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San José, Costa Rica, 9-11 March 2009

REGIONAL RISK ASSESSMENT AND RISK MANAGEMENT CAPACITY-BUILDING NEEDS AND STRATEGIES

Compilation of the conclusions and recommendations from the regional workshops on capacity-building and exchange of experiences on risk assessment and risk management of living modified organisms organized by the Secretariat of the Convention on Biological Diversity

Note by the Executive Secretary

INTRODUCTION

The Executive Secretary is circulating herewith, for the information of participants in the fifth Coordination Meeting for Governments and Organizations Implementing or Funding Biosafety Capacity-building Activities, a compilation of the conclusions and recommendations from the four regional workshops on capacity-building and exchange of experiences on risk assessment and risk management of living modified organisms (LMOs) that were organized for Africa (23-25 August 2007 in Addis Ababa), Central and Eastern Europe (26-28 November 2007 in Chisinau), Latin America and the Caribbean (10-12 December 2007 in Bridgetown) and the Asia subregion (7-9 April 2008 in Kuala Lumpur) in response to the requests in paragraph 2 of decision BS-II/9 and paragraph 10 of decision BS-III/11 of the Conference of the Parties serving as the meeting of the Parties to the Protocol.

AFRICAN WORKSHOP

1. The main issues raised 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

2. 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

3. 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.

4. 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.

5. 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.

6. 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.

7. 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

8. 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.

9. 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.

10. 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

11. 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.

12. 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/

13. 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.

14. 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

15. 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.

16. 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.

17. 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.

18. 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 Biosafety Clearing-House

19. 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.

20. The proposed changes to the expanded common format for risk assessment summaries, which is contained annex II to the report of the African regional workshop (UNEP/CBD/BS/RW-RA&RM/Afr./1/2), are necessary in order to enable Governments submitting summaries to provide key additional information that would be useful to other countries.

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

7. Regional and technical cooperation

21. 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.

22. 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.

23. 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

24. 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

25. 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.

26. 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

27. 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.

28. 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.

29. 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

30. 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.

31. 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.

32. 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

33. 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.

34. 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

35. 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.

36. 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.

37. 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.

38. 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.

39. 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

40. 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 the report of the African regional workshop (UNEP/CBD/BS/RW-RA&RM/Afr./1/2).

7. Regional and technical cooperation

41. 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.

42. 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

43. 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.

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

45. 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).

CENTRAL AND EASTERN EUROPE

46. 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.

47. 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

48. 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

49. 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).

50. 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.

LATIN AMERICA AND THE CARIBBEAN

51. The following were identified as the main limitations/challenges for most countries in the region:

(a) Lack of experience in risk assessment and risk management in many of the GRULAC countries;

(b) Lack of adopted consensus and procedures for specific LMO risk assessment;

(c) Lack of relevant information regarding local biodiversity;

(d) Small land areas are available for the establishment of 'confinement' conditions and difficulties in maintaining eco-reserves;

(e) "Organic agriculture" is a means of livelihood in small island states and therefore different systems of agriculture cannot co-exist;

(f) Hurricanes capable of breaching 'containment' facilities and 'confinement';

(g) Island ecosystems are very vulnerable;

(h) Lack of financial, technical or infrastructural resources to carry out risk assessment and management;

(i) Insufficiency of accredited laboratories for LMO detection and analysis;

(j) Lack of dossiers for tropical crop species, particularly indigenous ones;

(k) Lack of experience on how to handle local biodiversity and protected areas;

(l) Lack of information on crop ecology in island ecosystems, including short-, medium- and long-term effects;

(m) Insufficient coordination among regulatory authorities (i.e., environment, agriculture, science and technology);

(n) Unstable regulatory and administrative systems, partly due to changes in the responsibilities and structure of agencies;

(o) Insufficient human capacity (e.g., experienced risk-assessment experts);

(p) Poor equipment facilities in institutions/laboratories;

(q) Difficulty in assessing, sorting and implementing available guidance materials;

(r) Limited experience in the use of the precautionary approach or risk-benefit analysis in decision-making;

(s) Difficulties arising from the complexity of the region (e.g., country, economy, biological diversity, societal values, etc.);

(t) Absence of national risk-assessment systems (methodology, steps, rules, etc.);

(u) Some countries in the GRULAC region are experiencing difficulties in accessing information for risk assessment (scientific publications, databases, etc);

(v) Difficulties in organizing constructive public participation in risk assessment and decision-making.

52. The following were identified as some of the main priority needs:

(a) Establishment of consensus criteria for risk assessment and risk management at the national level;

(b) Adoption of a common format for the submission of risk-assessment summaries;

(c) Establishment of subregional, regional and international cooperation to ensure the exchange of experience, available capacity and development of guidance materials relevant to the region;

(d) Establishment of LMO monitoring and inspection (surveillance) systems at the national level;

(e) Establishment of specialized laboratories for detection of LMOs;

(f) Better knowledge management and information sharing on biosafety;

(g) Development/compilation of guidelines for risk assessment and risk management related to LMOs in tropical environments;

(h) Establishment of relationships between perceived risks and variables that can be measured/monitored;

(i) Development of baseline information relevant to the region (e.g. centres of origin, reproductive biology, etc.);

(j) Based upon the model developed in Mexico 2/, establishment of measurable ecological models (e.g. using GIS to establish species distribution);

(k) Increase of government support for risk-assessment programmes;

(l) Mobilization of financial and technical resources from different sources; and

(m) Training on risk assessment and risk management.

2/ Additional details in the presentation made by Mexico available at http://www.cbd.int/doc/meeting.asp?mtg=RWCBGRULAC-01

ASIA SUBREGION

53. The following were identified in the regional presentations or by the discussion groups as some of the main limitations or challenges to risk assessment and risk management in the Asian subregion:

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

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

(c) Lack or insufficiency of training opportunities;

(d) Lack of a regulatory framework for LMOs;

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

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

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

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

(i) Difficulties in interpreting and understanding research data;

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

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

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

(b) Promoting formal and informal education on biosafety;

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

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

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

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

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

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

(i) Improving regional sharing of infrastructure;

(j) Identifying centres of excellence in biotechnology;

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

(l) Improving information sharing;

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

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

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

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

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

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

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

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

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

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