UNEP

CBD

Convention on Biological Diversity

Distr.
GENERAL

UNEP/CBD/BS/COP-MOP/4/INF/15
21 April 2008

ENGLISH ONLY

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

REPORT OF THE CENTRAL AND EASTERN EUROPE REGIONAL WORKSHOP ON CAPACITY-BUILDING AND EXCHANGE OF EXPERIENCES ON RISK ASSESSMENT AND RISK MANAGEMENT OF LIVING MODIFIED ORGANISMS

INTRODUCTION

1. The Central and Eastern Europe Regional Workshop on Capacity-building and Exchange of Experiences on Risk Assessment and Risk Management of Living Modified Organisms (LMOs) was held in Chisinau, Republic of Moldova, from 26 to 28 November 2007.

2. The Workshop was attended by 21 participants from 13 countries and 4 organizations involved in risk assessment and risk management of living modified organisms.

3. The following countries were represented: Armenia, Belarus, Bosnia and Herzegovina, Bulgaria, Croatia, Georgia, Hungary, Republic of Moldova, Romania, Serbia, Slovenia, Tajikistan, The former Yugoslav Republic of Macedonia and Ukraine.

4. The following organizations were represented: Black Sea Biotechnology Association, Ecospectrum-Bender, Eco-Tiras International Environmental Association and Global Industry Coalition.

5. Five resource persons from the following organizations facilitated the Workshop: Austrian Federal Environment Agency, The Netherlands National Institute of Public Health and Environment, Norwegian Institute of Gene Ecology, Swiss Federal Institute of Technology Zurich and United Nations Environment Programme-Global Environment Facility (UNEP-GEF).

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

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

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

/…

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

(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 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 Hon. Constantin Mihailescu, Minister of Ecology and Natural Resources. 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, Executive Secretary of the Convention on Biological Diversity.

8. In his remarks, Hon. Mihailescu underscored the importance of capacity-building and sharing of experiences in the areas of risk assessment and risk management. He noted that the Biosafety Protocol requires Parties to make decisions regarding the import of living modified organisms for intentional introduction into the environment in accordance with scientifically sound risk assessments. It also requires Parties to establish and maintain appropriate mechanisms, measures and strategies to manage and control risks identified in the risk assessment. Hon. Mihailescu reported that Republic of Moldova ratified the Protocol in 2002 and has taken numerous steps to implement it. In particular, the Government developed a National Biosafety Framework and adopted a Law on Biosafety as well as regulations on the authorization of testing, production, use or marketing of LMOs. It also established National Biosafety Testing Center for the detection and testing of LMOs. With support from UNEP-GEF, the Government is also currently implementing projects to strengthen national capacities to implement the national biosafety framework, raise public awareness and to access and effectively use the Biosafety Clearing-House. On 8 November 2007, the Parliament of the Republic of Moldova approved the law on ratification of amendments to the Article 6 of the Aarhus Convention with respect to public participation in decisions on the deliberate release into the environment and placing on the market of genetically modified organisms. This amendment was strongly supported by Moldavian delegates at the COP-2 in Almaty, in May 2005. In conclusion, Hon. Mihailescu emphasized the need for scientific and technical cooperation at regional and sub-regional levels in the area of risk assessment and risk management, especially in light of limited experience and capacities in the region. He expressed hope that the workshop would identify opportunities and ways of strengthening such cooperation.

9. In his statement, Mr. Gbedemah thanked the Governments of Switzerland and Norway for the funding for the workshop and the Government of the Republic of Moldova for hosting it. He reported that this was the second in the series of the regional workshops to be held prior to the fourth meeting of the Conference of Parties serving as the meeting of the Parties to the Protocol which will be held in May 2008 in Bonn. The first one was held in Africa in August 2007. 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 noted that workshops were intended, among other things, to contribute to capacity-building in this field, promote the sharing of experiences, review existing guidance materials on risk assessment and risk management and identify gaps that need to be addressed. The outcomes of the workshops would contribute to the discussions at the fourth meeting of the Parties which is expected, *inter alia*, to consider the need for developing further guidance on specific aspects of risk assessment and risk management and consider the appropriate modalities for developing such guidance. In conclusion, Mr. Gbedemah 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. He thanked Hon. Mihailescu for his support in the organization of the workshop and for his personally opening it. He also recognized the contribution made by Dr. Angela Lozan and her team in handling the logistical arrangements for the Workshop. Finally, he expressed the Secretariat's gratitude to the resource persons who offered to facilitate the Workshop.

ITEM 2. ORGANIZATIONAL MATTERS

10. Participants elected Dr. Angela Lozan (Republic of Moldova) to serve as Chairperson of the Workshop and Ms. Anastasia Idrisova (Tajikistan) as Rapporteur.

11. The Workshop adopted its agenda on the basis of the provisional agenda that was proposed by the Executive Secretary (UNEP/CBD/BS/RW-RA&RM/CEE/1/1). The proposed programme of work for the Workshop (UNEP/CBD/BS/RW-RA&RM/CEE./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 presented by Mr. Jan Husby of the Norwegian Institute of Gene Ecology.

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. Mr. Husby gave a brief historical account of the evolution of biosafety regulation and risk assessment in the United States and other OECD countries. He reported that in 1983, OECD member countries established an Ad hoc Group of governmental experts on "Safety and Regulations in

Biotechnology" to review the country positions regarding the safety in use of genetically engineered organisms and identify the criteria adopted to monitor or authorize their production and use. In 1986, the OECD published the report of the Ad Hoc Committee, referred to as the "Blue Book" which became in many respects the basis for biosafety regulations of LMOs and gene technology in the western world. Mr. Husby described the general the principles and methodology of risk assessment specified in the Protocol (Article 15 and Annex III) with illustrations from the experiences in the European Union and Norway in conducting risk assessments. He also gave an overview of risk management systems and methodologies. He gave examples of risk management measures commonly applied to plant LMOs that are plants, including: isolation distances or "buffer zones", border rows with non-transgenic plants (to catch pollen), after release treatment (e.g. inactivation of remaining plants and seeds and specific soil treatment after harvest), after release control (e.g. removal of volunteers) and partial or full restrictions preventing planting in specified areas (e.g. to prevent horizontal gene flow).

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

16. Under this item, Workshop participants shared information on the current status, experiences and lessons learned in the implementation of risk assessment and risk management provisions of the Biosafety Protocol. They discussed the challenges encountered and capacity-building needs. The following participants made sub-regional case study presentations: Dr. Boris Anoshenko of Belarus (Baltic States), Dr. Maria-Mihaela Antofie of Romania (Black Sea sub-region), Ms. Anastasia Idrisova of Tajikistan (the Caucasus and Central Asian countries), Prof. Branka Javornik of Slovenia (Central Europe) and Dr. Aleksej Tarasjev of Serbia (the West Balkan countries). Copies of these presentations were posted on the web page of the workshop: http://www.cbd.int/doc/meeting.asp?mtg=RWCBCEE-01. In addition, brief country presentations were made by participants from: Armenia, Bulgaria, Hungary, Republic of Moldova and Ukraine. Participants from the Black Sea Biotechnology Association and Eco-Tiras International Environmental Association also made short presentations on the activities and experiences of their organizations in the area of risk assessment and risk management.

17. In his presentation, Dr. Anoshenko described the situation in Belarus, Estonia, Latvia and Lithuania. He reported that Estonia and Latvia had not received any application for LMO field release or placing on the market. Belarus received a notification from AgrEvo (Bayer CropScience) in 1999 for field trial of the GM sugar beet Edda with tolerance to herbicide (Glufosinate). The risk assessment was done by experts from Academy of Sciences. The Ministry of Environment allowed the field trials to proceed for a period of three years. Lithuania received two notifications in 2007 for field trials from Monsanto for the GM maize MON-00603-6 and from BASF for GM oilseed rape, which were assessed by the GMO Experts committee. He noted that there is limited risk assessment and risk management (RARM) experience in the Baltic region. He outlined the main challenges faced, which include: a lack of good and experienced RARM experts, absence of legally approved risk assessment system (methodology, steps, rules, etc.), difficulties in finding information to support risk assessments and difficulties in organizing constructive public participation in risk assessment and decision making. He made a number of recommendations for improving risk assessment and risk management in the sub-region, including the need to establish risk assessment and risk management systems and LMO monitoring and inspection (surveillance) systems and training in statistical methods for risk assessment, estimation of long term effects of LMOs and LMO identification.

18. Dr. Antofie described the situation in Romania and some of the other countries in the Black Sea sub-region (Bulgaria, Ukraine, Russian Federation and Turkey). She reported that in Romania a Biosafety Commission established in 2002 has reviewed more than 14 applications for field testing of GM maize, soybean, sugar beet, potato and plum tree and one application for placement on the market of GM maize (MON810). She noted that Bulgaria, Ukraine and Turkey had not yet approved any LMO for placing on the market. Dr. Antofie highlighted the need for cooperation among countries in the region so as to maximize the use of available institutional, financial, technical, and human resources. She noted that

for small countries capitalizing on the expertise and information available in the region may in the short-term be imperative for implementing the Protocol. In a supplementary presentation, Dr. Nevena Alexandrova of Bulgaria described the procedure for biosafety risk assessment in Bulgaria and outlined existing biosafety related research projects. She reported that the Council for Biosafety of GM higher plants had authorized a number of small scale field trials for GM potato, sunflower, tobacco, maize, vine, and oil rose but had not granted approval for commercialization of any GM crop. Dr. Boris Sorochynskyi of Ukraine also gave a short country presentation. He described the status of Ukrainian agriculture and the existing research capacity and described the national biotechnology policy and regulatory framework. He reported that reported that in 1998 the Ukrainian government authorized field trials of a few GM Crops, including GM potato, sugar beet, corn and rapeseed. However none of them has received final approval for commercial release. He also reported that a National Law on Biosafety and LMO regulation was adopted by the Ukrainian Parliament in 2007.

19. Ms. Idrisova described the situation in Azerbaijan, Armenia, Georgia, Kyrgyzstan, Kazakhstan, Tajikistan, Turkmenistan and Uzbekistan. She reported that all countries in the sub-region, except Turkmenistan and Uzbekistan, had developed draft national biosafety frameworks (NBF), with assistance from the UNEP-GEF project. Kyrgyzstan and Tajikistan had adopted their national biosafety law. However, there was limited practical experience in conducting risk assessment and risk management. Ms. Idrisova described the procedures and institutional mechanisms specified in the different NBFs with regard to the future conduct of risk assessment and risk management. She noted that most countries in the sub-region lack experts with relevant knowledge and skills and the necessary infrastructure (including laboratory equipment and chemical agents). She highlighted the need for regional cooperation to promote the sharing of experience and available expertise, development of joint risk assessment guidelines and training of specialists.

20. Prof. Javornik described the situation in the following Central European countries: Czech Republic, Hungary, Slovakia and Slovenia. She noted that as new members of the European Union (EU), those countries have to carry out risk assessments in accordance with the EU legislation and guidance on GMOs, including Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms, Regulation EC/1829/2003 on genetically modified food and feed and Regulation EC/1946/2003 on transboundary movements of genetically modified organisms. She reported that currently there is limited experience in risk assessment and risk management in the sub-region. In a supplementary presentation, Ms. Lippai Kitti of Hungary described the national experience in the risk assessment and outlined the roles of different institutional bodies. She reported that in 2005 the Hungarian Government commissioned an independent environment risk assessment of GM maize MON810 and plans to embark on new investigations for other LMOs authorized for cultivation in the EC, e.g. MON 88017.

21. Dr. Tarasjev described the situation in the West Balkan countries (Albania, Bosnia and Herzegovina, Croatia, Montenegro, The FYR of Macedonia and Serbia). He outlined the biosafety regulatory regimes and administrative systems in those countries and noted that as potential future members of the EU most of them were working towards aligning their systems with the EU legislation and risk assessment approaches and guidelines. Dr. Tarasjev noted that was limited risk assessment and risk management experience in the sub-region. So far only Croatia and Serbia have authorized field trials for GM maize. In 2007, Serbia also authorized field trials for GM Arabidopsis to be used for landmine detection. He outlined some of the constraints encountered and the priority needs. These include a need for: stable regulatory and administrative systems, capacity to implement existing systems, harmonization of regulatory systems of different countries in the sub-region, efficient systems for sharing of information and experiences, and regional approaches on capacity building in biosafety and training of specialists in risk assessment and risk management fields, including LMO detection and sampling methods.

22. As a follow up to this agenda item, three discussion groups were established on the second day of the workshop to deliberate on the following questions and make recommendations:

(a) What are the main capacity-building needs in the area of risk assessment and risk management in the sub-region (at the individual, institutional and systemic levels)?

(b) What measures should be taken to address the identified needs at the national and sub-regional levels and by who and when?

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

23. The following were identified as the main limitations/challenges faced by most countries in the region:

(a) A lack of procedures and criteria for LMO risk assessment;

(b) A lack of methods and national standards for LMO detection and quantification;

(c) A lack of accredited laboratories for LMO detection and analysis;

(d) Insufficiency of the existing laws in facilitating effective risk assessment and risk management. There is a need for supplementary regulations;

(e) Limited access to existing risk assessment and risk management guidance materials;

(f) Poor or lack of infrastructure (including laboratory facilities, equipment and consumables) for risk assessment and risk management;

(g) A scarcity of financial resources;

(h) Absence of good and experienced risk assessment and risk management experts;

(i) Absence of legally approved risk assessment and risk management systems (procedures and standards, etc.);

(j) Difficulties in finding and accessing relevant data and information for risk assessment and risk management (scientific publications, databases etc);

(k) Difficulties in organizing constructive public participation in risk assessment and risk management and decision making; and

(l) Unstable regulatory and administrative systems, partly due to changes in agencies' responsibilities and structure.

24. The following were identified as the main priority needs:

(a) Development of regulations and guidelines on risk assessment and risk management;

(b) Training of experts/specialists;

(c) Opportunities for gaining hands-on" experience on risk assessment and risk management;

(d) Strengthening of the regulatory and administrative systems to effectively facilitate risk assessment and risk management;

(e) Acquisition of laboratory equipment and consumables;

(f) Exchange of experience, available capacity and development of joint documents and decisions;

(g) Establishment of sustainable risk assessment and risk management systems;

(h) Establishment of LMO monitoring and inspection (surveillance) systems;

(i) Regular education, training and experience sharing in risk assessment and risk management particularly in statistical methods for risk assessment, monitoring of long term effects of LMOs, and parameters for LMO identification.

(j) Development of guidelines for risk assessment and management of LMOs;

25. The recommendations of the workshop regarding are presented under item 8 of this report (Conclusion and recommendations).

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

26. Under this item, two presentations were made. The first was by Dr. Helmut Gaugitsch from the Austrian Federal Environment Agency 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. The second 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".

27. Dr. Gaugitsch presented the main outcomes (observations and recommendations) of the Canada-Norway expert workshop which focused 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 modeling 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.

28. 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 organizations (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 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.

29. The participants welcomed the two presentations and noted that although a number of risk assessment guidance materials have been developed, many institutions and individuals in the region to not have easy access to them. They 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.

30. Following the presentations three focus discussion groups were established to deliberate on the following questions and make recommendations:

(a) On what specific aspects of risk assessment and risk management might additional guidance be required?

(b) What would be the most appropriate modalities for development of any such guidance?

31. The working groups discussed the above questions from the regional perspective and also in the context of the decision BS-III/11, paragraph 9, regarding the need for further guidance on specific aspects of risk assessment and risk management, and the appropriate modalities for development of any such guidance. The focus group reports were discussed in the plenary and integrated into one set of recommendations for transmission to the fourth meeting of the Parties to the Protocol. The recommendations are presented under item 8 of this report (Conclusion and recommendations).

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

32. Under this item, two presentations were made. The first was by Dr. Angelika Hilbeck on the "Key Elements of Environmental Risk Assessment for LMOs and the Required Scientific Capacities." 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".

33. Dr. Hilbeck described the basic elements of an environmental risk assessment, including: problem formulation/hazard identification, exposure characterization, effects characterization and risk characterization using a concrete case study . She also described elements of risk management, including: risk management strategies and field monitoring and evaluation. She gave a distinction between the narrow (exclusive) and broad (inclusive) approach to risk assessment, depending on what 'adverse effects' are considered and which are excluded. Furthermore, Dr. Hilbeck described and made a comparison between the ecotoxicology model and the functional model for LMO risk assessment. The latter model was developed by the GMO Environmental Risk Assessment (ERA) project. She noted that the ecotoxicology model uses the surrogate species concept while the functional model uses selected functional indicator species. Using a risk assessment case study for assessing potential risks to non-target organisms, she illustrated the key considerations that need to be taken into account in the risk assessment process. In conclusion, Dr. Hilbeck urged participants involved in risk assessment to think on their own and endeavour to know how and where to get the right experts. She also advised them to familiarize themselves with the different the RA models out there and to determine the desired level of robustness in the risk assessment. Most importantly, participants were advised to make informed decisions regarding which RA models fit their specific situations best.

34. Dr. Bergmans highlighted the recommendations of the Ad Hoc Technical Expert Group on Risk Assessment which met in Rome, 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.

35. Following the presentations and brief discussions in the plenary, participants reviewed and proposed amendments to the common format for risk assessment summaries submitted to the Biosafety Clearing-House, taking into account the proposals by the resource persons and those made by the African workshop. An expanded format for risk assessment summaries, 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, as appropriate, 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

36. Under this item, Mr. David Duthie 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 Central & Eastern Europe". This was followed by discussions in the plenary and working groups.

37. In his presentation, Mr. Duthie noted that mechanisms for cooperation in biosafety can be formal or informal, and physical or virtual. He outlined examples of possible mechanisms for cooperation. These include formal-physical such as: Inter-governmental regional meetings (e.g. meetings of the EFSA), meetings organized by UN and intergovernmental agencies in the region (e.g. FAO, ICGEB), meetings organized under the Cartagena Protocol (e.g. COP-MOP, Expert Group meetings and regional workshops) as well as mechanisms under regional projects (e.g. UNEP biosafety projects). Formal-virtual mechanisms for cooperation include websites, portals or clearing-house mechanisms maintained by different organizations (EU, OECD, FAO, UNEP, UNIDO and IPPC web-pages), internet-based networks and discussion fora. Other mechanisms include rosters of experts, virtual libraries, institutional exchanges and secondments and other tools. He also noted the importance of "informal" mechanisms for cooperation, including scientific collaborative initiatives, professional association meetings, annual conferences and symposia, and side events at margins of formal meetings. Mr. Duthie outlined some of the main Challenges for regional cooperation in the CEE. These include lack of experience in risk assessment and risk management since many countries in the region have not received any notifications/dossiers. Another challenge is the controversy surrounding biotechnology and the

difficulties in balancing the science-based risk assessment and the socio-economic considerations in decision-making.

ITEM 8. CONCLUSIONS AND RECOMMENDATIONS

38. In general, participants noted that scientific risk assessment is the cornerstone of regulatory systems and decision-making regarding the safety and acceptability of LMOs. It was also observed that for small countries, where the national science community is small, it may be necessary to capitalize on external expertise and information. Furthermore, it was observed that harmonization of risk analysis principles, information requirements, and standards of assessment can be instrumental to maximizing the use of institutional, financial, technical, and human resources within a region.

39. Participants made a number of general observations/conclusions and recommendations on the different issues. The main issues raised and discussed during the Workshop related: 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

40. The following general observations were made:

(a) Most countries in Central and Eastern Europe have limited practical experience in risk assessment and risk management of LMOs. Many have not received or approved any applications for import or release of LMOs. A few have authorized field trials of GM crops.

(b) Almost all countries in the region have developed national biosafety frameworks and some have enacted national laws on biosafety. However, most of them have not yet established systems (including administrative structures, procedures and guidelines) LMO risk assessment and risk management.

(c) Some countries such as Bulgaria, Slovenia, Romania and Ukraine have institutions and infrastructure (including laboratories, greenhouses, etc) which can support risk assessment and risk management and scientific research on LMOs. However, many other countries lack or have poorly equipped infrastructure for risk assessment and risk management. Some of the existing laboratories have only capabilities for LMO detection.

(d) Most of the countries in the region lack of trained specialists in various fields relevant to risk assessment and risk management.

B. Recommendations

1. Measures for enhancing risk assessment and risk management

41. The participants recommended the following measures for improving risk assessment and risk management in the region and addressing the capacity-building needs:

(a) Development of regulations and national guidelines (including operational manuals) on risk assessment and risk management, taking into account guidelines developed by other countries and relevant international organizations;

(b) Development of projects and activities for implementation of existing or planned regulatory and administrative systems needed for risk assessment/ risk assessment evaluation and risk management;

(c) Establishment of mechanisms for regional cooperation and sharing of experiences in risk assessment and risk management, including:

(i) Organization of additional regional and sub-regional workshops to share experiences and discuss issues, challenges and opportunities;

(ii) Establishment of sub-regional networks of experts on risk assessment and risk management;

(iii) Organization of e-forums to discuss topical issues and challenges.

(d) Organization of training workshops on risk assessment and risk management for experts and government officials;

(e) Organization of training courses for specialists in different risk assessment and risk management fields, including detection and sampling methods for different LMOs;

(f) Encouraging universities offering training courses on biosafety to integrate risk assessment and risk management topics in their curriculum;

(g) Mobilizing financial and technical resources from different sources;

(h) Promoting the exchange of information and experience with regard to risk assessment including results of risk assessments, final decisions and results of inspections and monitoring;

(i) Establishment of Interdisciplinary Biosafety Advisory Panels on risk assessment and risk management;

(j) Harmonization, as appropriate, of the national systems for implementation of the Protocol with EU directives, regulations, risk assessment guidance and regulatory practices;

(k) Harmonization of tools for monitoring of long term effects of LMOs in the region;

(l) Making use of information available on the websites of relevant organizations, such as the Black Sea Biotechnology Association (BSBA).

42. In addition, UNEP-GEF and the CBD Secretariat were invited to:

(a) Organize regular training workshops to facilitate exchange of knowledge and experience in risk assessment and risk management;

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

(c) Organize electronic mailing and on-line discussion forums to facilitate exchange of information and news on biosafety and biotechnology and clarification of emerging issues.

2. Additional guidance on specific aspects of risk assessment and risk management

43. The participants recommended that additional guidance may be required on the following specific aspects of risk assessment and risk management:

(a) Types of LMOs: GM trees (mostly on fruit trees, e.g. plums) and GM viruses and may be GM fish and GM pharmaplants;

(b) Specific traits: (i) abiotic stress tolerance (in particular drought resistance), (ii) pathogen and disease resistance; (iii) reproductive alteration/ genetic containment;

(c) Particular intended uses – LMOs intended for biofuels, bioremediation and GM trees intended for paper production;

(d) Types of the risk: need for guidance expressing communication of uncertainty, instead of unexpected effects;

(e) Particular receiving environments – guidelines for specific centres of origin as well as forest and soil environments. Guidelines are also need on how to identify and characterize a receiving environment;

(f) Long term monitoring of LMOs released into the environment – specific guidance (including cost-effective protocols) to enable competent national authorities to gather, utilize and share relevant data.

44. Regarding appropriate modalities for development of further guidance on specific aspects of risk assessment and risk management, it was recommended that an Ad-hoc technical group be established first with the mandate to set up the agenda and then the issues to be discussed in an open-ended expert group. The participants also noted that regional consultative workshops would be very valuable.

ITEM 9. OTHER MATTERS

45. There were no other matters raised.

ITEM 10. ADOPTION OF THE REPORT

46. 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, 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 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

47. The Workshop was closed at 4.30 pm on Wednesday, 28 November 2007.

Annex I

WORKSHOP PROGRAMME

	Plenary
Monday ***26 November 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 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*: 4. National and regional experiences and lessons learned: • Case-study presentations from different sub-regions • Short presentations on national experiences by participants
1 p.m. – 2 p.m.	**Lunch Break**
2 p.m. – 3.30 p.m.	Agenda 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;
Tuesday ***27 November 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.
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 assessments of living modified organisms: 6.1. Basic elements, and considerations in the preparation and/or review, of environmental risk assessments of living modified organisms and the key scientific capacity and information requirements;
1 p.m. – 2 p.m.	**Lunch**

	Plenary
2 p.m. – 3.30 p.m.	*Agenda item*: 6.2. Format for risk assessment summaries submitted to the Biosafety Clearing-House in accordance with paragraph 3 (c) of Article 20 of the Protocol.
3.30 p.m. – 4 p.m.	**Coffee/Tea Break**
4 p.m. – 5.30 p.m.	*Agenda item*: 7. Regional and sub-regional cooperation on risk assessment and risk management, including the sharing of information and expertise.
Wednesday ***28 November 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.	**Coffee Break/Tea**
11 a.m. – 1 p.m.	*Agenda items*: Agenda item 8 *(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 or voluntarily submitting the risk assessment report:	<Controlled vocabulary: countries 2/>
2. Title of the risk assessment document: 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> (controlled vocabulary)
10. Method of transformation	<Text entry>
11. Novel genotypic and phenotypic characteristics:14/	<Text entry>
Detection and identification of the living modified organism	
12. Detection and identification methods: 15/	<Text entry> add cv
Intended use and receiving environment	
13. Intended use of the LMO: 16/	<Text entry>
14. Receiving environment:17/	<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/ 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/ Suggested detection and identification methods and their specificity, sensitivity and reliability, as elaborated in Annex III, paragraph 9 (f) of the Protocol.

16/ 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.

17/ 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.

Risk assessment summary 18/	
15. Novel genotypic and phenotypic characteristics taken into account in the risk assessment:19/	<Text entry>
16. Adverse effects taken into account in the risk assessment: 20/	
17. Likelihood of adverse effects being realized:21/	<Text entry >
18. Possible consequences:22/	<Text entry>
19. Estimation of overall risk:23/	<Text entry>
20. Recommendation on risks:24/	<Text entry>
21. Risk management strategies:25/	<Text entry>
OVERALL RISK ASSESSMENT SUMMARY	
22. Overall summary of the risk assessment or environmental review:26/	<Text entry>
Access to the detailed risk assessment information	
23. Availability of, and ways of accessing, the detailed risk assessment information:27/	<Text entry>

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

19/ 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.

20/ 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.

21/ 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.

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

23/ 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.

24/ 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.

25/ 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.

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

Additional information	
24. Other relevant information:28/	<Text entry>
25. Relevant documents or web-links:29/	<Web address (URL and website name or description) or attachment>
26. Notes:30/	<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
Montreal, Quebec, Canada
H2Y 1N9
SCBD: http://www.cbd.int
Tel.: 1 514 288-2220
Fax: 1 514 288-6588
Email: bch@cbd.int
BCH: http://bch.cbd.int

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

28/ Please use this field to provide any other relevant information that may not have been addressed elsewhere in the record, e.g. names of the risk assessors involved, etc.

29/ 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.

30/ 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.

Annex III
LIST OF PARTICIPANTS

Parties/Governments

Armenia

1.Ms. Siranush Muradyan
Head of Division of Dendroparks Management
Agency of Bioresources Management
Ministry of Nature Protection
3 Government Building, Republic Square
Yerevan 0010
Armenia
Tel.: +37410 580 711
Fax: +37410-585-469; 37410 527 952
E-Mail: sirush@freenet.am, sirush_murad@mail.ru

Belarus

2. Dr. Boris Anoshenko
Leading Specialist
National Co-ordination Biosafety Centre
27, Akademicheskaya Str.
Minsk 220072
Belarus
Tel.: +375 17 284 0297
Fax: +375 17 284 1917
E-Mail: biosafety@biosafety.org.by

Bosnia and Herzegovina

3. Ms. Silajdzic Elma
Institute for Genetic Engineering and Biotechnology
Gajev trg 4
Sarajevo
Bosnia and Herzegovina
Tel.: +387 33 220 926
Fax: +387 33 442 891
E-Mail: silajdzic_elma@yahoo.com

Bulgaria

4. Dr. Nevena Alexandrova
Head
Biotech Information Center
AgroBioInstitute
8 Dragan Tzankov Blvd.
Sofia 1164
Bulgaria
Tel.: +359 2 963 5411
Fax: +359 2 963 5408
E-Mail: alexandrova@abi.bg; nevialex@yahoo.com

Croatia

5. Ms. Renata Hanzer
Institute for Seed and Seedlings
Vinkovacka Cesta 63C
Osijek 31000
Croatia
Tel.: +385 031 275 705
Fax: +385 031 275 701
E-Mail: renata.hanzer@gmail.com

Georgia

6. Dr. Nelly Datukishvili
Deputy Director
Institute of Molecular Biology and Biological Physics
12, Gotua Str.
Tbilisi 0160
Georgia
Tel.: +995 32 38 83 39
Fax: +995 32 939 157
E-Mail: nellydatukishvili@yahoo.com
Web: www.imbbp.org

Hungary

7. Ms. Kitti Lippai
GMO Expert
Biosafety Unit
Ministry of Environment and Water
Fö utca 44-50
Budapest H-1011
Hungary
Tel.: +36 1 457 3555; +36 1 395 6857
Fax: +36 1 275 4505
E-Mail: lippai@mail.kvvm.hu

Republic of Moldova

8. Dr. Anastasia Batco
Researcher
Institute for Plant Protection and Ecological Agriculture
Padurilor 26/1
Chisinau MD2062
Republic of Moldova
Tel.: +373 22 770402
Fax: +373 22 779641
E-Mail: smatco@mail.ru

Republic of Moldova

9. Mrs. Valentina Caldarus
Deputy-Head
Natural Resources and Biodiversity Division
Ministry of Ecology and Natural Resources
9, Cosmonautilor Str.
Chisinau MD-2005, Republic of Moldova
Tel.: +373 22 204528
Fax: +373 22 226858
E-Mail: caldarus@mediu.gov.md
Web: http://www.mediu.gov.md

10. Dr. Angela Lozan
Head of the Biosafety Office
Ministry of Ecology and Natural Resources
9, Cosmonautilor Str.
Chisinau MD-2005, Republic of Moldova
Tel.: +373 22 22 68 74
Fax: +373 22 22 68 74
E-Mail: angelalozan@yahoo.com, angela.lozan@biosafety.md
Web: http://www.mediu.gov.md

11. Dr. Victor Lupascu
Lector
Moldova State University
Mateevici Str 60
Chisinau MD2018, Republic of Moldova
Tel.: +373 22 577781
Fax: +373 22 577535
E-Mail: vlupashcu@yahoo.com
Web: http://www.usm.md

Romania

12. Dr. Maria-Mihaela Antofie
Head of Biodiversity Biosafety Unit
Nature Conservation, Biodiversity and Biosafety Directorate
Ministry of Environment and Sustainable Development
12 Blvd Libertatii, Sector 5
Bucharest 040129, Romania
Tel.: +40 21 316 3382
Fax: +40 21 316 0282
E-Mail: mihaela.antofie@mmediu.ro

Serbia

13. Dr. Aleksej Tarasjev
Institute for Biological Research
Despota Stefana
Belgrade 11060, Serbia
Tel.: +63 7214 250
Fax: +381 11 761 433
E-Mail: tarasjev@ibiss.bg.ac.yu, tarasjev@yandex.ru

Slovenia

14. Dr. Branka Javornik
Professor of Genetics & Biotechnology
Department of Agronomy, Biotechnical Faculty
University of Ljubljana
Jamnibarjeva 101
Ljubljana 1000, Slovenia
Tel.: +3861 423 1161
Fax: +3861 423 1088
E-Mail: branka.javornik@bf.uni-lj.si

Tajikistan

15. Dr. Anastasia Idrisova
Head
Department on Strategy and Priority Projects Implementation
National Biodiversity & Biosafety Center
47 Shevchenko Str.
Dushanbe 734025, Tajikistan
Tel.: +(992-372) 21 8978
Fax: +(992-372) 21 8978
E-Mail: AIdrisova@biodiv.tojikiston.com, biodiv@biodiv.tojikiston.com

The former Yugoslav Republic of Macedonia

16. Mrs. Marija Dirlevska-Caloska
Advisor
Ministry of Environment and Physical Planning
Dresdenska 52
Skopje 1000
The former Yugoslav Republic of Macedonia
Tel.: +389 2 3066 930, ext 153
Fax: +389 2 3066 931
E-Mail: m.caloska@moepp.gov.mk
Web: http://www.moepp.gov.mk

Ukraine

17. Dr. Boris Sorochinsky
Head
Laboratory of GMOs Detection and Biosafety
Institute of the Cell Biology and Genetic Engineering
148 Zabolotnogo Str.,
Kiev 03143
Ukraine
Tel.: +380 44 5261498
Fax: +380 44 5267104
E-Mail: bsorochinsky@yahoo.com, bvs.phyto.kiev.ua

Organizations

Black Sea Biotechnology Association

18. Dr. Alexander Golikov
Executive Secretary
Black Sea Biotechnology Association
1-1-46 B. Sadovaya Str
Moscow 123001
Russian Federation
Tel.: +7 495 228 5867
Fax: +7 495 2285867
E-Mail: golikov@bsbanet.org, agolikov@mac.com

Ecospectrum-Bender

19. Dr. Ivan Ignatiev
President
Ecospectrum-Bender
33, app.16, Kishinevskaia stf.
Bender 3200
Republic of Moldova
Tel.: +373 532 69304
Fax: +373 22 225615
E-Mail: ecospectrum@mail.ru

Eco-Tiras International Environmental Association

20. Dr. Ilya Trombitsky
Executive Director
Eco-Tiras International Environmental Association
Str. Teatrala 11A
Chisinau 2012
Republic of Moldova
Tel.: +373 22 225615
Fax: +373 22 550953
E-Mail: ecotiras@mtc.md, ilyatrom@mail.ru

Global Industry Coalition

21. Dr. Marin Velcev
Director, Regulatory Affairs
Global Industry Coalition
Monsanto Europe SA
NA Safrance 27
Prague 10, 101 00
Czech Republic
Tel.: +420 2 7273 7573
E-Mail: marin.velcev@monsanto.com

Resource Persons

Federal Environment Agency

22. Dr. Helmut Gaugitsch
Head of Unit, BSP Focal Point
Federal Environment Agency
Spittelauer Lände 5
Vienna A-1090, Austria
Tel.: +43 1 31 304 / 3133
Fax: +43 1 31 304 / 3700
E-Mail: helmut.gaugitsch@umweltbundesamt.at
Web: http://www.umweltbundesamt.at

National Institute of Public Health and Environment

23. Dr. Hans Bergmans
Senior Scientist
GMO Office
National Institute of Public Health and Environment
Antonie van Leeuwenhoeklaan 9, PO Box 1
Bilthoven 3720 BA
Netherlands
Tel.: +31 30 274 4195
Fax: +31 30 274 4461
E-Mail: hans.bergmans@rivm.nl

Norwegian Institute of Gene Ecology

24. Mr. Jan Husby
Senior Advisor
Norwegian Institute of Gene Ecology
Science Park, PO 6418
Tromso N-9294, Norway
Tel.: +47 48 04 57 33
Fax: +47 77 64 61 00
E-Mail: jan.husby@genok.org

Swiss Federal Institute of Technology Zurich

25. Ms. Angelika Hilbeck
Senior Scientist
Institute of Integrative Biology - Swiss Federal Institute of Technology
Swiss Federal Institute of Technology Zurich
Universitätstr 16
Zurich CH-8092
Switzerland
Tel.: +41 44 632 4322; 41-44-430-30-60
Fax: +41 44 632 1215; 41-44-430-30-61
E-Mail: angelika.hilbeck@ecostrat.ch
angelika.hilbeck@env.ethz.ch
Web: www.gmo-guidelines.info

United Nations Environment Programme, Global Environment Facility (UNEP/GEF)

26. Mr. David Duthie
SCBD Liaison Officer
United Nations Environment Programme, Global Environment Facility (UNEP/GEF)
15 Chemin des Anémones
Chatelaine
Geneva CH-1219
Switzerland
Tel.: +41 22 917 8741
Fax: +41 22 917 8070
E-Mail: david.duthie@unep.ch
Web: http://www.unep.ch/biosafety

Secretariat of the Convention on Biological Diversity

27. Mr. Charles Gbedemah
Senior Programme Officer
Biosafety Division
Secretariat of the Convention on Biological Diversity
413 St. Jacques Street, Office 800
Montreal Quebec, H2Y 1N9
Canada
Tel.: +1 514 287 7032
Fax: +1 514 288 6588
E-Mail: charles.gbedemah@cbd.int
Web: http://www.cbd.int

28. Mr. Erie Tamale
Programme Officer
Biosafety Division
Secretariat of the Convention on Biological Diversity
413 St. Jacques Street, Office 800
Montreal Quebec, H2Y 1N9
Canada
E-Mail: erie.tamale@cbd.int
Web: http://www.cbd.int
