Report of the Sub-Regional Workshops

for Anglophone Africa on:

Risk Assessment and Management

and

Public Awareness and Participation

November 12 -15, 2002, Windhoek, Namibia

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 sub-regional 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);

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

(f) Raising public awareness and improving information flow to the public on the issues involved around 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 has 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 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 sub-regional 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 sub-regional groupings would be addressed: Francophone Africa: Anglophone Africa; Asia; Small Island Developing States (SIDS); Latin America; and Central and Eastern Europe, including Central Asia. The rationale behind the sub-regional workshops lay in the country-driven preference for more regional meetings; the need to promote networking within a region and sub-regions; a desire to help to meet special development needs; the need to increase opportunities for participation; the need to optimize scarce human resources; and the desire to achieve economies of scale.

5. The Anglophone Africa Sub-regional Workshop: Risk Assessment and Management, and Public Awareness and Participation, was held from 12 to 15 November 2002, at the Safari Hotel Conference Centre, Windhoek, Namibia. The Workshop was convened by the UNEP/GEF Biosafety Project Team, in collaboration with the Government of Namibia.

6. A list of participants is attached as Annex I to the present report.

I. OPENING OF THE WORKSHOP

7. The joint plenary session of the Workshop was opened at 8.30 a.m on Tuesday, 12 November 2002. Mr. Christopher Briggs, Global Programme Manager of the UNEP-GEF Biosafety Unit, welcomed participants and invited the Hon P.N. Malima, Minister of Environment and Tourism of the Republic of Namibia, to formally open the proceedings. Mr. Briggs also expressed thanks to the Government of Namibia for hosting the Workshop, and pointed to Namibia's leading role in the implementation of an NBF.

8. In his opening address, Minister Malima welcomed all participants and said that Namibia was honoured to host this important workshop. Noting that Parties to the Convention on Biological Diversity were obliged to control biotechnology applications that might harm their biological diversity or human health, and needed to identify the potential impacts of biotechnology applications, he also underlined the importance of the products of biotechnology to meet the food, shelter and health demands of an expanding global population. It was of the utmost importance that the decisions on how to use such technologies be based not only on a scientific evaluation, but also on economic, social and ethical evaluations. Each country had to decide which route it would follow, and why.

9. After pointing to Namibia's ten-year strategic plan of action for sustainable development through biodiversity conservation 2002 – 2010 and outlining its national policy for the safe use of biotechnology, he stressed the country's efforts to increase the public awareness of the issue of biosafety. He expressed gratitude for the assistance his country had received in its endeavours from UNEP/GEF, and also from other institutions, including ISNAR-Holland, USAID, Innovation Biotechnology, GAIA, and the Third World Network, in providing technical expertise and materials, and noted that Namibia's project for the implementation of its national biosafety framework would be launched during the current week.

10. He expressed the hope that the current workshop would provide an opportunity for stakeholders, scientists and policy makers to gain up-to-date relevant information and knowledge regarding the issues of

risk assessment in relation to the release of LMOs into the environment, public participation in the biosafety debate, and the most important ways to educate the public. He wished all participants an enjoyable stay in Namibia and a successful outcome to their work.

11. The Workshop had the following agenda:

Day 1 Joint Session

- Formal opening
- UNEP-GEF project update
- Introduction to the workshop
- General introduction to public engagement and discussion groups
- General introduction to risk management systems and discussion groups

Day 2 Risk Assessment &Management:

- Introduction to risk assessment and management systems
- Plenary discussion on precautionary approach and Annex III of the Cartagena Protocol
- Introduction to socio-economic issues and other international treaties dealing with risk assessment
- Group exercise on risk management system definition and general discussion on outputs from exercise

Day 2 Public Awareness and Participation

- Introduction to public awareness and participation
- Stakeholder analysis: plenary discussion and group exercise to identify roles and responsibilities
- Introduction to the IDS study and experiences with public participation in biosafety
- Group exercise on analysis of regional experience

Day 3 Risk Assessment &Management

- Setting up a regulatory system for handling application of transgenic organisms (plenary and group exercise on a sample notification document)

Day 3 Public Awareness and Participation

- Plenary discussion on lessons from regional experiences
- Group exercises on results expected from public participation in the development of the NBF and in decision process on LMOs
- Plenary and group discussion on methodologies and action plans for public engagement

Day 4 Joint Session

a) Group and plenary discussions on action plans for a risk management system and public engagement
b) Exercise on drawing each country's Biosafety Framework and discussion
c) Plenary discussion on possible interactions between public engagement and risk management system
d) Conclusion of the workshop.

12. The participants agreed to follow the programme of work as set out in Annex II to the present report, whereby the Workshops would hold joint sessions on 12 and on 15 November 2002. The two Workshops themselves, on Risk Assessment and Risk Management, and on Public awareness and Public Participation,

respectively, were convened on 13 and 14 November 2002. Within each of the Workshops, Focus Groups were set up to consider specific tasks and issues.

UNEP/GEF Biosafety Project Update

13. At the joint session on 12 November 2002, Mr Christopher Briggs, Global Programme Manager, UNEP-GEF Biosafety Unit, described the background of the GEF Initial Strategy on Biosafety, outlining the selection of GEF as the funding mechanism for capacity-building in biosafety; the history of the Biosafety Enabling Activity Project; and the process leading to adoption of the Cartagena Protocol. He pointed to the adoption of the GEF Initial Strategy by the 16th Meeting of the GEF Council, as well as its main objectives and proposed activities. He drew attention to the starting date of the UNEP-GEF Global Project on the Development of NBFs and its overall objectives in June 2001 and pointed to the approval, by the GEF Council in December 2001, of 10 demonstration projects to assist in implementing NBFs (in Bulgaria, Cameroon, China, Cuba, Kenya, Mexico, Namibia, Poland, Uganda, Malaysia), with a further two in process in Colombia and India.

14. After noting the four regional workshops held in 2002, and the 12 sub-regional training workshops planned from November 2002, he outlined the progress made at the national level and gave a regional breakdown of the 108 countries that were on board as at 16 October 2002. He stressed that 20 more countries could still join the project (10 in all of Africa; four in Central and Eastern Europe; three in the Latin America and Caribbean region; and three in the Asia-Pacific region), but they needed to start before December 2002 in order to take full advantage of the human resources available under the project. He presented the eligibility criteria for joining the project, outlined its key elements and described the four-phase approach to be applied in drafting the NBF. In conclusion, he introduced the members of the UNEP-GEF Biosafety Team.

15. In answer to a query, he explained that, for those countries that had taken part in the pilot project and for other countries that had developed draft Biosafety Frameworks, GEF would be considering, with the

advice from the 1st Meeting of the Parties for the Cartagena Protocol how best to provide obtain support for implementation stage projects. Provisions were also being put in place to ensure that those countries that had ratified the Cartagena Protocol would receive assistance to enable them to fulfil their obligations.

Introduction to the Workshop

16. Mr. Charles Gbedemah, Regional Coordinator for Africa, UNEP-GEF Biosafety Unit, explained that, under the Cartagena Protocol, risk assessment and risk management were obligatory. The aim of the current Workshop was to explain to participants the kind of structures they needed put in place, and to point to existing examples of such structures. That approach also applied with regard to public participation. Stressing that the Workshop was intended to be interactive, he underlined the importance of information exchange in helping the decision-making process, as well as the continuing need to establish linkages and networking within the African region.

Expectations and concerns

17. Countries 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 III to the present report.

Ground Rules of the Workshop

18. Participants nominated and agreed to adhere to a set of ground rules for the Workshop, as contained in Annex IV to the present report.

Introduction to Public Awareness and Public Participation

19. Introducing the item, Mr. Francis Lelo (Kenya), facilitator of the Workshop on Public Awareness and Participation, presented the main reasons for the importance of public awareness and participation in the NBF process: to promote decision-making and involve all sectors of society; to bridge the differences between various parts of society concerning the safe use of LMOs; to ensure an inclusive process, involving all stakeholders, to share a common vision and purpose; to promote improved decision-making, based on

information; and to promote transparency and equitability in the decision-making process. The process itself called for commitment; the creation of an appropriate environment; access to participatory mechanisms; capacity-building; information; and, most important, appropriate timing and timeliness. Participation was needed in the analysis of the issues; in decision-making and strategic planning; in implementation; and for monitoring and evaluation. Concerning who should be involved in the public participation process, he pointed to government agencies; the private sector; groups or individuals whose lives and interests could be directly or indirectly affected; and bodies, groups or individuals with particular knowledge that could be called upon.

20. By random selection, participants were invited to form six focus groups to address the following questions:

Question 1: What does public awareness and participation mean?

Question 2: Why do we need it?

Question 3: How do we incorporate public awareness and participation in developing and drafting the NBF?

Question 4: How do we get public awareness and participation formally implemented?

21. The rapporteurs of each of the focus groups convened informally to produce a synthesis report on the outcome of their discussions on the four introductory questions. The designated rapporteur for the focus groups reported the following results to the plenary.

22. Concerning question 1, the focus groups considered that public awareness meant:

- imparting relevant information to stakeholders about specific issues;
- providing balanced information in terms of pros and cons;
- providing universal access to information;
- enlightening the public;
- providing for informed participation;
- translating available information;
- bringing knowledge to people to empower them;
- sharing of knowledge;
- and improving the understanding of issues.

Public participation meant:

- involving stakeholders (at all levels of society) in decision- making and all processes;
- obtaining opinion from other people, passing on the information;
- getting feedback from people;
- giving everyone a chance to express views;
- using a democratic process in reaching a common understanding and coming out with a common solution.

23. Concerning question 2, the focus groups considered that public awareness and participation were needed:

- for consensus-building on issues that affect people directly or indirectly;
- to ensure implementation of the decision;
- to build transparency and accountability;
- to facilitate informed participation;
- to be in a better position to take action;
- to facilitate inclusiveness;
- to provide balanced information in terms of pros and cons;
- to harmonize institutions that provide awareness activities; to remove bias;
- to build a sense of ownership and collective responsibility;
- to build stakeholder confidence;
- to bridge the knowledge gap;
- to ensure sustainability;
- to minimize conflicts;
- to create a platform for action;
- and to attract attention and interest.

24. Concerning question 3, the focus groups considered that public awareness and participation in developing the NBF could be incorporated by:

- creating a forum for all stakeholders;
- targeting decision/policy makers; information packaging, e.g. pictorial demonstration;
- encouraging public debate prior to decision-making;
- giving public notification; involving representatives of key groups in the NCC;
- ensuring feedback mechanisms;
- prior consultation before representation;
- stakeholder identification and role analysis;
- identifying key issues, concerns and interest;
- and priority-setting.

25. Concerning question 4, the focus groups believed that public awareness and participation could be formally implemented by:

- organizing workshops and seminars for policy and decision makers at different levels;
- having a two-way process;
- civic education for the public to put pressure on their leaders;

- creating institutional frameworks including specific institutions responsible for public participation; incorporating public participation into a legal instrument;
- issuing gazette notices;
- holding public hearings;
- defining the limits of confidentiality;
- developing strategies and action plans;
- training of trainers in participatory methods, e.g. capacity-building; decentralized decision-making;
- defining policy objectives;
- and involving all levels of the government.

26. Representatives questioned how to define the limits of confidentiality for the provision of information to the public. It was observed that a statute on access to information might be needed. Another view held that the responsibility for deciding what represented confidential product information lay with the national government, in consultation with the company concerned, since a government needed to have the right to ask for all relevant information. One representative pointed to the need to address the costs of various levels of public participation.

How do you Explain Science to the Public?

27. Ms. Patricia Kameri-Mbote, Facilitator of the Workshop on public awareness and public participation, gave a presentation on communicating science to the public. Noting the context of the discussion and its relevance to decision-making on LMOs, she asked who did one want to inform? Was there provision for feedback? And was it necessary to have acceptance at all costs? Communication methods were influenced by the objectives, and the mode of communication could alienate people. Pointing out that no one group of people could be called the public, she said that individuals or groups had their own perceptions and ways of approaching issues, their interests, experiences, beliefs, peer groups, and social aspects. It was necessary to define the target group and be sensitive to its issues of concern. Clarity of communication was also required.

28. She asked what was science? Was it the preserve of “scientists”, and who were they? The answers to those questions determined the message and the messenger. To communicate the given message to the chosen audience one needed to know that audience, to see the message from their point of view, and to engage them. To communicate effectively, it was also necessary to listen to what was said, and what was

left unsaid. The choice of time was important, as were the choice of communication medium and the locus of the communication. Dialogue required honesty, openness, transparency and inclusiveness, with mutual respect and an absence of condescension. The public had valid points of view which needed to be voiced and understood, taking into account room for variance.

29. In conclusion, she observed that there was no single way to communicate. As a rule, it had to be taken as a two-way process, based on trust. It was critical to invest efforts in engaging different sectors of the public. Effective implementation of the Cartagena Protocol was predicated on effective communication, and public participation had to be based on access to information. In that context, it was necessary to see how information could be packaged and communicated, and to bear in mind the rule that "no size fits all".

30. Mr. Julian Kinderlerer, UNEP consultant, citing examples from the European press and the results of surveys, drew attention to the concern at LMOs resulting from modern biotechnology that was currently prevalent among the peoples of Europe. However, he cautioned against assigning reasons for the public's rejection of the technology for specific applications. Referring to the Public Perception of Agricultural Biotechnologies in Europe (PABE Report), commissioned by the European Union, he cited a number of statements purporting to explain the public's attitude, and challenged participants to ask themselves whether the statements represented myths or truth. Stressing the importance of public engagement in the process, he said that the main task lay in providing people with the information which allowed them to make a choice – and, on that basis, they could chose to accept or reject the technology in question. He offered to make available electronic versions of the reports cited to those participants requiring further data.

31. In answer to a question on how to separate what it would be necessary for the public to know, and what it would be nice for the public to know, it was noted that it was difficult to gauge just how much information to provide. Indeed, it was first necessary to decide who exactly constituted "the public". The question also involved looking at what data were available for those who wanted further information, and making it available in an appropriate way.

32. The observer from the Secretariat of the Convention on Biological Diversity considered that, essentially, two issues were involved: making information accessible; and the targeted communication of information.

Introduction to Risk Assessment and Risk Management

33. Mr. Giovanni Ferraiolo, Regional Coordinator for the Latin America and Caribbean region, UNEP-GEF Biosafety Unit, introduced the topic, noting that it was not simple, nor was it a subject that would be familiar to everybody, particularly in light of the specialized vocabulary used. However, he underlined the fact that risk assessment and public participation had to go hand-in-hand. For that reason, the terminology also needed to be understood. He drew attention to the following definitions, as set out in the Cartagena Protocol: "modern biotechnology", "living organism", "living modified organism" (Article 3); objective of the Protocol (Article 1); risk assessment (Article 15); risk management (Article 16); and relevant provisions on general principles and on use of risk assessments (Cartagena Protocol, Annex III), and invited participants to point out those elements with which they were unfamiliar, or which seemed unclear.

34. He considered that a possible definition of "risk" might be the likelihood that an organism introduced into the environment may cause harm to that environment and could be seen as comprising two factors: (a) the consequence of a particular event; (b) the likelihood of the event occurring. Risk arises from exposure and hazard. There was no risk, regardless of how hazardous a particular organism might be, if there was no exposure. Hazard might be regarded as the potential to cause harmful effects. A number of representatives highlighted specific terms from among the definitions addressed, and there was some discussion on the meaning of the term "biological entity.

35. By random selection, participants were invited to form six focus groups to address the following questions: [I think random selection is a super term – is it Darwinian?]

Question 1: What does risk assessment and management mean?

Question 2: Why do we need it?

Question 3: How do we move to get risk assessment and management procedures in place?

Question 4: How do we get risk assessment and management formally implemented?

36. The rapporteurs of each of the focus groups convened informally to produce a synthesis report on the outcome of their discussions on the four introductory questions. The designated rapporteur for the focus groups reported the following results to the plenary.

37. Concerning question 1, the focus groups considered that risk assessment meant the identification, quantification and characterization of the level of exposure to potential hazards and harm to human health and the environment. Risk management meant the use of a sustainable mechanism or process to mitigate, reduce, or control risks.

38. Concerning question 2, the focus groups believed risk assessment and management were needed to assist in making informed decisions on releasing LMOs with a view to ensuring environmental safety and human health.

39. Concerning question 3, the focus groups considered that risk assessment and risk management could be put in place by:

- taking into consideration socio-economic issues;
- setting up an institutional or administrative structure;
- capacity-building;
- information and networking;
- a legal framework;
- reviewing existing procedures;
- putting scientific mechanisms in place to assist monitoring and evaluation;
- and public awareness.

40. Concerning question 4, the focus groups considered that risk assessment and management could be formally implemented by:

- formulating strategies, policies and legislation;
- establishing or appointing a competent authority;
- setting up a monitoring system to ensure the implementation of policies;

- defining clearly the mandate of a task force team, which should be assigned to a specific ministry, with shared responsibility;
- stakeholder participation;
- regional interaction and coordination;
- incorporating risk assessment and risk management into existing national plans and strategies;
- and putting in place sustainable financial mechanisms.

The focus groups noted that risk assessment and management were a science-based issue, and were only one of the tools that could be used for decision-making. Other issues that could be involved in the process included socio-economic and ethical issues.

41. Participants pointed to the need for regional and sub-regional cooperation and information exchange on the subject of risk assessment and management, in order to harmonize the process, complement the efforts of others and make best use of scarce resources. Attention was drawn to the need to differentiate between the tools available to assist in informed decision-making, particularly between those that were purely science-based, and the socio-economic factors.

II. Proceedings of the Workshop on Risk Assessment and Risk Management

42. The Workshop on Risk Assessment and Risk Management held four discussions, on 13 and 14 November 2002.

43. At the first plenary session of the Workshop, Mr. Giovanni Ferraiolo, Regional Coordinator for the Latin America and Caribbean region, introduced the subject, stressing that participants would not be asked to do any actual risk assessment but, rather, would examine what they needed to put in place and what action they needed to carry out in order for them to be able to deal with an eventual notification of the transfer of an LMO. He drew attention to the background paper "Regulation of biotechnology: needs and burdens for developing countries", prepared for the UNEP-GEF Biosafety Unit by Mr. Kinderlerer.

Risk Assessment

44. In his opening presentation to the Workshop, Mr. Kinderlerer underlined the fact that, worldwide, very few individuals had actually carried out a risk assessment of an LMO and there was still a lack of clarity about what such an assessment actually entailed. It was, however, clear that structures did need to be put in place to address the questions posed in conducting a risk assessment. Relatively little scientific information existed even about the movement of genes between many common wind-pollinated crops and their wild and cultivated relatives, or about the interaction between micro-organisms and the soil. One of the reasons for the concern at the release of LMOs was that it might well be impossible to recall transgenic organisms or material once they had been introduced into the environment.

45. The definition of "risk" might be the likelihood that an organism introduced into the environment might cause harm to that environment, and could be seen as comprising two factors: (a) the consequence of a particular event; (b) the likelihood of the event occurring. A risk assessment was the first step in any attempt to minimize or prevent possible adverse effects on the environment. The question was: what constituted an acceptable or manageable risk? It was to be noted that an LMO release did not imply that there was no risk involved but, by rejecting an LMO out of hand, a country was also denying itself the potential benefits of using the product. Risk assessment involved a number of steps, including identification of the potential adverse effects and the assessment of the likelihood that the potential adverse effects would occur. Risk evaluation, as referred to the Cartagena Protocol, looked at the consequences that might arise if the adverse effects were to be realized.

46. In answer to a query about why there was a need for concern at the possible introduction of new genetic material into an organism, since gene flows had been going on naturally for aeons, it was observed that the level of concern often was based on the nature of the genetic material that could potentially be transferred. Opinions varied and, while some involved parties might not consider genetic movement to be a cause of concern, others might be greatly worried. One participant considered that the lack of knowledge called for an increased level of vigilance and considered the monitoring of LMOs and their effects to be a basic requirement.

47. Mr. Kinderlerer pointed to the way in which the Cartagena Protocol addressed the issue of risk assessment, with reference to its Article 15 and its Annex III. He highlighted the crucial choice of terminology contained therein, and the manner in which it could be interpreted. Pointing to the wide range of issues that needed to be addressed within risk assessment, he listed a long series of scientific disciplines, which could be of relevance in such an undertaking, but noted that no single specialist area alone could provide a sufficient level of knowledge or expertise.

48. With reference to Article 15, paragraph 2, he explained that, if so decided, Parties were free to ask the exporter to carry out the risk assessment. However, while the activity itself could be delegated, the ultimate responsibility for carrying it out lay with the importing[1] Party itself. Moreover, in the case where an LMO had been imported by one Party for cultivation and subsequent export of the harvest, the importing Party could be required to carry out a risk evaluation, even though the product had been modified and exploited elsewhere first**.**

49. Turning to potential adverse effects, Mr. Kinderlerer illustrated the difference between "direct effects" (the primary effects on human health or the environment which were a result of the LMO itself and which did not occur through a causal chain of events) and "indirect effects" (which occurred through a causal chain of events, through mechanisms such as interactions with other organisms, transfer of genetic material, or changes in use or management, and which were likely to be delayed). He observed that it was questionable whether all indirect effects of introduction of an LMO could be predicted, although an attempt should be made to be as comprehensive as possible. With reference to the words of a European Directive concerning "delayed effects", he pointed to problems which might not be observable during the period of release, but which could become apparent as a direct or indirect effect either at a later stage, or after the termination of the release. The major issue was how to find those effects, or even where to start looking for them, and there was even disagreement between some scientists and environmentalists on the question.

[1] Corrigendum (May 2005): "exporting" in original report transcript changed to "importing" – rapporteur error

50. It was observed that, because of the divergence of opinion on the question of effects of LMOs, particularly with reference to the issue of liability and redress, there were problems in obtaining insurance cover for LMO-related activities. It was recalled that governments would need to address the issue of liability and redress within four years of the Protocol's entry into force.

51. In answer to a query, it was explained that risk assessment involved a stepwise approach. The first questions could be: have we got all the information we need? What information is not available now? What will not be available at all? Then it was necessary to examine the consequences of an LMO release, and to set up a checklist to enable the examining committee to identify which questions would occur. It might be necessary to re-examine the approaches used for an assessment and, for that reason, it was advisable, if at all possible, to use more than one approach in order to be able to catch all the factors.

52. On the question of which body would actually do the risk assessment, Mr. Kinderlerer noted that, in some countries, the government prepared the assessment, on the basis of information provided by the applicant or notifier. In others, the authority responsible for the decision carried out an audit of the assessment that had been prepared by the applicant or notifier. He observed that in many countries the government of the importing country might not have the capacity to conduct the risk assessment or audit, and could call upon assistance, for example from the roster of experts, to review the information and risk assessment provided by the applicant or notifier, as set out in Article 10, paragraph 7 of the Protocol. Concerning the costs of the assessment, Article 15, paragraph 3 of the Protocol provided that the cost would be borne by the notifier (Exporting Party) if the Party of import so required.

Risk Management

53. Mr. Kinderlerer explained that risk management addressed how to manage, in an appropriate and effective manner, any risk that might have been identified during the process of risk assessment. He stressed the importance of maintaining risk management as a totally separate and distinct procedure from risk

assessment. Risk assessment should be seen as an objective scientific process, whereas other factors, such as ethical, political and socio-economic considerations could enter into play in the risk management and decision-making process.

54. He drew attention to Article 16, paragraphs 1 to 5, of the Cartagena Protocol, which set out the provisions pertaining to risk management. He said that the reference to Article 8 (g) of the Convention on Biological Diversity contained in Article 16, paragraph 1, related to the establishment of an internal, national system for risk management. Under the Cartagena Protocol, however, the system needed to be geared towards managing the external risks as well. Concerning Article 16, paragraph 3, calling upon Parties to take appropriate measures to prevent unintentional transboundary movements of LMOs, he indicated that Parties releasing LMOs on their own territory could be obliged to inform neighbouring countries of their intentions. Paragraph 4 of Article 16 referred to an appropriate period of observation that was commensurate with the life-cycle or generation time of an LMO, but that gave rise to difficulties in the case of some organisms, for example a transgenic oak tree.

55. With an objective and scientific risk assessment in place, the management procedure required a mechanism for people to review the assessment. It was necessary to see how that could be done, for example by publishing the assessment, and also to look at the timing to allow sufficient time for comment and review of the assessment.

56. Article 26 of the Protocol allowed for socio-economic considerations to be taken account in the decision-making process. Thus, it might be possible to set up a parallel review of the ethical issues entailed in the assessment. However, the incorporation of socio-economic issues was not an open book. They could only be taken into account where they could be justified under the Cartagena Protocol. The socio-economic issues are applicable only in relation to the conservation and sustainable use of biological diversity, where the LMO would impact on local and indigenous communities.

57. In answer to a query about whether a transboundary movement could take place without a formal agreement, as set out in Article 24 of the Protocol, Mr. Kinderlerer said that, while that would be possible, a Party was obliged to ensure that any transfer was consistent with the Protocol. There were many examples of special agreements between countries, e.g. US-Canada agreement .

58. With regard to the relationship between the Cartagena Protocol and other international agreements, attention was drawn to the Codex Alimentarius (covering food safety), Organisation International de l'Epizootie (covering animal issues) and the International Plant Protection Convention (IPPC), all of which WTO recognized as being treaties that set standards that could be used in a case of dispute. Although risk assessment could be identified as a part of those treaties, the assessments carried out were of a different nature, with different objectives that did not necessarily relate to environmental issues.

59. The relevant WTO agreements, including the Agreement on Sanitary and Phytosanitary Measures (SPS), the Agreement on Technical Barriers to Trade (TBT) and the Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS), were backed by a compulsory and binding dispute system that could authorize bilateral trade sanctions. The Cartagena Protocol contained a provision to the effect that it was neither above, nor subordinate to any other treaty. However, the risk assessment procedures under the Cartagena Protocol represented trade-related measures, since they could delay the approval of the import of a covered product and could also provide the basis for a decision to ban or restrict imports under Article 10. Since the risk assessment procedures under the WTO Agreements were not identical with those of the Protocol, disputes might arise that called for a Party to show that the provisions of both regimes were being applied in a compatible way.

60. The GATT, the SPS Agreement and the TBT Agreement required a Party of import to demonstrate that any import bans had a rational basis; were in support of legitimate policy objectives; were no more trade-restrictive than necessary to achieve their objectives; and were not being applied in an arbitrary or discriminatory manner. Moreover, Article 5.7 of the SPS Agreement provided that, in cases where relevant

scientific evidence was insufficient, a member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information and should seek the necessary additional information and review the measures within a reasonable period of time. However, in the case of the LMOs covered by the Cartagena Protocol, any existing uncertainty might not be resolved, since the additional information might not be available in the foreseeable future.

61. At the 2nd plenary session, participants in the Workshop undertook an exercise in setting up a regulatory system for dealing with applications for handling transgenic organisms. It was explained that there were many decision points in a regulatory system to address risk assessment, risk management and risk communication. The questions set for the participants are contained in Annex V to the present report.

62. The first two questions of the exercise were addressed in plenary, where participants were given a set time to provide their own answers. It was observed that there were no "correct" answers to the questions, and participants were requested to supplement and explain any omissions they felt they had been made. Subsequently, Mr. Kinderlerer went through the questions with participants, looking at the answers required and the reasoning behind them.

63. For questions 3 and 4, participants were divided into three groups to hold discussions and decide on their answers. Since it was expected that, at some future time, the countries would be interacting mainly with their immediate neighbours in the conduct of activities relating to the handling of LMOs, for the purpose of the exercise participants were placed in the following three groups: East Africa (Ethiopia, Kenya, Rwanda, Sudan, Uganda, United Republic of Tanzania); Southern Africa (Botswana, Lesotho, Malawi, Mauritius, Mozambique, Namibia, Swaziland, Zimbabwe); and West Africa (Egypt, Gambia, Ghana, Liberia, Nigeria, Sierra Leone).

64. After a period of consultation in the groups, their reports were given to Mr. Kinderlerer who read out a synthesis of their findings to plenary and they were also reproduced for distribution to all participants.

Concerning the questions set, the groups identified the points at which decisions needed to be made, the list of activities required, and the timing to be applied to the activities. Where there were no clear-cut solutions, groups reported on the reasoning behind their decisions. In the course of the plenary discussion of the answers to the questions, the issues raised included:

- when to inform the public of receipt of a notification;
- when to inform neighbouring countries of receipt of a notification;
- when to inform the Biosafety Clearing House and notifier of a decision on the notification;
- the existing practices for charging the notifiers for the assessment;
- the cost elements of the assessment;
- the issue of confidentiality;
- and the existing practices for conducting assessments and reviewing them, or not.

65. At the 3rd plenary session of the Workshop, participants resumed the exercise on risk management and risk assessment, taking up question 5, on Assessors (see Annex V). In introducing the question, Mr. Kinderlerer asked participants to look at the process they could follow, once a risk assessment was in hand, to justify the decision they would make on whether to accept or reject a notification. Examples of existing practices varied from the establishment of a committee of experts, which would draw its strengths from the interaction of its members, to a system of designation of separate individual assessors, who are forbidden to mutually interact. Each country had to choose not only the methodology to follow, but also the procedures for identifying and recruiting the persons to act as experts. If experts are to be used from outside the government, issues of confidentiality and conflict of interest might require that such experts sign a formal declaration of secrecy and/or impartiality. To illustrate the complex nature of the ethical issues involved, it was observed that those most qualified to serve as assessors were often engaged in research activities, which might be funded by the same corporation that was submitting the application. All such factors needed to be taken into account in the selection of outside expertise. Moreover, in the analysis of a risk assessment, practical experience in the field often counted as much as technical expertise.

66. Regarding the question of a procedure to enable the notifier to appeal an unfavourable decision, it was noted that, in some countries, the decision on the notification was the responsibility of a competent authority that was not the minister. An appeal against the decision would be made to the minister, who might empower a competent panel to consider the appeal. In other cases, there was provision for a judicial review of the

decision procedure by the law courts. It was up to the individual country to set up whatever appeal mechanism it chose, if it chose a mechanism at all, in line with its own administrative structures.

67. On the subject of how to deal with objections to a decision that were valid in one part of the country, but not in another, it was noted that many examples existed where LMO releases had been authorized only in particular areas of a single country for scientific reasons. The Cartagena Protocol also gave Parties the right to refuse to authorize LMO releases in specific areas on socio-economic grounds.

68. For the consideration of question 6 (see Annex V), participants held consultations in the three designated focus groups. Subsequently, their reports were given to Mr. Kinderlerer who read out the findings to plenary. Copies of the reports of the focus groups were also distributed to all participants. In the course of the discussion on the answers to the question, attention was drawn in particular to the need to provide capacity building for risk assessment in a number of developing countries, in line with the provisions of Article 22 of the Cartagena Protocol.

69. Since many of the aspects contained therein had already been touched upon in dealing with the previous questions, the final question of the exercise (see Annex V) was addressed by participants in plenary. Mr. Kinderlerer explained that, once all the various reports and information for the decision had been gathered in, it was necessary to look at the question of what effects the decision to be taken would actually have. To illustrate the kind of process that could occur, he noted that a decision to permit an LMO might lead to a change in agricultural working practice, which could in turn lead to rural unemployment, which might then lead to increased urban migration, which could entail a whole further chain of issues. The scientific report on the introduction of the LMO thus had to be weighed against the impacts of the decision. Because of the impacts, there could be a multiplicity of inputs into the decision. Indeed, it was observed that the socio-economic inputs were often more contentious and divergent than the purely science-based issues. That implied that a multidisciplinary approach was needed, using multiple panels, each with a specific mandate to provide targeted advice to the competent authority.

70. It was also crucial to determine the level of input from the public at the different stages of the decision-making process. That required decisions on what to place in the public domain, and when. The decision document itself, for example, was a kind of legal permit. Examples were cited from existing practice to show how the public was enabled to determine the details of the decision taken by the competent authority.

71. Concerning who would make the final decision, it was noted that the issue was entirely at the discretion of the Party itself and its administrative policy. For example, in some countries the Ministry of the Environment might play the major role, while in others the Ministry of Environment would not be able to play that role, and a combination of Ministries might be responsible. One important element for consideration was the idea that general policy guidelines needed to be decided before applications for LMO releases were considered. Where this was the case, the consideration of a notification would become an administrative, and not a political, procedure. If a policy issue arose during the consideration of a specific notification, it could be separately referred to a higher level, but the broad policy for the consideration of individual applications would be in place. As was stressed at many of the points in the discussion within the provisions of the Cartagena Protocol, in the ultimate analysis, the Party itself was free to chose the procedures, and fully responsible for it.

72. At the 4th plenary session of the Workshop, on the basis of the knowledge gained during the discussions and exercises, participants prepared a comprehensive checklist, setting out the actions to be taken and the elements to be considered within the establishment of a regulatory system for handling applications for the release of LMOs. The checklist also identified the possible entry points for public participation in the process.[GF (see Annex VI),]

III. Proceedings of the Workshop on Public Awareness and Public Participation

74. Mr. Christopher Briggs, Global Programme Manager, UNEP-GEF Biosafety Unit, introduced the Facilitator; Mr. Francis Lelo who explained that session was to facilitate an in-depth analysis of the public awareness and public participation component in relation to Article 23 of the Cartagena Protocol. He

reviewed the importance of critical issues and best practices that facilitate public awareness and public participation such as:

a. The need to explain the rationale to stakeholders through open discussions and explanations of the benefits to the country and to the communities;
b. The need to take into consideration the viewpoints of stakeholder so as to capture their interest;
c. The clear identification of objectives for participation so that the public is fully aware of the ultimate goals to be achieved;
d. The definition of roles and responsibilities of each stakeholder group;
e. The establish of clear timeframe and deadline for the achievement of the set objectives, and
f. The standardization or formalization methods of participation that are clearly understood by all stakeholders.

75. Mr. Lelo further explained that each country could apply specific participatory methods but recommended the following:

a. Convening public meetings and information days in accordance with the local practice in each country or community, such as Farmers' Day, etc. Other public gatherings for meetings with local leaders could also be used to disseminate information.
b. Conducting follow-up general meetings with smaller groups of opinion leaders to further explain and exchange ideas. The opinion leaders are often more learned and have a greater influence on the larger communities.
c. Advertising widely to disseminate information on forthcoming information days and public meetings. This could be achieved through schools, churches, and the media.
d. Venues of public meetings should be gender-sensitive, accessible and comfortable to all.

76. The workshop participants were then divided into three sub-regional groups: East Africa (Ethiopia, Kenya, Rwanda, Sudan, Uganda, United Republic of Tanzania); Southern Africa (Botswana, Lesotho,

Malawi, Mauritius, Mozambique, Namibia, Swaziland, Zimbabwe); and West Africa (Egypt, Gambia, Ghana, Liberia, Nigeria, Sierra Leone) to examine the following questions:

Question 1: What are the minimum requirements for the implementation of Article 23?

Question 2: What do you consider to be an enabling environment for public awareness and participation in biosafety?

77. As a result of these discussions, the matrix below was produced using the results from the different focus groups. In the Plenary following this focus group exercise, selected rapporteurs for each sub-regional group presented their findings. In answering Question 1: "What are the minimum requirements for the implementation of Article 23?", there was a general consensus on the need to identify stakeholders in order to promote and facilitate public awareness and public participation, to establish an appropriate legal framework and secure sustainable funding for the implementation of Article 23.

78. On Question 2: "What do you consider to be an enabling environment for public awareness and participation in biosafety?" Participants agreed on:

- the need for good governance, political will and political stability,
- the elaboration of appropriate programmes and policy guidelines on participatory approaches, institutional arrangements, capacity building, networking and regional/sub-regional and global cooperation as the conditions that create an enabling environment.

MATRIX OF SUB-GROUP ACTIVITY
PUBLIC AWARENESS AND PARTICIPATION

	Eastern Africa	Western Africa	Southern Africa
1. What are the minimum requirements for the implementation of Art. 23	• Development of appropriate strategies for public awareness and participation • Promotion and facilitation of public awareness e.g. through educational institutions • Institutionalization and nomination of focal points • Identification of stakeholders • Establishment of a Biosafety Clearing House and promotion of information access and exchange through media and other means as a means of increase public awareness • Legal framework • Sustainable funding for programme together with firm government commitment to finance projects • Integration of public participation into national legislative frameworks • Public empowerment in decision-making • District-level in decision-making	• Establishment of a national focal point • Identification of all stakeholders • Appropriate medium of information exchange • Establishment of an inventory of LMOs • Trained personnel • Establishment of Biosafety Clearing House • Clear definition of roles of relevant institutions • Identification	• Establishment of BCH and facilitation of access to it. • Promotion and facilitation of public awareness, education and participation • Establishment and facilitation of consultations in decision-making process • Cooperation with other states and harmonization of regional regulations • Establishment of legislation and access to such legislation • Respect for confidentiality of information • Identification of lead agencies. • Information dissemination
2. What would you consider to be an enabling environment for public awareness and participation in biosafety	• Legal framework • Decentralized decision-making • Political will • Public awareness (among specialists and non-specialists) at all levels of society including high-level of government. • Availability of biotechnology capacity and products in the country	• Political will • Transparency/accountability • Legal framework • Programmes and procedures • Policy guidelines on (a) strategies/participatory approaches, (b) institutional arrangements, (c) capacity building (d) networking and regional/sub-regional and global cooperation • Good governance/political stability	• Need legislation • Need for lead agency and administrative structure • Need for effective/reliable communication channels • Systematic methods which are nationally accepted • Human capacity and other resources • Development of appropriate information packages for different target groups • Establishment of mechanisms/policies to protect confidential information • Use of appropriate technologies • Ownership – motivation to participate and sustain interest • Motivation of the public to participate and sustaining their interest • Development of mechanisms to enhance sense of decisions/processes.

79. In introducing the next exercise in plenary, Mr. Christopher Briggs asked participants, in plenary, to brainstorm on who were the stakeholders in Biosafety issues, so as to produce a list of all stakeholders potentially involved in the development of the National Biosafety Framework, and subsequently list them in order of priority. The results of this discussion led to the matrix below:

PRIORITIZED LIST OF STAKEHOLDERS

A. Policymakers/Ministries	
B. Farmers	
C. Consumers	
D. Scientists/ Research Institutions	
E. Ministry of Agric	
F Biotech companies	
G. Health Institutions, Nutritional experts, Traditional Healers	
H. Law enforcement/ customs	
I. Media	
J. NGOs and CBOs	
K. Natural resources/ environment groups	
LIST OF OTHER STAKEHOLDERS	
1. Vendors	
2. Educational Institutions	
3. Consumers	
4. Food processors	
5. Politicians	
6. Pharmaceutical companies	
7. District Councils	
8. CBOs	
9. Judiciary	
10. Natural Resource Institutions	
11. Bureau of standards	
12. Trade Groups	
13. Women's Groups	
14. NGOs	
15. International Organizations	
16. Extension Workers	
17. Diplomatic Groups	
18. Religious Groups	
19. Youth organizations	
20. Ministry of Commerce	

21.	IGOs
22.	Financial institutions
23.	Traditional Leaders
24.	Information Centers
25.	Tourism Interests
26.	Educational Interests

80. Participants then reconvened in their sub-regional focus groups and started to complete a matrix with the main stakeholders and their envisaged roles in various stages in the development the NBF. It however emerged from this focus group exercise that there were participants who were not fully conversant with the stages of the development of the NBF. Mr. Briggs thus made a brief review of the stages and stakeholders at each level of the project and in response to a question from one participant, clarified that the National Coordinating Committee should be composed of representatives of priority groups of stakeholders. He further explained that the purpose of the exercise was to determine the level of involvement of these priority groups/stakeholders at each level. He noted the importance of prioritizing stakeholders and ensuring their representation in the National Coordinating Committee (NCC).

Presentation of the Study on Public Participation and the Cartagena Protocol on Biosafety

81. Chris Briggs introduced the study and indicated that its aim was to present a summary of study of the methods adopted by the countries in the case-study to promote public awareness and participation in the design and implementation of their national biosafety frameworks (NBFs). He reviewed the different levels or degrees of participation such as information sharing, consultations, joint decision-making and citizen-led initiatives. He also indicated that the study found that different actors may be responsible for the creation of and promotion of participation. He indicated that this could be either top-down or bottom-up depending on the local systems of governance. Key considerations for participation that had been outlined in the study included issues such as expectations and responsiveness of the convening institution(s) since lack of clarity could lead to rejection of the expected outcomes. Due notice and timings of meetings should be communicated in advance. Every means should be used to gather and disseminate information to all stakeholders who should be representative of all priority groups.

82. Among the key challenges of participation in biosafety regulation found by the study were issues such as how to simplify highly scientific information to facilitate and increase the comprehension of the concepts by the general public. The existence of polarized views due to the safety and ethical implications of LMOs and the need to maintain commercial confidentiality and adhere to international trade laws.

The Uganda Biosafety Support Project

83. Mr. Julian Smith of CAB International presented participants with an overview of the work undertaken by the Uganda Biosafety Support Project to demonstrate the involvement of local farmers. He also explained how experiences from the UK and South America were demonstrated to these farmers.

SWOT analysis on national experiences of Public Awareness & Participation

84. Mr. Lelo, introduced the SWOT analysis session and implored the participants to critically examine the existing conditions in their sub-regions in order to come out with a matrix that could help participants in the development of their NBFs. Participants deliberated in their focus groups and came out with the matrix below.

MATRIX OF SUB-GROUP ACTIVITY ON SWOT ANALYSIS
PUBLIC AWARENESS AND PARTICIPATION

	Eastern Africa	Western Africa	Soutern Africa
Strengths	• Government support • Existing regional initiatives on public awareness and participation • Existing structures/framework • Interest/goodwill of stakeholders	• Government support • Strong public enthusiasm to participate (curiosity) • Available human resource • Decentralized system of governance • Existence of nature clubs • Active media (FM radios with wide outreach) • Enabling policies and legislation	• High literacy level • Political will (many countries in the region have ratified the Convention) • Common language facilitating information dissemination • Existing administrative structures • Information sharing structures • Existing human resources (biotech specialists, etc) • Relevant legislation and policies
Weaknesses	• Inadequate biotech specialists • Fear of new technology, acceptance and adaptability • Inadequate information packages to grass-root community • High level of illiteracy • Ignorance at all levels of society including government and civic leaders • Low level of biotech capacity • Lack of adequate funding	• High level of illiteracy • Poor road network • Poverty • Lack of transparency, cooperation and trust (among stakeholders) • Inadequate communication facilities	• Lack of programmes and capacity for modern biotechnology • Lack of policies on biotechnology and biosafety • Ignorance of biotechnology as an impediment to the dissemination of information • Lack of sustainable funding • Illiteracy
Opportunities	• Potential human resource base • Existing regional initiatives • Existing demand for high technology • Available ICT for information dissemination	• Donor interest and availability of funding (GEF, GTZ, etc) • Regional cooperation • NGOs/IGOs	• Existing Public Awareness and Participation programmes which can be used to disseminate information such as HIV/AIDs, … • Decentralized system of governance • Availability of UNEP-GEF funding • Existing sub-regional programmes (SADC) • Innovative financial instruments which could be used to generate additional funds for programmes such as taxes, levies, and other fees
Threats	• Lack of sustainable funding • Distortion of and/or dissemination of biased information • Political instability • Overzealous Anti- or Pro-GMO activities	• Corruption of leaders who divert funding away from the project • Political instability • Donor fatigue • Traditional beliefs and customs • Distortion of message • Influence of interest groups	• Lack of networking among scientists and with other political and civic leaders • Lack of communication between scientists and other interest groups such as sociologist, politicians and civil society

Public Participation in the development of NBFs: Application of lessons learned

85. In this session it was emphasised that the lessons learned to date, could be used and be applied in the following areas of NBF development

- In designing Terms of Reference
- As a reference point throughout the planning process.
- To give guidance in establishment of the National Coordinating Committee (NCC) and define various steps in the development of the NBF
- Holding regular meetings with stakeholders.
- Creating more awareness about the NBF process and broaden participation at all levels.
- NCC/NPC may use participants as resource persons in the planning process.

86. During the ensuing discussions, one participant noted the difficulty encountered sometimes in communicating with National Executing Agencies (NEAs), National Project Coordinators (NPC) and the National Coordinating Committees (NCC) and requested more transparency and a participatory approach in the planning process. Further discussions on this submissions showed that some of the participants were already part of the NEA/NCC or NPCs and thus were conversant with the terminology, roles and responsibilities while others were not. Countries that had not yet established these structures were called upon to urgently identify and set up their own administrative structures to facilitate the participatory process. The issue of creating public awareness at all levels was also raised.

87. In response to a suggestion on the need to raise funds for the development of the NBF project, a participant noted that start-up funds had already been or were being provided by UNEP-GEF together with counterpart contributions. It was also agreed that additional funds were needed to take on the results and progress on the project once the funding from UNEP-GEF was used.

88. In summary, the principal facilitator, Mr. Francis Lelo recalled important factors in the establishment of the NBF that have to be taken into consideration such as:

- The need to devise mechanisms for comprehensive involvement of the government
- Identification of all stakeholders
- Implementation of capacity building and public awareness programmes in order to encourage active participation
- Transparent monitoring and evaluations mechanisms
- Establishment of clear time frames

- Matching stakeholder expectations throughout the entire process.

Formulation of Regional Action Plans

89. In the next focus group discussions, the participants were asked to formulate Sub-Regional Action Plans reflecting all the lessons learnt during the workshop. The final products were aimed at being used as blue-prints in elaborating the respective national action plans.

The following questions were considered during these focus group discussions:

1. **What are the specific results you would expect from public participation in the development of the NBF?**
2. **What are the specific results you would expect from public participation in the decision-making on LMOs?**

Participants were provided with a matrix and requested to identify 6 expected results in their order of priority.

90. Before splitting up into the focus groups, one participant sought to know whether it was worthwhile to conduct this exercise without input from their colleagues from the workshop on "Risk Assessment and Management". The facilitator clarified that, after completion of this specific session, all participants should be able to see the role and relevance of public awareness and public participation within the overall process of the development of the NBFs and during the final plenary session understand the inputs of the public during the process of each notification and response.

91. Each sub-group then prepared a matrix on the role and relevance of public awareness and public participation within the overall process of the development of the NBFs. These are presented in Annex VII and demonstrate the wide range of responses in different sub-regions to this issue.

92. In the ensuing plenary session after this exercise, the rapporteur of the Western Africa focus group, after presenting the group's findings noted that all the expected results were with particular regard to public

participation and not so much focussed on Public education. He further indicated that the public awareness could be enhanced through the risk assessment and decision making procedures.

93. During the presentation of the Southern Africa focus group, the facilitator reminded participants to consider how to carefully use indicators in assessing the proposed expected results. The effectiveness of transparency by the involvement of greater involvement and participation of the public in the decision-making process was also emphasised.

94. Following the presentation by the Eastern Africa focus group, an explanation was given that during the development of NBFs, the supporting legal instruments could be a revision of existing laws and/or creation of new ones.

95. In response to further questions on the role of the NEA, Mr. Briggs outlined the role as the main contact point with UNEP. He further explained the roles of the NCC and told participants to refer to the Terms of Reference as contained in the Annex to the NBF Project Document. He invited any participant who was not familiar with this to request for a copy of the document from the Biosafety team.

96. Various general questions were then raised on the involvement of public participation in the development and structures of the NBFs. Among them were the following:

97. On the type of activity for public participation and information dissemination during the NBF development, it was made clear that consultation and information dissemination to the public must be a continuous process that should go beyond the project life, since it takes a long time for the public to change its mentality. It was also emphasised that there was a need to regularly consult and update the public on new and emerging issues.

98. Mr. Briggs drew the attention of the participants to the main elements of the NBFs and also the various stages indicated in their development. In response to a query from one participant who wished to know the implications of the non-completion of the project within the 18-month period, Mr. Briggs explained that such countries could face problems since the project funds were limited to the project life and such delays could engender difficulties in terms of technical support for countries after the project had ended.

99. On the assistance that countries, which have already developed a NBF, could receive, Mr. Briggs explained that they could conduct NBF revision, evaluation or other specific activities since implementation-type activities could not be funded within the framework of the current project. Such advanced stage countries could review and fine-tune their NBFs. It could be said that most of the draft NBFs would still not completely meet the obligations of the Cartagena Protocol.

100. Mr. Kinderlerer responding to a query on how drama could be used to disseminate information on biotechnology recounted an actual experience in the UK in 1999 where a play called "As sweet as you are" was commissioned to look at ethical and other issues related to Biotechnology and Biosafety, and was staged in various towns. He explained how scientists came on stage at the end of the play and interacted with the public to respond to questions on biotechnology.

101. Mr. Charles Gbedemah then gave a brief presentation on the Advanced Informed Agreement (AIA) procedure and explained how the notifier should provide full information on the LMO and its characteristics to the country of import as part of the application dossier. He explained how the country of import had 90 days in which to examine the dossier to ensure its completeness and send a written acknowledgement to the notifier. Mr. Gbedemah further said that the country of import could employ tools such as risk assessment, and could draw on socio-economic, ethical and other parameters in arriving at informed decisions in accordance with its (the country of import) establishment legislation, and its obligations under other international agreements. He further explained that a decision on the dossier had to be made within a

maximum of 270 days. He also said that all Parties to the Protocol are obliged to give a written response to the notifier within the established timeframe and failure to do so would be in breach of the Protocol, even though lack of response does not necessarily imply consent or disapproval. The Protocol did not envisage penalties but presumed that all countries would meet the established deadlines.

IV. OTHER MATTERS

Presentation on the Environment Initiative of the New Partnership for Africa's Development (NEPAD)

102. On the closure of the Workshop, on 14 November 2002, Mr. Charles Gbedemah, Regional Coordinator for Africa, UNEP-GEF Biosafety Unit, speaking on behalf of UNEP, gave a presentation on the UNEP/GEF Medium-Sized Project (MSP) on development and implementation of the Environment Initiative of the New Partnership for Africa's Development (NEPAD), with particular reference to biosafety. After describing the background to NEPAD, he explained that the Environment Initiative was a coherent action plan and strategy to address the region's environmental challenges, while combating poverty and promoting socio-economic development. He outlined the milestones in implementation of the MSP; its structure, overall objectives and specific aims; the programmatic areas and activities; cross-cutting issues; and the implementation plan.

103. Concerning biosafety within the Action Plan, he described the strategy to develop and implement NBFs, to promote information sharing and collaboration, especially at the regional and sub-regional levels, and to promote collaboration for capacity building. The biosafety targets in African countries included: a regulatory system; an administrative system; a mechanism for a decision-making system that included risk assessment and management; and mechanisms for public participation and information. The recommended capacity-building initiatives included institutional capacity building; human resources development and training; public awareness, participation and education; information exchange and management.

104. There was a full discussion of the issues and interest in the initiative, stressing the need to have fully complementary and supportive activities in Biosafety to assist African countries with limited resources.

Launching of the UNEP/GEF Implementation of the National Biosafety Framework of Namibia

105. On 14 November 2002, at 5pm, all participants in the Workshop attended the launching of the "UNEP-GEF Project on Implementation of the National Biosafety Framework of the Republic of Namibia". The ceremony was opened by Mr. E. Thomas, Ministry of Higher Education, Training and Employment Creation, who expressed thanks to the Hon Hadingo Nghishongwa, Deputy Minister of Higher Education, Training and Employment Creation, for attending the launch. Mr. Thomas introduced the Chair, Mr. A. van Kant.

106. In his introductory statement, Mr. van Kant welcomed all participants to Namibia. He stressed that the development of biotechnology and the safe use of the products of modern biotechnology were subjects of great importance to Africa. In that respect, Africa needed to place an emphasis on human development. Pointing to the importance of new communications, he underlined the need to develop networking within the African region, and invited all participants to pursue such networking with their colleagues and counterparts in other countries.

107. On behalf of the Namibia UNEP/GEF project, Ms. M. Kandawa-Schultz, Chairperson of the Namibian Biotechnology Alliance, gave an overview of the activities under the project and noted that a number of difficulties had had to be overcome to develop the NBF. The current challenge lay in trying to implement it. Describing the background to the project, she said that the lack of institutional and resource capacities had initially delayed Namibia's ratification of the Cartagena Protocol. Namibia had found it necessary to draw up a balance of its capacities, and she was grateful that it had ultimately been selected to participate in the pilot phase of the UNEP/GEF project. Among the activities now required were the finalization of the country's Draft Act in relation to biotechnology, and the undertaking of large-scale training, particularly of customs and border officials. In conclusion, she expressed the certainty that, with the commitment of all involved, Namibia would achieve what was required.

108. Mr. Christopher Briggs, Global Programme Manager of the UNEP-GEF Biosafety Unit, expressed thanks to the Government of Namibia for hosting the current Workshop, providing the excellent facilities for participants, and for the tireless assistance in making the Workshop a success. Highlighting the importance of the Namibia NBF project, he said that it had now reached a new stage and he hoped that it would increase in strength. Namibia was a leader in the field. Support for the project had been gained within the government and among the people, and significant progress had been made over a short period of time. He hoped that other countries in Africa would be encouraged to replicate the success of Namibia, and that they could have an opportunity to learn from its experiences. Paying tribute to the considerable efforts of all those involved in the project, he expressed thanks on behalf of UNEP/GEF and on behalf of all those who would wish to learn from Namibia's success.

109. In his keynote speech, Deputy Minister Nghishongwa welcomed all participants and said that Namibia was honoured to host the Anglophone Africa Sub-regional Workshop: Risk Assessment and Management, and Public Awareness and Participation in Windhoek. The workshop was a part of the UNEP/GEF project on the development of National Biosafety Frameworks for developing countries. Namibia had already benefited from the pilot project, and took the hosting of the workshops as a compliment and a recognition of Namibia's achievements in this matter. Namibia's efforts towards establishing and implementing a biosafety framework already had a history. In 1992, the Honourable President of the Republic of Namibia signed the Convention on Biodiversity and it was ratified in May 1997. Article 16 of the Convention called for measures to guarantee the safe use of biotechnology – in other words, Namibia was obliged to do something from that moment.

110. To facilitate the implementation of the Convention, Namibia initiated its National Biodiversity Programme, which established a number of working groups to deal with the many themes addressed by the Convention. At that time, the National Biodiversity Programme, under the Ministry of Environment and Tourism, received funding from the German Technical Cooperation Association (GTZ) and GEF. The Namibian Biotechnology Alliance (NABA) had been established as a working group under that programme

to deal with biosafety and biotechnology issues and to advise the government on biosafety measures and the procedures to be put in place. Namibia joined the Regional Biosafety Focal Point in 1997 in an attempt to participate in a harmonization process and exchange of ideas on biosafety, which unfortunately came to an end a year later. However, Namibia successfully applied for the UNEP/GEF funded Pilot Phase on establishing biosafety frameworks.

111. Namibia's first attempt was to identify and evaluate its resources in the field of biotechnology and biosafety and one of the first results of NABA's activities was the completion of a country report on the matter. That gave us an opportunity to start a lengthy but necessary process to involve and inform more and more stakeholders – and make those objectives a truly national activity. Recognizing the need for some technical advice and guidelines, the second achievement was the development of technical guidelines for work with GMOs. With two subsequent national biosafety workshops, there was finally enough momentum to propose a national policy document, which was approved in 1999 by Cabinet and which lay down procedures for the regulation of GMO imports, use and handling.

112. He said that the policy document also assigned the Ministry responsible for Science and Technology as the competent authority for Namibia. Based on that policy document, NABA and stakeholders from the private and public sector began to develop a legislative and administrative framework. At the current time, it appeared that Namibia had a final draft of a Biosafety Act and clear ideas on how to deal with this sensitive issue in the interim. However, apart from having nice proposals and sound policies, infrastructure and capacity were needed to achieve the objectives and goals -- and Namibia was obliged to achieve the objectives. The country's output was not measured in the amount of policy documents but, rather, in the ability to cope with the issue on a daily basis and on a professional level. Namibia was already living in the global village. The country had economic relations with Europe and was bound within regional networks like SADC or SACU.

113. Concerning capacity development, Namibia was very thankful to be one of the few countries that were found to be advanced enough to enter into the second phase – and that was what the launching of Namibia's Biosafety Implementation project was all about. Of course, Namibia considered it as both an incentive to proceed with its efforts and even add to them, and as a compliment for a job well done.

114. He enumerated the objectives: to support the establishment of the legal and administrative basis to an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms (LMOs) resulting from modern biotechnology, with specific focus on transboundary movements in Namibia and the SADC region and to meet the obligations foreseen under the Cartagena Protocol; to improve the ability to screen LMOs in order to monitor and manage the risks associated to their handling, transport, use, transfer and release; to strengthen capacity-building of main stakeholders through training courses and workshops; to strengthen information sharing of relevant stakeholders; and o enhance public awareness on biosafety-related issues.

115. Namibia had come a long way to this point and there was still a long way to go. However, he was sure Namibia had built the confidence and competence to tackle this issue and to be successful in its endeavour.

116. He expressed thanks to UNEP/GEF for the generous financial and technical support and the many experts and friends who would assist Namibia further – not forgetting those who had assisted Namibia along the way to the current point. Everything would only work out fine if Namibia could manage to share its resources, experiences and expertise, respect its concerns and visions. He therefore hoped that the Sub-regional Workshop would provide another platform for exchanging ideas and views, and networking. It could be understood as an important sign that Namibia was using the opportunity to launch its national biosafety implementation project, embedded in the UNEP/GEF regional workshop on risk assessment, management, public awareness and participation.

117. After expressing thanks to the Deputy Minister for attending the launch, and to UNEP/GEF and all who had provided expertise and assistance throughout the project, Mr. van Kant expressed the hope that participants would be able to take time out from their work and see something more of Namibia.

V. Concluding Joint Sessions of the Workshop

118. On 15 November 2002, the Workshop held its concluding joint plenary sessions.

Consideration of the work of the Workshop on Public Awareness and Public Participation

119. Mr. Fancis Lelo, Facilitator of the Workshop on Public Awareness and Public Participation, presented a summary of the work in the Workshop.

120. One example of the 'Action Plans for Public Awareness and Participation in the Development of an NBF' that had been drawn up was then looked at, and the East African Countries Group's work was selected at random. From this, participants were able to envision a proposed matrix, covering the following fields:

- The expected results;
- Activities to achieve the results;
- Who will carry out activities;
- Resources available and required to complete activities;
- Timeframe for activity completion;
- Measurable Indicators of success in reaching the expected results;
- Follow-up.

121. It was pointed out that the matrix was only a summary, and that many of the elements included were multi-layered, referring to government as well as "the public". During the discussion of the matrix, participants proposed specific amendments and clarifications. It was explained that it was necessary to bring out the fact that the paper produced as a result of the SWOT analysis should be seen as an introduction to the Action Plan. It was made clear that what had been produced at the current Workshop was only a bare summary framework, a guide to how to conduct the process. The actual national matrix thus needed to be considerably supplemented and fleshed out, in line with the situation in the individual Parties themselves. In particular, the question of timing of the various steps needed further consideration. Participants should return

home and use the matrixes as a basis for their own process, and they should ensure that others involved in the process in their country, particularly the NCC, as well as stakeholders, would be familiar with its content and the reasoning behind it.

122. In answer to a query, it was explained that, under the UNEP/GEF project, the National Project Coordinator would be paid, for the duration of the project, to be responsible for the running of the project. There would also be a contact point within the National Executing Agency, which would be responsible for dealing with UNEP/GEF on formal matters.

123. Attention was drawn to the problem of the high proportion of illiteracy among rural populations in a number of countries, and to the need for special activities such as public meetings, films, videotapes or use of extension workers to bring the information to those people.

Consideration of the work of the Workshop on Risk Assessment and Risk Management

124. Mr. Giovanni Ferraiolo, Regional Coordinator for the Latin America and Caribbean region, UNEP-GEF Biosafety Unit, briefly summarized the work in the Workshop and presented the checklist prepared by participants (see Annex VI), setting out the actions to be taken and the elements to be considered within the establishment of a regulatory system for handling applications for the release of LMOs, and identifying possible entry points for public participation in the process. He described the reasoning behind the various elements included in the checklist. There then followed a discussion on the timing and type of public participation that could go on at different periods of the notification process.

125. Mr. Kinderlerer explained that it was necessary to see how the public consultation process could be incorporated into the process. While a number of potential entry points had been identified (see Annex VI), since the whole process had be carried out within the timeframe of 270 days, as provided in the Cartagena Protocol, it might not be possible to use all of the entry points. The Party itself had to chose at what points of the process the public would be enabled to participate.

126. It was noted that two interlinked, but entirely separate, processes were taking place in parallel in these workshops. Firstly the role of the public in the development of the NBF was being discussed and at the same time there had to be set up a coherent system for informing and consulting with the public on proposals for a specific LMO for a specific purpose, as part of the risk assessment and management process.

127. During the discussion, it was explained that, under Article 10 (d) of the Protocol, it was possible to extend the time limit of 270 days, but only with regard to a particular decision, and not as a general principle. Concerning the procedure to be adopted for a regulatory framework, it was pointed out that, under the terms of Article 9, paragraph 2.c of the Cartagena Protocol, there was certain flexibility in the options to be chosen. For example the procedures could be according to the domestic regulatory framework, where consistent with the Protocol.

128. Another view held that the available expertise within the public should be taken into account from the very beginning of the process, right through to the end.

Preparation of NBF diagrams

129. On the basis of what had been covered so far with respect to risk assessment, risk management, public awareness and public participation, the members of each country delegation were called upon to consult among themselves and to design a flow chart, setting out all the elements they expected to be contained in an NBF. Participants were invited to display their completed diagrams on the wall, so that comparisons could be made.

130. For the discussion on the diagrams, participants were invited to provide their impressions of both the process of preparing them, and of the finished products themselves. It was observed that the diagrams prepared showed wide variations, which reflected the different levels of development of the system within the countries themselves and their different starting points. Some representatives observed that, during the

exercise, they had kept in mind the existing guidelines and legal frameworks in the country, and had considered ways of merging into them the elements that had been covered during the Workshop. Attention was drawn to the fact that every country had its own unique legal system. Thus, the way in which they implemented the requirements of the Cartagena Protocol, or even went beyond them, depended on the nature of the system in place. It was not possible to use a template, and in a way that was a good thing, because it forced a country to think carefully about what it was setting up and gave it a sense of true ownership of its NBF.

131. Concerning the information that any Party, considering an LMO release, was obliged to provide to a neighbouring country, it was explained that there was no formal requirement to provide the information specified under Annex I of the protocol, nor was there any requirement to pass on confidential information without the consent of the notifier. Attention was drawn to Article 17, paragraph I of the Protocol, where it was observed that neighbours needed to be given sufficient information for them to judge the impact which the release could have on their territory, and enough time to provide their comments. In a case where a neighbour was releasing LMOs on its territory, it was explained that, because of the Protocol's implied obligation on a Party to protect the neighbour's territory, a country had the right to request relevant information and to comment, and could remind the releasing country of that obligation.

132. On the question of public participation, it was recalled that the government itself was under the influence of the public, and that represented another important avenue of participation.

133. Another point was that the appeal procedure for an unfavourable decision should be open not only to the notifier, but also to the public. Expectations and Concerns - Revisited

134. At the closing session of the Workshop, Mr. Christopher Briggs 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. After the exercise, it was generally agreed

that about 70 per cent of participants' expectations had been met. A number of points were not intended to be covered under these workshops, while some others were not considered to have been fully covered in the workshops.

135. He stressed that one of the aims of holding the two Workshops simultaneously was to encourage all the members of a country's delegation who had attended one Workshop to talk over their experiences and discuss with their colleagues who had attended the other Workshop how to integrate the lessons learnt and provide training for those who had not attended either meeting back in country. In such ways, all the country delegation would learn about the whole process, and would also be stimulated to hold an interactive exchange with each other.

136. It was observed that those countries that had ratified the Protocol should explain to those that had yet to ratify it how they had managed to instil in their respective governments the political will and interest to complete the ratification process.

Evaluation Exercise and Closure of the Workshop

137. Mr. Briggs informed participants that their comments on the Workshop would provide important feedback to help the Biosafety Team further refine the process. He assured all participants that their opinions would be taken very much into account, and invited them to complete the evaluation form provided for the purpose.

138. In his closing statement, he said that UNEP/GEF was aware that, considering the potential for the Cartagena Protocol to enter into force within the next year or so, all countries that had ratified the Protocol already were in a different situation than those that had not. Some of them, who would soon be facing their obligations under the treaty, had already developed NBFs, some were moving into the implementation stage, and others had yet to develop an NBF. It was necessary to obtain information on each of the countries' state of preparedness and on what was already in place. It was also important to find out what was immediately

necessary to be done to assist ratified countries to meet their minimum obligations to the Protocol on its entry into force. He assured countries, particularly those that had ratified the Protocol, that UNEP/GEF stood ready to ensure that they received all the help they needed to meet their minimum obligations under the Protocol. They would need to understand the risk assessment procedure relatively rapidly, and it was already established that they would be able to attend the risk assessment and risk management courses to be organized over the next year. However, funds for their attendance would need to be secured for their attendance.

139. In conclusion, he reiterated his special thanks to Namibia for hosting the Workshop and thanked all who had participated and who had worked in front of, and behind the scenes to make it such a success.

The Workshop was closed at 3 p.m. on Friday, 15 November 2002.

ANNEX 1

LIST OF PARTICIPANTS

(intentionally removed from this report published on the web)

Annex II

Work plan

Day 1 Joint Session

8:30 Formal opening (Namibia)

8:45 Update on National Biosafety Frameworks (NBF)

9:15 Purpose of workshop

9:25 Introduction of participants (name and role) [One from each country or representative of organization]

10:00 Expectations and concerns

10:15 Ground rules for the workshop

10:30 Coffee break – 15 mins

10:45 Introduction to Public Awareness and Participation

12:15 – 13.45 Lunch break (Rapporteurs will meet over lunch to collate).

13:45 How do you explain science to the public?

14:45 Introduction to Risk Assessment and Management

16:15 Coffee break (All Rapporteurs will meet to collate). *30 mins*

16:45 Presentation of 2 synthesized Reports and panel guided discussions

18:00 End of Day 1 with homework

Day 2: Group on Risk Assessment and Management

9:00 Introduction to the risk assessment and management workshop: Why we are here? and what will we discuss?

9:15 Introduction on Risk Assessment and Cartagena Protocol

10:45 Coffee break 15 mins

11:00 Introduction to Risk Management and decision

12:30 Lunch break

14:00 Risk Assessment and Management Exercise. Part 1.

18:00 End of Day 2

Day 2: Group on Public Awareness and Participation

9:00 Introduction to Public Awareness and Participation

9:15 Focus Groups on Art. 23.

9:55 Report in plenary and discussion.

10:30 Coffee break

11:00 Plenary guided discussion on defining a prioritised list of Stakeholders

11:40 Stakeholder analysis on "How different stakeholders will be involved in different phases of the NBF?"

12:30 Plenary guided discussion on the Stakeholders matrix

13:30 Lunch break

15:00 Presentation of IDS study and CABI experiences

15: 30 Introduction to SWOT analysis (plenary).

16:00 SWOT analysis on national experiences of Public Awareness & Participation (In 3 groups) - Coffee break in the middle

17:00 Reports to plenary

18:00 End of Day 2

Day 3 Group on Risk Assessment and Management (RA & RM)

9:00 Risk Assessment and Management Exercise. Part 2.

16:30 (Joint session) Presentation of NEPAD initiative and implications for Biosafety

17:00 Launching of Namibia Implementation Project

19:00 Conference Dinner

Day 3 Group on Public Awareness and Participation

9:00 Guided plenary discussion to review discussions of Days 1 and 2

9:45 Focus group discussion on specific results you would expect from

A) public participation in the development of the NBF?

B) public participation in the decision-making on LMOs?

10:30 Coffee break 30 mins

11:00 Presentations of results

11:45 Group discussions on "How these results are to be achieved based on the four pillars of participation

- Awareness raising
- Education
- Mechanisms for participation
- Information – access, type, etc

13:00 Lunch break

14:30 Presentations of matrix of activities against "expected results".

15:30 Group discussions to develop Action plans.

16:30 (Joint session) Presentation of NEPAD initiative and implications for Biosafety

17:00 Launching of Namibia Implementation Project

19:00 Conference Dinner

Day 4 Joint session

9:00 Presentations of summaries of the work of the RA&RM and PA&P Workshops and discussion of how to synthesize the different elements of the results.

10:30 Coffee break

11:45 Drawing of NBF diagrams.

12:30 Lunch

13:30 Guided Plenary discussion on NBF diagrams

14:30 Final Discussion (refer to Expectations and Concerns in Day 1)

15:00 Personal Evaluation and End of the Workshop

Annex III.

Expectations and concerns regarding the Workshop

Expectations	**Concerns**
Know how to involve public in public participation	How to sustainably harmonize biosafety issues with successive government policies
How to assess risk	Potential impact of GMOs on genetic erosion of resources
Sharing of experiences between countries	How to build and sustain strong regional networks on biosafety
Be prepared for explaining to, and understanding decision makers	Who should pay the high costs of public involvement?
Explanation of public participation to stakeholders	How to boost awareness of the political elite (policy makers)
Examine risk assessment & management more critically	How can we have laboratories to inspect imported food
Be able to involve the public better	How do we move from development to implementation
Understand how other countries are progressing	How to resolve conflicts of interest between consumer lobbyists, Biotechnologists and environmentalist
Relate to other countries better	Short time span of workshops
Better able to implement articles.15, 16, and 23 of the Cartagena Protocol	Who is the public? Who are the stakeholders?
Better understanding of stepwise approach of risk assessment and management	How do we handle developed countries and explain to them our viewpoint?
See examples of GM crop introduction	How to involve most illiterate people in decision making in areas related to health and environment
Know how to deal with proposed introduction of GMOs	Relief food may contain GMOs
Deal with relations of public better	How to ensure harmonious cooperation between unequal countries
How to put public participation into practice back in country	How to carry out risk assessment on a scientific basis
Different roles of stakeholders in NBF	Where are other NGOs to ensure their inputs to decision-making?
Understand level and needs for risk assessment and management and understand how FAO could complement projects	How to do risk management in countries with porous borders and refugees
Know procedures for risk assessment and management	How to control Food aid with GMOs
Understand how to run public participation campaign	How to ensure and enforce risk management when there are other priorities
Recognize requirements to complete public participation activities	Participants cannot attend both workshops
Practical know-how in employing risk assessment and management	How to build safe biotechnology if no biotechnology has been developed
Best practices in risk assessment and share	Why no industry representatives in workshop?

experiences	
Understand cost implications of NBF	
See comparative advantages of different media and types of approaches in public participation	
How to get balance and consensus	
Learn from other countries carrying out implementation	
How to reach a heterogeneous public	
Learn what not to do	
How to resolve conflicting interests and build partnership	
How to reach out to policy makers and get political support	
Learn needs of other countries and how to support them	
Learn best practices in public participation and understand whether methods used are effective	

Annex IV: Workshop Ground Rules

- We shall switch off our mobile phones
- We shall not smoke in the hall
- We shall be on time
- Facilitators will ensure no sleeping
- We shall have energizers
- We shall make our statements very brief and to the point
- We shall not repeat the same statements
- We shall avoid being personal
- We shall speak one at a time
- We shall prioritize the business of workshop
- Facilitators will provide background material in good time
- We shall accept constructive interruptions
- We shall respect each other
- There is a maximum of 4 official representatives for countries

Observers may only take the floor in the plenary, and only after all the country representatives have made their statements. If an observer has important substantive information to provide, the floor may be given to the observer on an exceptional basis.

ANNEX V

Exercise in Setting up a Regulatory System for handling Applications for Handling Transgenic Organisms

I. Examine Articles 1, 4, 5 and 6 of the Cartagena Protocol, as copied below this section. Consider what uses of transgenic organisms are likely to fall within the terms of the Protocol. (plenary)

a.	Pharmaceuticals for human use?	☐
b.	Pharmaceuticals for animal use?	☐
c.	LMOs in **transit**?	☐
d.	LMOs that are used in **containment** only	☐
e.	LMOs that are destined for food use only?	☐
f.	LMOs destined for food and feed use?	☐
g.	LMOs intended to be released into the environment?	☐
h.	Products derived from LMOs	☐
i.	LMOs produced within the borders of your country	☐
j.	Imported LMOs only?	☐
k.	Animals intended for food use?	☐
l.	Farm Animals?	☐
m.	Other animals – pets, race-horses….?	☐
n.	Microorganisms when used in diagnostic kits?	☐
o.	Animal or human cells in culture?	☐
p.	Any other Living modified organisms?	☐

II Can any uses of LMOs that are not included in the scope of the Protocol be included within the Scope of a National Biosafety Framework? (plenary)

III As an official you would need to set up the system on Advance Informed Agreement (AIA) to allow the import of an LMO for release into the environment in your country. Articles 8, 9, 10 and Annex 1 of the Protocol could help you to become more familiar with the procedure on AIA.(3 groups)

(a) Make a list of the actions that need to be taken.

(b) Set the time limits needed to comply with the Advanced Informed Agreement (AIA) Procedure assuming that there is an intention to import an LMO for release into the environment in your country.

(c) You have to make your decision on the LMO within a defined time, yet you may also need to ask the applicant to provide more information. How should you account for the time taken between your request for information and receipt of the applicant's response?

(d) Would you provide a system where notifiers can discuss a possible notification with relevant government officials before a notification is formally made? – If so, how would you ensure that this process is not abused and is open to public scrutiny?

(e) Who will pay for processing any notification?

Risk Assessment procedures: Introduction – Audit of Risk Assessment vs. Risk Assessment

IV Before a dossier is received, a number of actions need to be decided by the National Competent Authority. How would you answer the following points? (3 groups)

(a) Who is to perform the 'risk-assessment'– notifier or competent authority?

(b) Who pays for the 'risk- assessment'– notifier or competent authority?

(c) As this is an application for a release, will there be a requirement for field-tests within your territory, or will you accept the results of field tests done elsewhere? If you are willing to accept field-testing done elsewhere, will there likely to be any geographical or climatological restrictions on acceptability?

(d) How will the public be given an opportunity to comment on the specific dossier?

(e) What information in the dossier will be

I. Made public?

II. Made available on request to permit any member of the public to comment on the notification?

III. Be confidential? – how will the decision be made as to what is confidential and what is open?.

V. Whether you use people from inside or outside government you need assessors. (3 groups)

(a) Do you have such assessors available?

(b) If the assessors are not within government, how will you ensure confidentiality?

(c) Would you set up "technical panels" to provide science-based advice on the risk to the environment and/or human health?

(d) If you set up technical panels, what relation would there be between the Competent Authority and the "technical panels"?

VI If you were to decide to set up "technical panel[s]...(3 groups***)***

(a) How will you choose the members?

(b) If expertise is missing in-country, how will you fill the gaps?

(c) Will these panel[s] have responsibility for scientific risk assessment only, or will they take other issues into account?

(d) How will the panel[s] take comments from the public into account?

(e) Will the report[s] of the panel[s] be made public?

VII Decision Making process *(plenary)*

(a) Will there be any input to the decision making process other than by the panel[s]?

(b) What can the decision document address?

(c) Who makes the final decision?

(d) Will there be an opportunity for the public to comment on the decision before it takes effect?

(e) Will there be a document, which either accepts or refutes the comments and criticisms made by the public?

Annex VI

Setting a regulatory system for handling applications of LMOs

(Possible entry points for public involvement are proposed in italic and in bold)

a. Identification of institutional structures (Set up competent authority/ies,)

UNEP – GEF Project:
National Executing Agency, National Project Coordinator, National Coordinating Committee

i. Phase 1 - Inventories
ii. Phase 2 - Consultations
iii. Phase 3 - Drafting of NBF

b. Set up law or policy or regulations or guidelines or executive order or law amendments that enable regulation.
c. It has to identify how to set up standing or ad hoc panel(s) and/or individual(s) responsible for risk assessment
d. It has to define mandate/TOR and broad remuneration terms
e. On receiving a notification start the clock
f. (Payment of a fee)
g. Check the notification for completeness
h. May ask for additional details (stop the clock)
i. Identification of confidential information
j. Acknowledge the receipt in writing (within 90 days)

Possible notification to public

k. (Notify adjacent countries)
l. Send dossier to panel[s]/risk assessors and include where appropriate TOR, timeline, restrictions.

Panel[s] may consider public comments

m. Panel[s]/risk assessors produce report(s)

Reports may be made public and comments invited

n. Additional information can be requested at any point in the process
o. Decision making [national biosafety committee, CNA, Minister, Minister(s) based on recommendation from NBC]

Decision may take into account public comments

p. Decision could be acceptance, conditional, requesting additional time or rejection (Art 10.3d)
q. Notify the applicant
r. Notify the BCH of the decision (within 270 days)

Appeal option

Annex VII

Sub-Regional Action Plans for Public participation in the Development of the NBF in Africa

East Africa Action Plan for Public Participation in the Development of the NBF

Expected results	Activities to achieve expected results	Who will do it?	Resources	Timeframe	Indicators	Follow up
1) NBF concept understood	1) Seminars	1) National Project Coordinator	1) Project Funds 2) Government 3) Other funders	By Month 6	1) Seminar reports	1) National Coordinating Committee
	2) Survey on SH understanding of NBF	1)) National Project Coordinator	1) Project Funds 2) Government 3) Other funders	By Month 6	1) Seminar reports 2) Feedback from SHs	1) National Coordinating Committee
	3) Information dissemination through print & electronic media	2) Consultants	1) Project Funds 2) Government 3) Other funders	Continuous	1) Seminar reports 2) Feedback from SHs 3) No. of print & electronic media radio programmes, leaflets etc)	1) National Coordinating Committee
2) Information about existing structures collected	1) Conduct surveys	1)) National Project Coordinator	1) Project Funds 2) Government 3) Other funders	Within 6 Months	1) Survey report	1) National Coordinating Committee & National Project Coordinator

	2) Build database	2) Teams put together by NFP	1) Project Funds 2) Other funders 3) Government	By Month 8	1) Database	National Coordinating Committee & National Project Coordinator
	3) Information disseminated to relevant SHs	1)) National Project Coordinator 2) Teams put together by NFP	1) Project funds 2) Government 3) Other funders	Within 6 Months	1) Number of SHs reached 2) Number of channels used	National Coordinating Committee
3) Roles of different stakeholders defined	1) SH identification & analysis	1) National Project Coordinator	1) Project funds 2) Government 3) Other funders	By Month 12	1) List of SHs & roles 2) Workshop report	National Coordinating Committee
	2) Consultations in SH seminars & workshops	1)) National Project Coordinator	1) Project funds 2) Government 3) Other funders	By Month 12	1) List of SHs & roles 2) Workshop report	National Coordinating Committee
4) Wider awareness created on NBF & LMOs	1) Training of trainers for various groups	1)) National Project Coordinator 2) Experts/consultants	1) Project funds 2) Government 3) Other funders	Two by Month 12	1) Number of trainers trained	National Coordinating Committee
	2) Workshops, seminars for SHs	1)) National Project Coordinator 2)Experts/consultants	1) Project funds 2) Government 3) Other	At least three by Month 12	1) Number of participants	National Coordinating Committee
	3) Media activities	1)) National Project Coordinator 2)Experts/consultants	1) Project funds 2) Government 3) Other	By Month 12	1) Number of programmes, leaflets etc	National Coordinating Committee
5) Legal Instruments for NBF prepared	1) Consultation with relevant SHs to determine main elements of NBF	1)) National Project Coordinator 2)Experts/consultants	1) Project funds 2) Government 3) Other	By Month 14	Report with main elements of NBF	National Coordinating Committee
	2) Drafting of NBF & regulations	1)) National Project Coordinator	1) Project funds 2) Government 3) Other	By Month 15	Draft NBF & regulations	National Coordinating Committee
	3) Meeting of Stakeholders to review draft	1) National Project Coordinator	1) Project funds 2) Government 3) Other	By Month 16	Final draft of NBF & regulations	National Coordinating Committee

6) NBF accepted by most stakeholders	1) Final meeting of stakeholders to review draft	1)) National Project Coordinator	1) Project funds 2) Government 3) Other	By Month 17	1) Final draft of NBF & regulations 2) Workshop report	National Coordinating Committee

West African Action Plan for Public Participation in the Development of the NBF

Expected results (not in order of importance)	**Activities to achieve expected results**	**Who will do it?**	**Resources**	**Timeframe**	**Indicators**	**Follow up**
1) Knowledge base of stakeholders enhanced	Survey, site visits, interviews, etc..	NBF NCC, consultants	Financial, human resources	15th Jan – 15th June 2003	Inventory of biotech institutions & their roles, national database established	NBF NCC & NPC
				July – Dec 2003		
				Jan – June 2004		
	Seminars, workshops and meetings	NBF NCC, facilitators,	Financial, materials and equipment, human resources	15th Jan – 15th June 2003		
				July – Dec 2003	2 workshops; 2 seminars, implemented	NBF NCC & NPC
				Jan – June 2004	1 workshop	NBF NCC & NPC
	Drama	Environment	Financial, materials	15th Jan – 15th June 2003		

		'clubs', drama groups	and equipment, human resources	July – Dec 2003	5 drama performances	NPC
				Jan – June 2004		
	Use of media	NBF NCC, facilitators, journalists	Financial, human resources	15th Jan – 15th June 2003		
				July – Dec 2003		
				Jan – June 2004		
2) Stakeholders views accommodated into NBF						
3) Continuous flow of views and information of the NBF ascertained						
4) SWOT identified						
5) Confidence between various stakeholders established						
6) NBF structures relating to PA.P established						
7) Sources of funding identified						

Southern Africa Action Plan for Public participation in the development of the NBF

Expected results	Activities to achieve expected results	Who will do it?	Resources	Timeframe	Indicators	Follow up
1) Key stakeholders identified and engaged	Hold stakeholder analysis workshops	NEA, NCC in conjunction with specialised groups	Financial Equipment and facilities Human resources	First quarter of the project duration	- Proceedings	Who: - NCC How: - Through audits
	Establish a national stakeholders database	-do-			- Number of stakeholders in the completed database	
	Organize consultative meetings for different stakeholder groups					-
2) An informed public	1. Organize training workshops 2. Organize media debates 3. Hold open days (exhibitions and discussions) 4. Disseminate relevant information in local languages 5. Organize public gatherings (especially in rural areas) 6. Establish a national Biosafety Clearing-House (BCH)	Project personnel in conjunction with: - Local leaders - NGOs and relevant organizations - Public media	- Trained personnel - Information materials - Equipment - Transport - Financial resources	Through out the project duration	- Number of trained people - Number of workshops - Increased levels of participation and understanding of issues based on results of evaluation of conducted workshops - Positive results of assessment interviews - Number of visits (hits) to the BCH	Who: - NCC How: - Assessment interviews - Continuous assessment of the number of hits in the BCH

3) Increased ability to make informed decisions (choices)						
4) Universally agreed strategy to implement the NBFs in place	1. Organize workshops, meetings, seminars to deliberate and agree on the strategy 2. Organize public debates using various means	NEA	Financial Human Materials	Within the last six months	• Number and diversity of stakeholders consulted • Workshop proceedings • Endorsed strategy	Who - NEA, NPC, NCC How - Through audits
5) Existing human resources and responsibilities clarified						
6) National ownership of decisions made						

ANNEX VIII

DETAILED LIST OF DOCUMENTS PROVIDED TO PARTICIPANTS

1. A Biosafety Framework Development Toolkit Phase 0 and Phase 1

2. UNEP Brochure on Building Capacity for the Implementation of the Cartagena Protocol on Biosafety

3. IDS Document on Public Participation

4. The Aarhus Convention: a new instrument promoting Environmental Democracy

5. Risk Assessment and Management Exercise

6. The Text and Annexes of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity

7. A Workshop evaluation form

Annex IX

Workshop Evaluation Form
For Anglophone Africa Sub-regional Workshop on:
(i) Risk Assessment and Management
(ii) Public Awareness and Participation

Please take a few minutes to help us to evaluate our workshop by answering the following questions.

If you took part in the risk assessment and management workshop, please answer the questions in Part A and Part C.

If you took part in the public awareness and participation workshop, please answer the questions in Part B and C.

In each case, indicate your answer by circling the number which best describes your assessment of the workshop.

Part A: Risk Assessment and Management (RA&RM)

On a rating of 1 to 6, assess how much the workshop has improved your:

(i). Understanding of what is meant by the term "risk assessment and management decision systems"	1 2 3 4 5 6 Not Useful Useful Very Useful
(ii). Understanding of how your country can put in place the necessary risk assessment and management systems in developing your national biosafety framework (NBF)	1 2 3 4 5 6 Not Useful Useful Very Useful
(iii). Understanding of how you can take into account your country's national priorities, needs, expectations and approaches in setting up these risk assessment and management systems	1 2 3 4 5 6 Not Useful Useful Very Useful
(iv). Understanding of your country's capacity building needs in setting up risk assessment and management systems in developing your NBF	1 2 3 4 5 6 Not Useful Useful Very Useful
(v). Understanding of the requirements for risk assessment under the Cartagena Protocol	1 2 3 4 5 6 Not Useful Useful Very Useful
(vi). Understanding of Annex 3 of the Protocol and how it applies to the development of risk assessment and management systems for a NBF	1 2 3 4 5 6 Not Useful Useful Very Useful
(vii). Understanding of Article 26 of the Protocol in terms of taking into consideration socio-economic issues in decision making:	1 2 3 4 5 6 Not Useful Useful Very Useful
(viii). Understanding of what it means to take a Precautionary approach in decision-making on biosafety;	1 2 3 4 5 6 Not Useful Useful Very Useful
(ix). Understanding of the process for handling individual applications for the importation and/or release of LMOs in your NBF;	1 2 3 4 5 6 Not Useful Useful Very Useful
(x). Understanding the role of the public in the risk assessment and management systems established in developing your NBF.	1 2 3 4 5 6 Not Useful Useful Very Useful

Part B: Public awareness and participation

On a rating of 1 to 6, assess how the workshop has improved your:

(i). Understanding of the requirements of Article 23 of the Cartagena Protocol in terms of public awareness and participation in the development of a NBF for your country;	1 2 3 4 5 6 Not Useful Useful Very Useful
(ii). Understanding of **when** and **how** to involve the public in the development of your country's NBF;	1 2 3 4 5 6 Not Useful Useful Very Useful
(iii). Understanding of **when** and **how** to involve the public in the decision-making process on LMOs that will be set up in your country's NBF;	1 2 3 4 5 6 Not Useful Useful Very Useful
(iv). Ability to identify **who** should be involved in developing your country's NBF and what their roles and responsibilities would be;	1 2 3 4 5 6 Not Useful Useful Very Useful
(v). Ability to develop public awareness and education programmes on biosafety and the NBF;	1 2 3 4 5 6 Not Useful Useful Very Useful
(vi). Understanding of how to allow access to information for all stakeholders in developing your country's NBF whilst ensuring that issues of confidentiality are respected;	1 2 3 4 5 6 Not Useful Useful Very Useful
(vii). Understanding of how to set up mechanisms for public participation in the development of your country's NBF:	1 2 3 4 5 6 Not Useful Useful Very Useful
(viii). Ability to develop and implement an action plan for public participation that is appropriate to your country's situation;	1 2 3 4 5 6 Not Useful Useful Very Useful
(ix). Understanding of the role of public participation in the process for handling individual applications for the importation and/or release of LMOS in your NBF;	1 2 3 4 5 6 Not Useful Useful Very Useful
(x). Understanding of what is meant by risk assessment and management systems within the context of your country's NBF.	1 2 3 4 5 6 Not Useful Useful Very Useful

C: Overall workshop assessment:

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

(i). How useful was the workshop for you as an individual?	1 2 3 4 5 6 Not Useful Useful Very Useful
(ii). How well organised was the workshop?	1 2 3 4 5 6 Not Useful Useful Very Useful
(iii). How did you find the balance of presentations and discussions?	1 2 3 4 5 6 Not Useful Useful Very Useful
(iv). How well presented was the material?	1 2 3 4 5 6 Not Useful Useful Very Useful
(v). Overall, how would you rate the workshop?	1 2 3 4 5 6 Not Useful Useful Very Useful

6 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 workshop organisers before leaving the room.

Thank you

Annex X

Workshop Evaluation by Participants

Introduction

The Sub-Regional Workshop for Anglophone Africa on: Risk Assessment and Public Participation organised by the UNEP-GEF Biosafety Project on the "Development of National Biosafety Frameworks" was held in Windhoek, Namibia from 12th to 15th November 2002. The workshop was designed to be participatory and required all participants to make an active contribution to discussions on risk assessment and management, and public awareness and participation. The workshops were also to explain to participants the kind of structures they needed put in place in order to meet the obligations of Articles 15, 16 and 23 of the Cartagena Protocol, and to point to existing examples of such structures

At the end of the workshop, participants were asked to evaluate the workshop both in terms of the expected results from the workshop and in terms of 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 sub-regional workshop;

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 workshops achieved its stated objectives;

4 Demonstrate to country participants how they could evaluate their own national workshops.

Methodology

The form used for evaluation of the workshop (see Annex IX) asked participants to give a quantitative indication of their own assessment of the workshop's achievement of the following results:

Risk Assessment and Management Systems:

- Understanding of what is meant by the term "risk assessment and management decision systems"
- Understanding of how your country can put in place the necessary risk assessment and management systems in developing your national biosafety framework (NBF)
- Understanding of how you can take into account your country's national priorities, needs, expectations and approaches in setting up these risk assessment and management systems
- Understanding of your country's capacity building needs in setting up risk assessment and management systems in developing your NBF
- Understanding of the requirements for risk assessment under the Cartagena Protocol
- Understanding of Annex 3 of the Protocol and how it applies to the development of risk assessment and management systems for a NBF
- Understanding of Article 26 of the Protocol in terms of taking into consideration socio-economic issues in decision making
- Understanding of what it means to take a Precautionary approach in decision-making on biosafety;
- Understanding of the process for handling individual applications for the importation and/or release of LMOs in your NBF;
- Understanding the role of the public in the risk assessment and management systems established in developing your NBF.

Public Awareness and Participation:

- Understanding of the requirements of Article 23 of the Cartagena Protocol in terms of public awareness and participation in the development of a NBF for your country;
- Understanding of when and how to involve the public in the development of your country's NBF;

- Understanding of when and how to involve the public in the decision-making process on LMOs that will be set up in your country's NBF;
- Ability to identify who should be involved in developing your country's NBF and what their roles and responsibilities would be;
- Ability to develop public awareness and education programmes on biosafety and the NBF;
- Understanding of how to allow access to information for all stakeholders in developing your country's NBF whilst ensuring that issues of confidentiality are respected;
- Understanding of how to set up mechanisms for public participation in the development of your country's NBF:
- Ability to develop and implement an action plan for public participation that is appropriate to your country's situation; Ability to develop and implement an action plan for public participation that is appropriate to your country's situation;
- Understanding of the role of public participation in the process for handling individual applications for the importation and/or release of LMOS in your NBF;
- Understanding of what is meant by risk assessment and management systems within the context of your country's NBF.

Overall Workshop assessment

- How useful was the workshop for you as an individual?
- How well organised was the workshop?
- How did you find the balance of presentations and discussions?
- How well presented was the material?
- Overall, how would you rate the workshop?

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 (i.e. from 38 replies received for Risk Assessment and 40 for Public Participation). This figures, in conjunction with the range of scores for each question, gave an indication of the overall

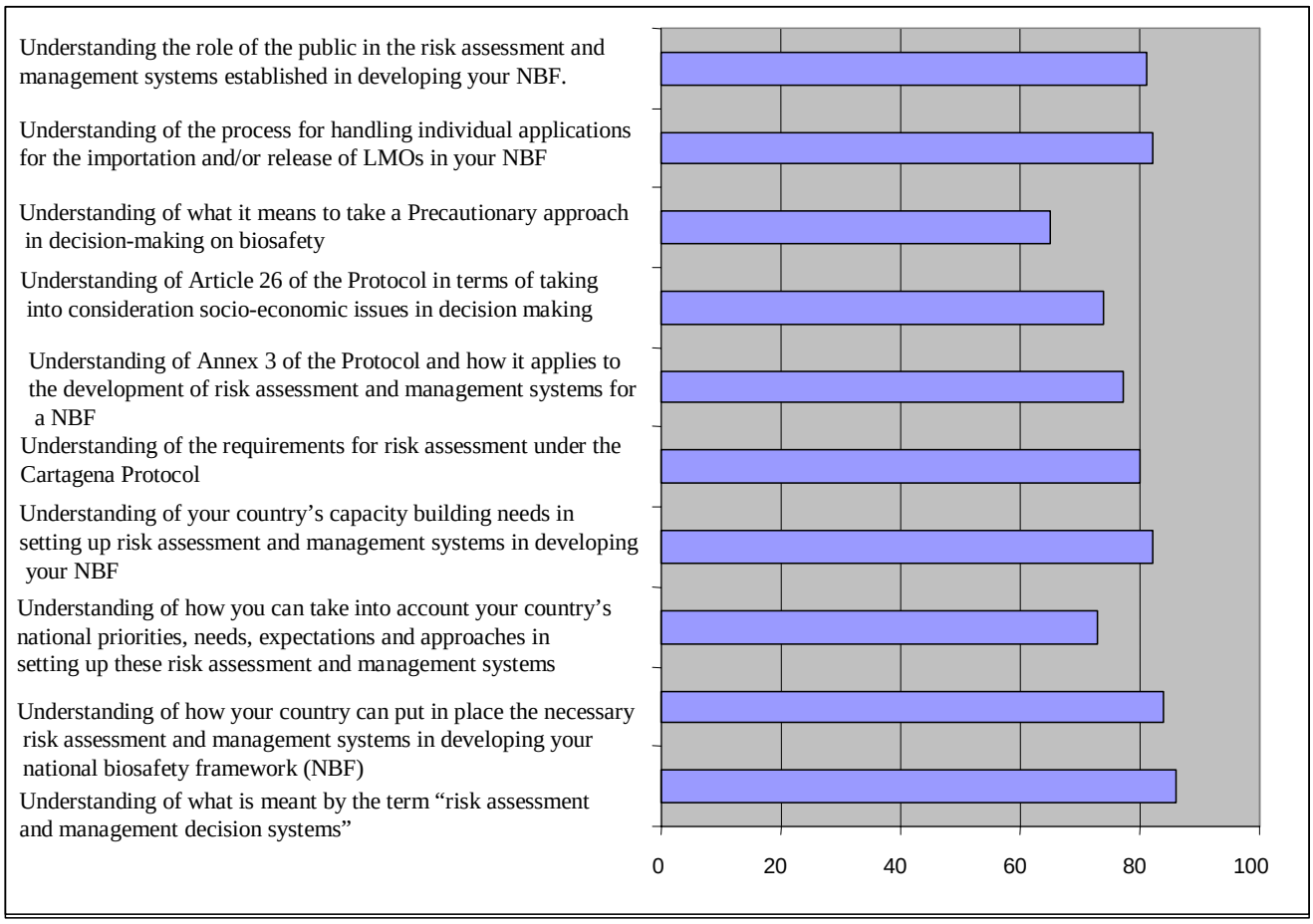
assessment by participants for each of the questions. A high percentage indicates that there was a greatly increased understanding of the topic or a strong agreement with the statement.

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 of the workshop by participants was very good, with all participants giving positive feedback on the contents and on organisation of the workshop. The results also showed that participants considered the workshop to be highly successful in achieving the expected outputs.

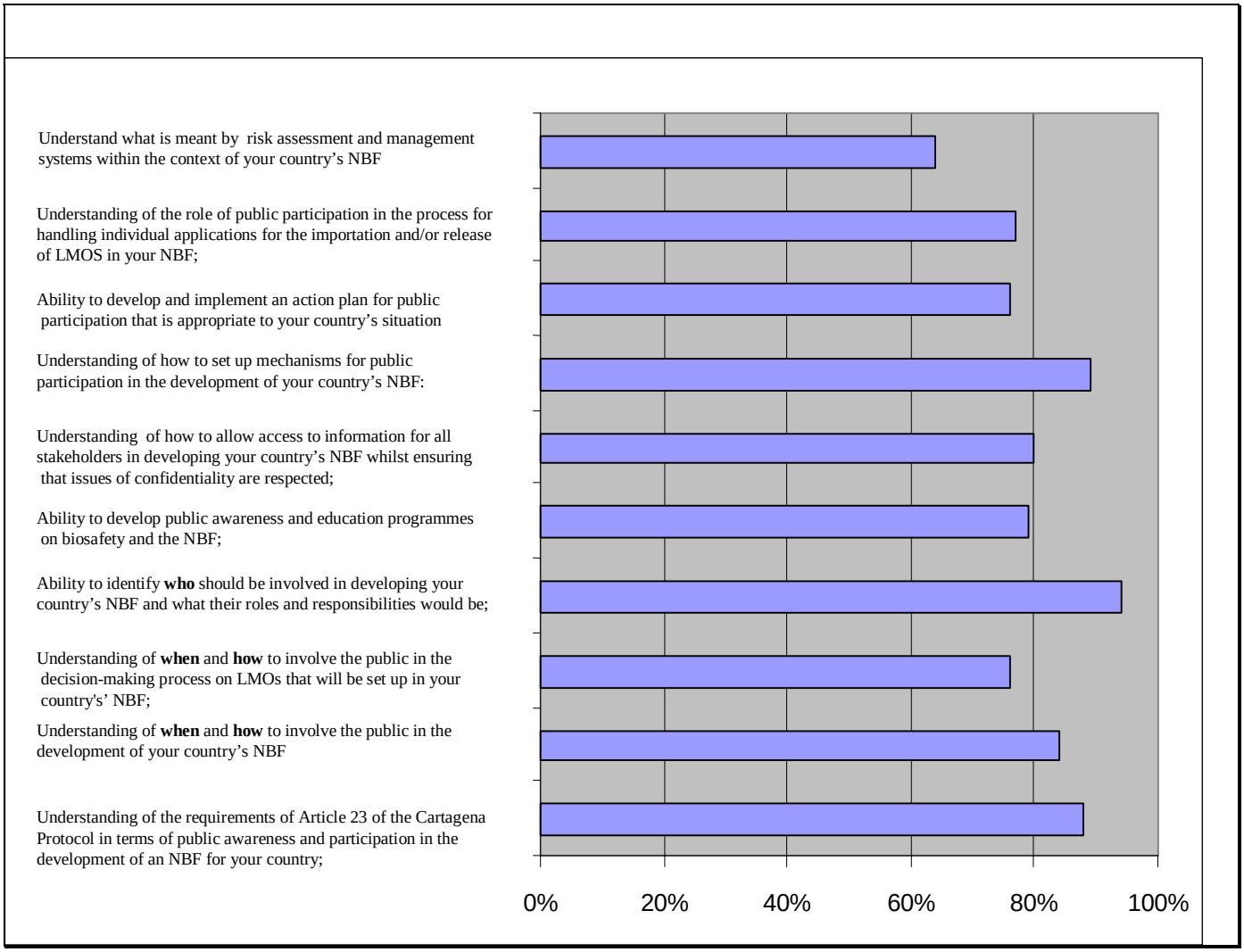
1. Risk Assessment and Management



The understanding of participants in the risk assessment workshops of the term " risk assessment and management system" was rated highest at 86%. This particular rating depicts the success of the workshop on risk assessment and management as indicated under Article 15 and 16 of the Cartagena Protocol on Biosafety. A rating of 84% was shown in the understanding of how participants could put in place the necessary risk assessment and management systems in the development of national biosafety frameworks. The participants' understanding of the process for handling individual applications for the importation and/or release of LMOs was also rated at 82% alongside their increased understanding of the capacity needs in setting up of risk assessment and management systems.

The subject of Precautionary approach had the lowest rating of 64%. It is important that in the subsequent workshops particular attention is paid to this subject to increase the understanding of the participants.

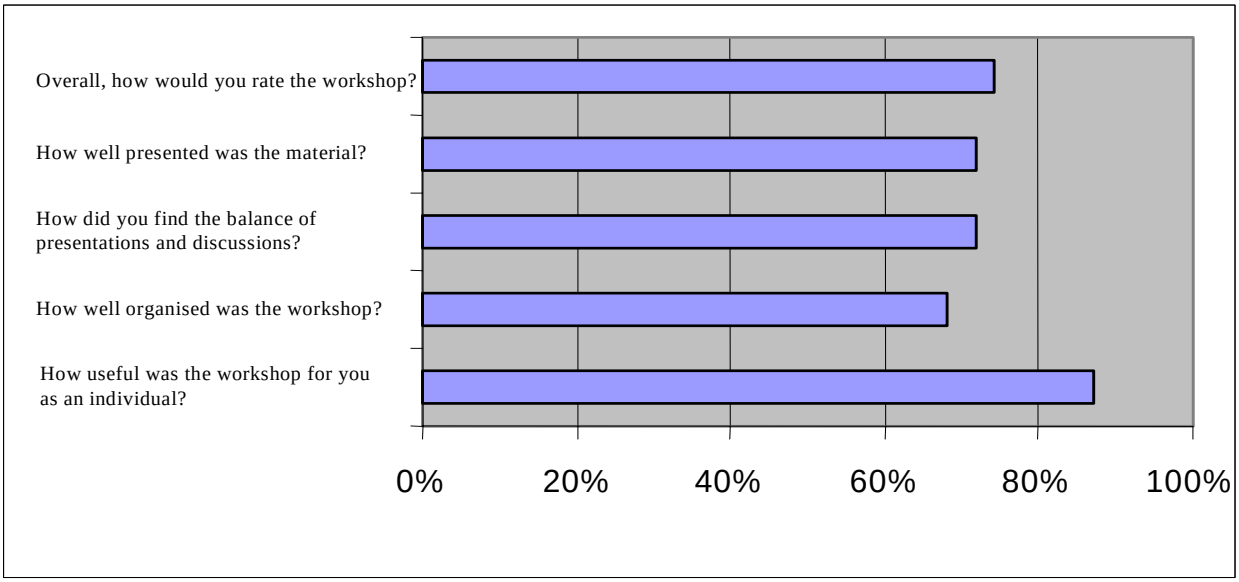
2. Public Awareness and Participation



The question on identification of who should be involved in developing their NBFs and their roles and responsibilities scored highest in the public participation group and was rated 94%. Understanding the mechanisms for public participation in the development of a country's NBF was also rated at 89%. The workshop also clearly increased the participants' knowledge of the requirements put on countries by Article 23, public awareness and participation. That result was rated at 88%.

The least understood of the topics treated at the public awareness and participation workshop was the meaning of risk assessment and management within the context of the national biosafety frameworks, rated at 64%. It is recommended that a more proactive approach be adopted to correct this anomaly at subsequent workshops.

3. Overall workshop assessment



The overall assessment of the workshop by the participants was very good at 74%. The workshop was found by the individual participants to be very useful to them, as this point was rated the highest among the overall assessment attributes at 87%. Participants found some problem with the logistics arrangements during the workshop principally due to their not being paid their Daily Subsistence Allowance (DSA) on the first day, as they would have wished. Participants had also wished they had been given all their DSA so that they could make their own arrangement for accommodation and boarding. This arrangement would have been counter productive to the workshop since it would have been very difficult to control participants.

On some of the personal comments to improve future workshops, participants had wished they could have taken part in the two workshops one after another instead of the concurrent structure, which did not allow this arrangement. Participants were also of the view that the workshops should have been longer since the contents were rather new and complex to many of them.

The participants were full of praise for the openness of views and transparency attached to the workshops when discussing the contents of NBFs. They were also happy with the workshop methodology and the learning by doing method of conducting the workshops, and the balance between plenary and smaller group discussions. In all, a success on a country and an individual basis, and as usual many lessons learnt by participants and organizers