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SERVING AS THE MEETING OF THE PARTIES TO
THE CARTAGENA PROTOCOL ON BIOSAFETY
Third meeting
Curitiba, Brazil, 13-17 March 2006
Item 11 of the provisional agenda *

RISK ASSESSMENT AND RISK MANAGEMENT (ARTICLES 15 AND 16)

Note by the Executive Secretary

I. INTRODUCTION

1. In accordance with the medium-term programme of work adopted in decision BS-I/12, the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety considered risk assessment and risk management at its second meeting, and adopted decision BS-II/9 on this item.

2. In paragraph 4 of decision BS-II/9, the Conference of the Parties serving as the meeting of the Parties to the Protocol decided to establish an Ad Hoc Technical Expert Group on Risk Assessment, and welcomed the offer of the Government of Italy to provide the necessary financial support for a meeting of the Group prior to the third meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol. The group met in Rome from 15 to 18 November 2005.

3. The work of the Ad Hoc Technical Expert Group on Risk Assessment focused on the following, as specified in the terms of reference annexed to decision BS-II/9:

(a) Consideration of the nature and scope of existing approaches to risk assessment based on national experiences and existing guidance materials;

(b) Evaluation of the relevance of existing approaches and guidance materials to risk assessment under the Protocol, and identification of gaps in those existing approaches and guidance materials;

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(c) 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.

4. Also in decision BS-II/9, the Conference of the Parties serving as the meeting of the Parties to the Protocol requested the Executive Secretary to prepare a pre-sessional paper for its third meeting synthesizing:

(a) The findings of the meeting of the Ad Hoc Technical Expert Group on Risk Assessment;

(b) Information on experiences and progress in implementing Articles 15 and 16 received in interim national reports under the Protocol, noting that this information would also be reviewed in a synthesis report prepared in advance of the meeting of the Ad Hoc Technical Expert Group on Risk Assessment;

(c) The submissions on risk assessment and risk management received from Parties, other Governments and international organizations (UNEP/CBD/BS/COP-MOP/2/INF2), as well as the synthesis of views and compilation of guidance materials (UNEP/CBD/BS/COP-MOP/2/9).

5. The report of the Ad Hoc Technical Expert Group on Risk Assessment is available in an information document (UNEP/CBD/BS/COP-MOP/3/INF/1).

6. The synthesis of information related to risk assessment and risk management received in interim national reports on implementation of the Protocol was made available to the Ad Hoc Technical Expert Group (UNEP/CBD/BS/AHTEG-RA/1/2).

7. Section II of this paper reviews the main conclusions drawn from the information received in interim national reports. Section III reviews the main conclusions identified in the report of the Ad Hoc Technical Expert Group. Section IV recalls the views on risk assessment and risk management submitted in advance of the second meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol. Section V briefly analyses elements of sections II to IV which can be compared. Finally, section VI of the document presents elements of a draft decision.

II. ANALYSIS OF INTERIM NATIONAL REPORTS

8. Information related to risk assessment and risk management received in interim national reports on implementation of the Biosafety Protocol was synthesized in a note by the Executive Secretary (UNEP/CBD/BS/AHTEG-RA/1/2). The information was based on the 44 interim national reports that had been received. There were eight questions in the interim reporting format related to risk assessment and risk management (the full format can be found annexed to decision BS-I/9 of the first meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol).

9. Results should be interpreted carefully, in particular because only about one third of the Parties submitted interim reports, and because reporting countries are self-selecting (i.e. results were analysed only from those Parties that submitted reports), therefore results may be biased towards countries that are better able to submit the reports for any reason, such as stronger monitoring and reporting capacities, or language accessibility.

10. A few preliminary general conclusions were drawn from the analysis:

(a) Few countries have imported living modified organisms for intentional introduction into the environment. Most of those countries that have imported living modified organisms for intentional introduction into the environment have required the exporter to carry out the risk assessment and have required the notifier to pay for the risk assessment;

(b) Mechanisms and measures to implement the risk-assessment and risk-management provisions of the Protocol are operational to a large extent in the Western Europe and Others Group (WEOG) and Central and Eastern European (CEE) regions, and to a lesser extent in Asia and the Pacific, Africa, and Latin America and the Caribbean;

(c) Many Central and Eastern European countries use the European Community (EC) legislation as their basis for risk assessment of living modified organisms, and are operationalizing EC directives in that regard;

(d) Many developing countries seem to be at a stage where they have developed a draft framework for biosafety but are not yet at a stage of implementation.

11. In addition to the information provided in interim national reports regarding risk assessment and risk management, a number of Parties noted, in the section on capacity-building, specific capacity needs in the area of risk assessment and risk management (see document UNEP/CBD/BS/COP-MOP/3/12).

12. It should also be noted that one interim national report expressed the view that further guidelines supplementing Articles 15, 16 and annex III of the Protocol are necessary for a common approach. The same report expresses the view that a scientific committee could be appointed with the task of providing scientific and technical guidance on risk assessment guidelines.

III. MAIN CONCLUSIONS OF THE AD HOC TECHNICAL EXPERT GROUP

13. The report of the Ad Hoc Technical Expert Group (UNEP/CBD/BS/COP-MOP/3/INF/1) is divided into a short procedural report and a longer substantive report. The substantive report includes a number of findings as well as potential follow-up activities. The following is a summary of some of the main points raised in the report, with particular focus on potential follow-up activities that were identified.

(i) Consideration of existing guidance materials

14. 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. Rather, there may be need for specific types of guidance to address, for example, particular types of living modified organisms or particular uses of living modified organisms. Specific areas where guidance may be appropriate are highlighted throughout the report, and are noted in subsections (iii) to (vi) below.

15. *Follow-up*: A more comprehensive list of available guidance documents needs to be prepared, with information on how the various types of guidance are applicable to risk assessment in particular cases (e.g., for plants, animals or micro-organisms; 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.

(ii) Information to support risk assessments

16. There is a great deal of existing information, including basic ecological information and experiences with both modified and non-modified organisms, that is relevant to risk assessment of living modified organisms. This information needs to be thoroughly considered in risk assessment. Nevertheless, since risk assessment is carried out on a case-by-case basis, the information needed to support risk assessment will vary, and there may often be limitations to information for particular types of organisms and particular types of receiving environments.

17. There are limitations in the accessibility of existing information, including limitations in understanding of how existing information can be used to support risk assessment. Limitations in accessibility of information may occur for various reasons, including language as well as limited sharing of information through Internet-based databases.

18. The following potential *follow-up* activities may improve accessibility of existing information:

(a) Governments should be encouraged to submit risk-assessment summaries to the Biosafety Clearing-House in the standardized format, giving attention to, as appropriate, how risk assessment problems have been solved, in particular how existing information has been used to support risk assessments in these cases;

(b) A more comprehensive list of relevant databases and information sources needs to be developed, and should be made available through the Biosafety Clearing-House;

(c) Both Governments and organizations should be encouraged to provide the Biosafety Clearing-House 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.

19. In cases where certain information considered to be important for a risk assessment does not exist, it may be necessary to generate further empirical data, for example through lab and/or field studies. This need may arise, for example, when considering risks in a new receiving environment about which there is limited basic biological and physical information relevant for the risk assessment.

(iii) Scope of approaches to risk assessment

20. A key challenge lies in extrapolating data from studies to conclusions about potential effects of living modified organisms on biodiversity.

21. *Follow-up*: Practical guidance on how to relate endpoints of risk assessments to conservation and sustainable use of biodiversity may be appropriate.

22. Human health is taken into account in risk assessment under the Protocol, and at national level, different agencies and experts may be involved in addressing human health and environment issues.

23. *Follow-up*: Collaboration among agencies at national and international level is important and should be encouraged.

24. Scientific uncertainties are inherent in any risk assessment, and existing tools and expertise for addressing uncertainties can be applied to some degree to support risk assessments of living modified organisms.

(iv) Plants

25. There is guidance available for risk assessment of genetically modified plants, mostly focused on crop plants and less so on other plants such as trees.

26. *Follow-up*: Examples of specific areas where existing guidance may not be sufficient include:

(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 genetically modified 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 genetically modified 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.

(v) Animals

27. Application of risk assessment for animals can differ significantly depending on the intended use and the type of animal considered, and that there are guidance materials and relevant information available that address certain types of genetically modified animals specifically, or that address topics relevant to risk assessment of genetically modified animals.

28. Potential *follow-up* regarding guidance for particular types of uses for genetically modified animals includes (note: these uses are intended to be indicative and not exhaustive):

(a) With respect to genetically modified animals in contained use, 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 living modified organisms used in containment;

(b) There is a need for further development of guidance, research on ecological effects, and capacity-building regarding risk assessment of genetically modified animals used in agriculture, aquaculture and the pet industry;

(c) There is limited guidance related to use of genetically modified 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 genetically modified animals in control of invasive alien species.

(vi) Micro-organisms

29. Risk assessment for micro-organisms can be particularly challenging for a number of reasons, and specific issues for risk assessment may vary significantly depending on the intended use and the type of micro-organism.

30. There are guidance materials relevant to risk assessment of genetically modified micro-organisms, and considerable work has been done and is currently under way within the Organisation for Economic Co-operation and Development (OECD).

31. *Follow-up*: There may be need for specific guidance in relation to particular uses of genetically modified micro-organisms, for example (note: the group made an indicative but not exhaustive list of nine uses of genetically modified micro-organisms, and made observations regarding some of these as detailed in the report):

(a) Regarding contained use, 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 living modified organisms used in containment;

(b) There may be a need for guidance on specific aspects of the use of genetically modified micro-organisms as biocontrol agents;

(c) International guidance on the use of genetically modified micro-organisms for bioremediation is an area that may not be covered by existing international bodies, and may need to be addressed.

(vii) Capacity-building

32. There are several areas where limitations in capacity may be an impediment to effective implementation of the risk-assessment provisions of the Protocol at national level. These relate to, *inter alia*, human capacity-needs and infrastructure needs.

33. Possible ways to address capacity limitations include the following (see the report for full list and additional details):

(a) Promoting partnerships including South-South and North-South cooperation;

(b) Promoting synergy at national level between agencies and experts;

(c) Developing a facility or network at international level to allow experts to link with other experts;

(d) Increasing the availability of degree-granting programmes that focus on training biosafety professionals, as well as exchange and scholarship programmes;

(e) Training in aspects of interdisciplinary teamwork;

(f) Training in research to support risk assessment and how to conduct risk assessment;

(g) Training in knowledge management, including how to find, use and interpret existing information, how to identify and address need-to-know gaps in information, and how to present risk assessments;

(h) Identifying, strengthening, or where appropriate, establishing testing and detection facilities for living modified organisms;

(i) Identifying, strengthening, or where appropriate, establishing regional, subregional and national centres of excellence in biosafety research;

(j) Sharing of risk assessment information through the internet and other mechanisms, including through the Biosafety Clearing-House;

(k) Increasing funding to support risk assessment research.

IV. VIEWS ON RISK ASSESSMENT AND RISK MANAGEMENT SUBMITTED PRIOR TO THE SECOND MEETING OF THE CONFERENCE OF THE PARTIES SERVING AS THE MEETING OF THE PARTIES TO THE PROTOCOL

34. Prior to the second meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol, submissions on risk assessment and risk management were compiled in an information document (UNEP/CBD/BS/COP-MOP/2/INF/2), and summarized in a note by the Executive Secretary (UNEP/CBD/BS/COP-MOP/2/9).

35. Among the small number of submissions received, only three commented directly on the need for additional guidance related to risk assessment. Specifically, two submissions stated that additional guidance expanding on the Protocol text is not necessary, while one expressed the view that risk assessment requires further collaboration.

V. COMPARATIVE ANALYSIS

36. The Ad Hoc Technical Expert Group explored existing guidance and capacity-building relevant to risk assessment in considerable detail. While the information on experiences and progress in implementing Articles 15 and 16 received in interim national reports under the Protocol, and the submissions on risk assessment and risk management received in advance of the second meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol, are not as detailed, it is nevertheless possible to make a couple of general comparisons of the findings arising from these three sources of information.

37. With regard to the possible need for additional guidance related to risk assessment, as mentioned above, two submissions received in advance of the second meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol stated that additional guidance expanding on the Protocol text is not necessary, while one expressed the view that risk assessment requires further elaboration. In the interim national reports, one Party submitted the view that further guidelines supplementing Articles 15, 16 and annex III of the Protocol are necessary for a common approach. None of these views explicitly distinguish between the possible need for generic guidance and the possible need for more specific types of guidance, which was an important distinction made by the Ad Hoc Technical Expert Group.

38. With regard to capacity-building, the information in interim national reports supports the general conclusion that capacity limitations are, for developing country Parties in particular, an impediment to effective implementation of the risk assessment and risk management provisions of the Protocol. In addition to the specific suggestions of the Ad Hoc Technical Expert Group for addressing capacity limitations, findings from the comprehensive review of the Action Plan for the Effective Implementation of the Cartagena Protocol on Biosafety may also be relevant to risk assessment.

VI. ELEMENTS OF A DRAFT DECISION

A. Existing guidance and information to support risk assessment

39. With regard to existing guidance and information to support risk assessment, the Conference of the Parties serving as the meeting of the Parties to the Protocol may wish to consider the following elements of a draft decision:

"The Conference of the Parties serving as the meeting of the Parties to the Protocol,

"1. *Requests* the Executive Secretary to

"(a) Expand the compilation of available guidance documents on risk assessment contained in the Biosafety Information Resource Centre;

"(b) Provide an overview, through the Biosafety Clearing-House, showing the scope and applicability of each guidance material (e.g., for plants, animals or micro-organisms; for specific types of risk pathways; for particular traits; for particular receiving environments, etc.);

"2. *Invites* Parties, other Governments and relevant organizations to provide the Biosafety Clearing-House with additional links to databases and information sources relevant to risk assessment and, where possible and appropriate, translate relevant information into one or more languages that are commonly used internationally;

"3. *Encourages* Parties and other Governments, in submitting risk assessment summaries to the Biosafety Clearing-House in accordance with Article 20 of the Protocol, to include details regarding how particular challenges have been addressed and how existing information has been used to support risk assessments;

"4. *Recommends* that Parties and other Governments put in place mechanisms for ensuring collaboration among agencies at national level dealing with, *inter alia*, environment and human health issues related to biosafety;

"5. *Urges* relevant United Nations bodies and other organizations that deal with biodiversity and human health issues to continue to collaborate, as appropriate, with regard to biosafety."

B. Potential need for additional guidance

40. With regard to the potential need for additional guidance related to *specific* aspects of risk assessment, the Conference of the Parties serving as the meeting of the Parties to the Protocol may wish to consider the findings of the report of the Ad Hoc Technical Expert Group, including the potential follow-up activities referred to above in paragraphs 21, 26, 28 and 31.

41. In considering any potential follow-up activities, the Conference of the Parties serving as the meeting of the Parties to the Protocol may wish to consider specifically:

1. Whether further discussion is needed in order to determine whether and exactly what type of additional guidance may be appropriate, and if so, the mechanism for such further consideration;

2. In the event that a need for additional guidance is identified, what bodies, forums or processes would be suitable for development of additional guidance;

C. Capacity-building

42. With regard to capacity-building relevant to risk assessment, the Conference of the Parties serving as the meeting of the Parties to the Protocol may wish to consider the following elements of a draft decision:

The Conference of the Parties serving as the meeting of the Parties to the Protocol,

1. *Recalls* the emphasis given to risk assessment and other scientific and technical expertise, as a key element requiring concrete action, in the Action Plan for Building Capacities for the Effective Implementation of the Cartagena Protocol on Biosafety;

2. *Urges* Parties, other Governments and relevant organizations to promote south-south and north-south partnerships as a means to increase the capacity available to Parties to implement the risk assessment provisions of the Protocol;

3. *Urges* Parties and other Governments to promote cooperation and synergies at national level between agencies and experts in order to draw widely on the experience and expertise relevant to risk assessment;

4. *Requests* the Executive Secretary to collaborate with relevant organizations such as the Food and Agriculture Organization of the United Nations, to promote networking and inter-linkages between experts in risk assessment of living modified organisms and experts in other relevant fields of risk assessment (e.g., plant health, animal health, food safety), using, *inter alia*, Internet portals such as the Biosafety Clearing-House and the International Portal on Food Safety, Animal & Plant Health;

5. *Encourages* Parties and other Governments to invite universities and colleges to develop and/or expand degree-granting programmes that focus on training biosafety professionals;

6. *Encourages* Parties, other Governments and relevant organizations to promote, develop, and/or participate in, as appropriate, exchange and scholarship programs related to biosafety;

7. *Encourages* relevant donor Governments and organizations to support and/or develop, as appropriate, practical training activities in the following areas:

(a) Interdisciplinary teamwork in the context of risk assessment;

(b) Research to support risk assessment and how to conduct risk assessment;

(c) Knowledge management, including how to find, use and interpret existing information, how to identify and address need-to-know gaps in information, and how to present risk assessments;

8. *Encourages* relevant donor Governments and organizations to support, strengthen, or where appropriate, establish testing and detection facilities for living modified organisms, as well as regional, sub-regional and national centres of excellence in biosafety research;

9. *Encourages* Parties, other Governments and relevant organizations to share information related to risk assessment of living modified organisms through the Biosafety Information Resource Centre of the Biosafety Clearing-House, as well as through other Internet and non-Internet based mechanisms;

10. *Encourages* relevant donor Governments and organizations to fund and support risk-assessment research.
