to pronounce itself on GMOs on the basis of the Precautionary Principle; to take preliminary measures to protect the environment and society from potential adverse impacts associated with GMOs, even before there is hard evidence that danger actually exists. The Protocol provides for Contracting Parties to signal whether or not they are willing to accept imports of commodities containing LMOs.

The Protocol provides minimum standards, and reaffirms a Party’s right to take national action. Stricter Advance Informed Agreement procedures apply to seeds, live fish, and other LMOs meant for intentional introduction into the environment. In these cases, the exporter must provide detailed information to each importing country in advance of the first shipment, and the importer must then authorize the shipment. This means that the recipient country must have both the opportunity and the capacity to assess the risks involving products of modern biotechnology.

The Protocol deals with risk assessment and risk management which is the core provision for the operation of the Protocol. Risk assessment and risk management underline the critical task countries face in giving operational reality to the Protocol. It is the onerous task of the country accepting LMOs to ensure that products arising from such organisms are not a risk to biodiversity and human health taking into account socio-economic and cultural concerns. Needless to say, the effectiveness of the Protocol lies in the capacity of countries to engage in scientific analysis of the nature of LMOs and related biotechnological processes. To enforce the Protocol, detection procedures and facilities for GMOs are required. The ability to test for the presence of GMOs is fundamental to the control of the movement of GMOs. This is critical to the prevention of dumping of GM products resulting from public rejection in their countries of origin.

Unregulated movement holds the real possibility of GMO contamination of local or indigenous seed sources, with far-reaching implications in terms of sustainable agriculture. To be truly effective, knowledge and infrastructure are a necessary precondition for safety in biotechnology. The Biosafety Protocol provides an international framework to reconcile the respective needs of the global biotechnology industry. It creates an enabling environment for environmentally sound
technology, making it possible to derive the maximum benefit from the potential that biotechnology has to offer, while minimizing the potential risks to the environment and human health. Tanzania requires the adoption of modern technologies to eradicate poverty. In order to apply these technologies in a manner that is safe and which contributes to sustainable development, we have to be equipped. We have to understand the wide range of issues related to biotechnology. Our local institutions, the business community and the general public must be informed about what is available for them to safety benefit from.

In this era of globalization, it is essential to speedily develop regulatory frameworks to harness the potential benefits of modern biotechnology and to effectively assess and manage the inherent risks in order to prevent potential harmful effects of such technologies. National Biosafety Frameworks should guide our countries on all aspects concerning the import, export, development, production, use, application and release into the environment of genetically modified organisms (GMOs).

The challenge in implementing the Cartagena Protocol on Biosafety derives from limited capacity in terms of equipment, skilled human resource base, funding as well as limited public awareness. Building functional infrastructure to support the safe development and use of modern biotechnology is a necessary undertaking since the application of modern biotechnology is on the verge of rapid expansion. As far as Tanzania is concerned, capacity building in risk assessment, risk management and detection of genetically modified food and products thereof are urgent areas.

You have a lot of issues to cover in these four days. Your task is to under-take in-depth review of Regulatory Regime and Administrative Systems for National Biosafety Frameworks, and build the basic consensus needed for viable National Biosafety Frameworks. I urge all participants to freely and constructively contribute to the workshop in order to ensure that positions on key issues of interest are adequately covered and are well articulated for the challenges before us.

Let me conclude by expressing my confidence for the best outcome of your workshop. The composition of participants to this workshop reflects the necessary expertise and experience to achieve the objective of this workshop.
Last but not least I invite you to find time outside workshop hours to explore the beautiful city of Dar es Salaam, the countryside and Zanzibar for your memorable times.

I wish to commend the organizers of this workshop for choosing Tanzania to be the host, and express my appreciation to UNEP-GEF for their financial support to this workshop.

Mr. Chairperson, distinguished participants, ladies and gentlemen, with these remarks, it is now my pleasant duty to declare the sub-regional workshop on developing Regulatory Regime and Administration Systems for National Biosafety Frameworks for the Anglophone African Countries officially open.

I thank you all for your attention
## Annex III: Workplan

<table>
<thead>
<tr>
<th>Day / Time</th>
<th>Subject</th>
</tr>
</thead>
<tbody>
<tr>
<td>9 March, Day 1</td>
<td></td>
</tr>
<tr>
<td>9.00 – 10.00</td>
<td><strong>Opening ceremony</strong></td>
</tr>
<tr>
<td>10.00 – 10.15</td>
<td>Introduction of participants (nationality, name, professional responsibility, working place)</td>
</tr>
<tr>
<td>10.45-11.15</td>
<td><strong>Introduction to the workshop:</strong></td>
</tr>
<tr>
<td>10-15 min</td>
<td>Objectives of the workshop</td>
</tr>
<tr>
<td></td>
<td>Better understanding of:</td>
</tr>
<tr>
<td></td>
<td>• elements of regulatory regimes of NBFs</td>
</tr>
<tr>
<td></td>
<td>• how the laws, regulations, and guidelines are part of the administrative processes that make an NBF actually work</td>
</tr>
<tr>
<td></td>
<td>• how a well coordinated NBF makes it possible for countries to meet their obligations under CP</td>
</tr>
<tr>
<td></td>
<td>• promote interactions among national coordinators that might lead to enhanced regional and sub regional cooperation.</td>
</tr>
<tr>
<td>5-10 min</td>
<td>Introduction to the workplan</td>
</tr>
<tr>
<td>10 min</td>
<td>Ground rules</td>
</tr>
<tr>
<td></td>
<td>• Switch off cell phones</td>
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<tr>
<td></td>
<td>• Please talk to facilitator</td>
</tr>
<tr>
<td></td>
<td>• Minimise background discussions etc</td>
</tr>
<tr>
<td>11.15 – 11.30</td>
<td>Expectations and concerns for the workshop (brainstorm by participants)</td>
</tr>
<tr>
<td>Time</td>
<td>Activity</td>
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<tr>
<td>--------------</td>
<td>--------------------------------------------------------------------------</td>
</tr>
<tr>
<td>11.30 – 12.00</td>
<td>Introduction to the UNEP-GEF Biosafety Projects and brief history</td>
</tr>
<tr>
<td>12.00 – 12.15</td>
<td>Overview of key components of National Biosafety Framework</td>
</tr>
<tr>
<td>12.15 – 12.45</td>
<td>Discussion on presentations</td>
</tr>
<tr>
<td>9 March, Day 1</td>
<td><strong>Overview of the present NBF status of the sub-region</strong></td>
</tr>
<tr>
<td>13.45 – 14.00</td>
<td>Trends in the development of NBF in the sub region: synthesis of regional experience</td>
</tr>
<tr>
<td>14.00 – 14.45</td>
<td>Country presentations</td>
</tr>
<tr>
<td></td>
<td>Questions:</td>
</tr>
<tr>
<td></td>
<td>1. What regulatory regime (laws, regulations, guidelines) and</td>
</tr>
<tr>
<td></td>
<td>administrative systems does the country have in place or is the</td>
</tr>
<tr>
<td></td>
<td>country putting in place?</td>
</tr>
<tr>
<td></td>
<td>2. Why and how did the country arrive at this choice?</td>
</tr>
<tr>
<td></td>
<td>3. Does it cut across government departments or centred in only one</td>
</tr>
<tr>
<td></td>
<td>department?</td>
</tr>
<tr>
<td></td>
<td>4. What process/mechanism did the country establish to get all the</td>
</tr>
<tr>
<td></td>
<td>Ministries or government machinery involved? Was it a stepwise process?</td>
</tr>
<tr>
<td></td>
<td>Was there an established stakeholder process?</td>
</tr>
<tr>
<td>14.45 – 15.45</td>
<td>Plenary: Discussion on sub-regional experience</td>
</tr>
<tr>
<td></td>
<td>Some possible questions from facilitator:</td>
</tr>
<tr>
<td></td>
<td>1. What lessons have the legal surveys brought out at country level?</td>
</tr>
<tr>
<td></td>
<td>2. How are the consultation mechanisms of the surveys going?</td>
</tr>
<tr>
<td></td>
<td>3. Are scientists involved in the legal survey analysis?</td>
</tr>
<tr>
<td></td>
<td>4. What are some of the possible laws etc that can address LMOs?</td>
</tr>
<tr>
<td>9 Dec, Day 1</td>
<td><strong>International obligations</strong></td>
</tr>
<tr>
<td>16.05 – 16.45</td>
<td>Introduction to national obligations and rights under the Cartagena</td>
</tr>
<tr>
<td></td>
<td>Protocol</td>
</tr>
<tr>
<td>Time</td>
<td>Activity</td>
</tr>
<tr>
<td>-----------</td>
<td>--------------------------------------------------------------------------</td>
</tr>
<tr>
<td>16.45 – 17.00</td>
<td>Discussion 30 min</td>
</tr>
<tr>
<td>17.00 – 17.30</td>
<td>Introduction to other international instruments and to national obligations and rights that may affect NBF regulatory systems 30 min</td>
</tr>
<tr>
<td></td>
<td>IPPC, OIE, WTO with GATT, TBT, SPS etc</td>
</tr>
<tr>
<td>17.30 – 18.00</td>
<td>Discussion 30 min</td>
</tr>
<tr>
<td>10 March, Day 2</td>
<td>Project overview and linkage to NBF 9.00 – 9.15 15 min.</td>
</tr>
<tr>
<td></td>
<td>How to pass from phase 1 and 2 to Phase 3 of the Project</td>
</tr>
<tr>
<td></td>
<td>What elements to consider in drafting the NBF</td>
</tr>
<tr>
<td></td>
<td>How to draft</td>
</tr>
<tr>
<td></td>
<td>Where to start</td>
</tr>
<tr>
<td></td>
<td>Who will draft, etc.</td>
</tr>
<tr>
<td>9.15 – 9.55</td>
<td>Regulatory regime 40 min</td>
</tr>
<tr>
<td></td>
<td>Introduction to choices of a Regulatory Regime</td>
</tr>
<tr>
<td></td>
<td>Implications of biosafety policy on a regulatory regime</td>
</tr>
<tr>
<td></td>
<td>Explanation of different approaches for a legally binding system (including use of existing or new regulatory system)</td>
</tr>
<tr>
<td></td>
<td>Explanation of different terms, levels and principles of norms (law/regulations/guidelines/policy)</td>
</tr>
<tr>
<td></td>
<td>Factors that may influence the choice and examples of legal approaches</td>
</tr>
<tr>
<td>9.55 – 10.25</td>
<td>2 Studies by CISDL 30 mins</td>
</tr>
<tr>
<td>Time</td>
<td>Activity</td>
</tr>
<tr>
<td>--------------</td>
<td>--------------------------------------------------------------------------</td>
</tr>
</tbody>
</table>
| 10.25-11.15  | Short presentations before discussions of the following experiences:      | Kenya, Tanzania, Ghana and Slovenia  
Identify rationale for choosing one of the approaches  
What factors influenced the choice?  
How did you make and justify the choice? |
| 50 min       |                                                                          |                                                                                                                                               |
| 10 March, Day 2 | 11.30 – 12.10  
40 min       | *Introduction to elements of a Regulatory Regime and General provisions*  
Introduction to main elements of a regulatory regime: General provisions, Operational provisions (incl. RA and RM procedures and decision making), and other elements  
Introduction to General provisions: objective, scope, definition of terms, institutional arrangements, general obligations |
|              |                                                                          |                                                                                                                                               |
| 12.10 – 13.00| Discussion                                                               |                                                                                                                                               |
| 50 min.      |                                                                          |                                                                                                                                               |
| 10 March, Day 2 | 14.00 – 14.30  
30 min       | *Introduction to operational provisions of a Regulatory Regime*  
Worked example on one Operational Provision - release into the environment. |
|              |                                                                          |                                                                                                                                               |
| 14.30 – 15.30| Worked out examples on other Operational Provision:                      | 1. export and import  
2. placing on the market                                                                                       |
| 60 min       |                                                                          |                                                                                                                                               |
| 10 March, Day 2 | 15.50 – 16.30  
30 min.      | *Introduction to other elements of a Regulatory Regime*  
Other elements that are usually included and other elements that could be included as a country’s choice (e.g. Enforcement, Transparency, Accountability, Information & Public participation, Monitoring, Confidentiality, Emergency measures, Knowledge management, Offences and penalties, Appeal system, Transition period, Liability & Redress, New information, Revision of decision, Labelling and traceability, Entry into Force, Ethical issues etc.)  
One worked example (information and public participation + confidentiality) |
### UNEP-GEF Project on Development of National Biosafety Workshops
Anglophone Africa Subregional Workshop (*March 9-12, 2004, Dar Es Salaam, Tanzania*)

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td>Short discussions after presentations</td>
</tr>
<tr>
<td>16.30 – 18.00</td>
<td>Focus Group exercises on Other Elements of a Regulatory Regime</td>
</tr>
<tr>
<td>60 min</td>
<td>(Theme: Post-permit Other elements)</td>
</tr>
<tr>
<td></td>
<td>2 Focus Groups per each topic:</td>
</tr>
<tr>
<td></td>
<td>1. Monitoring, compliance and Enforcement</td>
</tr>
<tr>
<td></td>
<td>2. Liability and Redress</td>
</tr>
<tr>
<td></td>
<td>3. Review: Appeal System and New Information</td>
</tr>
<tr>
<td>11 March, Day 3</td>
<td>Reports from focus groups</td>
</tr>
<tr>
<td>8.30 – 9.30</td>
<td>Administrative Systems</td>
</tr>
<tr>
<td>9.30 – 10.00</td>
<td>Introduction to General Administrative Tasks</td>
</tr>
<tr>
<td>30 min</td>
<td>Implications of the general and specific administrative tasks required by the NBF (Refer: ICCP check list and all administrative tasks in CP, on top of AIA and FFE, eg art 20 etc). For example, implications of the designation of one national authority responsible for liaison with the Secretariat AND/OR competent authorities responsible for performing administrative functions under the Protocol.</td>
</tr>
<tr>
<td>10.00 – 10.30</td>
<td>From regulatory theory to practice:</td>
</tr>
<tr>
<td>30 min.</td>
<td>S. Africa - Muffy</td>
</tr>
<tr>
<td>10.30 – 11.00</td>
<td>Discussion</td>
</tr>
<tr>
<td>30 min</td>
<td>Introduction to administrative tasks relevant under the AIA procedures</td>
</tr>
<tr>
<td>11.15 – 11.45</td>
<td>Overview on when and which to apply AIA (Art 7-10) or FFP (Art. 11) procedures</td>
</tr>
</tbody>
</table>
## UNEP-GEF Project on Development of National Biosafety Workshops
### Anglophone Africa Subregional Workshop (March 9 -12, 2004, Dar Es Salaam, Tanzania)

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>11.45 – 12.15 30 min</td>
<td><strong>Summary, Discussions and Introduction to Focus Group Work</strong></td>
</tr>
</tbody>
</table>
| 12.15 – 13.30 75 min | **Focus Groups**  
Questions:  
1. Discuss the main administrative tasks required under  
a) Cartagena Protocol Art. 11 procedure for product imported into your country;  
b) Cartagena Protocol AIA procedure; |
| 12 March, Day 4 | **Reports from focus groups**                                          |
| 9.00 – 9.45 45 min | **Discussion**                                                          |
| 9.45 – 10.30 45 min | **Case study presentation on Administrative tasks**  
One case study – monitoring, compliance and enforcement |
| 11.00 – 11.25 25 min | **Second case study – administrative tasks related to RA and RM**         |
| 11.25 – 11.50 25 min | **Discussion**                                                          |
| 11.50 – 12.45 55 min | **Introduction to sub regional grouping cooperation**  
NEPAD biosafety vision for Africa  
Presentations: ASEAN, SARB  
A Framework for Regional Cooperation – Lessons learned from the Seed Sector |
| 14.00 – 16.00 120 mins | **ASARECA: Conceptual Biosafety Cooperation**                         |

48
<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.15 mins</td>
<td>Discussions in small geographical groupings as to the way forward on cooperation with short reports presented at plenary (ECOWAS, ASARECA, SARBS etc</td>
</tr>
<tr>
<td>30 mins</td>
<td>Plenary discussion of geographical grouping reports</td>
</tr>
<tr>
<td>16:00 – 16:20</td>
<td>Response to “Expectations &amp; Concerns”</td>
</tr>
<tr>
<td>16:20 – 16:40</td>
<td>Workshop evaluation by participants on standard forms</td>
</tr>
<tr>
<td>16:40 – 17:00</td>
<td>Closure of the workshop</td>
</tr>
</tbody>
</table>
Annex IV: Ground Rules

Participants agreed on the following ground rules for the meeting:

Switch off cell phones

Be punctual

Respect other points of view, but be assertive in putting forward your own view

Minimize background noise and discussions

Keep interventions concise and to the point

In focus groups, observers speak only when requested to by the government participants.
## Annex V: Participants Expectations and Concerns

<table>
<thead>
<tr>
<th>EXPECTATIONS</th>
<th>CONCERNS</th>
</tr>
</thead>
<tbody>
<tr>
<td>To learn about the Protocol and implementation☺</td>
<td>Define terminology and components of framework structure☺</td>
</tr>
<tr>
<td>Learn from other countries☺☺</td>
<td></td>
</tr>
<tr>
<td>Learn and benefit from experience from countries more advanced in developing guidelines☺</td>
<td></td>
</tr>
<tr>
<td>Establish new contacts and networking☺☺</td>
<td></td>
</tr>
<tr>
<td>Learn about other regulatory issues☺</td>
<td></td>
</tr>
<tr>
<td>Brand new regime vs. existing laws☺</td>
<td></td>
</tr>
<tr>
<td>Learn about linkages between guidelines, regulations, laws☺</td>
<td></td>
</tr>
<tr>
<td>Guidance in administrative issues for improvement☺</td>
<td></td>
</tr>
<tr>
<td>Admin. systems – how countries can work together☺</td>
<td></td>
</tr>
<tr>
<td>Establish mechanism for harmonizing expectations and avoid prescription by countries☺</td>
<td></td>
</tr>
<tr>
<td>Learn about common elements and achieve harmony an sub-regional cooperation for sustainability☺</td>
<td></td>
</tr>
<tr>
<td>Cost of awareness building to be reduced☺</td>
<td></td>
</tr>
</tbody>
</table>
Annex VI: Results of the Focus Group Exercise on Regulatory Regimes

Blue Group

Review of Decisions

Article 12 of Cartagena Protocol (CP)

Where could new information come from?

BCH
Scientific community
User communities
International networking
Cabinet/Council of Ministers/government
NGOs
Media
Importer
Exporter
Applicant

New information could reveal impacts, harm, negative and positive results

Importer has a right to review: notification duty (within 30 days) plus written reasons

Party of export has the right to ask for review

How broad a standing should be given and will be given to Parties beyond Party of import and Party of export to initiate or request review? Matter of discretion for country.

Review relates strongly to the science of the risk assessment and this review may track back into the risk assessment

The implications of the new information decisions map onto liability and redress (governed by general causation rules cf asbestos and tobacco litigation)

Who will verify the new information and who has the duty to make the decision? Duty still rests with the authority making the first decision (Party of import-thread of authority)

Appeals

Only reference in CP is to new information and countries have discretion to devise appeal systems.
Leaving this to domestic law raises questions of compatibility and will this cause problems?

What might go wrong?
We might have a wrong decision or a contested decision.

Wrong decision
Error of fact or error of law or administrative procedure
Mechanisms for resolution could be by internal review or tribunal or arbitration or by ministerial decision e.g. tribunal with judge and two lawyers

This sectoral review could map into normal constitutional appeal structures e.g. High Court appeal

Decision as to form of mechanism determined by cost and time implications for all parties

Question of conflict of laws (jurisdiction) This concerns an internal decision therefore warrants an internal review (dispute with US exporter for a Tanzanian permit is a Tanzanian decision therefore resolved in Tanzania). However, exporter must have standing if non-resident

Guiding principles for operation of appeal: precautionary principle, the right to be heard, sovereignty of country (right to decide), treat like cases alike, duty to give written reasons and independent adjudication.

Contested decision
Disagreement over interpretation of science or of socio-political or socio-economic decisions

How could this be resolved? Could be by committee of experts.

However, does this fundamentally conflict with the democratic principle i.e. a primary decision maker is delegated the power to make decisions in relation to such interpretations, therefore that decision should not be second-guessed. The only appeal rights should be to wrong decisions (1. above)

Green group

LIABILITY AND REDRESS

Ground Rules:
Follow what is in CP (use ICUN explanatory guide for elaboration)
Existing civil liability regimes

Priorities:
Expected damages
Expected remedies
Preventive measures
Who should pay
In what circumstances
Intentional
Accidental
Negligence
Country experiences:
Ghana – use existing liability and redress regime in the civil law
Kenya – same as Ghana
Rwanda – Civil law takes precedence
Swaziland – 1.) civil law; 2.) international law; 3.) precedence
Botswana – same as Ghana
Angola – 1.) civil law; 2.) international law
Lesotho – civil law

How are priorities set?
Multidisciplinary group of experts to set the background (surveys, studies)
Consultation with all stakeholders.
/s

Complainants:
Could be anyone (individuals, institutions, governments, states-international)

What bodies can be responsible?
Court of law
A prove of damage
Police

Plenary question:
1. What does one do if civil and international laws are silent?
2. Who pays if producer has permit issued by government polluted its neighbor?

Orange Group

Liability and Redress

What are the priorities for these activities, and how are they set?

Liability

Ensure existence of liability clauses in the legislation
Identifying the person responsible for the damage
Avoidance of Adverse impact on the environment
Quantification of the damage
Cross border damage (who is responsible?)
Define type of violations (either civil or criminal)
Scope of liability (civil, criminal or administrative)
Mixture of jurisprudence and common law
Extent/limit of liability

Redress

Criminal liability, imprisonment, or fine or both
Civil liability, compensation
Administrative Action, revocation of license, confiscation, destruction, etc…
Who/What bodies can be responsible for its application and what factors affect this choice?

Individual countries should decide based on their national laws. Because in some countries there may be more than one competent authorities.

Purple Group

Monitoring, compliance and enforcement

PRIORITY

Capacity building
Human Resources
Laboratories
Infrastructure (designation of institutions etc.)
Feedback from public
Setting up a Compliance Committee at national level
Setting up a reporting system
Collaboration at regional and international level
Stakeholder involvement

How are priorities set?

Consultation with stakeholders at national level
Regional collaboration towards harmonization

Rational:

Control of adverse impact on biodiversity, health and socio-economic aspects

Compliance enables Parties to carry out obligations under the Protocol.

BODIES RESPONSIBLE
National Coordinating Committee (NCC)
National Biosafety Committee
Compliance Committee
Research Institutions
NGOs (monitoring)
Other relevant authorities (police, customs, minister of agriculture etc.)

Factors affecting the choice
National policy
Institutional arrangement
Legal system
Capacity
Historical background
International cooperation

RED GROUP

PRIORITIES FOR MONITORING
1 Priorities for monitoring at point of entry
   Customs officials, border controls, quarantine inspectors
2 Setting indicators of monitoring based on risk assessment and EIA
   Applicants and regulators
3 Monitoring compliance with permit conditions
   Applicant, audit by inspectors / regulators
4 Verification of information
   Applicant, audit by inspectors / regulators
5 Setting guidelines/criteria for monitoring
   Regulator with help of scientific advisors in consultation with stakeholders
6 Building capacity for monitoring
   Government, NGOs, private sector

PRIORITIES FOR COMPLIANCE
1 Compliance at point of entry
   Customs officials, border control, inspectors, applicants
2 Compliance with permit conditions
   Inspectors, general public and applicant
3 Certification of compliance
   NCA, or its delegated authority
4 Capacity building for compliance
   NCA, NGOs, private sector

PRIORITIES FOR ENFORCEMENT
1 Legal provisions for enforcement
   Legislative, executive, judiciary
2 Institutional capacity for enforcement
   NCA, Judiciary
3 Meeting the Cost of enforcement
   Government – judiciary to retrieve through fines
4 Incentives and punitive measures for enforcement
   Legislative, executive, judiciary

Yellow group

Mechanisms for Review: Appeal System
   and Response to New Information
Appeal Systems

Priorities

Who can appeal: Applicant and anyone else
Where appeals should go?
   Timeframe within which an appeal can be submitted
   Timeframe for response
Who pays – cost?
Form of appeal (written / phone etc)
Format of appeal
Supporting documents
CC to original decision-making body
Government to government appeal – to be dealt by another system

Who

Who is the CA for an appeal system?
Implementing agency
The board
Administrator within government
Agency – Minister – Court
To the original decision-making body
Minister or Court
Minster appoints special appeals board

Why

Exhaustion of local remedies before going to court
Depends on which institution hosts the legislation
The appeal shall be to a body that is not influenced by first decision (unbiased position)

Response to New Information

Priorities

Two steps:
    Throughout the process till decision is made
    After the decision is made **

Timeframe
Substantiated information
Risk assessment audit and risk management
** Priority for monitoring and enforcing compliance

Who

Applicant (code of conduct)
Decision-makers (Board, committee etc.)
An independent source
NGOs
General Public
Media
Research institutions

Why

Fairness
Annex VII: Focus Group Exercise on Administrative Systems

BLUE GROUP

Checklist Item:

Ensure that risk assessments are carried out for decisions taken under Article 10 and that they are carried out in a scientifically sound manner

<table>
<thead>
<tr>
<th>Country</th>
<th>Status</th>
<th>What still needs to be done &amp; how?</th>
</tr>
</thead>
</table>
| Botswana  | No regulations and no risk assessment procedures                        | • Establish meaning of “scientifically-sound”
|           |                                                                        | • Incorporating RA procedures in framework being developed
|           |                                                                        | • Establish appropriate body to be responsible for RA                                              |
| Ethiopia  | Same as Botswana                                                        | • To develop RA guidelines as part of NBF
|           |                                                                        | • Through National Competent Authority, establish and capacitate a pool of RA experts            |
| Sierra Leone | No regulations and no RA procedures as yet. However, currently the NBC is doing capacity-assessments | • Will wait for recommendations from ongoing survey                                               |
| Lesotho   | No regulations and no RA procedures in place. Policy development is in progress, including a workshop to prepare draft regulations being planned. Some training on RA conducted | • Development of policy, regulations and procedures
|           |                                                                        | • Capacity-building
|           |                                                                        | • Public awareness                                                                             |
| Zimbabwe  | Legal framework and RA guidelines in place, as well as institutional framework. Database of independent reviewers available. Training of field inspectors for RA done | • More capacity needed – to be achieved through training, networking and exposure tours
|           |                                                                        | • Development and/or strengthening of risk communication and public participation mechanisms |
| Mozambique | No regulations, no RA procedures                                       | • Development of biosafety policy, regulations and institutional framework
|           |                                                                        | • Public participation mechanisms                                                                 |
| Sudan     | No regulations, but have just concluded a national survey              | • Develop NBF                                                                                  |
Brainstorming

- Importance of training and public participation
- Risk Assessment is an audit – liability and resources
- Inter-relationship of Ministries – difficulty in observing hierarchies
- Ensuring that experts and authorities have sufficient competence and authority
- Scientifically sound method – Environmental Impact Assessment may provide some help – but basic principle is replicability

**GREEN GROUP**

**Promote and facilitate public participation**

Ground rules:
- Apply Cartagena Protocol
- Use the successful experiences of other countries

Factors to consider:
- Literacy level
- Area / population
- Number of languages
- Right to information
- Sustainability - funding
- Different existing information channels

Public awareness:
- Identify competent organizations and individuals
- Educate scientists how to communicate
- Training of trainers
- Use of opinion leaders

Public participation
- NCA be more proactive
- Feed back mechanism
- Ministerial responsibility
- Use existing methods of participation

<table>
<thead>
<tr>
<th>Country</th>
<th>Current status?</th>
<th>What still need to be done and how?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lesotho</td>
<td>Just started developing NBF; consultations; stakeholders workshop, workshop for trainings of trainers; public meeting to raise</td>
<td>Workshop for law society; ; Farmers will participate NCC meeting; system of education; training of trainers to cascade to others</td>
</tr>
<tr>
<td>Country Name</td>
<td>Current Status</td>
<td>What needs to be done and how</td>
</tr>
<tr>
<td>--------------</td>
<td>--------------------------------------------------------------------------------</td>
<td>-----------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Nigeria</td>
<td>• Consultancy: on going survey on best practice system&lt;br&gt;• Roaster of national scientific experts and institutions&lt;br&gt;• Develop guidelines/checklist for risk assessment</td>
<td>• Formulate the outputs of the consultancy to suite national needs of Nigeria</td>
</tr>
<tr>
<td>Swaziland</td>
<td>• No mechanism for risk assessment</td>
<td>• Identify NCA&lt;br&gt;• Identify review panels&lt;br&gt;• Preparation of guidelines</td>
</tr>
<tr>
<td>Mozambique</td>
<td>• No mechanism for risk assessment&lt;br&gt;• There is a draft Focal point is in place&lt;br&gt;• NCA and NCC</td>
<td>• Development of guidelines&lt;br&gt;• Establishment of roster of national experts and reviewers</td>
</tr>
<tr>
<td>Country</td>
<td>Achievements</td>
<td>Challenges</td>
</tr>
<tr>
<td>-----------------</td>
<td>------------------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Lebanon</td>
<td>• No mechanism in place</td>
<td>• Put in place NBF&lt;br&gt;• Appropriate agencies&lt;br&gt;• Train personnel&lt;br&gt;• Identify experts&lt;br&gt;• Develop manuals and guidelines&lt;br&gt;• Procedure to examine notification (put administrative set up in place)</td>
</tr>
<tr>
<td>Sierra Leone</td>
<td>• No mechanism in place&lt;br&gt;• Focal point is in place&lt;br&gt;• NCA and NCC in place</td>
<td>• Roster of experts&lt;br&gt;• Conduct survey&lt;br&gt;• Develop guidelines and procedures, manuals</td>
</tr>
<tr>
<td>South Africa</td>
<td>• The guideline is in place</td>
<td>• Identify gaps in guidelines&lt;br&gt;• Publish the guidelines of risk assessment</td>
</tr>
<tr>
<td>Kenya</td>
<td>• Roaster of national experts and reviewers in place&lt;br&gt;• Institutional Biosafety Committee in place&lt;br&gt;• NCA&lt;br&gt;• Focal Point BCH&lt;br&gt;• NCC&lt;br&gt;• Biosafety Bill and Biotech. Policy&lt;br&gt;• NBC in place&lt;br&gt;• Regulatory agencies in place</td>
<td>• Training&lt;br&gt;• Seminars and workshops&lt;br&gt;• Manuals and guidelines</td>
</tr>
<tr>
<td>Sudan</td>
<td>• No mechanism in place&lt;br&gt;• NCC is in place&lt;br&gt;• Made draft roster of institutions and scientists survey&lt;br&gt;• EIA regulations</td>
<td>• Ratification of the Protocol&lt;br&gt;• Adoption of policy</td>
</tr>
<tr>
<td>The Gambia</td>
<td>• No mechanism in place&lt;br&gt;• NCC is in place</td>
<td>• Training&lt;br&gt;• Validation&lt;br&gt;• Setting up on</td>
</tr>
</tbody>
</table>
How?

1. Reviewers must have expert knowledge in relevant fields.
2. There must be independent parties.
3. Follow national guidelines.
4. Relevant appropriate equipments.

Purple Group

Decision making under article 10 and scientifically sound risk assessment.

<table>
<thead>
<tr>
<th>Country group</th>
<th>Current status</th>
<th>What still needs to be done and how?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gambia</td>
<td>Administrative system in place (advisory bodies, biosafety coordinating mechanism etc)</td>
<td>Government needs to set a policy New legal system has to be drafted Administrative procedures Capacity needs to be built</td>
</tr>
<tr>
<td>Country</td>
<td>Status and Issues</td>
<td>Recommendations</td>
</tr>
<tr>
<td>------------</td>
<td>-----------------------------------------------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Swaziland</td>
<td>Stakeholder consultation in place, Some legal acts in place (e.g., food control act)</td>
<td>Improve public involvement into decision making process, Monitoring and enforcement system needs to be set, Designate central competent authority</td>
</tr>
<tr>
<td>Liberia</td>
<td>Surveys done (legislation, capacity etc)</td>
<td>Government needs to set a policy, New legal system has to be drafted, NCA might change (Ministry of Agriculture), Capacity needs to be built, Infrastructure (laboratories etc)</td>
</tr>
<tr>
<td>Rwanda</td>
<td>Competent authority in place (Ministry of Environment), Administrative system in place (advisory body etc), Stakeholders identified, National surveys done (legal, capacity etc), No special acts on biosafety</td>
<td>Government needs to set a policy, New legal system has to be drafted, Capacity needs to be built, Institutions, training, facilities, Biosafety Coordinating Committee could be reconstituted, New legal system has to be drafted, Preparation of guidelines, Public involvement</td>
</tr>
</tbody>
</table>

63
Red Group
Public participation

Compilation of feedback from Botswana, Ethiopia, Ghana, Kenya, Lebanon, Lesotho, Mozambique, Nigeria, South Africa, Swaziland, Uganda, Zimbabwe

<table>
<thead>
<tr>
<th>Current status</th>
<th>What still needs to be done and how?</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Awareness</strong></td>
<td><strong>Awareness</strong></td>
</tr>
<tr>
<td>• Limited awareness of biotechnology and biosafety</td>
<td>• Find out status of knowledge of LMOs amongst stakeholders thru surveys using PRA</td>
</tr>
<tr>
<td>• Survey show a low level of awareness</td>
<td>• Intensify public awareness campaign</td>
</tr>
<tr>
<td>• Public awareness growing.</td>
<td>• More extensive coverage needed to raise awareness levels, enhance education and increase participation</td>
</tr>
<tr>
<td>• Resulted in better information, knowledge, participation and education</td>
<td>• Broaden public awareness, education, participation at all levels, esp grassroots</td>
</tr>
</tbody>
</table>
### Mechanisms
- Awareness workshop
- Workshop targeted awareness to key groups
- Annual stakeholder workshops on specific projects
- Public workshops and lectures
- Workshops and lectures for policy makers and legislators
- Surveys and consultations with local communities and farmers
- Consulting (educating) political principals
- Many awareness programmes: Workshops, seminars, exhibitions, competitions, school curricula. Carried out by government (PUB); NGOs (eg AfricaBio, Consumer Orgs); Science Councils; Universities; Industry (Food, Retail, Agric, Manuf.)
- Awareness workshops held: parliamentarians, scientists, extension officers, NGOs, Media, Senior government officials, senior private officials.
- DONE. But need much wider coverage
- Used workshops, meetings, newspapers, radio/TV, etc

### Mechanisms
- Complete consultation with political principals
- More awareness outreach to national, provincial and local government. Include, civil servants, health care workers, etc.
- Workshop, focus groups, seminars,
- Public lectures by an expert
- Field days
- Use media, focus groups, etc
- Use consultants, public workshop, flyers, reference materials, newsletter, etc.
- Use of workshops, publications, TV, radio, etc in local languages to target all stakeholders including politicians
- Include traditional authorities in workshops to enable outreach to communities
- Stakeholder workshops and seminars
- Lectures at educational institutions
- Zonal workshops; media slots; advertorials; school programmes; religious programmes; private sector; total immersion (e.g. scientists in risk assessment); school biology curricula

### Capacity building
- Training of extension officers
- Capacity building for people in seed industry and farmers’ organisations
- Capacity building for scientists, universities, industry,
- Training at all levels including NCA, inspectors, etc.
- Training and equipment for GMO detection
- Press and mass media education
- Improve communication skills of scientists
Yellow Group:
Promote and Facilitate Public Awareness, Education and Participation for…

Current Status

- Public participation began with launch of NBF
- Draft guidelines prepared for public participation
- Notification in newspapers of GMO permit applications
- National biotech strategy provides for strengthening public participation and inclusion into curricula (3 degree level and high school) (SA)
- Active participation of NGOs and professional associations to create awareness and provide information
- Environmental bill which includes GM-related provisions is in parliament
- A database developed through surveys for public access to information
- Seminars and workshops
- Public talks with targeted groups (Private Sector)
- Developing websites that will link to BCH

Needs to be Done

- More time and finance to sensitize people country-wide (farmers to politicians)
- Need to develop promotional and educational material (Radio, TV etc)
- Community meetings (to educate)
- Curriculum development at all levels about biotech and biosafety
- Need to finalize public participation guidelines and translate to local languages
• Need to operationalize guidelines
• Use of print and mass media
• Review existing GMO Acts to strengthen public participation (SA)
• Action plans to implement biosafety strategy (SA)
• Create synergies between various Acts and strategies relating to biotech and biosafety
• Develop and implement a strategy for public participation
• Put public participation clause in all environmental law
Annex VIII: Exercise in geographically based group cooperation

East and Central Africa

Why do we need regional cooperation

1. There is always movement between neighbouring countries therefore the cooperation will harmonize the transboundary movements
2. Sharing of resources.
3. Exchange of expertise among countries (free flow of capacities among countries).
4. Optimum use of resources.
5. Political unity of regions.
6. Forging common positions in international debates.
7. Improve regional trade.
8. Collaborate on decision making and have a common stand.
9. Facilitate information flow between the countries

What are the areas where regional cooperation is needed?

- Areas of biosafety and biotechnology
- Environmental natural resources in general

What mechanisms do we need for this?

a) Consideration of environmental issues.
b) Conduct risk assessment.
c) Conduct monitoring and evaluation
d) Capacity building
e) Initiate forums to discuss liability and redress issues

How?

- Set up a standard voluntary guideline
- Forum for NGOs
- Community networking
- Industry networks, agro-based networks, environmental networks
- Community of parties/informal associations

Who meets the costs?

1. countries themselves
2. assistance form other donors

68
West Africa

Why?

To promote collaboration/consultation and sharing/exchange of information

Similar ecology in the sub-region and shared common values and common legal system, historical and political traditions amongst English speaking countries

Ensure regional compliance with Biosafety Protocol

Capacity building

Technical expectation and dispersal

Monitoring LMO/GMO movement

Enforcement

How?

Meetings

Conferences

Negotiations

Putting it on the political agenda

Setting institutional framework/mechanism

Implementation of existing common parties, protocols, conventions

Development of centers of excellence

Mechanism

Training in the various sectors

Common website with publications, newsletter

Using credible existing institutions

Appropriate funding mechanism

Collaboration with other sub-regions, regional, inter-regional organizations and institutions

Development of rosters of experts and information in the sub-region

Southern Africa
Rationale for cooperation

transboundary movement of LMOs
Porous borders
Harmonisation
Procedures
Rule/laws
Technical cooperation (centres of excellence)
Information exchange
Transparency, confidence in NB systems

Which issues need cooperation

Sharing of resources
Risk assessment
Identify capacity amongst nations

Opportunities to market as a single market
Promotion of inter-regional trade
Resource mobilization
Negotiation/bargaining power block

Nature of cooperation

Network recognized by focal points and competent authorities, SADC Council of Ministers
UNEP-GEF Project on Development of National Biosafety Workshops
Anglophone Africa Subregional Workshop (March 9-12, 2004, Dar Es Salaam, Tanzania)

MOU

Will recognize other initiatives on BIOSAFETY

Audit of other MOUs

Other initiatives such as Technical Committees

Mechanisms

Participation

Risk assessment to all focal points

UNEP-GEF Project on Experts on BIOSAFETY

Creation of information hub/websites

SADC Secretariat is asked to get information from contact points
Annex IX: Workshop Evaluation by Participants

Introduction

The Anglophone African Countries Sub-regional Workshop on the development of a regulatory regime and administrative systems, was held from 9 to 12 March 2004 at the Golden Tulip Hotel, Dar-es-salaam, United Republic of Tanzania. The Workshop was convened by the UNEP/GEF Biosafety Project Team, in collaboration with the Government of the United Republic of Tanzania.

At the end of the workshops, participants were asked to evaluate the workshop both in terms of the expected results, and workshop organisation and design. The purpose of the evaluation by participants was to:

1. Provide feedback to the Biosafety team on the workshop so that the lessons learned, in terms of content and format, could be used to improve the design of future workshops;
2. Provide an assessment by participants of the quality of the inputs from the Biosafety team;
3. Enable the Biosafety team to assess the extent to which the workshop achieved its stated objectives;

Methodology

The form used for evaluation (see below) of the workshop asked participants to give a quantitative indication, on a scale of 1 to 6, of their assessment of:

The expected results from the regulatory regime and administrative systems workshop, Section A, questions (i) to (x).

An overall assessment of the workshop, Section B, questions (i) to (ix).

The rating for each question, on a scale of 1 to 6, was converted to a percentage figure based on the mean of all the responses for that particular question. This figure, in conjunction with the range of scores for each question, gave an indication of the overall assessment by participants for each of the questions.

In addition, participants were also asked to give a short written assessment of the overall workshop. This allowed them the opportunity to comment on any aspect of the workshop. All evaluation forms were anonymous so that respondents were free to give their honest opinion of the workshop.

Results

The overall evaluation by participants of the workshop was excellent, with an overall rating of 80% (±4%) (see Figure 1) and all participants gave positive feedback on the contents and organisation of the workshop. The results also showed that participants considered the workshop
to be successful in achieving the expected results in terms of learning about the development of a regulatory regime and administrative systems for their NBF.

The results for the technical and overall assessments are discussed below under Parts A and B; this is followed by a discussion of the written comments from participants.

Part A: Regulatory and Administrative Issues

The evaluation of this workshop is discussed under each of the ten questions in the evaluation form (see annex IX). These questions are based on the expected results from the workshop as formulated by the biosafety team. The numerical results are also summarised in a chart (Figure 1).

The overall rating for the technical aspects of the workshop was 79% ±3%; this indicates a very high level of satisfaction by participants of the technical content of the workshop. The results for individual areas of the workshop are discussed below under each question (see Figure 1 below):

(i). Improved understanding of national rights and obligations under the Cartagena Protocol and other international agreements that may impact on an NBF.

The purpose of this question was to find out if participants had improved their understanding of the national rights and obligations resulting both from the Cartagena Protocol and other relevant international agreements. This is an important aspect of the training and was designed to help participants see the development of their regulatory regime within the broader context of relevant international agreements, and was therefore carried out in the early stages of the workshop. This question received a rating of 81% ±16% indicating that the participants found this aspect of the workshop to be very useful.

(ii). Improving your understanding of the specific needs of your country in terms of national priorities and policies in setting up the regulatory regime and administrative systems for your NBF.

The purpose of this question was to see if participants were able to better understand the need to develop their biosafety regulations within the overall context of their national priorities and policies. Although there was no specific part of the training that addressed this aspect, both the session on sub-regional experiences and focus group discussions allowed participants an opportunity to discuss this aspect. The responses to this question gave a rating of 78% ±15% indicating that again participants found the workshop to be useful in improving their understanding of the national policy context in developing their NBF.

(iii). Improved understanding of what are the main elements of a regulatory regime for an NBF.
This question addressed one of the main aims of the entire workshop, i.e. whether participants had improved their understanding of the main elements of a regulatory regime that they would need to include in their NBF. An understanding of the overall concept of the regulatory regime is necessary if participants are to develop the specific provisions needed for a workable regime. The rating given by participants for this aspect of the training was excellent at 84% ±18%, indicating that the participants found the workshop to be very useful in improving their understanding of this crucial aspect of the training.

(iv) Improved understanding of the different approaches that can be taken in developing a regulatory regime for an NBF.

This question was designed to find out if participants considered that the presentation on this topic at the workshop, and the plenary discussions with examples from other countries that had gone through the same process, had given them a better understanding of making choices in deciding on their regulatory regime. The results showed that the respondents gave a rating of very good to this question, 80%±17%, indicating that they had found this session of the workshop to be very useful.

(v) Improved understanding of what General provisions that need to be included in the regulatory regime of an NBF.

This question sought to find out whether participants thought that the presentation on the general provisions that needed to be included in their regulatory regime and the subsequent focus group discussions had helped them to understand what general provisions they needed to include in their draft regulations. The results indicated that participants found this session to be very useful, with a score of 79% ±17%.

(vi) Improved understanding of what Operational provisions need to be included in the regulatory regime of an NBF.

This question sought to find out if participants had found this session, the presentation plus the plenary discussions and examples, to be useful in improving their understanding of the operational provisions in a regulatory regime. The score for this session was 79% ±14%, indicating that participants had found the session to be very useful.

(vii) Improved understanding of what other elements or consideration need to be included in the regulatory regime of an NBF.

This question addressed the next session of the workshop which included both a presentation on the subject and focus group discussions. The results, 78% ±13% indicated that participants also found the session to be very useful to very useful in improving their understanding of this subject.
(viii). Improved understanding of the linkages between a regulatory regime and administrative systems in an NBF.

The purpose of this session was to help participants to understand the linkages between the regulatory regime and the administrative system in formulating their NBF; this session was intended to provide the interface between the two topics covered by the workshop. The results showed that respondents gave a rating of useful, 78% ±14%, to this session.

(ix) Improved understanding of the legal and administrative requirements for AIA in your NBF.

This question sought to determine whether participants had improved their understanding of the legal and administrative requirements for AIA in their NBF. The responses to this question showed that participants also found the session to be useful in improving their understanding of requirements for AIA, with a rating of 77% ±18%. These results, supported by the results of the question on FFP (see next question) indicating that participants found the presentations to be useful in improving their understanding of these complex topics.

(x). Improved understanding of the legal and administrative requirements for Article 11 (FFP) in your NBF.

This question addressed the parallel issue of FFPs and whether participants felt that they had improved their understanding of the legal and administrative requirements for Article 11 on FFP. The results indicated that, as for the sessions on AIA, participants found this session to be useful to very useful with a rating of 77% ±18.
Figure 1: A. Regulatory & Administrative Issues

- A(i). Improving your understanding of national rights and obligations under the Cartagena Protocol and other international agreements that may impact on your NBF?
- A(ii). Improving your understanding of the specific needs of your country in terms of national priorities and policies in setting up the regulatory regime and administrative systems for your NBF?
- A(iii). Improving your understanding of what are the main elements of a regulatory regime for an NBF?
- A(iv). Improving your understanding of the different approaches that can be taken in developing a regulatory regime for your NBF?
- A(v). Improving your understanding of what General provisions need to be included in the regulatory regime of an NBF?
- A(vi). Improving your understanding of what Operational provisions need to be included in the regulatory regime of an NBF?
- A(vii). Improving your understanding of what other elements or consideration need to be included in the regulatory regime of an NBF?
- A(viii). Improving your understanding of the linkages between a regulatory regime and administrative systems in an NBF?
- (ix). Improving your understanding of the legal and administrative requirements for AIA in your NBF?
- A(x). Improving your understanding of the legal and administrative requirements for Article 11 (FFP) in your NBF?
Figure 2: B. Overall workshop assessment

- B(i). Has the workshop improved your understanding of how to develop a regulatory regime for your NBF? 84%
- B(ii) Has the workshop improved your understanding of how to set up the necessary administrative systems for your NBF? 79%
- B(iii) Has the workshop improved your understanding of how your country could handle individual applications for the importation and/or release of LMOs? 74%
- B(iv) Has the workshop helped you to learn more about how other countries in Africa are developing or implementing their NBF? 73%
- B(v). How useful was the workshop for you as an individual? 89%
- B(vi). How well organised was the workshop? 82%
- B(vii). How did you find the balance of presentations and discussions? 75%
- B(viii). How well did the speakers present their materials? 79%
- B(ix). Overall, how would you rate the workshop? 83%
**Part B: Overall workshop assessment**

The evaluation of this workshop is discussed under the nine headings based on the nine questions in the evaluation form (see annex IX). These questions are based on the expected results from the workshop and are intended to give the participants’ evaluation of the overall workshop, as well as focusing on its organisation. The overall assessment of 80% ±5% indicating a high level of satisfaction with the workshop as a whole, including its organisation and the participants’ assessment of the overall contribution of the workshop to their understanding of their NBF.

The numerical results are also summarised in a chart (Figure 2).

(i). **Improved understanding of how to develop a regulatory regime for an NBF.**

This question sought to find out if participants considered that the workshop had managed to achieve one of its major aims, i.e. to help them improve their understanding of how to develop one of the pillars of their NBF, a regulatory regime. The responses to this question indicated that participants had found the workshop to be very useful in improving their understanding of this concept, with a rating of 84% ±13%. Thus the workshop was highly successful in achieving its main aim on improving participants understanding of the development of a regulatory regime.

(ii) **Improved understanding of how to set up the necessary administrative systems for an NBF.**

This question sought to find out if participants considered that the workshop had managed to achieve its other major aim, i.e. to help them improve their understanding of how to develop one of the pillars of their NBF, an administrative system. The responses to this question indicated that participants had found the workshop to be very useful in improving their understanding of this concept, with a rating of 79% ±14%. Thus the workshop was also successful in achieving its second main aim.

(iii) **Improved understanding of how a country could handle individual applications for the importation and/or release of LMOs.**

This question addressed a practical outcome of the workshop, i.e. whether participants had found that the workshop had helped them to better understand how their NBF systems would work in practice. This aspect was addressed through presentations of a number of practical examples from countries with existing systems in place rather than through formal presentations of the subject. The results showed that the rating was slightly lower at 74% ±15% indicating that participants found that the workshop was useful in improving their understanding of how to handle applications for import and/or release.

(iv) **Helped participants to learn more about how other countries in Anglophone Africa are developing or implementing their NBF.**

This question addressed one of the main objectives of the workshop, which was to promote an exchange of experiences between countries in Africa on the development of their NBF. The intention had been to provide a forum for exchange of experiences throughout the workshop by allowing participating countries to discuss their own experiences in order to illustrate various points raised by the presenters. The results showed that the participants found the workshop to be useful in promoting this exchange of experiences and gave a rating of 73% ±17%. This was the lowest rating for any of the responses in this evaluation questionnaire and was probably due to the fact that there was an error in the evaluation form and instead of “Africa”, the question read “CEECCA”. The informal evaluation at the end of the workshop had earlier indicated that participants had found this aspect of the workshop to be very useful.

(v). **How useful was the workshop for you as an individual?**

This question sought to find out if participants had found this workshop to be useful to them as individuals. This is an assessment of the workshop from their viewpoint as individuals and is in many ways one of the most important questions in evaluating the overall success or otherwise of the workshop. The participants gave this question the highest rating of any question for this workshop at 89% ±14%, indicating that participants had found the workshop very useful to them as individuals. This result indicates that the workshop was highly successful in achieving its main purposes.
(vi). How well organised was the workshop?
This question addressed the organisational aspects of the workshop rather than the technical inputs and discussions. The overall rating for this question was 82% ±16%, indicating a high level of satisfaction for the organisation of the workshop as a whole.

The results for this question is a compliment to both the Tanzanian hosts for the workshop organisation team for their excellent efforts in organising the workshop and facilitating the travel of participants, as well as selecting an excellent venue for the workshop.

(vii). How did you find the balance of presentations and discussions?
This question was designed to address one of the main features of an interactive workshop, i.e. the balance between presentations to convey difficult concepts and discussions to draw out experiences and opinions from participants. The results indicated that participants found this aspect to be useful with a rating of 75% ±16%. These results indicate that this aspect of the workshop could be further strengthened in future workshops.

(viii). How well did the speakers present their materials?
This question asked participants to assess the speakers in terms of how well they presented their materials in order to provide feedback on the quality of the presentations. The results indicated that participants rated this aspect at 79% ±13% indicating that they found the presentation materials to be useful in helping them to understand the concepts.

(ix). Overall, how would you rate the workshop?
This final question sought an general evaluation of the workshop as a whole from the viewpoint of the participants. This question received the one of the highest ratings of any of the questions, 83% ±13%, indicating that most of the participants found the workshop to be very useful. These results indicate that participants, as the intended clients, gave the entire workshop a rating of excellent.

Written comments from participants
Participants were asked to provide written comments on the workshop in order to enable a more qualitative assessment to support the quantitative evaluation. This assessment focussed on three questions and the responses from participants are summarised below under each of the questions.

(i) What did you consider to be the most helpful part of the workshop?

The participants expressed their satisfaction at the usefulness of the content of the workshop to their individual country agenda in biosafety. They appreciated very much the presentations, the sharing of experiences and the developing of linkages and contacts among themselves. These can be summarised in the following comments from participants:

- “Meeting and talking to participants and learning from the richness within the various countries in Africa”
- “It brought many experiences to learn from. Highlighted the importance of linking science to laws, and meeting other people and creating relationship for the future contact”
- “David from Sheffield Law Faculty’s presentation was very useful and overall presenters have done best”
- “The plenary discussions were very useful as they served to answer questions that tend to linger in one’s mind. The small group discussions were also very useful as they encouraged participation and integration on a personal level”
• “The presentations and the country specific experiences were very helpful”
• “As a scientist, the cross-fertilization with lawyers”
• “The need to drive the process on our own and essentially define our destiny”
• “Learning from what other countries are doing, mistakes encountered and mechanisms to achieve the intended objectives”
• “The diversity of participants and presentations”

(ii). What did you find the least helpful about the workshop?

Most participants made no comments under this section. Few participants were concerned about the workshop being packed heavily with work rather than having free time to themselves and for sightseeing. Some participants thought it was just an ideal workshop. Below are a few of the comments under this section:

• “Sincerely none”
• The workshop was near perfect”
• “Everything is very helpful”
• The days were too long with a lot of information to digest”
• “There was no room to see Tanzania”
• “The programme was too packed”
• “Everything about the workshop was interesting, educative and useful for the preparation of the regulatory regime and administrative systems of the NBF”

(iii). What suggestions do you have for improving future workshops?

Participants made a number of suggestions for improving the workshop. Participants also expressed their satisfaction at the workshop. Specific suggestions included:

• “Stick to time and let people be concise to express themselves (learning process)”
• ”A more relaxed timetable to prevent the participants from getting stress”
• “More regional experience on collaboration”
• “I think the time frame was very crushing, it should be taken into consideration next time.”
• “At least organise a better travel arrangement and sessions to allow some form of social event and rewarding field visits”
• “Prepare presentation material and distribution so that we can insert notes while the presentations are going on”
• “Reduce pressure and time table for presentations which have been over loaded and no rest period. Extend the number of days”

• “The workshop was very well handled by open-minded, transparent and dedicated people. I am highly impressed – It was worthwhile! The opportunity to re-work out workplans and budget was fantastic idea – Keep it up!”

• “Perfect arrangement. Needs little improvement”

Conclusions

The evaluation of the workshop by participants indicated that the workshop has achieved its set objectives: Better understanding of elements of regulatory regimes of NBFs, how the laws, regulations, and guidelines are part of the administrative processes that make an NBF actually work, how a well coordinated NBF makes it possible for countries to meet their obligations under CP and promote interactions among national coordinators that might lead to enhanced regional and sub regional cooperation. In particular, the assessment of the workshop in terms of its usefulness to participants was very high as was the overall organisation of the workshop.

The use of examples from the region generated a lot of discussions and enriched the learning process at the workshop. The quality and arrangement of presentations were very well received by participants.
Annex X: Workshop Evaluation Form

UNEP-GEF Biosafety Sub-Regional Workshop for Anglophone Africa on the Development of a Regulatory Regime and Administrative Systems for National Biosafety Frameworks (NBFs)

Dar Es Salaam, Tanzania, 9-12 March 2004

Instructions:

1. Please take a few minutes to help us to evaluate our workshop by answering the following questions.
2. In each case, indicate your answer by circling the number which best describes your assessment of the workshop.
### Part A: Regulatory and Administrative issues

*On a rating of 1 to 6, assess how useful the workshop has been in:*

<table>
<thead>
<tr>
<th>(i) Improving your understanding of national rights and obligations under the Cartagena Protocol and other international agreements that may impact on your NBF?</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not Useful</td>
<td>Useful</td>
<td>Very Useful</td>
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<tr>
<td>(ii) Improving your understanding of the specific needs of your country in terms of national priorities and policies in setting up the regulatory regime and administrative systems for your NBF?</td>
<td>1</td>
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<tr>
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<tr>
<td>(iii) Improving your understanding of what are the main elements of a regulatory regime for an NBF?</td>
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<td>(iv) Improving your understanding of the different approaches that can be taken in developing a regulatory regime for your NBF?</td>
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<td>(v) Improving your understanding of what general provisions need to be included in the regulatory regime of an NBF?</td>
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<td>(vi) Improving your understanding of what operational provisions need to be included in the regulatory regime of an NBF?</td>
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<tr>
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<tr>
<td>(vii) Improving your understanding of what other elements or consideration need to be included in the regulatory regime of an NBF?</td>
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<tr>
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<td>(viii) Improving your understanding of the linkages between a regulatory regime and administrative systems in an NBF?</td>
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<tr>
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<td>(ix) Improving your understanding of the legal and administrative requirements for AIA in your NBF?</td>
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<tr>
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<tr>
<td>(x) Improving your understanding of the legal and administrative requirements for Article 11 (FFP) in your NBF?</td>
<td>1</td>
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<td>4</td>
<td>5</td>
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<tr>
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</tbody>
</table>
**B: Overall workshop assessment:**

*Please rate the overall workshop on a scale of 1 to 6 by circling the appropriate number:*

| (i). Has the workshop improved your understanding of how to develop a regulatory regime for your NBF? | 1 2 3 4 5 6 |
|---|---|---|---|---|---|
| Not Useful | Useful | Very Useful |
| (ii) Has the workshop improved your understanding of how to set up the necessary administrative systems for your NBF? | 1 2 3 4 5 6 |
| Not Useful | Useful | Very Useful |
| (iii) Has the workshop improved your understanding of how your country could handle individual applications for the importation and/or release of LMOs? | 1 2 3 4 5 6 |
| Not Useful | Useful | Very Useful |
| (iv) Has the workshop helped you to learn more about how other countries in CEECCA are developing or implementing their NBF? | 1 2 3 4 5 6 |
| Not Useful | Useful | Very Useful |
| (v). How useful was the workshop for you as an individual? | 1 2 3 4 5 6 |
| Not Useful | Useful | Very Useful |
| (vi). How well organised was the workshop? | 1 2 3 4 5 6 |
| Not Useful | Useful | Very Useful |
| (vii). How did you find the balance of presentations and discussions? | 1 2 3 4 5 6 |
| Not Useful | Useful | Very Useful |
| (viii). How well did the speakers present their materials? | 1 2 3 4 5 6 |
| Not Useful | Useful | Very Useful |
| (ix). Overall, how would you rate the workshop? | 1 2 3 4 5 6 |
| Not Useful | Useful | Very Useful |
Your personal comments on the Workshop:

(i). What did you consider to be the most helpful part of the workshop?

(ii). What did you find the least helpful about the workshop?

(iii). What suggestions do you have for improving future workshops?

Please hand your completed form to one of the organisers before leaving the room. Thank you