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AFRICAN REGIONAL WORKSHOP ON CAPACITY-BUILDING AND EXCHANGE OF EXPERIENCES ON RISK ASSESSMENT AND RISK MANAGEMENT OF LIVING MODIFIED ORGANISMS
Addis Ababa, 23-25 August 2007

REPORT OF THE WORKSHOP

INTRODUCTION

1. The African Regional Workshop on Capacity-building and Exchange of Experiences on Risk Assessment and Risk Management of Living Modified Organisms was held in Addis Ababa, Ethiopia, from 23 to 25 August 2007. It was organized back-to-back with the African Union (AU) Experts Meeting on the Revised African Model Law on Safety in Biotechnology. The Workshop was hosted by the African Union Commission and was funded by the Government of the Netherlands through the Ministry of Housing, Spatial Planning and the Environment.

2. The Workshop was attended by 57 participants from 25 countries and 16 organizations that are involved in risk assessment and risk management of living modified organisms.

3. The following countries were represented: Burundi, Chad, Cote d'Ivoire, Democratic Republic of the Congo, Ethiopia, Gabon, Ghana, Guinea, Kenya, Liberia, Libyan Arab Jamahiriya, Mali, Mozambique, Namibia, Nigeria, Rwanda, Senegal, Seychelles, South Africa, Sudan, Swaziland, Togo, Uganda, Zambia and Zimbabwe.

4. The following organizations were represented: Addis Ababa University, AfricaBio, African Biodiversity Network, African Union Commission, Agence Africaine de Biotechnologie (AAB), Community of Sahel-Saharan States, COPAGEN, Eastern Africa Farmers Federation, Environmental Rights Action/Friends of the Earth Nigeria (ERA/FOEN), Forum for Agricultural Research in Africa (FARA), Haramaya University, Institute for Sustainable Development, New Partnership for Africa's Development (NEPAD) Secretariat, NEPAD Biosciences east and central Africa (BecA), United Nations Economic Commission for Africa (UNECA) and University of Rome "La Sapienza".

5. Ten resource persons from the following organizations facilitated the Workshop: Association for Agricultural Research in East and Central Africa (ASARECA), Institute of Sahel (INSAH), Makerere University Kampala, Netherlands Ministry of Housing, Spatial Planning and the Environment, Netherlands National Institute of Public Health and Environment, United Nations Environment Programme - Global Environment Facility (UNEP-GEF), University of Minnesota, BiosafeTrain Project - University of Nairobi, and the Secretariat of the Convention on Biological Diversity.

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

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

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

(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;

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

ITEM I. OPENING OF THE WORKSHOP

7. The Workshop was officially opened by Mrs Raymonde Agossou, Acting Director, Department of Human Resources, Science and Technology at the African Union Commission. Mr. Charles Gbedemah, Head of the Biosafety Division at the Secretariat of the Convention on Biological Diversity (CBD) also made opening remarks on behalf of Mr. Ahmed Djoghlaf, the Executive Secretary of the Convention on Biological Diversity.

8. In her remarks, Mrs Agossou welcomed participants on behalf of the African Union Commission. She said the African Union Commission was honoured to host the Workshop and was pleased to have worked with the Secretariat of the Convention on Biological Diversity in organizing it. She informed participants about the decision taken in 2005 by the African Union Executive Council which stresses the need for Member States of the African Union to build necessary human and institutional capacities to address biosafety issues within the framework of the Cartagena Protocol on Biosafety. She also highlighted the African Strategy on Biosafety which was adopted along with the report of the African High-Level Panel on Modern Biotechnology at the extraordinary session of the African Ministerial Council on Science and Technology in November 2006. She noted that the pillars of the Strategy included capacity-building, preparedness for international negotiations and international cooperation. Mrs Agossou also made reference to the draft revised African Model Law on Safety in Biotechnology which had been discussed by the experts just prior to the Workshop. She expressed the hope that the revised model law, once adopted, would help to facilitate the regulation of modern biotechnology by the African Union Member States. Mrs Agossou concluded her remarks by expressing gratitude for the collaboration between the African Union Commission and the Secretariat of the Convention on Biological Diversity in organizing the Workshop and wished participants fruitful deliberations.

9. In his statement, Mr. Gbedemah noted that a lack of capacity, particularly with respect to limited expertise in the field of risk assessment and risk management, continued to be a major challenge facing many developing countries and countries with economies in transition in the implementation of the Protocol. He recalled decision BS-III/11 taken by the Conference of the Parties to the Convention on Biological Diversity serving as the meeting of the Parties to the Cartagena Protocol on Biosafety (COP-MOP) at its third meeting in Curitiba, Brazil in March 2006. In that decision, the Parties had, *inter alia*, urged Parties and other Governments to undertake a number of activities to foster capacity-building in risk assessment and risk management. The Parties had also noted a potential need for further guidance focussed on particular types of living modified organisms, for example on risk assessment for emerging applications of living modified organisms. In this regard, the Parties agreed to consider at their next meeting the need for developing further guidance on specific aspects of risk assessment and risk management and consider the appropriate modalities for developing such guidance. Mr. Gbedemah outlined the objectives of the Workshop and urged participants to discuss freely and make concrete recommendations to enhance the capacity for undertaking and/or reviewing risk assessment in the region and to facilitate the discussions at the next meeting of the Parties to the Convention on Biological Diversity serving as the meeting of the Parties to the Cartagena Protocol on Biosafety. He thanked the Government of the Netherlands for providing financial support for the Workshop and the African Union Commission for co-organizing and hosting the Workshop. In particular he recognized the contribution

made by Bather Kone and Mahlet Teshome in handling the logistical preparations for the Workshop. Finally, Mr. Gbedemah expressed the Secretariat's gratitude to the resource persons who offered to facilitate the Workshop.

ITEM 2. ORGANIZATIONAL MATTERS

10. Participants elected Mr. Matthew Dore (Nigeria) to serve as Chairperson of the Workshop and Mr. Joseph Francois (Seychelles) as Rapporteur.

11. The Workshop adopted its agenda on the basis of the provisional agenda proposed by the Executive Secretary (UNEP/CBD/BS/RW-RA&RM/Afr./1/1). The proposed programme of work for the Workshop (UNEP/CBD/BS/RW-RA&RM/Afr./1/1/Add.1) was also adopted (see annex I below).

12. The following substantive items were addressed:

(a) Introduction to risk assessment and risk management of living modified organisms;

(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.

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

13. 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 Secretariat of the Convention on Biological Diversity. The second one entitled: "Risk assessment and risk management concepts, general principles, steps and methodologies: An overview", was jointly prepared by Dr. Jenesio Kinyamario from the BiosafeTrain Project – University of Nairobi and Dr. Gabor Lövei from the BiosafeTrain Project - University of Aarhus.

14. Mr. Tamale described the Cartagena Protocol's provisions on risk assessment (i.e. Article 15 and Annex III) and risk management (Article 16). He underlined the central role of risk assessment in decision-making regarding the import or release of living modified organisms into the environment. He noted that the Protocol provides that risk assessments should be carried out in a scientifically sound and transparent manner and on a case-by-case basis, taking into account recognized risk assessment techniques and guidelines developed by relevant international organizations. He also observed 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 and 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 noted that risk assessment and risk management are closely interlinked noting that the latter encompasses mechanisms, measures and strategies for regulating, managing and/or controlling risks identified in the risk assessment. Finally, he outlined the programme of work and decisions of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety with respect to risk assessment and risk management and the issues to be addressed at its next meeting.

15. Dr. Kinyamario discussed the ecological approach to risk assessment and highlighted its importance. He described the nature, importance of and threats to different types of ecosystem services and emphasized the need to take these into account in the risk assessment of living modified organisms. He stated that a scientifically sound risk assessment should be case-specific and must account for the

whole transgenic organism. It must also treat a transgenic organism within an integrated biological system consisting of the organism, the novel trait and the receiving environment. He briefly highlighted the general principles and the main steps involved in a risk assessment, i.e. (i) hazard identification; (ii) exposure assessment; (iii) consequences evaluation; (iv) risk characterization; and (v) mitigation/ risk management options.

16. In the ensuing discussion, many participants emphasized the need to build capacities at the national level noting that Africa lags far behind other regions in this regard. It was reported that the demand for training is very high while the opportunities are very few. For example, the University of Bamako has developed an intensive interdisciplinary course in biosafety for French-speaking Africa but only a limited number of students can be sponsored due to limited resources. The African Union Commission was urged to collaborate with the Secretariat of the Convention on Biological Diversity to organize more training workshops and disseminate existing risk assessment guidance materials to member States and other agencies.

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

17. Under this item, Workshop participants shared information about the current status, experiences gained and lessons learned in the implementation of the risk assessment and risk management provisions of the Protocol. They discussed the challenges encountered and capacity-building needs. Two detailed presentations were made on regional-level experiences from Eastern Africa and West Africa. The first was by Dr. Charles Mugoya of the Association for Agricultural Research in East and Central Africa (ASARECA) and the second was by Dr. Siaka Dembele of the Institute of Sahel (INSAH). Four countries – South Africa, Nigeria, Kenya and Uganda – made presentations on their national experiences as well. Participants from other countries also made brief remarks.

18. Dr. Mugoya described the status of biotechnology and biosafety in Kenya, Uganda, Tanzania, Sudan, Ethiopia and Burundi with respect to existing infrastructure, regulatory frameworks and human resource capacities for risk assessment as well as stakeholder involvement and overall experience in risk assessment. He outlined past and ongoing biosafety capacity-building efforts, including training in risk assessment and noted that there is still limited capacity and experience in most countries in the subregion with regard to risk assessment and the handling of applications for LMO imports or release into the environment. So far no application for commercial use of living modified organisms has been approved in the subregion. However, Kenya and Uganda have approved some field trials.

19. Dr. Dembele described the Economic Community of West African States (ECOWAS) Regional Biosafety Program which is coordinated by the Sahel Institute (INSAH). The programme aims at assisting countries of the subregion in developing capacities for implementation of biosafety measures. He reported the ECOWAS Plan of Action on Biosafety was adopted in March 2007 and that common biosafety regulations are being developed for submission to the next ECOWAS summit. Under the biosafety programme an ECOWAS risk assessment framework will be developed. Dr. Dembele emphasised the need for ECOWAS member countries to work together in developing a regional framework for risk assessment and in building the necessary capacities.

20. Ms. Wadzanayi Mandivenyi briefly described the South African experience on risk assessment and risk management and outlined areas where additional guidance is required. She described the national biosafety regulatory framework, in particular the Genetically Modified Organisms Act (Act No. 15 of 1997). She outlined the activities that have been approved under the Act. These include: (i) general release (commercial use) approvals for GM maize, cotton and soybean; (ii) commodity clearance (food and/or feed, not planted) of maize, soybean and oilseed rape; and (iii) contained use applications (GM bacteria producing amino acids, insect resistant sweet potato and cassava for improved starch content). She reported that South Africa still needs guidance with regard to: (i) genetic modification of indigenous

crops, trees and fish; (ii) long term monitoring of living modified organisms released into the environment; (iii) pharmaceuticals in plants; and (iv) guidance on socio-economic considerations.

21. Mr. Mathew Dore briefly described the experience with the GM cassava application in Nigeria and the challenges that were encountered. Mr. Arthur Makara shared experience with the handling of the application for the confined field trial of genetically modified sweet banana which has resistance to the bacterial wilt and Black Sigatoka fungal disease. Mr. Harrison Macharia reported that Kenya has approved five applications to date, including trials for GM rinderpest vaccinia, and is currently considering two other applications, including one for GM soybean feed.

22. During the discussions, participants identified a number of issues and capacity-building requirements that need to be addressed. Key issues raised included (i) limited institutional and human resource capacities to undertake risk assessments; (ii) lack of data and information to support risk assessments; (iii) poor coordination and collaboration among countries; and (iv) the need for transparency and accountability by regulatory authorities. A summary of the issues and the recommendations proposed for enhancing the level and capacity for carrying out risk assessments in the region appear in Section III of this report.

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

23. Under this item, two presentations were made. The first was by Dr. Hans Bergmans, from the Netherlands National Institute of Public Health and Environment, entitled "Overview of the nature, scope and applicability of existing guidance materials for risk assessment and risk management of living modified organisms". The second was by Prof. Opuda-Asibo, from Makerere University, on the outcomes of the Canada-Norway Expert Workshop on Risk Assessment for Future Applications of Modern Biotechnology, which was held in Montreal from 4 to 6 June 2007.

24. Dr. Bergmans highlighted some of the existing guidance materials, which range from specific scientific articles to national-level guidelines to generic guidance documents agreed to in international fora. He provided examples of possible sources where they 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. Goggle scholar). He indicated that the BCH also contains guidance materials and 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 in deciding which existing guidance materials and information to use: (i) the type of resource (scientific paper, book, conference report, interpretative report); (ii) the author of the material/information (scientific expert, regulator, NGO activist, etc.,); (iii) the purpose for which they were compiled (scientific discussion, regulatory underpinning, NGO dissident view, etc), (iv) the 'endpoints' of the process (environmental safety, food/feed safety, etc); and (v) when it was published. Furthermore, Dr. Bergmans described the basic information needed to support risk assessments, including: characteristics of the recipient, characteristics of the insert, characteristics of the LMO, conditions of the release and characteristics of the environment.

25. Prof. Opuda-Asibo presented the main outcomes (observations and recommendations) of the Canada-Norway expert workshop which focussed on the following emerging applications of living modified organisms: transgenic fish, trees, pharmaplants and viruses for the management of animal populations. The workshop, *inter alia*, considered the available risk assessment guidance for these applications and identified gaps in information and science that could have an impact on the risk assessments. It further considered the appropriateness of using the current models for risk assessment with respect to these applications. The workshop observed that the general principles and methodologies for risk assessment contained in Annex III of the Protocol also apply to transgenic fish, trees, viruses and pharmaplants. However it was noted that there is a need to develop specific methodologies and specific protocols for conducting risk assessments for transgenic fish, trees and viruses. It was also noted that

there is insufficient guidance on how to perform risk assessment for transgenic fish and viruses. Furthermore, the workshop observed that there are major gaps in knowledge on several elements necessary to conduct risk assessments for all the above applications, including a lack of baseline data and the empirical data needed for modelling purposes. Accordingly, it was recommended that further research should be undertaken to fill the knowledge gaps, including the specific gaps identified during the workshop. The workshop also recommended that the new information and existing guidance, methodologies, baseline information and risk assessments should be made readily available through the Biosafety Clearing-House and other relevant international databases.

26. Participants welcomed the two presentations. They noted that although a number of risk assessment guidance materials have been developed, many institutions and individuals in Africa to not have easy access to them. They also took note of the outcomes of the Canada-Norway workshop underscored the need to address the gaps identified by the workshop and to implement its recommendations. Following the presentations and brief discussions in the plenary, two working groups were established, one for English-speaking countries and another for French-speaking countries. These working groups shared experience gained in using existing guidance materials in Africa, discussed the need for additional guidance on specific aspects of risk assessment and risk management and made recommendations for consideration at the next meeting of the Parties to the Convention on Biological Diversity serving as the meeting of the Parties to the Cartagena Protocol on Biosafety. A summary of the discussions and recommendations appear in section III of this report. Finally, each participant was given a CD-ROM containing some of the existing guidance materials on risk assessment and risk managements and other relevant resource materials.

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

27. Under this item, two presentations were made. The first was by Dr. David Andow on the "Key scientific capacity requirements for environmental risk assessment of living modified organisms". The second was by Dr. Hans Bergmans on the "Format for risk assessment summaries submitted to the Biosafety Clearing-House in accordance with paragraph 3 (c) of Article 20 of the Protocol".

28. Dr. Andow described the basic elements of an environmental risk assessment, including: (i) analysis of the recipient organism, the transgene and transgene products and the transgene in the recipient organism; (ii) the scope of the release; and (iii) analysis of the LMO in the local environment. He emphasized that risk assessment is much more than the detection of living modified organisms. Furthermore, he described some of the key considerations in, and the scientific capacity requirements for, risk assessment of living modified organisms with respect to the following ecological challenges: (i) gene flow and its consequences; (ii) effects of LMOs on non-target organisms; and (iii) development of resistance in target organisms. He emphasized the need for coordination of scientific expertise needed to address different aspects of a risk assessment and also stressed the importance of mobilizing, motivating and engaging scientists who are not currently involved in risk assessments but whose expertise is nonetheless relevant.

29. 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 the standardized format and setting out, as appropriate, how risk assessment problems have been solved (in particular the extent to which existing information has been used to support risk assessments). Dr. Bergmans 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. In this regard, he made a number of recommendations for additional elements/fields or sub-headings to the current common format and gave the rationale for the different additions. In summary, the main proposed changes included the following:

(a) Under the section, "general information, add the following fields:

(i) Name and contact details of the applicant,

(ii) Scope of the risk assessment; and

(iii) Methodology of the risk assessment (to provide information on the methodology used, including the endpoints and links to applicable legislation, guidance materials and other relevant documents).

(b) Under the section, "LMO information":

(i) Add a new field, "Characteristics of the recipient organism" – to describe the characteristics that are relevant to the risk assessment

(c) Under the section "Characteristics of modification"

(i) Add a new field "Method of transformation" – to describe the method of transformation and the vector/DNA sequences used in the transformation process

(ii) Expand the field entitled "Insert or inserts" to add the following elements/sub-headings:

- Molecular characterization of DNA inserted into the genome of the recipient
- Functional characterization of the coding sequences inserted into the genome of the recipient

(d) Modify the section "further information" to highlight, inter alia: issues taken into consideration, the potential risk scenarios, the point in the risk assessment at which the conclusion is drawn that the scenario poses no risk and how and on what grounds was it decided that the information provided is sufficient.

30. Following the presentations and brief discussions in the plenary, two working groups were again established, one for English-speaking countries and the other for Francophone countries. The working groups discussed the need to further develop the common format for risk assessment summaries submitted to the Biosafety Clearing-House. In doing so, they took into account the proposals that were made by the resource persons. The groups then presented the results of their discussions to the plenary. An expanded format for risk assessment summaries, which is contained in annex II to this report, was adopted at the end of the plenary discussions. Participants agreed to submit the revised common format for consideration by the CBD Secretariat and the Conference of the Parties serving as the meeting of the Parties to the Protocol at its fourth meeting.

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

31. Under this item, Mr. Alex Owusu-Biney of the UNEP-GEF Biosafety Programme gave a presentation entitled "Mechanisms, opportunities and challenges for regional cooperation and sharing of information and expertise in risk assessment and risk management in Africa". This was followed by discussions in the plenary and working groups.

32. Mr. Owusu-Biney emphasized the importance of regional cooperation in risk assessment and risk management, especially in view of the limited capacities in Africa. He highlighted some of the potential benefits of regional cooperation, including: access to a wider resource base, sharing of human and material resources and guidance materials and exchange of data and information. He noted that regional cooperation could, *inter alia*, facilitate: collaborative biosafety research and training, development of standardized sampling methodologies and validation procedures, establishment of thresholds and detection limits, development of common techniques for targeted analyses and profiling of living modified organisms, scientific risk assessment reviews, development of common application formats and development of regional biosafety guidelines. Finally, he recommended that the African region should:

(a) Foster continuous dialogue and collaboration to build regional biosafety research capacity and expertise;

(b) Establish harmonised databases with adequate data to support risk assessment and risk management, including botanic and product files/databases;

(c) Facilitate the development of, and/or access to existing risk assessment and risk management guidance materials;

(d) Galvanize regional political commitment to address biosafety issues and the scientific challenges;

(e) Establish regional advisory groups/panels; and

(f) Undertake biosafety research and training through either new or existing networks/platforms, including centres of excellence and mentorship or scholarship programmes.

33. During the discussions, participants explored ways to strengthen cooperation in risk assessment and risk management of living modified organisms at the regional and subregional levels. They identified existing opportunities for cooperation and discussed a possible framework/mechanism for networking between experts and agencies involved in risk assessment and risk management at the regional level, including exchange of information, expertise, training materials and risk assessment tools. The results of the discussions are summarised in the next section of this report.

34. Also during this session it was reported that the African Ministerial Council on Science and Technology (AMCOST) at its second conference in 2005 adopted the Africa's Science and Technology Consolidated Plan of Action (CPA). One of the initiatives under the CPA, i.e. the NEPAD African Biosciences Initiative, has established four regional networks/ centres of excellence throughout the continent which might provide useful mechanisms for networking in risk assessment and risk management. These are: the Biosciences eastern and central Africa (BecANet), Southern African Network for Biosciences (SANBio), West Africa Biosciences Network (WABNet) and the North Africa Biosciences Network (NABNet). It was agreed that there is a need to enhance biosafety activities in those networks and accordingly the African Union Commission was urged to collaborate with these regional centres of excellence in order to facilitate further development of biosafety activities in the region.

35. It was also reported that the Eastern Africa subregion, with the assistance of the Association for Strengthening Agricultural Research in Eastern and Central Africa (ASARECA), has established a mechanism to facilitate regional collaboration on risk assessment and risk management. The West African subregion as well hopes to enhance collaboration among countries in the subregion on biosafety issues, including risk assessment and risk management, through the ECOWAS regional biosafety programme and other subregional biosafety capacity-building initiatives.

ITEM 8. CONCLUSIONS AND RECOMMENDATIONS

36. Participants made several general observations/conclusions and proposed a number of recommendations on the different issues. The main issues raised and discussed during the Workshop were: human resources and institutional capacity-building, data and information to support risk assessments, risk assessment and risk management guidance materials, a common format for risk assessment summaries submitted to the BCH and regional and technical cooperation on biosafety in general and risk assessment in particular.

A. Observations and conclusions

1. General observations

37. Participants made the following general observations and conclusions regarding the situation in Africa with respect to biosafety in general and risk assessment and risk management in particular:

(a) Few countries in Africa have actually undertaken risk assessment and risk management of living modified organisms. By and large, there is limited hands-on practical experience in most

countries. It would be useful for countries in the region that have undertaken risk assessment to share their experiences with those that have not yet done so;

(b) Many countries in Africa do not yet have biosafety regulatory frameworks in place to facilitate the handling of applications and risk assessments. Most of the countries are still developing their national biosafety frameworks. In the interim, they are using other related laws and regulations to handle applications for import or release of living modified organisms;

(c) Most of the local experts in the region who are qualified to undertake or review risk assessments work in academia, the private sector and government research institutions that are involved in biotechnology research. They are often invited to serve as members of national biosafety committees or technical/ expert advisory bodies that review applications and/or undertake risk assessments. Some participants raised concern that in some cases there is a potential conflict of interest where the applications and risk assessments are submitted by local institutions which have members on the national biosafety committees or technical expert/ advisory committees. In order to build public confidence in regulatory systems and to ensure transparency and accountability, it is important for members serving on different committees to declare their interests;

(d) In view of the limited number of experts in fields relevant for risk assessment and risk management of living modified organisms that are available in different countries, it would be unrealistic to automatically disqualify experts working with institutions involved in biotechnology research from serving on the national biosafety committees and expert panels or advisory groups;

(e) It is important to involve the public, including farmers and consumers, in the risk assessment review process. It is equally important to make relevant information publicly available in order to foster informed participation in the process, to identify issues of public concern and identify areas where additional information is needed to address those concerns.

2. Human resources capacity

38. There is a general shortage of expert human resources in most African countries to conduct and review risk assessments. Generally, most of the key officials, including regulators, legal officers, risk managers and members of the national biosafety committees lack adequate training and hands-on experience in undertaking risk assessments and risk assessment reviews.

39. Most countries currently have a limited pool of local experts and sometimes rely on external experts from other countries or international organizations. In this regard, participants underscored the need for African countries to identify and facilitate the sharing of experts available in the region. This could be achieved, for example, through existing mechanisms such as the regional and subregional centres of excellence and through a regional roster of experts.

40. Currently there are limited training opportunities for risk assessment and risk management in the region. Only a small number of universities have started offering undergraduate and graduate programmes in biosafety and biotechnology. Moreover, there are limited scholarships/fellowships for students to study these fields in the region and abroad.

41. There is a high turnover of experts in government institutions that address biosafety issues. The unpredictable staff movements combined with reliance upon a limited pool of experts creates a major problem for most countries in Africa.

42. The use of experts from industry in undertaking or reviewing risk assessments is also limited. There is some reluctance to include experts from industry on technical/scientific panels set up by the National Competent Authorities to provide technical opinions on specific applications and risk assessment reports.

3. Institutional, technical and infrastructure capacities for risk assessment

43. A number of countries in Africa currently lack the infrastructure needed for risk assessment and risk management. Many lack or have poorly equipped laboratories, greenhouses, containment facilities

for field trials and other facilities. They also often lack adequate supplies of consumables required for research to support risk assessments.

44. Internet systems in many African countries are still poorly developed. Accordingly, many countries have limited access to risk assessment tools, databases and resource materials such as scientific journal articles on biosafety available through internet, including those in the Biosafety Clearing-House.

45. Institutions responsible for risk assessment and biosafety programmes in most African countries generally have limited financial support for their activities. This is, in part, due to a lack of political commitment to prioritise biosafety and biotechnology research for funding in national budgets and bilateral funding programmes.

4. Data and information to support risk assessments

46. A number of countries in Africa lack relevant data and information needed to support risk assessments and risk management. Even countries that have handled applications for import or release of living modified organisms or conducted risk assessments have often lacked baseline data on the specific local receiving environments (e.g. taxonomic information, distribution, ecology of local species, etc.) Generally, in the region, there is limited ongoing biosafety research that undertakes the collection of relevant data and information to support risk assessments and risk management.

47. Overall, there are very few biosafety research projects have been conducted in the region to collect relevant data and information to support risk assessments and risk management. Examples include: (i) the International Project on GMO Environmental Risk Assessment Methodologies (GMO-ERA project); (ii) the East African Regional Programme and Research Network for Biotechnology, Biosafety and Biotechnology Policy Development (BIO-EARN), which included a component to establish a database of botanic files or biological data on common crops and their wild relatives (including their taxonomic status, geographical distribution, ecology and biotic characteristics); and (iii) the Biotechnology and Biodiversity Interface (BBI) component of the Program for Biosafety Systems (PBS) funded by USAID. 1/

48. There are also other relevant research projects which have been conducted by scientists in other related field for different purposes. However, it is often difficult to know what data already exists and where it is located. Overall, there is limited access to and sharing of existing data and information among countries in the region that would facilitate risk assessments.

49. When carrying out a risk assessment review, it is important to make a distinction between "nice to know" and "need to know" information. In view of resource limitations it would advisable to focus on the "need to know" information when reviewing particular applications and risk assessments. Unfortunately, regulatory authorities in some African countries do not have the capacity to determine what specific information is needed and how the information provided should be interpreted and used in the risk assessment. Sometimes too much information that is not particularly necessary is requested or supplied.

5. Risk assessment and risk management guidance materials

50. Many countries in the region are not aware about the different existing guidance materials and tools on risk assessment and risk management and do not have easy access to relevant databases, websites and other sources where those materials can be obtained.

51. Accessibility to existing materials is also limited due to language barriers. Most of the existing guidance documents are available in English. Only a few are available in French and the other official languages used in Africa.

1/ Further details about these research projects can be obtained from the following websites: http://www.gmo-guidelines.info; http://www.ifpri.org/pbs/pdf/bbiprojects.pdf and http://bch.biodiv.org/database/record.shtml?id=5669

52. A few countries in Africa, such as Ghana and South Africa, have developed or are in the process of developing national guidelines or frameworks for risk assessment of living modified organisms. However these have not yet been shared with other African countries.

53. There is a lack of guidance materials for emerging applications of modern living modified organisms including: transgenic fish, trees, pharmaplants and viruses for the management of animal populations, and guidance on specific types of risks pathways. There is also limited guidance with regard to risk management, including post-release monitoring of the impacts of living modified organisms released into the environment.

6. Common format for risk assessment summaries submitted to the BCH

54. African countries need to share available risk assessments in order to learn from each other. A common format for risk assessment reports is necessary to make it easier for other countries/users to understand the information provided in the summarised report and to compare different reports. In view of the fact that the scope and structure of risk assessment reports for different applications might vary significantly according to the type of application or national requirements, common format is helpful.

55. The proposed changes to the expanded common format for risk assessment summaries, which is contained Annex II to this report, are necessary in order to enable governments submitting summaries to provide key additional information that would be useful to other countries.

7. Regional and technical cooperation

56. Currently, there is limited cooperation and exchange of knowledge, experience and expertise on risk assessment and risk management among relevant national institutions at the regional and subregional levels. There is a need to establish a mechanism to facilitate the exchange of existing information, including completed risk assessments in the region and experiences.

57. There are also few private–public institutional partnerships and partnerships between biosafety and biotechnology centres of excellence in the region and relevant international organizations, including centres around the world that have commercialized or conducted trials of LMOs. There is a need for countries in the region to work more closely together and to strengthen technical cooperation and partnerships in order to share experiences and learn from each other.

58. Finally, a number of biosafety capacity-building initiatives have been developed in the region. However, there is a lack of coordination and collaboration among them. As a result, efforts and resources have often been dispersed.

B. Recommendations

59. Following the brainstorming sessions in the different working groups which were established in the course of the Workshop and the general discussions during the plenary sessions, participants adopted the following recommendations.

1. General recommendations

60. Parties and other Governments in Africa should:

(a) Finalize and adopt their biosafety regulatory frameworks as soon as possible, if they have not done so. This is especially critical for those countries that have already received or are considering applications for import or release of living modified organisms and reviewing risk assessments. The African Model Law on Safety in Biotechnology should be used as much as possible for guidance;

(b) Require members selected to serve on national biosafety committees and technical expert panels or advisory committees to declare their affiliations and interests. With respect to specific applications, members should voluntarily disqualify themselves from considering applications where there is a potential, real or perceived, conflict of interest.

61. The African Union Commission should:

(a) Set up a permanent and functional biosafety unit within its Secretariat in order to provide technical and other support to member States, coordinate region-wide biosafety initiatives and facilitate collaboration and exchange of information between initiatives of member States regarding those initiatives;

(b) Play a leadership role in mobilizing political and financial support for biosafety programmes and activities in Africa;

(c) Disseminate to all relevant institutions engaged in biosafety issues in the region the African Strategy on Biosafety, which provides a road map to address the biosafety needs of the region, and facilitate its timely implementation;

(d) Facilitate the development of subregional biosafety strategies, in collaboration with the regional economic communities (RECs) of the African Union (i.e. the Arab Maghreb Union (UMA), Community of Sahel-Saharan States (CEN-SAD), Common Market for Eastern and Southern Africa (COMESA), East African Community (EAC), Economic Community of West African States (ECOWAS), Economic Community of Central African States (ECCAS), Inter-Governmental Authority on Development (IGAD), and Southern African Development Community (SADC);

(e) Set up a regional technical advisory panel on biosafety to provide, upon on request, independent expert scientific opinion and advice to member States on different biosafety issues, including the review of applications and risk-assessment reports;

(f) Create a mechanism to facilitate the establishment a regional network of certified laboratories and greenhouses in Africa that work in the field of living modified organisms, to assist countries in their biosafety research and risk-assessment activities;

(g) Take the lead in the identification and the establishment of a database of existing biosafety and biotechnology centres of excellence in the African region.

2. Human resources capacity development

62. Parties and other Governments in the region should:

(a) Invest in increasing the pool of trained experts and trainers in various fields that are relevant to risk assessment and risk management in order to provide a reservoir of human resources at the national and regional levels;

(b) Maximize the use of existing human resources in the region through, *inter alia*, staff exchanges and the mobilization of available expertise at various regional and subregional centres of excellence;

(c) Identify and mobilize local experts in different national institutions and establish a roster of experts at the national and/or subregional and regional levels;

(d) Compile and submit to the African Union Commission and to the respective regional economic communities (RECs), by December 2007, a list of experts (including those identified during the development of the national biosafety frameworks) for countries in the subregions to use them in conducting risk assessments;

(e) Organize risk-assessment and risk-management training workshops for policy makers, regulators, risk-management officials and members of national biosafety committees to enable them gain an understanding of the basic principles, steps and requirements. They will then be able to know what information to ask for and how to evaluate the information submitted.

63. The African Union Commission should:

(a) Follow up with the national focal points for the Cartagena Protocol on Biosafety, as well as the regional economic communities, to ensure that the recommendations contained in this report are implemented;

(b) Organize more training workshops for member States on various aspects of risk assessment and risk management, in collaboration with the Secretariat of the Convention on Biological Diversity and other relevant agencies;

(c) Identify and disseminate to member States existing risk-assessment and risk-management training/resource materials, including guidance documents;

(d) Encourage and support member States and relevant regional and subregional organizations to develop fellowship and mentorship programmes in the field of biosafety;

(e) Work with regional economic communities to identify which universities would be appropriate for the development of academic programmes in biosafety and biotechnology.

64. Relevant organisations working at the regional, subregional and national levels, including United Nations agencies (such as UNEP-GEF, UNDP and UNECA), NEPAD and the private sector should:

(a) Proactively reach out to countries and assist them in developing and implementing biosafety capacity-building initiatives;

(b) Develop or provide financial and technical support to countries and subregions in order to establish short-term training activities for different target groups (e.g. trainers, regulators, inspectors, etc);

(c) Assist countries in the development of harmonized frameworks for risk assessment and risk management.

3. Institutional, technical and infrastructure capacities for risk assessment

65. Parties and other Governments should:

(a) Increase funding for risk-assessment research on living modified organisms;

(b) Galvanize political commitment for increased funding to public institutions;

(c) Develop functional biosafety systems and upgrade biosafety-research facilities;

(d) Maximize, in the short term, the use of existing infrastructure, including that available at regional and subregional centres of excellence.

(e) Invest resources, in the medium to long term, in the development of their own infrastructure for risk assessment and risk management, including building, refurbishing and re-equipping laboratories, greenhouses and other facilities for contained field trials;

(f) Identify and submit to the African Union Commission and the respective regional economic communities, by December 2008, a list of facilities (e.g., GM detection laboratories) and centres of excellence within their jurisdiction which can be used by other countries.

66. The African Union Commission should:

(a) Take a leadership role in mobilizing political and financial support for biosafety programmes and activities in Africa;

(b) Identify centres of excellence in the different subregions that can assist member States in the development of their capacities in risk assessment and risk management (and biosafety in general);

(c) Identify and develop a directory of institutions or offices that member States can contact directly to request and access risk-assessment information and expert advice when required;

(d) Compile a list of all ongoing and planned initiatives in biosafety and modern biotechnology and make it available to all member States.

67. The regional economic communities should:

(a) Set up of biosafety offices with dedicated staff to develop and coordinate biosafety activities in the subregions.

4. Data and information to support risk assessments

68. Parties and other Governments should:

(a) Exchange available data and information relevant for risk assessment and risk management through the BCH, national websites and databases and other mechanisms such as regional networks and centres of excellence;

(b) Strengthen biosafety-research capacity in the region in order to facilitate the gathering of baseline data to support risk assessments and post-release monitoring;

(c) Promote research exchanges, scholarship/fellowship programmes and other programmes to support scientific research on biosafety;

(d) Submit risk-assessment summaries to the database established in Biosafety Clearing-House and make available complete risk assessments through the Biosafety Information Resource Centre of the Biosafety Clearing-House. This documentation should also be submitted to the African Union Commission and the regional economic communities.

69. The African Union Commission should:

(a) Research and collect information on existing biosafety studies and make it available online to make it easier for Governments to access it;

(b) Develop initiatives to strengthen biosafety-research capacity;

(c) Establish a database for reports of risk assessments carried out in Africa and make the reports available through the Biosafety Clearing-House;

(d) Collect and disseminate to member States reports of risk assessments carried out.

5. Risk assessment and risk management guidance materials

70. In order to develop risk-assessment guidance relevant to the Africa region, it was recommended that Governments should:

(a) Compile biology documents (e.g. botanic files) for crops coming from common ecological regions;

(b) Fund research that addresses biosafety questions that are specifically relevant for Africa;

(c) Use graduate and postgraduate students, research fellows and scientists to undertake research in order to fill gaps in data and information required to support risk assessments;

(d) Share all guidance materials and information generated;

(e) Develop guidance materials on secondary issues, such as manuals, management of trials, etc.

71. The African Union Commission should:

(a) Collect and review existing guidance materials on risk assessment information that are of relevance to Africa;

(b) Initiate a project to gather and compile regional databases on risk assessment;

(c) Create database for above-mentioned information and make it accessible through the Biosafety Clearing-House;

(d) Establish a "competitive" research-grants scheme for generating Africa-specific data on biosafety.

72. The Secretariat of the Convention on Biological Diversity is requested to:

(a) Create a support mechanism, through the Biosafety Clearing-House, to respond to queries from Parties on risk assessment and risk management.

(b) Inform Parties and other governments when new risk assessment and risk assessment guidance materials are submitted to the Biosafety Clearing-House.

73. The next meeting of the Conference of the Parties to the Convention on Biological Diversity serving as the meeting of the Parties to the Cartagena Protocol on Biosafety is invited to consider the need for further guidance and capacity-building to address the following issues in risk assessment and risk management:

(a) Dynamics of pollination biology;

(b) Soil-biology systems;

(c) Isolation distances - linked to pollen movement;

(d) Evolution of resistance;

(e) Understanding of refugia niches;

(f) Information on characteristics of the receiving environments;

(g) Long-term monitoring of environmental releases.

74. The next meeting of the Conference of the Parties to the Convention on Biological Diversity serving as the meeting of the Parties to the Cartagena Protocol on Biosafety is also invited to consider the following needs:

(a) Guidance on how to access information regarding characteristics of the environment (e.g. work on gene-flow);

(b) Development of the country capacity to review and interpret information contained in guidance tools and materials;

(c) Facilitation of access to information relating to specific ecosystems;

(d) Provision of assistance to build country capacity to review and interpret information contained in guidance tools and materials;

(e) Encouragement and facilitation of countries to share information on specific species sharing similar ecological zones;

(f) Establishment of facilities or support services through the Biosafety Clearing-House to assist countries in coping with risk assessment issues;

(g) Translation of existing guidance materials into French, and Arabic languages (the two official United Nations languages other than English used in Africa).

6. Common format for risk assessment summaries submitted to the BCH

75. The next meeting of the Conference of the Parties to the Convention on Biological Diversity serving as the meeting of the Parties to the Cartagena Protocol on Biosafety and the Secretariat of the Convention are invited to consider the revisions to the BCH common format for risk-assessment summaries, contained in annex II to this report.

7. Regional and technical cooperation

76. Parties and other Governments should:

(a) Foster collaboration and exchange of expertise among competent authorities and centres of excellence;

(b) Establish an inter-ministerial task force to foster coordination and collaboration and promote a consolidated approach to biosafety in region.

77. The African Union Commission should:

(a) Request the ministers of environment of the member States to hold regular dialogue sessions to pursue a common strategy on biosafety and to ensure the harmonized implementation of existing regional strategies and policies;

(b) Finalize the common position of Africa on genetically modified organisms and seek its full endorsement by the African Union Assembly;

(c) Facilitate efforts to enhance synergies between the ongoing processes for science and technology in the African Union under the African Ministerial Council on Science and Technology (AMCOST) and the African Ministerial Conference on the Environment (AMCEN).

8. Other recommendations

78. Governments, the African Union Commission and the regional economic communities should:

(a) Engage and actively involve civil-society organizations, farmers and the public in relevant biosafety processes and activities (including decision-making processes);

(b) Develop and implement more public-awareness and information-dissemination programmes on biosafety in the region.

79. Parties and other Governments should establish efficient traceability systems as part of their risk-management measures in order to mitigate cases of undesirable occurrences.

80. In order to facilitate the fullest participation of the non-English speakers, all the materials used in the workshops should be made available in French and Arabic (the two official languages of the United Nations, other than English, used in Africa).

ITEM 9. OTHER MATTERS

81. There were no other matters.

ITEM 10. ADOPTION OF THE REPORT

82. During the last session, participants considered the draft report prepared by the Rapporteur with the assistance of the Secretariat. The draft report included preliminary conclusions and recommendations directed to governments, the African Union Commission and other relevant organizations and to the fourth meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol. Participants adopted the amended draft report and requested Secretariat to incorporate the proceedings of the last day and send the final draft to all participants for comments. The present report has been finalized on that basis.

ITEM 11. CLOSURE OF THE MEETING

83. The Workshop was closed at 6.10 p.m. on Saturday, 25 August 2007.

Annex I

WORKSHOP PROGRAMME

	Plenary
Thursday *23 August 2007* 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 of living modified organisms • Introduction to risk assessment and risk management of living modified organisms in the context of the Cartagena Protocol on Biosafety; *presentation by the CBD Secretariat* • An overview of risk assessment and risk management concepts, general principles, steps and methodologies, by *Dr. Jenesio Kinyamario* • Discussions
10.15 a.m.– 10.45 a.m.	Coffee/Tea Break
10.45 a.m. – 1 p.m.	*Agenda items*: 4. National and regional experiences and lessons learned • Risk assessment and risk management of living modified organisms: Experiences and lessons learned from Eastern Africa, *by Dr. Charles Mugoya* • Risk assessment and risk management of living modified organisms: Experiences and lessons learned from West Africa, *by Dr. Siaka Dembele* *Discussions on the case study presentations* • Short country presentations
1 p.m.– 2 p.m.	Lunch Break
2 p.m. – 3.30 p.m.	*Agenda item 4* (*continued*) • Short country presentations
3.30 p.m. – 4 p.m.	Coffee/Tea Break

	Plenary
4 p.m. – 5.30 p.m.	*Agenda items*: **5.** Risk assessment and risk management guidance materials 5.1. Guidance materials for risk assessment and risk management of living modified organisms: • Overview of the nature, scope and applicability of existing guidance materials, by *Dr. Hans Bergmans* *Discussions* • Main outcomes of the Canada-Norway expert workshop on risk assessment for future applications of modern biotechnology, held from 4-6 June 2007 in Montreal, *by Prof. Opuda Asibo* *Discussions*
Friday ***24 August 2007*** 9 a.m. – 10.30 a.m.	*Agenda item*: 5.2. Consideration of the need for further harmonized guidance on specific aspects of risk assessment and risk management • Group Discussions
10.30 a.m. – 11 a.m.	Coffee/Tea Break
11 a.m. – 1 p.m.	*Agenda items***:** 6. Key considerations in the preparation and/or review of risk assessment reports: 6.1. Core elements and format of risk assessment reports/dossiers • Basic elements, and considerations in the preparation, of environmental risk assessments of living modified organisms and the key scientific capacity requirements, *by Prof. David Andow* • *Discussions*
1 p.m. – 2 p.m.	Lunch
2 p.m. – 3.30 p.m.	*Agenda item*: 6.2. Format for risk assessment summaries • Consideration of the common format for risk assessment summaries submitted to the Biosafety Clearing-House in accordance with paragraph 3 (c) of Article 20 of the Protocol, by *Dr. Hans Bergmans* • *Discussions*
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 on risk assessment and risk management • Mechanisms, opportunities and challenges for regional cooperation and sharing of information and expertise in risk assessment and risk management in Africa, *by Mr. Alex Owusu-Biney* • *Discussions*

	Plenary
Saturday ***25 August 2007*** 9 a.m. – 10.30 a.m.	*Agenda items*: *Agenda item 7 (continued)* 8. Conclusions and recommendations
10.30 a.m. – 11.00 a.m.	Tea/Coffee Break
11 a.m. – 1.00 p.m.	*Agenda items*: Agenda item 8: Conclusion and recommendations (*continued*) 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 I1

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. Competent National Authorities:	<Competent National Authority common format 4/>
4. Name and contact details of the Applicant	<Text entry>
5. Scope of the risk assessment	<Text entry>
LMO information 5/	
6. Living modified organism:	<Choose from list: LMOs 6/> *or* <Living modified organism common format 7/>
7. Characteristics of the recipient organism 8/	<Text entry>
CHARACTERISTICS OF MODIFICATION 9/	
8. Vector characteristics: 10/	<Text entry>

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.

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 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 can be used as an alternative to, or in addition to, the information under the subcategory "Characteristics of modification" (i.e. fields 5 and 6).

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

7/ 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.

8/ Provide relevant information on the characteristics of the recipient organism used to value the outcome of the risk assessment.

9/ The fields in this subcategory can be used as an alternative to, or in addition to, the "LMO information" field above.

10/ 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.

9. Insert or inserts: 11/	<Text entry>
a) Molecular characterization of DNA inserted into the genome of the recipient 12/	<Text entry>
b) Functional characterization of the coding sequences inserted into the genome of the recipient 13/	<Text entry>
c) Selectable markers used	<Text entry>
10. Method of transformation	<Text entry>
Detection and identification of the living modified organism	
11. Detection and identification methods: 14/	<Text entry>
Intended use and receiving environment	
12. Intended use of the LMO: 15/	<Text entry>
13. Receiving environment:16/	<Text entry>
Risk assessment summary 17/	
14. Novel genotypic and phenotypic characteristics:18/	<Text entry>

11/ 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.

12/ 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.

13/ Describe: a) the criteria used to check the completeness and validity of the data supplied by the notifier; b) the function of the genes and ORFs identified as relevant for the risk assessment in the molecular characterization; the level of expression in absolute terms and/or in relative terms, e.g. as percentage of total dry weight; c) the explicit conclusion drawn from the data, and the list of items stemming from the functional characterization that are relevant for the risk assessment.

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

15/ 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.

16/ 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.

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

18/ 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.

15. Likelihood of adverse effects being realized:19/	<Text entry >
16. Possible consequences:20/	<Text entry>
17. Estimation of overall risk:21/	<Text entry>
18. Recommendation on risks:22/	<Text entry>
19. Risk management strategies:23/	<Text entry>
OVERALL RISK ASSESSMENT SUMMARY	
20. Overall summary of the risk assessment or environmental review:24/	<Text entry>
Access to the detailed risk assessment information	
21. Availability of, and ways of accessing, the detailed risk assessment information:25/	<Text entry>
Additional information	
22. Any other relevant information:26/	<Text entry>
23. Relevant documents or links:27/	<Web address (URL and website name or description) or attachment>
24. Notes:28/	<Text entry>

19/ An evaluation of the likelihood of these adverse effects being 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.

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

21/ 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.

22/ 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.

23/ 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.

24/ Provide an overall executive summary of the risk assessment.

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

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

27/ 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.

28/ 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.

Name of person authorizing publication:
Signature:
Date:

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Annex III

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