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INTERGOVERNMENTAL COMMITTEE FOR THE
CARTAGENA PROTOCOL ON BIOSAFETY
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Item 4.1.4 of the provisional agenda *

CAPACITY-BUILDING (ARTICLE 22, ARTICLE 28)

Note by the Executive Secretary

I. INTRODUCTION

1. At its second meeting, held in Nairobi from 1 to 5 October 2001, the Intergovernmental Committee for the Cartagena Protocol on Biosafety (ICCP) endorsed the Action Plan for Building Capacities for the Effective Implementation of the Cartagena Protocol on Biosafety" which was prepared by the Open-ended Expert Meeting on Capacity-Building for the Cartagena Protocol on Biosafety, that was held in Havana from 11 to 13 July 2001.

2. In its recommendation 2/9 A, the Committee requested the "Executive Secretary to develop a coordination mechanism for the implementation of the Action Plan with a view to promoting partnerships and to maximize complementarities and synergies between various capacity-building initiatives". In response to this request, the present note proposes elements of the coordination mechanism and ways and means of enhancing collaboration.

3. The Action Plan identifies a series of processes/steps to be undertaken prior to the first meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol. One of the processes is the identification of the coverage and gaps in capacity-building initiatives and resources, in support of the ratification and implementation of the Protocol. Section III of the note provides a preliminary overview of the coverage and major gaps in the projects and other initiatives currently contained in the "biosafety capacity-building projects" database, maintained by the Secretariat as part of the Biosafety Clearing-House.

4. In addition, the Action Plan identifies the development of indicators for evaluating capacity-building measures as another important process to be undertaken. In the draft Action Plan, section 5 on indicators and monitoring, the Open-ended Expert Meeting had anticipated that a preliminary set of indicators for the Action Plan would be addressed by the ICCP at its second meeting. However, the issue

* UNEP/CBD/ICCP/3/6

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was not fully addressed due to time constraints. In order to enable the Committee to consider this issue further, section IV and annex I of the present note include a possible framework of preliminary indicators for monitoring and evaluation of the Action Plan.

5. Furthermore, the Open-ended Expert Meeting called for a detailed consideration of the role of different organizations in contributing to capacity-building for the Protocol by the ICCP at its second meeting, which was also not possible due to time constraints. In order to enable the ICCP to re-consider the issue at its third meeting, the same analysis that was presented in the note by the Executive Secretary on capacity-building prepared for the second meeting of ICCP (UNEP/CBD/ICCP/2/10) is included in annex II to the present note.

6. Finally, given that the report of the Expert Meeting had a number of attachments that the Meeting considered as useful complements to the Action Plan, including appendix I (Rights and obligations) and appendix II (Preliminary list of key required capacities) to the Action Plan, and annex II to the report itself (Implementation tool kit), but were not adequately considered by ICCP at its second meeting because of time constraints, the third meeting of the ICCP may wish to re-consider those attachments which are reproduced for ease of reference as annexes III-V of the present note, and make recommendations accordingly.

7. The views expressed by Parties, Governments and relevant organizations regarding capacity-building, in response to ICCP recommendation 2/9 A, are outlined in an information paper (UNEP/CBD/ICCP/3/INF/4).

II. ELEMENTS OF THE COORDINATION MECHANISM FOR THE IMPLEMENTATION OF THE CAPACITY-BUILDING ACTION PLAN

8. At its second meeting, the ICCP requested the Executive Secretary to "develop a coordination mechanism for the implementation of the Action Plan with a view to promoting partnerships and to maximize complementarities and synergies between various capacity-building initiatives". This section proposes possible elements of the Coordination Mechanism, and ways and means of enhancing coordination and collaboration, for consideration by the ICCP at its third meeting. The proposed mechanism is intended to provide a platform for linking the initiatives of various institutions and facilitating the sharing of information, harmonization and optimization of efforts and leverage of resources towards the implementation of the Action Plan.

9. There have been some efforts to ensure coordination and collaboration among various biosafety capacity-building efforts. Examples include those by the Inter-Agency Network for Safety in Biotechnology (IANB) coordinated by the Organization for Economic Cooperation and Development (OECD) and by the Global Environment Facility (GEF). The IANB was established in 1999 and currently comprises nine intergovernmental organizations with activities related to safety in biotechnology, including: Consultative Group on International Agricultural Research (CGIAR), Secretariat of the Convention on Biological Diversity, Food and Agriculture Organization of the United Nations (FAO), Organisation for Economic Co-operation and Development (OECD), Organization Internationale des Epizooties (OIE), United Nations Conference on Trade and Development (UNCTAD), United Nations Industrial Development Organization (UNIDO), World Health Organization (WHO) and World Trade Organization (WTO). The aim of the network is to enhance the exchange of information and facilitate co-operation.

Among its activities, IANB publishes a six monthly newsletter; maintains a web site, and organizes networking meetings. 1/

10. The Global Environment Facility, in its Initial Strategy for Assisting Countries to Prepare for the Entry into Force of the Cartagena Protocol on Biosafety, highlighted a specific objective to promote coordination and collaboration with other bilateral and multilateral organizations to assist capacity-building for the Protocol. 2/ GEF will promote greater information exchange between organizations providing assistance for biosafety activities with a view to facilitating openness among donors, sharing of lessons learned, building synergies and complementarity, promoting effective and efficient delivery of assistance and strengthening partnerships to optimize resources and increase the potential for success. GEF will periodically consult interested organizations to review activities and assistance being provided to developing countries in the area of biosafety. GEF is also in the process of developing a comprehensive database on investments in its four focal areas, including biodiversity and biosafety. This database, when established, will facilitate coordination of funding of biosafety activities and identification of the funding coverage and gaps.

11. The Open-ended Expert Meeting on Capacity-Building for the Cartagena Protocol on Biosafety and the UNEP/GEF Workshop on Financial Support for National Biosafety Frameworks, which were held in Havana, Cuba from 11-14 July 2001, also emphasized the urgent need for better coordination and collaboration between existing and planned capacity-building projects so as to minimize duplication of efforts and wastage of resources and to promote complementarities, strong partnerships, and sharing of information and lessons. The draft Action Plan which was prepared by the Expert Meeting identified "enhancing synergies and coordination of capacity-building initiatives" as one of the key processes/steps that should be undertaken in implementing the plan.

12. The UNEP/GEF International Workshop on Financial Support for the Creation and Implementation of National Biosafety Frameworks also emphasized the need to create comprehensive information/database on funding sources and opportunities for capacity-building. Participants also called for stronger donor-recipient partnerships so that the donors' support is better aligned with the identified capacity needs of the latter. Likewise, the workshop highlighted the need to strengthen donor-donor partnerships in order to enhance harmonization of their funding support and minimize duplication or inadvertent omission of some countries and capacity-building areas. The workshop recommended that coordination meetings among donor/support agencies be organized on a regular basis with a view to promote coordination and alignment of the activities of various agencies with the priorities identified in the Action Plan for Building Capacities for the Effective Implementation of the Cartagena Protocol on Biosafety. It also recommended regular reporting on capacity-building activities, through the Biosafety Clearing-House, and the development of an agreed uniform reporting format for this purpose.

Elements of the coordination mechanism

13. On the basis of the recommendations from various workshops and the experience of different coordination initiatives, the following five inter-related elements of the coordination mechanism for the implementation of the Action Plan, to be administered by the Secretariat, are proposed for consideration by the ICCP:

1/ Details about the IANB can be obtained at the following website < http://www1.oecd.org/ehs/biobin/IANB.htm>

2/ GEF, 2000. Initial Strategy for Assisting Countries to Prepare for the Entry into Force of the Cartagena Protocol on Biosafety, Washington D.C.

(a) *A regionally-balanced liaison group on capacity building for biosafety* could be established by the Executive Secretary to provide expert advice to the Secretariat and the ICCP/COP-MOP on ways and means to enhance the coordination and effective implementation of the Action Plan.

(b) *The biosafety capacity building projects' database*: The projects database currently maintained by the Secretariat on the Biosafety Clearing-House could be strengthened and kept up-to-date to facilitate coordination and exchange of information, and also to serve as a tool for identifying the coverage, overlaps and gaps in the capacity-building activities and funding by different organizations.

(c) *An information sharing and networking mechanism*: An appropriate information sharing system (including, for example, an e-mail list-server or postage of hard copies where electronic communication is difficult) could be established to facilitate regular and timely exchange of information and lessons especially between people in different countries, relevant organizations and donor agencies who are involved in promoting biosafety capacity-building. In addition, a more focused Ad Hoc Network or Inter-Agency Taskforce consisting of major agencies involved in biosafety capacity-building activities at the global level could be established to encourage regular interaction and networking. The ad-hoc Inter-Agency Network for Safety in Biotechnology (IANB), coordinated by OECD, could be expanded and strengthened to play this role.

(d) *Coordination meetings and workshops*: Periodic coordination meetings, workshops or roundtables for regional government representatives, relevant organizations and donors agencies could be organized on a regular (e.g., annual) basis, to promote dialogue, identify and promote synergies, encourage partnerships, address emerging common issues, promote greater understanding of evolving capacity needs of countries and encourage mutually supportive strategies across organizations involved in capacity-building for biosafety;

(e) *Reporting and monitoring mechanism*: A central reporting mechanism for major capacity-building projects and other initiatives using a uniform format, for example, a central portal or database linked to relevant national, regional or institutional nodes/ databases, could be established to facilitate monitoring of the coverage, progress and impact made, and to identify any major gaps. The biosafety projects database currently maintained by the Secretariat as part of the Biosafety Clearing-House could be expanded and resourced to play this role.

Functions of Secretariat as the administrator of the coordination mechanism

14. The overall goal of Coordination Mechanism is to facilitate effective and comprehensive implementation of the Action Plan for Capacity Building for the Cartagena Protocol on Biosafety in a collaborative and synergetic manner. The functions of the Secretariat, as the administrator of the Coordination Mechanism should, in pursuit of the above goal, include the following:

(a) Maintain the capacity-building project database, including its regular updating based on submissions received from the participating Parties, Governments, relevant organizations and donors;

(b) Facilitate the synthesis and dissemination of relevant information and lessons learned on biosafety capacity-building initiatives through the Biosafety Clearing-House, the Convention newsletter and information documents to the ICCP/Conference of the Parties serving as the meeting of the Parties to the Protocol;

(c) Facilitate reporting by governments and relevant organizations on their progress in implementing various elements of the Action Plan, using a common format;

(d) Convene and service meetings of the liaison group on capacity building on biosafety, as necessary;

(e) Organize, in collaboration with GEF, UNEP and relevant organizations, periodic coordination meetings, workshops or roundtable for regional government representatives, relevant organizations and donors to promote dialogue, sharing of experiences, identification of gaps and overlaps and promote synergies, initially on an annual basis;

(f) Promote broad and common understanding of the capacity-building needs for the effective implementation of the Protocol; and

(g) Where possible and appropriate, provide brokerage between Parties and Governments requiring financial and technical assistance for capacity-building and those providing such assistance.

15. It is important to note that effective coordination of the implementation of the Action Plan would need to take place at various levels (global, regional and national) and between different sectors and would involve processes of continuous interaction, collaboration and information sharing between the different players, both vertically and horizontally. Therefore, it is critical to establish strong links between the global coordination efforts and those taking place at the regional and national levels so that measures taken at the global level are able re-enforce those taken at the lower levels.

16. Coordination is also critical between international organizations and between donors at the global level; between regional and sub-regional efforts and between implementation agencies and organizations at the national level. At the global level, the emphasis should be placed on rallying together different international inter-governmental, non-governmental and private sector organizations to collaborate and coordinate their activities. At the regional and sub-regional levels, countries and organizations should seek to pull together and coordinate their resources to develop core regional expertise and centers of excellence. At the national level, the forms and functions of coordination mechanisms will vary from country to country but the majority would fall in the following categories: coordination units, committees, coordination groups or networks, either formal and informal.

III. IDENTIFICATION OF THE COVERAGE AND GAPS IN CAPACITY-BUILDING INITIATIVES AND RESOURCES FOR THE PROTOCOL

17. A number of projects and activities related to capacity-building in biosafety have been initiated in recent years by a broad range of organizations, including: intergovernmental organizations, bilateral programmes, United Nations agencies, regional organizations, industry, non-governmental organizations and foundations. 3/ Most of the projects, however, have been undertaken in the broader context of biotechnology development, some with specific components on promoting safety in the application of biotechnology. The sizes and duration of the projects vary significantly, with some being only short-term interventions such as study tours while others are comprehensive and long-term. The organizations with projects registered in the "biosafety capacity building projects" database maintained by the Secretariat of the Convention on Biological Diversity as part of the pilot phase of the Biosafety Clearing-House include the following: 4/

3/ Examples of biosafety capacity-building projects can be found in the database maintained by the Secretariat of the Convention on Biological Diversity at: http://bch.biodiv.org/Pilot/CapacityBuildingStart.asp.

4/ It should be noted that some of projects (19) recorded in the database are completed and one is only planned.

(a) United Nations and specialized agencies: GEF, FAO, UNEP/GEF, UNCTAD, UNIDO and UNITAR;

(b) Intergovernmental organizations: CGIAR, ISNAR, ISAAA and ICGEB;

(c) Bilateral programmes supported by: Australia, Canada, Denmark, Germany, Netherlands, Sweden, Switzerland, United States and the European Commission;

(d) Regional organizations: African Agency of Biotechnology, APEC, ASEAN and OECD;

(e) Industry: Global Industry Coalition, BIOTECanada, EUROPABIO and Japan Bioindustry Association;

(f) Non-governmental organizations and foundations: The Edmonds Institute, Third World Network, Rockefeller Foundation and Swaminathan Foundation.

18. Following the endorsement of the Action Plan for Building Capacities for the Effective Implementation of the Cartagena Protocol on Biosafety by ICCP at its second meeting, the Secretariat re-designed the projects database along the lines of the action plan in order to facilitate the implementation processes of the Action Plan, including: information sharing, identification of the coverage and gaps in capacity-building initiatives and resources and enhancement of synergies and coordination of such initiatives. The new format of the database has been incorporated in the pilot phase of the Biosafety Clearing-House and a common electronic form designed to enable persons authorized by Parties, Governments and relevant organizations to register and update projects in the database, directly online. 5/

19. As of 15 February, 2002, there were 55 recorded in the "Biosafety Capacity Building Projects" database out of which 19 projects are completed, one is planned and 35 projects are currently on-going. The coverage of these projects, in terms of capacity-building areas addressed and the regions where they are implemented is shown in tables 1 and 2 below. The number of projects implemented by different types of organizations are indicated in table 3 while the sources of funding is indicated in Table 4.

Table 1: Coverage of Projects in the Biosafety Capacity Building Project Database (Number of Projects Addressing the Different Elements in the Action Plan)

Main capacity-building areas/ elements	**Number of Projects**
National frameworks	23
Institutional strengthening	23
Human-resources development	38
Risk assessment	19
Risk management	3
Public awareness, education	20
Information exchange & data management	31
Scientific/technical collaboration	20
Technology transfer	12
Identification of LMOs	0

5/ The database can be accessed at <http://bch.biodiv.org/Pilot/CapacityBuildingStart.asp>.

20. Based on the information currently in the database it is evident that the coverage of the projects in terms of the capacity-building elements of the action plan addressed and the geographical scope varies significantly. The majority of projects are focused on promoting human resource development and training, institutional strengthening and elaboration of regulatory frameworks, while major gaps are evident for some elements, notably risk management, identification of LMOs and technology transfer. Examples of specific activities undertaken in support of the various priority elements of the Action Plan are included in annex VI below.

Table 2: Geographical distribution of projects in the database

Region where implemented	**Number of Projects**
Africa	11
Asia/Pacific	16
CEE	2
GRULAC	9
WEOG	0
Global	27

21. In terms of geographic coverage, most of the capacity-building activities (over 49%) have a global scope. In terms of regional coverage, the majority of projects are currently implemented in the Asia/Pacific region while the Central and Eastern Europe (CEE) region has the least number of projects. It should be noted, however, that the number of projects implemented in the region does not necessarily imply broader coverage since some of the projects are small and concentrated in a few countries. For example, while there are only two projects recorded as being implemented in the CEE region, one of the projects namely the Dutch-funded regional project on "Implementation of national biosafety frameworks in pre-accession countries in Central and Eastern Europe" has assisted more than 12 countries 6/ in the region to establish and implement regulatory frameworks for biosafety and mechanisms for risk assessment and public information.

Table 3: Number of projects implemented by different types of agencies

Type of implementing agency	
Bilateral programme	23
Regional Organization	4
UN agency	8
International IGO	5
NGO/ Foundation	4
Industry	10
Research Institution	0

Table 4: Number of projects funded from different sources

Source of funding	**Number of Projects**
Bilateral	31

6/ The participating countries are: Belarus, Bulgaria, Czech Republic, Estonia, Hungary, Latvia, Moldova, Lithuania, Poland, Romania, Slovakia and Yugoslavia.

Multilateral	12
GEF	3
National budget	1
NGO	0
Industry	8

22. Regarding funding, the majority of projects (over 57%) are funded through bilateral programmes, and a few through multi-lateral funding (22%) and the private sector (15%). In terms of the implementation agencies, the majority of projects are implemented by bilateral agencies (42%) i.e. the relevant government agencies of the respective donor countries, and by Industry (18%).

23. It should be emphasized that the information presented above is not exhaustive but is indicative of the overall picture. It is evident that the majority of existing projects are focused on promoting human resource development and training, institutional strengthening and elaboration of regulatory frameworks and that there are gaps in risk management, identification of LMOs and technology transfer. The Committee may wish to encourage Parties, Government and relevant organizations to address the apparent gaps and also endeavor to balance the geographic coverage of projects.

IV. A PRELIMINARY SET OF INDICATORS OF THE ACTION PLAN FOR BUILDING CAPACITIES FOR THE CARTAGENA PROTOCOL ON BIOSAFETY

24. The Open-ended Expert Meeting on Capacity-Building for the Cartagena Protocol on Biosafety highlighted the need to develop a preliminary set of indicators for the Action Plan for Building Capacities for the Effective Implementation of the Protocol. The Action Plan, in subsection 3(g), identifies the development of indicators for evaluating capacity-building measures as one of the key processes/steps to be undertaken. This section and Annex II to this note present proposals on a possible framework for the preliminary set of indicators for consideration of the ICCP.

25. Monitoring and evaluation (M&E) of capacity-building programmes is an important management tool for tracking and ensuring the relevance, effectiveness, efficiency and impact of such programmes. M&E involves a number of activities, tools and approaches. One such tool is the development and use of indicators. 7/

26. In the context of capacity-building, indicators can be described as quantitative or qualitative measures used to monitor changes/ progress made in building capacities, in terms of inputs (e.g. number of training workshops), outputs (e.g. number of persons trained), outcomes/results (e.g. increased capacity of a government agency to conduct risk assessment or risk management), and where possible impact (e.g. countries able to take effective science-based decisions on LMO transfers leading to minimized risks to biodiversity and human health). Indicators are monitored against certain reference points such as baselines/benchmarks, targets or milestones, usually established through assessment processes, such as capacity-building needs assessments. 8/

7/ Other tools for M&E could include: use of databases, indices or checklists.

8/ UNEP/CBD/SBSTTA/3/Inf.13

27. Capacity-building indicators can be categorized into three main groups, namely: input-output indicators, indicators of results and indicators of impact. 9/

(a) *Input and output indicators* illustrate the level of implementation and accomplishment of planned activities and processes, and the effectiveness in producing outputs, based on agreed performance criteria. Performance can also be measured in relation to the effective use of available resources (inputs) and basic outputs achieved (effectiveness). 10/ Examples of performance indicators might include the following: number of awareness raising activities organized; seminars and workshops held (input indicators); educational materials published and disseminated; specialists trained or research institutions equipped (output indicators). A detailed set of indicators of performance for the Action Plan to Build Capacities for the Effective Implementation of the Protocol are included in Annex … to the present note. The advantage of performance indicators is that they easy to measure, but it is important to note that they do not necessarily imply that capacity has been built but rather that planned activities and processes have been implemented.

(b) *Indicators of results* relate to the overall outcomes (results) attained and the positive changes made towards realizing the set objectives. With respect to the Action Plan, indicators of results would relate to the overall capacities or competences built and the improvements made to facilitate early ratification and effective implementation of the Protocol. Likewise, capacity as an outcome also relates to increased effectiveness, efficiency, productivity and adaptability of individuals, institutions or systems. Examples of indicators of results might include the following: existence of national biosafety frameworks; efficient administrative procedures in and processes in place; increased awareness and understanding of the provisions of the Protocol or increased national capacity to carry out risk assessment. Other examples are included in annex I below. While indicators of results are generally more difficult to measure than input-output indicators, they are important because they deal more directly with evaluating the intended outcome of capacity-building efforts;

(c) *Impact indicators*: Usually, these are related to the overall contribution of a given undertaking to the general goal and mission. With respect to the Action Plan, impact indicators would illustrate the extent to which the capacities built through implementation of action plan are contributing to the realization of the objectives of the Protocol i.e. to ensure an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology. Examples might include the following: effective implementation of national biosafety regulatory frameworks and the efficient administration of the IAI procedure contributing to reduced number of incidences of illegal transboundary movement of LMOs or increased capacity to conduct reliable risk assessments and increased levels of preparedness in cases of emergencies resulting in minimized to biodiversity and human health due adverse effects of LMOs. Impact indicators are generally larger in scope and time frame than indicators of achievement, and are therefore more difficult to measure, but they are critical to ensuring that the broad, long-term goal of capacity-building is met.

28. The analysis above clearly indicates that capacity-building indicators can be tracked at various levels i.e. in terms of performance, achievement or impact. In general, performance indicators are simple and straightforward because they measure activities and processes. In many cases, performance

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9/ Boesen, J. and Lafotentaine, A., 1998. "*Indicators and Monitoring of Capacity Development in Environment (CDE) Initiatives*". A paper presented at the International Workshop on Danish Assistance to Capacity Building in Environment; Snekkersten, Denmark; 12-14 May 1998.

10/ Lusthaus, C., Anderson, G. and Murphy, E., 1995. *Institutional Assessment: A Framework for Strengthening Organizational Capacity for IDRC's Research Partners*, IDRC, Ottawa, Canada.

indicators are quantitative or yes/no measures. Such quantitative measures are easy to evaluate, but they are often inadequate for establishing indicators of achievement and impact, which are more difficult to measure.

29. Furthermore, there are a number of inherent difficulties involved in monitoring and assessing capacity-building indicators, including: lack of reliable baseline data, limitations in assessing value-based performance and the varying levels and contexts. Therefore, it is not easy, nor feasible, to develop indicators that are relevant for all situations.

30. In view of the above limitations, it is important to note that the preliminary set of indicators proposed in annex I to present note is not intended to be a universal set of indicators for all countries, but rather to provide a framework of indicative types of indicators that Parties, governments and relevant organizations might wish to use to develop their own indicators.

31. The primary role of the proposed preliminary set of indicators is to facilitate monitoring and assessment of progress in achieving the objectives of the Action Plan to Build Capacities for the Effective Implementation of the Cartagena Protocol on Biosafety, especially with regard to the identified key elements requiring concrete action. However, the indicators may serve other several purposes including the following: 11/

(a) Enable the different stakeholders (planners, policy makers and practitioners) to think systematically about, and to clarify, the objectives, activities and the specific expected results of the capacity-building activities and projects being undertaken.

(b) Help those initiating projects to focus attention on the real specific capacity-building needs and priorities in order to reduce the level of abstract interventions and ineffective investment of resources.

(c) Facilitate project implementers to identify emerging gaps and take corrective measures.

(d) Help to track changes and trends in levels of performance and effectiveness of individuals, institutions and systems, and to devise measures to maintain the positive changes.

(e) Facilitate organizational learning.

32. The Intergovernmental Committee for the Cartagena Protocol on Biosafety may wish to consider the proposed preliminary indicators, contained in annex I below and to encourage Parties, Governments and relevant organizations to use them while designing and implementing their capacity-building initiatives in support of the action plan.

V. CONCLUSION AND RECOMMENDATIONS

33. Capacity-building is one of the critical requirements for the successful implementation of the Protocol. The Action Plan for Building Capacities for the Effective Implementation of the Cartagena Protocol on Biosafety, which was adopted by the ICCP at its second meeting, represented a major step forward. However, the main challenge lies in implementing the plan effectively, efficiently and in a coordinated manner. The present note has discussed some of the key tools and mechanisms that are

11/ Morgan, P., 1999. An Update on the Performance Monitoring of Capacity Building Development Programmes – What are we learning? A paper prepared for the Canadian International Development Agency (CIDA), Ottawa, Canada.

critical for addressing that challenge. The first section presented a point-by-point analysis of role of different organizations in contributing to capacity-building for the Protocol to enable the ICCP to re-consider the issue. It is obvious that organizations play differentiated but complementary roles. The Intergovernmental Committee may wish recommend that Parties take into account the comparative roles and niches of different entities in supporting capacity-building for biosafety.

34. The note has also highlighted the importance of different types of indicators for capacity-building. A preliminary set of indicators for monitoring the implementation of the Action Plan for Building Capacities for the Effective Implementation of the Cartagena Protocol on Biosafety has been proposed in annex I below. The ICCP may wish to review the proposed set of indicators and encourage Parties, governments and relevant organizations to use them while designing and implementing their capacity-building initiatives in support of the action plan.

35. Furthermore, the note has presented a preliminary analysis of the coverage and gaps in capacity-building projects and initiatives, the projects and other initiatives currently contained in the "Biosafety Capacity Building Projects database" which is maintained by the Secretariat on the Biosafety Clearing-House. It is evident that the majority of existing projects are focused on promoting human resource development and training, institutional strengthening and elaboration of regulatory frameworks and that there are major gaps in risk management, identification of LMOs and technology transfer. The Intergovernmental Committee may wish to encourage Parties, Government and relevant organizations to address the apparent major gaps in the priority capacity-building elements of the Action Plan and endeavor to balance the geographic coverage of projects.

36. Finally, the note has highlighted the importance of enhancing coordination and collaboration in order to ensure effective implementation of the Action Plan. Accordingly it has proposed key elements and functions of the coordination mechanism that would help to promote coordination and collaboration among different initiatives. The ICCP may wish consider the proposed mechanism and recommend that Conference of the Parties serving as the meeting of the Parties to the Protocol adopts it and requests the Executive Secretary to operationalize it.

Draft recommendations

37. In the light of the above, the Intergovernmental Committee may wish to adopt a recommendation along the following lines:

The Intergovernmental Committee for the Cartagena Protocol on Biosafety,

Affirming that capacity-building is critical to the ratification and effective implementation of the Cartagena Protocol on Biosafety,

Taking note of the biosafety capacity-building projects database incorporated in the Biosafety Clearing-House,

Welcoming the submissions made by Parties, governments and relevant organizations to the biosafety capacity-building projects database on their capacity-building initiatives,

Recognizing the need to coordinate capacity-building efforts at all levels (national, regional and international and sectoral levels),

Emphasizing the importance of identifying the coverage and gaps in existing activities in the field of biosafety capacity-building,

Acknowledging that capacity-building is a continuous and long-term process,

Recommends that the Conference of the Parties serving as the meeting of the Parties to the Protocol:

1. *Endorses* the elements and functions of the coordination mechanism [to be outlined in an annex to the decision] aimed at promoting partnerships, synergies, complementarities and optimization of resources and requests the Executive Secretary to facilitate their implementation, in collaboration with relevant organizations;

2. *Invites* developed country Parties and other donors to provide voluntary financial support to enable organization of coordination meetings and meetings of the liaison group on capacity-building for biosafety;

3. *Encourages* Parties, Governments and relevant organizations to designate focal points for capacity-building and to establish their own capacity-building coordination bodies, as appropriate;

4. *Invites* Parties, Governments and relevant organizations to register their biosafety capacity-building initiatives in biosafety capacity building projects database on the Biosafety Clearing-House;

5. *Also invites* Parties, governments and relevant organizations to submit to the Executive Secretary annual progress reports on their capacity-building initiatives implemented in support of the Action Plan, including in particular the major achievements, lessons learned and opportunities for cooperation;

6. *Encourages* Parties, governments and relevant organizations to use the implementation toolkit contained in annex V below, as appropriate.

7. *Takes notes* of the indicative list of the possible roles of different entities in supporting capacity-building for the effective implementation of the preliminary set of indicators, contained in annex II below;

8. *Takes note also,* of the preliminary analysis of the coverage and gaps in capacity-building projects and initiatives and invites Parties, Governments and relevant organizations to address the apparent gaps in the priority capacity-building elements of the Action Plan and endeavour to balance the geographic coverage of the capacity-building projects;

9. *Further takes note* of the preliminary set of indicators for monitoring implementation of the Action Plan to Build Capacities for the Effective Implementation of the Cartagena Protocol on Biosafety, contained in annex I below and invites Parties, Governments, and relevant organizations to submit comments the Executive Secretary by [date] with a view to preparing a revised set of indicators consideration by the Conference of the Parties serving as the meeting of the Parties to the Protocol;

10. *Invites* Parties, governments and relevant organizations to use the preliminary set of indicators referred to in paragraph 9 above while designing and implementing their respective capacity-building initiatives in support of the Action Plan.

11. *Requests* the Executive Secretary to prepare a progress report on the implementation of the Action Plan and proposals for improvement based on the synthesis of reports submitted by Parties, Governments and relevant organization.

Annex I

A PRELIMINARY SET OF INDICATORS FOR THE ACTION PLAN TO BUILD CAPACITIES FOR THE EFFECTIVE IMPLEMENTATION OF THE CARTAGENA PROTOCOL ON BIOSAFETY

Key Capacity Building Element	**Input/Output Indicators (related to extent to which activities and processes have been implemented and the outputs produced)**	**Indicators of results (related to the overall positive changes/ improvement in implementing the Protocol).**	**Indicators of Impact (related to overall contribution to the realization of the Protocol's objectives)**
1. Institutional capacity-building			
a) Legislative and policy frameworks	• Number of countries that have ratified the Protocol • Number of countries that have developed biosafety national biosafety frameworks - NBFs (including biosafety strategies, laws, regulations and guidelines) • Level of clarity and comprehensiveness of the biosafety policies, legislation and guidelines developed • Level of stakeholder involvement in the development of NBFs • Existence of enforcement measures, standards and compliance mechanisms • Level of effectiveness in implementing/ enforcing biosafety agreements, laws, regulations and guidelines	• Majority of countries are Parties to the Protocol • Existence of National biosafety frameworks in all countries • Biosafety regulations effectively being implemented in a participatory manner • Improved implementation/ enforcement of biosafety laws and regulation • Increased levels of adherence to the biosafety guidelines by importers, researchers or users of LMOs. • Better biosafety policies in place in most countries	• Parties and governments complying effectively with the provisions of the Protocol. • Fewer incidences of illegal transboundary movement, handling and use of LMOs with adverse effects on biodiversity and human health. • Fewer or no cases of non-compliance.

Key Capacity Building Element	**Input/Output Indicators (related to extent to which activities and processes have been implemented and the outputs produced)**	**Indicators of results (related to the overall positive changes/ improvement in implementing the Protocol).**	**Indicators of Impact (related to overall contribution to the realization of the Protocol's objectives)**
b) Administrative Framework	• Number of countries with national institutional mechanisms (e.g. biosafety units, steering committees or advisory groups), with clear mandates, established to oversee biosafety • Number of national research and regulatory bodies with biosafety liaison offices/ committees at the institutional level • Level of clarity, and harmonisation, of institutional responsibilities for various national bodies dealing with biosafety • Level and quality of collaboration between different national institutions and processes • Level of coherence and effectiveness of the administrative processes and procedures, including approval of permits, acknowledgement of notification, review period, etc. • Existence of monitoring and enforcement mechanisms • Level of efficiency in administering the Advance Informed Agreement (AIA) procedure • Level of efficiency in decision-making	• Increased level of effectiveness and efficiency in administering the AIA procedure. • Improvements in administrative procedures and pragmatic delivery of services (faster and efficient). • Existence of fully staffed National Biosafety Agencies, Division or Units and functional National Biosafety Committees in all countries by COP-MOP.2 • Increased efficiency in decision-making • Improved quality of decisions on notifications and in cases of emergencies	• Streamlined and efficient administration of the AIA procedure motivating exporters to avoid illegal transactions, thus facilitating safer transboundary movement of LMOs. • Efficient decision-making systems and procedures leading to reduced non-compliance.
c) Infrastructure	• Existence of adequate infrastructure – office facilities, services and communications systems • Existence of necessary equipment and supplies, computers and transportation to support and facilitate daily work of individuals and institutions • Number of research laboratories and field stations established/ strengthened • Existence of border control and inspection facilities	• Availability of adequate office facilities, equipment and supplies for biosafety work • Improvement in the number and quality of research facilities (including well equipped laboratories, field stations, etc).	• Well equipped institutions effectively regulating the import and use of LMOs thus minimizing potential adverse effects of LMOs on biodiversity and human health

Key Capacity Building Element	**Input/Output Indicators (related to extent to which activities and processes have been implemented and the outputs produced)**	**Indicators of results (related to the overall positive changes/ improvement in implementing the Protocol).**	**Indicators of Impact (related to overall contribution to the realization of the Protocol's objectives)**
d) Funding	• Levels of total funding for biosafety, both national budgetary allocations and international contributions • Growth rate in expenditures on biosafety research and regulation • Percentage of expenditure (investment) on biosafety in relation to the overall annual government budget • Ratio of the total funding for biosafety work provided by the public sector to that provided by the private commercial sector • Relative ratio of expenditures on capital: personnel: operating costs: research costs • Level of mobilization and leverage of funds from different sources • Levels of sustainability of funding for biosafety	• Increased budgetary allocations for biosafety activities • Improved and timely release of funds • Increased availability and sustainability of financial resources for biosafety activities • Existence of diverse and secure source of funding for biosafety.	Availability of adequate, sustainable and easily accessible funding enabling timely implementation of biosafety measures thus increasing levels of preparedness and effectiveness in minimizing chances of adverse effects of LMOs on biodiversity and human health due to lack of preventative and timely action.
e) Monitoring and Assessment mechanism	• Number of countries that have established monitoring and enforcement mechanisms • Number of countries with mechanisms for border control and inspection of LMOs	• Reduced number of cases of illegal importation and use of LMOs. • Improved consumer confidence.	• Lower risk of adverse effects on biodiversity and human health due to illegal importation of LMOs

Key Capacity Building Element	**Input/Output Indicators (related to extent to which activities and processes have been implemented and the outputs produced)**	**Indicators of results (related to the overall positive changes/ improvement in implementing the Protocol).**	**Indicators of Impact (related to overall contribution to the realization of the Protocol's objectives)**
2. Human Resources Development and Training	• Number of biosafety training events (courses, seminars, internships, fellowships and study tours) organized • Number of institutions providing specialized in key biosafety areas • Number of experts trained at BSc., MSc. and PhD degree levels in different fields relevant to biosafety • Number of professional staff (administrators, policy makers, regulators, legislators, scientists) and technicians (e.g. laboratory technicians, biometricians, etc) appropriately deployed to work on biosafety issues • Number of experts registered in the rosters of experts at various levels • The ratio of technical staff to research staff to managerial staff	• Existence of a critical mass of well trained experts in biosafety available in each country or sub-region • More trained staff deployed appropriately and performing effectively • Existence of highly motivated and efficient permanent staff working in biosafety • Lower rates of staff turnover • Reduced demand for the use of experts from the Roster maintained by the Secretariat.	• Existence of well trained experts capable of regulating the importation and use of LMOs and conducting reliable risk assessments leading to minimization of potential adverse effects of LMOs on biodiversity and human health.
3. Risk assessment and other scientific and technical expertise	• Number of countries that have established and are effectively using risk-assessment frameworks and guidelines • Existence of risk assessment/risk management review processes and mechanisms (e.g. review bodies, directory of scientists) established • Level of effectiveness in reviewing risk assessment reports • Number of risk assessments effectively carried out or reviewed by local experts • Extent to which science based risk assessment methods and techniques are used effectively.	• Improved capacity in assessing risks of LMOs • Reduced incidences of "disguised" importation of LMOs with potential risks to the biodiversity and human health • Reduced incidences of inappropriate release of inadequately assessed LMOs with potential adverse effects on biodiversity and human health	• Minimized risks of adverse effects of LMOs on biodiversity and human health due to effective implementation of reliable, scientifically based risk assessments

Key Capacity Building Element	**Input/Output Indicators (related to extent to which activities and processes have been implemented and the outputs produced)**	**Indicators of results (related to the overall positive changes/ improvement in implementing the Protocol).**	**Indicators of Impact (related to overall contribution to the realization of the Protocol's objectives)**
4. Risk management	• Number of countries with clear risk management strategies and mechanisms • Existence of mechanisms for providing immediate assistance in case of emergencies that may arise from LMOs • Level of effectiveness in implementing risk management strategies.	• Improved monitoring and prevention of potential risks to the environment due to deliberate or unintentional release of LMOs • Improved level of preparedness to handle judiciously cases of emergencies that may arise from unintentional release of LMOs	• Minimized emergence of unpredicted adverse effects of LMOs on biodiversity and human health due to effective risk management strategies.
5. Awareness, education and participation	• Number of organizations involved in promoting awareness on biosafety • Number of awareness workshops, symposia, seminars and other dialogues organized at the national, sub-regional, regional and global levels on biosafety themes • Number of news agencies covering biosafety issues on a regular basis • Average number of news articles related to biosafety appearing in news papers weekly or monthly • Number and volume of awareness materials (posters, brochures, booklets, guidebooks) produced and disseminated to specific target audiences • Number and range of stakeholders participating effectively in national, regional and international biosafety meetings, processes and dialogues • Number of countries that have conducted stakeholder analyses (outlining the interests, strengths and limitations of relevant stakeholders) • Existence of formal stakeholder consultative mechanisms/ forums at various levels.	• Increased media coverage of biosafety issues • Policy briefs and fact sheets on emerging biosafety issues being produced and disseminated regularly • Increased public awareness and understanding of the provisions of the Protocol and of the necessary actions. • Increased political support for the Protocol at various levels • Existence of mechanisms for open dialogue in all countries • Increased level of stakeholder participation in biosafety activities/processes • Increased and transparent public involvement in risk assessment leading to increased objectivity • Increased and transparent involvement of the private sector in biosafety processes	• Increased awareness, informed public participation and the resulting Informed action and decision making enabling different stakeholders to comply with the obligations under the Protocol

Key Capacity Building Element	**Input/Output Indicators (related to extent to which activities and processes have been implemented and the outputs produced)**	**Indicators of results (related to the overall positive changes/ improvement in implementing the Protocol).**	**Indicators of Impact (related to overall contribution to the realization of the Protocol's objectives)**
6. Information Exchange and data management	• Number, and regional balance, of countries effectively participating in the Biosafety Clearing-House (BCH) • Number of national BCH nodes established and interoperable with the global BCH • Number of National BCH Focal Points registered • Number of countries with well maintained databases established and interoperable with others • Number of new information networks linking relevant national, regional and other international systems established • Number of requests for information by the public and other stakeholders handled by the BCH and the national nodes • Frequency of use of information in databases for planning and decision-making • Number of publications on biosafety – books, papers and journal articles– produced and disseminated • Level of participation in, and use of, relevant global scientific information systems	• Increased availability of, and accessibility to, reliable and science-based biosafety information at all levels • Effective documentation, information-exchange mechanisms and communication systems in place • Existence of effective mechanisms for the collection, processing and diffusion of data related to biosafety • Improved level of interoperability between different information systems and databases at various levels	• Increased availability of reliable information resulting in reduced cases of irrational inadvertent release of LMOs.

Key Capacity Building Element	**Input/Output Indicators (related to extent to which activities and processes have been implemented and the outputs produced)**	**Indicators of results (related to the overall positive changes/ improvement in implementing the Protocol).**	**Indicators of Impact (related to overall contribution to the realization of the Protocol's objectives)**
7. Scientific, technical and institutional collaboration	• Number of regional centres of excellence in biosafety established • Number of joint regional research and training programmes initiated • Level of harmonization of regulatory frameworks, including risk-assessment procedures, standards and guidelines • Level of mutual acceptance of the validity of biosafety data at various levels • Extent to which individual researchers and regulators are in contact and exchanging knowledge with appropriate peers at various levels • Existence of mechanisms for national, regional and international consultations and cooperation on biosafety issues that span beyond institutional or national boundaries • Extent to which existing regional organisations (e.g. OECD, ASEAN, AMCEN, etc) are engaged in promoting co-operation in biosafety • Existence of mechanisms for sharing information between countries within respective regions/ sub-region.	• Improved interaction and coordination between different countries and agencies • Increased harmonization of regulatory frameworks and efforts across sectors and regions • Improved partnerships and leverage of resources	Improved regional and institutional collaboration resulting in reduced in incidences of adverse impacts of LMOs on biodiversity across national boundaries.
8. Transfer of technology and know-how	• Number of countries that have clearly identified their technological needs • Number of joint North-South collaborative ventures established • Level and quality of transfer of technology and know-how	• Increased access to and transfer of relevant technologies from developed to developing countries • Increased accessibility to relevant technologies by most developing country Parties to the Protocol • Private sector actively facilitating transfer of relevant technologies to developing countries in accordance with the relevant provisions of the Protocol.	• Improved access to up-to-date technologies and know-how in all countries resulting in increased effectiveness and levels of preparedness in early detection and prevention/ minimization of negative effects of LMOs on the biodiversity and human health.

Key Capacity Building Element	**Input/Output Indicators (related to extent to which activities and processes have been implemented and the outputs produced)**	**Indicators of results (related to the overall positive changes/ improvement in implementing the Protocol).**	**Indicators of Impact (related to overall contribution to the realization of the Protocol's objectives)**
9. Identification of LMOs and LMO-FFPs	• Number of countries with clear and consistent procedures and mechanisms for identification of LMOs • Number of universally accepted LMO identification systems.	• Existence of clear and consistent LMO identification systems • Regulators, operators and users of LMOs in a better position to make informed choices.	• Existence of clear identification systems of LMOs resulting in reduced incidences of injudicious transfer, handling and use of those with potential adverse effects on biodiversity.

Annex II

THE ROLE OF DIFFERENT ENTITIES IN SUPPORTING CAPACITY-BUILDING 12/

1. The present annex summarizes, in a point-by-point list form, the views of Parties and governments regarding the roles which different entities could play to facilitate capacity-building to assist countries in preparing for the entry into force of the Protocol received by the Secretariat in response to a questionnaire that was sent to all national focal points together with the notification of 12 January 2001. The countries and regional economic integration organizations that specifically addressed this issue in their responses to the questionnaire were: Argentina, Costa Rica, Cuba, Ecuador, the European Union, India, Jamaica, Japan, Switzerland, Turkey, United States of America and Uruguay.

2. *The role of the ICCP*:

(a) Assuming the overall responsibility for decisions regarding the establishment of the work programme related to capacity-building and evaluation of its implementation (as illustrated in document UNEP/CBD/ICCP/1/9);

(b) Setting norms for harmonization;

(c) Developing common formats to build capacity and encouraging consistency of standards in such matters as risk assessment and information exchange;

(d) Revising and updating the capacity-building framework in the light of responses to the questionnaire and the outcome of inter-sessional workshops and projects;

(e) Providing general guidelines from an international perspective;

(f) Gathering information required for the first meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol to decide what capacity-building projects will be the most effective in assisting countries to implement the provisions of the Protocol, including information on national priority capacity needs and how to meet them;

3. *The role of the Secretariat*:

(a) Providing an administrative framework for creation of technical and scientific capacity;

(b) Implementing the pilot phase of the Biosafety Clearing-House, taking account of priority needs regarding the capacities of Governments for access to the BCH and the views of Governments on monitoring progress;

(c) Administering the Biosafety Clearing-House;

(d) Undertaking further synthesis and analysis of the identified needs of countries for implementation of the Protocol, and available means for assistance and information exchange;

12/ UNEP/CBD/ICCP/2/10, paras. 11-20.

(e) Serving as a focal point for organizations to submit information to be made public as regards capacity-building initiatives for the implementation of the Protocol, as well as for identifying needs for capacity-building;

(f) Facilitating the flow of information;

(g) Promoting synergies and keeping countries abreast of important developments and opportunities with respect to capacity-building – e.g., roster of experts;

(h) Facilitating the functioning of the roster of experts;

(i) Implementing the relevant recommendation of ICCP and later the decisions of COP-MOP;

(j) Cooperating with the UNEP/GEF enabling project on national biosafety frameworks;

(k) Facilitating and promoting collaboration and coordination among existing initiatives on capacity-building; and

(l) Providing coordination and leadership and suggesting ways and means to build capacity in countries, taking into account the recommendations of the ICCP.

4. *The role of the Global Environment Facility (GEF)*:

(a) Providing funds necessary to build legislative and administrative frameworks, and for training in risk assessment and risk management;

(b) Deciding on further areas for financial support for capacity-building in accordance with the identified priority needs of developing countries, including results of the first meeting of the ICCP, responses to the questionnaire, the outcomes of inter-sessional workshops, and its previous pilot project on biosafety;

(c) Implementing the GEF Initial Strategy adopted by the GEF Council in November 2000, which describes how the GEF will support, through the GEF/UNEP enabling activity, capacity-building to assist countries to prepare for the entry into force of the Cartagena Protocol on Biosafety;

(d) Facilitating the provision of technical support; and

(e) Facilitating the use of existing and developing regional networks.

5. *The role of other bilateral and multilateral donors*:

(a) Providing funding to Parties, governments and to the Secretariat, for relevant activities;

(b) Co-financing or providing matching funds for building scientific capacity at the sub regional level, including sponsoring regional and sub-regional workshops;

(c) Providing short- or long-term experts to advise on identified needs and demands for assistance on specific issues, including those listed in Article 22 of the Protocol;

(d) Reinforcing collaboration among capacity-building projects on biotechnology and biosafety in order to avoid duplication and to efficiently use the limited resources available.

6. *The role of intergovernmental organizations*:

(a) Assisting national authorities of Parties to take decisions;

(b) Sharing "best practices", models and information pertinent to relations between obligations under trade agreements and obligations under the Protocol;

(c) Developing advice or standards on particular technical or regulatory issues: e.g., the work of the Organization for Economic Co-operation and Development (OECD) on a unique identifier for LMOs and on Consensus Documents on common elements of risk assessment for particular species;

(d) Contributing to implementation of the project on *Development of National Biosafety Frameworks*, in line with the terms agreed by the GEF Council and relevant decisions taken at the first meeting of the ICCP;

(e) Providing access to databases containing information relevant to implementation of the Protocol: e.g. OECD's Biotrack, the International Centre for Genetic Engineering and Biotechnology (ICGEB), UNIDO's BIOBIN;

(f) Developing common principles for public participation and access to information: e.g. the work of the United Nations Economic Commission for Europe under the Aarhus Convention;

(g) Ensuring coordination and mutual supportiveness with other bodies and conventions concerned with LMO issues: e.g., the International Plant Protection Convention (IPPC), the Office International des Epizooties (OIE), the Food and Agriculture Organization of the United Nations (FAO) and the Codex Alimentarius Commission;

(h) Reinforcing collaboration among capacity-building projects on biotechnology and biosafety in order to avoid duplication and to efficiently use the limited resources available; and

(i) Providing co-financing for capacity-building activities.

7. *The role of regional networks*:

(a) Promoting harmonization of technical, legal and scientific mechanisms in the countries;

(b) Identifying and disseminating information related to best practice in the development of national biosafety frameworks, procedures for risk assessment and risk management, decision taking, information exchange, and the use of human resources;

(c) Developing regional centres that enable/ ensure sharing of expertise and information as well as experiences and concerns;

(d) Participating in the development of the Biosafety Clearing-House and

(e) Providing co-financing for capacity-building activities;

8. *The role of non-governmental organizations*:

(a) Cooperating in consensus-building and assisting in raising public education and awareness;

(b) Participating in and assisting in national and regional efforts to implement the Protocol, including helping to implement the Biosafety Clearing-House;

(c) Contributing to guidance on Protocol implementation issues;

(d) Integrating the views and interests of wider stakeholders, including indigenous and local communities, through increased public awareness, education and participation in decision-making and the development of policy and procedures;

(e) Representing specialist or sectoral interests in relation to risk assessment and risk management issues;

(f) Reinforcing collaboration among capacity-building projects on biotechnology and biosafety in order to avoid duplication and to efficiently use the limited resources available;

(g) Associating with capacity-building initiatives, ensure public participation and promote public awareness on biosafety issues; and

(h) Providing co-financing for capacity-building activities.

9. *The role of private sector/industry*:

(a) Participating in the effective implementation of the Protocol, including creation of awareness and provision of technical advice;

(b) Creating confidence with consumers;

(c) Developing techniques for identification, detection and analytical assessment and for monitoring;

(d) Developing systems for labeling, traceability and unique identifier;

(e) Improving capabilities of accessing and handling electronic information;

(f) Providing scholarships in the areas mentioned above;

(g) Undertaking risk assessment, and addressing information needs and concerns of industry;

(h) Associating with initiatives on capacity-building and share experience with risk assessment and management of LMOs; and

(i) Providing co-financing for capacity-building activities.

10. *The role of scientific/academic institutions*:

(a) Promoting public awareness and implementing training and education activities;

(b) Developing of centres of expertise and excellence for particular risk assessment and risk management issues;

(c) Providing participants for the roster of experts;

(d) Implementing exchange and scholarship programmes aimed at enhancing the teaching and research capacities of higher education and other private and public institutions in developing countries as regards biosafety related issues;

(e) Cooperating on research and information exchange on socio-economic impacts, especially on indigenous and local communities;

(f) Assisting in training and conducting risk assessment, research in GMOs for improved crop production;

(g) Participating in capacity-building initiatives as well as in other activities in relation with the implementation of the Protocol; and

(h) Providing co-financing for capacity-building activities.

Annex III

RIGHTS AND OBLIGATIONS OF PARTIES UNDER THE CARTAGENA PROTOCOL ON BIOSAFETY 13/

1. The general rights and obligations set out in the Protocol include:

(a) *Article 2, paragraph 1*: take the necessary and appropriate legal, administrative and other measures to implement obligations under the Protocol;

(b) *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;

(c) *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;

(d) *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;

(e) *Article 6, paragraph 2*: right to set standards for contained use within a Party's jurisdiction;

(f) *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;

(g) *Article 16, paragraph 4*: endeavor 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;

(h) *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;

(i) *Article 19*: designation of one national focal point and competent national authorities;

(j) *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;

(k) *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;

13/ UNEP/CBD/BS/EM-CB/1/3, annex I, appendix I.

(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;

(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.

Annex IV

PRELIMINARY LIST OF KEY REQUIRED CAPACITIES FOR IMPLEMENTATION OF THE CARTAGENA PROTOCOL 14/

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

14/ UNEP/CBD/BS/EM-CB/1/3, annex I, appendix II.

INSTITUTION BUILDING	RISK ASSESSMENT	RISK MANAGEMENT
(g) Enforcement capacity at borders	capacities	
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 longer-term 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		

* *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
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 V

IMPLEMENTATION TOOLKIT [15]

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	

15/ UNEP/CBD/BS/EM-CB/1/3, annex II.

	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

	Tasks	*Article*	Ö
1.	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)	
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)	
3.	Ensure that any domestic regulatory framework used in place of the AIA procedures is consistent with the Protocol.	9(3)	
4.	Ensure that AIA decisions are taken in accordance with Article 15.	10(1)	
5.	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)	
6.	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)	
7.	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)	
8.	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)	
9.	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)	
10.	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)	
11.	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)	
12.	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 are consigned.	18(2)(b)	

	Tasks	*Article*	*Ö*
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 **i**llegal transboundary movement through repatriation or destruction, as appropriate, upon request by an affected Party.	25(2)	

III. PROCEDURAL REQUIREMENTS: ADVANCED INFORMED AGREEMENT

	Tasks	*Article*	*Ö*
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 accordance with the domestic regulatory framework or in accordance with Article 10; **OR** - Whether the import may proceed after 90 days without further written consent.	10(2)(a), 9(2)(c) 10(2)(b)	
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; **AND**	10(3)(a)-(d)	

	Tasks	*Article*	*Ö*
	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*	*Ö*
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; **OR** - 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 VI

EXAMPLES OF BIOSAFETY CAPACITY-BUILDING ACTIVITIES OF PROJECTS CURRENTLY REGISTERED IN THE PROJECTS DATABASE IN THE PILOT PHASE OF THE BIOSAFETY CLEARING-HOUSE

Examples of activities of the projects in the database that are contributing to the various priority capacity-building elements outlined in the Action Plan include the following: 16/

Legislative and regulatory framework:

- Supporting efforts to harmonize legislation in different regions
- Assisting countries to conduct national surveys of existing relevant legal instruments or guidelines (e.g. UNEP/GEF, BIOTECanada, GIC projects)
- Assisting countries to prepare national biosafety frameworks, including regulations for genetically engineered plants (e.g. UNEP/GEF, ISNAR, Netherlands, Germany and US projects)
- Assistance in defining the minimum requirements of a legal and administrative infrastructure (e.g. Germany/GTZ project)
- Assisting in harmonization of guidelines, regulations or laws at the national level with those in neighbouring countries (UNEP/GEF project)
- Formulation of evaluation criteria for assessment of biosafety policy (e.g. BMZ/GTZ project)
- Organization of workshops to strengthen national biosafety regulatory frameworks (e.g. APEC, Australia, USA, UNEP/GEF, BIOTECanada projects)
- Institutional strengthening (including administrative frameworks, infrastructure and funding)
- Assessment of the special capacity-building needs at the country level (e.g. GEF/UNEP project)
- Helping governments to identify priorities and establish appropriate institutions (e.g. UNITAR project)

Institutional strengthening:

- Assessment of the capacity-building needs at the country level (e.g. GEF, UNEP, Netherlands-CEE projects)
- Helping governments to identify priorities and establish appropriate institutions (e.g. UNITAR)
- Help governments to identify priorities and establish/ strengthen appropriate institutional structures (e.g. UNITAR, UNEP/GEF, AAB, GIC, BIOTECanada and Rockefeller Foundation)

Human resources development and training:

- Capacity mapping and assessment of the human resources needs (e.g. UNEP/GEF, IUCN Asia)
- Training courses at MSc. or PhD levels (e.g. BIO-EARN and EC projects)
- Training seminars and workshops (e.g. ICGEB, ISAAA, GIC and Netherlands-CEE projects)
- Study tours, internships and fellowships (e.g. ISAAA, GIC and EC projects)
- Develop and disseminate training materials, including technical manuals and best practice guidelines (e.g. UNEP/GEF project and UNITAR)
- Supporting post-graduate training – providing post-doctoral fellowships (e.g. EC project)
- Preparation and distribution of materials for a distance learning correspondence course (e.g. UNITAR project).

16/ Details can obtained at: http://bch.biodiv.org/Pilot/CapacityBuildingStart.asp

Risk Assessment

- Demonstration projects in risk assessment and risk management (e.g. BIOTECanada, GIC)
- Development of an online decision support system for risk assessment of GMOs (e.g. UNIDO)
- Development manuals, guidelines, methodologies, procedures and suitable strategies for risk assessment and risk management (e.g. UNEP/GEF, BIOTECanada and Edmonds Institute)
- Strengthening of scientific capacities for risk assessment (e.g. CGIAR, FAO and GIC)
- Seminars and workshops on risk assessment and risk management of transgenic organisms (e.g. BIOTECanada, GIC, APEC, Australia and USA)
- Provision of advice and scientific knowledge on the development of risk assessment procedures based on the precautionary principle to enable and facilitate decision-making (e.g. Germany/GTZ project).

Risk Management

- Enhancement of regulatory aspects of field trials, product development and distribution (e.g. BIOTECanada)

Awareness, education and participation

- Involvement of non-governmental organizations, representatives of consumer organizations and the private sector in the training activities (e.g. UNITAR and EUROPABIO projects)
- Publication and dissemination of biosafety awareness/outreach materials including publications, video, brochures, news articles (e.g. UNEP/GEF, UNIDO, Third World Network-TWN projects)
- Publication of biosafety newsletters (e.g. UNEP/GEF, OECD and ICGEB)
- Publication of a monthly news service on global developments in biosafety (e.g. UNIDO)
- Development of 'media packages' on biosafety related issues (e.g. IUCN Asia)
- Promotion of better mutual understanding of ethical concerns related to biotechnology, through dialogue and consensus (e.g. EUROPABIO)
- Identification of all stakeholders and of mechanisms for their participation in the national biosafety frameworks (e.g. UNEP/GEF)
- Organizing briefing sessions and panel discussions (e.g. TWN)
- Analysis and distribution of scientific information and national and international developments in biosafety (through documents, articles and papers) to government officials - national decision makers (e.g. TWN)

Information exchange and data management

- Database management and dissemination of information including: biotechnology guidelines, regulations, standards and field trials for the releases of LMOs (e.g. ICGEB, UNIDO and OECD)
- Establishment of Biosafety Information Network and Advisory Services (e.g. UNIDO)
- Provision of technical assistance to establish information network tools and linkages with Canadian and international databases, web-sites and discussion lists (e.g. BIOTECanada, FAO)
- Establishment of websites and a list server to allow rapid exchange of information (e.g. UNEP/GEF, UNIDO, OECD and IUCN)
- Establishment of a regional website for CEE countries (e.g. Netherlands-CEE project)
- Publication of resource kit and information documents for specialists and non-specialists and media on biosafety issues (e.g. IUCN Asia)
- Publication and distribution of books, reports, briefing papers, case studies and best practice guidelines on biosafety (e.g. TWN, Edmonds Institute and FAO)

- Exchange of information on technical issues and policy matters, including regulations and product authorization procedures for GMOs (e.g. EC).

Scientific, technical and institutional collaboration

- Establishment of a Biotechnology Consultative Group for Latin America and the Caribbean (e.g. UNIDO)
- Facilitating sharing of scientific assessments at sub-regional levels (e.g. UNEP/GEF)
- Supporting sub-regional/regional consultations for harmonizing guidelines, identifying regional expertise; enhancing compatibility of initiatives and collaboration possibilities, and identification of capacity-building priorities (e.g. UNEP/GEF)
- Establishment of sub-regional support centers (e.g. Netherlands-CEE project).

Transfer of technology and know-how

- Support joint research projects with developing countries, concentrating on biotechnology applications for agriculture, health and natural resources management (e.g. EC, USA and GIC)
- Establishment of strategic alliances between Latin American and Canadian agencies and companies (e.g. BIOTECanada)
- Transfer of knowledge and experience through "on location" training (e.g. Netherlands-CEE project.

LIST OF ACRONYNMS:

AAB	African Agency of Biotechnology (AAB) Plant Biotechnology Programme
APEC	Asia Pacific Economic Cooperation - Agricultural Technical Cooperation Experts' Group
BIO-EARN	East African Regional Programme and Research Network for Biotechnology, Biosafety and Biotechnology Policy Development
CGIAR	Consultative Group on International Agricultural Research
EC	European Commission
EUROPABIO	European Association for Bioindustries
FAO	Food and Agricultural Organization of the United Nations
GEF	Global Environment Facility
GIC	Global Industry Coalition
GTZ	Germany Technical Cooperation
ICGEB	International Centre for Genetic Engineering and Biotechnology
ISAAA	International Service for the Acquisition of Agri-biotech Applications
ISNAR	International Service for National Agricultural Research
IUCN	World Conservation Union
OECD	Organisation for Economic Co-operation and Development
TWN	Third World Network
UNEP	United Nations Environment Programme
UNIDO	United Nations Industrial Development Organization
UNITAR	United Nations Institute for Training and Research
