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CONFERENCE OF THE PARTIES TO THE CONVENTION ON BIOLOGICAL DIVERSITY SERVING AS THE MEETING OF THE PARTIES TO THE CARTAGENA PROTOCOL ON BIOSAFETY
Fourth meeting
Bonn, 12-16 May 2008
Item 11 of the provisional agenda**

RISK ASSESSMENT AND RISK MANAGEMENT (ARTICLES 15 AND 16)

Note by the Executive Secretary

I. INTRODUCTION

1. The Cartagena Protocol on Biosafety sets out provisions on risk assessment (Article 15 and Annex III) and risk management (Article 16) in order to identify, evaluate, regulate, manage and control possible adverse effects and risks of living modified organisms on the conservation and sustainable use of biodiversity, taking also into account risks to human health.

2. At its second meeting, the Conference of the Parties serving as the meeting of the Parties to the Protocol (COP-MOP) adopted a decision on risk assessment and risk management (decision BS-II/9), which, among other things, acknowledged that any guidance on risk assessment and risk management developed by the Parties to the Protocol should support a harmonized approach, in accordance with Annex III of the Protocol, taking into account internationally-agreed principles and techniques developed by relevant international organizations and bodies.

3. In the same decision, the Executive Secretary was requested to convene, prior to the fourth meeting of the Parties to the Protocol, and subject to the necessary financial resources being made available, regional workshops on capacity-building and exchange of experiences on risk assessment and risk management of living modified organisms.

4. At their third meeting, the Parties to the Protocol took note of the report of the Ad Hoc Technical Expert Group on Risk Assessment (UNEP/CBD/COP-MOP/3/INF/1), held in Rome in November 2005. The report noted that there are potential gaps in the guidance for risk assessment for emerging applications of modern biotechnology, namely in trees, fish, veterinary applications and specific plant varieties. In paragraph 2 of decision BS-III/11, the Parties requested the Executive Secretary to expand

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** UNEP/CBD/BS/COP-MOP/4/1.

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the compilation of available guidance documents on risk assessment and risk management and to provide an overview of the scope and applicability of each guidance material.

5. With the objective of generating information to assist the discussion, at the fourth meeting of the Parties to the Protocol, on the potential need for additional guidance regarding specific aspects of risk assessment and risk management of living modified organisms, the Governments of Norway and Canada offered to support an expert workshop on risk assessment for emerging applications of modern biotechnology. Section III of this document presents an analysis of workshop results.

6. In paragraph 9 of decision BS-III/11, the Parties to the Protocol agreed to "consider at its fourth meeting the need for further guidance on specific aspects of risk assessment and risk management, and the appropriate modalities for development of any such guidance such as a further meeting of the Ad Hoc Technical Expert Group on Risk Assessment, taking into account, *inter alia:*

(a) The compilation and overview of guidance materials provided through the Biosafety Clearing-House;

(b) The results of the regional workshops on capacity-building and exchange of experiences on risk assessment and risk management called for in paragraph 2 of decision BS-II/9; and

(c) The ongoing work of relevant United Nations bodies and other organizations."

7. In addition, the COP-MOP are invited to further address an item in the medium-term programme of work regarding cooperation in identifying living modified organisms or specific traits that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and taking appropriate measures regarding the treatment of such living modified organisms or specific traits. 1/

8. This document has been prepared to assist the Parties to the Protocol in their consideration of the agenda item on risk assessment and risk management. Section II contains an analysis of the main achievements and conclusions drawn from the regional workshops on capacity building and exchange of experiences on risk assessment and risk management of living modified organisms. Section III contains an overview of other relevant activities on risk assessment and risk management during the intersessional period that might be relevant to the discussion. Section IV reviews the current status of guidelines on risk assessment and risk management available in the Biosafety Information Resource Centre of the Biosafety Clearing-House. Section V contains an overview of available decisions and opinions identifying living modified organisms or specific traits that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health. Section VI derives some conclusions while section VII proposes some elements of a draft decision on risk assessment and management for the consideration of the Parties.

1/ Decision BS-I/12, paragraph 4 (b).

II. ANALYSIS OF THE REGIONAL WORKSHOPS ON CAPACITY-BUILDING AND EXCHANGE OF EXPERIENCES ON RISK ASSESSMENT AND RISK MANAGEMENT OF LIVING MODIFIED ORGANISMS

9. In responding to decision BS-II/9, the Secretariat organized three regional workshops on capacity-building and exchange of experiences on risk assessment and risk management of living modified organisms. 2/

10. The objectives of the workshops were as follows:

(a) To learn more about risk assessment and risk management in the context of the Biosafety Protocol and to review the general concepts, principles and methodologies;

(b) To exchange practical experiences and lessons learned in conducting/reviewing risk assessments and implementing risk management measures;

(c) To review existing guidance materials on risk assessment and risk management and consider the need for further guidance;

(d) To review the format and key elements of risk-assessment reports/dossiers and summaries for living modified organisms; and

(e) To identify mechanisms for promoting cooperation and networking in risk assessment and risk management at the regional level, including the exchange of information, expertise, training materials and risk assessment tools.

11. The workshop participants identified several challenges and priorities for the effective implementation of risk assessment and risk management in their countries and regions. These priorities and challenges are primarily related to issues in the application of the emerging regulatory frameworks, human and financial resources, guidance material, networking and public participation. Within their emerging regulatory frameworks, the participants identified the lack of adopted procedures and criteria, as well as methods and national standards for LMO detection and quantification as some of the main challenges for conducting effective LMO risk assessment. The lack of resources was characterized by an insufficiency of accredited laboratories for LMO detection and analysis, scarce financial resources and the limited number of experienced experts in the area of risk assessment and risk management. Challenges in accessing guidelines on how to conduct risk assessment and a lack of guidance for specific types of risk assessment were pointed out as the main challenges related to guidance material. Establishing official cooperation with risk-assessment experts among countries and within regions was the main challenge related to developing networks.

12. Workshop participants made the following recommendations related to implementation, training, guidance material and networking aimed at improving risk- assessment and risk-management procedures and building capacities:

(a) *Implementation*: developing projects and activities for the implementation of existing or planned regulatory and administrative systems needed for risk assessment and risk management;

2/ The workshops were held in Addis Ababa (23-25 August 2007) for the Africa region; Chisinau (26-28 November 2007) for the CEE region; and Bridgetown (10-12 December 2007) for the GRULAC region. The workshops were attended by 97 participants from 51 countries and 23 organizations involved in risk assessment and risk management of living modified organisms. A workshop for the Asia subregion is scheduled to be held in Kuala Lumpur in April 2008.

development of the mechanism of reviewing the outcomes of the risk assessment by the national biosafety commissions/committees (NBC), including NBC procedures and guidelines on risk assessment;

(b) *Training*: holding of training activities on biosafety, risk-assessment and risk-management topics for specialists of the various multidisciplinary sectors for re-orientation into biosafety risk assessment; organizing training courses on detection and sampling methods for different LMOs; inclusion of biosafety, risk assessment and risk management topics in university curricula to help increase the capacity of the necessary specialists;

(c) *Guidance material*: promoting the exchange of information and experience with regard to risk assessment, results of risk assessment, final decisions and results of inspections and monitoring; preparation of a directory with the technical guiding principles of risk assessment;

(d) *Networking*: establishing mechanisms for regional and international cooperation and sharing of experiences in risk assessment and risk management; establishing an Intergovernmental Biosafety Advisory Council for the harmonization of biosafety legislation systems and efficient cooperation between biosafety administrative systems; organizing efficient ways for official collaboration between countries on risk assessment and management through exchange of information, as well as joint inspections and monitoring, especially in boundary regions.

13. In addition, UNEP-GEF and the Convention Secretariat were invited to:

(a) Facilitate the organization of regular hands-on training for risk assessment and risk management experts;

(b) Organize regular workshops for the exchange of experience for experts and national authorities;

(c) Publish and distribute educational materials, guidelines on risk assessment and risk management and materials about global experience in these fields;

(d) Organize efficient online systems for sharing news and information on biosafety, risk assessment and bioengineering.

14. A recommendation of the Ad Hoc Technical Expert Group on Risk Assessment, held in Rome in November 2005, encouraged governments to submit risk assessment summaries to the BCH in a standardized format and to set out, as appropriate, how risk assessment problems have been solved. In this regard, the workshops noted that the current BCH common format for risk assessment summaries lacks certain elements/fields that would enable countries to submit key useful factual information. Therefore the regional workshops on risk assessment made a number of recommendations for additional elements/fields or sub-headings to the current common format. A new common format for risk-assessment summaries is therefore being prepared.

15. The full reports of the workshops on capacity-building and exchange of experiences on risk assessment and risk management of living modified organisms are available as information documents (UNEP/CBD/BS/COP-MOP/4/INF/14-17).

III. OTHER RELEVANT ACTIVITIES ON RISK ASSESSMENT AND RISK MANAGEMENT OF LIVING MODIFIED ORGANISMS

A. Canada-Norway Expert Workshop on Risk Assessment for Future Applications of Modern Biotechnology, Montreal, 4-6 June 2007

16. The Canada-Norway Expert Workshop on Risk Assessment for Future Applications of Modern Biotechnology was organized to generate information to assist the discussion of the fourth meeting of the Parties to the Protocol on the potential need for additional guidance on specific aspects of risk assessment and risk management of living modified organisms, such as guidance on particular types and intended uses of living modified organisms. The workshop was held in Montreal from 4 to 6 June 2007 and was attended by 62 experts, including experts from the Parties to the Protocol, other Governments and relevant organizations.

17. The experts at the workshop agreed that the general principles and methodologies for risk assessment contained in Annex III to the Cartagena Protocol also apply to transgenic fish, trees, viruses and pharmaplants (i.e., plants that produce pharmaceutical compounds). Further it was agreed that all risk assessments of living modified organisms should be conducted on a case-by-case basis as the impacts depend upon the trait inserted, the recipient organism, and the environment into which it is released.

18. It was noted that there is insufficient guidance on how to perform risk assessment for certain living modified organisms and, hence, there is a need for additional data on several elements necessary to conduct risk assessments for all four types of modified organisms (fish, trees, viruses and pharmaplants). There may be a need to develop specific methodologies and specific protocols for generating data necessary to conduct risk assessments for future applications of modern biotechnology, especially for transgenic fish, trees and viruses. Further research was recommended to fill the knowledge gaps and, specifically, the gaps identified during the workshop and listed in the report.

19. During the workshop, it was recommended that existing guidelines, methodologies, baseline information and risk assessments should be made readily available through the Biosafety Clearing-House and other relevant international databases.

20. The full report of the Canada-Norway Expert Workshop on Risk Assessment for Future Applications of Modern Biotechnology is available as an information document (UNEP/CBD/BS/COP-MOP/4/INF/13).

B. South East Asian Workshop on Risk Assessment of GMOs/LMOs and Enforcement of Biosafety Regulations, Kuala Lumpur 4-6 December 2007

21. The South East Asian Workshop on Risk Assessment of GMOs/LMOs and Enforcement of Biosafety Regulations was organized by the Ministry of Natural Resources and Environment of Malaysia and the Federal Environment Agency of Austria in collaboration with the ASEAN Centre for Biodiversity, Third World Network and UNDP-GEF. The seventy-three (73) participants in this workshop included representatives from government, academia, industry and non-governmental organizations. UNEP and UNDP representatives were also present. The Workshop provided training in scientific risk assessment of GMOs/LMOs and served to increase knowledge in issues necessary for the enforcement of biosafety regulations such as inspection and detection; and provided a platform for learning from the biosafety implementation experiences of other countries in the region.

C. Ninth International Symposium on Biosafety of Genetically Modified Organisms, Jeju Island, South Korea, 24-29 September 2006

22. The Ninth International Symposium on Biosafety of Genetically Modified Organisms was organized by the International Society for Biosafety Research (ISBR). The theme of the 2006 symposium was "Biosafety Research and Environmental Risk Assessment" and covered topics on: Biosafety Research and Risk Assessment; Identifying and Defining Hazards and Potential Consequences; Estimating Likelihood and Exposure; Risk Management and Monitoring; and Future Developments. As in previous ISBR symposia, the meeting focused on scientific findings that are relevant to regulatory decision-making worldwide. The symposium fostered an open exchange of ideas and information to facilitate outreach between scientists with biosafety research experience and parties interested in developing effective regulatory or biosafety programs. Documents from this symposium are available through BIRC. 3/

IV. AVAILABILITY OF GUIDELINES ON RISK ASSESSMENT AND MANAGEMENT IN THE BIOSAFETY INFORMATION RESOURCE CENTRE OF THE BIOSAFETY CLEARING-HOUSE

23. In its report, the Ad Hoc Technical Expert Group on Risk Assessment 4/ identified a need for additional guidance on specific aspects of risk assessment and risk management. Some potential follow-up activities were suggested to improve accessibility of existing information through the Biosafety Clearing-House. These include:

(a) 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;

(b) A more comprehensive list of relevant databases and information sources needs to be developed;

(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.

24. Following a request made to the Executive Secretary in paragraph 2 of decision BS-III/II (see paragraph 4 above, 5/ the compilation of guidance documents on risk assessment and risk management was expanded and made available at the Biosafety Information Resource Centre (BIRC) of the Biosafety Clearing-House. A list of available guidance documents with categorized sub-topics according to specific

3/ https://bch.cbd.int/database/record.shtml?id=41912.

4/ The Ad Hoc Technical Expert Group on Risk Assessment met in order to: (i) consider the nature and scope of existing approaches to risk assessment based on national experiences and existing guidance materials; (ii) evaluate 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; and (iii) identify 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. The report of the Ad Hoc Technical Expert Group on Risk Assessment was made available during COP-MOP-3 as an information document (UNEP/CBD/BS/COP-MOP/3/INF/1) available at http://www.cbd.int/doc/?meeting=MOP-03.

5/ See paragraph 4 above.

aspects of risk assessment was prepared and is available in the information document UNEP/CBD/BS/COP-MOP/4/INF/22. A search option for finding external databases and sources information was also added to the BIRC.

25. Guidance on many specific aspects of risk assessment and risk management was deemed insufficient both by the experts in the Ad Hoc Technical Expert Group on Risk Assessment meeting and at the Canada-Norway Workshop on Risk Assessment for Future Applications of Modern Biotechnology. In order to fulfil the need for guidance on specific aspects of risk assessment and risk management, it was acknowledged that it may be necessary to generate further empirical data, for example through laboratory and/or field studies. This need may arise, for example, when considering risks in a new receiving environment with limited basic biological and physical information relevant for the risk assessment. Accordingly, it was suggested that it might be necessary to establish a mechanism/networks able to generate these data to fill up the information gaps.

V. OVERVIEW OF AVAILABLE DECISIONS AND OPINIONS IDENTIFYING LIVING MODIFIED ORGANISMS OR SPECIFIC TRAITS THAT MAY HAVE ADVERSE EFFECTS ON THE CONSERVATION AND SUSTAINABLE USE OF BIOLOGICAL DIVERSITY, TAKING ALSO INTO ACCOUNT RISKS TO HUMAN HEALTH

26. Opinions with respect to the environmental impacts of some LMOs (whether positive or negative) do not necessarily apply to all transformation events carrying a novel trait. Thus, risk assessment to identify the potential of LMOs or specific traits that may cause an adverse impact on the environment or on human health must be carried out on a case-by-case basis and in a sound scientific manner. Based on compiled information from biosafety regulatory bodies, the assessment of potential impacts originating from the release of living modified organisms to the environment are mostly concerned with:

(a) Gene-flow/escape into wild genetic resources and/or landraces;

(b) Adverse effects on non-target organisms;

(c) Adverse effects on human health;

(d) Living modified organisms becoming invasive and more competitive;

(e) Insects and micro-organisms acquiring resistance;

(f) Changes in the interactions within the ecosystem.

27. According to Article 21 of the Protocol on confidential information, while the Party of import is required to respect the confidentiality of commercial and industrial information, a summary of the risk assessment of the effects on the conservation and sustainable use of biological diversity shall not be considered confidential. Furthermore, if a notifier withdraws an application, unless notifier and the Party of import disagree as to its confidentiality, the risk-assessment summary shall also not be considered confidential. In spite of that, there is a scarcity of publicly available information on applications for intentional release of LMOs that have been rejected and, in most cases, no information is made available on applications withdrawn during the decision process. This lack of available information poses challenges to regulatory bodies in identifying examples of potential adverse effects of specific LMOs or traits.

28. Information from relevant scientific bodies on the potential adverse impact of specific novel traits has been difficult to find. An example is one from the Scientific Panel on genetically modified organisms of the European Food Safety Authority (EFSA) on the potential risks associated with specific antibiotic resistance marker genes (ARMGs; also known as ABR genes) taking into account the possibility and impact of horizontal gene transfer from genetically modified plants to microbes. 6/ Another example, a SBSTTA recommendation, later adopted in COP decision V/5, states that in the current absence of reliable data on genetic use restriction technologies (GURTs) and in accordance with the precautionary approach, products incorporating such technologies should not be approved by Parties. 7/

29. In some instances, regulatory agencies have failed to approve applications for intentional release of LMOs into the environment due, among other reasons, to potential adverse effects of an LMO or its specific traits. For instance, in Australia, the Commonwealth Gene Technology Regulator rejected an application for commercial release of two types of genetically modified cotton in northern Australia because of uncertainty about their potential to become a weed problem. Moreover, several EU member states invoked the safeguard clause in EU legislation (Article 16 in Directive 90/220 or Article 23 in 2001/18) after approval consent had been given by the European Commission for several LMOs including swede rape MS1/RF1 resistant to glufosinate (safeguard clause invoked by France, 20 November 1998), maize Bt-176 tolerant to glufosinate ammonium (Austria, 14 February 1997; Luxembourg, 17 March 1997; Germany, 28 February 2000), swede rape Topas 19/2 tolerant to glufosinate (Greece, 5 November 1998), maize MON 810 expressing the Bt cryIA(b) gene (Austria, 1 June 1999; Hungary, 20 January 2005), and maize T25 tolerant to glufosinate (Austria, 8 May 2000). The Swiss Federal Office for the Environment rejected applications for experimental release of genetically modified apple and maize lines containing ARMGs, taking into account the great complexity of the soil microflora and the scant knowledge available on its composition and interactions, and concluding that the presence of such a gene represents a risk that is difficult to evaluate.

30. Similarly, few records referring to the prohibition of the release into the environment or marketing of LMOs based on possible adverse effects have been submitted to the Biosafety Clearing-House. Among these records, the following examples provide a brief overview of some LMOs and specific traits that were identified as having the potential to cause adverse effects.

31. Mexico decided not to allow the experimentation and intentional release into the environment of genetically-modified maize that has been modified to obtain pharmaceutical products, vaccines,

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6/ The Panel considered the frequency of horizontal gene transfer from genetically modified plants to other organisms as very low for all antibiotic resistance marker genes considered. However, with respect to clinical importance the Panel has categorised ARMGs into three groups with different potentials for compromising human health and the environment. ARMGs in the first group include the genes conferring resistance to kanamycin and hygromycin. The Panel is of the opinion that with regard to safety there is no rationale for inhibiting or restricting the use of genes in this category, either for field experimentation or for the purpose of placing on the market. The second group of ARMGs, which includes resistance to chloramphenicol, ampicillin, streptomycin and spectinomycin, should be restricted to field trial purposes and should not be present in GM plants to be placed on the market. The third group of ARMGs includes those conferring resistance to amikacin and tetracyclines. Given their current importance in clinical usage, the EFSA panel advised that GM plants containing these marker genes should not be released into the environment either for trials or commercial purposes.

7/ In the current absence of reliable data on genetic use restriction technologies (GURTs), without which there is an inadequate basis on which to assess their potential risks, and in accordance with the precautionary approach, products incorporating such technologies should not be approved by Parties for field testing until appropriate scientific data can justify such testing, and for commercial use until appropriate, authorized and strictly controlled scientific assessments with regard to, *inter alia*, their ecological and socio-economic impacts and any adverse effects for biological diversity, food security and human health have been carried out in a transparent manner and the conditions for their safe and beneficial use validated (COP decision V/5, paragraph 23). A list of potential negative and positive impacts of GURTs is available in the report of the Ad Hoc Technical Expert Group Meeting on the Potential Impacts of Genetic Use Restriction Technologies on Smallholder Farmers, Indigenous and Local Communities and Farmer's Rights, which was held in Montreal, Canada from 19-21 February 2003 (UNEP/CBD/SBSTTA/9/INF/6-).

industrial oils, plastics, or any modification that limits or affects its properties as food. This decision was based on the fact that Mexico is a centre of origin and diversification of maize, and was substantiated by the reproductive biology of maize as an open-pollinated crop and the dynamic character of the traditional farming systems regarding seed exchange increasing the risks of gene flow between local varieties and varieties originated in several geographical regions. 8/

32. The Belgium Biosafety Advisory Council raised concerns about the possible adverse impacts resulting from the cultivation of herbicide-tolerant rapeseed. These concerns included the potential risks of gene flow due to intrinsic characteristics of oilseed rape such as long-distance pollen dispersal and pod shattering causing losses of large amounts of seeds during harvest. Pollen dispersal could result in the potential fertilization of wild relatives currently present in European wild flora and the adventitious presence of GM material in neighbouring fields. Seed dispersal in and outside the cultivation fields would result in the development of herbicide-tolerant oilseed rape volunteers and the potential development of resistant or tolerant weeds. Moreover, based on the scientific data provided by the UK Farm-Scale Evaluation trials, the Belgium Biosafety Advisory Council also raised concerns that the short-term impacts on the biodiversity in the fields, namely a decline in crop accompanying weed population and all organisms living on these weeds, could be expected. If these wildlife forms in the field are to be preserved, compensating actions would be necessary. The Council also pointed out that the long-term effects of growing herbicide-tolerant oilseed rape and its accompanying herbicide regime remain hard to predict.

33. The Austrian Competent Authority decided to prohibit the placing on the market of a maize line expressing the Bt cryIA(b) gene as a safeguard measure according to Article 16 of Directive 90/220/EEC. The objection of Austria was supported by concerns of "possible unintended effects of the Bt toxin on non-target insects"; "uncertainty about the effectiveness of the refuge strategy in order to prevent the development of Bt resistance in the European Corn Borer"; "effects of other Bt plants, e.g. cry1Ab Bt cotton in Australia, such as the increase of secondary pests and consequently additional use of synthetic plant protection products" and "uncertainty about the specificity of Bt plants". 9/

34. Austria also invoked Article 16 of Directive 90/220/EEC to prohibit the placing on the market of T25 maize on the basis of the following environmental concerns: "no realistic conditions of the use of the herbicide and corresponding agricultural practices were used during the assessment of T25"; "long term effects of the herbicide use should not be evaluated independently from the respective GMHT 10/ plant and long-term effects of glufosinate-ammonium in combination with GMHT maize T25 were not fully investigated"; "an evaluation of regional aspects of the herbicide use should be considered"; "approval conditions were not foreseeing a protection of ecologically sensitive areas"; and "a major further point was the risk of contamination of conventional maize – the coexistence issue. 11/

35. On another occasion, the Austrian Government decided to prohibit the placing in the market of herbicide tolerant oilseed rape GT73, because, among other reasons, "unprocessed oilseed rape is transported to Austria in considerable amounts, feral oilseed rape populations can be found along transport routes where glyphosate is applied and oilseed rape seeds can establish and are likely to build up persistent populations. Therefore it can be considered as highly likely that imported GT73 oilseed rape will spread and persist in certain habitats in Austria. Due to the fact that GT73 oilseed rape is herbicide tolerant the application of glyphosate in these habitats would confer a selective advantage to feral GT73 oilseed rape plants. Finally, co-existence issues of accidental seed spills of GT73 oilseed rape

8/ BCH Record ID 8601 available at https://bch.cbd.int/database/record.shtml?id=8601.

9/ BCH Record ID 37308 available at https://bch.cbd.int/database/record.shtml?id=37308.

10/ Genetically-modified herbicide tolerant.

11/ BCH Record ID 37309 available at https://bch.cbd.int/database/record.shtml?id=37309.

with conventional oilseed rape production are still unsolved". 12/

36. According to the Directorate for Nature Management of Norway, "deliberate release in Norway of the genetically modified maize line Bt176 would entail a risk of adverse effects to health and the environment". In their report, the Directorate concluded that "the risks and the lack of sufficient knowledge about horizontal gene transfer of antibiotic resistance genes and the possible undesirable effects of the Bt toxin on both target and non-target insects implies that marketing of the product would conflict with the precautionary principle and the requirement for sustainable development. No benefits to the community, or other aspects, can outweigh the risks associated with marketing the product". 13/ Import, usage and sale of this maize line were also prohibited by Austria. 14/

VI. CONCLUSIONS

37. The workshops on capacity-building and exchange of experiences on risk assessment and risk management of living modified organisms and the Canada-Norway Expert Workshop on Risk Assessment for Future Applications of Modern Biotechnology, corroborating the opinion of the Ad Hoc Technical Expert Group, concluded that guidance on several *specific* aspects of risk assessment and risk management, such as guidance focused on particular types and particular intended uses of living modified organisms, is not readily available at present. These workshops concluded that: (i) further guidance is necessary particularly on emerging issues and novel organisms; (ii) in order to fulfil the need for guidance on specific aspects of risk assessment and risk management, it may be necessary to generate further empirical data, for example through laboratory and/or field studies; and (iii) it might be necessary to establish a mechanism able to generate these data to fill up the information gaps.

38. There are few findings issued by relevant scientific bodies about the potential of specific living modified organisms and novel traits that may cause adverse effects on the conservation and sustainable use of biological diversity. This may be partially due, among other things, to scarcity of reliable scientific data and publicly available information on these issues.

39. With regard to capacity-building, the information received in the first national reports supports the general notion 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. Specific suggestions for addressing capacity limitations were made by the Ad Hoc Technical Expert Group. In support of implementation activities for building capacity, risk assessment and other scientific and technical expertise, as well as risk management, were considered "key elements requiring concrete action" in the updated Action Plan for Building Capacities for the Effective Implementation of the Biosafety Protocol. 15/

VII. ELEMENTS OF A DRAFT DECISION

40. The Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety, recalling its decision BS-III/11, on risk assessment and risk management and Annex III of the Cartagena Protocol on Biosafety, in which it stressed the importance of assessing risks of living modified organisms in a scientifically sound manner and on a case-by-case basis, may wish to:

(a) Welcome the reports of the regional and sub-regional workshops on capacity-building and exchange of experiences on risk assessment and risk management of living modified organisms, and

12/ BCH Record ID 37310 available at https://bch.cbd.int/database/record.shtml?id=37310.

13/ BCH Record ID 11461 available at https://bch.cbd.int/database/record.shtml?id=11461.

14/ BCH Record ID 37307 available at https://bch.cbd.int/database/record.shtml?id=37307.

15/ Annex to decision BS-III/3.

express its gratitude to the Governments of Germany, the Netherlands, Norway, Spain and Switzerland for their financial contributions and the Governments of Barbados, Ethiopia and the Republic of Moldova, and the African Union for their organizational support, and request the Executive Secretary to convene, at the earliest convenient date and subject to the availability of financial resources, a workshop on capacity-building and exchange of experiences on risk assessment and risk management of living modified organisms in the Pacific subregion;

(b) Welcome the report of the Canada-Norway Workshop on Risk Assessment for Future Applications of Modern Biotechnology, and *expresses its gratitude* to the Governments of Canada and Norway for their financial and organizational support in organizing this workshop.

A. Existing guidance and information to support risk assessment and risk management

41. Concerning existing guidance and information to support risk assessment and risk management, the Parties to the Protocol may wish to:

(a) Note that a significant volume of general guidance on risk assessment and risk management has been collected and is readily available to the public through the Biosafety Information Resource Centre of the Biosafety Clearing-House;

(b) Urge the Parties, other Governments and relevant organizations to continue sharing guidance material on risk assessment and management 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.

B. Further guidance on specific aspects of risk assessment and risk management

42. With regard to the need for further guidance on *specific* aspects of risk assessment and risk management, the Parties to the Protocol may wish to:

(a) Reiterate the conclusions of the above-mentioned workshops about the need to develop additional guidance on how to conduct risk assessments of specific types of living modified organisms, including, fish, trees, viruses and pharmaplants;

(b) Recalling decision BS-III/11, in which Parties agreed to "consider at its fourth meeting the need for further guidance on specific aspects of risk assessment and risk management, and the appropriate modalities for development of any such guidance such as a further meeting of the Ad Hoc Technical Expert Group on Risk Assessment", request the Executive Secretary to proceed with the necessary arrangements to assemble an expert group to identify modalities and scientific criteria for the development of guidance material on *specific* aspects of risk assessment and risk management.

(c) Request the Executive Secretary to continue gathering and promoting the exchange of information, also by using online conference systems, with the purpose to facilitate deliberations by the Ad Hoc Technical Expert Group on Risk Assessment on issues related to guidance on specific aspects of risk assessment and risk management.

C. Collaboration in identifying LMOs or specific traits that may have an adverse effect on the conservation and sustainable use of biological diversity, taking also into account risks to human health

43. In recalling the medium-term programme of work regarding cooperation in identifying living modified organisms or specific traits that may have adverse effects on the conservation and sustainable

use of biological diversity, taking also into account risks to human health, and taking appropriate measures regarding the treatment of such living modified organisms or specific traits, the Parties to the Protocol may wish to:

(a) Urge Parties, other Governments and relevant organizations to submit to the Biosafety Clearing-House decisions, risk assessment reports and other communications that identify LMOs and traits as posing potential risks to the environment, biodiversity and human health. In this context, the Parties to the Protocol also recalls that according to Article 21, if a notifier withdraws an application, unless notifier and the Party of import disagree as to its confidentiality, a summary of the risk assessment of the effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, shall not be considered confidential;

(b) Request the Executive Secretary to call for submissions from Parties, other Governments and relevant organizations on the identification of potential risks to the conservation and sustainable use of biological diversity, taking also into account risks to human health;

(c) Consider modalities for collaboration in identifying of LMOs or specific traits that may have an adverse effect on the conservation and sustainable use of biological diversity, taking also into account risks to human health, when making a decision whether to establish a scientific and technical advisory body for the provision of scientific and technical advice as presented in item 13 of the provisional agenda (UNEP/CBD/BS/COP-MOP/4/12).

D. Capacity-building relevant to risk assessment

44. In recalling decision BS-III/11, which includes "risk assessment and other scientific and technical expertise" as part of the "key elements requiring concrete action" in the updated Action Plan for Building Capacities for the Effective Implementation of the Biosafety Protocol, the Parties to the Protocol may wish to:

(a) Request the Executive Secretary, subject to availability of funds, to coordinate and facilitate, along with relevant United Nations bodies and other organizations, an exchange of experiences among scientists, technologists and regulators on risk assessment and risk management of living modified organisms for the development of training modules and to convene, prior to the sixth meeting of the Parties to the Protocol, training activities including but not limited to the following areas:

(i) Research needed to support risk assessment and how to conduct risk assessment;

(ii) Preparation of scientifically sound risk assessment and risk management reports;

(iii) Interdisciplinary teamwork in the context of risk assessment; and

(iv) 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 assessment approvals.

(b) Encourage relevant donor Governments and organizations to make generous contributions of financial and/or organizational support, as appropriate, to the above-mentioned training activities.
