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Fourth meeting
Bonn, 12-16 May 2008

REPORT OF THE ASIA SUBREGIONAL WORKSHOP ON CAPACITY-BUILDING AND EXCHANGE OF EXPERIENCES ON RISK ASSESSMENT AND RISK MANAGEMENT OF LIVING MODIFIED ORGANISMS

INTRODUCTION

1. The Asia Subregional Workshop on Capacity-building and Exchange of Experiences on Risk Assessment and Risk Management of Living Modified Organisms (LMOs) was held in Kuala Lumpur, Malaysia, from 7 to 9 April 2008.

2. The workshop was attended by 40 delegates from 21 countries and 7 representatives from organizations involved in risk assessment and risk management of LMOs.

3. The following countries were represented: Bangladesh, Bhutan, Cambodia, Indonesia, Iran, Japan, Jordan, Kuwait, Lao People's Democratic Republic, Malaysia, Mongolia, Myanmar, Pakistan, Qatar, Saudi Arabia, Sri Lanka, Syrian Arab Republic, Thailand, Timor-Leste, Viet Nam and Yemen.

4. The following organizations were represented: Asian Farmers Association, B A Proactive Planning, Global Industry Coalition, Malaysian Biotechnology Information Centre, Public Research and Regulation Initiative (PRRI), Third World Network and United Nations Development Programme (UNDP/Malaysia).

5. Six resource persons from the following organizations facilitated the workshop: Centre for Research in Biotechnology for Agriculture, University of Malaya (Malaysia), Federal Environment Agency (Austria), International Centre for Genetic Engineering and Biotechnology (ICGEB, India), Kasetsart University (Thailand), Ministry of Natural Resources and Environment (Malaysia) and National Institute of Public Health and Environment (the Netherlands).

6. The objectives of the workshop were to enable participants to:

(a) 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) Exchange practical experiences and lessons learned in conducting/reviewing risk assessments and implementing risk management measures in Asia;

/…

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

(d) Review the format and key elements of risk assessment reports/dossiers and summaries for LMOs;

(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.

ITEM 1. OPENING OF THE WORKSHOP

7. The Workshop was officially opened by Hon. Datuk Douglas Uggah Embas, Minister of Natural Resources and Environment of Malaysia. Opening remarks were also made by Datuk Suboh Mohd Yassin, Secretary General of the Ministry of Natural Resources and Environment, Malaysia, and Mr. Erie Tamale on behalf of Mr. Ahmed Djoghlaf, Executive Secretary of the Convention on Biological Diversity (CBD).

8. In his remarks, Hon. Embas welcomed participants to Malaysia on behalf of his Government. He expressed his appreciation to the CBD Secretariat for having agreed to hold the workshop in Malaysia and for its support during the preparations of the workshop. Hon. Embas reported that Malaysia has identified modern biotechnology as an important sector with a great potential to contribute to the nations socio-economic development in its five-year development plan (2006-2011). He noted, however, that while modern biotechnology may have potential benefits, there are concerns over its potential adverse effects on biodiversity and human health. In this regard, he noted that the Government of Malaysia recently enacted the Biosafety Act 2007, which will allow modern biotechnology to grow without compromising the safety to human health and the environment. The law is expected to come into force later this year. Hon. Embas observed that having the legal framework alone is not enough to ensure biosafety. It is important to carry out proper science-based risk assessment before any decision on LMOs is taken. Accordingly, there is a need to develop the necessary capacity to do risk assessments and to adhere to biosafety standards. He observed that workshops like the current one are important channels for enhancing capacity and providing platforms for direct exchange of information and expertise. He further emphasized the need for training to develop interdisciplinary expertise at the national and regional levels. He also urged researchers in the region, especially those involved in modern biotechnology, to include biosafety components in their research and funding proposals. Furthermore, Hon. Embas underscored the importance of developing scientific and technical guidance in this rapidly growing area of science to assist Parties to formulate appropriate policies, undertake science-based risk assessments and ultimately make informed decisions. Further, he strongly recommended the establishment of an expert committee or technical body under the Protocol, along the lines of the Intergovernmental Panel on Climate Change (IPCC), to provide advice on scientific and technical issues to facilitate the implementation of the Protocol.

9. In his opening remarks, Datuk Suboh Yassin highlighted the central role of risk assessment and risk management in ensuring the safety of LMOs and LMO products. However, he noted that most countries in the Asian region lack capacity in those key fields. He expressed the hope that this workshop would act as a catalyst for the development of capacity-building initiatives to address this limitation. He cautioned against duplication of efforts and emphasized the need to build upon and compliment existing initiatives. Underscoring the importance of South-South cooperation, Datuk Suboh Yassin urged countries in the region to work together in developing capacities in risk assessment, which is highly scientific and technical in nature. He reported that Malaysia with the assistance from UNIDO has established a post graduate course on biosafety at the University of Malaya. The course covers different aspects of biosafety, including risk assessment and risk management. He invited all countries in the region to take advantage of the course.

10. In his statement, Mr. Tamale expressed gratitude to the Government of Malaysia for hosting the workshop. He also thanked the Governments of Norway and Spain for the providing the funding support

that enabled the participation of developing countries and the Government of the Netherlands for providing at its cost a resource person for the workshop. He further expressed the Secretariat's gratitude to the resource persons who agreed to share their expertise and experience and to facilitate the workshop. Mr. Tamale noted that risk assessment is one of the cornerstones of decision-making under the Biosafety Protocol. However, most developing countries and countries with economies in transition lack the necessary capacity and experience in this crucial field. In this regard, the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety (COP-MOP) requested the CBD Secretariat to organize regional workshops to contribute to capacity-building and exchange of experiences on risk assessment and risk management of LMOs. Mr. Tamale reported that this workshop was the fourth in the series of similar regional workshops organized by the CBD Secretariat. He highlighted the objectives of the workshop and noted that the results of the workshop will contribute to the discussions at the fourth meeting of the COP-MOP, to be held in Bonn, Germany in May this year, especially with regard to the issue of the need for further guidance on specific aspects of risk assessment and risk management, and the appropriate modalities for developing such guidance. He urged participants to share their experiences, views and recommendations freely and openly.

ITEM 2. ORGANIZATIONAL MATTERS

11. The participants elected Prof. Mr. Mohamad Osman (Malaysia) to serve as Chairperson of the workshop and Dr. Wansuk Senanan (Thailand) as Rapporteur.

12. The workshop adopted its agenda on the basis of the provisional agenda proposed by the Executive Secretary 1/. The proposed programme of work for the workshop 2/ was also adopted (see annex I).

13. The following substantive items were addressed:

(a) Introduction to risk assessment and risk management of LMOs;

(b) National and regional experiences and lessons learned in the implementation of the risk-assessment and risk-management provisions of the Protocol;

(c) Guidance materials for risk assessment and risk management;

(d) Key considerations in the preparation and/or review of risk assessments; and

(e) Regional cooperation and sharing of information and expertise on risk assessment and risk management.

14. To facilitate the discussions, each participant was given a CD-ROM containing the available presentations as well as some of the existing guidance materials on risk assessment and risk management and other relevant resource materials prior to the workshop.

ITEM 3. INTRODUCTION TO RISK ASSESSMENT AND RISK MANAGEMENT OF LIVING MODIFIED ORGANISMS

15. Under this item, two presentations were made. The first one, entitled "Introduction to risk assessment and risk management of living modified organisms in the context of the Cartagena Protocol", was made by Mr. Erie Tamale from the CBD Secretariat. The second one, entitled "Risk assessment and risk management concepts, general principles and methodologies: An overview", was presented by Dr. Rofina Yasmin Othman from the Centre for Research in Biotechnology for Agriculture, University of Malaya, Malaysia.

1/ UNEP/CBD/BS/RW-RA&RM/AS/1/1

2/ UNEP/CBD/BS/RW-RA&RM/AS/1/1/Add.1

16. Mr. Tamale described the Cartagena Protocol's provisions on risk assessment (i.e. Article 15 and Annex III) and risk management (Article 16) and underlined the central role of risk assessment in the decision-making process with regard to the import or release of LMOs into the environment. He noted that Annex III of the Protocol provides a general harmonized framework for risk assessment agreed to by the Parties to the Convention on Biological Diversity during the negotiation of the Protocol. It describes the objective and use of risk assessments under the Protocol, the general principles and methodology of risk assessment and the key points to consider in carrying out a risk assessment. Furthermore, Mr. Tamale described the inter-linkage between risk assessment and risk management. Finally, he outlined the programme of work and decisions adopted by the COP-MOP with respect to risk assessment and risk management and the issues to be addressed at its next meeting in Bonn, Germany, 12-16 May 2008.

17. Dr. Othman gave an overview of the key concepts and general principles and methodologies for risk assessment, risk management and risk communication. She noted that risk assessment is an important first step in minimizing or preventing possible adverse effects LMOs on biodiversity and human health and for enabling informed decision-making regarding transboundary movement of LMOs. Its objective is to identify and systematically evaluate the possible adverse effects. She gave a brief historical background of risk-assessment concepts and principles and their application in other fields. She outlined the risk-assessment principles with respect to LMOs as specified in the Protocol and presented a flowchart of the main steps involved in risk assessment and risk management. The key steps include: (i) identification of the potential adverse effects (hazard identification); (ii) estimation of the likelihood of exposure (exposure characterization); (iii) evaluation of the magnitude of the consequences (exposure assessment); and (iv) estimation of the risk including the severity and probability of occurrence of the adverse effects (risk characterization). Dr. Othman described three models used in risk assessment of LMOs namely: (a) "predictive" and "empirical" mathematical models used to simulate environmental processes to predict probabilities of various consequences; (b) event-tree analysis model used for identifying hazards and characterizing risks arising from LMO applications; and (c) fault-tree analysis model, which focuses on characterizing risks arising from the occurrence of an identified hazard and the ways a particular risk occurs. She outlined some methodological assumptions in the risk assessment of LMOs, including the concept of familiarity and the comparability of risk between transgenic and non-transgenic plants.

18. With regard to risk management, Dr. Othman noted that this process involves consideration of the risk assessment and other factors, identification of mitigation options, weighing policy alternatives and mitigation options for efficiency, feasibility and impacts, in consultation with all interested parties and, if needed, selecting appropriate prevention and control options. She noted that risk-management measures in the context of LMOs could include: isolation distances or 'buffer zone', border rows with non-transgenic plants, after-release treatment and/or control, and partial or full retractions preventing planting in specified areas. Factors that could assist in determining which risk-management options should be considered include: degree of scientific certainty; the potential for catastrophic consequences; inability to reduce or reverse harm; the occasionally involuntary nature of exposure; the potential of harm to future generations; and the degree of equitability of risk.

19. Following Dr. Othman's presentation, Dr. Hans Bergmans added that although a risk-assessment team can collect a variety of data, there may still be some scientific uncertainty. Therefore, in some cases, the risk assessment has to rely on the precautionary approach. Risk analysts may need to start the risk-assessment process by assuming worst-case scenarios. This approach allows for fine-tuning during the risk-assessment process.

ITEM 4. NATIONAL AND REGIONAL EXPERIENCES AND LESSONS LEARNED IN THE IMPLEMENTATION OF THE RISK ASSESSMENT AND RISK MANAGEMENT PROVISIONS OF THE PROTOCOL

20. Under this item, workshop participants shared information on the current status, experiences and lessons learned in the implementation of risk assessment and risk management in their respective sub-regions and countries. They also discussed the challenges they encountered as well as their capacity-

building needs. Case-study presentations were made for the South Asia sub-region by Dr. Vanga Siva Reddy of ICGEB, New Delhi, and the South-East Asia sub-region by Dr. Vilasini Pillai from the Ministry of Natural Resources and Environment of Malaysia.

21. Dr. Vanga Siva Reddy presented the experiences of Afghanistan, Bangladesh, Bhutan, India, Maldives, Nepal, Pakistan and Sri Lanka. He highlighted that these countries are at different stages of adoption and implementation of their national biosafety frameworks. Dr. Reddy also explained the differences in areas covered by the biosafety legislation of different countries, namely health and environmental risks and socio-economic considerations.

22. Discussions following Dr. Reddy's presentation focused on the need for further training in the region. The delegates from Pakistan and Malaysia offered assistance to the delegate of Qatar in sharing experiences to develop a regulatory framework and biosafety law.

23. In her presentation, Dr. Vilasini Pillai reported on the current status of biosafety in the countries of the South East Asia sub-region (including Brunei Darussalam, Cambodia, Indonesia, Lao People's Democratic Republic, Malaysia, Myanmar, Philippines, Singapore, Thailand, Timor-Leste and Vietnam). Some of these countries already have biosafety frameworks whereas others are at various stages of development. She described the current status, experiences gained and lessons learned and challenges faced by the five countries in this sub-region that have carried out or reviewed risk assessments, namely Indonesia, Malaysia, Philippines, Singapore and Thailand. These countries have gained confidence in regulating LMOs; the other countries that have not yet carried out any risk assessment are looking to them for guidance and training in the area of biosafety. She also identified the areas where capacity training has been carried out and areas where more training is needed. Recommendations were also made by these countries for them to effectively implement risk-assessment and risk-management programmes.

24. Mr. Kazuyuki Suwabe (Japan), Mr. Ghanem Abdulla Mohammad (Qatar) and Ms. Iresha Rajapaksha (Sri Lanka) also made presentations on their respective countries, including the status of their biosafety frameworks as well as experiences and challenges encountered.

25. Following the presentations and brief discussions in the plenary, countries were divided into three focus discussion groups (one for Western Asia, another for Eastern and South Asia, and a third for South-Eastern Asia and Japan chaired by Dr. Yousef S. Al-Hafedh, Dr. Afzaal Ahmad Naseem and Dr. Mohana Anita Anthonysamy, respectively) to deliberate on and make recommendations to the following questions:

(a) What are the main capacity-building priority needs in the area of risk assessment and risk management in the Asia sub-region?

(b) What measures should be taken to address the identified needs at the: (a) national level and (b) regional/sub-regional level? (NB: specify what exactly should be done, by whom and by when?)

(c) What are the existing and potential opportunities and mechanisms for subregional and regional cooperation and how should they be maximized/developed?

(d) What measures could be taken at the regional level to develop or mobilize a pool of risk-assessment experts or scientific competence and by whom, how and when?

(e) What existing mechanisms or centres of excellence could be used to facilitate subregional cooperation on capacity-building in risk assessment and risk management of LMOs?

26. The results of the discussion groups were discussed in the plenary. The following were identified in the regional presentations or by the discussion groups as some of the main limitations or challenges to risk assessment and risk management in the Asian sub-region:

(a) Lack of knowledge and understanding on the concepts of risk assessment and risk management;

(b) Technological constraints in verifying or monitoring GM products;

(c) Lack or insufficiency of training opportunities;

(d) Lack of a regulatory framework for LMOs;

(e) Difficulties in finding and accessing relevant information which is currently scattered in many different places;

(f) Lack of conclusive details about some of the decisions taken regarding LMOs, for instance, the reason for rejecting a notification;

(g) Lack of or insufficient information on certain types of LMOs and information pertaining to tropical countries as research is often done in countries with temperate climates;

(h) Lack or insufficient replication of experiments as most of the available data are originated from single experiments;

(i) Difficulties in interpreting and understanding research data;

(j) Insufficient funding for accessing information in sites which require payment of fees.

27. The following compiled actions were proposed to enhance capacity and promote cooperation in the region and for consideration by the COP-MOP:

(a) Promoting hands-on training opportunities for scientists and regulators;

(b) Promoting formal and informal education on biosafety;

(c) Identifying national and regional experts and institutions related to biotechnology;

(d) Developing a pool of national and regional experts;

(e) Improving the sharing of human resources in the region;

(f) Designing and implement a plan to ensure transfer and retention of knowledge;

(g) Developing national and regional databases to improve exchange of information

(h) Improving existing facilities for inspection and monitoring of LMOs

(i) Improving regional sharing of infrastructure;

(j) Identifying centres of excellence in biotechnology;

(k) Establishing regional training centers and promote collaborative research;

(l) Improving information sharing;

(m) Issuing handbooks on risk assessment and risk management.

ITEM 5. GUIDANCE MATERIALS FOR RISK ASSESSMENT AND RISK MANAGEMENT OF LIVING MODIFIED ORGANISMS

28. Three presentations were made under this item. The first presentation on the "Nature, scope and applicability of existing guidance materials on risk assessment and risk management of LMOs" was given by Dr. Hans Bergmans, from the National Institute for Public Health and the Environment, Netherlands. The second presentation was given by Dr. Napompeth Banpot from the National Biological Control Research Center, Kasetsart University, Thailand, on the "Overview of the international standards for pest risk analysis under the International Plant Protection Convention (IPPC) and their relevance to risk assessment of LMOs under the Biosafety Protocol". The third presentation was given by Dr. Helmut Gaugitsch of the Federal Environment Agency in Austria on the "Report of the Canada-Norway Expert Workshop on Risk Assessment for Emerging Applications of LMOs", which was held from 4 to 6 June 2007 in Montreal, Canada.

29. Dr. Bergmans highlighted some of the existing guidance materials, which range from specific scientific articles and national-level guidelines to generic guidance documents agreed to in international fora. He pointed out that different guidance materials may be relevant at different stages of risk assessment. He provided examples of possible sources where guidance materials can be obtained, including: the Biosafety Information Resource Centre (BIRC) in the Biosafety Clearing House (BCH), international organisations (e.g., FAO, OECD, ICGEB CGIAR centres, etc.), websites of national regulatory agencies (e.g., EU, USA, etc) and reliable bibliographic databases and search engines (e.g., Google scholar). He indicated that the BCH also contains links to relevant databases, websites and bibliographic information provided by governments and relevant organizations. He advised that users need to take into account the following general considerations when using existing guidance materials and information to use: (i) the type of resource (scientific paper, book, conference report, interpretative report, etc); (ii) the author of the material/information (scientific expert, regulator, NGO, etc); (iii) the purpose for which they were compiled (scientific discussion, regulatory underpinning, NGO view, etc); (iv) the 'endpoints' of the process (environmental safety, food/feed safety, etc); and (v) the publication date.

30. Dr. Banpot described the IPPC and explained that it is an international treaty which aims to secure action to prevent the spread and introduction of pests of plants and plant products, and to promote appropriate measures for their control. IPPC is governed by the Commission on Phytosanitary Measures (CPM) which adopts International Standards for Phytosanitary Measures (ISPMs). He noted that ISPM No. 2 (Guidelines for pest risk analysis (1995), ISPM No.3 (Guidelines for he export, shipment, import and release of biological control agents and other beneficial organisms (2005), ISPM No.11 (Pest risk analysis for quarantine pests including analysis of environmental risks and living modified organisms (2004) and ISPM No. 21 (Pest risk analysis for regulated non-quarantine pests (2004) include provisions applicable to LMOs and are, thus, relevant to risk assessment and risk management of LMOs.

31. The IPPC Secretariat was established in 1992 by FAO with responsibility of coordinating the work program on (i) development of ISPMs, (ii) information exchange through the International Phytosanitary Portal (IPP), (iii) providing technical assistance and capacity building to facilitate the implementation of IPPC. Under the IPPC, the term "plant pest" refers to all organisms harmful to plants or plant products. It includes other plants (weeds), bacteria, fungi, insects and other animals, mites, molluscs, nematodes, and viruses. The IPPC recognizes and defines two categories of regulated pests of plants: regulated quarantine pests, and regulated non-quarantine pests.

32. The pest risk analysis (PRA) process evaluates technical, scientific and economic evidence to determine whether an organism is a potential pest of plants and, if so, how it should be managed. The PRA, therefore, is a science-based process that assists in determining whether a pest fits one of these two categories and the strength of phytosanitary measures, if any that should be taken in response to it. The PRA process consists of three stages: (i) initiation of the PRA through the identification of a pest or pathway, or review or revision of an existing phytosanitary policy, (ii) pest risk assessment, and (iii) pest risk management. Risk communication is an integral component that occurs throughout each step. Dr. Banpot also highlighted that, in 2005, the IPPC Secretariat and the SCBD signed a Memorandum of Cooperation (MOC) to promote collaboration and avoid unnecessary duplication of efforts.

33. Dr. Gaugitsch presented the main outcomes (observations and recommendations) of the Canada-Norway expert workshop which focussed on emerging applications of living LMOs, namely transgenic fish, trees, pharmaplants and viruses, particularly for the management of animal populations. The workshop i) addressed the availability of guidance materials on risk assessment for emerging applications of modern biotechnology; ii) assessed available guidance material; and (iii) identified gaps in knowledge and information that could impact on the ability to perform appropriate risk assessments. In the workshop, environmental risk assessment issues that are unique to fish were raised such as the fact that fish are not domesticated, but wild animals that can move easily to different, possibly large geographical areas and, as such, fish have potential for rapid population expansion. The recommendations of the workshop with regard to fish were to: (i) develop different worldwide scenarios on the introduction of modified fish into the environment including ecology, fish physiology and genetics; (ii) identify more model-fish studies for environmental risk assessments; and (iii) develop case-by-case protocols for the risk assessment of

genetically modified (GM) fish. With regard to modified trees, knowledge gaps were identified, such as how to properly measure fitness as a basis for risk assessment, and what is the appropriate duration of field trials. Scarcity of baseline information to understand the state of the environment before introduction of GM-trees was also pointed out. The recommendations with regard to trees were to: (i) consider trees in the managed and wild habitats differently; (ii) study effective way of risk assessment for trees, taking into account the life cycle of trees; and (iii) identify effective measurements of fitness suitable for trees. The conclusions of the workshop on GM viruses were that very little data or information exist on environmental effects of GM viruses as research has so far focused on human or animal health, and that guidance on environmental effects is limited or non-existent. With regard to pharmaplants, issues raised at the workshop related to the toxicity of these plants to non-target organisms and persistence of the pharma protein in the environment. The overall conclusions and recommendations of the workshop were: (i) the Annex III of the Protocol also applies to these new types of LMOs; (ii) there is insufficient guidance for GM fish, viruses and pharmaplants and further research is needed to fill the knowledge gaps; (iii) field trials and alternative methods should be used for generating data; and (iv) the BCH should be used for exchange of information on these issues.

34. During the question and answer session, participants noted that although a number of risk assessment guidance materials have been developed, many institutions and individuals in the region do not have easy access to them. They also took note of the outcomes of the Canada-Norway workshop and underscored the need to address the gaps identified by the workshop and to implement its recommendations.

35. Three focus discussion groups were established and invited to deliberate on and make recommendations to the following questions:

(a) On what specific aspects of risk assessment and risk management might additional guidance be required (e.g., particular types of LMOs, traits, receiving environments)?

(b) What would be the most appropriate modalities for the development of guidance on specific aspects of risk assessment?

(c) How should the available guidance be organized for improving user friendliness?

36. The discussion groups further shared experiences gained in using existing guidance materials and discussed the need for additional guidance on specific aspects of risk assessment and risk management. The results of the discussion groups were discussed in the plenary and the following needs were identified and compiled:

(a) Further guidance for specific types of LMOs, particularly for fish, insects, trees, pharmaplants and algae;

(b) Further guidance on particular receiving environments, “gene ecology”, multi-gene traits and specific traits;

(c) Guidance on how to generate baseline information;

(d) Guidance on the available guidance material.

37. With regard to the appropriate modalities for the development of guidance on specific aspects of risk assessment and risk management, the following options were identified:

(a) Ad-hoc expert working group;

(b) A permanent subsidiary body to the Protocol similar to SBSTTA or IPCC;

(c) Existing CG centres could tackle the development of guidance materials and training on specific aspects of RA of LMOs within their scope.

38. The existing guidance materials should be categorized per types of LMOs, theme, types of environment, publishing date, publisher, who wrote it (e.g., regulator, NGO), geographical scope, stage of

risk assessment process. Efforts should be undertaken to produce harmonized and simplified guidance documents and a "macro" guidance document on how to use the available guidance material should be prepared.

ITEM 6. KEY CONSIDERATIONS IN THE PREPARATION AND/OR REVIEW OF RISK ASSESSMENTS

39. Under this item, three presentations were made. The first presentation, entitled "Key considerations in the preparation of environmental risk assessments of living modified organisms and the required scientific capacities: a scientist's perspective" was made by Dr. Vanga Siva Reddy. The second presentation on "Key considerations in the review of environmental risk assessments of living modified organisms: a regulator's perspective" was given by Dr. Helmut Gaugitsch. The third presentation was made by Dr. Hans Bergmans on "Overview of the risk-assessment summaries submitted to the Biosafety Clearing-House in accordance with paragraph 3 (c) of Article 20 of the Protocol, and the need for a standardized format".

40. In his presentation, Dr. Reddy explained the role of scientific research in environmental risk assessments, and listed what information must be provided in a risk assessment dossier. The stages of research needed prior to an application for release of an LMO consists of decreasing levels of containment starting at the laboratory and ending at field trials. For a confined environmental release (small-scale field testing), the experimental set-up must include methods for preventing escape into the environment, persistence of the plant in the environment and entry of the GM product into the food/feed chain. In evaluating an application for confined environmental release, it is important to consider the biology of the host plant, environment and the credibility of the applicant to conform to risk-management measures. To exemplify the process of preparing a risk-assessment dossier of an LMO, Dr. Reddy used a case-study with Bt corn and its potential effect on a non-target organisms.

41. Dr. Gaugitsch described the evaluation of risk-assessment notifications, with particular reference to the European Union and Austrian experience. He reported that under the European Food Safety Authority (EFSA) guidance, a risk-assessment notification must contain the following information: (i) name and contact of the applicant; (ii) scope of application; (iii) recipient or parental plants (non-GM plants); (iv) genetic modification methods (vector, source of donor DNA, etc.); and (v) characteristics of the GM plant. With regard to the information needed on the GM plant, there are four major required areas: (i) molecular and phenotypic characteristics (insert, expression, phenotype, stability, etc.); (ii) toxicology, allergenicity, nutritional assessment and substantial equivalence; (iii) environmental effects; and (iv) monitoring plan. With regard to the evaluation of notifications for environmental release, Dr. Gaugitsch pointed out that one of the challenges faced is that field trials are most often carried out in the USA and South America and data generated in EU often does not exist. Another problem that regulators may face, according to Dr. Gaugitsch, is that the evaluation of field trial results is often unclear and of poor statistical quality. He concluded his presentation with the following recommendations: (i) in risk assessment dossiers, the relevant statements should always be supported by references; (ii) guidance documents should be followed; and (iii) more detailed guidance needs to be developed to include definitions, criteria (e.g., "biological relevance"), parameters to be tested, methods to be applied and environments to be considered.

42. Dr. Bergmans highlighted the recommendations of the Ad Hoc Technical Expert Group on Risk Assessment, which met in Rome, Italy from 15 to 18 November 2005. One of these recommendations encouraged governments to submit risk assessment summaries to the BCH in a standardized format and explain, as appropriate, how risk assessment problems have been solved, in particular to which extent the existing information and guidance materials have been used to support the risk assessments. Dr. Bergmans noted that the current BCH Common Format for risk assessments lacks certain elements/fields that would enable countries to submit key useful factual information. In view of that limitation, Dr. Bergmans presented a proposal for a common format for risk assessment summaries that contained a number of recommendations for additional elements/fields or sub-headings to the current common

format. He noted that the proposed common risk assessment format presented at the workshop for Asia incorporated the discussions and inputs from participants in the previous regional workshops for Africa, Central and Easter Europe, and Latin America and the Caribbean.

43. Following the presentations, the rationale for the different additions to the common format for risk assessment summaries was discussed in the plenary, and the workshop participants were asked to review the revised draft and to provide suggestions. The participants adopted the revised common format, contained in annex II to this report, and agreed to its incorporation in the BCH Management Centre.

ITEM 7. REGIONAL COOPERATION AND SHARING OF INFORMATION AND EXPERTISE ON RISK ASSESSMENT AND RISK MANAGEMENT

44. Under this item, two presentations were made: by Mr, Erie Tamale from the CBD Secretariat, and Mr. K. Nagulendran from the Ministry of Natural Resources and Environment of Malaysia.

45. Mr. Tamale discussed the rationale and possible mechanisms for regional cooperation on biosafety. He noted that regional cooperation could lead to: mobilization of a wider resource base for addressing risk assessment and risk management; improved sharing of human resources and existing infrastructure; streamlining of regulatory processes; harmonization of guidance materials and instruments; and more effective handling of unintentional and/or illegal transboundary movement of LMOs. In terms of mechanisms, he noted that cooperation in biosafety could take place through formal or informal mechanisms, either physically or virtually (e.g. via internet, telephone or other means). Possible formal mechanisms could include existing regional and subregional bodies, regional economic integration organizations (e.g., ASEAN), centres of excellence and professional associations. Cooperation could also be established through joint training activities and projects, staff exchanges and informal correspondence between experts. It could also take place virtually through web-based networks, mailing lists or online discussion fora. Mr. Tamale also noted a number of challenges to regional cooperation with regard to risk assessment of LMOs. These include a lack of political will, low priority for biosafety in some countries, a lack of resources, disparity in capacities and levels of internet connectivity between countries, differences in language and others. In conclusion, Mr. Tamale emphasized the need to maximize existing mechanisms to promote cooperation.

46. Mr. Nagulendran described examples of existing regional and subregional cooperation mechanisms and initiatives on biosafety in Asia. These include: ASEAN Secretariat (which has developed regional guidelines on risk assessment of agriculture-related GMOs), ASEAN GM Food Testing Network, ASEAN Centre for Biodiversity Conservation, FAO BIONET, Biotechnology Information Network for Asia (BINASIA), Asia-Pacific Cooperation (APEC), International Life Sciences Institute (ILSI) South East Asia program, Asia-Pacific Consortium on Agricultural Biotechnology (APCoAB), South Asia Biosafety Program (SARB) and the UNIDO/University of Malaya Biosafety Course. He concluded by emphasizing the need to cooperate through existing bodies. He also recommended the establishment of an ad-hoc working group on risk assessment and risk management at the regional level to, *inter alia*, develop or improve existing guidance materials and develop a regional project on risk assessment and risk management for GEF funding.

ITEM 8. CONCLUSIONS AND RECOMMENDATIONS

47. Participants made a number of general observations/conclusions and recommendations on the different issues related to risk assessment and risk management of LMOs. The main issues raised and discussed during the workshop include: (i) human resources and institutional capacity-building; (ii) data and information to support risk assessments and risk-management guidance materials; (iii) a common format for risk assessment summaries submitted to the BCH; and (iv) regional and technical cooperation on biosafety in general, and risk assessment in particular.

48. Measures that could be taken at the regional level to enhance collaboration among risk assessment experts or scientific competence included:

(a) Developing a roster of experts at national and regional levels. The ASEAN centre of biodiversity could assist in compiling a list of experts at the regional level;

(b) Establishing a GMO Testing Network using information from existing biosafety databases to facilitate exchange of information. Representatives of the network should meet on a regular basis (e.g., yearly);

(c) Establishing a regional association/society on biosafety focused on risk assessment.

49. With the view to improving regional capacity and developing guidance materials for risk assessment and risk management, the workshop participants invited the COP-MOP at its fourth meeting to consider taking decisions to:

(a) Facilitate and organize hands-on training activities on risk assessment and management for regulators and scientists;

(b) Establish an Ad Hoc Technical Experts Group (AHTEG) meeting to: (a) facilitate the development of guidance material to fill the knowledge gaps in specific aspects of risk assessment (e.g., specific types of LMOs, such as fish, insects, trees, pharmaplants and algae, "gene ecology", multi-gene traits, and specific traits); and (b) draw a "roadmap" for the development and compilation of guidance materials on the specific aspects of risk assessment (i.e., "guidance on the available guidance material");

(c) Encourage CGIAR centres to tackle the development of guidance and training on specific types of risk assessment;

(d) Consider the establishment of a permanent body under the Cartagena Protocol on Biosafety (e.g., similar to the Intergovernmental Panel on Climate Change) to provide advice on scientific and technical issues related to risk assessment and risk management issues.

ITEM 9. OTHER MATTERS

50. There were no other matters.

ITEM 10. ADOPTION OF THE REPORT

51. During the last session, participants considered the draft report prepared by the Rapporteur with the assistance of the SCBD. The draft report included preliminary conclusions and recommendations directed to Governments, other relevant organizations and the fourth meeting of the COP-MOP.

ITEM 11. CLOSURE OF THE MEETING

52. The workshop was closed at 16 hours and 33 minutes on Wednesday, 9 April 2008.

Annex I

WORKSHOP PROGRAMME

	Plenary
Monday ***7 April 2008*** 9 a.m. – 9.30 a.m.	*Agenda item*: 1. Opening of the Workshop.
9.30 a.m. – 10.15 a.m.	*Agenda items*: 2. Organizational matters: 2.1. Election of officers; 2.2. Adoption of the agenda; 2.3. Organization of work. 3. Introduction to risk assessment and risk management: 3.1. Introduction to risk assessment and risk management of LMOs in the context of the Cartagena Protocol on Biosafety.
10.15 a.m.– 10.45 a.m.	**Coffee/Tea Break**
10.45 a.m. – 1 p.m.	*Agenda items*: Item 3 (*continued*) 3.2. Risk assessment and risk management concepts, general principles, steps and methodologies: an overview. 4. National and regional experiences and lessons learned: 4.1. Case-study presentations from different subregions 4.2. Short presentations on national experiences by participants
1 p.m. – 2 p.m.	**Lunch Break**
2 p.m. – 3.30 p.m.	*Agenda items*: Item 4 (*continued*)
3.30 p.m. – 4 p.m.	**Coffee/Tea Break**
4 p.m. – 5.30 p.m.	*Agenda items*: 5. Guidance materials for risk assessment and risk management of living modified organisms: 5.1. Overview of the nature, scope and applicability of existing guidance materials on risk assessments and risk management of LMOs; 5.2. Overview of the international standards for pest risk analysis under the International Plant Protection Convention (IPPC) and their relevance to risk assessment of LMOs under the Biosafety Protocol.
Tuesday ***8 April 2008*** 9 a.m. – 10.30 a.m.	*Agenda item*: Item 5 *(continued)* 5.3. Report of the Canada-Norway Expert Workshop on Risk Assessment for Emerging Applications of Living Modified Organisms, 4-6 June 2007, Montreal
10.30 a.m. – 11 a.m.	**Coffee/Tea Break**

	Plenary
11 a.m. – 1 p.m.	*Agenda items*: 6. Elements and formats of risk assessment reports/dossiers and risk assessment summaries for the BCH: 6.1. Key considerations in the preparation of environmental risk assessments of living modified organisms and the required scientific capacities: a scientist's perspective;
1 p.m. – 2 p.m.	**Lunch**
2 p.m. – 3.30 p.m.	*Agenda item*: Item 6 *(continued)* 6.2. Key considerations in the review of environmental risk assessments of living modified organisms: A regulator's perspective 6.3. Overview of the risk assessment summaries submitted to the Biosafety Clearing-House in accordance with paragraph 3 (c) of Article 20 of the Protocol and the need for a standardized format. 6.4. Mechanisms, opportunities and challenges for regional cooperation and sharing of information and expertise in risk assessment and risk management in Asia and the Pacific region.
3.30 p.m. – 4 p.m.	**Coffee/Tea Break**
4 p.m. – 5.30 p.m.	*Agenda item*: 7. Regional cooperation and sharing of information and expertise: 7.1. Mechanisms, opportunities and challenges for regional cooperation and sharing of information and expertise in risk assessment and risk management in Asia and the Pacific region; 7.2. Focus groups: capacity building and guidance material.
	Agenda item: Item 7 *(continued)*
10.30 a.m. – 11.00 a.m.	**Coffee Break/Tea**
11 a.m. – 1 p.m.	*Agenda items*: 8. Conclusions and recommendations. 9. Other matters.
1 p.m. – 2 p.m.	**Lunch**
2 p.m. – 4 p.m.	10. Adoption of the Workshop report. 11. Closure of the Workshop.

Annex II

REVISED BCH COMMON FORMAT FOR RISK ASSESSMENT SUMMARIES 1/

General information	
1. Country taking decision or making declaration:	<Controlled vocabulary: countries 2/>
2. Title of risk assessment: 3/	<Text entry>
3. Date	<controlled vocabulary>
4. Competent National Authorities:	<Competent National Authority common format 4/>
5. Name and contact details of the Applicant/Notifier:	<Text entry>
6. Name of risk assessor: 5/	<same as competent authority> or <Text entry>
7. Scope of the risk assessment	<Text entry> 6/ <Controlled vocabulary> 7/
LMO information	
8. Living modified organism:	<Choose from list: LMOs 8/> *or* <Living modified organism common format 9/> *or* <text entry> 10/

1/ The procedure for risk assessments is further elaborated in Annex III of the Biosafety Protocol. Summaries of risk assessments or environmental reviews generated by a government's regulatory process are made available to the BCH in accordance with Article 20, paragraph 3 (c) of the Protocol. This risk assessment summary may also include environmental reviews.

2/ The BCH Controlled Vocabulary for Countries is available at: http://bch.biodiv.org/thesaurus/domain.aspx?domainid=1

3/ The complete title of the risk assessment and/or the reference number to an entry in a national database where information on the risk assessment can be found, and that can be used to identify it.

4/ Please provide a BCH record number for previously registered information, or complete the Competent National Authority common format, available under the "National Contacts" heading at: http://bch.biodiv.org/resources/commonformats.shtml.

5/ This field should be filled in case the competent authority has chosen another body to perform the risk assessment.

6/ Provide a reference to the national or regional legislative system applicable to the risk assessment, and a description of the scope if 'other' is chosen from the controlled vocabulary.

7/ Provide a description of the scope of the risk assessment from the list: 'commercial cultivation'; use for food, feed or processing; field trial; contained use; other scope.

8/ The List of LMOs includes all living modified organisms currently in the LMO Registry, available at https://bch.biodiv.org/organisms/lmoregistry.shtml

9/ If the LMO is not already in the database (i.e. included in the controlled vocabulary), please complete the living modified organism (LMO) common format available under the "Organisms" heading at: http://bch.biodiv.org/resources/commonformats.shtml.

10/ If no unique identification is provided (yet), for instance because the risk assessment concerns a field trial at an early stage of development, another reference number should be considered e.g. the reference number mentioned in footnote 3.

CHARACTERISTICS OF MODIFICATION	
9. Characteristics of the recipient organism 11/	<Text entry>
10. Vector characteristics: 12/	<Text entry> *[Explore the possibility of a controlled vocabulary]*
11. Insert or inserts: 13/	<Text entry> *[Explore the possibility of a controlled vocabulary, next to the text entry] [use GenBank gene accession as a link when available]*
a) Molecular characterization of DNA inserted into the genome of the recipient 14/	<Text entry> <Link to the record in the BCH where molecular characterization can be found> 15/
b) Functional characterization of the coding sequences inserted into the genome of the recipient 16/	<Text entry> *[Explore the possibility of a controlled vocabulary, next to the text entry]*
c) Selectable markers used	<Text entry> *[Explore the possibility of a controlled vocabulary, replacing the text entry]*
12. Method of transformation	<Text entry> *[Explore the possibility of a controlled vocabulary, replacing the text entry]*
Detection and identification of the living modified organism	
13. Detection and identification methods: 17/	<Text entry>
Intended use and receiving environment	

11/ Provide relevant specific information on the characteristics of the recipient organism used to value the outcome of the risk assessment, e.g. persistence or presence of crossable relatives in the specific receiving environment.

12/ Characteristics of the vector, should include its identity, if any, and its source or origin, and its host range, as elaborated in Annex III paragraph 9 (c) of the Protocol.

13/ Genetic characteristics of the inserted nucleic acid and the function it specifies, and/or characteristics of the modification introduced, as elaborated in Annex III paragraph 9 (d) of the Protocol.

14/ If a molecular characterisation of the LMO is available elsewhere in the CBH, describe which, if any, details of the molecular characterization were taken into specific consideration in the risk assessment.

15/ If no reference is available, describe as appropriate: a) the criteria used to check the completeness and validity of the data supplied by the notifier; b) the type of data (e.g. hybridization and sequence data) used, *inter alia*, for determining the overall structure and for detailed characterization of the insert; c) an interpretation of the characterization data, in terms of genes and relevant ORFs that are expected to be expressed; and d) the explicit conclusion drawn from the data, and the list of items stemming from the molecular characterization that are relevant for the risk assessment.

16/ Describe the phenotypic characteristics that (are expected to) result from expression of the sequences described in the molecular characterization, taking into account as appropriate, the level of expression and the specific tissues where and the timing when expression occurs,

17/ Suggested detection and identification methods and their specificity, sensitivity and reliability, as elaborated in Annex III, paragraph 9 (f) of the Protocol.

14. Intended use of the LMO: 18/	<Text entry> *[Explore the possibility of a controlled vocabulary] [add checkbox FFP or not]*
15. Receiving environment:19/	<Text entry> *[Explore the possibility of a controlled vocabulary]*
Risk assessment summary 20/	
16. Novel genotypic and phenotypic characteristics:21/	<Text entry>
17. Potential adverse effects that may be realized:22/	<controlled vocabulary with multiple options: impact on non-target organisms, gene flow, etc> and <Text entry>
18. Likelihood of the potential adverse effects to be realized 23/	<Text entry> *[attempt to link to each adverse effect identified in item 17]*
19. Possible consequences:24/	<Text entry> *[attempt to link to each adverse effect identified in item 17]*
20. Cumulative Overall estimation and evaluation of risk: 25/	<Text entry>
21. Risk management strategies:26/	<Text entry>

18/ Information relating to the intended use of the living modified organism, including new or changed use compared to the recipient organism or parental organisms, as elaborated in Annex III paragraph 9 (g) of the Protocol.

19/ Information on the location, geographical, climatic and ecological characteristics, including relevant information on biological diversity and centres of origin of the likely potential receiving environment, as elaborated in Annex III paragraph 9 (h) of the Protocol. Also provide a general discussion on the expected impact of the intended use of the LMO on the receiving environment, and how this is taken into account within the scope of the risk assessment.

20/ Provide a summary of the risk assessment information in accordance with paragraphs 8 (a) to 8 (f) of Annex III to the Protocol.

21/ An identification of any novel genotypic and phenotypic characteristics associated with the living modified organism that may have adverse effects on biological diversity in the likely potential receiving environment, taking also into account risks to human health, as elaborated in Annex III paragraph 8 (a) of the Protocol.

22/ Provide an identification of adverse effects that may be realized, taking into account the level and kind of exposure of the likely potential receiving environment to the living modified organism, as elaborated in Annex III paragraph 8 (b) of the Protocol.

23/ Provide an evaluation of the likelihood that the potential adverse effects listed in item 15 may occur.

24/ An evaluation of the consequences should these adverse effects be realized, as elaborated in Annex III paragraph 8 (c) of the Protocol.

25/ An estimation of the overall risk posed by the living modified organism based on the evaluation of the likelihood and consequences of the identified adverse effects being realized, as elaborated in Annex III paragraph 8 (d) of the Protocol.

26/ A recommendation as to whether or not the risks are acceptable or manageable, including, where necessary, identification of strategies to manage these risks, as elaborated in Annex III paragraph 8 (e) of the Protocol. Where there is uncertainty regarding the level of risk, it may be addressed by requesting further information on the specific issues of concern or by implementing appropriate risk management strategies and/or monitoring the living modified organism in the receiving environment, as elaborated in Annex III paragraph 8 (f) of the Protocol.

CONCLUSION OF THE RISK ASSESSMENT	
22. Summary of the risk assessment or environmental review:27/	<Text entry>
Access to additional detailed risk assessment information	
23. Availability of, and ways of accessing, the detailed risk assessment information:28/	<Text entry>
Additional information	
24. Any other relevant information:29/	<Text entry>
25. Relevant documents or links:30/	<Web address (URL and website name or description) or attachment>
26. Notes:31/	<Text entry>

Name of person authorizing publication:
Signature:
Date:

Please return to:
Secretariat of the Convention on Biological Diversity
413 rue Saint-Jacques, suite 800
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Tel.: +1 514 288 2220
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BCH website: http://bch.cbd.int
SCBD website: http://www.cbd.int

27/ Provide an overall executive summary of the risk assessment including the final decision.

28/ Please indicate whether more details on the risk assessment are available and how they can be accessed.

29/ Please use this field to provide any other relevant information that may not have been addressed elsewhere in the record.

30/ Please provide website addresses containing relevant information, and/or attach one or more relevant documents that will be stored in the database for users to download.

31/ The notes field is for your personal use only: you can see it when you edit the record, but it is not visible to others when the record is viewed through search pages.

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