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OPEN-ENDED EXPERT MEETING ON CAPACITY-BUILDING FOR THE CARTAGENA PROTOCOL ON BIOSAFETY Havana, 11-13 July 2001

### REPORT OF THE OPEN-ENDED EXPERT MEETING ON CAPACITY-BUILDING FOR THE CARTAGENA PROTOCOL ON BIOSAFETY

#### INTRODUCTION

#### A. Background

- 1. At its first meeting, held from 11 to 15 December 2000, in Montpellier, France, the Intergovernmental Committee for the Cartagena Protocol on Biosafety (ICCP) invited the Executive Secretary to convene in collaboration with the United Nations Environment Programme (UNEP) an openended expert meeting to further develop proposals on the implementation of capacity-building provisions of the Protocol for consideration by the Committee at its second meeting, to be held in October 2001.
- 2. Accordingly, and following the acceptance by ICCP of an offer made by the Government of Cuba to host the meeting, the Open-ended Expert Meeting on Capacity-Building for the Cartagena Protocol on Biosafety was held from 11 to 13 July 2001, at the Palacio de las Convenciones in Havana, with financial support from the Governments of Canada, Denmark, Spain, Sweden, Switzerland and the United Kingdom of Great Britain and Northern Ireland, as well as from the Global Environment Facility (GEF) and the United Nations Environment Programme (UNEP).

#### B. Attendance

3. Experts from the following Parties to the Convention on Biological Diversity and other States were present at the meeting: Albania, Antigua and Barbuda, Argentina, Armenia, Bahamas, Belarus, Belgium, Benin, Bhutan, Bolivia, Bulgaria, Burkina Faso, Cameroon, Canada, Chad, Chile, China, Colombia, Comoros, Congo, Côte d'Ivoire, Cuba, Czech Republic, Democratic Republic of the Congo, Denmark, Djibouti, Dominica, Dominican Republic, Ecuador, Egypt, El Salvador, Equatorial Guinea, Estonia, Ethiopia, France, Gambia, Georgia, Germany, Grenada, Guatemala, Haiti, Honduras, India, Indonesia, Iran (Islamic Republic of), Jamaica, Japan, Jordan, Kazakhstan, Kenya, Lao People's Democratic Republic, Latvia, Lesotho, Madagascar, Malawi, Malaysia, Mali, Mauritius, Mexico, Mozambique, Myanmar, Namibia, Nepal, Netherlands, Nicaragua, Niger, Nigeria, Oman, Palau, Peru, Philippines, Philippines, Poland, Romania, Saint Kitts and Nevis, Saint Lucia, Sao Tome and Principe, Senegal, Seychelles, Slovakia, Spain, Sri Lanka, Sudan, Suriname, Switzerland, United Republic of Tanzania, Togo, Tunisia, Turkey, Uganda, Ukraine, United States of America, Uruguay, Viet Nam.

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- 4. Observers from the following United Nations bodies, Secretariat units, specialized agencies and convention secretariats also attended:
- 5. The following other organizations were represented: Food and Agriculture Organization of the United Nations (FAO), Global Environment Facility (GEF), United Nations Development Programme (UNDP), United Nations Environment Programme (UNEP), UNDP/GEF, UNEP/GEF, United Nations University (UNU).
- (a) *Intergovernmental organizations:* Organisation for Economic Co-operation and Development (OECD), South Pacific Regional Environment Programme (SPREP);
- (b) Non-governmental organizations: Academia de Ciencias de Cuba, Carnegie Endowment, Cubasolar, Dupont, Fundacion El Hombre y La Naturaleza, Greenpeace, Institute for Social, Economic and Ecological Sustainability (ISEES), International Environmental Resources, IUCN (The World Conservation Union), Le Groupe Conseil Baastel Ltee, Meridian Institute, Monsanto South Africa, ProNaturaleza, Rockefeller Foundation , The Edmonds Institute, Third World Network, Washington Biotechnology Action Council, World Resources Institute (WRI), World Wide Fund for Nature (WWF) International

#### ITEM 1. OPENING OF THE MEETING

- 6. The meeting was opened by the Chair of the ICCP, Ambassador Philemon Yang (Cameroon), at 10 a.m. on Wednesday, 11 July 2001.
- In his opening statement, Ambassador Yang conveyed his appreciation to the Government of Cuba for hosting the meeting and to all those countries that had contributed financially to enable it to take place. He said that, for the Protocol to succeed, the momentum gathered at the end of negotiation process and through the ICCP meeting at Montpellier must not be lost. The current meeting represented an opportunity keep up that momentum. It represented an opportunity to focus expert minds on one of the fundamental requirements for the successful implementation of the Protocol – the building of capacity to implement, among other things, the advanced informed agreement procedure and the information exchange provisions of the Protocol. The current meeting would provide an opportunity for all participants to express their own views on the priorities and needs to advance capacity-building for the Protocol. As decided by the Bureau, there would also be an opportunity for relevant organizations currently involved in capacity-building initiatives on biosafety to make presentations on their activities. It was hoped that that exercise would be useful in helping participants see what was being done, how it matched their needs and what was the potential for synergies and complementarities among the various initiatives. Participants were in a unique position to make a significant contribution to the deliberations of the ICCP when it met again in October 2001. The recommendations would also serve as useful guidance to GEF and other multilateral and bilateral organizations involved in capacity-building for biosafety.
- 8. Other opening and welcoming remarks were made by: Mr. Paul Chabeda, speaking on behalf of Mr. Klaus Töpfer, Executive Director of the United Nations Environment Programme (UNEP); Mr. Avani Vaish, Secretariat of the Global Environment Facility (GEF), speaking on behalf of Mr. Mohamed El-Ashry, Chairman and Chief Executive Officer of GEF; Mr. Hamdallah Zedan, Executive Secretary of the Convention on Biological Diversity; and Mr. Fabio Fajardo, Vice-Minister of Environment of Cuba, speaking on behalf of Ms. Rosa Helena Simeón, Minister of Science, Technology and Environment, who was also in attendance.
- 9. Mr. Chabeda expressed UNEP's gratitude for the offer of the Government of Cuba to host the meeting. He also thanked the six Governments that had provided financial support for the meeting, as well as the GEF. He expressed the hope that the International Conference on New Biotechnology Food and Crops, which was about to conclude in Bangkok, would send a clear message to the upcoming G-8

Summit in Genoa, Italy, on the need for channelling new and additional resources to meet priority needs for capacity-building. In the light of limited financial, technical and human resources, a major avenue for synergy, supplementarity and complementarity of efforts through collaboration and cooperation was the recently approved UNEP/GEF programme on biosafety, under which up to 100 eligible countries would be assisted to develop their national biosafety frameworks. In conclusion, he said that the Protocol offered a unique opportunity to forge global partnerships between Governments, of both North and South, the private sector and civil society. UNEP looked forward to playing its role in that endeavour in collaboration with the Convention Secretariat, GEF, bilateral/multilateral funding or donor agencies, and relevant international organizations and institutions, as well as the global international community.

- Mr. Vaish said that the meeting provided an excellent opportunity to hear a range of thoughts on capacity-building for biosafety and on the ways in which GEF could assist. It was also a good occasion to share experiences with other partners and to explore ways of working together. In November 2000, the GEF Council had approved an Initial Strategy for Assisting Countries to Prepare for the Entry into Force of the Cartagena Protocol on Biosafety. Of the several elements in the Initial Strategy, the umbrella project for the development of national biosafety frameworks was now being initiated, through UNEP. The other elements of the Strategy were also being activated. The results of the UNDP/GEF Capacity Development Initiative, an effort to identify needs across the GEF focal areas, had been presented to the GEF Council in May 2001. Having reviewed the results, the Council had approved the first step in a process towards implementation, which consisted of a needs assessment with a view to identifying and prioritizing areas for GEF support, national action, or support through other multilateral or bilateral mechanisms. He commended the process to participants as a means of placing capacity-building for biosafety in the context of capacity-building to address other global environmental concerns. Finally, he said that he looked forward to the workshop on financing national biosafety frameworks, which would take place immediately after the current meeting and offered an opportunity for further discussions on the subject with various partners.
- Mr. Zedan welcomed participants and expressed his gratitude to the host Government and to the 11. Governments of Canada, Denmark, Spain, Sweden, Switzerland and the United Kingdom, as well as the Global Environment Facility (GEF), for their financial support. The Cartagena Protocol now had 104 signatures and five ratifications or accessions. In view of the expressed desire for the first meeting of the Parties to the Protocol to be held in conjunction with the sixth meeting of the Conference of the Parties to the Convention, he urged the other Parties to the Convention to become Parties to the Protocol as soon as possible. He said that capacity-building was a prerequisite for the effective implementation of the Protocol and must go beyond single, short-term interventions to encompass long-term efforts. All areas of capacity-building would have to be supported through the provision of financial resources and technical and scientific cooperation. Drawing attention to the documentation before the Meeting, he said that the purpose of the Expert Meeting was to develop focused proposals for the ICCP to consider at its second meeting. Given its heavy agenda, the work of that meeting would be greatly facilitated if ICCP could, at the outset of its deliberations, have before it proposals that were both focused and as allinclusive as possible. In conclusion, he assured participants of the Secretariat's commitment to playing fully whatever role might be assigned it in the efforts to put in place, in all countries, the capacity needed for the implementation of the Protocol.
- 12. Mr. Fajardo said that, generally speaking, developing countries did not have the infrastructure or the know-how and experience in handling modern biotechnology. Those gaps created difficulties for many countries when it came to evaluating the risks of processes and products of modern biotechnology and led to justifiable doubts, if not outright rejection, which could deprive those countries of the benefits of such technologies. The limited capacities of developing countries stood in contrast to their great wealth of biological diversity. It was iniquitous for them to be turned into providers of cheap germplasm, which would come back to the same countries in the form of costly patented products with risks that they could not always appreciate. Access to biological resources, intellectual property rights to the products thereof and biosafety were therefore three inseparable issues, and capacity-building in biosafety should

take all three into account. The success of the Biosafety Protocol depended on the indigenous capacities of developing countries to fulfil the obligations under it. Human and financial resources, information exchange, technical assistance, capacity-building in various areas, and the creation of appropriate infrastructures were essential elements to achieve that objective. For its part, Cuba had adopted biotechnology as one of its paths of development. It was preparing itself in the field of biosafety, both through its own efforts and through its involvement in the UNEP/GEF pilot project. It was also getting ready to participate in the new UNEP/GEF project, which would allow it to strengthen its regulatory efforts and increase its capacity for risk assessment and management. Cuba welcomed such international initiatives and invited new and renewed efforts from international agencies in that area. Stressing the importance of regional cooperation, he offered his country's experience in biosafety for that purpose. Within the regional strategy, thought should be given to the establishment of independent centres of excellence, or the strengthening of existing ones. Special attention should be given to the development of databases, as well as of systems for information exchange, at the national, regional and international levels, in order to promote greater knowledge of research and development activities with regard to products of biotechnology and the rules governing their handling, release and commercialization. Those changes should be accompanied by information programmes on the risks and benefits of modern biotechnology and other economic and social impacts, so that the public would be in position to take decisions on the matter. The management of biosafety must be transparent and take into account the different public perspectives of the issue, including that of consumers.

#### ITEM 2. ORGANIZATIONAL MATTERS

#### 2.1. Officers

13. The Bureau of the ICCP served as the Bureau for the meeting, as follows:

Chair: Ambassador Philémon Yang (Cameroon)

Vice-Chairs: Mr. Eric Schoonejans (France)

Mr. P.K. Ghosh (India)

Mr. Mohammad Reza Salamat (Islamic Republic of Iran)

Mr. Andrzej Aniol (Poland)

Mr. Raymond Solomon (Saint Kitts and Nevis)

Ms. Khungeka Njobe (South Africa) Mr. François Pythoud (Switzerland) Mr. Andriy D. Ostapenko (Ukraine)

Rapporteur: Ms. Antonietta Gutiérrez Rosati (Peru)

- 14. On the proposal of the Chair of the ICCP, the Expert Meeting agreed that two co-chairs should be designated to preside over its plenary discussions of the substantive items on its agenda, namely:
  - (a) Mr. Orlando Rey Santos (Cuba), for items 3 and 4; and
  - (b) Mr. Mohammad Reza Salamat (Islamic Republic of Iran), for agenda items 5 and 6.

#### 2.2. Adoption of the agenda

15. The Open-ended Expert Meeting on Capacity-Building for the Cartagena Protocol on Biosafety adopted the following agenda on the basis of the provisional agenda (UNEP/CBD/BS/EM-CB/1/1) prepared by the Executive Secretary after consultation with the ICCP Bureau, and taking into account various observations that were made during the first meeting of the ICCP and the resulting decisions and requests of the ICCP on ways and means to encourage inputs that would enhance and further the discussion on the issue of capacity-building for the implementation of the Protocol:

- 1. Opening of the meeting.
- 2. Organizational matters:
  - 2.1 Officers;
  - 2.2 Adoption of the agenda;
  - 2.3 Organization of work.
- 3. Report of the Executive Secretary summarizing information received in response to the questionnaire on capacity-building.
- 4. Presentation of ongoing initiatives on capacity-building for the implementation of the Cartagena Protocol on Biosafety.
- 5. In-depth consideration of capacity-building requirements for priority issues identified by Governments.
- 6. Approaches, options and strategies to effect capacity-building for priority issues identified by Governments.
- 7. Other matters.
- 8. Adoption of the report.
- 9. Closure of the meeting.

#### 2.3. Organization of work

16. At the 1st plenary session of the meeting, the Open-ended Expert Meeting agreed on the its organization of work on the basis of the proposals contained in annex II to the annotations to the provisional agenda. It was agreed that the meeting should be conducted entirely in plenary session, on the understanding that contact or drafting groups could be set up as the need arose, in order to further develop the discussions conducted in plenary on specific issues and present the plenary with draft recommendations for its consideration.

## ITEM 3. REPORT OF THE EXECUTIVE SECRETARY SUMMARIZING INFORMATION RECEIVED IN RESPONSE TO THE QUESTIONNAIRE ON CAPACITY-BUILDING

- 17. Agenda item 3 was taken up by the Open-ended Expert Meeting at its 1st plenary session, on 11 July 2001. In considering the item, the Meeting had before it a note by the Executive Secretary (UNEP/CBD/BS/EM-CB/1/2) summarizing information received by the Secretariat as of 30 April 2001 in response to a questionnaire on capacity-building developed by the Executive Secretary, pursuant to a request by the ICCP at its first meeting, and forwarded to all national focal points and to relevant organizations on 12 January 2001.
- 18. Introducing the report, the Executive Secretary said that as of 30 April 2001 information had been received from Argentina, Costa Rica, Cuba, Ecuador, Estonia, the European Union, India, Jamaica, Slovenia, Switzerland and Turkey. The United States had also submitted information, which had been circulated as a information document (UNEP/CBD/BS/EM-CB/1/INF/2). Subsequently, submissions had also been received from Japan and Uruguay, while Cuba had submitted additional information.. In

addition, Spain had made available the report of the First Latin American Course on Capacity-Building in Biosafety, which was also before the meeting as an information document (UNEP/CBD/BS/EM-CB/1/INF/3).

- 19. The Executive Secretary also drew attention to the other documents that were available at the meeting, namely:
  - (a) A submission by India on capacity-building needs (UNEP/CBD/BS/EM-CB/1/INF/1);
- (b) A note by the Executive Secretary on an indicative framework for capacity-building under the Cartagena Protocol on Biosafety that had been prepared for the first meeting of ICCP (UNEP/CBD/ICCP/1/4);
- (c) A note by the Executive Secretary on biosafety capacity-building: completed, ongoing and planned projects/programmes, also prepared for the first meeting of ICCP (UNEP/CBD/ICCP/1/INF/1);
- (d) The report of the African Regional Meeting on the Biosafety Clearing-House and the Clearing-House Mechanism, held in Nairobi from 26 to 28 February 2001 (UNEP/CBD/BCH/Afr.Reg/1/2).
- 20. In the ensuing general discussion, statements were made by experts from the following Governments: Antigua and Barbuda, Bahamas, Bolivia, Chile, China, Colombia, Cuba, Czech Republic, Egypt, El Salvador, Equatorial Guinea, Georgia, Grenada, Guatemala, Indonesia, Jordan, Malaysia, Myanmar, Nicaragua, Niger, Nigeria, Peru, Sudan, Togo (on behalf of the African group), Tunisia, Uganda, Viet Nam.
- 21. In their statements, the experts informed the Meeting of the main capacity-building needs in their countries, many of which were the same, or similar to, those expressed in the responses to the questionnaire already received by the Secretariat. Areas identified included: the creation or strengthening of institutions; development of national risk assessment and risk management capacities; development of legal and regulatory frameworks for managing living modified organisms; promotion of public awareness and education; human resources development, which would include increasing the knowledge base of legal expert and policy makers, as well as scientists and technical staff, in the field of biotechnology; and enhancing capacities in compliance procedures.
- 22. Many experts described the efforts undertaken to date in their countries to provide a framework for biosafety. Several also described the similar efforts that had been undertaken at the subregional level, which was considered to be of particular importance when it came to international trade, especially in terms of cooperation, information-sharing and the harmonization of legal and regulatory measures. Some also highlighted the usefulness of initiatives such as the African Regional Meeting on the Biosafety Clearing-House and the Clearing-House Mechanism, which had taken place in Nairobi in February 2001.
- 23. Some experts said that they would submit reports on national activities to the Secretariat for information purposes. Several also informed the Meeting on progress made in their countries toward ratification of the Protocol.
- 24. Following the general discussion, the Secretariat encouraged all those Governments that had not yet responded to the questionnaire on capacity-building needs to do so in the course of the current meeting.

## ITEM 4. PRESENTATION OF ONGOING INITIATIVES ON CAPACITY-BUILDING FOR THE IMPLEMENTATION OF THE CARTAGENA PROTOCOL ON BIOSAFETY

- 25. The Meeting took up agenda item 4 at its 2nd plenary session, on 11 July 2001. Introducing the item, the Chair said that, following a recommendation from the Bureau, the Secretariat had invited a number of relevant public, private, non-governmental and intergovernmental organizations currently involved in initiatives relating to capacity-building in biosafety to make short presentations on their activities. It was the view of the Bureau that such an arrangement would help highlight the synergies and complementarities among the various initiatives and assist the Expert Meeting in its task of further developing proposals for implementation of the capacity-building provisions of the Protocol.
- 26. In response, presentations were made by experts from the following Governments: Canada, Denmark, Germany, India, Netherlands, Spain, Switzerland, and United States of America.
- 27. At the end of his presentation, the expert from Canada drew attention to a model database and retrieval system on commodities designed by his Government, which might prove suitable for use in accessing the information called for in annex II of the Protocol. He offered this model, available at <a href="http://64.26.172.90/bch2/default.php">http://64.26.172.90/bch2/default.php</a>, for the consideration of participants and invited to them to provide feedback to his Government on its usefulness.
- 28. Representatives of UNEP and GEF also made a presentation on the UNEP/GEF biosafety framework development project.
- 29. The representative of the South Pacific Regional Environment Programme (SPREP) informed the Meeting of ongoing biosafety capacity-building activities and future plans in the South Pacific region.
- 30. Representatives of the Edmonds Institute (jointly with the Institute for Social, Economic and Ecological Sustainability (ISEES)), the Global Industry Coalition (GIC), the Rockefeller Foundation and the Third Network also made presentations on the biosafety capacity-building activities of their respective organizations.
- 31. Following the presentations, the expert from Belgium made a statement on the work of the Belgian Clearing-house Mechanism.
- 32. At the 5th plenary session, the representative of IUCN also gave a presentation on his organization's activities, focusing on the preparation of a *Guide to the Cartagena Protocol on Biosafety* along the lines of the similar guide prepared for the Convention on Biological Diversity.

## ITEM 5: IN-DEPTH CONSIDERATION OF CAPACITY-BUILDING REQUIREMENTS FOR SOME PRIORITY ISSUES IDENTIFIED BY GOVERNMENTS

and

## ITEM 6. APPROACHES, OPTIONS AND STRATEGIES TO EFFECT CAPACITY-BUILDING FOR PRIORITY ISSUES IDENTIFIED BY GOVERNMENTS

33. Agenda items 5 and 6 were taken up concurrently at the 3rd plenary session of the meeting, on 12 July 2001.

- 34. Introducing the item, the Chair announced that the conclusions of the Ministerial Round-Table on Capacity-building in Developing Countries to Facilitate the Implementation of the Cartagena Protocol on Biosafety, which had taken place in Nairobi on 23 May 2000 during the fifth meeting of the Conference of the Conference of the Parties to the Convention, had been made available at the current meeting. He invited participants to engage in an action-oriented exchange of views focusing on two issues: first, capacity-building needs and priorities and the kind of activities required; and, secondly, who should carry out the necessary activities and how.
- 35. In the general discussion under these items, statements were made by the experts from the following Governments: Bahamas, Bolivia, Cameroon, Canada, Chile, China, Colombia, Cuba, Denmark, Grenada, Haiti, India, Japan, Jordan, Kenya, Mexico, Namibia, Netherlands, Peru, Togo (on behalf of the African group), Tunisia, Uruguay.
- 36. Following the general discussion, the Meeting agreed that the Chair, together with the Secretariat and with the assistance of the other members of Bureau, would prepare a draft indicative action plan for building capacities for the effective implementation of the Cartagena Protocol for consideration at the next plenary session.
- 37. At the 4th plenary session, the Expert Meeting took up the draft indicative action plan submitted by the Chair. After a number of amendments were made, it was agreed that a revised draft should be presented to plenary for final consideration and approval.
- 38. At the 5th plenary session, the Co-Chair introduced a revised text of the draft Action Plan (UNEP/CBD/BS/EM-CB/1/L.2).
- 39. After some discussion, the draft Action Plan was approved for transmittal to the ICCP at its second meeting, with a number of amendments.
- 40. The draft Action Plan as approved by the Expert Meeting was subsequently circulated as document UNEP/CBD/BS/EM-CB/1/L.2/Rev.1 and is contained in annex I to the present report.
- 41. Following the approval of the draft Action Plan, the expert from the Bahamas expressed concern that his delegation had not been given a fair opportunity to advance its views, especially with regard to the establishment of national biosafety offices, along the lines of the ozone units set up under the Montreal Protocol on Substances that Deplete the Ozone Layer. He believed that subgroups set up for drafting purposes should have clear rules of procedure and terms of reference and should also submit a report explaining why certain proposals were retained while others were not. The Bahamas had accepted the document as proposed but had concerns about the lack of time the meeting had been given to consider it.
- 42. The representative of Cameroon noted that there was no reference to the financial mechanism in the draft Action Plan and expressed the view that some such reference should be included under section 3 (Processes/steps).
- 43. On a point of clarification in response to a question raised by the representative of Belgium, the Chair said that the appendices to the draft Action Plan were simply examples that had been extracted from the note by the Executive Secretary prepared for the first meeting of ICCP (UNEP/CBD/ICCP/1/4) and, as such, did not require discussion.
- 44. Following the approval of the draft Action Plan at the 5th plenary session, one expert, speaking on behalf of the Bureau introduced an informal paper containing an implementation toolkit that had been prepared by the Bureau to supplement the draft Action Plan and the preliminary list of capacities required for the implementation of the Protocol. The sole purpose of the paper was to assist in the discussions on

the draft Action Plan and possibly to serve as the basis for action at the international level based on the provisions of the Protocol. The paper could also be included in the Biosafety Clearing-House if delegations thought it was useful.

- 45. Also at the 5th plenary session, the expert from Canada introduced an informal paper containing a suggested sequence of actions necessary to implement the Protocol, which had been prepared on the basis of Canada's own experience. He stressed that the paper did not represent a list of priorities but, rather, a sequence of actions that could help countries develop their own priorities in their own time. The paper could also be of use to developed countries. It was in no way prescriptive but was intended to serve as an enabling structure that was open to suggestions.
- 46. At the 6th plenary session, on 13 July, the Expert Meeting agreed, after some discussion, that the implementation toolkit introduced on behalf of the Bureau should be annexed to the report of the meeting. The Meeting noted that, during the discussion, some experts had welcomed the toolkit as a useful contribution, others were of the view that it should first be reviewed by their national legal experts to ensure that it was comprehensive and in line with the Biosafety Protocol. It was therefore decided that the implementation toolkit should be annexed to the report of the meeting (see annex II below) for consideration by delegations with a view to making suggestions at the second meeting of the ICCP on how it might be used, as well as on its legal status.
- 47. At the same session, the Expert Meeting also took up the suggested sequence of actions introduced by the expert from Canada. After some discussion, it was decided to set up a small group, comprised of the experts from Canada, Denmark, India, Switzerland and Turkey, to revise the text to take into account the comments made from the floor, in particular to bring it into line with the language included in the draft Action Plan already approved by the Expert Meeting.
- 48. Subsequently, at the same session, the expert from Canada introduced a revised text of the suggested sequence of actions, which had been amended by the small group to make it clear that the text was not a priority-setting exercise, to remove one element that had created difficulties for one delegation, and to bring the language into line with the wording of the draft Action Plan.
- 49. The Expert Meeting agreed that the revised suggested sequence of actions as introduced by the expert from Canada should be included, with one further amendment, as an annex to the report of the meeting (see annex III below).
- 50. Following the discussion on the two papers, it was suggested that the Expert Meeting should discuss in more detail the role of how other organizations especially, non-governmental organizations, the private sector and scientific and academic institutions could contribute to capacity-building for the implementation of the Protocol. However, in view of the complexity of the subject and the lack of time remaining, the Meeting agreed that, in order to prepare for a detailed discussion of the matter at the second meeting of ICCP, the Secretariat should prepare a point-by-point analysis of the role of such bodies, based on the replies received to the questionnaire that had been distributed. At the same time, the Chair invited comments from the representatives of such organizations present at the meeting.
- 51. In response, the representative of the Global Industry Coalition (GIC) said that draft Action Plan for Building Capacities for the Effective Implementation of the Cartagena Protocol on Biosafety, together with the many useful ideas and clear explanations of the needs and priorities of developing countries expressed at the meeting, would enable the private sector to conduct a comprehensive review of its existing and planned capacity-building activities and to consider how it can tailor its activities in the future to better meet the needs of the developing countries. GIC would be undertaking that review between now and second meeting of ICCP and looked forward to engaging in more detailed discussions at that meeting with countries, both donors and developing countries, on the specific projects and

activities the private sector might support and contribute to in order to ensure the successful implementation of the Cartagena Protocol.

52. The representative of the Washington Biotechnology Action Council, speaking on behalf of a number of non-governmental organizations represented at the meeting, said that the potential role and involvement of non-governmental organizations and civil society in general had not been adequately addressed at the meeting. Many non-governmental organizations had demonstrated expertise that should be utilized for capacity-building activities. Capacity-building required a commitment to certain values – environmental protection, ecological wholeness, citizen involvement and transparency. Concepts of "efficiency", "best practices" or "regulatory harmonization" were best received as sincere when they were not used to trim back meaningful participation by affected communities. Decisions about capacitybuilding were intimately tied to an understanding of the precautionary principle, the existence of which in the Protocol made it clear that no Party needed to put its ecosystems, food security or people's health at risk where it might lack the capacity in biosafety – it had the legal right simply to say "no". In addition, claims that information on genetically modified organisms must be kept secret as confidential could distort the risk-assessment process. Finally, while he welcomed the involvement of all stakeholders in biosafety capacity-building and industry's movement toward concern for biosafety, he said that care must be taken not to put "the foxes in charge of the hen house".

#### ITEM 7. OTHER MATTERS

Presentation by the Secretariat on progress in the pilot phase of the Biosafety Clearing-House

- 53. At the 3rd plenary session of the meeting, on 12 July 2001, the Secretariat made a presentation on the pilot phase of the Biosafety Clearing-House, which had been initiated by the ICCP at its first meeting. The Secretariat said that the first stage of the pilot phase was already accessible on the Secretariat's website. The second stage, which would include additional information in the central portal and central database, including a management centre for outside users to register information, was under development. The Secretariat demonstrated the operation of the Biosafety Clearing-House, stressing the need to use common formats that had been developed, as well as a common set of controlled vocabularies that could be easily translated into all United Nations languages. It was also important for users to advise the Secretariat whenever a national database was being designed, so that the Secretariat could assist in ensuring interoperability with the Biosafety Clearing-House. A toolkit has also been developed to provide information on the Biosafety Clearing-House, assist in navigation and facilitate the development of national databases and interoperability. It gave step-by-step instructions on how to register information and provided information on other, non-electronic and non-Web-based means of using the Biosafety Clearing-House. The Secretariat stressed, however, that Internet access for all was the ultimate goal and encouraged comments on the operation of the system so that needs could be met to the extent possible.
- 54. In response to a statement by the expert from the Netherlands, who said that he was pleased with the progress made in the pilot phase of the Biosafety Clearing-House and intended to use it at a workshop his Government was organizing for Central and Eastern European countries, the Secretariat said that it looked forward to attending the workshop being organized by the Netherlands. For its part, following the regional meeting for Africa that had been held in Nairobi in February 2001, the Secretariat intended to organize similar meetings for Latin America and the Caribbean, Central and Eastern Europe, and Asia and the Pacific. Funding for those workshops and for the development of the toolkit was being provided by the United States Government.

International Workshop on Financial Support for the Creation and Implementation of the National Biosafety Frameworks

55. At the 5th plenary session of the meeting, on 13 July 2001, the representative of UNEP drew attention to the International Workshop on Financial Support for the Creation and Implementation of the

National Biosafety Frameworks that was to be held the next day, 14 July, at the same venue. The purpose of the meeting was to identify and promote synergies and complementarities between existing funding initiatives. He said that the meeting would bring together a range of partners, including donors, developing countries, non-governmental organizations, funding agencies, and the private sector. Because of space limitations, only twenty developing countries and countries with economies in transition had intially been invited. However, other experts from such countries attending the current meeting should contact the UNEP representatives if they too wished to attend.

International Conference on New Biotechnology, Food and Crops: Science, Safety and Society

56. At the 6th plenary session, on 13 July 2001, the representative of the OECD reported to the Expert Meeting on the International Conference on New Biotechnology, Food and Crops: Science, Safety and Society, which had been held in Bangkok from 10 to 12 July 2001. He said that the Conference had brought together more than 300 participants from 50 countries, including scientists, government officials and representatives of civil society. In his summary, the Chair of the Conference had recommended to the agencies and Governments involved in developing capacity that there should be an accelerated, internationally coordinated programme of capacity-building activities, stating that, if the effect was to speed up ratifications and entry into force of the Cartagena Protocol, it would be a very desirable outcome as it would provide an important operational structure to take forward a number of the issues raised at the Conference and alleviate public concerns about genetically modified crops. The representative of OECD concluded by saying that the conclusions of the Conference would be presented to the forthcoming G-8 Summit in Genoa, Italy. OECD had a strong desire to continue its cooperation with the Convention Secreta riat for the implementation of the Cartagena Protocol and, in particular, for the implementation of the Biosafety Clearing-House.

Regional meeting for Latin America and the Caribbean

57. At the 6th plenary session of the meeting, on 13 July, one expert, speaking on behalf of the Group of Latin American and Caribbean States said that those States were strongly convinced of the need for a regional meeting on capacity-building for the Cartagena Protocol, focusing particularly on the Biosafety Clearing-House, to be held prior to the second meeting of ICCP. Peru had offered to host such a meeting in early September, with the assistance of the Secretariat, and the Group of Latin American and Caribbean States requested that all national focal points in the region should be officially informed of it as soon as possible.

Preparatory meeting for the second meeting of the ICCP

58. Also at the 6th plenary session, in response to a proposal from the expert from Cameroon, the Chair said that provision could be made for a one-day preparatory meeting for developing countries, in particular the least developed countries, in Nairobi during the weekend immediately prior to the second meeting of ICCP.

#### ITEM 8 ADOPTION OF THE REPORT

59. The present report was adopted at the 6th plenary session of the meeting on the basis of the draft report that had been circulated as document UNEP/CBD/BS/EM-CB/1/L.1.

#### ITEM 9. CLOSURE OF THE MEETING

60. Following the customary exchange of courtesies, the Chairman declared the Open-ended Expert Meeting on Capacity-building for the Cartagena Protocol on Biosafety closed at 5.05 p.m. on Friday, 13 July 2001.

#### Annex I

### DRAFT ACTION PLAN FOR BUILDING CAPACITIES FOR THE EFFECTIVE IMPLEMENTATION OF THE CARTAGENA PROTOCOL ON BIOSAFETY

The Open-ended Expert Meeting on Capacity-Building for the Cartagena Protocol on Biosafety,

Having met in Havana from 11 to 13 July 2001,

*Recommends* for the consideration and approval of the Intergovernmental Committee for the Cartagena Protocol on Biosafety (ICCP) the following draft Action Plan:

#### 1. Objective of the Action Plan

- 1. The objective of this Action Plan is to facilitate and support the development and strengthening of capacities for the effective implementation of the Cartagena Protocol on Biosafety at the national, subregional, regional and global levels in a timely manner. In this regard, the provision of financial, technical and technological support to developing countries, in particular the least developed and small island developing states among them, as well as countries with economies in transition is essential.
- 2. To achieve the objective, this action plan aims at identifying country needs, priorities, mechanisms of implementation and sources of funding.

#### 2. Key elements requiring concrete action

- 3. The following key elements, based on the indicative list of capacity requirements in appendix 2 to the present document, and which require concrete action, are meant to be considered in a flexible manner, based on a demand-driven approach, taking into account the different situations, capabilities and stages of development of each country.
  - 1. Institutional capacity-building
    - a. Legislative and regulatory framework
    - b. Administrative framework
    - c. Technical and telecommunications infrastructures
    - d. Funding and resource management
    - e. Mechanisms for follow-up, monitoring and assessment
  - 2. Human-resources development and training
  - 3. Risk assessment and other scientific and technical expertise

- 4. Risk management
- 5. Awareness, participation and education at all levels including for decision makers, stakeholders and general public
- 6. Information exchange and data management
- 7. Scientific, technical and institutional collaboration at subregional, regional and international levels
- 8. Technology transfer

#### 3. Processes/steps

- 4. The following processes/steps should be undertaken within specific timeframes:
  - 1. Identification of capacity needs, including the needs that are not covered prior to the second meeting of ICCP.
  - 2. Prioritization of the key elements prior to the first meeting of the Conference of the Parties to the Convention serving as the meeting of the Parties to the Protocol.
  - 3. Sequencing of actions, including timelines for the operation of capacity-building prior to first meeting of the Conference of the Parties to the Convention serving as the meeting of the Parties to the Protocol.
  - 4. Identification of the coverage and gaps in capacity-building initiatives and resources that could support the implementation, prior to first meeting of the Conference of the Parties to the Convention serving as the meeting of the Parties to the Protocol, from the following:
    - a. Multilateral agencies
    - b. Other international sources
    - c. Bilateral sources
    - d. Other stakeholders
    - e. National sources
  - 5. Enhancing the effectiveness and adequacy of financial resources to be provided by multilateral and bilateral donors and other donors to developing countries, in particular the least developed and small island developing States among them, as well as countries with economies in transition.
  - 6. Enhancing synergies and coordination of capacity-building initiatives.
  - 7. Development of indicators for evaluating capacity-building measures.

#### 4. Implementation

#### 4.1 National level

- 5. The activities hereunder are not listed in any order of priority:
  - 1. Development of national regulatory frameworks on biosafety
  - 2. Development and/or strengthening of institutional, administrative, financial and technical capacities, including the designation of national focal points and competent national authorities
  - 3. Establishment of a mechanism to inform all stakeholders
  - 4. Appropriate participation of all relevant stakeholders
  - 5. A mechanism for handling requests or notifications, including risk assessment and decision-making, as well as public information and participation
  - 6. Mechanisms for monitoring and compliance
  - 7. A short- and long-term assessment for internal and external funding
    - 4.2 Subregional and regional levels
  - 1. Regional and subregional collaborative arrangements
  - 2. Regional and subregional advisory mechanisms
  - 3. Regional and subregional centre of excellence and training
  - 4. Regional website and database
  - 5. Mechanisms for regional and subregional coordination and harmonization of regulatory frameworks, where appropriate.

#### 4.3 International level

- 1. Effective functioning of the Biosafety Clearing-House
- 2. Development/updating of international guidance (IUCN, UNEP, FAO etc.)
- 3. Strengthening South-South cooperation
- 4. Development and effective use of the roster of experts
- 5. Regular review and provision of further guidance by the Conference of the Parties to the Convention serving as the meeting of the Parties to the Protocol

#### 5. Indicators and monitoring

6. It is recognized that a preliminary set of indicators for this Action Plan and its monitoring will be addressed in relevant draft decision of ICCP at its second meeting.

#### Appendix 1 1/

- 1. The general rights and obligations set out in the Protocol include:
- (c) Article 2, paragraph 1: take the necessary and appropriate legal, administrative and other measures to implement obligations under the Protocol;
- (d) Article 2, paragraph 2: ensure that the development, handling, transport, use, transfer and release of living modified organisms are undertaken in a manner that prevents or reduces the risks to biological diversity, taking also into account risks to human health;
- (e) Article 2, paragraph 4: take action that is more protective than called for in the Protocol, provided such actions are consistent with the Protocol and other obligations under international law;
- (f) Article 6, paragraph 1: right of any Party of transit to regulate the transport of living modified organisms through its territory and to communicate any decision regarding transit to the Biosafety Clearing-House;
- (g) Article 6, paragraph 2: right to set standards for contained use within a Party's jurisdiction;
- (h) Article 16, paragraph 1: establish and maintain appropriate mechanisms, measures and strategies to regulate, manage and control risks identified in the risk assessment provisions of the Protocol associated with the use, handling and transboundary movement of living modified organisms;
- (i) Article 16, paragraph 4: endeavour to ensure that any living modified organism whether imported or locally developed, has undergone an appropriate period of observation before it is put to its intended use;
- (j) Article 17: notify affected or potentially affected States of an unintentional transboundary movement of a living modified organism and consul such States to determine appropriate responses, including emergency measures;
  - (k) Article 19: designation of one national focal point and competent national authorities;
- (l) Article 23: promote and facilitate public awareness, education and participation, including access to information on living modified organisms identified in accordance with the Protocol that may be imported;
- (m) Article 25: preventing and, if appropriate, penalizing transboundary movements carried out in contravention of domestic measures to implement the Protocol.
- 2. Specific rights and obligations set out in the Protocol most relevant to capacity-building include:
  - (a) Article 7: application of the advanced informed agreement procedure;
- (b) Article 8: Party of export to notify competent national authority of Party of import prior to the intentional transboundary movement of a living modified organism;

<sup>1/</sup> Taken from UNEP/CBD/ICCP/1/4, paras. 9-10.

- (c) Article 9: Party of import to acknowledge receipt of notification and of whether it will proceed according to its domestic regulatory framework or the decision procedure under the Protocol;
- (d) Article 10: take decision on import in accordance with risk assessment provisions of the Protocol and inform the notifier whether the intentional transboundary movement may proceed;
- (e) Article 12: review of a decision regarding an intentional transboundary movement in light of new or relevant scientific or technical information or a change in circumstances that may influence the outcome of the risk assessment;
- (f) Article 11, paragraph 1: inform the Parties through the Biosafety Clearing-House of a final decision regarding domestic use, including placing on the market, of a living modified organism that may be subject to transboundary movement for direct use as food, feed or for processing;
- (g) Article 11, paragraph 4: take a decision on the import of living modified organisms intended for direct use as food, feed, or for processing under its domestic regulatory framework;
- (h) Article 15 and Annex III: undertake risk assessments pursuant to the Protocol in a scientifically sound manner, taking into account recognized risk assessment techniques and in accordance with the steps outlined in Annex III;
- (i) Article 16: risk management including to impose measures to the extent necessary to prevent adverse effects of a living modified organism, and to take appropriate measures to prevent unintentional transboundary movements of living modified organisms;
- (j) Article 18, paragraph 1: take necessary measures to require that living modified organisms that are subject to intentional transboundary movement within the scope of the Protocol are handled, packaged and transported under conditions of safety, taking into consideration relevant international rules and standards;
- (k) Article 20: make available to the Biosafety Clearing-House information, including summaries of risk assessments or environmental reviews and decisions regarding importation or release of living modified organisms;
  - (l) Article 21: protect confidential information received under the Protocol;
- (m) Article 26: in reaching a decision on import, take into account socio-economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biodiversity, consistent with the international obligations of Parties.

#### Appendix 2 2/

### PRELIMINARY LIST OF KEY REQUIRED CAPACITIES FOR IMPLEMENTATION OF THE CARTAGENA PROTOCOL

INSTITUTION BUILDING	RISK ASSESSMENT	RISK MANAGEMENT
Needs assessment and biosafety framework planning	General risk assessment capacities	General risk management capacities
(a) Inventory of existing and anticipated biotechnology programmes and practices	<ul><li>(a) Ability to coordinate multi- disciplinary analyses</li><li>(b) Enhancement of</li></ul>	Understanding of application of risk management tools to different biotechnology sectors
(b) Capacity to develop present and future import/export data	technological and institutional capacities for	Decision-making capacities
<ul><li>(c) Accurate understanding of industry biotechnology practices in relevant sectors</li><li>(d) Capacity to compile and</li></ul>	risk assessment (c) Capacity to identify and access appropriate outside expertise	(a) Identification and quantification of risks, including through sound application of the
analyse existing legal and administrative biosafety regimes	(d) Understanding of relevant bio-technology processes and applications	precautionary approach (b) Capacity to assess relative effectiveness of management
<ul><li>(e) Multi-disciplinary strategic planning capacity</li><li>(f) Capacity to relate biosafety</li></ul>	Science and socio-economic capacities*	options for import, handling and use, where appropriate (c) Capacity to assess relative
regime to other international obligations	(a) Analyse risks to conservation and	trade impacts of management options, where appropriate
Biosafety regime development	sustainable use of biodiversity	(d) Impartial review of proposed management regime prior to
(a) Develop/strengthen legal and regulatory structures	(b) Undertake life-cycle analysis	decision-making  Implementation of decisions
(b) Develop/strengthen administrative processes to	(c) Analyse risks to human health of effects on	(a) Identification and handling of
manage risk assessment and risk management	biodiversity (d) Analyse ecosystem effects	living modified organisms at point of import
(c) Develop domestic/regional risk assessment capacity	of living modified organism introduction	(b) Monitoring of environmental impacts against expected
(d) Capacity to administer notification, acknowledgement and	(e) Assess food security issues arising from risks to biodiversity	impacts (c) Capacity to monitor, enforce and report on compliance
decision response process  (e) Capacity to make and report decision on LMO import in	(f) Value and roles of biodiversity to local and indigenous communities	
required time frames (f) Emergency notification and planning and response	(g) Other socio-economic considerations related to biodiversity	
capacity (g) Enforcement capacity at borders	(h) Enhancement of related scientific, technical capacities	

<sup>&</sup>lt;u>2</u>/ UNEP/CBD/ICCP/1/4, the table after paragraph 18.

<sup>\*</sup> Note: Specific types of scientific expertise required will vary from case to case, but broadly involve two areas:- evaluation of genetic modifications- evaluation of interactions with the receiving environment

#### INSTITUTION BUILDING

#### RISK ASSESSMENT

#### RISK MANAGEMENT

### Long-term regime building/maintenance

- (a) Capacity to monitor, review and report on the effectiveness of risk management programme, including legal, regulatory and administrative mechanisms
- (b) Capacity to monitor longerterm environmental impacts, if any (based on current baselines)
- (c) Establishment of environmental reporting systems

#### **CROSS-CUTTING CAPACITIES**

#### Data management and information-sharing

- (a) Exchange of scientific, technical, environmental and legal information
- (b) Collection, storage and analysis of scientific, regulatory and administrative data
  - (c) Communication to the Biosafety Clearing-House

#### Human resources strengthening and development

- (a) All aspects of regime development, evaluation and maintenance for risk assessment and risk management
- (b) Raising awareness of modern biotechnology and biosafety among scientists, government officials
  - (c) Training and longer-term education
  - (d) Procedures for safe handling, use and transfer of living modified organisms

#### Public awareness and participation

- (a) Administer and disseminate information on legal and administrative framework
  - (b) Public awareness of/participation in scientific assessment process
    - (c) Risks associated with handling and use

#### Regional capacity development

- (a) Scientific assessment of risk
- (b) Harmonization of legal regimes
- (c) Training of human resources
  - (d) Information sharing

#### Annex II

#### IMPLEMENTATION TOOLKIT

This implementation toolkit provides a compilation, as a checklist, of obligations found in the Cartagena Protocol on Biosafety. These obligations are organized in the following categories:

- Administrative tasks (initial and future)
- Legal requirements and/or undertakings
- Procedural requirements (AIA and Article 11)

#### I. ADMINISTRATIVE TASKS

#### Initial actions

	Tasks	Article	Ö
1.	Designate one national authority responsible for liaison with the Secretariat and provide name/address to Secretariat.	19(1),(2)	
2.	Designate one or more competent authorities responsible for performing administrative functions under the Protocol and provide name(s)/address(es) to the Secretariat. If more than one, indicate the types of LMOs for which each competent authority is responsible.	19(1),(2)	
3.	Provide to the Biosafety Clearing House: - any relevant existing laws, regulations or guidelines, including those applicable to the approval of LMO-FFPs; and - any bilateral, regional or multilateral agreements or arrangements.	20(3)(a)-(b), 11(5), 14(2)	
4.	Specify to the Biosafety Clearing House cases in which import may take place at the same time as the movement is notified.	13(1)(a)	
5.	Specify to the Biosafety Clearing House imports of LMOs exempted from the AIA procedures.	13(1)(b)	
6.	Notify the Biosafety Clearing House if domestic regulations shall apply with respect to specific imports.	14(4)	
7.	Provide the Biosafety Clearing House with a point of contact for receiving information from other States on unintentional transboundary movements in accordance with Article 17.	17(2)	
8.	Notify the Secretariat if there is a lack of access to the Biosafety Clearing House and hard copies of notifications to the Clearing House should be provided.	(e.g., 11(1))	
	Follow up actions		
9.	Provide to the Biosafety Clearing House:  - Summaries of risk assessments or environmental reviews of LMOs generated by regulatory processes and conducted in accordance with Art. 15;  - Final decisions concerning the import or release of LMOs; and - Article 33 reports.	20(3)(c)-(e)	
10.	Make available to the Biosafety Clearing House information concerning cases of illegal transboundary movements.	25(3)	
11.	Monitor the implementation of obligations under the Protocol and submit to the Secretariat periodic reports at intervals to be determined.	33	

	Tasks	Article	Ö
12.	Notify the Biosafety Clearing-House of any relevant changes to the information provided under part I above.		

#### II. LEGAL REQUIREMENTS AND/OR UNDERTAKINGS

	Article	'
Ensure that the development, handling, transport, use, transfer and release of LMOs are undertaken in a manner that prevents or reduces the risks to biological diversity, taking also into account risks to human health.	2(2)	
Ensure that there is a legal requirement for the accuracy of information provided by domestic exporters for purposes of notifications for export to another country and by domestic applicants for domestic approvals for LMOs that may be exported as LMO-FFPs.	8(2) 11(2)	
Ensure that any domestic regulatory framework used in place of the AIA procedures is consistent with the Protocol.	9(3)	
Ensure that AIA decisions are taken in accordance with Article 15.	10(1)	
Ensure that risk assessments are carried out for decisions taken under Article 10 and that they are carried out in a scientifically sound manner.	15(1),(2)	
Establish and maintain appropriate mechanisms, measures and strategies to regulate, manage and control risks identified in risk assessments associated with the use, handling and transboundary movement of LMOs under the Protocol.	16(1)	
Take appropriate measures to prevent the unintentional transboundary movements of LMOs, including measures such as requiring a risk assessment prior to the first release of an LMO.	16(3)	
Endeavor to ensure that LMOs, whether imported or locally developed, have undergone an appropriate period of observation that is commensurate with its life cycle or generation time before it is put to its intended use.	16(4)	
Take appropriate measures to notify affected or potentially affected States, the Biosafety Clearing House, and, where appropriate, relevant international organizations, when there is an occurrence within its jurisdiction that leads or may lead to an unintentional transboundary movement of and LMO that is likely to have significant adverse effects on the sustainable use and conservation of biodiversity, taking also into account risks to human health in such States.	17(1)	
Take necessary measures to require that LMOs that are subject to transboundary movement under the Protocol are handled, packaged and transported under conditions of safety, taking into account relevant international rules and standards.	18(1)	
Take measures to require that documentation accompanying LMO-FFPs - clearly identifies that they "may contain" LMOs and are not intended for intentional introduction into the environment; and - provides a contact point for further information.	18(2)(a)	
Take measures to require that documentation accompanying LMOs destined for contained use:  - Clearly identifies them as LMOs; - Specifies any requirements for their safe handling, storage, transport and use; - Provides a contact point for further information; and - Provides the name and address of individuals or institutions to which they	18(2)(b)	
	taking also into account risks to human health.  Ensure that there is a legal requirement for the accuracy of information provided by domestic exporters for purposes of notifications for export to another country and by domestic applicants for domestic approvals for LMOs that may be exported as LMO-FFPs.  Ensure that any domestic regulatory framework used in place of the AIA procedures is consistent with the Protocol.  Ensure that AIA decisions are taken in accordance with Article 15.  Ensure that risk assessments are carried out for decisions taken under Article 10 and that they are carried out in a scientifically sound manner.  Establish and maintain appropriate mechanisms, measures and strategies to regulate, manage and control risks identified in risk assessments associated with the use, handling and transboundary movement of LMOs under the Protocol.  Take appropriate measures to prevent the unintentional transboundary movements of LMOs, including measures such as requiring a risk assessment prior to the first release of an LMO.  Endeavor to ensure that LMOs, whether imported or locally developed, have undergone an appropriate period of observation that is commensurate with its life cycle or generation time before it is put to its intended use.  Take appropriate measures to notify affected or potentially affected States, the Biosafety Clearing House, and, where appropriate, relevant international organizations, when there is an occurrence within its jurisdiction that leads or may lead to an unintentional transboundary movement of and LMO that is likely to have significant adverse effects on the sustainable use and conservation of biodiversity, taking also into account risks to human health in such States.  Take necessary measures to require that LMOs that are subject to transboundary movement under the Protocol are handled, packaged and transported under conditions of safety, taking into account relevant international rules and standards.  Take measures to require that documentation accompanying LMO-FFPs -	taking also into account risks to human health.  Ensure that there is a legal requirement for the accuracy of information provided by domestic exporters for purposes of notifications for export to another country and by domestic applicants for domestic approvals for LMOs that may be exported as LMO-FFPs.  Ensure that any domestic regulatory framework used in place of the AIA procedures is consistent with the Protocol.  Ensure that AIA decisions are taken in accordance with Article 15.  Ensure that risk assessments are carried out for decisions taken under Article 10 and that they are carried out in a scientifically sound manner.  Establish and maintain appropriate mechanisms, measures and strategies to regulate, manage and control risks identified in risk assessments associated with the use, handling and transboundary movement of LMOs under the Protocol.  Endeavor to ensure that LMOs, whether imported or locally developed, have undergone an appropriate period of observation that is commensurate with its life cycle or generation time before it is put to its intended use.  Take appropriate measures to notify affected or potentially affected States, the Biosafety Clearing House, and, where appropriate, relevant international organizations, when there is an occurrence within its jurisdiction that leads or may lead to an unintentional transboundary movement of and LMO that is likely to have significant adverse effects on the sustainable use and conservation of biodiversity, taking also into account risks to human health in such States.  Take necessary measures to require that LMOs that are subject to transboundary movement under the Protocol are handled, packaged and transported under conditions of safety, taking into account relevant international rules and standards.  Take measures to require that documentation accompanying LMO-FFPs  - clearly identifies them as LMOs;  - Specifies any requirements for their safe handling, storage, transport and use;  - Provides a contact point for further information; and  - Provi

	Tasks	Article	V
13.	Take measures to require that documentation accompanying LMOs that are intended for intentional introduction in the environment and any other LMOs within the scope of the Protocol:  - Clearly identifies them as LMOs - Specifies the identify and relevant traits and/or characteristics; - Provides any requirements for the safe handling, storage, transport and use; - Provides a contact point for further information; - Provides, as appropriate, the name and address of the importer and exporter; and - Contains a declaration that the movement is in conformity with the requirements of the Protocol.	18(2)(c)	
14.	Provide for the designation of confidential information by notifiers, subject to the exclusions set forth in Article 21(6).	21(1),(6)	
15.	Ensure consultation with notifiers and review of decisions in the event of disagreement regarding claims of confidentiality.	21(2)	
16.	Ensure the protection of agreed-upon confidential information and information claimed as confidential where a notification is withdrawn.	21(3),(5)	
17.	Ensure that confidential information is not used for commercial purposes without the written consent of the notifier.	21(4)	
18.	Promote and facilitate public awareness, education and participation concerning the safe transfer, handling and use of LMOs, taking also into account risks to human health.	23(1)(a)	
19.	Endeavor to ensure that public awareness and education encompass access to information on LMOs identified in accordance with the Protocol that may be imported.	23(1)(b)	
20.	In accordance with relevant domestic laws, consult with the public in decision making under the Protocol, while respecting confidential information.	23(2)	
21.	Endeavor to inform the public about the means of public access to the Biosafety Clearing House.	23(3)	
22.	Adopt appropriate measures aimed a preventing and, if appropriate, penalizing transboundary movements in contravention of domestic measures to implement the Protocol.	25(1)	
23.	Dispose, at its expense, LMOs that have been the subject of an illegal transboundary movement through repatriation or destruction, as appropriate, upon request by an affected Party.	25(2)	

#### III. PROCEDURAL REQUIREMENTS: ADVANCED INFORMED AGREEMENT

	Tasks	Article	1
1.	Provide written acknowledgement of receipt of notification to notifier within 90 days, including:		
	- Date of receipt of notification;	9(2)(a)	
	- Whether notification meets requirements of Annex I;	9(2)(b)	
	- That the import may proceed only with written consent and whether to proceed in	10(2)(a),	
	accordance with the domestic regulatory framework or in accordance with Article 10; <b>OR</b>	9(2)(c)	
	- Whether the import may proceed after 90 days without further written consent.	10(2)(b)	

	Tasks	Article	1
2.	Communicate in writing to the notifier, within 270 days of receipt of notification:  - Approval of the import, with or without conditions;  - Prohibition of the import;  - A request for additional relevant information in accordance with domestic regulatory framework or Annex I; or  - Extension of the 270 day period by a defined period of time; <b>AND</b>	10(3)(a)-(d)	
	Except where approval is unconditional, the reasons for the decision, including the reasons for the request for additional information or for an extension of time.	10(4)	
3.	Provide in writing to the Biosafety Clearing House the decision communicated to the notifier.	10(3)	
4.	Respond in writing within 90 days to a request by an Exporting Party for a review of a decision under Article 10 where there has been a change in circumstances or additional relevant scientific or technical information has been made available, providing the reasons for the decision upon review.	12(2),(3)	

## III. PROCEDURAL REQUIREMENTS: LIVING MODIFIED ORGANISMS FOR DIRECT USE AS FOOD, FEED OR FOR PROCESSING

	Tasks	Article	$\sqrt{}$
1.	Upon making a final decision regarding domestic use, including placing on the market, of LMOs that may be subject to transboundary movement for direct use as food or feed, or for processing, inform the Biosafety Clearing House within 15 days of making that decision, including the information listed in Annex II.	11(1)	
2.	Except in the case of field trials, provide hard copies of the final decision to the National Focal Point of Parties that have notified the Secretariat in advance that they do not have access to the Biosafety Clearing House.	11(1)	
3.	Provide additional information contained in paragraph (b) of Annex II about the decision to any Party that requests it.	11(3)	
4.	In response to the posting of a decision by another Party, decide whether that LMO-FFP may be imported:  - either as approved under the domestic regulatory framework consistent with the Protocol; <b>OR</b> - in the absence of a regulatory framework, on the basis of a risk assessment in accordance with Annex III within no more than 270 days. In this case, a declaration must be made to the Biosafety Clearing-House.	11(4),(6)	

#### Annex III

#### SUGGESTED SEQUENCE OF ACTIONS

*Recognizing* that the sequence of action necessary to implement the Protocol is to be decided by Parties according to their national needs,

Cognizant of the urgent need to built capacities in developing countries, in particular the least developed and small island developing states among them, as well as countries with economies in transition,

Building on the identified elements in the Action Plan and without prejudice to the timeframes indicated therein.

As an aid to assist countries to establish national priorities and to facilitate regional and subregional activities the following sequence of actions based on experience and past practice is proposed for consideration.

#### Sequencing of activities identified in the action plan

Each activity has associated with it specific objectives/tasks identified in the Indicative Framework and associated documents which will facilitate priority setting by countries and enable the establishment of a timetable for capacity development. This sequence does not establish priorities of action to be taken by countries.

#### A. National level

- 1. Assessment of effectiveness and adequacy of existing capacity.
- 2. Assessment of the short- and long-term requirements for internal and external funding
- 3. Development of timelines.
- 4. Development of national regulatory frameworks on biosafety.
- 5. Development and/or strengthening of institutional, administrative, financial and technical capacities, including the designation of national focal points and competent authorities.
- 6. A mechanism for handling requests or notifications, including risk assessment and decision-making, as well as public information and participation.
- 7. Mechanisms for monitoring and compliance.
- 8. Establishment of a mechanism to inform all stakeholders.
- 9. Appropriate participation of all relevant stakeholders.

#### B. Subregional and regional levels

- 1. Assessment of national, bilateral and multilateral funding.
- 2. Regional website and database.

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- 3. Mechanisms for regional and sub-regional coordination and harmonization of regulatory frameworks, where appropriate.
- 4. Regional and sub-regional collaborative arrangements.
- 5. Regional and sub-regional advisory mechanisms.
- 6. Regional and sub-regional centers of excellence and training.

#### C. International level

- 1. Effective functioning of the Biosafety Clearing-House.
- 2. Enhancing the effectiveness and adequacy and coordination of financial resources to be provided by multilateral and bilateral donors and other donors to developing countries, in particular the least developed and small island developing States among them, as well as countries with economies in transition.
- 3. Development and effective use of the roster of experts.
- 4. Enhancing synergies and coordination of capacity-building initiatives.
- 5. Strengthening South-South cooperation.
- 6. Development/updating of international guidance (IUCN, UNEP, FAO etc.).
- 7. Regular review and provision of further guidance by the Conference of the Parties to the Convention serving as the meeting of the Parties to the Protocol.

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