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CONFERENCE OF THE PARTIES TO THE
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Curitiba, Brazil, 13-17 March 2006

REPORT OF THE AD HOC TECHNICAL EXPERT GROUP ON RISK ASSESSMENT

I. PROCEDURAL REPORT

1. The expert group met from 15 to 18 November 2005 in Rome, Italy, with the generous support of the Government of Italy.

2. Twenty-six participants were present, including experts selected from among nominations by Parties to the Protocol (Albania, Brazil, Cameroon, China, Cuba, Estonia, European Community, India, Italy, Kenya, Latvia, Mexico, Netherlands, Norway, Sudan, Syrian Arab Republic), other Governments (Australia, United States of America), and relevant organizations (Codex Alimentarius Commission, the International Plant Protection Convention, UNEP-GEF, the Organization for Economic Co-operation and Development, the Scientific and Technical Advisory Panel of the GEF, the Public Research and Regulation Foundation, and the Global Industry Coalition). A full list of the participants is contained in annex I.

3. The meeting was opened by a representative of the Executive Secretary to the Convention on Biological Diversity at 10 a.m. on Tuesday 15 November 2005. A representative of the Government of Italy welcomed participants. The Secretariat then explained the purpose of the meeting, its mandate, and the expected outputs.

4. The meeting adopted its agenda on the basis of the provisional agenda proposed by the Executive Secretary in document UNEP/CBD/BS/AHTEG-RA/1/1.

5. The meeting elected Mr. Nelson Marmiroli of Italy as its Chair, and Ms. Eliana Fontes of Brazil as its Rapporteur.

6. The work was undertaken entirely in plenary.

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7. The substantive work of the meeting occurred under agenda item 3. Under agenda items 3.1 and 3.2, the Expert Group was requested to consider the nature and scope of existing approaches to risk assessment based on national experiences and existing guidance materials, to evaluate the relevance of existing approaches and guidance materials to risk assessment under the Protocol, and identify gaps in those existing approaches and guidance materials. The meeting had, as a starting point for this agenda item, document UNEP/CBD/BS/AHTEG-RA/1/2 prepared by the Executive Secretary, and document UNEP/CBD/BS/COP-MOP/2/9.

8. The meeting discussed these agenda items at length and made several observations regarding existing guidance and gaps. The group noted that the issues it had identified may not be exhaustive, but cover what are believed to be some of the most important aspects of risk assessment linked to environmental release, but did not extensively consider specific risk-related issues for LMOs intended for direct use as food or feed, or for processing. In its substantive report, the expert group highlighted a few key follow-up activities that could address gaps in existing approaches and guidance materials for risk assessment.

9. The deliberations of the meeting included discussions regarding the decision-making context for risk assessment. This was not directly within the mandate of the meeting, but the group wished to note these discussions because it was apparent that there is not necessarily a common understanding about exactly what falls under risk assessment and what falls under decision-making. In this context, the meeting noted that Parties, in taking decisions under the Protocol on import or release of LMOs, may base those decisions not only on risk assessment as described in Annex III, but also on other considerations such as socio-economic considerations (Article 26). Second, the meeting noted that governments may take into account not only potential risks associated with LMOs, but also the potential environmental, human-health and socio-economic benefits of LMOs, in reaching decisions.

10. The meeting then considered agenda item 3.3 on identification of specific areas where limitations in capacity may be an impediment to effective implementation of the risk assessment provisions of the Protocol at national level, and where capacity-building activities may be particularly important.

11. In considering this item, the Expert Group took note of relevant guidance for capacity-building priorities, including the Action Plan for Building Capacities for the Effective Implementation of Protocol, and the Bali Strategic Action Plan for Technology Support and Capacity-Building of the United Nation's Environment Programme, as well as the comprehensive review of the capacity-building Action Plan planned for consideration at the third meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol.

12. Discussions under agenda item 3 are reflected in the Substantive Report.

13. Regarding agenda item 4 on other matters, the meeting noted the difficulty for some participants to keep up with the pace of discussions, due in part to language difficulties, and therefore emphasized the importance of considering this issue in future.

14. It was also noted that the observers had contributed extensively to the outcome of the meeting, and participated as full members of the group. Furthermore, the Group noted that many relevant organizations were not present in the meeting.

15. The meeting adopted the substance of its draft report, and requested the Chair, the Rapporteur, and the Secretariat to make final editorial changes, including formatting, and other minor changes as necessary.

16. The participants thanked the Government of Italy for hosting the meeting, and also thanked the Chair for guiding the discussions to a successful conclusion.

17. The meeting was closed at 5:00 p.m. on Friday, 18 November 2005.

II. SUBSTANTIVE REPORT

A. Consideration of guidance1/ on risk assessment

1. Diversity in Existing Guidance Materials and Approaches

- A large range of documents and materials exist that can be useful in providing guidance on aspects of risk assessment of LMOs, 2/ ranging from very specific scientific articles to national-level guidance documents, to generic guidance or other documents agreed in specific international fora. Consideration of all available guidance by the expert group during a single meeting is not realistic, but it is important to have a general sense of what guidance exists when identifying potential gaps. Some additional existing guidance materials, which were not covered in the review in document UNEP/CBD/BS/COP-MOP/2/9, are listed in the appendix to this document, but this list is not exhaustive. Further work may be needed to evaluate the relevance of existing guidance materials to the Protocol.
- There is generally a high degree of consistency among existing generic guidance for risk assessment of LMOs along the lines of Annex III of the Protocol and in other fora. As discussed in document UNEP/CBD/COP-MOP/2/9, terminology differs among generic frameworks for risk assessment of LMOs, and the precise delineation of methodological steps may vary, but the core elements, principles and overall methodology are the same. For the purposes of discussions under the Protocol, the terminology and elements contained in Annex III are the basis of discussions on risk assessment.
- Nevertheless, it is important for experts to understand differences in use of terminology in different fora in order to avoid misunderstanding. The Group noted that there are efforts in other fora to discuss issues related to terminology, including development of glossaries.
- The details of the application of risk assessment are case-specific, depending on *inter alia* the type of organism (e.g. plant, animal, micro-organism), the type of trait considered, the intended use of the LMO (e.g., contained use, field trials, commercial release), and the likely potential receiving environment.
- The group generally felt that, at this time, further generic guidance that is applicable to all assessments of risk as outlined in Annex III of the Protocol (e.g., all types of organisms, traits, and all types of hazards), is not a priority.
- There is considerably more guidance on LMO risk assessment available that is relevant to some crop plants, and less in relation to other types of LMOs such as other crop plants, non-crop plants, animals and micro-organisms.

FOLLOW-UP: It is strongly recommended that a more comprehensive list of available guidance documents needs to be prepared, with information on how the various types of guidance are

1/ This section addresses not only guidance materials, but also information such as data sets, case studies, etc., used to support risk assessments.

2/ The group noted that for purposes of discussion during the meeting, terms such as GMO were intended to be generally equivalent to LMO as defined in the Protocol.

applicable to risk assessment in particular cases (e.g., for plants, animals or microorganisms; for specific types of risk pathways; for particular traits; for particular receiving environments, etc.). This could take the form of an overview that shows the applicability of guidance materials, from generic to very detailed guidance, to types of assessments. Such an overview could be made available through the Biosafety Clearing-House.

2. Information to Support Risk Assessments

(i) General Observations

- There is a great deal of relevant existing scientific information on many ecosystems and on many non-GM organisms including those that are being targeted for genetic modification. It is recognized that this information may reflect experience gained in certain regions. This information and experience needs to be thoroughly considered as one of the reference points for risk assessment.
- Baseline information on, and familiarity with, recipient or parental organisms and their receiving environments, may be important to support risk assessment.
- There is a great deal of existing scientific information relevant to risk assessment, including experience gained with LMOs in specific environments over the past several years through research, contained use, field trials, commercial releases, and associated risk assessments.
- Risk assessments should focus on information that is relevant and proportional to the requirements of identification and evaluation of potential adverse effects of LMOs. In practice, this means that information should be requested only if it is clear how that information will be used in the risk assessment. In this context, it should be noted that as risk assessment is carried out on a case-by-case basis, certain data that are considered to be important for risk assessment in one case might not be considered as important in another case, consistent with paragraph 9 of Annex III of the Protocol.
- As stated in Annex III to the Protocol, risks associated with LMOs should be considered in the context of the risks posed by non-modified recipient or parental organisms in the likely potential receiving environment.
- Insufficient baseline information regarding environmental and human-health conditions may often be a key limitation to environmental risk assessment.
- The group noted that insufficient relevant scientific information and knowledge regarding the extent of potential adverse effects of a specific LMO on the conservation and sustainable use of biological diversity may pose challenges.
- Insufficient data may be a particular concern in countries that are centers of origin or centers of genetic diversity.
- Insufficient data is a common challenge for risk assessments in general, and countries may adapt and improve approaches based upon their experience and capabilities.

(ii) Accessibility of Existing Information

- While much relevant information exists, there are often limitations in access to information, as well as understanding of how existing information can be used to support risk assessment. This applies particularly in developing countries but also to developed countries.
- Limitations in access to scientific journals and other resources where new data or studies are reported, as well as material that is not yet available in the literature, can make it difficult for risk assessors to stay up-to-date on information related to risk assessment.

- One key factor contributing to poor accessibility of guidance materials is language, particularly in countries where the local languages are not commonly used at a global level. Many existing guidance documents are not translated, or are translated into few languages.
- National and international databases should play a role in facilitating improved access to existing information. These include databases on, for example, (a) basic biology of many organisms, including taxonomic information and information on distribution, ecology and identification, (b) existing risk assessments.
- The Protocol has established the Biosafety Clearing-House as its mechanism for information-sharing, and it includes risk assessments, guidance documents, compilations of databases and websites, and other relevant types of information. In the case of risk assessments, Parties are obliged to share risk assessment summaries through the BCH, in a standardized format, in accordance with Article 20. Only a few countries are reporting summaries of their risk assessments at this time.
- In addition to the databases on the BCH, other relevant databases include, *inter alia*, the OECD Bio-track database, the risk assessment database of the ICGEB, and databases of the International Life Sciences Institute, but there are many others including national databases that may not be as well known.

FOLLOW-UP: Governments should be encouraged to submit risk assessment summaries to the BCH in the standardized format, giving attention to, as appropriate, how risk assessment problems mentioned above have been solved, in particular how existing information has been used to support risk assessments in these cases.

FOLLOW-UP: The group recommended that a more comprehensive list of relevant databases and information sources needs to be developed, and should be made available through the Biosafety Clearing-House.

FOLLOW-UP: Both Governments and organizations should be encouraged to provide the BCH with links to relevant databases and information sources, and, where appropriate, translate relevant risk assessment data into one or more languages that are commonly used internationally.

- The CBD can help alleviate the lack of accessibility of information through its work on the Global Taxonomy Initiative as well as the programme of work on Agricultural Biodiversity, and through its collaboration with the Global Biodiversity Information Facility. Information-sharing is a key aspect of much of the work under the Convention.

(iii) Generating additional information to support a risk assessment

- In some cases, certain information considered to be important for a risk assessment may not exist, and in those cases it may be necessary to generate further empirical data (e.g., through lab and/or field studies).
- Capacity to generate new information may often be limited in particular regions or at a single-country level.
- Furthermore, determining what information is needed for a risk assessment can also be challenging in cases where capacity is limited.
- Even for traits and organisms for which there is significant experience in some receiving environments, such as Bt maize, risk assessment in a new receiving environment can be difficult if there is limited basic biological and physical information about that receiving environment, or limited familiarity with non-modified recipient or parental organisms.

- Where risk assessment indicates a high probability of gene flow, a major question is whether there may be potential consequences resulting from such gene flow, and how to evaluate those consequences. Information needed to study such consequences is sometimes limited, yet may be of considerable importance, particularly in countries that are centres of origin or centers of genetic diversity.
- When considering the consequences of gene flow as part of risk assessment, various methods, including detection methods, and event-specific information, that facilitate monitoring of the consequences of gene flow in the environment can be useful, depending on the particular case as specified in paragraph 9 of Annex III of the Protocol. Understanding of detection methods, and how and when to use them, are important in this context.

3. Observations Regarding the Scope of Approaches to Risk Assessment

(i) Consideration of Potential Adverse Effects on Conservation and Sustainable Use of Biodiversity

- A key challenge in risk assessment under the Protocol is identifying and evaluating potential adverse impacts of LMOs. Part of this challenge is interpreting and relating data in studies, including risk assessment studies, to enable conclusions about potential effects on conservation and sustainable use of biodiversity.

  FOLLOW-UP: Practical guidance on how to relate endpoints of risk assessments to conservation and sustainable use of biodiversity may be appropriate.

- Another related challenge in risk assessment is identifying, at the start of a risk assessment, what types of risks pathways should be considered.

(ii) Human Health

- The Group recalled that human health is also taken into account in risk assessment under the Protocol.
- Article 2(5) of the Protocol encourages Parties to take into account, as appropriate, available expertise, instruments and work undertaken in international forums with competence in the area of risks to human health
- Some areas of risks to human health, such as food safety, are addressed by other bodies such as the Codex Alimentarius Commission and the World Health Organization
- At national level, different agencies and experts may be involved in addressing human health and environment issues

  FOLLOW-UP: Collaboration among agencies at national and international level is important and should be encouraged.

(iii) Addressing uncertainty in LMO risk assessments

- Scientific uncertainties are inherent in any risk assessment, and it may be important for LMO risk assessments to explicitly identify uncertainties, for example identify sufficiency of scientific information, lack of scientific knowledge, or lack of scientific consensus. There are existing tools and existing expertise related to addressing uncertainty in risk assessment, that have been applied

to risk assessment in other fields. These tools and expertise can be applied to some degree to support risk assessments of LMOs.

(iv) Other considerations in the context of risk assessment

- Stakeholder involvement during a risk assessment process can be very useful in identifying issues of concern that may need to be addressed, and can identify areas where additional information is needed to satisfy those concerns. Stakeholder involvement in risk assessment is common practice in many countries, and there are many available examples at national level.
- Risk assessment processes should allow for the taking into account of relevant new scientific information, and to review the risk assessments as appropriate, even after decisions are taken.
- Risk assessment under the Biosafety Protocol can be, as appropriate, qualitative and/or quantitative.
- Risk assessment should take into account potential changes in selective pressures on biodiversity that may result from LMOs and new uses of LMOs, including changes in human activities associated with those uses.
- The ability or limitations to properly implement risk mitigation measures should be taken into account in risk assessment, in accordance with paragraph 8(e) of Annex III of the Protocol.

(v) Responsibilities for risk assessment

- The group noted that under the Advanced Informed Agreement procedure in the Protocol, the Party of Import's decisions are taken in accordance with risk assessment.
- The Party of Import may request the exporter to supply information that would support an assessment by the Party of Import, or it may request the exporter to conduct a risk assessment (Article 15.2) In either case, the Party of Import determines whether information or assessments supplied by an exporter are adequate to support a decision, or whether additional information or assessment is needed. Details regarding such requirements vary from case to case. Information specific to the receiving environment of the Party of Import may often be required.

4. Plants

(i) General Observations

- There is guidance available for GM plants, including guidance listed in document UNEP/CBD/BS/COP-MOP/2/9 and in the Appendix to this report. Existing guidance developed under IPPC, OECD and other organizations is relevant in some aspects.
- Available guidance is mostly focused on crop plants and not other plants such as trees, yet there is currently much research on the development of GM trees (e.g., for reduced lignin content). Although many aspects of risk assessment for crops are applicable to trees and other plants, other aspects would differ due to characteristics such as the long-life cycles of many tree species.

(ii) Existing Guidance and Specific Gaps

- Application of risk assessment for a specific type of plant or intended use can differ significantly depending on many factors including the nature of the genetic modification, the receiving environment, etc.

FOLLOW-UP: The following list is not exhaustive, but is intended to provide some examples of specific areas where existing guidance may not be sufficient.

(a) New traits introduced into plants
(b) Non-crop plants as recipients of traits
(c) Higher fungi and aquatic plants as recipients of traits
(d) Pharmaceutical or other industrial uses of GM crops (e.g., particular management measures that can be used to mitigate risks)
(e) Guidance on the concept of stacked genes
(f) Potential impacts of GM plants on soil organisms and the environment in general
(g) Risks associated with marker genes (guidance exists but may not be sufficient for all cases)
(h) Guidance on how to address position effects and epigenetic effects in risk assessment

5. Animals

(i) General Observations

- Application of risk assessment for animals can differ significantly depending on the intended use and the type of animal considered, such as fish, mammals, and insects, and even within these broad subgroups, assessments may vary significantly depending on key characteristics of organisms (e.g., flying insects versus non-flying).
- There may be particular concerns in cases where the organism that is modified is not domesticated and is difficult to control once released, as with many fish or insects, or even small rodents, or in cases where modifications may have higher potential to alter selection pressures or to alter ecological relationships in the environment.
- There are some guidance materials and relevant information available that address certain types of GM animals specifically, or that address topics relevant to risk assessment of GM animals. There are some existing guidance materials that may not be dedicated to animals but that have specific sections addressing animals or types of animals, or such materials as developed under the IPPC that deal with pests of plants such as insects and nematodes. These guidance materials include some of those listed in document UNEP/CBD/BS/COP-MOP/2/9 and in the Appendix to this report.

(ii) Existing Guidance and Specific Gaps

- Application of risk assessment for a specific type of animal can differ significantly depending on the intended use of the organism. There are numerous potential uses and the following list is intended to be indicative, not exhaustive. The group made observations regarding existing guidance and potential gaps in guidance for each of these types of uses as follows:

(a) Contained use

There is a significant amount of existing guidance and relevant information related to contained use, and although that guidance may not be totally comprehensive, additional guidance related to contained use may not be a high priority in comparison to the need for guidance related to other uses of GM animals that involve release into the environment.

FOLLOW-UP: However, practical guidance regarding how to use relevant information in risk assessment in specific cases may be appropriate, taking particularly into account the potential significance of the hazards of LMOs used in containment.

(b) Uses in agriculture, aquaculture and the pet industry

This is the dominant intended use of GM animals currently under development. There is some limited guidance and relevant information for risk assessment (e.g., some of the guidance listed in document UNEP/CBD/BS/COP-MOP/2/9 and in the Appendix to this report), and some new guidance is in preparation.

FOLLOW-UP: There is a need for further development of guidance, research on ecological effects, and capacity-building regarding risk assessment of GM animals used in agriculture, aquaculture and the pet industry.

The group noted that the World Organization for Animal Health (OIE) has decided to address biotechnology, and may put some effort into livestock (Resolution 28, 73rd General Session).

(c) Biological control of pests or invasive alien species

There is increasing research and development in this area, in several countries, particularly in light of the challenges in finding ways to effectively control pests or invasive alien species. One example is the use of biotechnology to create sterile insects to lower insect populations.

FOLLOW-UP: There is limited guidance related to use of GM animals as biocontrol agents, and there may be need for guidance in specific cases. There are some case studies that can provide useful information when considering the potential risks associated with biocontrol scenarios. There also is a need for biosafety research, and development of risk assessment methods, for use of GM animals in control of invasive alien species.

6. Microorganisms

(i) General Observations

- Although general risk assessment methodology will not be different for micro-organisms, specific issues for risk assessment can differ significantly, for micro-organisms in general, but also depending on the intended use and the type of micro-organism, such as bacteria, fungi, viruses, and protozoa.
- Risk assessment for micro-organisms can be particularly challenging for several reasons, including:
  (a) Taxonomy for micro-organisms is rapidly changing, mainly due to new genetic information. This makes interpretation of taxonomic data for risk assessment purposes difficult.
  (b) It has become apparent that we only know about a small percentage of the existing micro-organisms. Consequently, baseline information on, and familiarity with, the environmental role of micro-organisms is largely lacking.

(c) Environmental processes are often driven by consortia of micro-organisms that interact, making it even more difficult to understand baseline information about the microbial environment.

(d) While on the one hand prokaryotes and viruses are very susceptible to mutation, selective pressure plays a large role in determining which strains of micro-organisms are successful. Selective pressure is also the driving force for the persistence of microbial strains that have arisen through horizontal gene transfer. Selective pressure is existent in every particular niche in the environment, but human activity, such as large scale use of antibiotics, has created very important niches for particular bacterial strains.

(e) Baseline information on viruses in wild populations is not comprehensive and is important in the context of using GM viruses and vaccines.

(ii) Existing Guidance and Specific Gaps

- In some cases, there are relevant existing guidance materials that may not be specific to GM micro-organisms, for example those developed under the IPPC that deal with pests of plants such as bacteria, fungi and viruses.
- There is considerable work on GM micro-organisms within the OECD Working Group on Harmonization of Regulatory Oversight in Biotechnology. This group has developed guidance on: (a) the use of bacterial taxonomy in risk assessment; and (b) detection methods for micro-organisms in the environment. Work is also underway to draft a document on horizontal gene transfer, and another on the role of pathogenicity in risk assessment. The OECD Working Group is also preparing biology consensus documents for specific groups of micro-organisms.
- Application of risk assessment for a specific type of microorganism can differ significantly depending on the intended use and the type of organism. There are multiple and quite different types of intended use foreseen for modified micro-organisms. The group generated an indicative but not exhaustive list of some of these uses, and made observations for most of these as follows:

(a) Contained use

There is considerable existing experience and guidance related to contained use of GM micro-organisms, including some of the guidance listed in document UNEP/CBD/BS/COP-MOP/2/9 and in the Appendix to this document.

FOLLOW-UP: However, practical guidance regarding how to use relevant information in risk assessment in specific cases may be appropriate, taking particularly into account the potential significance of the hazards of LMOs used in containment.

(b) Live vaccines for use in animals

The group noted that OIE is currently addressing to some extent the issue of the use of live vaccines for use in animals, which has some relevance to risk assessment under the Protocol. There are also case studies on this topic that can be used as a basis for future risk assessments.

(c) Agricultural uses, such as improving soil fertility

(d) Biocontrol including the use of GM viruses

There is some relevant existing information, including some of the guidance referred to in document UNEP/CBD/BS/COP-MOP/2/9 and in the Appendix to this report.

FOLLOW-UP: There may be a need for guidance on specific aspects of the use of GM microorganisms as biocontrol agents.

(e) Industrial applications, such as to facilitate mineral extraction or oil extraction.

Those bacteria may be released into the environment, though potential effects may depend in part on the trait and the scale of release.

(f) Bioremediation

There is some relevant existing information, including some of the guidance referred to in document UNEP/CBD/BS/COP-MOP/2/9 and in the Appendix to this report.

FOLLOW-UP: International guidance on the use of GM micro-organisms for bioremediation is an area that may not be covered by existing international bodies, and may need to be addressed.

(g) Food and feed production

(h) Diagnostic kits

(i) Veterinary pharmaceuticals

B. Capacity-building

1. Specific areas where limitations in capacity may be an impediment to effective implementation of the risk assessment provisions of the Protocol at national level

(i) Human capacity needs

- Experts who have knowledge in scientific fields relevant to risk assessment of LMOs are not necessarily familiar with the methodology of risk assessment itself, yet that understanding is important to ensure that those experts contribute meaningfully to risk assessment.
- Regulators and risk managers who are not experts also need some understanding of risk assessment so that they know what information to ask for and how to evaluate information that is presented to them in assessments.
- Hands-on experience in assessing real cases, including working in interdisciplinary teams, is an effective way to gain competence in risk assessment.
- Building capacity of human resources is not always sustainable, for example due to high or unpredictable staff movements, something that in many cases is problematic and should be prevented.
- Inadequate incentives to retain appropriate personnel (including biosafety researchers, risk assessors and students), particularly in developing countries, contributes to a lack of human resources for risk assessments.

(ii) Infrastructure needs

- Lack of containment and confinement facilities for conducting environmental risk assessment studies.
- Lack of appropriate facilities such as laboratories, including those appropriate for conducting relevant analyses and detection.
- Inadequate access to Internet to retrieve information to support risk assessments.

(iii) Other considerations

- Different countries are at different stages of competency in both biosafety and biotechnology, so mechanisms need to be flexible enough to allow countries to come up to speed as appropriate.
- Mechanisms are needed to involve civil society and other stakeholders, such as farmers, during the risk assessment process.
- There is limited availability of scholarships/fellowships for students (local and foreign) to study risk assessment.
- Information contained in risk assessment reports prepared by other governments can be difficult to use or understand because formats and standards for reporting information, as well as associated rationale, vary widely according to national requirements.
- Some of the relevant expertise is located with the LMO developers (including industry and public sector researchers), but unfortunately use of this expertise may sometimes be limited for various reasons.

2. Specific areas where capacity-building activities may be particularly important with regard to implementation of risk assessment provisions of the Protocol

FOLLOW-UP: This section discusses possible ways to meet the needs identified in Part A on limitations in capacity.

(i) Building human capacity

(a) General aspects

- Ensure sustainability through training and retention of trainers who can perpetuate the benefits within the community, and at national and regional level.
- Build human, information, and infrastructure resources through identification, strengthening or development of centres of excellence, particularly for biosafety, and where possible promote access to needed resources through these centres, particularly at a regional level where they may have experience in similar ecosystems.
- Promote and support South-South and North-South cooperation as well as development of other partnerships.
- Promote synergy at national level between agencies and experts responsible for risk assessment in the context of biosafety, biodiversity conservation, animal health, plant health, ecology, and food safety, given the need for risk assessment expertise in all of those contexts.
- At international level, it is recommended to develop a facility or network, such as a directory, that helps risk assessment experts to link to experts in other countries to informally share experiences and expertise, including experts in closely related or specific fields such as plant health, animal health, ecology, and food safety, as well as mathematical modelling and statistical expertise.
- Ensure Government commitment to retaining and valuing human resources in biosafety.

(b) Training activities

- Increase availability of academic degree-granting programs that focus on training biosafety professionals. The Expert Group noted that this meets a different need than that addressed through short-term training that mostly targets working professionals.
- Provide hands-on training in aspects of interdisciplinary teamwork to risk assessment managers, to ensure the range of potential risks can be considered adequately. Such training might address:
    - How to use interdisciplinary teams during the assessment process
    - How to identify the appropriate expertise
    - How to bring the identified experts together
- Provide hands-on scientific and technical training to improve human capacities, particularly in the following areas:
    - Research to support risk assessment
    - How to conduct risk assessment
- Provide hands-on training in knowledge management to risk assessors, such as:
    - How to find existing information
    - How to use and interpret existing information in a way that addresses the scientific issues of the risk assessment
    - How to identify need-to-know gaps in existing information
    - How to formulate needs for research to fill these gaps
    - How to present risk assessments in a way that is consistent with the methodology of Annex III of the Protocol, to promote information-exchange
    - How to standardize laboratory data
- Accept that training activities are not one-off activities and need to be made available on a regular basis.
- Invest in local scientists, for example by including them in the pool of personnel that are 'trained as trainers' so that they may provide a reservoir of human resources.

(ii) Infrastructure

- Identify, strengthen, or where appropriate, establish facilities, including LMO testing and detection facilities, required to support risk assessments.
- Identify, strengthen, or where appropriate, establish sub-regional and national centres of excellence in biosafety research.

(iii) Other considerations

- Meet needs for research into biosafety, to assist in gathering data to support risk assessments.
- Meet needs for research into biotechnology methodologies.
- Support local biosafety research through exchange and scholarship programs.
- Support, in the context of the Convention of Biological Diversity, baseline research into determining baselines, including agro-biodiversity baselines.
- Share risk assessment information through the internet and other mechanisms, ideally using a standardized format corresponding to risk assessment methodology (such as the reporting formats used to sharing information through the Biosafety Clearing-House).
- There is a need to increase funding for risk assessment research on LMOs.

Appendix

Additional Risk Assessment Guidance and Information Materials Highlighted by Participants

- Office Internationale des Epizooties - World Organisation for Animal Health (OIE). 2004. *Handbook on Import Risk Analysis for Animals and Animal Products. Volume I: Introduction and qualitative risk analysis and Volume II: Quantitative risk analysis*
- Snow AA, Andow DA, Gepts P, Hallerman EM, Power A, Tiedje JM, Wolfenbarger LL. 2004. *Genetically engineered organisms and the environment: current status and recommendations:* Ecological Society of America Position Paper.
- World Trade Organisation. *Agreement on the Application of Sanitary and Phytosanitary Measures* (SPS Agreement). Provisions on risk assessment (e.g., Annex A and Article 5).
- Office Internationale des Epizooties - World Organisation for Animal Health (OIE). 2004. *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*
- Office Internationale des Epizooties - World Organization for Animal Health (OIE) Volume 24 (1), April 2005. *Scientific and Technical Review: Biotechnology Applications in Animal Health and Production*
- Publications of the ICGEB
- Belgian Biosafety Server – *International classification schemes for microorganisms based on their biological risks*
- World Health Organization. 2003. Laboratory Biosafety Manual - 2nd edition. Geneva, 2003.
- National Research Council. 2004. *Biological Confinement of Genetically Engineered Organisms*. Washington, DC. National Academy Press. <http://books.nap.edu/catalog/10880.html>
- National Research Council. 2002. *Animal Biotechnology; Science-Based Concerns*. Washington, DC. National Academy Press. <http://books.nap.edu/catalog/10418.html>
- National Research Council. 2002. *Environmental Effects of Transgenic Plants*. Washington, DC. National Academy Press. <http://books.nap.edu/catalog/10258.html>
- National Research Council. 2000. *Genetically Modified Pest-Protected Plants: Science and Regulation*. Washington, DC. National Academy Press. <http://books.nap.edu/catalog/9795.html>
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Annex I

LIST OF PARTICIPANTS

Chair:

Mr. Nelson Marmiroli, Italy

Experts:

Ms. Arjola Bacu, Albania
Ms. Eliana Maria Gouveia Fontes, Brazil
Mr. Akuro David Mbah, Cameroon
Mr. Wang Changyong, China
Ms. Julia Andrea La Rosa Peraza, Cuba
Mr. Hardo Lilleväli, Estonia
Mr. Eric Schoonejans, European Community
Mr. Terala Venkata Ramanaiah, India
Mr. Harrison Kamau Macharia, Kenya
Mr. Uldis Kalnenieks, Latvia
Ms. Francisca Acevedo Gasman, Mexico
Mr. Hans Bergmans, Netherlands
Mr. Jan Husby, Norway
Mr. Abdelbagi Mukhtar Ali, Sudan
Mr. Bassam Al-Safadi, Syrian Arab Republic

Observers:

Ms. Maria Antonietta Toscano, Italy
Mr. Peter Thygesen, Australia
Mr. David Heron, United States of America
Ms. Noriko Iseki, Codex Alimentarius Commission
Mr. Brent Larson, International Plant Protection Convention
Mr. Giovanni Ferraiolo, UNEP-GEF
Mr. Peter Kearns, Organization for Economic Co-operation and Development
Ms. Anne R. Kapuscinski, Scientific and Technical Advisory Panel of the GEF
Mr. Piet van der Meer, Public Research and Regulation Foundation
Mr. Thomas Nickson, Global Industry Coalition
